Quest Diagnostics Incorporated

Nichols Institute
14225 Newbrook Dr.
Chantilly, VA 20153-0841
703.802.6900
800.336.3718
www.questdiagnostics.com

Quest
Diagnostics

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

To WV Department of Health and Human Resources:

To begin, it is with great pleasure to present to the West Virginia Department of Health and Human Resources (WVDHHR), Quest Diagnostics response to the Lab Services RFP.

Contained within the contents of the binder are the following:

RFQ BHS80098
Exhibit A (Quest Diagnostics' Price Proposal)
Exhibit 1: Care360 Lab Orders & Results
Exhibit 2: Turnaround Time
Exhibit 3: Sample Invoice
Exhibit 4: Sample Utilization Report
Exhibit 5: CAP & CLIA Certification
Exhibit 6: Quality Policies
Exhibit 7: 2007 Quality Assurance Data
Exhibit 8: Referral Laboratories
Exhibit 9: Referral Laboratory Selection Process

Quest Diagnostics believes that with the range of services and competitive pricing offered we could provide a strong and reliable reference laboratory service for your hospitals.

It is with great anticipation to learn your thoughts and next steps relative to the selection of your laboratory services vendor. If there are any questions or points of clarification, please contact me at the following number: 724-433-7430.

Best Regards,

John Pickering M.T. (ASCP)
Account Executive
Quest Diagnostics

# Table of Contents

Quest Diagnostics' RFQ BHS80098 Response

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

# Request for Quotation

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| BHS80098 | 1 |

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

VENDOR
Quest Diagnostics Nichols Institute

14225 Newbrook Drive
Chantilly, VA 20151

SHIP TO
HEALTH AND HUMAN RESOURCES
BBH/HF
VARIOUS LOCALES AS INDICATED
BY ORDER

| DATE PRINTED | TERMS OF SALE | SHIP VIA | F.O.B. | FREIGHT TERMS |
|---|---|---|---|---|
| 02/25/2008 | | | | |

BID OPENING DATE: 03/27/2008 BID OPENING TIME 01:30PM

| LINE | QUANTITY | UOP | CAT NO. | ITEM NUMBER | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|---|
| | | | | OPEN-END BLANKET CONTRACT | | |
| 001 | 1 | JB | | 948-55 | | |

OPEN END CONTRACT FOR LABORATORY SERVICES

TO PROVIDE LABORATORY SERVICES TO THE WEST VIRGINIA DEPARTMENT OF HEALTH & HUMAN RESOURCES (WVDHHR), STATE OWNED FACILITIES PER THE ATTACHED LISTING AND DETAILED 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

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE [signature] TELEPHONE 800.336.3718 DATE 3/26/08

TITLE Managing Director FEIN 54-0854787 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 $125.00 registration fee.

5. All services performed or goods delivered under State Purchase Orders/Contracts are to be continued for the term of the Purchase Order/Contract, 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 Viginia 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 Covered Entity (45 CFR §160.103) and will be disclosing Protected Health Information (45 CFR §160.103) to the vendor.

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## 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 cases 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.

**SIGNED BID TO:**

Department of Administration
Purchasing Division
2019 Washington Street East
Post Office 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

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

VENDOR
Quest Diagnostics Nichols Institute

14225 Newbrook Drive
Chantilly, VA 20151

SHIP TO
HEALTH AND HUMAN RESOURCES
BBH/HF
VARIOUS LOCALES AS INDICATED
BY ORDER

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|---|---|---|---|---|
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BID OPENING DATE: 03/27/2008 BID OPENING TIME 01:30PM

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IN THIS CONTRACT DOCUMENT, THE TERMS, CONDITIONS AND PRICING SET HEREIN ARE FIRM FOR THE LIFE OF THE CONTRACT.

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 TRANSPORTATION 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

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE [signature] TELEPHONE 800.336.3719 DATE 3/26/08

TITLE Managing Director FEIN 54-0854787 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

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ADDRESS CORRESPONDENCE TO ATTENTION OF:
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304-558-0067

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Chantilly, VA 20151

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|---|---|---|---|---|---|---|

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 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
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

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE _____ TELEPHONE 800.336.3720 DATE 3/26/08

TITLE Managing Director FEIN 54-0854787 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
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Charleston, WV 25305-0130

# Request for Quotation

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

VENDOR
Quest Diagnostics Nichols Institute

14225 Newbrook Drive
Chantilly, VA 20151

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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 LIF 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 FOR THE LIFE OF THE CONTRACT.

ALTERNATE TERMS:

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

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

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE [signature] TELEPHONE 800.336.3721 DATE 3/26/08

TITLE Managing Director FEIN 54-0854787 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
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ADDRESS CORRESPONDENCE TO ATTENTION OF:
ROBERTA WAGNER
304-558-0067

VENDOR
Quest Diagnostics Nichols Institute

14225 Newbrook Drive
Chantilly, VA 20151

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BID OPENING DATE: 03/27/2008 BID OPENING TIME 01:30PM

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

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 EXTEN 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

INQUIRIES
WRITTEN QUESTIONS SHALL BE ACCEPTED THROUGH CLOSE OF BUSINESS ON 3/12/2008. 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 [signature] TELEPHONE 800.336.3722 DATE 3/26/08

TITLE Managing Director FEIN 54-0854787 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

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

VENDOR
Quest Diagnostics Nichols Institute

14225 Newbrook Drive
Chantilly, VA 20151

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|---|---|---|---|---|---|---|

PURCHASING CARD ACCEPTANCE: THE STATE OF WEST VIRGINIA 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.

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).

A. APPLICATION IS MADE FOR 2.5% 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 OWNERSHI 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

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE _____ TELEPHONE 800.336.3723 DATE 3/26/08

Managing Director FEIN 54-0854787 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
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# Request for Quotation

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

VENDOR
Quest Diagnostics Nichols Institute

14225 Newbrook Drive
Chantilly, VA 20151

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( ) BIDDER IS A CORPORATION 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.

B. APPLICATION IS MADE FOR 2.5% 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
( ) 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 BIDDERS' 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.

BIDDER UNDERSTANDS IF THE SECRETARY OF TAX & 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) RESCIND THE CONTRACT OR PURCHASE

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE [signature] TELEPHONE 800.336.3724 DATE 3/26/08

Managing Director FEIN 54-0854787 ADDRESS CHANGES TO BE NOTED ABOVE

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# Request for Quotation

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

VENDOR
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ORDER ISSUED; 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 TAX AND 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: Quest Diagnostics Nichols Institute

DATE: 3/26/08

SIGNED: [signature]

TITLE: Managing Director

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE [signature] TELEPHONE 800.336.3725 DATE 3/26/08

TITLE Managing Director FEIN 54-0854787 ADDRESS CHANGES TO BE NOTED ABOVE

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

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ADDRESS CORRESPONDENCE TO ATTENTION OF:
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BID OPENING DATE: 03/27/2008 BID OPENING TIME 01:30PM

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* CHECK ANY COMBINATION OF PREFERENCE CONSIDERATION(S) IN EITHER "A" OR "B", OR BOTH "A" AND "B" WHICH YOU ARE ENTITLED TO RECEIVE. YOU MAY REQUEST UP TO THE MAXIMUM 5% PREFERENCE FOR BOTH "A" AND "B".
(REV. 12/00)

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

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

RFQ. NO.:----------BHS80098----------

BID OPENING DATE:----------3/27/2008----------

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

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

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

| SIGNATURE | TELEPHONE | DATE |
|---|---|---|
| | 800.336.3726 | 3/26/08 |
| TITLE Managing Director | FEIN 54-0854787 | 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 |
|---|---|
| BHS80098 | 10 |

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

VENDOR
Quest Diagnostics Nichols Institute

14225 Newbrook Drive
Chantilly, VA 20151

SHIP TO
HEALTH AND HUMAN RESOURCES
BBH/HF
VARIOUS LOCALES AS INDICATED
BY ORDER

| DATE PRINTED | TERMS OF SALE | SHIP VIA | F.O.B. | FREIGHT TERMS |
|---|---|---|---|---|
| 02/25/2008 | | | | |

BID OPENING DATE: 03/27/2008 BID OPENING TIME 01:30PM

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

CONTACT PERSON (PLEASE PRINT CLEARLY):
John Pickering, Hospital Account Executive, 724-433-7430

****** THIS IS THE END OF RFQ BHS80098 ****** TOTAL: $316,172.00

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE [signature] TELEPHONE 800.336.3727 DATE 3/26/08

Managing Director FEIN 54-0854787 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 |
|---|---|
| BHS80098 | 1 |

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

VENDOR
Quest Diagnostics
John Pickering
875 Greentree Road
Four Parkway Center
Pittsburgh, PA 15220

SHIP TO
HEALTH AND HUMAN RESOURCES
BBH/HF
VARIOUS LOCALES AS INDICATED
BY ORDER

| DATE PRINTED | TERMS OF SALE | SHIP VIA | F.O.B. | FREIGHT TERMS |
|---|---|---|---|---|
| 03/18/2008 | | | | |

BID OPENING DATE: 03/27/2008 BID OPENING TIME 01:30PM

| LINE | QUANTITY | UOP | CAT NO | ITEM NUMBER | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|---|

ADDENDUM NO. 1

1. QUESTIONS AND ANSWERS ARE 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.: BHS80098

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 [signature] TELEPHONE 800.336.3727 DATE 3/26/08

TITLE Managing Director FEIN 54-0854787

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 $125.00 registration fee.
5. All services performed or goods delivered under State Purchase Orders/Contracts are to be continued for the term of the Purchase Order/Contract, 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 Viginia 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 Covered Entity (45 CFR §160.103) and will be disclosing Protected Health Information (45 CFR §160.103) to the vendor.

---

## 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 cases 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.

**SIGNED BID TO:**

Department of Administration
Purchasing Division
2019 Washington Street East
Post Office 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 |
|---|---|
| BHS80098 | 2 |

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

VENDOR
RFQ COPY
TYPE NAME/ADDRESS HERE
Quest Diagnostics Nichols Institute
14225 Newbrook Drive
Chantilly, VA 20151

SHIP TO
HEALTH AND HUMAN RESOURCES
BBH/HF
VARIOUS LOCALES AS INDICATED
BY ORDER

| DATE PRINTED | TERMS OF SALE | SHIP VIA | F.O.B. | FREIGHT TERMS |
|---|---|---|---|---|
| 03/18/2008 | | | | |

BID OPENING DATE: 03/27/2008 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.

Matt Lee
SIGNATURE
Quest Diagnostics, Inc.
COMPANY
3/26/08
DATE

REV. 11/96

END OF ADDENDUM NO. 1

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE Matt Lee TELEPHONE 800.336.3727 DATE 3/26/08

TITLE Managing Director FEIN 54-0854787

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 |
|---|---|
| BHS80098 | 3 |

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

VENDOR
RFQ COPY
TYPE NAME/ADDRESS HERE
Quest Diagnostics Nichols Institute
14225 Newbrook Drive
Chantilly, VA 20151

SHIP TO
HEALTH AND HUMAN RESOURCES
BBH/HF
VARIOUS LOCALES AS INDICATED
BY ORDER

| DATE PRINTED | TERMS OF SALE | SHIP VIA | F.O.B. | FREIGHT TERMS |
|---|---|---|---|---|
| 03/18/2008 | | | | |

BID OPENING DATE: 03/27/2008 BID OPENING TIME 01:30PM

| LINE | QUANTITY | UOP | CAT. NO | ITEM NUMBER | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|---|
| 0001 | 1 | JB | | 948-55 | | |
| | OPEN END CONTRACT FOR LABORATORY SERVICES | | | | | |
| | ****** THIS IS THE END OF RFQ BHS80098 ****** TOTAL: | | | | | $316,172.00 |

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE [signature] TELEPHONE 800.336.3727 DATE 3/26/08

TITLE Managing Director FEIN 54-0854787

ADDRESS CHANGES TO BE NOTED ABOVE

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

ADDENDUM #1 RQH BHS80098

Below are the responses to the vendor questions:

**QUESTION:** 1. Do you have a quote on what the cost is per interface for each hospital, regarding the Open VistA system and the interface to a reference lab?

**RESPONSE:** First, there will only be one interface on the Open VistA side as we have a central server, not one for each facility. There is no cost to the vendor for connectivity to the Open VistA server, Medsphere will configure the interface based on the file specs that the selected vendor will transmit. The vendor will only be responsible for the costs involved in transmitting the file with the lab results to Open VistA. We have no information on what the costs to the reference lab will be to create and transmit the lab results file.

**QUESTION:** 2. Do you have a volume for the number of stats ordered per hospital for 2007?

**RESPONSE:** 1. As Welch Community Hospital has an in-house lab, they do not send out stat lab orders unless a lab devise is inoperable. This occurred 10 times or less in 2007.

2. M.M. Bateman Hospital also has in-house lab, so their volume was 1 or 2 per month.

3. W.R. Sharpe Jr. Hospital had 277 stat orders in 2007.

4. Hopemont Hospital had approximately 75 stat orders in 2007.

5. John Manchin Sr. Health Care Center had less than 100 (inpatient and outpatient) stat orders in 2007.

6. Lakin Hospital had less than 20 stat orders. Currently, if the doctor orders a stat lab, the resident is transported to the hospital at Point Pleasant for the blood work.

7. Pinecrest Hospital had 1 - 3 stat orders per month.

**WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES** **BHS80098**
**BUREAU FOR BEHAVIORAL HEALTH AND HEALTH FACILITIES**
**OFFICE OF HEALTH FACILITIES – Laboratory Services**

# Open End Contract for Laboratory Services
**BHS80098**

1.1 Purpose:

To provide Laboratory services to the West Virginia Department of Health and Human Resources (WVDHRR), State owned facilities which include: William R. Sharpe, Jr. Hospital, Mildred Mitchell Bateman Hospital, Pinecrest Hospital, Lakin Hospital, Welch Community Hospital, Hopemont Hospital, and John Manchin Sr. Health Care Center, hereafter referred to as "hospitals".

