State of West Virginia
Department of Administration
Purchasing Division
2019 Washington Street East
Post Office Box 50130
Charleston, WV 25305-0130

Request for Quotation

RFQ NUMBER	PAGE
CME90108	1

ADDRESS CORRESPONDENCE TO ATTENTION OF:
ROBERTA WAGNER
304-558-0067

VENDOR
*308134754 800-626-0690
MICROGENICS CORPORATION
46360 FREMONT BOULEVARD

FREMONT CA 94538

SHIP TO
HEALTH AND HUMAN RESOURCES
BUREAU FOR PUBLIC HEALTH
OFFICE CHIEF MEDICAL EXAMINER
619 VIRGINIA STREET, WEST
CHARLESTON, WV
25302 304-558-4865

DATE PRINTED	TERMS OF SALE	SHIP VIA	F.O.B.	FREIGHT TERMS
01/21/2009				

BID OPENING DATE: 02/19/2009 BID OPENING TIME 01:30PM

LINE	QUANTITY	UOP	CAT NO	ITEM NUMBER	UNIT PRICE	AMOUNT
0001	1	EA	193-52		Varies*	$27,560.00*

RECEIVED
2009 FEB 18 A 10:54
PURCHASING DIVISION
STATE OF WV

OPEN-END BLANKET CONTRACT

IMMUNOASSAY REAGENT KITS

***PLEASE REFER TO THE CATALOG PRICING PAGE**

TO PROVIDE AN OPEN END CONTRACT FOR IMMUNOASSAY REAGENT KITS CAPABLE OF DETECTING DRUGS OF ABUSE AND TRICYCLIC ANTI-DEPRESSANT DRUGS IN URINE SAMPLES. KITS TO BE USED ON EXISTING EQUIPMENT AND MUST BE COMPATIBLE WITH A MICROGENICS MGC240 ANALYZER, PER THE ATTACHED SPECIFICATIONS.
EXHIBIT 3

LIFE OF CONTRACT: THIS CONTRACT BECOMES EFFECTIVE ON ..... AND EXTENDS FOR A PERIOD OF ONE (1) YEAR OR UNTIL SUCH "REASONABLE TIME" THEREAFTER AS IS NECESSARY TO OBTAIN A NEW CONTRACT OR RENEW THE ORIGINAL CONTRACT. THE "REASONABLE TIME" PERIOD SHALL NOT EXCEED TWELVE (12) MONTHS. DURING THIS "REASONABLE TIME" THE VENDOR MAY TERMINATE THIS CONTRACT FOR any REASON UPON GIVING THE DIRECTOR OF PURCHASING 30 DAYS WRITTEN NOTICE.

UNLESS SPECIFIC PROVISIONS ARE STIPULATED ELSEWHERE IN THIS CONTRACT DOCUMENT, THE TERMS, CONDITIONS AND PRICING SET HEREIN ARE FIRM FOR THE LIFE OF THE CONTRACT.

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE	TELEPHONE	DATE
	510-979-5195	12 Feb 2009
TITLE VP, US Sales	FEIN 68-0418167	ADDRESS CHANGES TO BE NOTED ABOVE

WHEN RESPONDING TO RFQ, INSERT NAME AND ADDRESS IN SPACE ABOVE LABELED 'VENDOR'

GENERAL TERMS & CONDITIONS
REQUEST FOR QUOTATION (RFQ) AND REQUEST FOR PROPOSAL (RFP)

1. Awards will be made in the best interest of the State of West Virginia.

2. The State may accept or reject in part, or in whole, any bid.

3. All quotations are governed by the ***West Virginia Code*** and the ***Legislative Rules*** of the Purchasing Division.

4. Prior to any award, the apparent successful vendor must be properly registered with the Purchasing Division and have paid the required $125 fee.

5. All services performed or goods delivered under State Purchase Order/Contracts are to be continued for the term of the Purchase Order/Contracts, contingent upon funds being appropriated by the Legislature or otherwise being made available. In the event funds are not appropriated or otherwise available for these services or goods, this Purchase Order/Contract becomes void and of no effect after June 30.

6. Payment may only be made after the delivery and acceptance of goods or services.

7. Interest may be paid for late payment in accordance with the ***West Virginia Code***.

8. Vendor preference will be granted upon written request in accordance with the ***West Virginia Code***.

9. The State of West Virginia is exempt from federal and state taxes and will not pay or reimburse such taxes.

10. The Director of Purchasing may cancel any Purchase Order/Contract upon 30 days written notice to the seller.

11. The laws of the State of West Virginia and the ***Legislative Rules*** of the Purchasing Division shall govern all rights and duties under the Contract, including without limitation the validity of this Purchase Order/Contract.

12. Any reference to automatic renewal is hereby deleted. The Contract may be renewed only upon mutual written agreement of the parties.

13. **BANKRUPTCY:** In the event the vendor/contractor files for bankruptcy protection, this Contract may be deemed null and void, and terminated without further order.

14. **HIPAA BUSINESS ASSOCIATE ADDENDUM:** The West Virginia State Government HIPAA Business Associate Addendum (BAA), approved by the Attorney General, and available online at the Purchasing Division's web site (**http://www.state.wv.us/admin/purchase/vrc/hipaa.htm**) is hereby made part of the agreement. Provided that, the Agency meets the definition of a Cover Entity (45 CFR §160.103) and will be disclosing Protected Health Information (45 CFR §160.103) to the vendor.

15. **WEST VIRGINIA ALCOHOL & DRUG-FREE WORKPLACE ACT:** If this Contract constitutes a public improvement construction contract as set forth in Article 1D, Chapter 21 of the West Virginia Code ("The West Virginia Alcohol and Drug-Free Workplace Act"), then the following language shall hereby become part of this Contract: "The contractor and its subcontractors shall implement and maintain a written drug-free workplace policy in compliance with the West Virginia Alcohol and Drug-Free Workplace Act, as set forth in Article 1D, Chapter 21 of the West Virginia Code. The contractor and its subcontractors shall provide a sworn statement in writing, under the penalties of perjury, that they maintain a valid drug-free work place policy in compliance with the West Virginia and Drug-Free Workplace Act. It is understood and agreed that this Contract shall be cancelled by the awarding authority if the Contractor: 1) Fails to implement its drug-free workplace policy; 2) Fails to provide information regarding implementation of the contractor's drug-free workplace policy at the request of the public authority; or 3) Provides to the public authority false information regarding the contractor's drug-free workplace policy."

INSTRUCTIONS TO BIDDERS

1. Use the quotation forms provided by the Purchasing Division.

2. **SPECIFICATIONS:** Items offered must be in compliance with the specifications. Any deviation from the specifications must be clearly indicated by the bidder. Alternates offered by the bidder as **EQUAL** to the specifications must be clearly defined. A bidder offering an alternate should attach complete specifications and literature to the bid. The Purchasing Division may waive minor deviations to specifications.

3. Complete all sections of the quotation form.

4. Unit prices shall prevail in case of discrepancy.

5. All quotations are considered F.O.B. destination unless alternate shipping terms are clearly identified in the quotation.

6. **BID SUBMISSION:** All quotations must be delivered by the bidder to the office listed below prior to the date and time of the bid opening. Failure of the bidder to deliver the quotations on time will result in bid disqualifications: Department of Administration, Purchasing Division, 2019 Washington Street East, P.O. Box 50130, Charleston, WV 25305-0130

State of West Virginia
Department of Administration
Purchasing Division
2019 Washington Street East
Post Office Box 50130
Charleston, WV 25305-0130

Request for Quotation

RFQ NUMBER	PAGE
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ADDRESS CORRESPONDENCE TO ATTENTION OF:
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304-558-0067

VENDOR
*308134754 800-626-0690
MICROGENICS CORPORATION
46360 FREMONT BOULEVARD

FREMONT CA 94538

SHIP TO
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619 VIRGINIA STREET, WEST
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25302 304-558-4865

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BID OPENING DATE: 02/19/2009 BID OPENING TIME 01:30PM

LINE	QUANTITY	UOP	CAT. NO.	ITEM NUMBER	UNIT PRICE	AMOUNT

RENEWAL: THIS CONTRACT MAY BE RENEWED UPON THE MUTUAL WRITTEN CONSENT OF THE SPENDING UNIT AND VENDOR, SUBMITTED TO THE DIRECTOR OF PURCHASING THIRTY (30) DAYS PRIOR TO THE EXPIRATION DATE. SUCH RENEWAL SHALL BE IN ACCORDANCE WITH THE TERMS AND CONDITIONS OF THE ORIGINAL CONTRACT AND SHALL BE LIMITED TO TWO (2) ONE (1) YEAR PERIODS.

CANCELLATION: THE DIRECTOR OF PURCHASING RESERVES THE RIGHT TO CANCEL THIS CONTRACT IMMEDIATELY UPON WRITTEN NOTICE TO THE VENDOR IF THE COMMODITIES AND/OR SERVICES SUPPLIED ARE OF AN INFERIOR QUALITY OR DO NOT CONFORM TO THE SPECIFICATIONS OF THE BID AND CONTRACT HEREIN.

OPEN MARKET CLAUSE: THE DIRECTOR OF PURCHASING MAY AUTHORIZE A SPENDING UNIT TO PURCHASE ON THE OPEN MARKET, WITHOUT THE FILING OF A REQUISITION OR COST ESTIMATE, ITEMS SPECIFIED ON THIS CONTRACT FOR IMMEDIATE DELIVERY IN EMERGENCIES DUE TO UNFORESEEN CAUSES (INCLUDING BUT NOT LIMITED TO DELAYS IN TRANS-PORTATION OR AN UNANTICIPATED INCREASE IN THE VOLUME OF WORK.)

QUANTITIES: QUANTITIES LISTED IN THE REQUISITION ARE APPROXIMATIONS ONLY, BASED ON ESTIMATES SUPPLIED BY THE STATE SPENDING UNIT. IT IS UNDERSTOOD AND AGREED THAT THE CONTRACT SHALL COVER THE QUANTITIES ACTUALLY ORDERED FOR DELIVERY DURING THE TERM OF THE CONTRACT, WHETHER MORE OR LESS THAN THE QUANTITIES SHOWN.

ORDERING PROCEDURE: SPENDING UNIT(S) SHALL ISSUE A WRITTEN STATE CONTRACT ORDER (FORM NUMBER WV-39) TO THE VENDOR FOR COMMODITIES COVERED BY THIS CONTRACT. THE ORIGINAL COPY OF THE WV-39 SHALL BE MAILED TO THE VENDOR AS AUTHORIZATION FOR SHIPMENT, A SECOND COPY MAILED TO THE PURCHASING DIVISION, AND A THIRD COPY

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE	TELEPHONE	DATE

TITLE	FEIN	ADDRESS CHANGES TO BE NOTED ABOVE

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State of West Virginia
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Purchasing Division
2019 Washington Street East
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Request for Quotation

RFQ NUMBER	PAGE
CME90108	3

ADDRESS CORRESPONDENCE TO ATTENTION OF:
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*308134754 800-626-0690
MICROGENICS CORPORATION
46360 FREMONT BOULEVARD

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RETAINED BY THE SPENDING UNIT.

BANKRUPTCY: IN THE EVENT THE VENDOR/CONTRACTOR FILES FOR BANKRUPTCY PROTECTION, THIS CONTRACT IS AUTOMATICALLY NULL AND VOID, AND IS TERMINATED WITHOUT FURTHER ORDER.

THE TERMS AND CONDITIONS CONTAINED IN THIS CONTRACT SHALL SUPERSEDE ANY AND ALL SUBSEQUENT TERMS AND CONDITIONS WHICH MAY APPEAR ON ANY ATTACHED PRINTED DOCUMENTS SUCH AS PRICE LISTS, ORDER FORMS, SALES AGREEMENTS OR MAINTENANCE AGREEMENTS, INCLUDING ANY ELECTRONIC MEDIUM SUCH AS CD-ROM.

REV. 04/11/2001

INQUIRIES:
WRITTEN QUESTIONS SHALL BE ACCEPTED THROUGH CLOSE OF BUSINESS ON 2/3/2009. QUESTIONS MAY BE SENT VIA USPS, FAX, COURIER OR E-MAIL. IN ORDER TO ASSURE NO VENDOR RECEIVES AN UNFAIR ADVANTAGE, NO SUBSTANTIVE QUESTIONS WILL BE ANSWERED ORALLY. IF POSSIBLE, E-MAIL QUESTIONS ARE PREFERRED. ADDRESS INQUIRIES TO:

ROBERTA WAGNER
DEPARTMENT OF ADMINISTRATION
PURCHASING DIVISION
2019 WASHINGTON STREET, EAST
CHARLESTON, WV 25311

FAX: 304-558-4115
E-MAIL: ROBERTA.A.WAGNER@WV.GOV

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE	TELEPHONE	DATE

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Purchasing Division
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Request for Quotation

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EXHIBIT 4

LOCAL GOVERNMENT BODIES: UNLESS THE VENDOR INDICATES IN THE BID HIS REFUSAL TO EXTEND THE PRICES, TERMS, AND CONDITIONS OF THE BID TO COUNTY, SCHOOL, MUNICIPAL AND OTHER LOCAL GOVERNMENT BODIES, THE BID SHALL EXTEND TO POLITICAL SUBDIVISIONS OF THE STATE OF WEST VIRGINIA. IF THE VENDOR DOES NOT WISH TO EXTEND THE PRICES, TERMS, AND CONDITIONS OF THE BID TO ALL POLITICAL SUBDIVISIONS OF THE STATE, THE VENDOR MUST CLEARLY INDICATE SUCH REFUSAL IN HIS BID. SUCH REFUSAL SHALL NOT PREJUDICE THE AWARD OF THIS CONTRACT IN ANY MANNER.

REV. 3/88
THE MODEL/BRAND/SPECIFICATIONS NAMED HEREIN ESTABLISH THE ACCEPTABLE LEVEL OF QUALITY ONLY AND ARE NOT INTENDED TO REFLECT A PREFERENCE OR FAVOR ANY PARTICULAR BRAND OR VENDOR. VENDORS WHO ARE BIDDING ALTERNATES SHOULD SO STATE AND INCLUDE PERTINENT LITERATURE AND SPECIFICATIONS. FAILURE TO PROVIDE INFORMATION FOR ANY ALTERNATES MAY BE GROUNDS FOR REJECTION OF THE BID. THE STATE RESERVES THE RIGHT TO WAIVE MINOR IRREGULARITIES IN BIDS OR SPECIFICATIONS IN ACCORDANCE WITH SECTION 148-1-4(F) OF THE WEST VIRGINIA LEGISLATIVE RULES AND REGULATIONS.
PURCHASING CARD ACCEPTANCE: THE STATE OF WEST VIRGINI CURRENTLY UTILIZES A VISA PURCHASING CARD PROGRAM WHICH IS ISSUED THROUGH A BANK. THE SUCCESSFUL VENDOR MUST ACCEPT THE STATE OF WEST VIRGINIA VISA PURCHASING CARD FOR PAYMENT OF ALL ORDERS PLACED BY ANY STATE AGENCY AS A CONDITION OF AWARD.

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

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EXHIBIT 6

PRICE ADJUSTMENT PROVISION:
THE STATE OF WEST VIRGINIA WILL CONSIDER BIDS THAT CONTAIN PROVISIONS FOR PRICE ADJUSTMENTS PRIOR TO THE ORIGINAL EXPIRATION OF THE CONTRACT, PROVIDED THAT SUCH PRICE ADJUSTMENT COVERS BOTH UPWARD AND DOWNWARD MOVEMENT OF THE COMMODITY PRICE, AND THAT ADJUSTMENT IS BASED ON THE "PASS THROUGH" INCREASE OR DECREASE OF RAW MATERIALS AND/OR LABOR, WHICH MAKE UP ALL OR A SUBSTANTIAL PART OF A PRODUCT. ADJUSTMENTS ARE TO BE BASED UPON AN ACTUAL DOLLAR FIGURE, NOT A PERCENTAGE. ALL PRICE ADJUSTMENT REQUESTS MUST BE SUBSTANTIATED IN A MANNER ACCEPTABLE TO THE DIRECTOR PURCHASING, E.G. GOVERNMENTAL BENCH MARKS, GENERAL MARKET INCREASE, PUBLISHED PRICE LISTS. SUCH REQUESTS FOR AND INCREASE SHOULD BE RECEIVED IN WRITING BY THE DIRECTOR OF PURCHASING AT LEAST 30 DAYS IN ADVANCE OF THE EFFECTIVE DATE OF THE INCREASE. ANY TIME THE VENDOR REQUESTS A PRICE ADJUSTMENT, THE PURCHASING DIVISION MAY EITHER ACCEPT THE PRICE ADJUSTMENT AND AMEND THE CONTRACT ACCORDINGLY OR REJECT THE ADUSTMENT IN ITS ENTIRETY AND CANCEL THE CONTRACT.

PREFERRED TERMS:
IT IS PREFERRED THAT THE PRICES ON THIS CONTRACT ARE FIRM FOR LIFE OF THE CONTRACT, AS INDICATED IN THE LIFE OF CONTRACT CLAUSE CONTAINED HEREIN, NOT TO EXCEED ONE (1) YEAR.

IF THE VENDOR CANNOT GUARANTEE A FIRM PRICE FOR THE LIFE OF CONTRACT, HE MUST INDICATE ONE OF THE PARAGRAPHS LISTED BELOW. FAILURE TO QUALIFY THE PREFERRED TERMS WILL BIND THE VENDOR TO A FIRM PRICE

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

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Request for Quotation

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ADDRESS CORRESPONDENCE TO ATTENTION OF:
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FOR THE LIFE OF THE CONTRACT.

ALTERNATE TERMS:

(x) THE PRICES ON THIS CONTRACT WILL REMAIN FIRM FOR ...1099. DAYS AFTER THE EFFECTIVE DATE OF THE CONTRACT. PRICES WILL REMAIN FIRM AFTER EACH PRICE ADJUSTMENT FOR A MINIMUM OF ..365. DAYS.

( ) THE VENDOR DOES NOT AGREE TO MAINTAIN A FIRM PRICE FOR THE LENGTH OF THE CONTRACT BUT OFFERS AN ALTERNATE PROPOSAL AS FOLLOWS:

.....

.....

.....

.....

NOTICE

A SIGNED BID MUST BE SUBMITTED TO:

DEPARTMENT OF ADMINISTRATION
PURCHASING DIVISION
BUILDING 15
2019 WASHINGTON STREET, EAST
CHARLESTON, WV 25305-0130

PLEASE NOTE: A CONVENIENCE COPY WOULD BE APPRECIATED.

THE BID SHOULD CONTAIN THIS INFORMATION ON THE FACE OF THE ENVELOPE OR THE BID MAY NOT BE CONSIDERED:

SEALED BID

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE [signature] TELEPHONE 510-979-5195 DATE 12 Feb 2009

TITLE VP, US Sales FEIN 68-0418167 ADDRESS CHANGES TO BE NOTED ABOVE

WHEN RESPONDING TO RFQ, INSERT NAME AND ADDRESS IN SPACE ABOVE LABELED 'VENDOR'

State of West Virginia
Department of Administration
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2019 Washington Street East
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Request for Quotation

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304-558-0067

VENDOR
*308134754 800-626-0690
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25302 304-558-4865

DATE PRINTED	TERMS OF SALE	SHIP VIA	F.O.B.	FREIGHT TERMS
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LINE	QUANTITY	UOP	CAT. NO.	ITEM NUMBER	UNIT PRICE	AMOUNT

BUYER:----------RW/FILE 22----------

RFQ. NO.:----------CME90108----------

BID OPENING DATE:--------2/19/2009----------

BID OPENING TIME:--------1:30 PM----------

PLEASE PROVIDE A FAX NUMBER IN CASE IT IS NECESSARY TO CONTACT YOU REGARDING YOUR BID:

510-979-5395

CONTACT PERSON (PLEASE PRINT CLEARLY):

Sherri Williams

****** THIS IS THE END OF RFQ CME90108 ****** TOTAL: $27,545.00

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE [signature] TELEPHONE 510-979-5195 DATE 12 Feb 2009

TITLE VP/ US Sales FEIN 68-0418167 ADDRESS CHANGES TO BE NOTED ABOVE

WHEN RESPONDING TO RFQ, INSERT NAME AND ADDRESS IN SPACE ABOVE LABELED 'VENDOR'

TO PROVIDE AN OPEN END CONTRACT TO PURCHASE IMMUNOASSAY REAGENT KITS CAPABLE OF DETECTING DRUGS OF ABUSE AND TRICYCLIC ANTI-DEPRESSANT DRUGS IN URINE SAMPLES USING A MICROGENICS MGC240 ANALYZER

Specifications and Requirements:

1. The methodology of detection must be a homogenous immunoassay, which does not require the separation of bound and free fractions. The assay is based on the competition between a drug which is labeled with the enzyme glucose-6-phosphate dehydrogenase, or G6PDH and an unlabeled drug within the test sample. A specific antibody then binds to the drug labeled with G6PDH resulting in a decrease in enzyme activity. This binding causes a direct relationship between the enzyme activity and the concentration of the drug in the sample being tested. Enzyme activity in the presence of G6PDH results in the conversion of nicotine adenine dinucleotide (NAD) to its reduced form (NADH) and the subsequent increase in absorbance which is measured by the Microgenics MGC240 Analyzer.

2. The vendor must manufacture specific reagent kits capable of detecting drugs, classes of drugs or drug metabolites. This list that comprises the 11 assay panel which will be tested by the OCME is as follows:

   *Amphetamines
   *Barbiturates
   *Benzodiazepines
   *Buprenorphine
   *Cocaine (metabolite)
   *Cannabinoids (THC metabolite)
   *Methadone (or metabolite)
   *Opiates
   *Oxycodone
   *Propoxyphene
   *Tricyclic anti-depressants

3. The full panel of assays will be tested on a minimum of one sample per each case submitted to the OCME Toxicology Lab. Accordingly, the kits purchased must be sufficient for analysis of case samples, controls and calibrators which is estimated to be approximately 3000 samples yearly. Therefore, based on an 11 assay panel, the total number of tests is approximately 33,000 per year. Please provide price information based on such 11 assay panel x 3000.

4. Each kit must be provided with thorough information as to the cross-reactivity of target analytes, as well as information on a group of relevant potentially interfering substances. Also included must be information about the performance of each assay at concentrations around the cut-off and specific settings for the use of their reagents on the Microgenics MGC240 Analyzer.

Contract shall be for a period of one year. At the end of one (1) year, an option is reserved to renew the agreement in accordance with the same terms and conditions as the original contract and shall be limited to two (2) one (1) year renewals.

RFQ COST SHEET

Bidders shall provide a cost for the following:

Line Item #	Name of Analyte	# of Tests Per Year	Cost Per Kit	Estimated Cost Per Year
1	Amphetamine	3,000	$387.00	$1935.00
2	Barbiturate	3,000	387.00	1935.00
3	Benzodiazepines	3,000	387.00	1935.00
4	Buprenorphine	3,000	276.00	3558.00
5	Cocaine (metabolite)	3,000	387.00	1935.00
6	Cannabinoids (THC metabolite)	3,000	387.00	1935.00
7	Methadone (or metabolite)	3,000	387.00	1935.00
8	Opiates	3,000	387.00	1935.00
9	Oxycodone	3,000	561.00	3927.00
10	Propoxyphene	3,000	387.00	1935.00
11	Tricyclic anti-depresents	3,000	130.00	4550.00
			Grand Total	$27,560.00

The award will be made to the vendor with the lowest overall total cost per kit which meets all requested specifications and requirements.

Vendor Signature

13 Feb 2009
Date

State of West Virginia

VENDOR PREFERENCE CERTIFICATE

Certification and application* is hereby made for Preference in accordance with ***West Virginia Code***, §5A-3-37. (Does not apply to construction contracts). ***West Virginia Code***, §5A-3-37, provides an opportunity for qualifying vendors to request (at the time of bid) preference for their residency status. Such preference is an evaluation method only and will be applied only to the cost bid in accordance with the ***West Virginia Code***. This certificate for application is to be used to request such preference. The Purchasing Division will make the determination of the Resident Vendor Preference, if applicable.

1. **Application is made for 2.5% resident vendor preference for the reason checked:**
___ Bidder is an individual resident vendor and has resided continuously in West Virginia for four (4) years immediately preceding the date of this certification; **or,**

___ Bidder is a partnership, association or corporation resident vendor and has maintained its headquarters or principal place of business continuously in West Virginia for four (4) years immediately preceding the date of this certification; or 80% of the ownership interest of Bidder is held by another individual, partnership, association or corporation resident vendor who has maintained its headquarters or principal place of business continuously in West Virginia for four (4) years immediately preceding the date of this certification; **or,**

___ Bidder is a nonresident vendor which has an affiliate or subsidiary which employs a minimum of one hundred state residents and which has maintained its headquarters or principal place of business within West Virginia continuously for the four (4) years immediately preceding the date of this certification; **or,**

2. **Application is made for 2.5% resident vendor preference for the reason checked:**
___ Bidder is a resident vendor who certifies that, during the life of the contract, on average at least 75% of the employees working on the project being bid are residents of West Virginia who have resided in the state continuously for the two years immediately preceding submission of this bid; **or,**

3. **Application is made for 2.5% resident vendor preference for the reason checked:**
___ Bidder is a nonresident vendor employing a minimum of one hundred state residents or is a nonresident vendor with an affiliate or subsidiary which maintains its headquarters or principal place of business within West Virginia employing a minimum of one hundred state residents who certifies that, during the life of the contract, on average at least 75% of the employees or Bidder's affiliate's or subsidiary's employees are residents of West Virginia who have resided in the state continuously for the two years immediately preceding submission of this bid; **or,**

4. **Application is made for 5% resident vendor preference for the reason checked:**
___ Bidder meets either the requirement of both subdivisions (1) and (2) or subdivision (1) and (3) as stated above; **or,**

5. **Application is made for 3.5% resident vendor preference who is a veteran for the reason checked:**
___ Bidder is an individual resident vendor who is a veteran of the United States armed forces, the reserves or the National Guard and has resided in West Virginia continuously for the four years immediately preceding the date on which the bid is submitted; **or,**

6. **Application is made for 3.5% resident vendor preference who is a veteran for the reason checked:**
___ Bidder is a resident vendor who is a veteran of the United States armed forces, the reserves or the National Guard, if, for purposes of producing or distributing the commodities or completing the project which is the subject of the vendor's bid and continuously over the entire term of the project, on average at least seventy-five percent of the vendor's employees are residents of West Virginia who have resided in the state continuously for the two immediately preceding years.