**Location of Hospitals:**

Pinecrest Hospital
105 S. Eisenhower Drive
Beckley, WV 25801

Lakin Hospital
1 Bateman Circle
Lakin, WV 25287

Welch Community Hospital
454 McDowell Street
Welch, WV 24801

William R. Sharpe, Jr. Hospital
936 Sharpe Hospital Road
Weston, WV 26452

Hopemont Hospital
Rt. 3, Box 330
Terra Alta, WV 26764

John Manchin Sr. Health Care Center
401 Guffey Street
Fairmont, WV 26554

Mildred Mitchell-Bateman Hospital
1530 Norway Ave.
Huntington, WV 25709

Quest Diagnostics Nichols Institute Chantilly will provide clinical laboratory services to the West Virginia Department of Health and Human Resources state-owned facilities as outlined in Section 1.1.

Quest Diagnostics Nichols Institute Chantilly does not wish to extend the prices, terms, and conditions of this bid to all political subdivisions of the State of West Virginia but welcomes the opportunity to submit separate bids to provide clinical laboratory services for other West Virginia government bodies.

1.2 Mandatory Requirements

1. The vendor shall provide point-to-point interface between Open VistA software and a reference lab to transmit electronically laboratory orders from hospital laboratories (listed above) to the laboratory service. The results of the reference lab specimen analysis will be electronically transmitted back to the Open VistA for provider review.

With over 400 interfaces implemented nationally, Quest Diagnostics Nichols Institute Chantilly is fully prepared to provide a point-to-point interface between Open VistA and Quest Diagnostics Nichols Institute Chantilly's system. Upon completion of interface build, Quest Diagnostics Nichols Institute Chantilly will electronically transmit test results through Open VistA for provider review.

During interface build and as a supplement to the interface following completion, Quest Diagnostics Nichols Institute Chantilly invites the hospitals listed in Section 1.1 to use Quest Diagnostics Nichols Institute Chantilly's Care360: Lab Orders & Results application. Available as either a web- or PC-based tool, users can order tests and view patient results. Additional information is available in Exhibit 1.

Standard HL-7 (Help Language 7) version 2.3 formatting rules shall be followed for batch and on-line import/export message segments VistA provides functionality to print a manifest to accompany the specimen. This manifest provides a check and balance with the electronic order to ensure the order and the physical specimen are correctly matched to the patient.

Quest Diagnostics Nichols Institute Chantilly's standard interface is based on HL-7 version 2.3 protocol. Printable manifests will be available for all orders.

2. The Vendor shall provide routine daily service with one (1) pick-up by 3:00 p.m. Lab results will be electronically transmitted to the hospital(s) no later than 9:00 a.m. the following day. Preliminary culture results will be returned to the hospital within 24 hours after pick-up, with final results being given in 48 hours. The vendor shall provide six-day service to the hospital(s) (Monday through Saturday). The vendor shall call the hospital(s) on Saturday and converse with the Nurse Clinical Coordinator to determine if Saturday pick-up is needed.

   Quest Diagnostics Nichols Institute Chantilly will provide routine daily courier service six days per week (Monday through Saturday) with a late afternoon or early evening pick up to each hospital listed in Section 1.1. Time of pickup of specimens will not affect turnaround time as specimens will arrive overnight in Chantilly, Virginia for testing regardless of pickup time.

   Through Quest Diagnostics Nichols Institute Chantilly's Open VistA interface, results will be transmitted electronically immediately after test completion to West Virginia State hospitals.

   Turnaround time has been provided in Exhibit 2. Please note, Quest Diagnostics Nichols Institute Chantilly's published turnaround time is measured from time of accessioning in the laboratory to time of final release.

STAT testing shall be provided 24 hours a day, six days per week (Monday through Saturday). Pick-up of STAT test specimens must be made within one (1) hour after notification and all STAT results shall be made available within two (2) hours after pick-up.

Through the use of our courier network, regional laboratories, and local hospital partners, STAT pickups and testing can be performed to meet a variety of requirements. Quest Diagnostics will provide STAT testing 24 hours a day, 6 days per week (Monday through Saturday) and will provide STAT pickups within one hour after notification with results available within two hours after pickup.

The Vendor shall provide all supplies and materials required for testing, such as tubes, needles, urine containers, etc.

At no charge, the supplies necessary for the proper collection, processing, handling and transport of specimen to be tested by Quest Diagnostics Nichols Institute Chantilly will be provided. Such supplies include tubes, needles, and urine containers.

The Vendor shall provide an itemized invoice monthly in arrears and statistical reports showing usage and volumes. (See Section 1.7).

Quest Diagnostics Nichols Institute Chantilly will provide an itemized invoice in arrears each month to the Department. Charges accumulate daily as testing is completed and each invoice will detail the previous month's services. Available electronically or in hard copy, each invoice will include a patient identifier, date of service, description of service, per unit cost and total cost. A sample invoice is available in Exhibit 3.

Quest Diagnostics Nichols Institute Chantilly will also provide a monthly utilization report to the Department. Available electronically or in hard copy, each utilization report will include test code, test description, monthly and yearly quantity, and monthly and yearly cost. A sample utilization report is available in Exhibit 4.

The Vendor must be certified by Clinical Laboratory Improvement Amendments (CLIA) and must meet all CAP (Certificate of Accreditation) Standards. The Vendor shall provide a copy of Clinical Laboratory Improvement Amendments (CLIA) certificate and AP certificate (Certificate of Accreditation) from the Centers for Medicare & Medicaid Services prior to award of contract.

Quest Diagnostics Nichols Institute Chantilly is a fully accredited and licensed facility in line with all applicable federal and state statutes. A copy of Quest Diagnostics Nichols Institute Chantilly's CAP certificate and CLIA certificate are available in Exhibit 5.

## Open End Contract for Laboratory Services
**BHS80098**

The Vendor shall operate in accordance with the standards and recommendations of Joint Commission (JC) or other equivalent standards.

Quest Diagnostics Nichols Institute Chantilly operates in accordance with the standards and recommendations of the College of American Pathologists (CAP), which meets the Joint Commission standards. A copy of Quest Diagnostics Nichols Institute Chantilly's CAP certificate is available in Exhibit 5.

The Vendor shall provide the hospital(s) with documentation of quality control measures being performed in the Laboratory upon request. Quality control data, quality assurance policies and results of proficiency testing surveys must be made available upon request.

Developed to establish and uphold the highest quality standards bearing upon the practice of laboratory medicine, Quest Diagnostics' corporate Quality Policies document addressees the principles, goals, and activities fundamental to Quest Diagnostics and serves as a reference guide for employees involved in all phases of reference testing. A copy of this document is available in Exhibit 6 and a summary of Quest Diagnostics Nichols Institute Chantilly's 2007 Quality Assurance data is available in Exhibit 7.

Quality control data and results of proficiency testing surveys are available for the State of West Virginia's review during normal business hours at Quest Diagnostics Nichols Institute Chantilly.

The Vendor shall provide the hospital(s) the above services and all testing services required by the hospital(s) for the life of the contract. Price per test quoted by the Vendor shall not change during the life of the contract.

Quest Diagnostics Nichols Institute Chantilly will hold prices firm for a period of three years at which point pricing will be reviewed with the State of West Virginia.

A list of the type and estimated quantity of tests required by the hospital(s) is attached as Exhibit A. The list only represents the most required and/or requested tests needed for evaluation purposes only. Additional types of tests shall be provided by the successful vendor, as ordered by the physician.

Quest Diagnostics Nichols Institute Chantilly has completed pricing for the tests listed in Exhibit A and understands that the list represents only the State of West Virginia's most required and/or requested tests. Quest Diagnostics Nichols Institute Chantilly has a full test menu with adequate capacity to perform additional types of tests as needed. A complete Directory of Services is available online at www.nicholsinstitue.com.

1.3 Subcontracts prohibited

The Vendor will be solely responsible for all work performed under the contract. The Vendor will not enter into written subcontracts for performance of work under the contract without written permission of the agency.

Approximately 99% of the testing sent to Quest Diagnostics Nichols Institute Chantilly is performed in-house and the majority of referred testing is sent to another laboratory within the Quest Diagnostics network with no impact to test cost. To ensure quality and service of subcontracted laboratories in the rare cases where tests must be referred out of the Quest Diagnostics network, Quest Diagnostics Nichols Institute Chantilly has developed high-level selection criteria based on quality of laboratory service, efficiency of service, and cost effectiveness.

The list of referral laboratories that will be performing services under this contract is available in Exhibit 8 and details about Quest Diagnostics Nichols Institute Chantilly's referral laboratory selection process are available in Exhibit 9.

1.4 Compliance with Law and Regulation

The Vendor shall pay sales, use and personal property taxes arising out of this contract and the transactions contemplated thereby. Any other taxes levied upon this contract, the transaction or the equipment or services delivered pursuant thereto shall be borne by the vendor.

Quest Diagnostics Nichols Institute Chantilly is of the opinion that Section 1.4 is not applicable to Quest Diagnostics Nichols Institute Chantilly.

The Vendor shall comply with all applicable laws, rules and regulations including, but not limited to those relating to hospital licensure, state and federal labor laws, and laws, rules and policies related to the WV Department of Health and Human Resources.

Quest Diagnostics Nichols Institute Chantilly is a fully accredited and licensed facility in line with all applicable federal and state statutes and would like to review the laws, rules and policies related to the West Virginia Department of Health and Human Resources.

The Vendor shall be responsible for compliance with all workplace safety requirements, including, but not limited to compliance with applicable Occupational Safety and Health Administration (OSHA) and all other applicable environmental agency requirements for storage, labeling, handling and disposal of all items used in the performance of duties

associated with laboratory (phlebotomy) services. The Vendor shall appropriately train its employees in proper workplace safety requirements.

Quest Diagnostics Nichols Institute Chantilly will be responsible for compliance with all applicable workplace safety requirements.

1.5 Termination of the Contract

The Department of Health and Human Resources (Department) may terminate a contract resulting from the RFQ at any time that the vendor fails to carry out its responsibilities under the terms of any contract to the satisfaction of the Department only with the approval of the Purchasing Division.

The Department shall provide the Vendor with notice of conditions endangering contract performance. If after such notice the vendor fails to remedy the conditions contained in the notice, within the time period contained in the notice, the Department shall issue the vendor an order to stop all work immediately (only with approval of the Purchasing Divison). The Department shall be obligated only for services rendered and accepted prior to the date of the notice of termination.

The contract may also be terminated upon mutual agreement of the parties with thirty (30) days notice prior notice.

Quest Diagnostics Nichols Institute Chantilly has read and is in agreement with Section 1.5.

1.6 Record Retention and Confidentiality

The Vendor will maintain financial records pertaining to the contract for five (5) years following the end of the State Fiscal year during which the contract is terminated or State and Federal audits of the contract have been completed, whichever is later. If questions about accounting records arise during an audit, the account records pertaining to the contract shall be retained until resolution of all pending audit questions and for one (1) year following the termination of any litigation relating to the contract if the litigation has not terminated within the above five (5) year period. Accounting records and procedures shall be subject to State and Federal approval.

Quest Diagnostics Nichols Institute Chantilly requires all employees to maintain all records in accordance with the company's record management program and invites the State of West Virginia to review this program on-site in Chantilly, Virginia.

1.7 Invoices and Payments

The Vendor shall provide an itemized invoice to the Department monthly in arrears for actual usage. State law forbids payment of invoices prior to receipt of services. Invoice shall include patient identifier, date of service, description of service, per unit cost and total cost.

Quest Diagnostics Nichols Institute Chantilly will provide an itemized invoice in arrears each month to the Department. Charges accumulate daily as testing is completed and each invoice will detail the previous month's services. Available electronically or in hard copy, each invoice will include a patient identifier, date of service, description of service, per unit cost and total cost. A sample invoice is available in Exhibit 3.

STATE OF WEST VIRGINIA
Purchasing Division

# PURCHASING AFFIDAVIT

**West Virginia Code §5A-3-10a states:** No contract or renewal of any contract may be awarded by the state or any of its political subdivisions to any vendor or prospective vendor when the vendor or prospective vendor or a related party to the vendor or prospective vendor is a debtor and the debt owed is an amount greater than one thousand dollars in the aggregate

**DEFINITIONS:**
"Debt" means any assessment, premium, penalty, fine, tax or other amount of money owed to the state or any of its political subdivisions because of a judgment, fine, permit violation, license assessment, defaulted workers' compensation premium, penalty or other assessment presently delinquent or due and required to be paid to the state or any of its political subdivisions, including any interest or additional penalties accrued thereon.

"Debtor" means any individual, corporation, partnership, association, limited liability company or any other form or business association owing a debt to the state or any of its political subdivisions. "Political subdivision" means any county commission; municipality; county board of education; any instrumentality established by a county or municipality; any separate corporation or instrumentality established by one or more counties or municipalities, as permitted by law; or any public body charged by law with the performance of a government function or whose jurisdiction is coextensive with one or more counties or municipalities. "Related party" means a party, whether an individual, corporation, partnership, association, limited liability company or any other form or business association or other entity whatsoever, related to any vendor by blood, marriage, ownership or contract through which the party has a relationship of ownership or other interest with the vendor so that the party will actually or by effect receive or control a portion of the benefit, profit or other consideration from performance of a vendor contract with the party receiving an amount that meets or exceed five percent of the total contract amount.

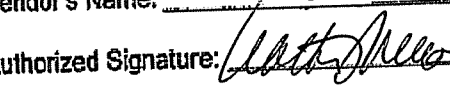
**EXCEPTION:** The prohibition of this section does not apply where a vendor has contested any tax administered pursuant to chapter eleven of this code, workers' compensation premium, permit fee or environmental fee or assessment and the matter has not become final or where the vendor has entered into a payment plan or agreement and the vendor is not in default of any of the provisions of such plan or agreement.

**LICENSING:** Vendors must be licensed and in good standing in accordance with any and all state and local laws and requirements by any state or local agency of West Virginia, including, but not limited to, the West Virginia Secretary of State's Office, the West Virginia Tax Department, West Virginia Insurance Commission, or any other state agencies or political subdivision. Furthermore, the vendor must provide all necessary releases to obtain information to enable the Director or spending unit to verify that the vendor is licensed and in good standing with the above entities.

**CONFIDENTIALITY:** The vendor agrees that he or she will not disclose to anyone, directly or indirectly, any such personally identifiable information or other confidential information gained from the agency, unless the individual who is the subject of the information consents to the disclosure in writing or the disclosure is made pursuant to the agency's policies, procedures and rules. Vendors should visit **www.state.wv.us/admin/purchase/privacy** for the Notice of Agency Confidentiality Policies.

Under penalty of law for false swearing (West Virginia Code, §61-5-3), it is hereby certified that the vendor acknowledges the information in this said affidavit and are in compliance with the requirements as stated.

Vendor's Name: Quest Diagnostics Nichols Institute

Authorized Signature:  Date: 3/26/08

Confidential

**West Virginia Department of Health and Human Resources**
**Bureau for Behavioral Health and Health Facilities**
**Office of Health Facilities---Laboratory Services**
**Exhibit A**

| Item Number | Test Name | Est. 12 month usage | Vendor Test Code | Bid Cost Per Test | Total Cost |
|---|---|---|---|---|---|
| 1 | Acetaminophen | 2 | 333 | $ 18.53 | $ 37.05 |
| 2 | AFB cu | 47 | 104 | $ 18.23 | $ 856.58 |
| 3 | Amitriptyline (Elavil) serum | 6 | 890 | $ 26.93 | $ 161.55 |
| 4 | Ammonia, Plasma | 94 | 55098 | $ 15.00 | $ 1,410.00 |
| 5 | Amylase, Serum | 33 | 27 | $ 3.25 | $ 107.25 |
| 6 | Antinuclear antibodies (ANA) | 144 | 18137 | $ 12.00 | $ 1,728.00 |
| 7 | Beta-Hemolytic Strep A | 3 | 6470 | $ 4.88 | $ 14.63 |
| 8 | Bilirubin Total | 36 | 47 | $ 3.25 | $ 117.00 |
| 9 | Bilirubin, Total/Direct, serum | 12 | 46 | $ 6.00 | $ 72.00 |
| 10 | BUN | 448 | 329 | $ 3.25 | $ 1,456.00 |
| 11 | C. diff. Toxin A | 85 | 500 | $ 14.00 | $ 1,190.00 |
| 12 | C-Reactive Protein | 19 | 65 | $ 7.35 | $ 139.65 |
| 13 | Calcium, serum | 98 | 425 | $ 3.25 | $ 318.50 |
| 14 | Carbamazepine (Tegretol) | 128 | 393 | $ 12.00 | $ 1,536.00 |
| 15 | CBC w/diff-platelet | 3339 | 74 | $ 3.75 | $ 12,521.25 |
| 16 | Chlorpromazine, (Thorazine) | 9 | 581 | $ 84.00 | $ 756.00 |
| 17 | Clomipramine (Anafranil) s. | 7 | 2040 | $ 27.68 | $ 193.73 |
| 18 | Clozapine (clozaril) serum | 38 | 15687 | $ 22.00 | $ 836.00 |
| 19 | Cortisol serum/plasma | 11 | 112818 | $ 16.00 | $ 176.00 |
| 20 | Creatinine Kinase (CK) MB/Total | 38 | 642 | $ 20.63 | $ 783.75 |
| 21 | Creatinie Kinase, serum | 68 | 99 | $ 3.25 | $ 221.00 |
| 22 | Creatinine, Serum | 451 | 97 | $ 3.25 | $ 1,465.75 |
| 23 | Desipramine, serum | 4 | 893 | $ 18.00 | $ 72.00 |
| 24 | Digoxin (Lanoxin) | 46 | 659 | $ 18.00 | $ 828.00 |
| 25 | Estrogen | 3 | 2803 | $ 38.55 | $ 115.65 |
| 26 | Ethanol serum/blood | 5 | 44389 | $ 11.25 | $ 56.25 |
| 27 | Ethosuximide (Zarontin) serum | 6 | 385 | $ 18.83 | $ 112.95 |
| 28 | Ferritin | 50 | 859 | $ 17.25 | $ 862.50 |
| 29 | Fluoxetine (Prozac) serum | 4 | 2540 | $ 26.93 | $ 107.70 |
| 30 | Folates (Folic Acid) | 37 | 265 | $ 6.00 | $ 222.00 |
| 31 | Gabapentin (Neurotin) serum | 11 | 5220 | $ 19.88 | $ 218.63 |
| 32 | Gabritril serum | 2 | 5220 | $ 19.88 | $ 39.75 |
| 33 | Glucose, 2hr P.P. | 16 | 148 | $ 3.25 | $ 52.00 |
| 34 | Glucose serum | 115 | 148 | $ 3.25 | $ 373.75 |
| 35 | Glucose plasma | 51 | 148 | $ 3.25 | $ 165.75 |
| 36 | Gynecologic Mono-Layer PAP | 9 | 5310 | $ 32.00 | $ 288.00 |
| 37 | Haloperidol serum | 8 | 670 | $ 29.10 | $ 232.80 |
| 38 | Hemoglobin A1C | 763 | 25 | $ 4.50 | $ 3,433.50 |
| 39 | HCG Beta subunity, Qual (s) | 151 | 235 | $ 6.23 | $ 939.98 |
| 40 | Heliobacter Pylori, Igg | 9 | 3341 | $ 9.00 | $ 81.00 |
| 41 | helper T-Lymph-CD4 | 12 | 2068 | $ 28.00 | $ 336.00 |
| 42 | Hepatitis A AB Igm | 17 | 1003 | $ 10.00 | $ 170.00 |
| 43 | Hepatitis A AB, Total | 59 | 1002 | $ 10.00 | $ 590.00 |
| 44 | Hepatitis B Surface AB | 270 | 718 | $ 8.00 | $ 2,160.00 |
| 45 | Hepatitis B Surface Ag | 126 | 453 | $ 8.00 | $ 1,008.00 |
| 46 | Hepatitis Panel-A,B,C | 87 | 4628 | $ 44.00 | $ 3,828.00 |
| 47 | Imipramine (tofranil) serum | 12 | 892 | $ 26.93 | $ 323.10 |
| 48 | Iron | 42 | 805 | $ 12.00 | $ 504.00 |
| 49 | Iron/TIBC | 54 | 175 | $ 9.00 | $ 486.00 |
| 50 | Lamotrigine (Lomictal) serum | 15 | 5896 | $ 28.00 | $ 420.00 |
| 51 | Lead (Adult) blood | 105 | 186 | $ 10.00 | $ 1,050.00 |
| 52 | LH & LSH | 48 | 1350 | $ 28.00 | $ 1,344.00 |
| 53 | Lipase serum | 93 | 187 | $ 3.25 | $ 302.25 |
| 54 | Lithium | 418 | 466 | $ 8.63 | $ 3,605.25 |
| 55 | LP Lipo El | 13 | 1961 | $ 18.60 | $ 241.80 |
| 56 | magnesium, serum | 171 | 195 | $ 3.25 | $ 555.75 |
| 57 | Microalbumin, 24 hour urine | 12 | 2687 | $ 14.00 | $ 168.00 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 58 | Microalbumin, Random urine | 466 | 2687 | $ 14.00 | $ | 6,524.00 |
| 59 | Nortriptyline (Aventyl) Serum | 4 | 891 | $ 26.93 | $ | 107.70 |
| 60 | Occult Blood (Stool) | 24 | 2364 | $ 6.83 | $ | 163.80 |
| 61 | Osmolality serum | 10 | 432 | $ 7.35 | $ | 73.50 |
| 62 | Osmolatity, urine | 74 | 2243 | $ 7.35 | $ | 543.90 |
| 63 | Ova and Parasite | 60 | 212 | $ 13.13 | $ | 787.50 |
| 64 | Perphenazine (Trilafon) | 5 | 1989 | $ 80.00 | $ | 400.00 |
| 65 | Phenobarbital serum | 111 | 214 | $ 9.00 | $ | 999.00 |
| 66 | Phenytoin (Dialantin) | 383 | 56 | $ 9.50 | $ | 3,638.50 |
| 67 | Phosphorus | 115 | 222 | $ 3.25 | $ | 373.75 |
| 68 | Potassium, serum | 109 | 231 | $ 3.25 | $ | 354.25 |
| 69 | Pregnancy Serum | 12 | 730 | $ 15.00 | $ | 180.00 |
| 70 | Pregnancy Test (Urine) | 55 | 235 | $ 6.23 | $ | 342.38 |
| 71 | Preimidone (Mysoline) | 32 | 4075 | $ 11.78 | $ | 376.80 |
| 72 | Prolactin | 99 | 245 | $ 12.00 | $ | 1,188.00 |
| 73 | Prostate-specific AG, Serum | 171 | 1054 | $ 9.00 | $ | 1,539.00 |
| 74 | Protein serum | 68 | 237 | $ 3.25 | $ | 221.00 |
| 75 | Prothrombin time | 725 | 241 | $ 3.50 | $ | 2,537.50 |
| 76 | PT & PTT | 318 | 213+241 | $ 7.00 | $ | 2,226.00 |
| 77 | Reticulocyte count | 24 | 251 | $ 5.48 | $ | 131.40 |
| 78 | RNA-PCR-Quant | 16 | 8316 | $ 125.00 | $ | 2,000.00 |
| 79 | STS | 602 | 2377 | $ 3.50 | $ | 2,107.00 |
| 80 | Sedimentation rate | 237 | 259 | $ 5.00 | $ | 1,185.00 |
| 81 | Sodium serum | 359 | 271 | $ 3.25 | $ | 1,166.75 |
| 82 | T3-uptake | 48 | 248 | $ 6.23 | $ | 298.80 |
| 83 | T4 | 66 | 634 | $ 7.28 | $ | 480.15 |
| 84 | T-Cell (T-Lymphocyte CD3 Cells) | 8 | 18094 | $ 42.15 | $ | 337.20 |
| 85 | Testosterone Serum | 23 | 15983 | $ 30.00 | $ | 690.00 |
| 86 | Theophylline Serum | 29 | 631 | $ 9.00 | $ | 261.00 |
| 87 | Topiramate (Topamax) serum | 8 | 8761 | $ 25.88 | $ | 207.00 |
| 88 | T-Pallidum Ab (FTA-Ab) | 5 | 62 | $ 13.50 | $ | 67.50 |
| 89 | T-Pallidum Antibodies (TP-PA) | 12 | 297 | $ 9.00 | $ | 108.00 |
| 90 | Triglycerides | 32 | 321 | $ 3.25 | $ | 104.00 |
| 91 | TSH | 186 | 6229 | $ 12.00 | $ | 2,232.00 |
| 92 | TSH 3rd Generation | 651 | 6229 | $ 12.00 | $ | 7,812.00 |
| 93 | UA Culture reflex | 1253 | 2542 | $ 2.78 | $ | 3,477.08 |
| 94 | Culture reflex @ additional cost | 594 | 665 | $ 8.18 | $ | 4,858.92 |
| 95 | Uric Acid | 25 | 331 | $ 3.25 | $ | 81.25 |
| 96 | Urinalysis, Complete | 1060 | 564 | $ 6.38 | $ | 6,757.50 |
| 97 | Valporic acid serum | 1419 | 712 | $ 9.00 | $ | 12,771.00 |
| 98 | Varicella Zoster IGG | 22 | 2306 | $ 12.00 | $ | 264.00 |
| 99 | Vitamin B-12 | 146 | 264 | $ 6.00 | $ | 876.00 |
| 100 | Vitamin B-12 and Folates | 294 | 278 | $ 12.00 | $ | 3,528.00 |
| | | | | | | |
| | ***Most Frequently Ordered Panels-Profiles, Screens and Cultures:*** | | | | | |
| | | | | | | |
| 101 | **Diagnostic Multi-Chem (28 tests)** | **1502** | 737 | $ 6.60 | $ | 9,913.20 |
| | Albumin | Phosphorus | | | | |
| | Alkaline Phos | Potasium | | | | |
| | ALT-SGPT | Sodium | | | | |
| | AST-SGOT | Bilirubin, Total | | | | |
| | BUN | Protein, Total | | | | |
| | BUN/Cratinine | Triglycerides | | | | |
| | Calcium | Uric Acid | | | | |
| | Chloride | HDL Cholesterol | | | | |
| | Cholesterol, Total | VLDL Cholesterol Cal | | | | |
| | Creatine | LDL Cholesterol Cal | | | | |
| | GGT | T. Chol/HDL Ratio | | | | |
| | Glucose | Estimated CHD Risk | | | | |
| | Iron, Total | Globulin, Total | | | | |
| | | | | | | |
| 102 | **Thyroid Profiles Includes: (4 Tests)** | **1208** | 792 | $ 25.50 | $ | 30,804.00 |
| | TSH (High Sensitivity) | T3 Uptake | | | | |
| | T4 Thyroxine | Free Thyroxine Index | | | | |