Bidder understands if the Secretary of Revenue determines that a Bidder receiving preference has failed to continue to meet the requirements for such preference, the Secretary may order the Director of Purchasing to: (a) reject the bid; or (b) assess a penalty against such Bidder in an amount not to exceed 5% of the bid amount and that such penalty will be paid to the contracting agency or deducted from any unpaid balance on the contract or purchase order.

By submission of this certificate, Bidder agrees to disclose any reasonably requested information to the Purchasing Division and authorizes the Department of Revenue to disclose to the Director of Purchasing appropriate information verifying that Bidder has paid the required business taxes, provided that such information does not contain the amounts of taxes paid nor any other information deemed by the Tax Commissioner to be confidential.

Under penalty of law for false swearing (West Virginia Code, §61-5-3), Bidder hereby certifies that this certificate is true and accurate in all respects; and that if a contract is issued to Bidder and if anything contained within this certificate changes during the term of the contract, Bidder will notify the Purchasing Division in writing immediately.

Bidder: Microgenics Corporation Signed: _____

Date: 13 Feb 2009 Title: VP / US Sales

**Check any combination of preference consideration(s) indicated above which you are entitled to receive.*

State of West Virginia
Department of Administration
Purchasing Division
2019 Washington Street East
Post Office Box 50130
Charleston, WV 25305-0130

Request for Quotation

RFQ NUMBER	PAGE
CME90108	1

ADDRESS CORRESPONDENCE TO ATTENTION OF:
ROBERTA WAGNER
304-558-0067

VENDOR
*308134754 800-626-0690
MICROGENICS CORPORATION
46360 FREMONT BOULEVARD

FREMONT CA 94538

SHIP TO
HEALTH AND HUMAN RESOURCES
BUREAU FOR PUBLIC HEALTH
OFFICE CHIEF MEDICAL EXAMINER
619 VIRGINIA STREET, WEST
CHARLESTON, WV
25302 304-558-4865

DATE PRINTED	TERMS OF SALE	SHIP VIA	F.O.B.	FREIGHT TERMS
02/04/2009				

BID OPENING DATE: 02/19/2009 BID OPENING TIME 01:30PM

LINE	QUANTITY	UOP	CAT. NO.	ITEM NUMBER	UNIT PRICE	AMOUNT

ADDENDUM NO. 1

1. QUESTIONS AND ANSWERS ATTACHED.
2. ADDENDUM ACKNOWLEDGEMENT IS ATTACHED. THIS DOCUMENT SHOULD BE SIGNED AND RETURNED WITH YOUR BID. FAILURE TO SIGN AND RETURN MAY RESULT IN DISQUALIFICATION OF YOUR BID.

EXHIBIT 10

REQUISITION NO.: CME90108

ADDENDUM ACKNOWLEDGEMENT

I HEREBY ACKNOWLEDGE RECEIPT OF THE FOLLOWING CHECKED ADDENDUM(S) AND HAVE MADE THE NECESSARY REVISIONS TO MY PROPOSAL, PLANS AND/OR SPECIFICATION, ETC.

ADDENDUM NO.'S:

NO. 1 .....

NO. 2 .....

NO. 3 .....

NO. 4 .....

NO. 5 .....

I UNDERSTAND THAT FAILURE TO CONFIRM THE RECEIPT OF THE ADDENDUM(S) MAY BE CAUSE FOR REJECTION OF BIDS.

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE _____ TELEPHONE 510-979-5195 DATE 13 Feb 2009

TITLE VP, US Sales FEIN 68-0418167 ADDRESS CHANGES TO BE NOTED ABOVE

WHEN RESPONDING TO RFQ, INSERT NAME AND ADDRESS IN SPACE ABOVE LABELED 'VENDOR'

State of West Virginia
Department of Administration
Purchasing Division
2019 Washington Street East
Post Office Box 50130
Charleston, WV 25305-0130

Request for Quotation

RFQ NUMBER	PAGE
CME90108	2

ADDRESS CORRESPONDENCE TO ATTENTION OF:
ROBERTA WAGNER
304-558-0067

VENDOR
*308134754 800-626-0690
MICROGENICS CORPORATION
46360 FREMONT BOULEVARD

FREMONT CA 94538

SHIP TO
HEALTH AND HUMAN RESOURCES
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OFFICE CHIEF MEDICAL EXAMINER
619 VIRGINIA STREET, WEST
CHARLESTON, WV
25302 304-558-4865

DATE PRINTED	TERMS OF SALE	SHIP VIA	F.O.B.	FREIGHT TERMS
02/04/2009				

BID OPENING DATE: 02/19/2009 BID OPENING TIME 01:30PM

LINE	QUANTITY	UOP	CAT. NO	ITEM NUMBER	UNIT PRICE	AMOUNT

VENDOR MUST CLEARLY UNDERSTAND THAT ANY VERBAL REPRESENTATION MADE OR ASSUMED TO BE MADE DURING ANY ORAL DISCUSSION HELD BETWEEN VENDOR'S REPRESENTATIVES AND ANY STATE PERSONNEL IS NOT BINDING. ONLY THE INFORMATION ISSUED IN WRITING AND ADDED TO THE SPECIFICATIONS BY AN OFFICIAL ADDENDUM IS BINDING.

SIGNATURE

Microgenics Corporation
COMPANY

13 Feb 2009
DATE

REV. 11/96

END OF ADDENDUM NO. 1

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE | TELEPHONE 510-979-5195 | DATE 13 Feb 2009

TITLE VP, US Sales | FEIN 68-0418167 | ADDRESS CHANGES TO BE NOTED ABOVE

WHEN RESPONDING TO RFQ, INSERT NAME AND ADDRESS IN SPACE ABOVE LABELED 'VENDOR'

GENERAL TERMS & CONDITIONS
REQUEST FOR QUOTATION (RFQ) AND REQUEST FOR PROPOSAL (RFP)

1. Awards will be made in the best interest of the State of West Virginia.

2. The State may accept or reject in part, or in whole, any bid.

3. All quotations are governed by the ***West Virginia Code*** and the ***Legislative Rules*** of the Purchasing Division.

4. Prior to any award, the apparent successful vendor must be properly registered with the Purchasing Division and have paid the required $125 fee.

5. All services performed or goods delivered under State Purchase Order/Contracts are to be continued for the term of the Purchase Order/Contracts, contingent upon funds being appropriated by the Legislature or otherwise being made available. In the event funds are not appropriated or otherwise available for these services or goods, this Purchase Order/Contract becomes void and of no effect after June 30.

6. Payment may only be made after the delivery and acceptance of goods or services.

7. Interest may be paid for late payment in accordance with the ***West Virginia Code***.

8. Vendor preference will be granted upon written request in accordance with the ***West Virginia Code***

9. The State of West Virginia is exempt from federal and state taxes and will not pay or reimburse such taxes.

10. The Director of Purchasing may cancel any Purchase Order/Contract upon 30 days written notice to the seller

11. The laws of the State of West Virginia and the ***Legislative Rules*** of the Purchasing Division shall govern all rights and duties under the Contract, including without limitation the validity of this Purchase Order/Contract.

12. Any reference to automatic renewal is hereby deleted. The Contract may be renewed only upon mutual written agreement of the parties.

13. **BANKRUPTCY:** In the event the vendor/contractor files for bankruptcy protection, this Contract may be deemed null and void, and terminated without further order.

14. **HIPAA BUSINESS ASSOCIATE ADDENDUM:** The West Virginia State Government HIPAA Business Associate Addendum (BAA), approved by the Attorney General, and available online at the Purchasing Division's web site (**http://www.state.wv.us/admin/purchase/vrc/hipaa.htm**) is hereby made part of the agreement. Provided that, the Agency meets the definition of a Cover Entity (45 CFR §160.103) and will be disclosing Protected Health Information (45 CFR §160.103) to the vendor.

15. **WEST VIRGINIA ALCOHOL & DRUG-FREE WORKPLACE ACT:** If this Contract constitutes a public improvement construction contract as set forth in Article 1D, Chapter 21 of the West Virginia Code ("The West Virginia Alcohol and Drug-Free Workplace Act"), then the following language shall hereby become part of this Contract: "The contractor and its subcontractors shall implement and maintain a written drug-free workplace policy in compliance with the West Virginia Alcohol and Drug-Free Workplace Act, as set forth in Article 1D, Chapter 21 of the West Virginia Code. The contractor and its subcontractors shall provide a sworn statement in writing, under the penalties of perjury, that they maintain a valid drug-free work place policy in compliance with the West Virginia and Drug-Free Workplace Act. It is understood and agreed that this Contract shall be cancelled by the awarding authority if the Contractor: 1) Fails to implement its drug-free workplace policy; 2) Fails to provide information regarding implementation of the contractor's drug-free workplace policy at the request of the public authority; or 3) Provides to the public authority false information regarding the contractor's drug-free workplace policy."

INSTRUCTIONS TO BIDDERS

1. Use the quotation forms provided by the Purchasing Division.

2. **SPECIFICATIONS:** Items offered must be in compliance with the specifications. Any deviation from the specifications must be clearly indicated by the bidder. Alternates offered by the bidder as **EQUAL** to the specifications must be clearly defined. A bidder offering an alternate should attach complete specifications and literature to the bid. The Purchasing Division may waive minor deviations to specifications.

3. Complete all sections of the quotation form.

4. Unit prices shall prevail in case of discrepancy.

5. All quotations are considered F.O.B. destination unless alternate shipping terms are clearly identified in the quotation.

6. **BID SUBMISSION:** All quotations must be delivered by the bidder to the office listed below prior to the date and time of the bid opening. Failure of the bidder to deliver the quotations on time will result in bid disqualifications: Department of Administration, Purchasing Division, 2019 Washington Street East, P.O. Box 50130, Charleston, WV 25305-0130

WV-38 (Rev 01/01/07)

STATE OF WEST VIRGINIA

PURCHASE CONTINUATION SHEET

Page ____ of ____ Pages

Requisition / P O No.: CME90108

File:

Acct. No.: 0407-2009-2937-045

Spending Unit: DHHR/OCME

Vendor: _____ P O Date: _____

Item No.	Quantity	Description	Unit Price	Amount
		VENDOR QUESTION #1: Please clarify the term LIFE OF CONTRACT. Is that defined as "A PERIOD OF ONE (1) YEAR" as outlined on page one? " THE TERMS, CONDITIONS AND PRICING SET....ARE FIRM FOR THE LIFE OF THE CONTRACT." Therefore, the vendor may, upon renewal of either "TWO (2) One (1) YEAR PERIODS," notify the State, within 30 days, of a "PRICE ADJUSTMENT?" In so doing, is the Vendor complying with the States "PREFERRED TERMS" since the PRICE ADJUSTMENT happens upon renewal of the State's OPTION? RESPONSE: The Life of the Contract will be for a period of one (1) year with the option to renew the contract for two (2) one (1) year periods. The option to renew the contract must be mutually agreed upon by the vendor and the spending unit. All terms, conditions and prices set in the original one (1) year period will remain firm for the life of the contract including the two (2) one (1) year periods, if renewed. No price adjustments will be allowed. As to the "Preferred Terms", its the preference of the spending unit that the prices on this contract are firm for life of the contract, as indicated above. If a vendor can not guarantee a firm price for the life of the contract, he must indicate one of the paragraphs listed as "Alternate Terms" which allows the vendor to state "how long the prices will remain firm (blank number of days)" or allows the vendor to offer an alternate proposal as to pricing Alternate Terms will not be acceptable in this contract. VENDOR QUESTION #2: Please clarify ALTERNATE TERMS. Is this referring to a mid-year PRICE ADJUSTMENT or does this apply to a PRICE ADJUSTMENT for either TWO (2) ONE (1) YEAR PERIODS? RESPONSE: Please see response to Vendor Question #1 above.		

microgenics

STATE OF WEST VIRGINIA
CHIEF MEDICAL EXAMINER

REQUEST FOR QUOTATION CME90108

Microgenics Corporation is pleased to present our response to the State of West Virginia Request for Quotation for Immunoassay Reagent Kits. It is with great anticipation that we look forward to the opportunity to expand our existing relationship with the State of West Virginia.

To meet the requirements of the bid, Microgenics is offering an Open End Contract to purchase our DRI® reagents for testing on the Microgenics MGC240 drug testing system. The annual reagent cost of $27,560 is based on screening approximately 33,000 samples per year The base year is twelve (12) months with two (2) one year periods. Pricing is firm for the life of the contract base year.

Upon award of the bid, Microgenics offers to provide technical service for reagent training, as requested. Our team of friendly, Technical Service professionals are experts in laboratory technology and are available 24/7 by calling our toll-free number.

Our reagent kits are capable of detecting the following:

Acetaminophen
Amphetamines *
Barbiturates (Serum Assay)
Barbiturates *
Benzodiazepine (Serum Assay)
Benzodiazepines *
Cannabinoids (THC) *
Chromate Detect
Cocaine Metabolite *
Cotinine
Creatinine Detect
Digoxin
Ecstasy
Gravity-Detect
Methadone *
Methadone Metabolite
Methaqualone
Nitrite Detect
Opiates *
Oxycodone *
pH-Detect
Phencyclidine
Primidone
Propoxyphene *
Salicylate
T Uptake
Total Thyroxine
Tricyclic Anti-Depressants *

Microgenics Corporation's approach and plans for accomplishing the scope of the Enzyme Immunoassay Reagents contract.

By understanding and responding to our customer's evolving needs, Microgenics is generating much of the industry momentum for bringing new diagnostic assays to market. Supported by one of the strongest research and development programs in the industry, we have leveraged our core technologies to develop two highly compatible product platforms. Our Customers benefit from the synergy offered by multiple technologies in drugs of abuse testing, therapeutic drug monitoring, endocrine function, and anemia diagnosis.

Microgenics' DRI reagents and assays are a liquid, ready-to-use homogeneous enzyme immunoassay and are intended for the qualitative or semi quantitative determination of drugs in human urine. The assay provides a simple and rapid analytical screening procedure for detecting drugs in urine.

The assays provide only a preliminary analytical test result A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/ mass spectrometry

(GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Microgenics' assays use specific antibodies, which can detect drugs in urine with minimal cross-reactivity to various over-the-counter compounds The assays are based on competition of a drug-labeled enzyme glucose-6-phosphate dehydrogenase (G6PDH). The free drug from the urine sample for a fixed amount of specific antibody binds the drug-labeled G6PDH and the enzyme activity it inhibited. This phenomenon creates a direct relationship between drug concentration in urine and the enzyme activity. The enzyme G6PDH activity is determined spectrophotometrically at 340 nm by measuring its ability to convert nicotinamide adenine dinucleotide (NAD) to NADH

Microgenics Corporation
46360 Fremont Blvd.
Fremont, CA 94538
Phone: 1-800-232-3342
Fax: 1-800-829-8115

Federal ID: 68-0418167

Remittance:
7055 Collection Center Dr.
Chicago, IL 66093

Contacts:
Paul Cook, Regional Sales Manager
1-800-232-3342, x. 5103

Saood Pervez, Asst, Dir., US Sales
1-800-232-3342, x. 5141

ThermoFisher SCIENTIFIC

Pricing Proposal - Product Volume Requirements

2/17/2009

Ver 15A

Customer: RFQ # CME90108	
Contract Length (Yrs):	3
Total Annual Tests:	33,000
Estimated Annual $ *:	$32,331

(*Annual $ includes estimated calibration)

33,000 Annual

$ 27,545 Annual

$ 82,635 Contract

Analyte	Product	Description	# Tests	# Kits	Yield	Kit Price	$/Test	Total $	Total $
Buprenorphine	100190	Kit Buprenorphine TSC	3,000	13	240	$ 276.00	$ 1.150	$ 3,588	$ 10,764
Oxycodone	100248	Kit OXY 70mL	3,000	7	488	$ 561.00	$ 1.150	$ 3,927	$ 11,781
Amphetamine	0017	Kit Amph 100ml	3,000	5	725	$ 387.00	$ 0.534	$ 1,935	$ 5,805
Barbiturate	0225	Kit Barb 100mL	3,000	5	725	$ 387.00	$ 0.534	$ 1,935	$ 5,805
Benzodiazepine	0039	Kit Benz 100ml	3,000	5	725	$ 387.00	$ 0.534	$ 1,935	$ 5,805
Cocaine	0055	Kit Cocaine 100ml	3,000	5	725	$ 387.00	$ 0.534	$ 1,935	$ 5,805
Methadone	0596	Kit Methadone 100ml	3,000	5	725	$ 387.00	$ 0.534	$ 1,935	$ 5,805
Opiate	0135	Kit Opiate 100mL	3,000	5	725	$ 387.00	$ 0.534	$ 1,935	$ 5,805
Propoxyphene	0432	Kit PPx 100ml	3,000	5	725	$ 387.00	$ 0.534	$ 1,935	$ 5,805
THC	0185	Kit THC 100mL	3,000	35	87	$ 130.00	$ 1.494	$ 4,550	$ 13,650
Tricyclics	1128	Kit Tricyclic Serum Tox							

Customer Signature/Date: _____

Microgenics Corporation
46360 Fremont Boulevard
Fremont, CA 94538 USA
Technical/Customer Service:
800-232-3342

ThermoFisher SCIENTIFIC

Version 15A

Customer: RFQ # CME90108

Primary Instrument: MGC 240

Pricing Proposal

Annual Testing Volume: 33,000

DRUGS OF ABUSE PRODUCTS

DRI DRUGS OF ABUSE ASSAYS

Cat #	Product Description	Kit Size (mL)	# Test/Kit	$/Kit
0017	Amphetamine	100	725	$ 387.00
0018	Amphetamine	500	3,688	$ 1,514.00
0225	Barbiturate	100	725	$ 387.00
0226	Barbiturate	500	3,688	$ 1,514.00
0039	Benzodiazepine	100	725	$ 387.00
0040	Benzodiazepine	500	3,688	$ 1,514.00
0185	Cannabinoid (THC)	100	725	$ 387.00
0186	Cannabinoid (THC)	500	3,688	$ 1,514.00
0055	Cocaine Metabolite	100	725	$ 387.00
0056	Cocaine Metabolite	500	3,688	$ 1,514.00
0394	Cotinine	100	725	$ 737.00
0395	Cotinine	500	3,688	$ 2,886.00
100075	Ecstasy	100	725	$ 758.00
100076	Ecstasy	500	3,688	$ 2,968.00
0037	Ethyl Alcohol	100	725	$ 387.00
0038	Ethyl Alcohol	500	3,688	$ 1,514.00
10011297	Kit ETG 70mL **	70	507	$ 961.00
10011226	Kit ETG 500mL **	500	3,830	$ 5,190.00
100115	Methadone Metab (EDDP)	100	725	$ 737.00
100116	Methadone Metab (EDDP)	500	3,688	$ 2,886.00
0596	Methadone	100	725	$ 387.00
0597	Methadone	500	3,688	$ 1,514.00
0514	Methaqualone	100	725	$ 387.00
0515	Methaqualone	500	3,688	$ 1,514.00
0135	Opiate	100	725	$ 387.00
[illegible]	Opiate	500	3,688	$ 1,514.00
[illegible]8	Oxycodone	70	488	$ 561.00
100249	Oxycodone	500	3,688	$ 3,028.00
0160	Phencyclidine	100	725	$ 387.00
0161	Phencyclidine	500	3,688	$ 1,514.00
0432	Propoxyphene	100	725	$ 387.00
0433	Propoxyphene	500	3,688	$ 1,514.00

DRI DAU CONTROLS

0170	THC Urine 40ng Ctrl	5		$ 22.00
0168	THC Urine 60ng Ctrl	5		$ 22.00
1401	Kit THC 40ng 25ml Ctrl	25		$ 107.00
1402	THC Urine 60ng Ctrl	25		$ 107.00
1404	THC Urine 125ng Ctrl	25		$ 107.00
0212	THC Urine 125ng Ctrl	5		$ 22.00
0214	THC Urine 75ng Ctrl	5		$ 22.00
0239	Alcohol 50mg Ctrl	5		$ 22.00
0243	Alcohol 300mg Ctrl	5		$ 22.00
0460	Low Cotinine Ctrl	5		$ 22.00
0470	Hgh Cotinine Ctrl	5		$ 22.00
100254	Oxycodone Control 100 C/O	2x10		$ 67.00
100255	Oxycodone Control 300 C/O	2x10		$ 67.00
10011209	ETG 500ng/ml Control **	10		$ 67.00
10011211	ETG 1000ng/ml Control **	10		$ 67.00

DRI DAU CALIBRATORS

Cat #	Product Description	Kit Size (mL)	# Test/Kit	$/Kit
0034	Low Urine Cal	5		$ 33.00
0036	High Urine Cal	5		$ 33.00
1609	Opiate Cal 1	25		$ 107.00
1610	Opiate Cal 3	25		$ 107.00
0235	THC Urine Cal 20ng	5		$ 22.00
1397	THC Urine Cal 20ng	25		$ 107.00
0042	THC Urine Cal 50ng	5		$ 22.00
1398	THC Urine Cal 50ng	25		$ 107.00
0044	THC Urine Cal 100ng	5		$ 22.00
1399	THC Urine Cal 100ng	25		$ 107.00
0206	THC Urine Cal 200ng	5		$ 22.00
1400	THC Urine Cal 200ng	25		$ 107.00
1664	Neg Urine Cal	10		$ 69.00
1388	Neg Urine Cal	25		$ 82.00
1588	MD Urine Cal 1	10		$ 69.00
1589	MD Urine Cal 1	25		$ 123.00
1591	MD Urine Cal 2 Low	10		$ 69.00
1592	MD Urine Cal 2 Low	25		$ 123.00
1594	MD Urine Cal 3	10		$ 69.00
1595	MD Urine Cal 3	25		$ 123.00
1597	MD Urine Cal 4 High	10		$ 69.00
1598	MD Urine Cal 4 High	25		$ 123.00
0311	Alcohol Neg Cal	5		$ 22.00
1405	Alcohol Neg Cal	25		$ 107.00
0241	Alcohol Cal 100mg	5		$ 22.00
1406	Alcohol Cal 100mg	25		$ 107.00
0404	Cotinine Cal Kit	6x5		$ 42.00
100117	Kit Metd Mtb Cal 150	10		$ 44.00
100118	Kit Metd Mtb Cal 300	10		$ 44.00
100120	Kit Metd Mtb Cal 1000	10		$ 44.00
100122	Kit Metd Mtb Cal 2000	10		$ 44.00
100079	Ecstasy 1000ng/mL Cal	10		$ 44.00
100080	Ecstasy 750ng/mL Cal	10		$ 44.00
100081	Ecstasy 500ng/mL Cal	10		$ 44.00
100082	Ecstasy 250ng/mL cal	10		$ 44.00
100250	Oxycodone Cal 100ng	10		$ 44.00
100251	Oxycodone Cal 300ng	10		$ 44.00
100252	Oxycodone Cal 500ng	10		$ 44.00
100253	Oxycodone Cal 1000ng	10		$ 67.00
10011207	ETG Neg Cal **	10		$ 67.00
10011208	ETG 100ng/ml Calibrator **	10		$ 67.00
10011210	ETG 500ng/ml Calibrator **	10		$ 67.00
10011212	ETG 1000ng/ml Calibrator **	10		$ 67.00
10011213	ETG 2000ng/ml Calibrator **	10		$ 67.00

** Products for Research Use Only

Customer Signature/Date:_____

Microgenics Corporation
46360 Fremont Boulevard Fremont CA 94538
Technical/Customer Service: 800 232-3342

Date Prepared: 2/17/2009

ThermoFisher SCIENTIFIC

Version 15A

Customer: RFQ # CME90108

P[illegible]ary Instrument: MGC 240

Pricing Proposal

Annual Testing Volume: 33,000

IA DRUGS OF ABUSE PRODUCTS

CEDIA DRUGS OF ABUSE ASSAYS

Cat #	Product Description	Kit Size (mL)	# Test/Kit	$/Kit
100083	Amphetamine TSC	51	240	$ 175.00
100092	Amphetamine MCC	65	315	$ 174.00
1661205	Amphetamine LC	500	2,490	$ 1,022.00
100104	Amph/Ecstasy TSC	51	342	$ 203.00
100103	Amph/Ecstasy MCC	65	450	$ 249.00
100040	Amph-Ecstasy LC	500	3,557	$ 1,460.00
100084	Barbiturate TSC	51	240	$ 175.00
100093	Barbiturate MCC	65	315	$ 174.00
1661213	Barbiturate LC	500	2,490	$ 1,022.00
100085	Benzodiazepine TSC	51	240	$ 175.00
100094	Benzodiazepine MCC	65	315	$ 174.00
1775561	Benzodiazepine LC	500	2,490	$ 1,022.00
100190	Buprenorphine TSC	51	240	$ 276.00
100240	Buprenorphine MCC	65	315	$ 337.00
100086	Cocaine TSC	51	240	$ 175.00
100095	Cocaine MCC	65	315	$ 174.00
1661230	Cocaine LC	500	2,490	$ 1,022.00
100107	Heroin Metab TSC	51	240	$ 280.00
100108	Heroin Metab MCC	65	315	$ 342.00
100186	Heroin Metab LC	500	2,490	$ 2,004.00
1732137	LSD SC	18	115	$ 155.00
100088	Methadone TSC	51	240	$ 175.00
100097	Methadone MCC	65	315	$ 174.00
1730916	Methadone LC	500	2,490	$ 1,022.00
100087	Methadone Metab TSC	51	240	$ 272.00
100096	Methadone Metab MCC	65	315	$ 332.00
[illegible]17	Methadone Metab LC	500	2,490	$ 1,948.00
[illegible]9	Opiate TSC	51	240	$ 175.00
100098	Opiate MCC	65	315	$ 174.00
1661248	Opiate LC	500	2,490	$ 1,022.00
100090	Opiate 2k TSC	51	240	$ 175.00
100099	Opiate 2k MCC	65	315	$ 174.00
1815296	Opiate 2K LC	500	2,490	$ 1,022.00
100172	PCP TSC	51	240	$ 175.00
100173	PCP MCC	65	315	$ 174.00
1815784	PCP LC	500	2,490	$ 1,022.00
100170	Propoxyphene TSC	51	240	$ 175.00
100171	Propoxyphene MCC	65	315	$ 174.00
1661523	Propoxyphene LC	500	2,490	$ 1,022.00
100091	THC TSC	51	240	$ 175.00
100100	THC MCC	65	315	$ 174.00
1661256	THC LC	500	2,490	$ 1,022.00
10010029	THC Plus TSC	51	240	$ 175.00
10010030	THC Plus MCC	65	315	$ 174.00
10010031	THC Plus LC	500	2,490	$ 1,022.00

CEDIA DAU CALIBRATORS

Cat #	Product Description	Kit Size (mL)	# Test/Kit	$/Kit
100031	Heroin Metab Cut off Cal	5		$ 67.00
100034	Heroin Metab High Cal	5		$ 67.00
1557416	Negative Cal	5		$ 22.00
1661388	Negative Cal	15		$ 53.00
1730401	MD Primary Cal Clin c/o	5		$ 38.00
1815326	MD Primary Cal 2K	5		$ 38.00
1815334	MD Primary Cal 2K	15		$ 89.00
1730428	MD Secondary Cal	5		$ 38.00
1730517	MD Secondary Cal	15		$ 89.00
1730380	MD Intermed Cal	5		$ 38.00
1732218	MD Intermed Cal	15		$ 89.00
1730398	MD High Cal	5		$ 38.00
1732226	MD High Cal	15		$ 89.00
1732153	LSD Cut off Cal	5		$ 44.00
1732161	LSD Intermed Cal	5		$ 44.00
1732196	LSD High Cal	5		$ 44.00
1662848	PPx/Mtd Cutoff Cal	5		$ 29.00
1662856	PPx/Mtd Intermed Cal	5		$ 29.00
1662864	PPx/Mtd High Cal	5		$ 29.00
1557505	THC 25 Cal	15		$ 89.00
1557513	THC 50 Cal	15		$ 89.00
1557521	THC 75 Cal	15		$ 89.00
1557530	THC 100 Cal	15		$ 89.00
1557548	THC 150 Cal	15		$ 89.00
100241	Kit Bup Cal 0ng/mL	1x7.5		$ 44.00
100242	Kit Bup Cal 5ng/mL	1x5		$ 44.00
100243	Kit Bup Cal 20ng/mL	1x5		$ 44.00
100244	Kit Bup Cal 50ng/mL	1x5		$ 44.00
100245	Kit Bup Cal 75ng/mL	1x5		$ 44.00

CEDIA DAU CONTROLS

1661086	THC 25 Control Set	2x15		$ 89.00
1661078	THC 50 Control Set	2x15		$ 89.00
1661060	THC 100 Control Set	2x15		$ 89.00
1815440	Specialty Control Set	3x5		$ 89.00
1868934	Opiate 2K High Control	15		$ 89.00
100246	Kit Bup Control	2x5		$ 67.00

DAU SPECIALTY PRODUCTS

127680	β-glucuronidase Enzyme	5		$ 292.00

CEDIA/DRI MULTI-DRUG DAU CONTROL SETS

100200	Kit MD Primary Ctrl	3x5		$ 134.00
100201	Kit MD Clinical Ctrl	3x5		$ 134.00
100202	Kit MD Select Ctrl	3x5		$ 134.00
100069	Kit MD Ctrl Optional	2x5		$ 71.00

CEDIA THC Plus Control and Calibrator SETS

10010032	Kit THC PLUS Cal 25	10		$ 67.00
10010033	Kit THC PLUS Cal 50	10		$ 67.00
10010034	Kit THC PLUS Cal 100	10		$ 67.00
10010035	Kit THC PLUS Cal 200	10		$ 67.00
10010036	Kit THC PLUS Ctrl 25	10		$ 67.00
10010037	Kit THC PLUS Ctrl 50	10		$ 67.00
10010038	Kit THC PLUS Ctrl 100	10		$ 67.00

ner Signature/Date:_____

Microgenics Corporation
46360 Fremont Boulevard Fremont CA 94538
Technical/Customer Service: 800 232-3342

Date Prepared: 2/17/2009

ThermoFisher SCIENTIFIC

Version 15A

Customer: RFQ # CME90108

Primary Instrument: MGC 240

Pricing Proposal

Annual Testing Volume: 33,000

THERAPEUTIC DRUG MONITORING (TDM) PRODUCTS

CEDIA TDM Assays

Cat #	Product Description	Kit Size (mL)	# Test/Kit	$/Kit
100006	Carbamazepine II	17,17	114	$ 120.00
100005	Digoxin II	18,18	107	$ 120.00
100016	Gentamicin II	13,11	75	$ 100.00
100015	NAPA	17,17	114	$ 120.00
100003	Phenobarbital II	17,17	114	$ 120.00
100002	Phenytoin II	17,17	114	$ 120.00
100014	Procainamide	17,17	114	$ 120.00
100008	Theophylline II	17,17	114	$ 120.00
100018	Tobramycin II	13,11	80	$ 100.00
100013	Valproic Acid	13,11	75	$ 100.00
100001	TDM Cardiac Cal	2x7.5,2x5.0		$ 53.00
100007	TDM Core Cal	2x7.5,2x5.0		$ 53.00
100017	TDM Antibiotic Cal	2x7.5,2x5.0		$ 53.00

DRI TDM Products

Cat #	Product Description	Kit Size (mL)	# Test/Kit	$/Kit
1669	Digoxin*	25,8	87	$ 175.00
0291	Kit Primidone	25mL	77	$ 100.00

QMS TDM Reagents

10010268	Kit Vancomycin QMS	22,22	97	$ 315.00
10010725	Kit Zonisamide QMS	2x22,2x8	164	$ 1,500.00
10010836	Kit Amikacin QMS	2x17,2x9	130	$ 275.00
10010838	Kit Quinidine QMS	2x17,2x9	130	$ 200.00
10011017	Kit Lamotrigine QMS	19,17	106	$ 775.00
10011028	Kit Topiramate QMS	22,16	105	$ 775.00

QMS TDM Controls and Calibrators

10010269	TDM Vancomycin Cal	6x1		$ 67.00
10010837	Amikacin Cal	A-F: 1x1		$ 80.00
10011018	Lamotrigine Cal	A:1x2,D-F:1x1		$ 89.00
10010839	Quinidine Cal	A-F: 1x1		$ 80.00
10011029	Topiramate Cal	A-F: 1x1		$ 112.00
10010726	Zonisamide Cal	A:1x2.5,D-F:1x1		$ 125.00
10011019	Lamotrigine Ctrl	3x2.5		$ 112.00
10011030	Topiramate Ctrl	3x2		$ 107.00
10010727	Zonisamide Ctrl	3x2.5		$ 112.00
TBD	Lidocaine Ctrl	#N/A		TBD

* Calibrators are included with kits

IMMUNO SUPPRESSIVE PRODUCTS

CEDIA ISD Assays

100147	Kit CsAII H911 H917 MGC	41,19	170	$ 1,408.00
10008656	Tacrolimus	26,11	96	$ 1,168.00
100276	Kit MPA MGC (Not Avail)	26,11	114	$ 1,443.00

CEDIA ISD MD-Controls and Calibrators

280-1	Kit ISD MD Control L1	4x4		$ 189.00
280-2	Kit ISD MD Control L2	4x4		$ 189.00
280-3	Kit ISD MD Control L3	4x4		$ 189.00

* LR Calibrators are included with kits

CEDIA ISD Controls* and Calibrators

100207	Kit CsA Ctrl 4	2x8,6x2		$ 145.00
100208	Kit CsA Ctrl 5	2x8,6x2		$ 145.00
100012	Kit CsA Hi Range Cal Set	2x4,2x4		$ 145.00
100009	Kit CsAII Lo Range MGC	2x4x2		$ 145.00
10008666	Kit Tacrolimus Cals	2x4,2x2		$ 189.00
100277	Kit MPA Cal	2x2,2x2		$ 189.00
100278	Kit MPA Ctrl 1	5x4		$ 189.00
100279	Kit MPA Ctrl 2	5x4		$ 189.00
100280	Kit MPA Ctrl 3	5x4		$ 189.00

ENDOCRINE PRODUCTS

CEDIA Endocrine Assays

Cat #	Product Description	Kit Size (mL)	# Test/Kit	$/Kit
100050	T 4 SC*	39,24	167	$ 125.00
100051	T 4 LC*	2X475,2X297	4,519	$ 1,511.00
100047	T Uptake SC*	49,11	176	$ 125.00
100049	T Uptake LC*	2X588,2X191	4,765	$ 1,593.00

* Calibrators are included with kits

DRI Endocrine Assays

Cat #	Product Description	Kit Size (mL)	# Test/Kit	$/Kit
0454	Total Thyroxine (T4)	100,34	350	$ 135.00
0723	T Uptake	100,34	350	$ 135.00
0476	Thyroxine (T4) Cal Kit	6x2		$ 42.00
0738	T Uptake Cal Kit	5x2		$ 38.00

Customer Signature/Date:_____

Microgenics Corporation
46360 Fremont Boulevard Fremont, CA 94538
Technical/Customer Service: 800 232-3342

Date Prepared: 2/17/2009

ThermoFisher SCIENTIFIC

Version 15A

Customer: RFQ # CME90108

Primary Instrument: MGC 240

Pricing Proposal

Annual Testing Volume: 33,000

ADULTERATION PRODUCTS

DRI Adulteration Assays				
Cat #	Product Description	Kit Size (mL)	# Test/Kit	$/Kit
1194	Gravity-Detect	2x500	2,760	$ 172.00
100054	pH-Detect	2x500	3,822	$ 239.00
1797	Creatinine Detect	500	3,688	$ 156.00
10009958	General Oxidant	2x500	3,822	$ 239.00

DRI Adulteration Controls and Calibrators				
1754	Low Gravity Cal	25		$ 71.00
1755	High Gravity Cal	25		$ 71.00
1756	Level 1 Gravity Ctrl	25		$ 71.00
1757	Level 2 Gravity Ctrl	25		$ 71.00
100272	Kit Creat Cal 2&20mg/dL	2x25		$ 116.00
100273	Kit Creat Ctrl 1.3mg/dL	25		$ 71.00
100274	Kit Creat Ctrl 7.5mg/dL	25		$ 71.00
100275	Kit Creat Ctrl 23mg/dL	25		$ 71.00
100283	Kit pH Detect Cal 3 & 11	2x25		$ 116.00
100282	Kit pH Detect Ctrl 3.6	25		$ 71.00
100284	Kit pH Detect Ctrl 7	25		$ 71.00
100285	Kit pH-Dt pH 10	25		$ 71.00
100281	Kit pH Detect Ctrl 11.5	25		$ 71.00
10009971	General Oxidant Cal Set (0, 200 ng/	2x25		$ 116.00
10009972	General Oxidant Control Set (100, 3	2x25		$ 116.00

DRI SERUM TOXICOLOGY

DRI TOX Assays				
Cat #	Product Description	Kit Size (mL)	# Test/Kit	$/Kit
1086	Acetaminophen	25,8	87	$ 130.00
0911	Barbturate	25,8	87	$ 130.00
0920	Benzodiazepine	25,8	87	$ 130.00
0977	Salicylate	25	61	$ 125.00
1128	Tricyclics	25,8	87	$ 130.00

DRI Toxicology Calibrators and Controls				
1091	Acetaminophen Cal Kit	1x5,5x2		$ 42.00
0980	Salicylate Cal Kit	1x5,1x2		$ 33.00
0962	Negative Cal	10		$ 22.00
0963	Cal 1	5		$ 33.00
0965	Cal2	5		$ 33.00
0967	Cal 3	5		$ 33.00
0976	Cal 4	5		$ 33.00
10011608	Multi Toxicology Control	2x5x3		$ 67.00

MGC 240 Instrument Consumables				
10007624	Cuvette Reaction			$ 227.00
10007625	Bottle Reagent 60 mL			$ 21.00
10007626	Bottle Reagent 40 mL			$ 18.00
10007627	Bottle Reagent 20 mL			$ 16.00
10009118	Paper Roll Thrml			$ 21.00
10010235	Plastic Test Tubes 8.5mL			$ 22.00
10010582	Sample Cups Hitachi			$ 17.00
100262	Kit Acid Wash 500mL			$ 33.00
100263	Kit Base Wash 500mL			$ 29.00

ner Signature/Date:_____

Microgenics Corporation
46360 Fremont Boulevard Fremont CA 94538
Technical/Customer Service: 800 232-3342

Date Prepared: 2/17/2009

DRI® CANNABINOID 20 and 50 ng/mL ASSAY APPLICATION – MGC 240™

Catalog Nos. 0185 and 0186

Homogeneous Enzyme Immunoassay for the Qualitative and Semi-quantitative Determination of Cannabinoid in Human Urine

For In Vitro Diagnostic Use Only

Intended Use

The information provided in this application sheet is intended as a supplement to the package insert. Refer to the package insert for information on intended use, reagent storage, specimen collection, specimen storage and quality control.

Ordering Information

Materials available from Microgenics:

Item	Catalog Number
DRI Cannabinoid Assay Reagent	0185, 0186 (100 mL, 500 mL)
DRI Negative Urine Calibrator	1664, 1388 (10 mL, 25 mL)
DRI THC Urine 20 ng/mL Calibrator	0235, 1397 (5 mL, 25 mL)
DRI THC Urine 50 ng/mL Calibrator	0042, 1398 (5 mL, 25 mL)
DRI THC Urine 100 ng/mL Calibrator	0044, 1399 (5 mL, 25 mL)
DRI THC 40 ng/mL Control	0170, 1401 (5 mL, 25 mL)
DRI THC 60 ng/mL Control	0168, 1402 (5 mL, 25 mL)

To place an order or for technical service contact (North America):

Microgenics Corporation
46360 Fremont Boulevard, Fremont, CA 94538 USA
U.S. Toll free: (800) 232-3342 / Tel: (510) 979-5001
U.S. Toll Free Fax (800) 829-8115 / Fax: (510) 979-5002

Reagent Storage

Refer to the package insert for information on reagent storage.

Procedure for Analyzer

Refer to the operator's manuals for information on analyzer operation.

Dispense adequate amounts of Antibody Reagent (first reagent) into a 40 mL reagent container and Enzyme Reagent (second reagent) into a 20 mL reagent container.
Ensure that the reagents have equilibrated to the temperature of the analyzer reagent compartment before starting analysis.

NOTE: Running a blank during calibration is a requirement of the MGC 240. For this assay, in both qualitative and semi-quantitative methods, run the negative calibrator as the blank.

Results and Data Interpretation

Refer to the package insert for information on results and data interpretation.

CE EC REP Microgenics GmbH, Spitalhofstrasse 94, D-94032 Passau, Germany
Tel: +49 (0) 851-88 6890 • Fax +49 (0) 851-88 68910

Microgenics Parameters, MGC 240
DRI CANNABINOID 20 ng/mL – Qualitative

Item Parameter

Item Name	ThcQ

DATA INFORMATION

UNITS	***
DECIMALS	0

ANALYSIS

TYPE	RATE
Main W.Length 1	340
Sub W.Length 2	450
METHOD	DRI

CORR

Y = SLOPE 1.000 X + INTER 0.000

CALIBRATION

TYPE	Linear

STANDARD

#1	20	#4	
#2		#5	
#3		#6	

NORMAL RANGE

	MALE		FEMALE	
	LOW	HIGH	LOW	HIGH
SERUM	0	19	0	19
URINE	0	19	0	19
Plasma	0	19	0	19
CSF	0	19	0	19
Dialysis	0	19	0	19
Other	0	19	0	19

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Item Parameter

Item Name	ThcQ

ASPIRATION

KIND ° Single • Double

	Volume	
SAMPLE	15	µL
REAGENT1	125	
REAGENT2	125	

Third Mix • OFF ° ON

R1 Blank • Water-Blank ° R1-Blank1

MONITOR

0 LEVEL POINT	1
SPAN	3

DATA PROCESS

READ

	Start	End
MAIN	38	42
SUB		

FACTOR

Blank correction	1

ABSORBANCE LIMIT

LOW	-3
HIGH	3

Endpoint Limit	
Linear Check(%)	99

PROZONE CHECK

	Start	End	Limit(%)	
FIRST				• Lo ° Hi
SECOND				• Lo ° Hi
THIRD				

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DRI CANNABINOID 20and 50 ng/mL APPLICATION – MGC 240

Catalog Nos 0185 and 0186

CE EC REP Microgenics GmbH, Spitalhofstrasse 94, D-94032 Passau, Germany
Tel: +49 (0) 851-88 6890 • Fax +49 (0) 851-88 68910

Microgenics Parameters, MGC 240
DRI CANNABINOID 50 ng/mL – Qualitative

Item Parameter

Item Name	ThcQ

DATA INFORMATION

UNITS	***
DECIMALS	0

ANALYSIS

TYPE	RATE
Main W.Length 1	340
Sub W.Length 2	450
METHOD	DRI

CORR

Y =	SLOPE	X +	INTER
	1.000		0.000

CALIBRATION

TYPE	Linear

STANDARD

#1	50	#4	
#2		#5	
#3		#6	

NORMAL RANGE

	MALE		FEMALE	
	LOW	HIGH	LOW	HIGH
SERUM	0	49	0	49
URINE	0	49	0	49
Plasma	0	49	0	49
CSF	0	49	0	49
Dialysis	0	49	0	49
Other	0	49	0	49

Page : 1 | Print | Next Page | Save | Return

Item Parameter

Item Name	ThcQ

ASPIRATION

KIND ° Single • Double

	Volume	
SAMPLE	15	µL
REAGENT1	125	
REAGENT2	125	

Third Mix • OFF ° ON

R1 Blank • Water-Blank ° R1-Blank1

MONITOR

0 LEVEL POINT	1
SPAN	3

DATA PROCESS

READ

	Start	End
MAIN	38	42
SUB		

FACTOR

Blank correction	1

ABSORBANCE LIMIT

LOW	-3
HIGH	3

Endpoint Limit

Linear Check(%) 99

PROZONE CHECK

	Start	End	Limit(%)	
FIRST				• Lo ° Hi
SECOND				• Lo ° Hi
THIRD				

Page : 2 | Print | Next Page | Save | Return

***USER DEFINED

DRI CANNABINOID 20and 50 ng/mL APPLICATION – MGC 240

CE EC REP Microgenics GmbH, Spitalhofstrasse 94, D-94032 Passau, Germany
Tel: +49 (0) 851-88 6890 • Fax +49 (0) 851-88 68910

Microgenics Parameters, MGC 240
DRI Cannabinoid 20 and 50 ng/mL – Semi-quantitative

Item Parameter

Item Name	ThcSQ

DATA INFORMATION

UNITS	ng/mL
DECIMALS	0

ANALYSIS

TYPE	RATE
Main W.Length 1	340
Sub W.Length 2	450
METHOD	DRI

CORR

SLOPE		INTER
Y = 1.000	X +	0.000

CALIBRATION

TYPE: Logit 1

STANDARD

#1	20	#4	
#2	50	#5	
#3	100	#6	

NORMAL RANGE

	MALE		FEMALE	
	LOW	HIGH	LOW	HIGH
SERUM	0	**	0	**
URINE	0	**	0	**
Plasma	0	**	0	**
CSF	0	**	0	**
Dialysis	0	**	0	**
Other	0	**	0	**

Page : 1 | Print | Next Page | Save | Return

Item Parameter

Item Name	ThcSQ

ASPIRATION

KIND: ○ Single • **Double**

	Volume	
SAMPLE	15	µL
REAGENT1	125	
REAGENT2	125	

Third Mix • **OFF** ○ ON

R1 Blank • **Water-Blank** ○ R1-Blank1

MONITOR

0 LEVEL POINT	1
SPAN	3

DATA PROCESS

READ

	Start	End
MAIN	38	42
SUB		

FACTOR

Blank correction	1

ABSORBANCE LIMIT

LOW	-3
HIGH	3

Endpoint Limit	
Linear Check(%)	99

PROZONE CHECK

	Start	End	Limit(%)	
FIRST				• Lo ○ Hi
SECOND				• Lo ○ Hi
THIRD				

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** Use 19 for the 20 ng/mL cutoff and 49 for the 50 ng/mL cutoff

DRI CANNABINOID 20and 50 ng/mL APPLICATION – MGC 240

MGC 240 Precision at 20 ng/mL

Within-run and total precision, evaluated with packaged reagents, controls and calibrators, yielded the following results (n=60):

Controls	Low Control	Cutoff Cal	High Control
Qualitative Assay			
Mean Rate (mA/min)	319	337	358
Within-Run SD (mA/min)	1.2	1.3	2.5
Within-Run CV (%)	0.4	0.4	0.7
Total SD (mA/min)	3.3	2.6	3.2
Total CV (%)	1.0	0.8	0.9
Semi-quantitative Assay			
Mean (ng/mL)	10	26	43
Within-Run SD (ng/mL)	1.3	1.1	1.3
Within-Run CV (%)	n/a	4.2	2.9
Total SD (ng/mL)	1.8	1.8	1.6
Total CV (%)	n/a	6.8	3.8

MGC 240 Accuracy and Correlation at 20 ng/ml

One hundred twenty-five (125) urine samples were assayed qualitatively with the DRI Cannabinoid Assay on the MGC 240 and the Hitachi 717 analyzers. 98.8% positive agreement (81 of 82 samples) and 100% negative agreement (43 of 43 samples) were observed between the two analyzers.

One hundred twenty-five (125) urine samples were assayed semi-quantitatively with the DRI Cannabinoid Assay on the MGC 240 and the Hitachi 717 analyzers. 98.8% positive agreement (81 of 82 samples) and 100% negative agreement (43 of 43 samples) were observed between the two analyzers.

MGC 240 Precision at 50 ng/mL

Within-run and total precision, evaluated with packaged reagents, controls and calibrators, yielded the following results (n=60):

Controls	Low Control	Cutoff Cal	High Control
Qualitative Assay			
Mean Rate (mA/min)	328	348	364
Within-Run SD (mA/min)	1.3	1.4	1.3
Within-Run CV (%)	0.4	0.4	0.4
Total SD (mA/min)	3.2	3.4	3.3
Total CV (%)	1.0	1.0	0.9
Semi-quantitative Assay			
Mean (ng/mL)	33	48	61
Within-Run SD (ng/mL)	0.9	1.0	1.2
Within-Run CV (%)	2.6	2.0	2.0
Total SD (ng/mL)	2.1	2.4	2.6
Total CV (%)	6.3	4.9	4.3

MGC 240 Accuracy and Correlation at 50 ng/mL

One hundred six (106) urine samples were assayed qualitatively with the DRI Cannabinoid Assay on the MGC 240 and the Hitachi 717 analyzers. 93.2% positive agreement (41 of 44 samples) and 100% negative agreement (62 of 62 samples) were observed between the two analyzers.

One hundred six (106) urine samples were assayed semi- quantitatively with the DRI Cannabinoid Assay on the MGC 240 and the Hitachi 717 analyzers. 100% positive agreement (43 of 43 samples) and 100% negative agreement (63 of 63 samples) were observed between the two analyzers.

DRI® BARBITURATE ASSAY APPLICATION – MGC 240™

Catalog Nos. 0225 and 0226

Intended for the Qualitative and Semi-quantitative Determination of Barbiturate in Human Urine

For In Vitro Diagnostic Use Only

Intended Use

The information provided in this application sheet is intended as a supplement to the package insert. Refer to the package insert for information on intended use, reagent storage, reagent preparation, specimen collection, specimen storage, quality control, and additional performance data.

Ordering Information

Materials available from Microgenics:

Item	Catalog Number
DRI Barbiturate Assay Reagent	0225 (100 mL), 0226 (500 mL)
DRI Negative Urine Calibrator	1664 (10 mL), 1388 (25 mL)
DRI Multi-Drug Urine Calibrator 1	1588 (10 mL), 1589 (25 mL)
DRI Multi-Drug Urine Calibrator 2	1591 (10 mL), 1592 (25 mL)
DRI Multi-Drug Urine Calibrator 3	1594 (10 mL), 1595 (25 mL)
DRI Multi-Drug Urine Calibrator 4	1597 (10 mL), 1598 (25 mL)
DRI Multi-Drug Urine Control 1	1599 (10 mL), 1553 (25 mL)
DRI Multi-Drug Urine Control 2	1600 (10 mL), 1555 (25 mL)

To place an order or for technical service contact (North America):

Microgenics Corporation
46360 Fremont Boulevard, Fremont, CA 94538 USA
U.S. Toll free: (800) 232-3342 / Tel: (510) 979-5001
U.S. Toll Free Fax (800) 829-8115 / Fax: (510) 979-5002

CE EC REP Microgenics GmbH, Spitalhofstrasse 94, D-94032 Passau, Germany
Tel: +49 (0) 851-88 6890 • Fax +49 (0) 851-88 68910

Reagent Storage

Refer to the package insert for information on reagent storage.

Procedure for Analyzer

Refer to the operator's manuals for information on analyzer operation.

Dispense adequate amounts of Antibody Reagent (first reagent) and Enzyme Reagent (second reagent) into appropriate containers.
Ensure that the reagents have equilibrated to the temperature of the analyzer reagent compartment before starting analysis.

NOTE: Running a blank during calibration is a requirement of the MGC 240. For this assay, in both qualitative and semi-quantitative methods, run the negative calibrator as the blank.

Results and Data Interpretation

Refer to the package insert for information on results and data interpretation.