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|---|---|---|---|---|---|
| | | | | | |
| 103 | **Electrolyte Panel Includes: (3 Tests)** | **316** | 610 | $ 4.10 | $ 1,295.60 |
| | Sodium | | | | |
| | Potassium | | | | |
| | Chloride | | | | |
| | | | | | |
| | **Drug Abuse Screen (7) Urine, w/o confirmaton** | **704** | 13210 | $ 15.00 | $ 10,560.00 |
| | Amphetamine | Cocaine | | | |
| | Barbituates | Opiates | | | |
| | Benzodiazapines | Phencyclidine | | | |
| | Cannabinoid | | | | |
| | | | | | |
| 104 | **HFP7 & 3 AC** | **455** | 11209+80+221+587 | $ 6.20 | $ 2,821.00 |
| | Protein, Total | Alkaline Phosphates | | | |
| | albumin, (s) | LGD | | | |
| | Bilirubin, Total | AST (SGOT) | | | |
| | Bilirubin, Direct | ALT (SGPT) | | | |
| | Cholesterol, Total | GGT | | | |
| | | | | | |
| 105 | **Lipid Profile Four Includes: (3 Tests)** | **5327** | 37 | $ 4.10 | $ 21,840.70 |
| | Cholesterol, Total | | | | |
| | Triglycerides | | | | |
| | HDL Cholesterol | | | | |
| | | | | | |
| 106 | **Drug Abuse Screen, Total-w/o Confirmation** | **27** | 2991 | $ 15.00 | $ 405.00 |
| | Amphetamine | Cocaine | | | |
| | Barbituates | Opiates | | | |
| | Benzodiazapines | Phencycline | | | |
| | Cannabinoid | | | | |
| | | | | | |
| 107 | **Cultures:** | | | | |
| | Lower Respiratory Culture | 107 | 5594 | $ 8.18 | $ 874.73 |
| | Upper Respiratory Culture | 96 | 5594 | $ 8.18 | $ 784.80 |
| | General Bacterial Culture | 137 | 663 | $ 10.00 | $ 1,370.00 |
| | Blood Culture | 842 | 103 | $ 17.78 | $ 14,966.55 |
| | Stool Culture | 55 | 664 | $ 8.18 | $ 449.90 |
| | Urine Culture | 1306 | 665 | $ 8.18 | $ 10,683.08 |
| | Sputum Culture | 98 | 14205 | $ 8.18 | $ 801.15 |
| | Sensitvity Organism | 529 | 261 | $ 5.18 | $ 2,737.58 |
| | | | | | |
| 108 | **Heavy Metal Profile (Blood)** | **21** | 599 | $ 39.00 | $ 819.00 |
| | Arsenic | | | | |
| | Lead | | | | |
| | Mercury | | | | |
| | | | | | |
| 109 | **Hepatitis Profile (Diagnostic follow up)** | **46** | 718+813 | $ 16.00 | $ 736.00 |
| | HBc Ag; Anti-HBc | | | | |
| | Anti-HBS; Interpretation | | | | |
| | | | | | |
| 110 | **Hepatitis Profile B & C** | **421** | 3165 | $ 56.00 | $ 23,576.00 |
| | HBs Ag; HBc Ag; Anti-HBC, total | | | | |
| | Anti-HBc; Igm; anti-HBc;anti-HBs;anti-HCV; interpretation | | | | |
| | | | | | |
| 111 | **Hepatitis Profile A & B** | **107** | 925 | $ 52.00 | $ 5,564.00 |
| | Anti-HAV; total; anti HAV, Igm; HBs Ag, HBc Ag; Anti-HBC, total; anti_HBC, Igm; Anti-HBc; anti-HBS; Interpretation | | | | |
| | | | | | |
| 112 | **Hepatitis A Profile** | **57** | 1004 | $ 20.00 | $ 1,140.00 |
| | Anti-HAV, total; anti-HAV, IgM Interpretation | | | | |
| | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| 113 | **Hepatitis B Profile** | **52** | 973 | $ 32.00 | $ 1,664.00 |
| | HBs Ag; HBc Ag; anti-HBc, total; Anti-HBC, IgM; Anti-HBc; Anti-HBs Interpretation | | | | |
| 114 | **Hepatitis C Virus Antibody** | **416** | 3571 | $ 8.00 | $ 3,328.00 |
| | **Additional Send-Outs:** | | | | |
| 115 | 4 hr. GTT | 6 | 148 | $ 3.25 | $ 19.50 |
| 116 | Albumin | 129 | 5890 | $ 4.73 | $ 609.53 |
| 117 | Alkaline phos panel | 2 | 142 | $ 6.98 | $ 13.95 |
| 118 | ALT | 112 | 319 | $ 3.25 | $ 364.00 |
| 119 | ALT-SGOT | 29 | 320 | $ 3.25 | $ 94.25 |
| 120 | ALT-SGPT | 23 | 319 | $ 3.25 | $ 74.75 |
| 121 | Amiodarone | 4 | 1990 | $ 34.13 | $ 136.50 |
| 122 | ANC | 80 | 10939 | $ 37.50 | $ 3,000.00 |
| 123 | AST | 146 | 320 | $ 3.25 | $ 474.50 |
| 124 | Basic Metabolic Panel | 70 | 2413 | $ 5.30 | $ 371.00 |
| 125 | BMP | 188 | 11206 | $ 5.60 | $ 1,052.80 |
| 126 | CA125 | 4 | 2138 | $ 26.10 | $ 104.40 |
| 128 | CBA | 70 | 10924 | $ 220.00 | $ 15,400.00 |
| 129 | Chloride | 86 | 79 | $ 3.25 | $ 279.50 |
| 130 | Cholesterol, Total | 6 | 80 | $ 3.25 | $ 19.50 |
| 131 | Comp metabolic panel 13 | 47 | 8870 | $ 6.80 | $ 319.60 |
| 132 | Comp metabolic panel 14 | 214 | 1491 | $ 7.10 | $ 1,519.40 |
| 133 | CPK | 24 | 99 | $ 3.25 | $ 78.00 |
| 134 | Creatine | 15 | 96 | $ 10.43 | $ 156.38 |
| 135 | Depakote | 60 | 712 | $ 9.00 | $ 540.00 |
| 136 | Dilantin | 20 | 56 | $ 9.50 | $ 190.00 |
| 137 | Free T4 | 598 | 634 | $ 7.28 | $ 4,350.45 |
| 138 | FSH | 2 | 494 | $ 22.65 | $ 45.30 |
| 139 | Gentamiacin | 2 | 7092 | $ 20.03 | $ 40.05 |
| 140 | GGT | 3 | 587 | $ 3.25 | $ 9.75 |
| 141 | H&H | 4 | 10249 | $ 393.00 | $ 1,572.00 |
| 142 | Hematocrit | 10 | 157 | $ 3.15 | $ 31.50 |
| 143 | Hemoglobin | 10 | 158 | $ 3.15 | $ 31.50 |
| 144 | HSV Culture | 3 | 841 | $ 28.80 | $ 86.40 |
| 145 | INR | 24 | 241 | $ 3.50 | $ 84.00 |
| 146 | Ldh | 4 | 113 | $ 4.73 | $ 18.90 |
| 147 | LFT | 45 | 11209 | $ 5.30 | $ 238.50 |
| 148 | Mumps IgG | 3 | 2084 | $ 25.20 | $ 75.60 |
| 149 | PAP | 52 | 5310 | $ 32.00 | $ 1,664.00 |
| 150 | Pro BNP | 20 | 15579 | $ 129.00 | $ 2,580.00 |
| 151 | Progesterone | 1 | 17183 | $ 74.00 | $ 74.00 |
| 152 | PTH (Intact) | 7 | 14176 | $ 50.85 | $ 355.95 |
| 153 | RA Panel | 56 | 19867 | $ 55.50 | $ 3,108.00 |
| 154 | Renal Panel | 165 | 11208 | $ 6.20 | $ 1,023.00 |
| 155 | Rubeola IGG | 4 | 2173 | $ 18.00 | $ 72.00 |
| 156 | Teanetal Level | 2 | No Match | $ - | $ - |
| 157 | Tegratol | 2 | 393 | $ 12.00 | $ 24.00 |
| 158 | Vit. D, 1-125 Dihydroxy | 2 | 1123 | $ 69.30 | $ 138.60 |
| 159 | Vit. D, -25- hydroxyl | 2 | 17306 | $ 67.20 | $ 134.40 |
| 160 | WBC | 508 | 2318 | $ 5.30 | $ 2,692.40 |
| | | | | **Grand Total** | **$ 316,172.28** |

Quest Diagnostics

# Care360 Lab Orders & Results

Quest Diagnostics has over 50,000 clinicians nationwide using Care360 Lab Orders & Results to order testing and view patient results. Care360 is available as either an Internet or PC based application. While it can be the primary ordering tool, it often supplements an existing LIS interface. It can be used for ordering tests that have not been built in the interface, or for order entry while the interface is under development.

## Orders

Quest Diagnostics understands the processes in the hospital laboratory and has designed a user experience for fast, easy ordering through our Care360 application. Some highlights of the system include:

- One page, reduced "click" ordering
- Order grids with your hospital's frequently ordered tests from Quest Diagnostics to reduce processing time
- Quick and easy access to test menu to verify specifics like specimen requirements, transport temperature, CPT codes
- Batch processing, which provides manifests based on temperature type (e.g., Frozen, Room Temperature, Refrigerated)

## Results

The Care360 report transmission process is independent of the bi-directional HL7 interface and will provide an alternative means of access to results regardless of the operational status of the Hospital's LIS system or the interface. Some of the reporting features that Care360 provides are:

- Access full or partial results anytime, anywhere
- Primary delivery channel for enhanced reports (e.g., Flow Cytometry Analysis, Hematopathology report)
- Simultaneous access by multiple users from multiple locations
- Abnormal reports are highlighted in red for quick reference
- Retrieve and print test results by patient, physician, date, test, or abnormal result
- Create cumulative graphs and reports for use as patient management and trending
- Automatic notification of new reports
- Automatic printing of reports in your laboratory
- Order reports for automatic delivery to other physicians
- Protect patient information and adhere to privacy regulations. Care360 meets all Health Insurance Portability and Accountability Act ("HIPAA") standards and protects

patient health information with 128-bit encryption and the services of Verisign™, an industry leader in system security verification.

Other important features include:

- Online client supply ordering
- Use of the Query Tool (see section on Query Tool for details) for secure, HIPAA compliant access to the Quest Diagnostics LIS for Work in Progress reports, specimen receipt logs, interface maps
- User management of several configurable features (e.g., setting to print specimen requirements with each requisition)

Care360 Premium Services*:

Add-on modules to extend the system capability and services to your physician population:

- Patient insurance eligibility lookup, verification, and information
- ePrescribing module including ability to write script on-line, drug-drug interactions, formulary lookup and verification based on patient's insurance, direct fax and two way integration with mail order and retail pharmacies (provides pharmacy to interact back with physician for eRx corrections and prescription refills.
- Disease Management/clinical integration – Artificial Intelligence system to analyze patient information against defined clinical protocols to alert and report on adherence to guidelines and identify gaps in care based on those protocols. Provides health risk ranking to assist in early and appropriate care of chronically ill patients to reduce health care costs and improve patient care.

*Charges apply for Premium Services and there is a one-time Generic Requisition Fee of $25.00 only in New York, pursuant to State Law.

As an extension to the Care360 Integration Services framework, the Care360 Hub is a web services based interface model for the delivery and receipt of laboratory data and services. The Care360 Hub is designed to be a lightweight, scalable, and highly available set of services which meet the needs of our clients to connect, integrate, and optimize the current laboratory interface landscape. The Care360 Hub has the following features:

- Simple, fast, and reliable laboratory orders and results via a client EHR system
- Uni-directional (discrete access to laboratory results via HL7) and bi-directional (discrete access to laboratory results and orders via HL7) support
- Access to PDF reports, standardizing lab result view to Quest Diagnostic's standards
- Standardized communication method to help minimize implementation times and reduce errors
- Access and support of workflow capability within EHR
- Support for single application acting as single point of reference for laboratory data
- Highly available communication method delivers up time of 24 hours a day 7 days a week

- Product support based on Quest Diagnostics' superior IT infrastructure and support staff
- Capable to provide access to Quest Diagnostics laboratory orders and results business logic within client's EHR
- Service offerings allow laboratory orders and results business logic to be defined, developed, and owned by laboratory experts

Additional information:

*Query Tool*

The LIS Query Tool is the latest addition to our suite of capabilities. It is a robust, web-based, user-friendly product that provides several ways for you to review pending and completed patient results, look up test requirements, compile a client activity report and determine the status of a sample. The Query Tool can be accessed from any terminal that has Internet access.

*Support*

Quest Diagnostics maintains 24/7 computer software and hardware support for all products and services that we will provide. Our Customer Product Support help desk is the first point of contact for external customer product questions or issues.

*Training*

Quest Diagnostics will train customer staff on the use of any IT products that we provide. Training is typically performed on site, but can also be done via online web conferencing service or via teleconference depending on the product and the customer's need. Additional training is available by request through the Hospital Sales representative.