CE EC REP Microgenics GmbH, Spitalhofstrasse 94, D-94032 Passau, Germany
Tel: +49 (0) 851-88 6890 • Fax +49 (0) 851-88 68910

Microgenics Parameters, MGC 240: DRI BARBITURATE – Qualitative

Item Parameter

Item Name	Barb

DATA INFORMATION

UNITS	***
DECIMALS	0

ANALYSIS

TYPE	RATE
Main W.Length 1	340
Sub W.Length 2	450
METHOD	DRI

CORR

Y = SLOPE 1.000 X + INTER 0.000

CALIBRATION

TYPE: Factor

STANDARD

#1	200	#4	
#2		#5	
#3		#6	

NORMAL RANGE

	MALE		FEMALE	
	LOW	HIGH	LOW	HIGH
SERUM	0	199	0	199
URINE	0	199	0	199
Plasma	0	199	0	199
CSF	0	199	0	199
Dialysis	0	199	0	199
Other	0	199	0	199

Page : 1 | Print | Next Page | Save | Return

Item Parameter

Item Name	Barb

ASPIRATION

KIND ◦ Single • **Double**

	Volume	
SAMPLE	15	µL
REAGENT1	125	
REAGENT2	125	

Third Mix	• **OFF**	◦ ON
R1 Blank	• **Water-Blank**	◦ R1-Blank1

MONITOR

0 LEVEL POINT	1
SPAN	3

DATA PROCESS

READ

	Start	End
MAIN	35	38
SUB		

FACTOR

Blank correction: 1

ABSORBANCE LIMIT

LOW	-3
HIGH	3

Endpoint Limit:

Linear Check(%): 90

PROZONE CHECK

	Start	End	Limit(%)	
FIRST				• **Lo** ◦ Hi
SECOND				• **Lo** ◦ Hi
THIRD				

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***USER DEFINED

DRI® BARBITURATE APPLICATION – MGC 240

Catalog Nos 0225 and 0226

CE EC REP Microgenics GmbH, Spitalhofstrasse 94, D-94032 Passau, Germany
Tel: +49 (0) 851-88 6890 • Fax +49 (0) 851-88 68910

Microgenics Parameters, MGC 240: DRI Barbiturate – Semi-quantitative

Item Parameter

Item Name	Barb

DATA INFORMATION

UNITS	ng/mL
DECIMALS	0

ANALYSIS

TYPE	RATE
Main W.Length 1	340
Sub W.Length 2	450
METHOD	DRI

CORR

Y = SLOPE 1.000 X + INTER 0.000

CALIBRATION

TYPE	Logit 1

STANDARD

#1	100.0	#4	1000.0
#2	200.0	#5	
#3	500.0	#6	

NORMAL RANGE

	MALE		FEMALE	
	LOW	HIGH	LOW	HIGH
SERUM	0	199	0	199
URINE	0	199	0	199
Plasma	0	199	0	199
CSF	0	199	0	199
Dialysis	0	199	0	199
Other	0	199	0	199

Page : 1 | Print | Next Page | Save | Return

Item Parameter

Item Name	Barb

ASPIRATION

KIND ° Single • **Double**

	Volume	
SAMPLE	15	µL
REAGENT1	125	
REAGENT2	125	

Third Mix • **OFF** ° ON

R1 Blank • **Water-Blank** ° R1-Blank1

MONITOR

0 LEVEL POINT	1
SPAN	3

DATA PROCESS

READ

	Start	End
MAIN	35	38
SUB		

FACTOR

Blank correction	1

ABSORBANCE LIMIT

LOW	-3
HIGH	3

Endpoint Limit	
Linear Check(%)	90

PROZONE CHECK

	Start	End	Limit(%)	
FIRST				• Lo ° Hi
SECOND				• Lo ° Hi
THIRD				

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DRI® BARBITURATE APPLICATION – MGC 240

Catalog Nos 0225 and 0226

CE EC REP Microgenics GmbH, Spitalhofstrasse 94, D-94032 Passau, Germany
Tel: +49 (0) 851-88 6890 • Fax +49 (0) 851-88 68910

MGC 240 Precision

Within-run and total precision, evaluated with packaged reagents, controls and calibrators, yielded the following results (n=60):

Controls	Low Control	Cutoff Cal	High Control
Qualitative Assay			
Mean Rate (mA/min)	461	493	529
Within-Run SD (mA/min)	1.5	1.7	1.2
Within-Run CV (%)	0.3	0.3	0.2
Total SD (mA/min)	3.6	3.3	3.3
Total CV (%)	0.8	0.7	0.6
Semi-quantitative Assay			
Mean (ng/mL)	149	242	389
Within-Run SD (ng/mL)	4.4	6.7	7.1
Within-Run CV (%)	3.0	2.8	1.8
Total SD (ng/mL)	5.7	8.2	10.3
Total CV (%)	3.8	3.4	2.6

MGC 240 Accuracy and Correlation

One hundred thirty-six (136) urine samples were assayed qualitatively with the DRI Barbiturates Assay on the MGC 240 and the Hitachi 717 analyzers. 97.3% positive agreement (72 of 74 samples) and 98.4% negative agreement (61 of 62 samples) were observed between the two analyzers.

One hundred forty-three (143) urine samples were assayed semi-quantitatively with the DRI Barbiturates Assay on the MGC 240 and the Hitachi 717 analyzers. 98.9% positive agreement (86 of 87 samples) and 98.2% negative agreement (55 of 56 samples) were observed between the two analyzers.

10008752-0
2004 04
Printed in USA

microgenics

DRI® METHADONE ASSAY APPLICATION – MGC 240™

Catalog Nos. 0596 and 0597

Intended for the Qualitative and Semi-quantitative Determination of Methadone in Human Urine

For In Vitro Diagnostic Use Only

Intended Use

The information provided in this application sheet is intended as a supplement to the package insert. Refer to the package insert for information on intended use, reagent storage, specimen collection, specimen storage and quality control.

Ordering Information

Materials available from Microgenics:

Item	Catalog Number
DRI Methadone Assay Reagent	0596, 0597 (100 mL, 500 mL)
DRI Negative Urine Calibrator	1664 (10 mL), 1388 (25 mL)
DRI Multi-Drug Urine Calibrator 1	1588 (10 mL), 1589 (25 mL)
DRI Multi-Drug Urine Calibrator 2	1591 (10 mL), 1592 (25 mL)
DRI Multi-Drug Urine Calibrator 3	1594 (10 mL), 1595 (25 mL)
DRI Multi-Drug Urine Calibrator 4	1597 (10 mL), 1598 (25 mL)
DRI Multi-Drug Urine Control 1	1599 (10 mL), 1553 (25 mL)
DRI Multi-Drug Urine Control 2	1600 (10 mL), 1555 (25 mL)

To place an order or for technical service contact (North America):

Microgenics Corporation
46360 Fremont Boulevard, Fremont, CA 94538 USA
U.S. Toll free: (800) 232-3342 / Tel: (510) 979-5001
U.S. Toll Free Fax (800) 829-8115 / Fax: (510) 979-5002

CE EC REP Microgenics GmbH, Spitalhofstrasse 94, D-94032 Passau, Germany
Tel: +49 (0) 851-88 6890 • Fax +49 (0) 851-88 68910

Reagent Storage

Refer to the package insert for information on reagent storage.

Procedure for Analyzer

Refer to the operator's manuals for information on analyzer operation.

Dispense adequate amounts of Antibody Reagent (first reagent) and Enzyme Reagent (second reagent) into appropriate containers.
Ensure that the reagents have equilibrated to the temperature of the analyzer reagent compartment before starting analysis.

NOTE: Running a blank during calibration is a requirement of the MGC 240. For this assay, in both qualitative and semi-quantitative methods, run the negative calibrator as the blank.

Results and Data Interpretation

Refer to the package insert for information on results and data interpretation.

CE EC REP Microgenics GmbH, Spitalhofstrasse 94, D-94032 Passau, Germany
Tel: +49 (0) 851-88 6890 • Fax +49 (0) 851-88 68910

Microgenics Parameters, MGC 240
DRI Methadone – Qualitative

Item Parameter

Item Name	Mtdn

DATA INFORMATION

UNITS	***
DECIMALS	0

ANALYSIS

TYPE	RATE
Main W.Length 1	340
Sub W.Length 2	450
METHOD	DRI

CORR

Y = SLOPE 1.000 X + INTER 0.000

CALIBRATION

TYPE: Linear

STANDARD

#1	300	#4	
#2		#5	
#3		#6	

NORMAL RANGE

	MALE		FEMALE	
	LOW	HIGH	LOW	HIGH
SERUM	0	299	0	299
URINE	0	299	0	299
Plasma	0	299	0	299
CSF	0	299	0	299
Dialysis	0	299	0	299
Other	0	299	0	299

Page : 1 | Print | Next Page | Save | Return

Item Parameter

Item Name	Mtdn

ASPIRATION

KIND ○ Single • Double

	Volume
SAMPLE	15
REAGENT1	125
REAGENT2	125

µL

Third Mix • OFF ○ ON

R1 Blank • Water-Blank ○ R1-Blank1

MONITOR

0 LEVEL POINT	1
SPAN	3

DATA PROCESS

READ

	Start	End
MAIN	35	38
SUB		

FACTOR

Blank correction: 1

ABSORBANCE LIMIT

LOW	-3
HIGH	3

Endpoint Limit:

Linear Check(%): 90

PROZONE CHECK

	Start	End	Limit(%)	
FIRST				• Lo ○ Hi
SECOND				• Lo ○ Hi
THIRD				

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DRI® METHADONE APPLICATION – MGC 240

Catalog Nos. 0596 and 0597

CE EC REP Microgenics GmbH, Spitalhofstrasse 94, D-94032 Passau, Germany
Tel: +49 (0) 851-88 6890 • Fax +49 (0) 851-88 68910

Microgenics Parameters, MGC 240
DRI Methadone – Semi-quantitative

Item Parameter

Item Name	Mtdn

DATA INFORMATION

UNITS	ng/mL
DECIMALS	0

ANALYSIS

TYPE	RATE
Main W.Length 1	340
Sub W.Length 2	450
METHOD	DRI

CORR: Y = SLOPE 1.000 X + INTER 0.000

CALIBRATION

TYPE	Logit 1

STANDARD

#1	150.0	#4	1000.0
#2	300.0	#5	
#3	500.0	#6	

NORMAL RANGE

	MALE		FEMALE	
	LOW	HIGH	LOW	HIGH
SERUM	0	299	0	299
URINE	0	299	0	299
Plasma	0	299	0	299
CSF	0	299	0	299
Dialysis	0	299	0	299
Other	0	299	0	299

Page : 1 | Print | Next Page | Save | Return

Item Parameter

Item Name	Mtdn

ASPIRATION
KIND ○ Single • **Double**

	Volume
SAMPLE	15
REAGENT1	125
REAGENT2	125

µL

Third Mix • **OFF** ○ ON

R1 Blank • **Water-Blank** ○ R1-Blank1

MONITOR

0 LEVEL POINT	1
SPAN	3

DATA PROCESS

READ

	Start	End
MAIN	35	38
SUB		

FACTOR

Blank correction	1

ABSORBANCE LIMIT

LOW	-3
HIGH	3

Endpoint Limit

Linear Check(%) 90

PROZONE CHECK

	Start	End	Limit(%)	
FIRST				• Lo ○ Hi
SECOND				• Lo ○ Hi
THIRD				

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DRI® METHADONE APPLICATION – MGC 240

Catalog Nos 0596 and 0597

CE EC REP Microgenics GmbH, Spitalhofstrasse 94, D-94032 Passau, Germany
Tel: +49 (0) 851-88 6890 • Fax +49 (0) 851-88 68910

MGC 240 Precision

Within-run and total precision, evaluated with packaged reagents, controls and calibrators, yielded the following results (n=60):

	Low Control	Cutoff Cal	High Control
Qualitative Assay			
Mean Rate (mA/min)	453	502	544
Within-Run SD (mA/min)	1.6	1.8	1.8
Within-Run CV (%)	0.4	0.4	0.3
Total SD (mA/min)	2.6	2.5	2.5
Total CV (%)	0.6	0.5	0.5
Semi-quantitative Assay			
Mean (ng/mL)	193	314	450
Within-Run SD (ng/mL)	3.5	4.8	6.7
Within-Run CV (%)	1.8	1.5	1.5
Total SD (ng/mL)	4.1	6.3	8.3
Total CV (%)	2.1	2.0	1.9

MGC 240 Accuracy and Correlation

One hundred twenty-two (122) urine samples were assayed qualitatively with the DRI Methadone Assay on the MGC 240 and the Hitachi 717 analyzers. 96.8% positive agreement (61 of 63 samples) and 100% negative agreement (59 of 59 samples) were observed between the two analyzers.

One hundred twenty-one (121) urine samples were assayed semi-quantitatively with the DRI Methadone Assay on the MGC 240 and the Hitachi 717 analyzers. 100% positive agreement (63 of 63 samples) and 100% negative agreement (58 of 58 samples) were observed between the two analyzers.

10008754-0
2004 04
Printed in USA

DRI® COCAINE METABOLITE ASSAY APPLICATION – MGC 240™

Catalog Nos. 0055 and 0056

Homogeneous Enzyme Immunoassay for the Qualitative and Semi-quantitative Determination of Cocaine Metabolite Drug Levels in Human Urine

For In Vitro Diagnostic Use Only

Intended Use

The information provided in this application sheet is intended as a supplement to the package insert. Refer to the package insert for information on intended use, reagent storage, specimen collection, specimen storage and quality control.

Ordering Information

Materials available from Microgenics:

Item	Catalog Number
DRI Cocaine Metabolite Assay Reagent	0055, 0056 (100 mL, 500 mL)
DRI Negative Urine Calibrator	1664, 1388 (10 mL, 25 mL)
DRI Multi-Drug Urine Calibrator 1	1588, 1589 (10 mL, 25 mL)
DRI Multi-Drug Urine Calibrator 2	1591, 1592 (10 mL, 25 mL)
DRI Multi-Drug Urine Calibrator 3	1594, 1595 (10 mL, 25 mL)
DRI Multi-Drug Urine Calibrator 4	1597, 1598 (10 mL, 25 mL)
DRI Multi-Drug Urine Control 1	1599, 1553 (10 mL, 25 mL)
DRI Multi-Drug Urine Control 2	1600, 1555 (10 mL, 25 mL)

To place an order or for technical service contact (North America):

Microgenics Corporation
46360 Fremont Boulevard, Fremont, CA 94538 USA
U.S. Toll free: (800) 232-3342 / Tel: (510) 979-5001
U.S. Toll Free Fax (800) 829-8115 / Fax: (510) 979-5002

CE EC REP Microgenics GmbH, Spitalhofstrasse 94, D-94032 Passau, Germany
Tel: +49 (0) 851-88 6890 • Fax +49 (0) 851-88 68910

Reagent Storage

Refer to the package insert for information on reagent storage.

Procedure for Analyzer

Refer to the operator's manuals for information on analyzer operation.

Dispense adequate amounts of Antibody Reagent (first reagent) into a 40 mL reagent container and Enzyme Reagent (second reagent) into a 20 mL reagent container.
Ensure that the reagents have equilibrated to the temperature of the analyzer reagent compartment before starting analysis.

NOTE: Running a blank during calibration is a requirement of the MGC 240. For this assay, in both qualitative and semi-quantitative methods, run the negative calibrator as the blank.

Results and Data Interpretation

Refer to the package insert for information on results and data interpretation.

CE EC REP Microgenics GmbH, Spitalhofstrasse 94, D-94032 Passau, Germany
Tel: +49 (0) 851-88 6890 • Fax +49 (0) 851-88 68910

Microgenics Parameters, MGC 240
DRI COCAINE METABOLITE – Qualitative

Item Parameter

Item Name	CocQ

DATA INFORMATION

UNITS	***
DECIMALS	0

CALIBRATION

TYPE	Linear

STANDARD

#1	300	#4	
#2		#5	
#3		#6	

ANALYSIS

TYPE	RATE
Main W.Length 1	340
Sub W.Length 2	450
METHOD	DRI

CORR

Y = SLOPE 1.000 X + INTER 0.000

NORMAL RANGE

	MALE		FEMALE	
	LOW	HIGH	LOW	HIGH
SERUM	0	299	0	299
URINE	0	299	0	299
Plasma	0	299	0	299
CSF	0	299	0	299
Dialysis	0	299	0	299
Other	0	299	0	299

Page : 1 | Print | Next Page | Save | Return

Item Parameter

Item Name	CocQ

ASPIRATION

KIND ° Single • **Double**

	Volume	
SAMPLE	10	µL
REAGENT1	125	
REAGENT2	125	

Third Mix • **OFF** ° ON

R1 Blank • **Water-Blank** ° R1-Blank1

MONITOR

0 LEVEL POINT	1
SPAN	3

DATA PROCESS

READ

	Start	End
MAIN	35	38
SUB		

FACTOR

Blank correction	1

ABSORBANCE LIMIT

LOW	-3
HIGH	3

Endpoint Limit	
Linear Check(%)	90

PROZONE CHECK

	Start	End	Limit(%)	
FIRST				• **Lo** ° Hi
SECOND				• **Lo** ° Hi
THIRD				

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DRI COCAINE METABOLITE APPLICATION – MGC 240

Catalog Nos. 0055 and 0056

CE EC REP Microgenics GmbH, Spitalhofstrasse 94, D-94032 Passau, Germany
Tel: +49 (0) 851-88 6890 • Fax +49 (0) 851-88 68910

Microgenics Parameters, MGC 240
DRI Cocaine Metabolite – Semi-quantitative

Item Parameter

Item Name	CocSQ

DATA INFORMATION

UNITS	ng/mL
DECIMALS	0

ANALYSIS

TYPE	RATE
Main W.Length 1	340
Sub W.Length 2	450
METHOD	DRI

CORR

Y = SLOPE 1.000 X + INTER 0.000

CALIBRATION

TYPE	Logit 1

STANDARD

#1	150	#4	1000
#2	300	#5	
#3	500	#6	

NORMAL RANGE

	MALE		FEMALE	
	LOW	HIGH	LOW	HIGH
SERUM	0	299	0	299
URINE	0	299	0	299
Plasma	0	299	0	299
CSF	0	299	0	299
Dialysis	0	299	0	299
Other	0	299	0	299

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Item Parameter

Item Name	CocSQ

ASPIRATION

KIND ° Single • **Double**

	Volume	
SAMPLE	10	µL
REAGENT1	125	
REAGENT2	125	

Third Mix • **OFF** ° ON

R1 Blank • **Water-Blank** ° R1-Blank1

MONITOR

0 LEVEL POINT	1
SPAN	3

DATA PROCESS

READ

	Start	End
MAIN	35	38
SUB		

FACTOR

Blank correction	1

ABSORBANCE LIMIT

LOW	-3
HIGH	3

Endpoint Limit

Linear Check(%) 90

PROZONE CHECK

	Start	End	Limit(%)	
FIRST				• **Lo** ° Hi
SECOND				• **Lo** ° Hi
THIRD				

Page : 2 | Print | Next Page | Save | Return

DRI COCAINE METABOLITE APPLICATION – MGC 240

Catalog Nos. 0055 and 0056

CE EC REP Microgenics GmbH, Spitalhofstrasse 94, D-94032 Passau, Germany
Tel: +49 (0) 851-88 6890 • Fax +49 (0) 851-88 68910

MGC 240 Precision

Within-run and total precision, evaluated with packaged reagents, controls and calibrators, yielded the following results (n=60):

Controls	Low Control	Cutoff Cal	High Control
Qualitative Assay			
Mean Rate (mA/min)	327	353	380
Within-Run SD (mA/min)	2.1	1.5	2.1
Within-Run CV (%)	0.6	0.4	0.5
Total SD (mA/min)	2.2	2.5	2.9
Total CV (%)	0.7	0.7	0.8
Semi-quantitative Assay			
Mean (ng/mL)	219	330	453
Within-Run SD (ng/mL)	7.9	9.7	9.3
Within-Run CV (%)	3.6	3.0	2.0
Total SD (ng/mL)	8.8	11.6	11.2
Total CV (%)	4.0	3.5	2.5

MGC 240 Accuracy and Correlation

One hundred twenty (120) urine samples were assayed qualitatively with the DRI Cocaine Metabolite Assay on the MGC 240 and the Hitachi 717 analyzers. 100% positive agreement (48 of 48 samples) and 100% negative agreement (72 of 72 samples) were observed between the two analyzers.

One hundred twenty (120) urine samples were assayed semi-quantitatively with the DRI Cocaine Metabolite Assay on the MGC 240 and the Hitachi 717 analyzers. 100% positive agreement (48 of 48 samples) and 100% negative agreement (72 of 72 samples) were observed between the two analyzers.

10008490-1
2004 08

DRI® PROPOXYPHENE ASSAY APPLICATION – MGC 240™

Catalog Nos. 0432 and 0433

Intended for the Qualitative and Semi-quantitative Determination of Propoxyphene in Human Urine

For In Vitro Diagnostic Use Only

Intended Use

The information provided in this application sheet is intended as a supplement to the package insert. Refer to the package insert for information on intended use, reagent storage, specimen collection, specimen storage and quality control.

Ordering Information

Materials available from Microgenics:

Item	Catalog Number
DRI Propoxyphene Assay Reagent	0432, 0433 (100 mL, 500 mL)
DRI Negative Urine Calibrator	1664 (10 mL), 1388 (25 mL)
DRI Multi-Drug Urine Calibrator 1	1588 (10 mL), 1589 (25 mL)
DRI Multi-Drug Urine Calibrator 2	1591 (10 mL), 1592 (25 mL)
DRI Multi-Drug Urine Calibrator 3	1594 (10 mL), 1595 (25 mL)
DRI Multi-Drug Urine Calibrator 4	1597 (10 mL), 1598 (25 mL)
DRI Multi-Drug Urine Control 1	1599 (10 mL), 1553 (25 mL)
DRI Multi-Drug Urine Control 2	1600 (10 mL), 1555 (25 mL)

To place an order or for technical service contact (North America):

Microgenics Corporation
46360 Fremont Boulevard, Fremont, CA 94538 USA
U.S. Toll free: (800) 232-3342 / Tel: (510) 979-5001
U.S. Toll Free Fax (800) 829-8115 / Fax: (510) 979-5002

Reagent Storage

Refer to the package insert for information on reagent storage.

Procedure for Analyzer

Refer to the operator's manuals for information on analyzer operation.

Dispense adequate amounts of Antibody Reagent (first reagent) and Enzyme Reagent (second reagent) into appropriate containers.
Ensure that the reagents have equilibrated to the temperature of the analyzer reagent compartment before starting analysis.

NOTE: Running a blank during calibration is a requirement of the MGC 240. For this assay, in both qualitative and semi-quantitative methods, run the negative calibrator as the blank.

Results and Data Interpretation

Refer to the package insert for information on results and data interpretation.

CE EC REP Microgenics GmbH, Spitalhofstrasse 94, D-94032 Passau, Germany
Tel: +49 (0) 851-88 6890 • Fax +49 (0) 851-88 68910

Microgenics Parameters, MGC 240
DRI Propoxyphene – Qualitative

Item Parameter

Item Name	Prpx

DATA INFORMATION

UNITS	***
DECIMALS	0

ANALYSIS

TYPE	RATE
Main W.Length 1	340
Sub W.Length 2	450
METHOD	DRI

CORR

Y =	SLOPE	X +	INTER
	1.000		0.000

CALIBRATION

TYPE	Linear

STANDARD

#1	300	#4	
#2		#5	
#3		#6	

NORMAL RANGE

	MALE		FEMALE	
	LOW	HIGH	LOW	HIGH
SERUM	0	299	0	299
URINE	0	299	0	299
Plasma	0	299	0	299
CSF	0	299	0	299
Dialysis	0	299	0	299
Other	0	299	0	299

Page : 1 | Print | Next Page | Save | Return

Item Parameter

Item Name	Prpx

ASPIRATION

KIND ○ Single • **Double**

	Volume	
SAMPLE	10	µL
REAGENT1	125	
REAGENT2	125	

Third Mix • **OFF** ○ ON

R1 Blank • **Water-Blank** ○ R1-Blank1

MONITOR

0 LEVEL POINT	1
SPAN	3

DATA PROCESS

READ

	Start	End
MAIN	35	38
SUB		

FACTOR

Blank correction	1

ABSORBANCE LIMIT

LOW	-3
HIGH	3

Endpoint Limit	
Linear Check(%)	90

PROZONE CHECK

	Start	End	Limit(%)	
FIRST				• **Lo** ○ Hi
SECOND				• **Lo** ○ Hi
THIRD				

Page : 2 | Print | Next Page | Save | Return

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DRI® PROPOXYPHENE APPLICATION – MGC 240

Catalog Nos. 0432 and 0433

CE EC REP Microgenics GmbH, Spitalhofstrasse 94, D-94032 Passau, Germany
Tel: +49 (0) 851-88 6890 • Fax +49 (0) 851-88 68910

Microgenics Parameters, MGC 240
DRI Propoxyphene – Semi-quantitative

Item Parameter

Item Name	Prpx

DATA INFORMATION

UNITS	ng/mL
DECIMALS	0

ANALYSIS

TYPE	RATE
Main W.Length 1	340
Sub W.Length 2	450
METHOD	DRI

CORR

Y = SLOPE 1.000 X + INTER 0.000

CALIBRATION

TYPE	Logit 1

STANDARD

#1	150.0	#4	1000.0
#2	300.0	#5	
#3	500.0	#6	

NORMAL RANGE

	MALE		FEMALE	
	LOW	HIGH	LOW	HIGH
SERUM	0	299	0	299
URINE	0	299	0	299
Plasma	0	299	0	299
CSF	0	299	0	299
Dialysis	0	299	0	299
Other	0	299	0	299

Page : 1 | Print | Next Page | Save | Return

Item Parameter

Item Name	Prpx

ASPIRATION

KIND ○ Single • Double

	Volume	
SAMPLE	10	µL
REAGENT1	125	
REAGENT2	125	

Third Mix • OFF ○ ON

R1 Blank • Water-Blank ○ R1-Blank1

MONITOR

0 LEVEL POINT	1
SPAN	3

DATA PROCESS

READ

	Start	End
MAIN	35	38
SUB		

FACTOR

Blank correction	1

ABSORBANCE LIMIT

LOW	-3
HIGH	3

Endpoint Limit	
Linear Check(%)	90

PROZONE CHECK

	Start	End	Limit(%)	
FIRST				• Lo ○ Hi
SECOND				• Lo ○ Hi
THIRD				

Page : 2 | Print | Next Page | Save | Return

DRI® PROPOXYPHENE APPLICATION – MGC 240

Catalog Nos. 0432 and 0433

CE EC REP Microgenics GmbH, Spitalhofstrasse 94, D-94032 Passau, Germany
Tel: +49 (0) 851-88 6890 • Fax +49 (0) 851-88 68910

MGC 240 Precision

Within-run and total precision, evaluated with packaged reagents, controls and calibrators, yielded the following results (n=60):

Controls	Low Control	Cutoff Cal	High Control
Qualitative Assay			
Mean Rate (mA/min)	258	336	368
Within-Run SD (mA/min)	1.5	6.7	2.5
Within-Run CV (%)	0.6	2.0	0.7
Total SD (mA/min)	3.1	7.6	3.1
Total CV (%)	1.2	2.3	0.8
Semi-quantitative Assay			
Mean (ng/mL)	164	393	492
Within-Run SD (ng/mL)	4.6	17.8	8.8
Within-Run CV (%)	2.8	4.5	1.8
Total SD (ng/mL)	8.3	20.5	13.2
Total CV (%)	5.0	5.2	2.7

MGC 240 Accuracy and Correlation

One hundred twenty (120) urine samples were assayed qualitatively with the DRI Propoxyphene Assay on the MGC 240 and the Hitachi 717 analyzers. 90.7% positive agreement (49 of 54 samples) and 100% negative agreement (66 of 66 samples) were observed between the two analyzers.