*Supplies*

Quest Diagnostics will provide barcode printers, ribbons, and labels solely for the use of our Care360 web based solutions.

| Chantilly Test Code | Seq | Chantilly Test Description | Vendor Test Description | Chantilly CPT Code(s) | Chantilly Turn-Around-Time |
|---|---|---|---|---|---|
| 333 | 1 | ACETAMINOPHEN | Acetaminophen | 82003 | 1-3 days |
| 104 | 2 | ACID-FAST BACILLI CULTUREPROGRESSIVE | AFB cu | 87015,87116 | 56 days |
| 890 | 3 | AMITRIPTYLINE | Amitriptyline (Elavil) serum | 80152 | 3 days |
| 55098 | 4 | AMMONIA, (P) | Ammonia, Plasma | 82140 | 1 day |
| 27 | 5 | AMYLASE, SERUM | Amylase, Serum | 82150 | 1 day |
| 18137 | 6 | ANACHOICE(TM)SCREEN W/REFLEX TO TITER, IFA | Antinuclear antibodies (ANA) | 86038 | 1-4 days |
| 6470 | 7 | THROAT CULTURE BETA STREPGROUP A ONLY | Beta-Hemolytic Strep A | 87081 | 3 days |
| 47 | 8 | BILIRUBIN, TOTAL | Bilirubin Total | 82247 | 1 day |
| 46 | 9 | BILIRUBIN, TOTAL + DIRECT & INDRECT, SERUM | Bilirubin, Total/Direct, serum | 82247,82248 | 1 day |
| 329 | 10 | UREA NITROGEN (BUN) | BUN | 84520 | 1 day |
| 500 | 11 | CLOSTRIDIUM DIFFICILETOXINS A & B | C. diff. Toxin A | 87324 | 1 day |
| 65 | 12 | C-REACTIVE PROTEIN SCREEN | C-Reactive Protein | 86140 | 1-3 days |
| 425 | 13 | CALCIUM, TOTAL | Calcium, serum | 82310 | 1 day |
| 393 | 14 | CARBAMAZEPINE | Carbamazepine (Tegretol) | 80156 | 1-3 days |
| 74 | 15 | CBC WITH DIFFERENTIAL | CBC w/diff-platelet | 85025 | 1 day |
| 581 | 16 | CHLORPROMAZINE(SJC34710P) | Chlorpromazine, (Thorazine) | 84022-90 | 7-9 days |
| 2040 | 17 | CLOMIPRAMINE | Clomipramine (Anafranil) s. | 80299 | 4 days |
| 15687 | 18 | CLOZAPINE(CLOZARIL) | Clozapine (clozaril) serum | 80154 | 1-5 days |
| 112818 | 19 | CORTISOL,TOTAL,LC/MS/MS | Cortisol serum/plasma | 82533-90 | 3-5 days |
| 642 | 20 | CK (CPK) ISOENZYMES, SERUM | Creatinine Kinase (CK) MB/Total | 82550,82552 | 1-3 days |
| 99 | 21 | CREATINE KINASE (CK) | Creatinie Kinase, serum | 82550 | 1 day |
| 97 | 22 | CREATININE WITH eGFR | Creatinine, Serum | 82565 | 1 day |
| 893 | 23 | DESIPRAMINE | Desipramine, serum | 80160 | 2-3 days |
| 659 | 24 | DIGITOXIN | Digoxin (Lanoxin) | 80299 | 2 days |
| 2803 | 25 | ESTROGENS, TOTAL | Estrogen | 82672 | 1-4 days |
| 44389 | 26 | ETHANOL | Ethanol serum/blood | 82055 | 2 days |
| 385 | 27 | ETHOSUXIMIDE | Ethosuximide (Zarontin) serum | 80168 | 1-2 days |
| 859 | 28 | FERRITIN | Ferritin | 82728 | 1 day |
| 2540 | 29 | FLUOXETINE | Fluoxetine (Prozac) serum | 83789-90 | 4-6 days |
| 265 | 30 | FOLIC ACID | Folates (Folic Acid) | 82746 | 1 day |
| 5220 | 31 | GABAPENTIN | Gabapentin (Neurotin) serum | 80299 | 3-5 days |
| 5220 | 32 | GABAPENTIN | Gabritril serum | 80299 | 3-5 days |
| 148 | 33 | GLUCOSE | Glucose, 2hr P.P. | 82947 | 1 day |
| 148 | 34 | GLUCOSE | Glucose serum | 82947 | 1 day |
| 148 | 35 | GLUCOSE | Glucose plasma | 82947 | 1 day |
| 5310 | 36 | THIN PREP, PAP SMEAR | Gynecologic Mono-Layer PAP | 88142 | 5 days |
| 670 | 37 | HALOPERIDOL | Haloperidol serum | 80173-90 | 3-5 days |
| 25 | 38 | GLYCOHEMOGLOBIN, HBA1C | Hemoglobin A1C | 83036 | 1 day |
| 235 | 39 | HCG, QL, URINE | HCG Beta subunity, Qual (s) | 84703 | 1 day |
| 3341 | 40 | HELICOBACTER PYLORI ANTIBODY (IGG) | Heliobacter Pylori, Igg | 86677 | 1-2 days |
| 2068 | 41 | T CELLS, HELPER/INDUCER SUBSET | helper T-Lymph-CD4 | 86361 | 1-2 days |
| 1003 | 42 | HEPATITIS A (IGM),ACUTESTATUS | Hepatitis A AB Igm | 86709 | 1-3 days |
| 1002 | 43 | HEPATITIS A TOTAL AB,IMMUNE STATUS | Hepatitis A AB, Total | 86708 | 1-3 days |
| 718 | 44 | HEPATITIS B SURF AB QL | Hepatitis B Surface AB | 86706 | 1-3 days |
| 453 | 45 | HEPATITIS B SURFACEANTIGEN (HBsAG) | Hepatitis B Surface Ag | 87340 | 1-2 days |
| 4628 | 46 | HEPATITIS A,B & C PANEL | Hepatitis Panel-A,B,C | 86704,86706,86708,86803,8734 0 | 1 day |
| 892 | 47 | IMIPRAMINE, QUANT. (INCLUDES DESIPRAMINE) | Imipramine (tofranil) serum | 80174 | 2-3 days |
| 805 | 48 | IRON, URINE | Iron | 83540 | 4-7 days |
| 175 | 49 | IRON AND IRON-BINDING CAPACITY | Iron/TIBC | 83540,83550 | 1 day |
| 5896 | 50 | LAMOTRIGINE | Lamotrigine (Lomictal) serum | 80299 | 2-3 days |
| 186 | 51 | LEAD, BLOOD(S.A. 14394) | Lead (Adult) blood | 83655 | 1-2 days |
| 1350 | 52 | FSH & LH | LH & LSH | 83001,83002 | 1-3 days |
| 187 | 53 | LIPASE | Lipase serum | 83690 | 1 day |
| 466 | 54 | LITHIUM | Lithium | 80178 | 1-2 days |
| 1961 | 55 | LIPOPROTEIN ELECTROPHORESIS | LP Lipo El | 82465,84478,83700-52 | 1 day |
| 195 | 56 | MAGNESIUM | magnesium, serum | 83735 | 1 day |
| 2687 | 57 | MICROALBUMIN | Microalbumin, 24 hour urine | 82043 | 1-2 days |
| 2687 | 58 | MICROALBUMIN | Microalbumin, Random urine | 82043 | 1-2 days |
| 891 | 59 | NORTRIPTYLINE | Nortriptyline (Aventyl) Serum | 80182 | 2-3 days |
| 2364 | 60 | OCCULT BLOOD, STOOL3 SPECIMENS | Occult Blood (Stool) | 82272 | 1-2 days |
| 432 | 61 | OSMOLALITY | Osmolality serum | 83930 | 1-2 days |
| 2243 | 62 | OSMOLALITY, URINE | Osmolality, urine | 83935 | 1-3 days |
| 212 | 63 | OVA AND PARASITES | Ova and Parasite | 87177 | 3 days |
| 1989 | 64 | PERPHENAZINE(NMS TC-3440) | Perphenazine (Trilafon) | 84022-90 | 4-6 days |
| 214 | 65 | PHENOBARBITAL | Phenobarbital serum | 80184 | 1 day |
| 56 | 66 | PHENYTOIN | Phenytoin (Dialantin) | 80185 | 1 day |
| 222 | 67 | PHOSPHATE (AS PHOSPHORUS) | Phosphorus | 84100 | 1 day |
| 231 | 68 | POTASSIUM | Potassium, serum | 84132 | 1 day |
| 730 | 69 | HCG,TOTAL,QN | Pregnancy Serum | 84702 | 1 day |
| 235 | 70 | HCG, QL, URINE | Pregnancy Test (Urine) | 84703 | 1 day |
| 4075 | 71 | PRIMIDONE | Preimidone (Mysoline) | 80188 | 1-2 days |
| 245 | 72 | PROLACTIN (PRL) | Prolactin | 84146 | 1 day |
| 1054 | 73 | PROSTATE SPECIFIC ANTIGEN TOTAL | Prostate-specific AG, Serum | 84153 | 1-4 days |
| 237 | 74 | PROTEIN, TOTAL | Protein serum | 84155 | 1 day |
| 241 | 75 | PROTHROMBIN TIME (PT) | Prothrombin time | 85610 | 1-2 days |
| 213+241 | 76 | PT & PTT | PT & PTT | 85730, 85610 | 1 day |
| 251 | 77 | RETICULOCYTE COUNT | Reticulocyte count | 85045 | 1 day |
| 8316 | 78 | HIV 1 RNA QN PCR V1.5 | RNA-PCR-Quant | 87536 | 1 day |
| 2377 | 79 | RPR, PROGRESSIVE | STS | 86592 | 1-2 days |
| 259 | 80 | SEDIMENTATION RATE, RBC | Sedimentation rate | 86651 | 1-2 days |
| 271 | 81 | SODIUM | Sodium serum | 84295 | 1 day |
| 248 | 82 | T3 UPTAKE | T3-uptake | 84479 | 1 day |
| 634 | 83 | T-4 (THYROXINE), TOTAL | T4 | 84436 | 1 day |
| 18094 | 84 | T CELLS CD3 | T-Cell (T-Lymphocyte CD3 Cells) | 86359 | 1-4 days |
| 15983 | 85 | TESTOSTERONE,TOTAL LC/MS/MS | Testosterone Serum | 84403 | 2-4 days |
| 631 | 86 | THEOPHYLLINE | Theophylline Serum | 80198 | 1-2 days |
| 8761 | 87 | TOPIRAMATE (TOPAMAX) | Topiramate (Topamax) serum | 80201 | 2 days |
| 62 | 88 | FTA-ABS | T-Pallidum Ab (FTA-Ab) | 86781 | 1-4 days |
| 297 | 89 | TREPONEMA PALLIDIUM AB(TP-PA) | T-Pallidum Antibodies (TP-PA) | 86781 | 1-2 days |
| 321 | 90 | TRIGLYCERIDES | Triglycerides | 84478 | 1 day |
| 6229 | 91 | TSH,3RD GENERATION | TSH | 84443 | 1-2 days |
| 6229 | 92 | TSH,3RD GENERATION | TSH 3rd Generation | 84443 | 1-2 days |
| 2542 | 93 | URINALYSIS, COMPLETE, W/REFLEX TO CULTURE | UA Culture reflex | 81001 | 1 day |
| 665 | 94 | CULTURE,URINE,ROUTINE | Culture reflex @ additional cost | 87086 | 3 days |

| Chantilly Test Code | Seq | Chantilly Test Description | Vendor Test Description | Chantilly CPT Code(s) | Chantilly Turn-Around-Time |
|---|---|---|---|---|---|
| 331 | 95 | URIC ACID | Uric Acid | 84550 | 1 day |
| 564 | 96 | URINALYSIS, CHEMICAL WITH MICROSCOPIC EXAMINATION | Urinalysis, Complete | 81001 | 1 day |
| 712 | 97 | VALPROIC ACID | Valporic acid serum | 80164 | 1 day |
| 2306 | 98 | VARICELLA-ZOSTER VIRUSIGG ANTIBODY | Varicella Zoster IGG | 86787 | 1-4 days |
| 264 | 99 | VITAMIN B12 | Vitamin B-12 | 82607 | 1 day |
| 264 | 99 | VITAMIN B12 | | 82607 | 1 day |
| 278 | 100 | VITAMIN B12 AND FOLIC ACID | Vitamin B-12 and Folates | 82607,82746 | 1 day |
| 737 | 101 | HEALTH PROFILE #1 | Diagnostic Multi-Chem (28 tests) | 82040,82247,82310,82374,82435,82465,82565,82947,82977,83615,84075,84100,84132,84155,84295,84450,84460,84478,84520,84550 | 1 day |
| 792 | 102 | HYPOTHYROID GROUP | Thyroid Profiles Includes: (4 Tests) | 84436,84443,84479 | 1 day |
| 610 | 103 | ELECTROLYTES, URINE | Electrolyte Panel Includes: (3 Tests) | 82436,84133,84300 | 1 day |
| 13210 | | UNCONFIRMED DRG PROF #58URINE | Drug Abuse Screen (7) Urine, w/o confirmaton | 80100 | 4 days |
| 11209+80+221 | | | HFP7 & 3 AC | 80076, 82465 | 1 day |
| +587 | 104 | HFP7 & 3 AC | Lipid Profile Four Includes: (3 Tests) | 82465,83718,84478 | 1 day |
| 37 | 105 | LIPID PANEL | Drug Abuse Screen, Total-w/o Confirmation | 80100 | 3-4 days |
| 2991 | 106 | TOXICOLOGY SCREEN, BLOOD, SERUM OR PLASMA | Lower Respiratory Culture | 87070 | 4 days |
| 5594 | | RESPIRATORY CULTURE | Upper Respiratory Culture | 87070 | 4 days |
| 5594 | | RESPIRATORY CULTURE | General Bacterial Culture | 87070 | 4 days |
| 663 | | WOUND CULTURE(ABSCESS OROTHER SITES | Blood Culture | 87040 | 7 days |
| 103 | | BLOOD CULTURE | Stool Culture | 87045 | 4-5 days |
| 664 | | CULTURE,FECES | Urine Culture | 87086 | 3 days |
| 665 | | CULTURE,URINE,ROUTINE | Sputum Culture | 87070 | 4 days |
| 14205 | | SPUTUM CULTURE | Sensitvity Organism | 87184 | 3 days |
| 261 | | ANTIBIOTIC SENSITIVITY(AEROBIC) | Heavy Metal Profile (Blood) | 82175,83655,83825 | 3-4 days |
| 599 | 108 | HEAVY METALS PANEL, BLOOD | Hepatitis Profile (Diagnostic follow up) | 8,670,686,704 | 1-2 days |
| 718+813 | 109 | Hepatitis Profile (Diagnostic follow up) | Hepatitis Profile B & C | 86704,86705,86706,86707,86803,87340,87350 | 1 day |
| 3165 | 110 | COMPREHENSIVE HBV & HCVPROFILE | Hepatitis Profile A & B | 86704,86705,86706,86708,86709,87340 | 1 day |
| 925 | 111 | COMPREHENSIVE HAV & HBV PROFILE #2 | Hepatitis A Profile | 86708,86709 | 2 days |
| 1004 | 112 | COMPREHENSIVE HAV PROFILE | Hepatitis B Profile | 86704,86705,86706,87340 | 1-2 days |
| 973 | 113 | VIRAL HEPATITIS B PROFILE | Hepatitis C Virus Antibody | 86803 | 1-3 days |
| 3571 | 114 | HEPATITIS C VIRUS AB,EIA | 4 hr. GTT | 82947 | 1 day |
| 148 | 115 | GLUCOSE | Albumin | 82040 | 1 day |
| 5890 | 116 | ALBUMIN | Alkaline phos panel | 84075,84078 | 1 day |
| 142 | 117 | ALKALINE PHOSPHATASE FRACTIONATION | ALT | 84460 | 1 day |
| 319 | 118 | ALANINE AMINOTRANS-FERASE (ALT) | ALT-SGOT | 84450 | 1 day |
| 320 | 119 | ASPARTATE AMINOTRANS-FERASE (AST) | ALT-SGPT | 84460 | 1 day |
| 319 | 120 | ALANINE AMINOTRANS-FERASE (ALT) | Amiodarone | 84460 | 1 day |
| 1990 | 121 | AMIODARONE | ANC | 82492 | 2-4 days |
| 10939 | 122 | NEUTROPHIL CYTOPLASMIC ABSCREEN/REFLEX TO TITER | AST | 86021-90 | 3-5 days |
| 320 | 123 | ASPARTATE AMINOTRANS-FERASE (AST) | Basic Metabolic Panel | 84450 | 1 day |
| 2413 | 124 | BASIC METABOLIC PANEL | BMP | 82374,82435,82565,82947,84132,84295,84520 | 1 day |
| 11206 | 125 | BASIC METABOLIC PANELW/E GFR | CA125 | 80048 | 1-2 days |
| 2138 | 126 | CA 125 | CBA | 86304 | 1-3 days |
| 10924 | 128 | VON WILLEBRAND FACTOR COLLEGEN BINDING ASSAY | Chloride | 83520-90 | 3-5 days |
| 79 | 129 | CHLORIDE | Cholesterol, Total | 82435 | 1 day |
| 80 | 130 | CHOLESTEROL, TOTAL | Comp metabolic panel 13 | 82465 | 1 day |
| 8870 | 131 | COMPREHENSIVE METABOLIC PANEL | Comp metabolic panel 14 | 82040,82247,82310,82374,82435,82565,82947,84075,84132,84155,84295,84450,84520 | 1 day |
| 1491 | 132 | COMPREHENSIVE METABOLIC PANEL - 1999 | CPK | 82040,82247,82310,82374,82435,82565,82947,84075,84132,84155,84295,84450,84520 | 1 day |
| 99 | 133 | CREATINE KINASE, TOTAL | Creatine | 82550 | 1 day |
| 96 | 134 | CREATINE | Depakote | 82540 | 1-3 days |
| 712 | 135 | VALPROIC ACID | Dilantin | 80164 | 1 day |
| 56 | 136 | PHENYTOIN | Free T4 | 80185 | 1 day |
| 634 | 137 | T-4 (THYROXINE), TOTAL | FSH | 84436 | 1 day |
| 494 | 138 | FSH, SERUM | Gentamiacin | 83001 | 1-3 days |
| 7092 | 139 | GENTAMICIN, SERUM | GGT | 80170 | 1 day |
| 587 | 140 | GAMMA GLUTAMYL TRANSFERASE (GGT) | H&H | 82977 | 1 day |
| 10249 | 141 | HEREDITARY HEMOCHROMATO-SIS DNA MUTATION ANAL. | Hematocrit | 83891,83892,83900,83909,83912 | 7-10 days |
| 157 | 142 | HEMATOCRIT | Hemoglobin | 85014 | 1-2 days |
| 158 | 143 | HEMOGLOBIN | HSV Culture | 85018 | 1 day |
| 841 | 144 | HERPES SIMPLEX VIRUS CULTURE | INR | 87255 | 1-3 days |
| 241 | 145 | PROTHROMBIN TIME (PT) | Ldh | 85610 | 1-2 days |
| 113 | 146 | LACTATE DEHYDROGENASE(LD) | LFT | 83615 | 1-2 days |
| 11209 | 147 | HEPATIC FUNCTION - 2000 | Mumps IgG | 80076 | 1 day |
| 2084 | 148 | MUMPS AB IGG, EIA | PAP | 86735 | 1-4 days |
| 5310 | 149 | THIN PREP, PAP SMEAR | Pro BNP | 88142 | 5 days |
| 15579 | 150 | PROBNP, N-TERMINAL(S.A. 14647) | Progesterone | 83880 | 1-3 days |
| 17183 | 151 | PROGESTERONE LC/MS/MS | PTH (Intact) | 84144 | 3-4 days |
| 14176 | 152 | INTACT PTH WITH CALCIUM | RA Panel | 82310,83970 | 2-4 days |
| 19867 | 153 | ANACHOICE(TM) RA PANEL | Renal Panel | 86038,86200,86431 | 1-4 days |
| 11208 | 154 | RENAL FUNCTION PANELW/EGFR | Rubeola IGG | 80069 | 1-2 days |
| 2173 | 155 | MEASLES IGG AB (RUBEOLA) | Tegratol | 86765 | 1-4 days |
| 393 | 157 | CARBAMAZEPINE | Vit. D, 1-125 Dihydroxy | 80156 | 1-3 days |
| 1123 | 158 | 1,25-DIHYDROXYVITAMIN D | Vit. D, -25- hydroxyl | 82652 | 2-5 days |
| 17306 | 159 | VITAMIN D,25-HYDROXY,LCMSMS | WBC | 82306 | 2-4 days |
| 2318 | 160 | WBC COUNT ONLY | | 85048 | 1 day |

Quest Diagnostics
Nichols Institute

Date: 03/03/03

Page: 1

**QUEST DIAGNOSTICS NICHOLS INSTITUTE**
**DETAILED INVOICE OF TESTS PERFORMED FOR:**

| ACCESSION | PATIENT | PID | DOS | TEST CODE | DESCRIPTION | CPT CODE | AMOUNT |
|---|---|---|---|---|---|---|---|
| 554806199902 | | | 02/27/1999 | 0009320 | ROTAVIRUS EIA | 87425 | 0.00 |
| 554806229902 | | | 02/27/1999 | 0001540 | GRAM STAIN | 87205 | 0.00 |
| 554806289902 | | | 02/27/1999 | 0005000 | CLOSTRIDIUM DIFFICILE | 87324 | 0.00 |
| 554827779902 | | | 02/27/1999 | 0020580 | RUBELLA VIRUS AB | 86762 | 0.00 |
| 554827799902 | | | 02/28/1999 | 0003540 | PROTEIN ELECTROPH. | 84165 | 0.00 |
| 554849399903 | | | 03/01/1999 | 0075960 | PRENATAL GROUP #176 | PROFILE | 0.00 |
| 554849499903 | | | 03/01/1999 | 0018630 | HIV-1 SEROLOGY | 86701 | 0.00 |
| 554849569903 | | | 03/01/1999 | 0029760 | LYME SEROLOGY | 86618 | 0.00 |
| | | | | | TOTAL | | 0.00 |

**Client:**
**Client #:**
**Utilization Report - February 2008**

| TEST CODE | NTC | TEST NAME | CPT** | JAN # | JAN $ | FEB # | FEB $ | YTD # | YTD $ |
|---|---|---|---|---|---|---|---|---|---|
| 1090 | | CYTOLOGY CERV-VAG SMEARS; | 88164 | 1 | | 3 | | 4 | |
| 5860 | | CYTOLOGY CERV-VAG SMEAR,;SINGLE | 88164 | 0 | | 0 | | 0 | |
| 53100 | 35455X | THIN PREP, PAP SMEAR; | 88142 | 1 | | 0 | | 1 | |
| 101610 | 31532X | HPV DNA, HIGH RISK; | 87621 | 0 | | 2 | | 2 | |
| 121730 | | PHYSICIAN INTERPRETATION; | 88141 | 0 | | 5 | | 5 | |
| 129390 | 30294X | MATERNAL SERUM SCREEN 4; | Profile | 0 | | 0 | | 0 | |
| 133690 | 31530X | THIN PREP REFLEX W/ HIGH;RISK HPV | 88142 | 12 | | 25 | | 37 | |
| 134560 | 15003X | THIN PREP AND HPV HIGH RK; | Profile | 0 | | 1 | | 1 | |

****The CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.**

*Advancing Excellence*

Accredited Laboratory

# The College of American Pathologists

*certifies that the laboratory named below*

***Quest Diagnostics Nichols Institute***
***dba Quest Diagnostics Nichols Institute***
***Chantilly, Virginia***
***Nathan Sherman, MD***

LAP Number: 1361101
AU-ID: 1179154
CLIA Number: 49D0221801

*has met all applicable standards for accreditation and is hereby fully accredited by the College of American Pathologists' Laboratory Accreditation Program. Reinspection should occur prior to April 22, 2009 to maintain accreditation.*

Accreditation does not automatically survive a change in director, ownership, or location and assumes that all interim requirements are met.

R Bruce Williams, MD
Chair, Commission on Laboratory Accreditation

Thomas Soderman MD FCAP
President, College of American Pathologists

CENTERS FOR MEDICARE & MEDICAID SERVICES

# CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

*CERTIFICATE OF ACCREDITATION*

LABORATORY NAME AND ADDRESS

QUEST DIAGNOSTICS NICHOLS INSTITUTE
14225 NEWBROOK DRIVE P O BOX 10841
CHANTILLY, VA 20153

CLIA ID NUMBER
49D0221801

EFFECTIVE DATE
02/09/2007

EXPIRATION DATE
02/08/2009

LABORATORY DIRECTOR
NATHAN SHERMAN MD

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.

Judith A. Yost, Director
Division of Laboratory Services
Survey and Certification Group
Center for Medicaid and State Operations

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

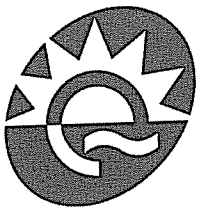
194 cms2_011307

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

| LAB CERTIFICATION (CODE) | EFFECTIVE DATE |
|---|---|
| HISTOCOMPATIBILTY (010) | 07/27/1995 |
| BACTERIOLOGY (110) | 07/27/1995 |
| MYCOBACTERIOLOGY (115) | 07/27/1995 |
| MYCOLOGY (120) | 07/27/1995 |
| PARASITOLOGY (130) | 07/27/1995 |
| VIROLOGY (140) | 07/27/1995 |
| SYPHILIS SEROLOGY (210) | 07/27/1995 |
| GENERAL IMMUNOLOGY (220) | 07/27/1995 |
| ROUTINE CHEMISTRY (310) | 07/27/1995 |
| URINALYSIS (320) | 07/27/1995 |
| ENDOCRINOLOGY (330) | 07/27/1995 |
| TOXICOLOGY (340) | 07/27/1995 |
| HEMATOLOGY (400) | 07/27/1995 |

| LAB CERTIFICATION (CODE) | EFFECTIVE DATE |
|---|---|
| ABO & RH GROUP (510) | 07/27/1995 |
| ANTIBODY TRANSFUSION (520) | 07/27/1995 |
| ANTIBODY NON-TRANSFUSION (530) | 07/27/1995 |
| ANTIBODY IDENTIFICATION (540) | 07/27/1995 |
| HISTOPATHOLOGY (610) | 07/27/1995 |
| ORAL PATHOLOGY (620) | 07/27/1995 |
| CYTOLOGY (630) | 07/27/1995 |
| RADIOBIOASSAY (800) | 09/29/2005 |
| CYTOGENETICS (900) | 07/27/1995 |

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.HHS.GOV/CLIA
OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR
YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER.
PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.



Quest Diagnostics®

# *QUALITY POLICIES*

includes

*Quality Assurance*
*Quality Control*
*Quality Improvement*

| | | | |
|---|---|---|---|
| **APPROVAL** | Joyce G. Schwartz, M.D.<br>**VICE PRESIDENT AND CHIEF LABORATORY OFFICER** | | 6/26/03<br>**DATE** |
| | Lilli Visnapuu, M.D.<br>**DIRECTOR, NATIONAL QUALITY ASSURANCE** | | 6/26/03<br>**DATE** |
| | Nathan Sherman, M.D.<br>**LOCAL LABORATORY DIRECTOR** | Chantilly, VA<br>**LOCATION** | 7/07/04<br>**DATE** |

# TABLE OF CONTENTS

# 1. Introduction

**Purpose of Policies**

- This set of policies addresses the principles, standards, goals and activities fundamental to the quality functions of Quest Diagnostics.
- It serves as a reference guide for Quest Diagnostics employees and describes the underlying quality principles that support the drive toward Six Sigma Quality.
- It also serves to introduce Quest Diagnostics' customers to the company's quality principles and standards.

**Scope**

These quality policies apply to the pre-analytic, analytic and post-analytic phases of laboratory testing within Quest Diagnostics.

**Quest Diagnostics Vision**

Dedicated People Improving the Health of Patients Through Unsurpassed Diagnostic Insights.

**Quest Diagnostics Mission**

We will be the Undisputed Leader in Diagnostic Testing, Information and Services in the Eyes of our Customers and Employees.

**Introduction continued:**

# Quest Diagnostics Corporate Values

**Quality** — The patient comes first in everything we do. Our passion is to provide every patient and every customer with services and products of uncompromising quality — error free, on time, every time. We work towards this goal by dedicating ourselves to the relentless pursuit of excellence in the services we provide.

**Integrity** — Credibility is the key to our success; therefore, all of our processes, decisions and actions ultimately are driven by integrity. We are honest and forthright in all our dealings with our customers and with each other. We are responsible corporate citizens in the communities we serve. We comply with the laws and regulations governing our business, not only as a legal obligation and a competitive necessity, but because it is the right thing to do.

**Innovation** — We constantly seek innovative ways to enhance patient care and provide value to our customers. We support the creativity, courage and persistence that transform information into knowledge, and knowledge into insights. We seek continuous advancement through the adaptation of existing knowledge, as well as through experimentation, with the full understanding that we learn from our failures as well as our successes.

**Accountability** — As a company and as individuals, we accept full responsibility for our performance and acknowledge our accountability for the ultimate outcome of all that we do. We strive for continuous improvement, believing that competence, reliability, and rigorous adherence to process discipline are the keys to excellence.