One hundred twenty (120) urine samples were assayed semi-quantitatively with the DRI Propoxyphene Assay on the MGC 240 and the Hitachi 717 analyzers. 100% positive agreement (62 of 62 samples) and 100% negative agreement (58 of 58 samples) were observed between the two analyzers.

10008755-0
2004 04
Printed in USA

microgenics

DRI® OXYCODONE ASSAY APPLICATION – MGC 240™

Catalog No. 100248, 100249

Intended for the Qualitative and Semi-quantitative Determination of Oxycodone and Oxymorphone in Human Urine

For In Vitro Diagnostic Use Only

Intended Use

The information provided in this application sheet is intended as a supplement to the package insert. Refer to the package insert for information on intended use, reagent storage, reagent preparation, specimen collection, specimen storage, quality control, and additional performance data.

Ordering Information

Materials available from Microgenics:

Item	Catalog Number
DRI Oxycodone Assay Reagent	100248 (70 mL)
DRI Negative Calibrator	1664 (10 mL), 1388 (25 mL)
DRI Oxycodone 100 ng/mL Calibrator	100250 (10 mL)
DRI Oxycodone 300 ng/mL Calibrator	100251 (10 mL)
DRI Oxycodone 500 ng/mL Calibrator	100252 (10 mL)
DRI Oxycodone 1000 ng/mL Calibrator	100253 (10 mL)
DRI Oxycodone Level I Control Kit	100254 (10 mL)
DRI Oxycodone Level II Control Kit	100255 (10 mL)

To place an order or for technical service contact (North America):

Microgenics Corporation
46360 Fremont Boulevard, Fremont, CA 94538 USA
U.S. Toll free: (800) 232-3342 / Tel: (510) 979-5001
U.S. Toll Free Fax (800) 829-8115 / Fax: (510) 979-5002

CE EC REP Microgenics GmbH, Spitalhofstrasse 94, D-94032 Passau, Germany
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Reagent Storage	Refer to the package insert for information on reagent storage.
Procedure for Analyzer	Refer to the operator's manuals for information on analyzer operation. Dispense an adequate amount of Antibody Reagent (first reagent) into a 40 mL reagent bottle and an adequate amount of Enzyme Reagent (second reagent) into a 20 mL reagent bottle. **Ensure that the reagents have equilibrated to the temperature of the analyzer reagent compartment before starting analysis.** **NOTE:** Running a blank during calibration is a requirement of the MGC 240. For this assay, in both qualitative and semi-quantitative methods, run the negative calibrator as the blank.
Calibration	Refer to the package insert for information on calibration.
Results and Data Interpretation	Refer to the package insert for information on results and data interpretation. When samples are analyzed using either the qualitative or semi-quantitative method, results greater than or equal to the desired cutoff will be flagged "high."

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Microgenics Parameters, MGC 240: DRI Oxycodone – Qualitative

Item Parameter

Item Name	Oxyc

DATA INFORMATION

UNITS	***
DECIMALS	0

CALIBRATION

TYPE	Linear

STANDARD

#1	§	#4	
#2		#5	
#3		#6	

ANALYSIS

TYPE	RATE
Main W.Length 1	340
Sub W.Length 2	450
METHOD	DRI

CORR

Y = SLOPE 1.000 X + INTER 0.000

NORMAL RANGE

	MALE		FEMALE	
	LOW	HIGH	LOW	HIGH
SERUM		†		†
URINE		†		†
Plasma		†		†
CSF		†		†
Dialysis		†		†
Other		†		†

Page : 1 | Print | Next Page | Save | Return

Item Parameter

Item Name	Oxyc

ASPIRATION

KIND ○ Single • **Double**

	Volume	
SAMPLE	‡	µL
REAGENT1	125	
REAGENT2	125	

Third Mix • **OFF** ○ ON

R1 Blank • **Water-Blank** ○ R1-Blank1

MONITOR

0 LEVEL POINT	1
SPAN	3

DATA PROCESS

READ

	Start	End
MAIN	35	38
SUB		

FACTOR

Blank correction	1

ABSORBANCE LIMIT

LOW	-3
HIGH	3

Endpoint Limit	
Linear Check(%)	90

PROZONE CHECK

	Start	End	Limit(%)	
FIRST				• Lo ○ Hi
SECOND				• Lo ○ Hi
THIRD				

Page : 2 | Print | Next Page | Save | Return

***USER DEFINED

§ Enter the cutoff concentration (100 or 300 ng/mL) in this field.
† Enter 99 for the 100 ng/mL cutoff; enter 299 for the 300 ng/mL cutoff.
‡ Enter 20 for the 100 ng/mL cutoff; enter 15 for the 300 ng/mL cutoff

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Microgenics Parameters, MGC 240: DRI OXYCODONE – Semi-quantitative

Item Parameter

Item Name	OxySQ

DATA INFORMATION

UNITS	ng/mL
DECIMALS	0

ANALYSIS

TYPE	RATE
Main W.Length 1	340
Sub W.Length 2	450
METHOD	DRI

CORR

Y = SLOPE 1.000 X + INTER 0.000

CALIBRATION

TYPE: Logit 1

STANDARD

#1	100.0	#4	1000.0
#2	300.0	#5	
#3	500.0	#6	

NORMAL RANGE

	MALE LOW	MALE HIGH	FEMALE LOW	FEMALE HIGH
SERUM		†		†
URINE		†		†
Plasma		†		†
CSF		†		†
Dialysis		†		†
Other		†		†

Page : 1 | Print | Next Page | Save | Return

Item Parameter

Item Name	OxySQ

ASPIRATION

KIND: ○ Single • **Double**

	Volume	
SAMPLE	15	µL
REAGENT1	125	
REAGENT2	125	

Third Mix: • **OFF** ○ ON

R1 Blank: • **Water-Blank** ○ R1-Blank1

MONITOR

0 LEVEL POINT	1
SPAN	3

DATA PROCESS

READ

	Start	End
MAIN	35	38
SUB		

ABSORBANCE LIMIT

LOW	-3
HIGH	3

FACTOR

Blank correction	1

Endpoint Limit	
Linear Check(%)	90

PROZONE CHECK

	Start	End	Limit(%)	
FIRST				• **Lo** ○ Hi
SECOND				
THIRD				• **Lo** ○ Hi

Page : 2 | Print | Next Page | Save | Return

† Enter 99 for the 100 ng/mL cutoff; enter 299 for the 300 ng/mL cutoff.

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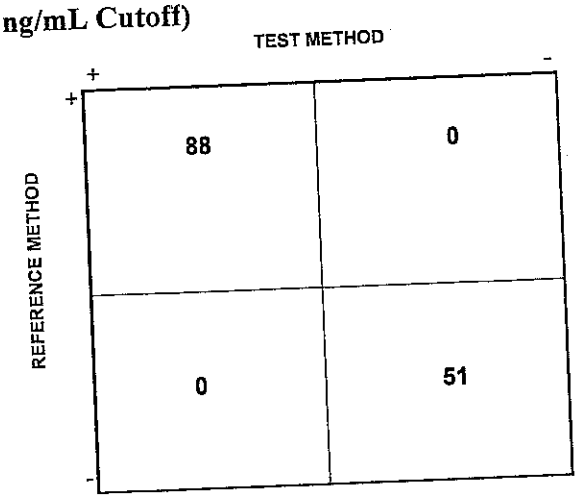
MGC 240 Precision

Within-run and total precision, evaluated with packaged reagents, controls and calibrators, yielded the following results (n=60):

Qualitative Method	Low Control	Cutoff Cal	High Control
100 ng/mL Cutoff			
Mean Rate (mA/min)	388	409	431
Within-Run SD (mA/min)	2.4	1.7	1.8
Within-Run CV (%)	0.6	0.4	0.4
Total SD (mA/min)	3.1	3.2	3.3
Total CV (%)	0.8	0.8	0.8
300 ng/mL Cutoff			
Mean Rate (mA/min)	473	504	528
Within-Run SD (mA/min)	1.7	1.7	1.5
Within-Run CV (%)	0.4	0.3	0.3
Total SD (mA/min)	3.8	3.8	3.1
Total CV (%)	0.8	0.8	0.6
Semi-quantitative Assay			
100 ng/mL Cutoff			
Mean (ng/mL)	62	90	124
Within-Run SD (ng/mL)	2.3	3.1	2.6
Within-Run CV (%)	3.8	3.4	2.1
Total SD (ng/mL)	5.0	7.3	8.0
Total CV (%)	8.0	8.1	6.5
300 ng/mL Cutoff			
Mean (ng/mL)	255	349	441
Within-Run SD (ng/mL)	5.9	9.8	8.6
Within-Run CV (%)	2.3	2.8	2.0
Total SD (ng/mL)	13.9	17.3	20.7
Total CV (%)	5.5	5.0	4.7

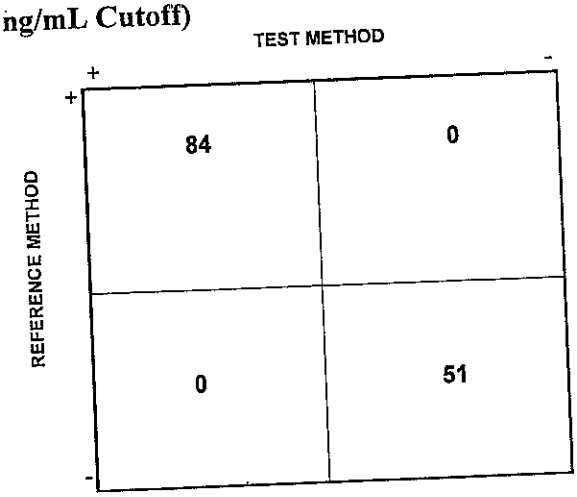
MGC 240 Accuracy and Correlation

Qualitative (100 ng/mL Cutoff)



One hundred thirty-nine (139) urine samples were assayed qualitatively at the 100 ng/mL cutoff using the DRI Oxycodone Assay on the MGC 240 and the Hitachi 717 analyzers. 100% positive agreement (88 of 88 samples) and 100% negative agreement (51 of 51 samples) were observed between the two analyzers.

Qualitative (300 ng/mL Cutoff)



One hundred thirty-five (135) urine samples were assayed qualitatively at the 300 ng/mL cutoff using the DRI Oxycodone Assay on the MGC 240 and the Hitachi 717 analyzers. 100% positive agreement (84 of 84 samples) and 100% negative agreement (51 of 51 samples) were observed between the two analyzers.

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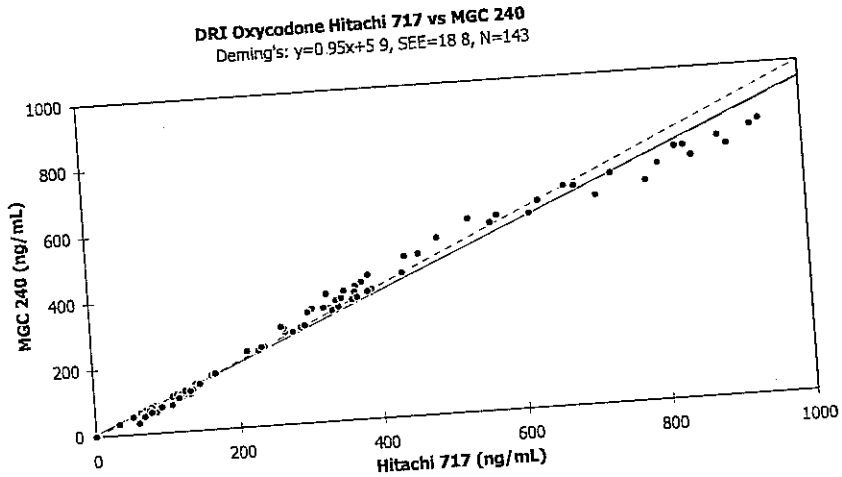
MGC 240 Accuracy and Correlation (continued)

Semi-quantitative

One hundred forty-three (143) urine samples were assayed semi-quantitatively using the DRI Oxycodone Assay on the MGC 240 and the Hitachi 717 analyzers. The following linear regression analysis equation was observed: MGC 240 = 0.95 (Hitachi 717) + 6, with a correlation coefficient of [r]= 0.994.



10008905-0
2004-07

DRI® Amphetamines Assay

microgenics

For In Vitro Diagnostic Use

Catalog No.: 0017 (100 mL Kit)
0018 (500 mL Kit)

Intended Use

The DRI® Amphetamines Assay is intended for the qualitative or semiquantitative determination of amphetamines in human urine. The assay provides a simple and rapid analytical screening procedure for detecting amphetamines in urine

This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.[1,2] Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Summary and Explanation of the Test

Amphetamines are synthetic derivatives of ephedrine. The most common amphetamines include d-amphetamine, d-methamphetamine, and d, l-amphetamine. They act as stimulants for the central nervous system. Amphetamine is the most sympathomimetic amine.[3,4] When amphetamine is ingested, it is either rapidly deactivated in the liver or excreted unchanged into the urine Other ephedrine derivatives such as methamphetamine can be metabolized and excreted in urine as amphetamine.

The DRI Amphetamines Assay is a liquid ready-to-use homogeneous enzyme immunoassay.[5] The assay uses specific antibodies, which can detect amphetamine and/or methamphetamine in urine with minimal cross-reactivity to various over-the-counter amphetamine-like compounds. The assay is based on the competition of an enzyme glucose-6-phosphate dehydrogenase (G6PDH) labeled drug and the drug from the urine sample for a fixed amount of specific antibody binding sites. In the absence of free drug from the sample, the enzyme-labeled drug is bound by the specific antibody and the enzyme activity is inhibited. This phenomenon creates a direct relationship between drug concentration in urine and the enzyme activity. The enzyme G6PDH activity is determined spectrophotometrically at 340 nm by measuring its ability to convert nicotinamide adenine dinucleotide (NAD) to NADH

Reagents

Antibody/Substrate Reagent. Contains monoclonal anti-amphetamines antibodies, glucose-6-phosphate (G6P), and nicotinamide adenine dinucleotide (NAD) in Tris buffer with sodium azide as a preservative.

Enzyme Conjugate Reagent. Contains amphetamines labeled with glucose-6-phosphate dehydrogenase (G6PDH) in Tris buffer with sodium azide as a preservative

Additional Materials Required (sold separately):

Catalog No.
- 1664 DRI Negative Calibrator, 10 mL
- 1388 DRI Negative Calibrator, 25 mL
- 1588 DRI MultiDrug Calibrator 1, 10 mL
- 1589 DRI MultiDrug Calibrator 1, 25 mL
- 1591 DRI MultiDrug Calibrator 2, 10 mL
- 1592 DRI MultiDrug Calibrator 2, 25 mL
- 1594 DRI MultiDrug Calibrator 3, 10 mL
- 1595 DRI MultiDrug Calibrator 3, 25 mL
- 1597 DRI MultiDrug Calibrator 4, 10 mL
- 1598 DRI MultiDrug Calibrator 4, 25 mL
- 1599 DRI MultiDrug Urine Control 1, 10 mL
- 1553 DRI MultiDrug Urine Control 1, 25 mL
- 1600 DRI MultiDrug Urine Control 2, 10 mL
- 1555 DRI MultiDrug Urine Control 2, 25 mL

Precautions and Warnings

1. This test is for in vitro diagnostic use only. The reagents are harmful if swallowed.
2. Reagents used in the assay components contain sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with a large volume of water to prevent azide build-up.
3. Do not use the reagents beyond their expiration dates.

Reagent Preparation and Storage

The reagents are ready for use. No reagent preparation is required. All assay components when stored at 2-8°C, are stable until the expiration date indicated on the label

Specimen Collection and Handling

Collect urine specimens in plastic or glass containers. Testing of fresh urine specimens is suggested.

The Mandatory Guidelines for Federal Workplace Drug Testing Programs; Final Guidelines recommends that specimens that do not receive an initial test within 7 days of arrival in the laboratory should be placed into secure refrigeration units.

Samples within a pH range of 3 to 11 are suitable for testing with this assay.

An effort should be made to keep pipetted samples free of gross debris. It is recommended that highly turbid specimens be centrifuged before analysis. Adulteration of the urine sample may cause erroneous results. If adulteration is suspected, obtain another sample and forward both specimens to the laboratory for testing.

Handle all urine specimens as if they were potentially infectious.

Assay Procedure

Analyzers capable of maintaining a constant temperature, pipetting samples, mixing reagents, measuring enzymatic rates at 340 nm and timing the reaction accurately can be used to perform this assay.

Before performing the assay, refer to the analyzer-specific protocol sheet, which contains parameters and/or additional instructions for use

Quality Control and Calibration

Good laboratory practice suggests the use of control specimens to ensure proper assay performance. Use controls near the cutoff calibrator to validate the calibration Control results must fall within established ranges are determined by your laboratory. If results fall outside of established ranges, assay results are invalid.

Qualitative Analysis

For qualitative analysis of samples, use the 1000 ng/mL calibrator as a cutoff level. The DRI® MultiDrug Urine Calibrator 2, which contains 1000 ng/mL d-methamphetamine, is used as a cutoff reference for distinguishing "positive" from "negative" samples

Semiquantitative analysis

For semiquantitative analysis, use all calibrators.

Results and Expected Values

Qualitative results

A sample that exhibits a change in absorbance (ΔA) value equal to or greater than the value obtained with the cutoff calibrator is considered positive A sample that exhibits a change in absorbance (ΔA) value lower than the value obtained with the cutoff calibrator is considered negative.

Semiquantitative results

A rough estimate of drug concentration in the samples can be obtained by running a standard curve with all calibrators and quantitating samples off the standard curve.

Limitations

1. A positive result from this assay indicates only the presence of amphetamines and does not necessarily correlate with the extent of physiological and psychological effects.
2. A positive result by this assay should be confirmed by another nonimmunological method such as GC, TLC or GC/MS
3. The test is designed for use with human urine only.
4. It is possible that other substances and/or factors (eg, technical or procedural) not listed in the specificity table may interfere with the test and cause false results.

Specific Performance Characteristics

Typical performance data results obtained on the Hitachi 717 analyzer are shown below [6]

Precision

The negative calibrator, 750 ng/mL control, 1000 ng/mL calibrator, 1250 ng/mL control and 2000 ng/mL calibrator were assayed, and the following results were obtained:

Calibrator/Control (n=10)	Mean ± SD (mA/min)	% CV
Negative	312 ± 1 0	0.3
750 ng/mL	418 ± 2.0	0 5
1000 ng/mL	443 ± 2.0	0.5
1250 ng/mL	468 ± 2 0	0 2
2000 ng/mL	513 ± 3.0	0.2

Sensitivity

Sensitivity, defined as the lowest concentration that can be differentiated from the negative urine with 95% confidence, is 10 ng/mL.

Accuracy

One hundred and fifty clinical urine specimens were tested with a commercially available EIA assay and DRI Amphetamines Assay There was 100% agreement between the two methods. Fifty-two samples were positive and ninety-eight were negative by both assays. In addition, all fifty-two positive samples were confirmed positive by the GC/MS method.

Specificity

Various potentially interfering substances were tested for cross-reactivity with the assay. The following table summarizes the results obtained at the concentrations tested for each potential cross-reactant

Concentrations of compounds tested that produced a result approximately equivalent to the cutoff calibrator:

Compound	Concentration Tested (µg/mL)
d-Amphetamine	1.0
d-Methamphetamine	1.0
Methylenedioxyamphetamine (MDA)	2 5
Methylenedioxymethamphetamine (MDMA)	5 0

Concentrations of compounds tested that produced a negative result relative to the cutoff calibrator:

Compound	Concentration Tested (µg/mL)	Compound	Concentration Tested (µg/mL)
l-Amphetamine	12.5	Acetaminophen	1000
l-Methamphetamine	10	Acetylsalicylic acid	1000
Benzphetamine	20	Benzoylecgonine	1000
d-Ephedrine	3000	Bupropion	50
l-Ephedrine	350	Caffeine	1000
d,l-Ephedrine	700	Codeine	1000
Fenfluramine	4	Chlorpromazine	500
Mephentermine	25	Dextromethorphan	1000
Nor-pseudoephedrine	1000	Isoxsuprine	100
Phendimetrazine	200	Meperidine	1000
Phenethylamine	100	Methadone	1000
Phenmetrazine	50	Methapyrilene	500
Phenetermine	25	Morphine	1000
Phenylephrine	500	Oxazepam	500
Phenypropanolamine	250	Phencyclidine	1000
Propranolol	200	Phenobarbital	1000
d-*Pseudoephedrine*	250	Phenothiazine	10
l-Pseudoephedrine	3000	Procainamide	20
Tyramine	500	Promethazine	500
3-OH-Tyramine	500	Ranitidine	30
Scopolamine	100	Secobarbital	1000
Thioridazine	1000	Triflupromazine	1000
Trifluoperazine	1000		

References

1. *Urine Testing for Drugs of Abuse.* National Insitute on Drug Abuse (NIDA). Research Monograph 73, 1986.
2. *Mandatory Guidelines for Federal Workplace Drug Testing Programs.* National Institute On Drug Abuse Federal Register Vol. 53, No 69, pp11970 (1988).
3. Kalant OJ *The Amphetamines: Toxicity and Addiction.* Thomas, Springfield. 151pp, 1966.
4. Morgan JP. *Substance Abuse: Clincal Problems and Perspectives.* Lowison JH and P Ruiz, Eds Williams & Wilkins, Baltimore, 167pp, 1981.
5. Rubenstein KE, Schneider RS, and EF Ullman: *Homogenous Enzyme Immunoassay: A New Immunochemical Technique* Biochem Biophys Res Commun 47, 846 (1972).
6. Data on file at Microgenics Corporation.

Manufacturer:

Microgenics Corporation
46360 Fremont Blvd
Fremont, CA 94538 USA
US Toll Free: 1-800-232-3342

CE

Authorized Representative in E.U.:

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Fax:+49 (0) 851 886 89 10

Other countries:
Please contact your local Microgenics representative

0138-2 2003 09

DRI® Barbiturate Assay

microgenics

For In Vitro Diagnostic Use

Catalog No.: 0225 (100 mL Kit)
0226 (500 mL Kit)

Intended Use

The DRI® Barbiturate Assay is intended for the qualitative and semiquantitative determination of barbiturates in human urine.

This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.[1,2] Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Summary and Explanation of the Test

Drug abusers may abuse various barbiturates, such as short-acting secobarbital and long-acting phenobarbital, through oral ingestion or by intravenous and/or intramuscular injection. Long-term abuse can lead to respiratory depression or, in severe cases, coma. When ingested, a barbiturate is rapidly metabolized and excreted into urine, allowing immunoassays to detect recent use.

The DRI Barbiturate Assay is a homogeneous enzyme immunoassay[3] using ready-to-use liquid reagents. The assay uses monoclonal antibodies that detect most barbiturates in urine. The assay is based on the competition of an enzyme glucose-6-phosphate dehydrogenase (G6PDH) labeled drug and the drug from the urine sample for a fixed amount of specific antibody binding sites. In the absence of drug from the sample, the G6PDH labeled drug is bound by the specific antibody and the enzyme activity is inhibited. This phenomenon creates a relationship between drug concentration in urine and the enzyme activity. The enzyme G6PDH activity is determined spectrophotometrically at 340 nm by measuring its ability to convert nicotinamide adenine dinucleotide (NAD) to NADH.

Reagents

Antibody/Substrate Reagent. Contains monoclonal anti-barbiturate antibody, glucose-6-phosphate (G6P), and nicotinamide adenine dinucleotide (NAD) in Tris buffer with sodium azide as preservative.