**Collaboration** — We believe in teamwork and the limitless possibilities of collaborative energy. We achieve excellence by putting collective goals ahead of personal interests. We support and encourage open communication and meaningful cooperation among colleagues from varying backgrounds and disciplines. We respect individual differences, and we value diversity.

**Leadership** — We strive to be the best at what we do — both as a company, and as individuals. We embrace the qualities of personal leadership — courage, competence, confidence and a passion for surpassing expectations. We will provide growth opportunities for our employees, quality services and products to our customers and superior returns to our shareholders.

## Introduction continued:

**Six Sigma Quality Overview**

- Quest Diagnostics is committed to Six Sigma Quality.
- Six Sigma Quality is both a measurable goal (number of errors in parts per million) and a rigorous process and management philosophy with a focus on striving for perfection.
- Specific projects are identified and specially trained project leaders called "Black Belts" are assigned for each. The Vice President of Six Sigma oversees these projects.
- Six Sigma projects are applied to all aspects of Quest Diagnostics' business.

**Six Sigma Quality Principles**

Six Sigma Quality is the shared responsibility of the company and its employees. As a company, we have an obligation to provide every employee with the tools, training and support needed to consistently satisfy our customers' requirements. As individuals, we each take responsibility for ensuring that our own work and our collective processes meet the highest quality standards.

- **Customer Driven**: Each of us maintains a relentless focus on defining, understanding and meeting the expectations of both our external and internal customers. To sustain that focus—now and in the future—we will constantly monitor our customers' changing needs and continuously measure how well we are meeting those needs.
- **Process Oriented**: All of our work is part of processes that are owned, measured, improved, standardized, and controlled. We recognize that our processes must work together and with the processes of our suppliers and partners to meet the requirements completely and consistently.
- **Error-free Work**: Our goal is Six Sigma Quality—meeting our customers' definition of "error-free" performance in everything we do. Six Sigma requires each of us to take responsibility for our errors and to focus on eliminating their root causes. Our processes will be designed and executed to help us in our goal to meet customer requirements completely and consistently.
- **Decisions Based on Facts and Data**: Our plans and decisions are based on reliable facts and data that enable us to recognize opportunities and problems, verify root causes and develop solutions.
- **Continuous Improvement**: We strive to continuously improve our processes, products and services, in a systematic way.

**Introduction continued:**

**Quality Measures**

- Quality measures are integral to the feedback loops that assure quality and drive continuous process improvement through corrective and preventive action.
- Quest Diagnostics has established quality measures throughout all aspects of its business.

**Quality Roadmap**

Each year, a corporate quality plan is developed under the direction of the Chairman's Council based on the review of quality measures, workload, business conditions and marketing strategy. The quality plan is clearly communicated each year in a "Roadmap" using:

- Strategic goals
- Critical success factors specific to the strategic goals
- Key measures specific to the critical success factors

**Quality of Laboratory Systems**

The quality of laboratory systems (general, pre-analytic, analytic, and post-analytic) is assured through local and national programs.

**Laboratory Systems Quality Measures**

Laboratory systems quality measures include (but are not limited to):

- Amended reports
- Proficiency Testing results
- Data entry quality
- Specimen handling measures
- Turn around time
- Missed pick-ups

**Quality of the Workplace**

Quest Diagnostics is committed to maintaining a safe and secure workplace. Corporate Environmental Health and Safety (EHS) programs address (at a minimum):

- Bloodborne Pathogens and other Occupational Safety and Health Administration (OSHA) standards
- Driver safety training
- Chemical hygiene and "Right to Know" standards
- Environmental Protection Agency (EPA) standards
- Department of Transportation (DOT) standards
- Nuclear Regulatory Commission (NRC) standards

## Introduction continued:

**Workplace Quality Measures**

Workplace quality measures include (but are not limited to):

- Lost work days
- Workers' compensation
- OSHA Recordable events

# 2. Quality Assurance

**Policy**

Quest Diagnostics has local and national Quality Assurance programs that collectively support the systems, personnel, processes and procedures that assure the quality of test results and service commensurate with Quest Diagnostics' mission and values.

**Definitions**

Quality Assurance (QA) is the planned and systematic monitoring of the ongoing and overall quality of the total testing process (pre-analytic, analytic and post-analytic phases). When problems or errors are found, corrective action is implemented and the effectiveness of the corrective action is later evaluated. The effectiveness of a QA program is reviewed regularly and adjustments to the program are made as necessary.

Note: In the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations, an "ongoing mechanism to monitor, assess, and when indicated, correct problems" is referred to as "Systems Assessment." It is fundamentally the same process called Quality Assurance by Quest Diagnostics.

**National Quality Assurance**

The National Quality Assurance (NQA) department monitors general laboratory performance across the network and supports the work and QA programs of the Local Quality Assurance Managers and Specialists.

**Responsibility**

While it is the responsibility of every employee to practice and implement quality related processes, specific duties are as follows:

| Staff | Responsibility |
|---|---|
| National QA | • Content and administration of national QA programs<br>• Support of the QA programs of the local laboratories |
| Local Laboratory Director | • Content and administration of local QA programs<br>• Compliance with NQA program requirements |
| Local QA Manager/ QA Specialist | • Implementation of local QA programs<br>• Local application of NQA programs |

## Quality Assurance continued:

**Local Quality Assurance Programs**

Each laboratory has a written laboratory-wide QA program that provides for planned and systematic monitoring of the quality and appropriateness of testing and services. These assessment activities include a review of the completeness, appropriateness, usefulness, accuracy and reliability of test results. At a minimum, the laboratory's QA program consists of the following elements:

- Assessment of general laboratory, pre-analytic, analytic and post-analytic systems
- Assessment of Quality Control policies, procedures and corrective actions
- Assessment of Proficiency Testing (PT) outcomes and processes
- A process for comparing test results among methods, instruments and satellite laboratories that perform the same test
- A procedure for evaluating the results of tests not included in a formal PT program
- A system to identify and evaluate test results that appear inconsistent with provided patient information
- Assessment of the effectiveness of personnel practices and evaluation techniques
- Mechanism to document and correct problems with customer communications
- Complaint investigation system
- Forum for reviewing QA data and information with staff

**Quality Assurance Records**

- QA activities are documented.
- QA records are retained in accordance with the requirements published in the Quest Diagnostics *Records Management Program Reference Guide.*

# 3. Quality Control

**Policy**

- Quality Control (QC) material is tested in parallel with patient specimens on every analytical run.
- Laboratory staff establish and follow written procedures for monitoring and evaluating the results of QC testing.
- Control results must meet stated acceptability criteria prior to the reporting of test results.

**Definitions**

- Quality Control is a component activity of Quality Assurance that occurs during the analytic phase of testing (i.e., before patient results are reported). Control materials, with known target values, are processed/tested in parallel with patient specimens on every analytical run. Before patient results are reported, the control results must meet the stated acceptability criteria.
- An analytical run, in the context of QC, is a time interval or series of measurements within which the accuracy and precision of the measuring system are stable.
- Allowable total error is the amount of error that can be tolerated without invalidating the medical usefulness of the analytical result and/or the maximum error defined for successful Proficiency Testing performance.

**Quality Control Procedures**

Each technical Standard Operating Procedure (SOP) includes instructions for the use of QC material, including:

- Specific control material to be used
- Instructions for the preparation and handling of control material
- Frequency at which controls are to be analyzed
- Criteria for accepting/rejecting a run
- Actions to be taken when QC results do not meet stated acceptability

**Analytical Runs**

- An analytical run may not exceed 24 hours.
- Run length is defined in each SOP and determined by the corporate Best Practice Team (BPT) responsible for the test. If the BPT has not defined the run length, it is defined by the laboratory.

## Quality Control continued:

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|---|---|
| **Control Material** | • Control material is used and stored according to the manufacturer's instructions.<br>• Outdated control material is not used. Stability may only be extended by the manufacturer via written documentation.<br>• All control material is labeled with the following information:<br>  • Identity/concentration<br>  • Lot number<br>  • Storage requirements<br>  • Preparation and/or expiration date<br>  • Date/time prepared (if applicable)<br>  • Initials of employee opening or preparing the material |
| **Quality Control Data** | • QC data are organized and presented to allow for effective evaluation.<br>• QC data are maintained according to established requirements. |
| **Quality Control Review** | The QC program is under active supervisory surveillance with daily, weekly and monthly review. |
| **Tolerance Limits** | Tolerance limits for all controls are defined and available to technical personnel. The limits are within the defined allowable total error for the test, as specified in the technical SOP. |
| **New QC Material Lot Numbers** | • Quest Diagnostics laboratories have procedures for the establishment or verification of target QC limits (mean and target range) prior to the initial use of new lot numbers of control materials.<br>• The corporate QC BPT establishes the procedures to be followed for introducing new lot numbers of control materials. |
| **Number and Frequency of Controls** | • In general, each run of patient specimens includes at least three levels of control material, although a fewer number of controls may be defined on a case-by-case basis.<br>• The corporate QC BPT determines the frequency at which control material is tested, this frequency being no less than as is specified by the manufacturer or regulatory standards. |

## Quality Control continued:

**Required Controls by Test Type**

- The general type or method of the test determines the type and number of controls that are included in each run of patient specimens.
- Control requirements according to test type are as follows:

| Test Type/Method | Minimum Controls per Run |
|---|---|
| Quantitative | 3 controls of different concentrations (or as defined in the SOP) |
| Semi-quantitative (tests reported in titers or units of measure such as optical density ratios) | 1 negative control or control below the detection limit, 1 weak positive control and 1 strong positive control (or as defined in the SOP) |
| Qualitative | 1 positive control and 1 negative control |
| Stains | Control with the intended reactivity |

**Changing Established Target QC Limits**

- Changing an established target QC limit (mean and target range) is thoroughly documented and approved by the Technical Supervisor or Laboratory Director or designee.
- If, upon review of monthly or other statistics, it is determined that the target QC limit needs to be adjusted, detailed documentation of the change and its explanation is maintained.
- Changes in target QC limits also include a review of patient mean or median values and interlaboratory comparison data when available.
- Target QC limits are defined within the allowable total error limits, as specified in the technical SOPs.

**Control Rules**

Procedures describing the QC rules or principles for evaluating the acceptability of control results are established and documented for each test.

## Quality Control continued:

**Remedial Action**

- Whenever control results fail to meet the laboratory's established criteria for acceptability, remedial action is taken.
- Patient test results in a run with a control failure, and since the last acceptable run, are evaluated to determine if the results have been adversely affected.
- Laboratory staff take and document all remedial action necessary to help ensure:
  - The reporting of accurate and reliable patient test results
  - That preventive measures are implemented to prevent future failures related to the same cause

**Quality Control Records**

- QC activities are documented.
- QC records are maintained in accordance with the requirements published in the Quest Diagnostics *Records Management Program Reference Guide.*

# 4. Quality Improvement

**Policy**

Each laboratory has a local Quality Improvement program for identifying and pursuing opportunities to improve customer service and patient care.

**Definitions**

- Quality Improvement (QI) is a separate activity that supplements Quality Assurance. It is more a proactive than monitoring/reactive process. With QI, opportunities for improving the effectiveness and efficiency of operations are sought in order to benefit customers and patients.
- The focus of QI is enhancing the quality of services provided and customer satisfaction.

Note: The College of American Pathologists' (CAP's) use of the term Quality Improvement is broader in scope than that of Quest Diagnostics. CAP rolls QA into QI, the latter described by CAP as the "monitoring of the quality and appropriateness of laboratory services to systematically identify and pursue opportunities to improve patient care and resolve problems" (equates to Quest Diagnostics' Quality Assurance plus Quality Improvement).

**Responsibility**

QI is a shared responsibility of the company and its employees.

**Local Quality Improvement Programs**

- Each laboratory has a QI program that fosters objective and systematic monitoring of the quality and appropriateness of the services provided by the laboratory through an operational plan approved by the Laboratory Director.
- The QI program identifies opportunities to improve systems and processes.
- Six Sigma projects are part of the local QI program.

**Scope**

- Local QI programs involve all areas of operations (pre-analytic, analytic and post-analytic) in each department of the laboratory.
- Each laboratory department participates in QI activities, which are integrated into the overall laboratory QI program.

## Quality Improvement continued:

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| **Service Quality Measures** | • Each laboratory tracks key service quality measures that:<br>  • Reflect issues important to the quality of patient care<br>  • Affect a significant segment of the laboratory's patients<br>  • Are objectively measured<br>  • Are systematically evaluated to identify improvement opportunities<br>  • Document the impact of specific actions taken to effect improvement<br>  • Track progress toward QI goals and objectives<br>• Service quality measures are tracked at the national level as well as locally. |
| **Service Solutions** | • Each laboratory has a defined process for responding to customer complaints and detecting errors that may affect the quality of service.<br>• Data are examined to detect trends and identify opportunities for systematic improvements. |
| **Quality Improvement Program Review** | • Local QI programs are evaluated for effectiveness by the Laboratory Director or designee at least annually.<br>• QI program review is documented and offers objective evidence when improvement has occurred. |
| **Quality Improvement Records** | • QI activities are documented.<br>• Where appropriate, service quality measures are graphed and displayed.<br>• QI records are retained in accordance with the requirements published in the Quest Diagnostics *Records Management Program Reference Guide.* |

# 5. National Quality Assurance Programs

**Policy**

- The National Quality Assurance (NQA) department monitors and supports quality through the administration of national programs.
- Participation in the national programs is required across all testing facilities, as applicable to local operations.

**Proficiency Testing Program**

- While the activities associated with Proficiency Testing (PT) are largely conducted at the local level, NQA is integrally involved.
- External [College of American Pathologists (CAP)] PT performance is monitored by NQA.
- Internal PT is provided by NQA for selected analytes not covered by the CAP's program.
  - NQA distributes internal PT materials or facilitates the sharing of patient specimens for interlaboratory comparison testing.
  - Performance is monitored by NQA.