Enzyme Conjugate Reagent. Contains barbiturate labeled with glucose-6-phosphate dehydrogenase (G6PDH) in Tris buffer with sodium azide as preservative

Additional Materials Required (sold separately):

Catalog No.
- 1664 DRI Negative Calibrator; 10 mL
- 1388 DRI Negative Calibrator; 25 mL
- 1588 DRI MultiDrug Calibrator 1, 10 mL
- 1589 DRI MultiDrug Calibrator 1, 25 mL
- 1591 DRI MultiDrug Calibrator 2, 10 mL
- 1592 DRI MultiDrug Calibrator 2, 25 mL
- 1594 DRI MultiDrug Calibrator 3, 10 mL
- 1595 DRI MultiDrug Calibrator 3, 25 mL
- 1597 DRI MultiDrug Calibrator 4, 10 mL
- 1598 DRI MultiDrug Calibrator 4, 25 mL
- 1599 DRI MultiDrug Urine Control 1, 10 mL
- 1553 DRI MultiDrug Urine Control 1, 25 mL
- 1600 DRI MultiDrug Urine Control 2, 10 mL
- 1555 DRI MultiDrug Urine Control 2, 25 mL

Precautions and Warnings

1. This test is for in vitro diagnostic use only. The reagents are harmful if swallowed.
2. Reagents used in the assay components contain sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with a large volume of water to prevent azide build-up.
3. Do not use the reagents beyond their expiration dates.

Reagent Preparation and Storage

The reagents are ready for use. No reagent preparation is required. All assay components, when stored at 2-8°C, are stable until the expiration date indicated on the label.

Specimen Collection and Handling

Collect urine specimens in plastic or glass containers. Testing of fresh urine specimens is suggested.

The Mandatory Guidelines for Federal Workplace Drug Testing Programs; Final Guidelines recommends that specimens that do not receive an initial test within 7 days of arrival in the laboratory should be placed into secure refrigeration units.

Samples within a pH range of 3 to 11 are suitable for testing with this assay.

An effort should be made to keep pipetted samples free of gross debris. It is recommended that highly turbid specimens be centrifuged before analysis. Adulteration of the urine sample may cause erroneous results. If adulteration is suspected, obtain another sample and forward both specimens to the laboratory for testing.

Handle all urine specimens as if they were potentially infectious.

Assay Procedure

Analyzers capable of maintaining a constant temperature, pipetting samples, mixing reagents, measuring enzymatic rates at 340 nm and timing the reaction accurately can be used to perform this assay.

Before performing the assay, refer to the analyzer-specific protocol sheet, which contains parameters and/or additional instructions for use.

Quality Control and Calibration

Good laboratory practice suggests the use of control specimens to ensure proper assay performance. Use controls near the cutoff calibrator to validate the calibration. Control results must fall within established ranges as determined by your laboratory. If results fall outside of established ranges, assay results are invalid

Qualitative Analysis

For qualitative analysis of samples, use the 200 ng/mL calibrator as a cutoff level. The DRI® MultiDrug Urine Calibrator 2, which contains 200 ng/mL secobarbital, is used as a cutoff reference for distinguishing "positive" from "negative" samples. In certain applications, 300 ng/mL has been used as a cutoff calibrator.

Semiquantitative analysis

For semiquantitative analysis, use all calibrators.

Results and Expected Values

Qualitative results

A sample that exhibits a change in absorbance (ΔA) value equal to or greater than the value obtained with the cutoff calibrator is considered positive. A sample that exhibits a change in absorbance (ΔA) value lower than the value obtained with the cutoff calibrator is considered negative

Semiquantitative results

A rough estimate of drug concentration in the samples can be obtained by running a standard curve with all calibrators and quantitating samples off the standard curve.

Limitations

1. A positive result from this assay indicates only the presence of barbiturates and does not necessarily correlate to the extent of physiological and psychological effects
2. A positive result by this assay should be confirmed by another nonimmunological method such as GC, TLC or GC/MS.
3. The test is designed for use with human urine only.
4. It is possible that other substances and/or factors (eg, technical or procedural) not listed in the specificity table may interfere with the test and cause false results.

Specific Performance Characteristics

Typical performance data results obtained on the Hitachi 717 analyzer are shown below[4]

Precision

The Negative, 200 ng/mL calibrator, 1000 ng/mL calibrator, Control 1 and Control 2 were assayed, and the following results were obtained:

Qualitative

	Within-run (n=20)		Run-to-run (n=17)	
Calibrator	Mean ± SD (mA/min)	% CV	Mean ± SD (mA/min)	% CV
0	147 ± 1.4	0.9	147 ± 0.7	0.5
200	239 ± 1.2	0.5	235 ± 0.8	0.3
1000	340 ± 2.1	0.6	332 ± 1.5	0.5

Semiquantitative

	Within-run (n=20)		Run-to-run (n=17)	
Control	Mean ± SD (ng/mL)	% CV	Mean ± SD (ng/mL)	% CV
Control 1	157 ± 1.4	0.9	161 ± 2.2	1.4
Control 2	264 ± 1.2	0.8	264 ± 3.3	1.3

Sensitivity

Sensitivity, defined as the lowest concentration that can be differentiated from the negative urine calibrator with 95% confidence, is 25 ng/mL.

Accuracy

One hundred and four clinical urine specimens were tested with a commercially available EIA assay and DRI Barbiturate Assay. There was 100% agreement between the two methods. Seventy-eight samples were positive and twenty-two were negative by both assays. In addition, all seventy-eight positive samples were confirmed positive by the GC/MS method

Specificity

Various potentially interfering substances were tested for cross-reactivity with the assay. The compounds listed in the table below produced a result approximately equivalent to the cutoff calibrator.

Compound	Concentration Tested (ng/mL)
Alphenal	250
Amobarbital	200
Aprobarbital	200
Barbital	1500
Butabarbital	250
Butalbital	300
Butethal	300
Diallybarbital	600
Pentobarbital	500
Phenobarbital	600
Secobarbital	200
Talbutal	60
Thiopental	600

The compounds listed in the table below produced a negative result relative to the cutoff calibrator.

Compound	Concentration Tested (µg/mL)
Acetaminophen	1000
Acetylsalicylic acid	1000
d-Amphetamine	1000
Benzoylecgonine	1000
Caffeine	100
Codeine	1000
Hydroxphenytoin (HPPH)	500
Meperidine	1000
Methadone	1000
Methaqualone	1000
Morphine	1000
Oxazepam	500
Phencyclidine	1000
Phenytoin (DPH)	500
Propoxyphene	1000

References

1. *Urine Testing for Drug of Abuse*. National Institute on Drug Abuse (NIDA) Research Monograph 73, 1986.
2. *Mandatory Guidelines for Federal Workplace Drug Testing Program*. National Institute on Drug Abuse. Federal Register Vol. **53**, No 69, pp 11970 (1988).
3. Rubenstein KE, Schneider RS, and EF Ullman: *Homogeneous enzyme immunoassay: a new immunochemical technique*. Biochem Biophys Res Commun 47:846-851 (1972).
4. Data on file at Microgenics Corporation.

Manufacturer:

Microgenics Corporation
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Fremont, CA 94538 USA
US Toll Free: 1-800-232-3342

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Other countries:
Please contact your local Microgenics representative.

0353-2 2003 08

DRI® Opiate Assay

microgenics

For In Vitro Diagnostic Use

Catalog No.: 0135 (100 mL Kit)
0136 (500 mL Kit)

Intended Use

The DRI® Opiate Assay is intended for the qualitative and semiquantitative determination of opiates in human urine.

The assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.[1,2] Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Summary and Explanation of the Test

Opiate compounds, such as morphine and codeine, are naturally occurring alkaloids of opium and are widely used as analgesics. Although drug abusers may abuse morphine and codeine, another opiate compound, heroin, is synthesized from morphine and is the most commonly abused opiate. When ingested or injected, heroin is metabolized to the molecule, 6-Monoacetyl morphine, which is hydrolyzed back to morphine. Opiates are rapidly metabolized by the body and excreted in urine, allowing immunoassays to detect recent use of morphine, codeine, and/or heroin.

The DRI Opiate Assay is a homogeneous enzyme immunoassay[3] using ready-to-use liquid reagents. The assay uses monoclonal antibodies that detect opiates in urine. The assay is based on the competition between an enzyme glucose-6-phosphate dehydrogenase (G6PDH) labeled drug and the free drug from the urine sample for a fixed amount of specific antibody binding sites. In the absence of free drug from the sample, the specific antibody binds the drug-labeled G6PDH and the enzyme activity is inhibited. This phenomenon creates a direct relationship between drug concentration in urine and the enzyme activity. The enzyme G6PDH activity is determined spectrophotometrically at 340 nm by measuring its ability to convert nicotinamide adenine dinucleotide (NAD) to NADH

Reagents

Antibody/Substrate Reagent. Contains monoclonal anti-morphine antibody, glucose-6-phosphate (G6P), and nicotinamide adenine dinucleotide (NAD) in Tris buffer with sodium azide as a preservative.

Enzyme Conjugate Reagent. Contains morphine labeled with glucose-6-phosphate dehydrogenase (G6PDH) in Tris buffer with sodium azide as a preservative.

Additional Materials Required (sold separately):

Catalog No.
- 1664 DRI Negative Calibrator, 10 mL
- 1388 DRI Negative Calibrator, 25 mL
- 1588 DRI MultiDrug Calibrator 1, 10 mL
- 1589 DRI MultiDrug Calibrator 1, 25 mL
- 1591 DRI MultiDrug Calibrator 2, 10 mL
- 1592 DRI MultiDrug Calibrator 2, 25 mL
- 1594 DRI MultiDrug Calibrator 3, 10 mL
- 1595 DRI MultiDrug Calibrator 3, 25 mL
- 1597 DRI MultiDrug Calibrator 4, 10 mL
- 1598 DRI MultiDrug Calibrator 4, 25 mL
- 1599 DRI MultiDrug Urine Control 1, 10 mL
- 1553 DRI MultiDrug Urine Control 1, 25 mL
- 1600 DRI MultiDrug Urine Control 2, 10 mL
- 1555 DRI MultiDrug Urine Control 2, 25 mL
- 1609 DRI Opiate Calibrator 1, 25 mL
- 0034 DRI Low Urine Calibrator, 5 mL
- 1610 DRI Opiate Calibrator 3, 25 mL
- 0036 DRI High Urine Calibrator, 5 mL
- 0210 DRI Level 1 Urine Control, 5 mL
- 0208 DRI Level 2 Urine Control, 5 mL

Precautions and Warnings

1. This test is for in vitro diagnostic use only. The reagents are harmful if swallowed
2. Reagents used in the assay components contain sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with a large volume of water to prevent azide build-up.
3. Do not use the reagents beyond their expiration dates.

Reagent Preparation and Storage

The reagents are ready for use. No reagent preparation required. All assay components, when stored at 2-8°C, are stable until the expiration date indicated on the label

Specimen Collection and Handling

Collect urine specimens in plastic or glass containers. Testing of fresh urine specimens is suggested.

The Mandatory Guidelines for Federal Workplace Drug Testing Programs; Final Guidelines recommends that specimens that do not receive an initial test within 7 days of arrival in the laboratory should be placed into secure refrigeration units.

Samples within a pH range of 3 to 11 are suitable for testing with this assay.

An effort should be made to keep pipetted samples free of gross debris. It is recommended that highly turbid specimens be centrifuged before analysis. Adulteration of the urine sample may cause erroneous results. If adulteration is suspected, obtain another sample and forward both specimens to the laboratory for testing.

Handle all urine specimens as if they were potentially infectious.

Assay Procedure

Analyzers capable of maintaining a constant temperature, pipetting samples, mixing reagents, measuring enzymatic rates at 340 nm and timing the reaction accurately can be used to perform this assay.

Before performing the assay, refer to the analyzer-specific protocol sheet, which contains parameters and/or additional instructions for use.

Quality Control and Calibration

Good laboratory practice suggests the use of control specimens to ensure proper assay performance. Use controls near the cutoff calibrator to validate the calibration. Control results must fall within established ranges as determined by your laboratory. If results fall outside of established ranges, assay results are invalid

Qualitative analysis
For qualitative analysis of samples, use the 300 ng/mL or 2000 ng/mL calibrator as a cutoff level for distinguishing "positive" from "negative" samples. The DRI® Opiate Low Urine Calibrator contains 300 ng/mL morphine. The DRI® MultiDrug Calibrator 2 contains 2000 ng/mL morphine.

Semiquantitative analysis
For semiquantitative analysis, use all calibrators.

Results and Expected Values

Qualitative results
A sample that exhibits a change in absorbance (ΔA) value equal to or greater than the value obtained with the cutoff calibrator is considered positive. A sample that exhibits a change in absorbance (ΔA) value lower than the value obtained with the cutoff calibrator is considered negative.

Semiquantitative results
A rough estimate of drug concentration in the samples can be obtained by running a standard curve with all calibrators and quantitating samples off the standard curve. Refer to the analyzer-specific protocol sheets.

Limitations

1. A positive result from this assay indicates only the presence of opiates and does not necessarily correlate with the extent of physiological and psychological effects.
2. A positive result by this assay should be confirmed by another nonimmunological method such as GC, TLC or GC/MS.
3. The test is designed for use with human urine only.
4. It is possible that other substances and/or factors (eg, technical or procedural) not listed in the specificity table may interfere with the test and cause false results

Specific Performance Characteristics

Typical performance results obtained on the Hitachi 717 analyzer are shown below.[4]

Precision

The following tables summarize the precision results obtained by testing the 300 ng/mL calibrator, 2000 ng/mL calibrator, and their respective low and high controls.

Qualitative

Using the 300 ng/mL cutoff calibrator	Within-run Precision		Total Precision	
	Mean ± SD	% CV	Mean ± SD	% CV
Low Control (225 ng/mL)	374 ± 2 2	0 6	374 ± 2 6	0 7
Cutoff	401 ± 2.3	0 6	401 ± 3 2	0 8
High Control (375 ng/mL)	421 ± 2.4	0.6	421 ± 3.0	0.7

Using the 2000 ng/mL cutoff calibrator	Within-run Precision		Total Precision	
	Mean ± SD	% CV	Mean ± SD	% CV
Low Control (225 ng/mL)	458 ± 2 6	0 6	458 ± 3.6	0 8
Cutoff	486 ± 3 2	0.7	486 ± 4.3	0 9
High Control (375 ng/mL)	507 ± 3 1	0 6	507 ± 4.2	0.8

Semiquantitative

Using the 300 ng/mL cutoff calibrator	Within-run Precision		Total Precision	
	Mean ± SD	% CV	Mean ± SD	% CV
Low Control (225 ng/mL)	226 ± 6 0	2 7	226 ± 8 2	3.6
Cutoff	303 ± 8.1	2.7	303 ± 9.4	3 1
High Control (375 ng/mL)	379 ± 15.1	4.0	379 ± 15.9	4.2

Using the 2000 ng/mL cutoff calibrator	Within-run Precision		Total Precision	
	Mean ± SD	% CV	Mean ± SD	% CV
Low Control (1500 ng/mL)	1513 ± 42.8	2.8	1513 ± 54 4	3 6
Cutoff	2008 ± 64 7	3 2	2008 ± 83.5	4.2
High Control (2500 ng/mL)	2517 ± 88.0	3.5	2517 ± 124.4	4.9

Sensitivity

Sensitivity, defined as the lowest concentration that can be differentiated from the negative urine with 95% confidence, is 6 ng/mL for the 300 ng/mL cutoff assay and 26 ng/mL for the 200 ng/mL cutoff assay.

Accuracy

One hundred and seventy-nine clinical urine specimens were tested using the 300 ng/mL as a cutoff calibrator and analyzed by GC/MS. Ninety-one samples were positive, eighty-one were negative, and seven were false positive using the 300 ng/mL cutoff calibrator. One hundred and sixty-three clinical urine specimens were tested using the 2000 ng/mL as a cutoff calibrator and analyzed by GC/MS. Eighty-nine were positive, seventy were negative, and four were false positive using the 2000 ng/mL cutoff calibrator.

DRI Opiate Qualitative Assay 300 ng/mL

GC/MS	+	-
+	91	0
-	7	81

DRI Opiate Qualitative Assay 2000 ng/mL

GC/MS	+	-
+	89	0
-	4	70

Interference from endogenous and exogenous substances were investigated. No interference was observed when urine samples were spiked with the following compounds up to the concentrations indicated.

Compound	Concentration	Compound	Concentration
Acetaminophen	100 µg/mL	Glucose	3 g/dL
Acetone	1000 mg/dL	Hemoglobin	300 mg/dL
Ascorbic acid	1500 mg/dL	HSA	500 mg/dL
Aspirin	100 µg/mL	Ibuprofen	100 µg/mL
Caffeine	100 µg/mL	Oxalic acid	100 mg/dL
Creatinine	500 mg/dL	Riboflavin	7 5 mg/dL
Ethanol	1%	Sodium Chloride	1 5 g/dL
Galactose	10 mg/dL	Urea	6 g/dL

Specificity

The specificity of the assay was evaluated using 300 ng/mL and 2000 ng/mL as cutoff calibrators. The following tables summarize the results.

The compounds in the table below produced a result approximately equivalent to the cutoff calibrator.

Compound	300 ng/mL Cutoff Concentration (ng/mL)	2000 ng/mL Cutoff Concentration (ng/mL)
6-Monoacetyl Morphine	380	2500
Codeine	180	1200
Dihydrocodeine	450	5500
Heroin	350	3000
Hydrocodone	1700	11000
Hydromorphone	4000	11000
Levorphanol	14000	87000
Morphine	300	2000
Morphine-3-Glucuronide	600	5000
Morphine-6-Glucuronide	300	1800
Oxycodone	16000	100000
Oxymorphone	40000	300000
Ranitidine	500000	2000000

Concentration of compounds that produced a negative result with both the 300 ng/mL and 2000 ng/mL cutoff calibrators:

Compound	Concentration (ng/mL)	Compound	Concentration (ng/mL)
Acetaminophen	500000	Imipramine	100000
Acetylsalicylic acid	500000	Maprotiline	100000
Amitriptyline	100000	Mepericine	20000
Amphetamine	1000000	Methadone	500000
Benzoylecgonine	1000000	Metronidazole	1000000
Caffeine	10000	Nalbuphine	1000000
Carbamazepine	500000	Naloxone	100000
Chlorpromazine	10000	Naltrexone	3000000
Clomipramine	100000	Normorphine	100000
Cyclazocine	35000	Nortriptyline	100000
Desipramine	100000	Oxazepam	250000
Dextromethorphan	100000	Phencyclidine	1000000
Doxepine	100000	Phenobarbital	1000000
Ephedrine	1000000	Secobarbital	1000000
Fentanyl	100000	Talwin	100000
Fluoxetine	100000	Thebaine	2000
Fluphenazine	100000	Thioridazine	100000
Ibuprofen	500000	Tramadol	100000

References

1. *Urine Testing for Drug of Abuse.* National Institute on Drug Abuse (NIDA). Research Monograph 73, 1986.
2. *Mandatory Guidelines for Federal Workplace Drug Testing Programs* National Institute on Drug Abuse. Federal Register Vol **53**, No 69, pp 11970 (1988).
3. Rubenstein KE, Schneider RS, and EF Ullman: *Homogeneous Enzyme Immunoassay: A New Immunochemical Technique.* Biochem Biophys Res Commun 47, 846-851 (1972).
4. Data on file at Microgenics Corporation.

Manufacturer:

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Please contact your local Microgenics representative.

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DRI® Ethyl Alcohol Assay

microgenics

For In Vitro Diagnostic Use

Catalog No.: 0037 (100 mL Kit)
0038 (500 mL Kit)

Intended Use

The DRI® Ethyl Alcohol Assay is intended for the quantitative determination of alcohol in human urine, serum or plasma.

Summary and Explanation of the Test

In addition to beverages, ethyl alcohol (ethanol or alcohol) can also be found in high concentrations in a variety of products such as mouthwashes, colognes, candies and medicinal preparations. When alcohol is ingested, it will permeate all tissues of the body within one hour. About 95% of the alcohol is metabolized in the liver, and the remainder is excreted unchanged.

Alcohol intoxication can lead to birth defects (eg, fetal alcohol syndrome), loss of alertness, stupor, coma and death. Determination of ethyl alcohol concentration is commonly used for measuring legal impairment, investigating forensic evidence, diagnosing and/or treating alcohol dependency, as well as detecting alcohol poisoning.

Gas chromatography techniques and several enzymatic methods are available for determination of ethyl alcohol.[1,2] These techniques either require specimen pretreatment or require incubation periods ranging from 10 to 60 minutes.[3]

DRI Ethyl Alcohol Assay is a liquid, ready-to-use, kinetic method based on the high specificity of alcohol dehydrogenase (ADH) for ethyl alcohol. In the presence of ADH and nicotinamide adenine dinucleotide (NAD), ethyl alcohol is readily oxidized to acetaldehyde and NADH. The enzymatic reaction can be monitored spectrophotometrically at 340 nm.

$$\text{Ethyl Alcohol} + \text{NAD} \xleftrightarrow{\text{ADH}} \text{NADH} + \text{Acetaldehyde}$$

aterials Provided

Buffer Reagent (A): Contains Tris buffer with sodium azide as preservative.

Enzyme Reagent (E): Contains alcohol dehydrogenase (ADH) and NAD in Phosphate buffer with stabilizer and sodium azide as a preservative.

Additional Material Required (sold separately):

DRI® Ethyl Alcohol Calibrators and Controls:
Catalog No.: 0311 Ethyl Alcohol Negative Calibrator, 5mL
1405 Ethyl Alcohol Negative Calibrator, 25 mL
0239 Ethyl Alcohol 50 mg/dL Control, 5 mL
0241 Ethyl Alcohol 100 mg/dL Calibrator, 5 mL
1406 Ethyl Alcohol 100 mg/dL Calibrator, 25 mL
0243 Ethyl Alcohol 300 mg/dL Control, 5 mL

Precautions and Warnings

1. This test is for in vitro diagnostic use only. The components are harmful if swallowed.
2. Reagents used in the assay components contain sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with a large volume of water to prevent azide build-up.
3. Do not use the reagents beyond their expiration dates.
4. Do not leave either calibrators or controls uncapped longer than necessary. Store tightly capped inside a refrigerator whenever possible to prevent evaporation of alcohol.
5. Increased levels of lactic acid and lactic dehydrogenase (LDH) in postmortem samples may cause elevated ethyl alcohol results.

Reagent Preparation and Storage

The reagents are ready for use. No reagent preparation is required. All assay components, when stored properly at 2-8°C, are stable until the expiration ıte indicated on the label.

Specimen Collection and Handling

Serum, plasma and urine can be used for this assay. Anticoagulants such as EDTA, citrate, fluoride/oxalate and heparin can be used for collection of plasma samples. Collect urine specimens in clean glass or plastic containers. Do not use alcohol as a disinfectant when collecting or storing blood specimens. Testing fresh urine specimens is suggested. Samples within a pH range of 3 to 11 are suitable for testing with this assay. An effort should be made to keep pipetted samples free of gross debris. It is recommended that highly turbid specimens be centrifuged before analysis. Adulteration of the urine sample may cause erroneous results. If adulteration is suspected, obtain another sample and forward both specimens to the laboratory for testing.

The *Mandatory Guidelines for Federal Workplace Drug Testing Programs* recommends that specimens that do not receive an initial test within 7 days of arrival at the laboratory should be placed into secure refrigeration units.[4]

Handle all urine specimens as if they were potentially infectious.

Assay Procedure

Before performing the assay, refer to the analyzer-specific protocol sheet, which contains parameters and/or additional instructions for use.

Instruments

Analyzers capable of maintaining a constant temperature, pipetting samples, mixing reagents, measuring enzymatic rates at 340 nm and timing the reaction accurately can be used to perform this assay.

Quality Control and Calibration

Good laboratory practices suggest the use of controls to ensure proper assay performance. Both 50 mg/dL and 300 mg/dL ethyl alcohol controls are available from Microgenics. Establish the acceptable control ranges for your own laboratory. Both negative and 100 mg/dL alcohol calibrators should be used to calibrate the assay. Controls should be used at least once a day to validate the assay performance.

Results

The rate of alcohol metabolism and excretion vary among individuals and are dependent upon factors such as gender, age, body weight, stomach content, concurrent use of medication and health condition. The DRI Ethyl Alcohol Assay can accurately quantitate alcohol concentrations within a range of 10 mg/dL (0.01%) to 600 mg/dL (0.6%).

The legal definition of intoxication varies. The following table is recommended as a general guideline for the significance of blood (serum and/or plasma) alcohol level:[5]

Blood Alcohol Level	Sporadic Drinkers	Chronic Drinkers
100 mg/dL or 0.1%	Legally intoxicated	Minimal signs
200-250 mg/dL or 0.2-0.25%	Alertness loss, lethargic	Effort needed to maintain control
300-350 mg/dL or 0.3-0.35%	Stupor to coma	Drowsy and slow
> 500 mg/dL or > 0.5%	Death possible	Coma

Urine alcohol concentrations are often used to estimate blood alcohol concentrations. During the elimination phase, the urine/blood alcohol ratio of 1.3 provides a valid estimate in most cases.[6]

Limitations

1. Legal alcohol intoxication levels vary. The test result should be interpreted in light of clinical signs and symptoms.
2. Ethyl alcohol is volatile. Precautions suggested in the Specimen Collection and Handling section are required to prevent alcohol evaporation from calibrators, controls and samples.
3. The test is designed for use with human urine, serum and plasma only.
4. Increased levels of lactic acid and LDH in postmortem samples may cause elevated ethyl alcohol results.

Typical Performance Characteristics

The following typical performance data were generated with a Hitachi 717 clinical chemistry analyzer.

Precision

Within-run and run-to-run precision were evaluated with the following results:

	Within-Run Precision		
Sample	n	Mean ± S.D (mg/dL)	%CV
50 mg/dL	12	48 6 ± 1 3	2 7
100 mg/dL	12	100 3 ± 1 2	1 2
300 mg/dL	12	290.2 ± 1.9	0.6

	Run-to-Run Precision		
Sample	n	Mean ± S D (mg/dL)	%CV
50 mg/dL	10	50 7 ± 4 5	4 5
250 mg/dL	10	253.7 ± 6.7	2.6

Sensitivity

Sensitivity, defined as the lowest concentration that can be differentiated from the negative sample, is 10 mg/dL (or 0 01%)

Linearity

The assay is linear up to a concentration of 600 mg/dL. Samples with an alcohol concentration greater than 600 mg/dL can be diluted with the negative calibrator. Repeat the assay and multiply the result with the dilution factor to obtain the true concentration

Specificity

Grossly hemolyzed (800 mg/dL hemoglobin) icteric (30 mg/dL bilirubin) and lipemic (1000 mg/dL triglycerides) samples were found to have no interference with the assay. Various structually related organic compounds were tested for cross-reactivity in the assay The following table summarizes the results:

Compound	Level Tested (mg/dL)	% Cross Reactivity
Acetaldehyde	2000	0
Acetone	2000	0
n-Butanol	2000	1 7
Ethylene Glycol	2000	0
Isopropanol	2000	0
Methanol	2000	0
n-Propanol	2000	10 7

Correlation

One hundred and twenty-five clinical specimens were assayed for ethyl alcohol concentration by both DRI Ethyl Alcohol Assay (y) and a commercially available ethyl alcohol assay (x). A linear regression equation of y = 1 02x + 2 05 and a correlation coefficient (r) of 0 982 were obtained

References

1. Baselt RC: *Disposition of Toxic Drugs and Chemicals in Man* ed Chicago, IL, Year Book Medical Publishers Inc 1989, pp 322-24
2. Beutler HO: Ethanol In: Bergmeyer HU, ed *Methods of Enzymatic Analysis,* Vol VI, 3rd ed. New York: Academic Press, 1984, pp 598 - 606
3. Redetzki HM, Dees WL, *Comparison of Four Kits for Enzymatic Determinaton of Ethanol in Blood.* Clin Chem 22. 83 (1976).
4. *Mandatory Guidelines for Federal Workplace Drug Testing Program.* National Institute on Drug Abuse Federal Register Vol **53** No 69, pp 11970 (1988)
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6. Heise HA. *Concentrations of Alcohol in Samples of Blood and Urine Taken at The Same Time* J For Sci 12, 454 (1967)

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DRI® General Oxidant-Detect® Test

DRAFT

microgenics

For In Vitro Diagnostic Use

Catalog No.: 10009958 (2 x 500 mL Kit)
10009971 General Oxidant-Detect Calibrator Kit (2 x 25 mL)
10009972 General Oxidant-Detect Control Kit (2 x 25 mL)

Intended Use

The DRI® General Oxidant-Detect® Test is intended for the detection of urine adulteration by oxidizing compounds.

Summary and Explanation of the Test

A complete urine drug of abuse testing program normally involves specimen collection, initial screening with an immunoassay, followed by a confirmation test, such as gas chromatography/mass spectrometry (GC/MS), for the positive samples.[1] Many drug users will attempt to evade detection by adulterating the specimen in order to produce false negative results during the initial immunoassay screening. Adulteration methods include dilution with water, substitution with a drug free liquid, addition of readily available household materials (e.g., vinegar, baking soda, liquid drain opener, detergent, etc.) or tampering with certain chemicals (e.g., Urine-Aid, which contains glutaraldehyde or Klear, which contains potassium nitrite). Additionally, drug users may alter their urine pH (acidity or alkalinity) to facilitate faster drug (e.g.,phencyclidine, amphetamines) elimination.

Several methods have been used to detect urine adulteration. These methods include measuring the temperature, pH, specific gravity and creatinine concentration of the sample. Fresh normal urine should have the following typical characteristics: temperature between 32.5-37.7°C or 90.5-99.8°F,[1] pH within 4.7-7.8,[2,3] specific gravity within a range of 1.003-1.035 g/mL[2,4,5] and creatinine concentration of 80-200 mg/dL.[5-8] If any of the urine parameters are outside the specified range, there is reason to believe that the urine sample has been adulterated.

Several oxidizing adulterants are being sold with a claim to clear all positive drug test results. The most commonly used oxidizing adulterants are Nitrite (Klear™), Chromate (Urine Luck™), Iodine, Bleach and Horse Radish Peroxidase/H_2O_2 (Stealth™). When added to urine, there is no significant change to the appearance, pH, specific gravity or creatinine concentration. Marijuana samples adulterated with oxidants can produce a positive result, during initial screening by immunoassy, notably the marijuana metabolite (THC). However, they can not be confirmed by GC/MS.[9,10]

The General Oxidant-Detect Test can be performed on any automated clinical chemistry analyzer to detect oxidants. The method is based on the reaction between the substrate Tetramethylbenzidine (TMB) and the oxidant in the sample producing color that can be measured at 660 nm.

Material Provided

General Oxidant-Detect Reagent: Contains 2 x 500 mL of 3,3',5,5' tetramethylbenzidine in an acidic solution.

Additional Materials Required (sold separately):
General Oxidant-Detect Calibrator Kit: Contains 1 x 25 mL of negative calibrator and 1 x 25 mL of 200 µg/mL nitrite in an aqueous solution.
General Oxidant-Detect Control Kit: Contains 1 x 25 mL of Negative Control (100 µg/mL nitrite) and 1 x 25 mL of Positive Control (300 µg/mL nitrite) in an aqueous solution.

Precautions and Warning

1. This test is for in vitro diagnostic use only. The reagents are harmful if swallowed.
2. The reagent contains an acidic solution. Wear suitable protective clothing, gloves and eye/face protection.
3. Do not use the reagent, calibrators and controls beyond the expiration date.

Reagent Preparation and Storage

The reagent, calibrators and controls are ready for use. No preparation is required. All assay components, when stored properly, are stable until the expiration date indicated on the label. The General Oxidant-Detect reagent, calibrators and controls should be stored at 2-8°C.

Specimen Collection and Handling

Collect urine specimens in plastic or glass containers. Fresh urine specimens should be used. *"The Mandatory Guidelines for Federal Workplace Drug Testing Programs: Final Guidelines: Notice"* recommends that specimens that do not receive an initial test within 7 days of arrival at the laboratory should be placed into secure refrigeration units. Repeated freezing and thawing of the sample should be avoided.

Handle all urine specimens as if they were potentially infectious.[12]

Assay Procedure

Analyzers capable of maintaining a constant temperature, pipetting samples, mixing reagents, measuring absorbance at 660 nm and timing the reaction accurately can be used to perform this assay.

Before performing the assay, refer to the analyzer-specific protocol sheet, which contains parameters and/or additional instructions for use.

Quality Control and Calibration

Good laboratory practice suggests the use of control specimens to validate the calibration and to ensure proper assay performance. The 100 µg/mL and 300 µg/mL Nitrite Controls are available from Microgenics for this purpose. Ensure that control results are within established ranges. Recalibrate the system when new reagents are used or when the control values are outside established ranges.

Use the Negative and 200 µg/mL Calibrators to generate the calibration curve.

Results

A linear calibration is generated to calibrate the assay. Most clinical chemistry analyzers have built-in software that can calculate the oxidant concentrations automatically with no additional requirement of data manipulation.

Expected Values

Some oxidants such as nitrite may be generated in the human body and excreted into urine through an enzymatic oxidation by the enzyme Nitric Oxide Synthase (NOS). However, most nitrite formed is oxidized to nitrate. Therefore, nitrate concentration in human urine from NOS activity is much greater than the nitrite concentration. Moshage et. al.[13] conducted a study with healthy volunteers and reported an average urine concentration of 61 µg/mL for nitrate and 0.2 µg/mL for nitrite.

Patients with urinary tract infection or pathological conditions may have urine nitrite as high as 100-150 µg/mL.[14] Urine samples to which Klear was added were found to contain between 1900 and 15,000 µg/mL nitrite.[14] Therefore, a urinary nitrite concentration of 200 µg/mL or greater is a scientifically valid and forensically defensible proof of adulteration of the specimen with a nitrite-containing substance.

Limitations

This assay is optimized for the quantitative determination of oxidants such as nitrite, chromate and stealth oxidants in human urine. Sodium azide may cause interference with the assay and should not be used as a preservative for the urine sample.

Typical Performance Characteristics

The following typical performance data were generated with a Hitachi 717 clinical chemistry analyzer:[15]

Precision

The within-run and total-run precision was evaluated using modified NCCLS method with the following results.

	Within-run Precision (n=120)		Total Precision (n=120)	
Calibrator or Control	Mean ± SD (µg/mL)	% CV	Mean ± SD (µg/mL)	% CV
100 µg/mL	84.8 ± 2.1	2.4	84.8 ± 2.7	3.2
200 µg/mL	199.3 ± 2.9	1.5	199.3 ± 3.6	1.8
300 µg/mL	322.1 ± 3.8	1.2	322.1 ± 5.8	1.8

Sensitivity

Sensitivity, defined as the lowest concentration of nitrite that can be differentiated from the negative calibrator with 95% confidence, is 2.65µg/mL.

Specificity

Specificity is defined as the minimum concentration of an oxidant that produces a result greater than or equal to 200 µg/mL nitrite. The following table provides a list of oxidants and concentrations that produce a positive result in the assay.

Oxidant	Concentration
Chromium	50 µg/mL
Bleach	2%
Iodine	0.2%
Peroxidase	50 U/mL

Interference

Interference of the following substances in urine was studied. No interference was observed when urine samples were spiked with these substances up to the concentrations indicated.

Compound	Concentration
Albumin	500 mg/dL
Ascorbic Acid	5 mg/dL
Creatinine	250 mg/dL
Galactose	10 mg/dL
Glucose	3000 mg/dL
Hemoglobin*	300 mg/dL
Riboflavin**	7.5 mg/dL
Urea	6000 mg/dL

* Hemoglobin interferes in the assay at 100 mg/mL in the presence of bleach and iodine.

**Riboflavin interferes in the assay at 5 mg/mL in the presence of bleach.

Accuracy and Correlation

A total of 93 samples adulterated with oxidants were tested with DRI General Oxidant-Detect Test and a commercially available method as reference. Method comparision results showed >95% agreement with reference method.

Reference

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15. Data on file at Microgenics Corporation

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10009957-0 2005 07

DRI® Cannabinoid Assay

microgenics

For In Vitro Diagnostic Use

talog No.: 0185 (100 mL Kit)
0186 (500 mL Kit)

Intended Use

The DRI® Cannabinoid Assay is intended for the qualitative and semiquantitative determination of cannabinoids (THC) in human urine.

This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.[1,2] Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Summary and Explanation of the Test

The principal active agent in marijuana and/or hashish that produces hallucinogenic and other biological effects is generally accepted to be Δ^9-tetrahydrocannabinol (Δ^9-THC). Δ^9-THC is rapidly absorbed and almost completely metabolized by inhalation or through the gastrointestinal tract. The major metabolites of Δ^9-THC (i.e. 11-nor-Δ^9-THC-9-carboxylic acid) becomes detectable in plasma, feces and urine within hours after exposure.[3] Passive inhalation of marijuana smoke can result in an elevation of urine THC concentration as high as 10-40 ng/mL.[4,5] In chronic users, THC may accumulate in fatty tissue faster than it can be excreted. This leads to longer detection times in urine for chronic users than for occasional users.

The DRI THC Assay is a homogeneous enzyme immunoassay using ready-to-use liquid reagents.[6] The assay uses specific monoclonal antibody which can detect the major metabolite of Δ^9-THC in urine. The assay is based on the competition of a drug labeled with enzyme, glucose-6-phosphate dehydrogenase (G6PDH), and the drug from the urine sample for a fixed amount of specific antibody binding sites. In the absence of drug from the sample, the specific antibody binds the drug labeled with G6PDH and the enzyme activity is inhibited. This phenomenon creates a direct relationship between the drug concentration in urine and the enzyme activity. The G6PDH activity is determined spectrophotometrically at 340 nm by measuring its ability to convert nicotinamide adenine dinucleotide (NAD) to NADH.

Reagents

Antibody/Substrate Reagent. Contains mouse monoclonal anti-Δ^9-THC antibodies, glucose-6-phosphate (G6P), and nicotinamide adenine dinucleotide (NAD) in Tris buffer with sodium azide as a preservative.

Enzyme Conjugate Reagent. Contains Δ^9-THC labeled with glucose-6-phosphate dehydrogenase (G6PDH) in Tris buffer with sodium azide as a preservative.

Additional Materials Required (sold separately):

Catalog No.		
	1664	DRI Negative Calibrator, 10 mL
	1388	DRI Negative Calibrator, 25 mL
	0235	DRI THC 20 ng/mL Calibrator, 5 mL
	1397	DRI THC 20 ng/mL Calibrator, 25 mL
	0042	DRI THC 50 ng/mL Calibrator, 5 mL
	1398	DRI THC 50 ng/mL Calibrator, 25 mL
	0044	DRI THC 100 ng/mL Calibrator, 5 mL
	1399	DRI THC 100 ng/mL Calibrator, 25 mL
	0206	DRI THC 200 ng/mL Calibrator, 5 mL
	1400	DRI THC 200 ng/mL Calibrator, 25 mL
	0170	DRI THC 40 ng/mL Control, 5 mL
	1401	DRI THC 40 ng/mL Control, 25 mL
	0168	DRI THC 60 ng/mL Control, 5 mL
	1402	DRI THC 60 ng/mL Control, 25 mL
	0214	DRI THC 75 ng/mL Control 5 mL
	1403	DRI THC 75 ng/mL Control, 25 mL
	0212	DRI THC 125 ng/mL Control, 5 mL
	1404	DRI THC 125 ng/mL Control, 25 mL

Precautions and Warnings

1. This test is for in vitro diagnostic use only. The reagents are harmful if swallowed.
2. The assay components contain sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents always flush with a large volume of water to prevent azide build-up.
3. Do not use the reagents beyond their expiration dates.

Reagent Preparation and Storage

The reagents are ready for use. No reagent preparation is required. All assay components when stored properly at 2-8°C, are stable until the expiration date indicated on the label.

Specimen Collection and Handling

Collect urine specimens in plastic or glass containers. Testing of fresh urine specimens is suggested.

The Mandatory Guidelines for Federal Workplace Drug Testing Programs: Final Guidelines: Notice recommends that specimens that do not receive an initial test within 7 days of arrival in the laboratory should be placed into secure refrigeration units.[2]

Samples within a pH of 3 to 11 are suitable for testing with this assay.

An effort should be made to keep pipetted samples free of gross debris. It is recommended that highly turbid specimens be centrifuged before analysis. Adulteration of the urine sample may cause erroneous results. If adulteration is suspected, obtain another sample and forward both specimens to the laboratory for testing.

Handle all urine specimens as if they were potentially infectious.

Assay Procedure

Clinical chemistry analyzers capable of maintaining a constant temperature, pipetting samples, mixing reagents, measuring enzymatic rates at 340 nm and timing the reaction accurately can be used to perform this assay. Before performing the assay, refer to the analyzer-specific protocol sheet, which contains parameters and/or additional instructions for use.

Quality Control and Calibration

Good laboratory practice suggests the use of control specimens to ensure proper assay performance. Use controls near the cutoff calibrator to validate the calibration. Control results must fall within the established range. If results fall outside of the established range, assay results are invalid.

Qualitative analysis
For qualitative analysis of samples, use the 20 ng/mL, 50 ng/mL, or 100 ng/mL 11-nor-Δ^9-THC-9-carboxylic acid calibrators as cutoffs. The DRI® THC Calibrators are used as cutoff references for distinguishing "positive" from "negative" samples.

Semiquantitative analysis
For semiquantitative analysis, use all calibrators.

Results and Expected Values

Qualitative results
A sample that exhibits a change in absorbance (ΔA) value equal to or greater than that obtained with the chosen cutoff calibrator is considered positive. A sample that exhibits a change in absorbance (ΔA) value lower than that obtained with the chosen cutoff calibrator is considered negative.

Semiquantitative results
A rough estimate of drug concentration in the samples can be obtained by running a standard curve with all calibrators and quantitating samples off the standard curve.

Limitations

1. A positive result from this assay indicates only the presence of THC metabolites and does not necessarily correlate with the extent of physiological and psychological effects.
2. A positive result by this assay should be confirmed by another nonimmunological method such as GC or GC/MS.
3. The test is designed for use with human urine only.
4. It is possible that other substances and/or factors (e.g., technical or procedural) not listed above may interfere with the test and cause false results.

Specific Performance Characteristics

Typical performance data results obtained on a Hitachi 717 analyzer are shown below.[7] The results obtained in your laboratory may differ from these data.

Precision

Within-run and run-to-run precision were evaluated using the negative and all the calibrator levels. The following results were observed:

	Within-run (n=20)		Run-to-run (n=12)	
Calibrator or Control	Mean ± SD (mA/min)	% CV	Mean ± SD (mA/min)	% CV
Negative	287 ± 2.9	1.0	287 ± 2.9	1.0
20 ng/mL	317 ± 2.9	0.9	319 ± 2.2	0.7
50 ng/mL	387 ± 3.5	0.9	388 ± 3.9	1.0
100 ng/mL	447 ± 4.0	0.9	449 ± 5.4	1.2
200 ng/mL	472 ± 2.4	0.5	473 ± 3.8	0.8

Accuracy

Five hundred and ninety-two clinical urine specimens were collected and tested with this assay, a commercial EIA assay, and a GC/MS technique for cannabinoid. A 15 ng/mL cutoff was used for GC/MS. The DRI Cannabinoid Assay showed a 100% correlation with GC/MS technique when a 50 ng/mL cutoff calibrator was used. Six GC/MS positive samples were quantitated as borderline negative by the assay when a 100 ng/mL cutoff calibrator was used. The assay also showed good correlation with a commercial EIA assay.

Sensitivity

Sensitivity, defined as the lowest concentration of THC analyte that can be differentiated from the negative urine calibrator with 95% confidence is 10 ng/mL.

Specificity

rious THC metabolites and potentially interfering substances were tested for cross-ctivity with the assay. The following table summarizes the results obtained at the ncentrations tested for each potential cross-reactant when a 50 ng/mL cutoff calibrator is used. For cross-reactivity information with the 20 ng/mL or 100 ng/mL cutoff calibrators, contact Microgenics Customer Technical Support

Table 1. Structurally related compounds that produce a positive result at the listed concentrations.

Compound	Concentration Tested (ng/mL)
11-Hydroxy-Δ^9-THC	100
l-11-Nor-Δ^9-THC-COOH	100
l-11-Nor-Δ^9-THC-COOH	50
8-β-Hydroxy-Δ^9-THC	100
8-β-11-Hydroxy-Δ^9-THC	50
Δ^9-THC	50
Cannabinol	100

Table 2. Structurally unrelated compounds that produce a negative result at the listed concentrations

Compound	Concentration Tested (ng/mL)
Acetaminophen	1 000,000
Acetylsalicylic acid	1,000 000
Amobarbital	1 000,000
Amphetamine	1,000 000
Benzoylecgonine	1,000,000
Caffeine	100 000
Cannabidiol	10,000
Cocaine	200,000
Codeine	1,000,000
Dextromethorphan	1,000,000
Meperidine	1 000,000
Methadone	1,000,000
Methamphetamine	1 000 000
Morphine	200 000
d-11-Nor-Δ^9-THC-COOH	100
Oxazepam	500,000
Phencyclidine	1 000,000
Phenobarbital	1,000,000
Propoxyphene	1 000,000
Secobarbital	1,000,000

References

1. *Urine Testing for Drugs of Abuse*. National Institute on Drug Abuse (NIDA) Research Monograph 73 (1986).
2. Mandatory Guidelines for Federal Workplace Drug Testing Program. National National Institute on Drug Abuse. Federal Register Vol. 53, No. 69, p 11979 (1988).
3. Wall ME, Brine DR and M Perez-Reyes: *Metabolism of Cannabinoids in Man*. Brande MC and S Szara, Eds.: *The Pharmacology of Marijuana*. Raven Press, 93 (1976).
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6. Rubenstein KE, Schneider RS and EF Ullman: *Homogeneous Enzyme Immunoassay: A New Immunochemical Technique*. Biochem Biophys Res Commun 47, 846 (1972)
7. Data on file at Microgenics Corporation

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0142-1 2003 06

DRI® Cocaine Metabolite Assay

microgenics

For In Vitro Diagnostic Use

ıtalog No.: 0055 (100 mL Kit)
0056 (500 mL Kit)

Intended Use

The DRI® Cocaine Metabolite assay is intended for the qualitative and semiquantitative determination of benzoylecgonine (cocaine metabolite) in human urine.

This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.[1,2] Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Summary and Explanation of the Test

Cocaine is a very common illicit drug. When ingested, it is rapidly metabolized and excreted into urine as benzoylecgonine (the major metabolite of cocaine) within four hours. Detection of benzoylecgonine in urine indicates use of cocaine.

The DRI Cocaine Metabolite Assay is a homogeneous enzyme immunoassay using ready-to-use liquid reagents.[3] The assay uses a specific antibody, which can detect benzoylecgonine in urine. The assay is based on the competition of an enzyme glucose-6-phosphate dehydrogenase (G6PDH) labeled drug and the drug from the urine sample for a fixed amount of specific antibody binding sites. In the absence of drug from the sample, the specific antibody binds to the drug labeled with G6PDH and the enzyme activity is inhibited. This phenomenon creates a direct relationship between the drug concentration in the urine and the enzyme activity. The enzyme G6PDH activity is determined ɔectrophotometrically at 340 nm by measuring its ability to convert cotinamide adenine dinucleotide (NAD) to NADH.

Reagents

Antibody/Substrate Reagent. Contains mouse monoclonal anti-benzoylecgonine antibody, glucose-6-phosphate (G6P), and nicotinamide adenine dinucleotide (NAD) in Tris buffer with sodium azide as preservative.
Enzyme Conjugate Reagent. Contains benzoylecgonine analog labeled with glucose-6-phosphate dehydrogenase (G6PDH) in HEPES buffer with sodium azide as preservative.

Additional Materials Required (sold separately):

Catalog No. 1664 DRI Negative Calibrator, 10 mL
1388 DRI Negative Calibrator, 25 mL
1588 DRI MultiDrug Calibrator 1, 10 mL
1589 DRI MultiDrug Calibrator 1, 25 mL
1591 DRI MultiDrug Calibrator 2, 10 mL
1592 DRI MultiDrug Calibrator 2, 25 mL
1594 DRI MultiDrug Calibrator 3, 10 mL
1595 DRI MultiDrug Calibrator 3, 25 mL
1597 DRI MultiDrug Calibrator 4, 10 mL
1598 DRI MultiDrug Calibrator 4, 25 mL
1599 DRI MultiDrug Urine Control 1, 10 mL
1553 DRI MultiDrug Urine Control 1, 25 mL
1600 DRI MultiDrug Urine Control 2, 10 mL
1555 DRI MultiDrug Urine Control 2, 25 mL

Precautions and Warnings

1. This test is for in vitro diagnostic use only The components are harmful if swallowed
2. Reagents used in the assay components contain sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azides When disposing of such reagents, always flush with a large volume of water to prevent azide build-up.
3. Do not use the reagents beyond their expiration dates.

Reagent Preparation and Storage

The reagents are ready for use. No reagent preparation is required. All assay components, when stored properly at 2-8°C, are stable until the expiration date indicated on the label.

Specimen Collection and Handling

Collect urine specimens in plastic or glass containers Testing of fresh urine specimens is suggested.

The Mandatory Guidelines for Federal Workplace Drug Testing Programs; Final Guidelines recommends that specimens that do not receive an initial test within 7 days of arrival in the laboratory should be placed into secure refrigeration units.

Samples within a pH range of 3 to 11 are suitable for testing with this assay.

An effort should be made to keep pipetted samples free of gross debris; it is recommended that highly turbid specimens be centrifuged before analysis. Adulteration of the urine sample may cause erroneous results. If adulteration is suspected, obtain another sample and forward both specimens to the laboratory for testing.

Handle all urine specimens as if they were potentially infectious.

Assay Procedure

Analyzers capable of maintaining a constant temperature, pipetting samples, mixing reagents, measuring enzymatic rates at 340 nm and timing the reaction accurately can be used to perform this assay.

Before performing the assay, refer to the analyzer-specific protocol sheet, which contains parameters and/or additional instructions for use.

Quality Control and Calibration

Good laboratory practice suggests the use of control specimens to ensure proper assay performance. Use controls near the cutoff calibrator to validate the calibration. Control results must fall within the established range. If results fall outside of the established range, assay results are invalid.

Qualitative analysis
For qualitative analysis of samples, use the 300 ng/mL calibrator as a cutoff level. The DRI® MultiDrug Urine Calibrator 2, which contains 300 ng/mL benzoylecgonine, is used as a cutoff reference for distinguishing "positive" and "negative" samples.

Semiquantitative analysis
For semiquantitative analysis, use all calibrators.

Results and Expected Values

Qualitative results
A sample that exhibits a change in absorbance (ΔA) value equal to or greater than the value obtained with the cutoff calibrator is considered positive. A sample that exhibits a change in absorbance (ΔA) value lower than the value obtained with the cutoff calibrator is considered negative.

Semiquantitative results
When a rough estimate of cocaine metabolites concentration is required, a calibration curve can be established with all calibrators. The concentration of the sample can be estimated by quantitation off the calibration curve. When the sample concentration is greater than the highest calibrator, it may be diluted and retested

Limitations

1 A positive result from this assay indicates only the presence of cocaine metabolites and does not necessarily correlate with the extent of physiological and psychological effects.
2 A positive result by this assay should be confirmed by an other nonimmunological method such as GC or GC/MS.

3. The test is designed for use with human urine only
4 It is possible that other substances and/or factors (eg, technical or procedural) not listed in the specificity table may interfere with the test and cause false results.

Specific Performance Characteristics

Precision

The Negative, 225 ng/mL, 300 ng/mL, 375 ng/mL were assayed with a Hitachi 717 analyzer. The following results were obtained:

	Within-run (n=20)		Run-to-run (n=20)	
Calibrator or Control	Mean ± SD (mA/min)	% CV	Mean ± SD (mA/min)	% CV
Negative	302 ± 2.0	0.7	302 ± 3.9	1.3
225 ng/mL	341 ± 2.5	0.7	342 ± 3.9	1.1
300 ng/mL	354 ± 3.4	0.9	354 ± 4.9	1.4
375 ng/mL	374 ± 2.4	0.6	374 ± 5.1	1.4

Accuracy

Two hundred and nine clinical specimens were tested with both DRI Cocaine Metabolite Assay and a commercially available cocaine metabolite assay. One hundred and four were tested positive and one hundred and five were tested negative by both assays. In addition, all positive specimens were confirmed by GC/MS to contain cocaine metabolites

Sensitivity

Sensitivity, defined as the lowest concentration that can be differentiated from the negative urine calibrator with 95% confidence, is 40 ng/mL.

Specificity

Benzoylecgonine, cocaine and other compounds that are concurrently present in the urine were tested for cross- reactivity in the assay. The following table summarizes the results obtained at the concentrations tested for each potential cross-reactant.

Compound	Concentration Tested (µg/mL)	Result
Benzoylecgonine	0.3	positive
Cocaine	50	positive
Ecgonine	100	positive
Acetaminophen	1000	negative
Acetylsalicylic acid	1000	negative
Amphetamine	1000	negative
Amobarbital	1000	negative
Benzocaine	1000	negative
Caffeine	100	negative
Chlorpromazine	500	negative
Codeine	1000	negative
Dextromethorphan	100	negative
Ecgonine Methyl Ester	100	negative
Lidocaine	1000	negative
Meperidine	1000	negative
Methadone	1000	negative
Morphine	200	negative
Oxazepam	100	negative
Phencyclidine	1000	negative
Phenobarbital	1000	negative
Promethazine	100	negative
Propoxyphene	1000	negative
Secobarbital	1000	negative

References

1. *Urine Testing for Drug of Abuse* National Institute on Drug Abuse (NIDA) Research Monograph 73, 1986.
2. Mandatory Guidelines for Federal Workplace Drug Testing Program. National Institute on Drug Abuse. *Federal Register* Vol. **53**, No 69, pp 11970 (1988)
3. Rubenstein KE, Schneider RS, and EF Ullman: Homogeneous enzyme immunoassay: a new immunochemical technique. *Biochem Biophys Res Commun* 47:846-851 (1972).

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0139-1 2003 05

DRI® Creatinine-Detect® Test

Microgenics

For In Vitro Diagnostic Use

talog No.: 1797 (500 mL Kit)
100109 Creatinine-Detect Calibrator Kit (2 x 25 mL)
100110 Creatinine-Detect Level 1 Control Kit (2 x 25 mL)
100111 Creatinine-Detect Level 2 Control Kit (2 x 25 mL)

Intended Use

The DRI® Creatinine-Detect® Test is intended for the quantitative determination of creatinine in human urine for the detection of urine adulteration by dilution or substitution with non-urine solution.

Summary and Explanation of the Test

A complete urine drug of abuse testing program normally involves specimen collection, initial screening with an immunoassay, followed by a confirmation test, such as gas chromatography/ mass spectrometry (GC/MS), for positive samples.[1] Many drug users attempt to evade detection by adulterating their specimen in order to produce false negative results during the initial immunoassay screening. Adulteration methods include dilution with water, substitution with a drug free liquid, addition of readily available household materials (e.g., vinegar, baking soda, liquid drain opener, detergent, etc.) or tampering with certain chemicals (e.g., Urine-Aid, which contains glutaraldehyde or Klear, which contains potassium nitrite).

Several methods have been used to detect urine adulteration. These methods include measuring the temperature, pH, specific gravity and creatinine concentration of the sample. Fresh normal urine should have the following typical characteristics: temperature between 32.5-37.7°C or 90.5-99.8°F,[1] pH within 4.7-7.8,[2,3] specific gravity within a range of 1.003-1.035 g/mL[2,4,5] and creatinine concentration of 80-200 mg/dL.[5-9] If any of these urine parameters is outside the specified range, there should be reason to believe that the urine sample has been adulterated.

Creatinine is secreted from muscle into urine daily. In the absence of renal disease, rate of creatinine clearance in an individual is relatively constant. Dilution of urine with water or any other non-urine solution can result in a lower creatinine concentration.

DRI Creatinine-Detect Test can be performed on automated clinical chemistry analyzers to measure creatinine concentration. This method is based on the Jaffe reaction,[10] whereby creatinine concentration is determined colorimetrically using alkaline picrate to form a reddish Janovski complex according to the following equation:

$$\text{Creatinine} + \text{Picric Acid} \xrightarrow{\text{NaOH}} \text{Janovski Complex (Red)}$$

The color intensity is directly proportional to the creatinine concentration and is measured spectrophotometrically at 505 nm.

Reagents

Creatinine-Detect Reagent 1: Contains 500 mL of sodium hydroxide in an aqueous solution
Creatinine-Detect Reagent 2: Contains 500 mL of picric acid in an aqueous solution.

Additional Materials Required (sold separately):
Creatinine-Detect Calibrator Kit: Contains 1 x 25 mL of 5.0 mg/dL creatinine and 1 x 25 mL of 20.0 mg/dL creatinine in an aqueous solution.
Creatinine-Detect Level 1 Control Kit: Contains 1 x 25 mL of Negative Control (3.0 mg/dL creatinine) and 1 x 25 mL of Positive Control (7.5 mg/dL creatinine) in an aqueous solution
Creatinine-Detect Level 2 Control Kit: Contains 1 x 25 mL of Negative Control (15.0 mg/dL creatinine) and 1 x 25 mL of Positive Control (25.0 mg/dL creatinine) in an aqueous solution

Reagent Preparation and Storage

The reagents are ready for use. No reagent preparation is required. All assay components, when stored properly, are stable until the expiration date indicated on the label. The Creatinine-Detect Reagents should be stored at room temperature while the calibrators and controls should be stored at 2-8°C.

Precautions and Warning

1. This test is for in vitro diagnostic use only. The reagents are harmful if swallowed.
2. Reagent 1 contains sodium hydroxide, which is caustic. Reagent 2 contains picric acid, which may cause local or generalized allergic reaction. Wear suitable protective clothing, gloves, and eye/face protection.
3. Do not use the reagents beyond their expiration dates.

Specimen Collection and Handling

Collect urine specimens in plastic or glass containers. Fresh urine specimens should be used. *"The Mandatory Guidelines for Federal Workplace Drug Testing Programs: Final Guidelines: Notice"* recommends that specimens that do not receive an initial test within 7 days of arrival at the laboratory should be placed into secure refrigeration units. Handle all urine specimens as if they were potentially infectious.[11]

Instruments

Analyzers capable of maintaining a constant temperature, pipetting samples, mixing reagents, measuring absorbance at 505 nm and timing the reaction accurately can be used to perform this assay.

Assay Procedure

Clinical chemistry analyzers with the specified characteristics are suitable for performing this assay. Refer to the specific application instructions and the specific parameters used for each analyzer before performing the assay.

Quality Control and Calibration

Use the 5.0 and 20.0 mg/dL Creatinine Calibrators to calibrate the test. Good laboratory practice suggests the use of control specimens to validate the calibration and to ensure proper assay performance. Creatinine Controls 3.0 and 7.5 mg/dL (Level 1), and 15.0 and 25.0 mg/dL (Level 2) are available from Microgenics for this purpose. The Level 1 and Level 2 controls are designed for use with the 5.0 mg/dL and 20.0 mg/dL cut-off levels respectively. Ensure that control results are within the established range. Recalibrate the system when new reagents are used or when the control values are outside the established range.

Results and Data Interpretation

A linear calibration curve is generated to calibrate the assay. The sample creatinine concentration is extrapolated from the calibration curve using the absorbance value of the sample. Most clinical chemistry analyzers have built-in curve-fit software that can calculate the creatinine concentration values automatically with no additional requirement of data manipulation. The 5.0 mg/dL calibrator is used to determine if the urine sample is substituted and the 20.0 mg/dL calibrator is used to determine if the sample is diluted.

Expected Values

Creatinine concentration in normal urine samples range from 80-200 mg/dL. Urine samples with < 20 mg/dL creatinine are considered to be adulterated. Adulteration of urine by substitution of urine sample with non-urine solution will give creatinine concentration < 5 mg/dL.

Limitations

This assay is optimized for the quantitative determination of creatinine in human urine for adulteration purposes only.

Typical Performance Characteristics

The following typical performance data were generated with a Hitachi 717 clinical chemistry analyzer:

Precision

The within-run and total precision was evaluated with three levels of creatinine controls with the following results:

Within-run				
mg/mL	3.0	7.5	15.0	25.0
n	120.0	120.0	120.0	120.0
$\bar{x}$	3.0	7.5	14.9	25.0
SD	0.1	0.2	0.3	0.5
%CV	2.4	2.1	1.7	2.0

Total run				
mg/mL	3.0	7.5	15.0	25.0
n	120.0	120.0	120.0	120.0
$\bar{x}$	3.0	7.5	14.9	25.0
SD	0.1	0.2	0.3	0.6
%CV	3.5	2.4	2.1	2.5

Interference by Endogenous Substances

Interference of endogenous substances in urine was studied. No interference was observed when urine samples were spiked with endogenous substances up to the concentration indicated.

Compound	Concentration	
Albumin	500	mg/dL
Ascorbic Acid	20	mg/mL
Galactose	10	mg/dL
Glucose	3000	mg/dL
Hemoglobin	300	mg/dL
Riboflavin	7.5	mg/dL
Urea	6000	mg/dL

Linearity

Serial dilutions of a 350 mg/dL creatinine urine sample were made to prepare 175, 87.5, 43.8, 21.9, 10.9 and 5.5 mg/dL creatinine solutions. These diluted solutions were assayed with the test. A correlation of 1.00 was obtained when the observed creatinine concentration of each solution was plotted against its corresponding expected creatinine concentration.

Sensitivity

Sensitivity, defined as the lowest creatinine concentration that can be differentiated from creatinine-free solution with 95% confidence, is 0.21 mg/dL.

Accuracy and Correlation

Recently proposed guidelines (*Federal Register Vol. 66, No. 160*) suggested using 5.0 and 20.0 mg/dL as cutoff calibrators to detect substitution and dilution of urine samples respectively. Therefore, one hundred and two urine samples were tested. Results using the old Calibrator Kit, 0 and 20 mg/dL, (x) were compared to results using the new Calibrator Kit, 5.0 and 20.0 mg/dL, (y). Correlation analysis yielded a linear regression equation of $y = 1.01(x) - 0.02$ and a correlation coefficient (r) of 0.999.

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Please contact your local Microgenics representative.

1795-4 2003 07

Material Safety Data Sheet

Product: DRI® Phencyclidine Enzyme Immunoassay

Catalog #: 0160, 0161, 100101

Description:

Antibody/Substrate Reagent	Liquid
Enzyme Conjugate Reagent	Liquid

Chemical Hazard/hazardous Ingredients: N/A

Fire, Explosion and Reactivity Data:

Flashpoint - Not determined.
Extinguishing media - Use extinguishing media appropriate for surrounding fire.
Unusual fire and explosion hazard - None
Reactivity - Stable. Hazardous polymerization will not occur.
Incompatibility - Avoid copper or lead plumbing. May form potentially explosive metal azides.

Health Hazards: HARMFUL IF SWALLOWED. The toxicological properties of this product has not been determined.

First Aid:

Ingestion - wash out mouth with water, provided the person is conscious. Call physician.
Inhalation - remove to fresh air. If breathing becomes difficult, give oxygen and call physician.
Skin contact - remove contaminated clothing and flush the contacted area with water and wash thoroughly with soap and water. If irritation persists call physician.
Eye contact - flush with copious amounts of water for 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Call physician.

Spill and Leak Procedure: Wear appropriate protective equipment. Sweep up or absorb material and place in a closed container. Ventilate and wash spill area. If material is disposed of using plumbing always flush with a large volume of water to prevent azide build-up. Disposal should be made in accordance with existing disposal practices employed for waste at your institution. Observe all federal, state and local laws.

Special Protection Information: Provide adequate general mechanical and local exhaust ventilation. Protect eyes and skin with safety glasses and gloves. Avoid contact with eyes and skin. Do not breathe solution vapor.

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Material Safety Data Sheet (cont.)

Special Storage Precautions:

Avoid high temperatures (200 °F).
Do not store with acids.

Doc: 10005189-1

Date: 2002 03

Material Safety Data Sheet

Product: DRI® Amphetamines Enzyme Immunoassay

Catalog #: 0017, 0018

Description:

Antibody/Substrate Reagent	Liquid
Enzyme Conjugate Reagent	Liquid

Chemical Hazard/hazardous Ingredients: N/A

Fire, Explosion and Reactivity Data:

Flashpoint - Not determined.
Extinguishing media - Use extinguishing media appropriate for surrounding fire.
Unusual fire and explosion hazard - None
Reactivity - Stable. Hazardous polymerization will not occur.
Incompatibility - Avoid copper or lead plumbing. May form potentially explosive metal azides.

Health Hazards: HARMFUL IF SWALLOWED. The toxicological properties of this product has not been determined.

First Aid:

Ingestion - wash out mouth with water, provided the person is conscious. Call physician.
Inhalation - remove to fresh air. If breathing becomes difficult, give oxygen and call physician.
Skin contact - remove contaminated clothing and flush the contacted area with water and wash thoroughly with soap and water. If irritation persists call physician.
Eye contact - flush with copious amounts of water for 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Call physician.

Spill and Leak Procedure: Wear appropriate protective equipment. Sweep up or absorb material and place in a closed container. Ventilate and wash spill area. If material is disposed of using plumbing always flush with a large volume of water to prevent azide build-up. Disposal should be made in accordance with existing disposal practices employed for waste at your institution. Observe all federal, state and local laws.

Special Protection Information: Provide adequate general mechanical and local exhaust ventilation. Protect eyes and skin with safety glasses and gloves. Avoid contact with eyes and skin. Do not breathe solution vapor.

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Material Safety Data Sheet (cont.)

Special Storage Precautions:

Avoid high temperatures (200 °F).
Do not store with acids.

Doc: 10005173-0

Date: 2000 09

Material Safety Data Sheet

Product: DRI® Ethyl Alcohol Assay

Catalog #: 0037, 0038

Description:

Antibody/Substrate Reagent	Liquid
Enzyme Conjugate Reagent	Liquid

Chemical Hazard/hazardous Ingredients: N/A

Fire, Explosion and Reactivity Data:

Flashpoint - Not determined.
Extinguishing media - Use extinguishing media appropriate for surrounding fire.
Unusual fire and explosion hazard - None
Reactivity - Stable. Hazardous polymerization will not occur.
Incompatibility - Avoid copper or lead plumbing. May form potentially explosive metal azides.

Health Hazards: HARMFUL IF SWALLOWED. The toxicological properties of this product has not been determined.

First Aid:

Ingestion - wash out mouth with water, provided the person is conscious. Call physician.
Inhalation - remove to fresh air. If breathing becomes difficult, give oxygen and call physician.
Skin contact - remove contaminated clothing and flush the contacted area with water and wash thoroughly with soap and water. If irritation persists call physician.
Eye contact - flush with copious amounts of water for 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Call physician.

Spill and Leak Procedure: Wear appropriate protective equipment. Sweep up or absorb material and place in a closed container. Ventilate and wash spill area. If material is disposed of using plumbing always flush with a large volume of water to prevent azide build-up. Disposal should be made in accordance with existing disposal practices employed for waste at your institution. Observe all federal, state and local laws.

Special Protection Information: Provide adequate general mechanical and local exhaust ventilation. Protect eyes and skin with safety glasses and gloves. Avoid contact with eyes and skin. Do not breathe solution vapor.

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Material Safety Data Sheet (cont.)

Special Storage Precautions:

Avoid high temperatures (200 °F).
Do not store with acids.

Material Safety Data Sheet

Product: DRI® Cocaine Metabolite Enzyme Immunoassay

Catalog #: 0055, 0056

Description:

Antibody/Substrate Reagent	Liquid
Enzyme Conjugate Reagent	Liquid

Chemical Hazard/hazardous Ingredients: N/A

Fire, Explosion and Reactivity Data:

Flashpoint - Not determined.
Extinguishing media - Use extinguishing media appropriate for surrounding fire.
Unusual fire and explosion hazard - None
Reactivity - Stable. Hazardous polymerization will not occur.
Incompatibility - Avoid copper or lead plumbing. May form potentially explosive metal azides.

Health Hazards: HARMFUL IF SWALLOWED. The toxicological properties of this product has not been determined.

First Aid:

Ingestion - wash out mouth with water, provided the person is conscious. Call physician.
Inhalation - remove to fresh air. If breathing becomes difficult, give oxygen and call physician.
Skin contact - remove contaminated clothing and flush the contacted area with water and wash thoroughly with soap and water. If irritation persists call physician.
Eye contact - flush with copious amounts of water for 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Call physician.

Spill and Leak Procedure: Wear appropriate protective equipment. Sweep up or absorb material and place in a closed container. Ventilate and wash spill area. If material is disposed of using plumbing always flush with a large volume of water to prevent azide build-up. Disposal should be made in accordance with existing disposal practices employed for waste at your institution. Observe all federal, state and local laws.

Special Protection Information: Provide adequate general mechanical and local exhaust ventilation. Protect eyes and skin with safety glasses and gloves. Avoid contact with eyes and skin. Do not breathe solution vapor.

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Material Safety Data Sheet (cont.)

Special Storage Precautions:

Avoid high temperatures (200 °F).

Do not store with acids.

SHELL TO REPRESENT MSDS FOR DRI ASSAYS

Material Safety Data Sheet

Product: DRI® Opiate Enzyme Immunoassay

Catalog #: 0135, 0136

Description:

Antibody/Substrate Reagent	Liquid
Enzyme Conjugate Reagent	Liquid

Chemical Hazard/hazardous Ingredients: N/A

Fire, Explosion and Reactivity Data:

Flashpoint - Not determined.
Extinguishing media - Use extinguishing media appropriate for surrounding fire.
Unusual fire and explosion hazard - None
Reactivity - Stable. Hazardous polymerization will not occur.
Incompatibility - Avoid copper or lead plumbing. May form potentially explosive metal azides.

Health Hazards: HARMFUL IF SWALLOWED. The toxicological properties of this product has not been determined.

First Aid:

Ingestion - wash out mouth with water, provided the person is conscious. Call physician.
Inhalation - remove to fresh air. If breathing becomes difficult, give oxygen and call physician.
Skin contact - remove contaminated clothing and flush the contacted area with water and wash thoroughly with soap and water. If irritation persists call physician.
Eye contact - flush with copious amounts of water for 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Call physician.

Spill and Leak Procedure: Wear appropriate protective equipment. Sweep up or absorb material and place in a closed container. Ventilate and wash spill area. If material is disposed of using plumbing always flush with a large volume of water to prevent azide build-up. Disposal should be made in accordance with existing disposal practices employed for waste at your institution. Observe all federal, state and local laws.

Special Protection Information: Provide adequate general mechanical and local exhaust ventilation. Protect eyes and skin with safety glasses and gloves. Avoid contact with eyes and skin. Do not breathe solution vapor.

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Material Safety Data Sheet (cont.)

Special Storage Precautions:

Avoid high temperatures (200 °F).
Do not store with acids.

Doc: 10005187-0

Date: 2000 09

Material Safety Data Sheet

Product: DRI® Methadone Enzyme Immunoassay

Catalog #: 0596, 0597

Description:

Antibody/Substrate Reagent	Liquid
Enzyme Conjugate Reagent	Liquid

Chemical Hazard/hazardous Ingredients: N/A

Fire, Explosion and Reactivity Data:

Flashpoint - Not determined.
Extinguishing media - Use extinguishing media appropriate for surrounding fire.
Unusual fire and explosion hazard - None
Reactivity - Stable. Hazardous polymerization will not occur.
Incompatibility - Avoid copper or lead plumbing. May form potentially explosive metal azides.

Health Hazards: HARMFUL IF SWALLOWED. The toxicological properties of this product has not been determined.

First Aid:

Ingestion - wash out mouth with water, provided the person is conscious. Call physician.
Inhalation - remove to fresh air. If breathing becomes difficult, give oxygen and call physician.
Skin contact - remove contaminated clothing and flush the contacted area with water and wash thoroughly with soap and water. If irritation persists call physician.
Eye contact - flush with copious amounts of water for 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Call physician.

Spill and Leak Procedure: Wear appropriate protective equipment. Sweep up or absorb material and place in a closed container. Ventilate and wash spill area. If material is disposed of using plumbing always flush with a large volume of water to prevent azide build-up. Disposal should be made in accordance with existing disposal practices employed for waste at your institution. Observe all federal, state and local laws.

Special Protection Information: Provide adequate general mechanical and local exhaust ventilation. Protect eyes and skin with safety glasses and gloves. Avoid contact with eyes and skin. Do not breathe solution vapor.

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Material Safety Data Sheet (cont.)

Special Storage Precautions:

Avoid high temperatures (200 °F).

Do not store with acids.

Doc: 10005184-0

Date: 2000 09

Material Safety Data Sheet

Product: DRI® Cannabinoid (THC) Enzyme Immunoassay

Catalog #: 0185, 0186

Description:

Antibody/Substrate Reagent	Liquid
Enzyme Conjugate Reagent	Liquid

Chemical Hazard/hazardous Ingredients: N/A

Fire, Explosion and Reactivity Data:

Flashpoint - Not determined.
Extinguishing media - Use extinguishing media appropriate for surrounding fire.
Unusual fire and explosion hazard - None
Reactivity - Stable. Hazardous polymerization will not occur.
Incompatibility - Avoid copper or lead plumbing. May form potentially explosive metal azides.

Health Hazards: HARMFUL IF SWALLOWED. The toxicological properties of this product has not been determined.

First Aid:

Ingestion - wash out mouth with water, provided the person is conscious. Call physician.
Inhalation - remove to fresh air. If breathing becomes difficult, give oxygen and call physician.
Skin contact - remove contaminated clothing and flush the contacted area with water and wash thoroughly with soap and water. If irritation persists call physician.
Eye contact - flush with copious amounts of water for 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Call physician.

Spill and Leak Procedure: Wear appropriate protective equipment. Sweep up or absorb material and place in a closed container. Ventilate and wash spill area. If material is disposed of using plumbing always flush with a large volume of water to prevent azide build-up. Disposal should be made in accordance with existing disposal practices employed for waste at your institution. Observe all federal, state and local laws.

Special Protection Information: Provide adequate general mechanical and local exhaust ventilation. Protect eyes and skin with safety glasses and gloves. Avoid contact with eyes and skin. Do not breathe solution vapor.

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Material Safety Data Sheet (cont.)

Special Storage Precautions:

Avoid high temperatures (200 °F).
Do not store with acids.

Doc: 10005176-0 Date: 2000 09

Material Safety Data Sheet

Product: DRI® Benzodiazepine Enzyme Immunoassay

Catalog #: 0039, 0040

Description:

Antibody/Substrate Reagent	Liquid
Enzyme Conjugate Reagent	Liquid

Chemical Hazard/hazardous Ingredients: N/A

Fire, Explosion and Reactivity Data:

Flashpoint: Not determined.
Extinguishing media: Use extinguishing media appropriate for surrounding fire.
Unusual fire and explosion hazard: None
Reactivity: Stable. Hazardous polymerization will not occur.
Incompatibility: Avoid copper or lead plumbing. May form potentially explosive metal azides.

Health Hazards: HARMFUL IF SWALLOWED. The toxicological properties of this product has not been determined.

First Aid:

Ingestion - wash out mouth with water, provided the person is conscious. Call physician.
Inhalation - remove to fresh air. If breathing becomes difficult, give oxygen and call physician.
Skin contact - remove contaminated clothing and flush the contacted area with water and wash thoroughly with soap and water. If irritation persists call physician.
Eye contact - flush with copious amounts of water for 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Call physician.

Spill and Leak Procedure: Wear appropriate protective equipment. Sweep up or absorb material and place in a closed container. Ventilate and wash spill area. If material is disposed of using plumbing always flush with a large volume of water to prevent azide build-up. Disposal should be made in accordance with existing disposal practices employed for waste at your institution. Observe all federal, state and local laws.

Special Protection Information: Provide adequate general mechanical and local exhaust ventilation. Protect eyes and skin with safety glasses and gloves. Avoid contact with eyes and skin. Do not breathe solution vapor.

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Material Safety Data Sheet (cont.)

Special Storage Precautions:

Avoid high temperatures (200 °F).
Do not store with acids.

Doc: 10005175-0 Date: 2000 09

Material Safety Data Sheet

Product: DRI® Barbiturate Enzyme Immunoassay

Catalog #: 0225, 0226

Description:

Antibody/Substrate Reagent	Liquid
Enzyme Conjugate Reagent	Liquid

Chemical Hazard/hazardous Ingredients: N/A

Fire, Explosion and Reactivity Data:

Flashpoint - Not determined.
Extinguishing media - Use extinguishing media appropriate for surrounding fire.
Unusual fire and explosion hazard - None
Reactivity - Stable. Hazardous polymerization will not occur.
Incompatibility - Avoid copper or lead plumbing. May form potentially explosive metal azides.

Health Hazards: HARMFUL IF SWALLOWED. The toxicological properties of this product has not been determined.

First Aid:

Ingestion - wash out mouth with water, provided the person is conscious. Call physician.
Inhalation - remove to fresh air. If breathing becomes difficult, give oxygen and call physician.
Skin contact - remove contaminated clothing and flush the contacted area with water and wash thoroughly with soap and water. If irritation persists call physician.
Eye contact - flush with copious amounts of water for 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Call physician.

Spill and Leak Procedure: Wear appropriate protective equipment. Sweep up or absorb material and place in a closed container. Ventilate and wash spill area. If material is disposed of using plumbing always flush with a large volume of water to prevent azide build-up. Disposal should be made in accordance with existing disposal practices employed for waste at your institution. Observe all federal, state and local laws.

Special Protection Information: Provide adequate general mechanical and local exhaust ventilation. Protect eyes and skin with safety glasses and gloves. Avoid contact with eyes and skin. Do not breathe solution vapor.

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Material Safety Data Sheet (cont.)

Special Storage Precautions:

Avoid high temperatures (200 °F).
Do not store with acids.

Doc: 10005174-0 Date: 2000 09