**Inspections Program**

- NQA staff perform internal inspections to help ensure compliance with regulatory, accreditation and corporate requirements.
  - NQA has a defined protocol for conducting internal inspections.
  - Documentation of effective corrective action for cited non-conformances is tracked by NQA.
- Laboratories report to NQA the results of external inspections (by regulatory or accreditation agencies, announced or unannounced).

**Quality Surveillance Program**

- The Quality Surveillance Program (QSP) helps to ensure compliance with standard procedures and regulatory/accreditation requirements through a methodical review of test specific documents.
- NQA releases "test of the month" assignments for which local QA staff perform a focused records review.
- Outcomes are monitored and corrective action is coordinated by NQA.

## National Quality Assurance Programs continued:

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| **Reportable Quality Issues Program** | • NQA is notified in the event of a Reportable Quality Issue (RQI), including but not limited to major product issues involving testing materials/customer supplies or major Information Technology issues where there is a known or potential effect on test results/interpretations.<br>• NQA coordinates the corrective action process for the affected laboratories and evaluates the occurrence of RQIs for patterns requiring proactive action on a company-wide basis. |
| **Patient Results Distribution Program** | • NQA monitors test result positivity rates for infectious disease and autoimmune serology tests where the assays are particularly subject to lot to lot antigen/conjugate variability.<br>• Interlaboratory comparisons of the data reveal developing trends/biases, which NQA can then manage on a proactive basis. |
| **Best Practice Team Initiative Verification Program** | • Working with the corporate Best Practice Teams (BPTs), NQA staff prepare customized BPT initiative verification forms, which are included in the corporate Technical Standards & Processes department's monthly rollout of new standard operating procedures and other initiatives.<br>• Completion of the forms by Local QA Managers documents correct implementation of the BPT initiatives.<br>• Completion of the forms is monitored by NQA. |

# 6. Proficiency Testing

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| **Policy** | • Each Quest Diagnostics laboratory participates in external Proficiency Testing (PT) as required by federal and, as applicable, state law.<br>• External PT enrollment includes all regulated analytes [i.e., tests where participation in Centers for Medicare and Medicaid Services (CMS) approved programs is required] as well as all other analytes where external PT survey material can be obtained from a commercial vendor.<br>• Laboratories are also required to participate, as applicable, in Quest Diagnostics' internal PT program, which supplements external PT participation. |
| **External Proficiency Testing** | • The College of American Pathologists (CAP) is a CMS approved provider of external PT surveys and the primary provider used by Quest Diagnostics.<br>• For tests not covered by CAP, laboratories enroll in other CMS approved programs (to the extent that such programs are available).<br>• Where required, laboratories are enrolled in state PT programs. |
| **Internal Proficiency Testing** | • National Quality Assurance (NQA) staff administer an internal PT program for selected analytes not covered by CAP or other external PT providers.<br>• The internal PT test menu is limited by need, sample availability and other factors.<br>• NQA distributes internal PT materials or facilitates the sharing of patient specimens for interlaboratory comparison testing.<br>• Every six months, each laboratory evaluates any remaining analytes not covered by external/internal PT for test result accuracy and reliability. |
| **Proficiency Testing Results Reporting** | • All Quest Diagnostics laboratories have authorized CAP to release results to CMS and applicable state agencies.<br>• All Quest Diagnostics laboratories report internal PT results and external PT non-conformances to NQA. |

## Proficiency Testing continued:

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| **Local PT Results Review** | • PT results (internal and external) are reviewed by local staff to identify problems that require corrective action.<br>• The Laboratory Director (or designee) documents this review. |
| **Corrective Action** | • Corrective action in response to unsatisfactory PT results is documented.<br>• Corrective action is evaluated for effectiveness as part of the laboratory's QA program. |
| **Proficiency Testing Sample Handling** | • Written procedures describe the appropriate handling of PT samples.<br>• PT samples (both internal and external) are examined or tested in the same manner as are patient specimens.<br>• Laboratory staff attest to the fact that PT samples are integrated into the routine patient workload to the greatest extent possible.<br>• Laboratory staff test PT samples the same number of times as patient specimens are routinely tested.<br>• There is no interlaboratory communication regarding PT results prior to submission of the results to the administering agency.<br>• Laboratories do not send PT samples or portions of samples to other laboratories for analysis prior to the reporting of results.<br>• Laboratories do not knowingly accept or test PT samples submitted by other laboratories.<br>• If a laboratory receives PT samples from another laboratory for testing, CMS is immediately notified. |
| **Proficiency Testing Records** | • PT records are retained in accordance with the requirements published in the Quest Diagnostics *Records Management Program Reference Guide.*<br>• Records include documentation of handling, preparation, processing, examination, testing and reporting of results for all PT samples. |

# 7. Laboratory Certification

**Policy**

- Laboratories owned or operated by Quest Diagnostics within the United States comply with federal regulations as promulgated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and hold the required certification from the Centers for Medicare and Medicaid Services (CMS).
- All laboratories are under the direction of a qualified Laboratory Director as required by CLIA.
- A certificate of accreditation (one means of satisfying the regulatory requirement) is granted by CMS approved agencies, the foremost of which is the College of American Pathologists (CAP).
- All Quest Diagnostics main laboratories maintain CAP accreditation.
- Where required, each laboratory and Patient Service Center maintains state and local certification, licensure or permit.
- Laboratories located outside of the United States meet their national/local government and applicable accreditation requirements. International laboratories maintain CAP accreditation in countries where it is offered.

**Notification of Changes in Ownership and Staffing**

- Laboratories holding a certificate of waiver, certificate for provider-performed microscopy procedures, certificate of compliance or certificate of accreditation notify CMS or its designee (and the accrediting agency, if applicable) within 30 days of any change(s) in ownership, name, location or directorship.
- For laboratories performing non-waived testing, changes in Technical Supervisor assignment are communicated as required.
- The Corporate Medical Compliance department coordinates the notification of changes in ownership or name.

**Notification of Changes in Testing**

- Laboratory staff notify the appropriate federal, state and/or accrediting agency, as required, of certain types of changes in their test menu.
- Notification is made no later than six months after the following changes:
  - Performance of a test or examination within a specialty or subspecialty area that is not included in the laboratory's certification
  - Changes in test methodology for any test or examination included in a specialty or subspecialty for which the laboratory has been issued a certificate

## Laboratory Certification continued:

**Regulatory Agency Inspections**

- CMS or its designee may conduct announced or unannounced inspections ("surveys") in laboratories holding any type of CLIA certificate. The reasons for and frequency of inspections varies by certificate type.
- State and local authorities may also conduct inspections.
- Laboratories cooperate with all regulatory agencies and comply with applicable policy as outlined in the Quest Diagnostics *Your Compliance Policy Handbook.*

# 8. Personnel

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| **Policy** | Quest Diagnostics has established and maintains personnel policies so that employees have the necessary qualifications and training required to appropriately perform their duties. |
| **Personnel Qualifications** | • Quest Diagnostics laboratories require all personnel engaged in the pre-analytic, analytic and post-analytic phases of testing to meet applicable federal, state and local regulatory requirements.<br>• Each site maintains the necessary records to document each employee's qualifications. |
| **Laboratory Director Responsibilities** | The Laboratory Director:<br>• Specifies, in writing, the duties and responsibilities of each qualified consultant and supervisor and indicates which Laboratory Director duties have been delegated.<br>• Documents, in writing, the authorization of duties for each employee engaged in the pre-analytic, analytic and/or post-analytic phases of testing. |
| **Training** | Before employees handle or test patient specimens, they are required to have education, experience and documented training appropriate for the type and complexity of work performed. |
| **Competency** | • Quest Diagnostics assesses the competency of all personnel who conduct pre-analytic, analytic and post-analytic phases of testing.<br>• Competency is assessed and documented at least semi-annually during the first year of employment and annually thereafter. |
| **Job Descriptions** | All personnel involved in the pre-analytic, analytic and post-analytic phases of testing have written job descriptions. |

**Personnel continued:**

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| **Visual Color Discrimination** | • Employees performing technical duties which require full color discrimination are evaluated for color discrimination pertinent to the job assignment.<br>• Color discrimination impaired technical personnel have job assignments and responsibilities assigned accordingly. |
| **Performance and Development Review** | • Quest Diagnostics has a defined process for performance appraisals.<br>• Employees and managers collaborate on reviewing performance goals and accomplishments and identifying developmental needs.<br>• This annual process is documented. |
| **Continuing Education** | • Employees are encouraged to take an active role in their continued vocational or professional development.<br>• The company provides a comprehensive educational assistance program for those who seek further education.<br>• The company seeks to provide employees and workgroups with the knowledge and skills necessary to meet the requirements of current and future jobs.<br>• The company provides access to continuing education programs that assist in satisfying certification renewal requirements. |
| **Personnel Records** | • Each Quest Diagnostics facility maintains procedures so that personnel records are complete and current.<br>• Personnel records may be housed in the Human Resources department, the work area, or both.<br>• Personnel records are maintained in accordance with the requirements published in the Quest Diagnostics *Records Management Program Reference Guide.* |

# 9. Specimen Management

**Policy**

Specimens are collected, transported and processed under conditions that allow for positive specimen identification and maintenance of specimen integrity throughout the testing process.

**Specimen Collection**

- Each Quest Diagnostics facility in which specimens are collected has written procedures for:
  - Specimen collection, labeling and preservation
  - Ensuring patient identification at the time of specimen collection
  - Specimen packaging and transport
- Specific requirements for patient preparation, the type and amount of specimen to be collected, appropriate preservatives or anticoagulants, or other information on special handling, can be found in the Quest Diagnostics *Directory of Services*, in each Laboratory Information System (LIS) and on www.questdiagnostics.com.

**Availability of Instructions to Customers**

- Written instructions for patient preparation, specimen collection, labeling, preservation and conditions for specimen transport are made available to customers.
- If the specific information is not available in the Quest Diagnostics *Directory of Services*, the laboratory to which the customer refers specimens provides this information.

**Specimen Transport**

- Specimens are properly packaged and labeled for transport.
- Specimens are transported to the laboratory in a manner that maintains specimen integrity.

## Specimen Management continued:

**Specimen Receipt**

- Upon specimen receipt in the laboratory, the following information (when provided on the test request) is entered into the LIS at order entry:
  - Patient name or other identifier
  - Name and address of the ordering authorized individual
  - Name or identifying code of test(s) ordered
  - Patient age or date of birth
  - Patient sex
  - Date and time of specimen collection
  - Source of specimen
  - Relevant clinical information
- If one or more of the first three items is/are not provided, the specimen and test request are entered into the LIS with a special code to prompt investigation that will continue until the issue has been resolved.
- The patient name or other identifier on the test request is verified against the name or identifier on the specimen.

**Specimen Identity**

- Upon receipt in the laboratory, each specimen is identified by a unique specimen number (accession number) to maintain positive specimen identification throughout specimen handling, processing, testing and results reporting.
- A label with the unique specimen/accession number is affixed to the test request form, specimen container and all aliquot tubes.
- Whenever possible, an electronic identifier (bar code) is used as a unique identifier.

**Specimen Rejection**

- Each Quest Diagnostics laboratory has written procedures and criteria for the rejection and handling of unacceptable specimens or the special handling of suboptimal specimens.
- The disposition of unacceptable or sub-optimal specimens is documented on the patient report.
- There are general specimen rejection criteria as well as those that are specific to certain tests.
- Test specific rejection criteria are listed in the technical procedure.

## Specimen Management continued:

**Specimen Referral**

- Quest Diagnostics has a defined process for selecting and evaluating laboratories not affiliated with Quest Diagnostics to which testing is referred (referral laboratories).
- Referral laboratories must hold a valid Clinical Laboratory Improvement Amendments of 1988 (CLIA) certificate appropriate to the complexity of the specialties and subspecialties of testing being referred.
- Referral laboratories are chosen with the approval of local and/or national medical staff.
- Each laboratory keeps the original or exact copies of patient reports from outside referral sites.
- The name and address of the laboratory that performed the testing is included on final patient reports.

**Specimen Retention**

- Original specimens are retained, at a minimum, until testing is completed.
- Stored specimens are maintained in a manner that helps to ensure specimen integrity.

# 10. Standard Operating Procedures

**Policy**

- Written Standard Operating Procedures (SOPs) are available and required to be followed by all personnel involved in the pre-analytic, analytic and post-analytic phases of testing.
- Technical SOPs are written in accordance with Quest Diagnostics defined protocol.

**Standard Operating Procedure Content**

Technical SOPs contain the following elements, as applicable:

- Requirements for patient preparation
- Information regarding specimen collection, labeling, preservation, transportation, processing, storage and referral
- Criteria for specimen acceptability
- Directions for microscopic examination, including the detection of inadequately prepared slides
- Step-by-step instructions for the performance of the procedure, including test calculations and interpretation of results
- Directions for the preparation of reagents, calibrators, standards, controls, solutions, culture media, stains and other testing supplies
- Calibration and calibration verification procedures
- Reportable range
- Quality Control procedures
- Corrective action to be taken when calibration or control results fail to meet the laboratory's criteria for acceptability
- Limitations of the test methodology, including interfering substances
- Reference ranges
- Critical Values
- Pertinent literature references
- The laboratory's system for results entry, repeat testing and repeat criteria
- Reference regarding what action is to be taken if the test system becomes inoperable
- Safety requirements

**Review and Approval**

- New procedures and changes in procedures are approved, signed, and dated by the Laboratory Director before use.
- SOPs are reviewed and re-approved annually.
- The Laboratory Director may delegate the annual review to qualified staff where the delegation is documented in writing.
- SOPs are re-approved whenever there is a change in directorship.

## Standard Operating Procedures continued:

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| **Standard Format** | Quest Diagnostics has established standard formats for technical and non-technical SOPs, based on the format recommended in the most current version of the National Committee for Clinical Laboratory Standards (NCCLS) guideline "Clinical Laboratory Technical Procedure Manuals." |
| **SOP Review by Testing Personnel** | • All testing personnel are required to be knowledgeable of the contents of the SOPs relevant to the scope of their work.<br>• Documentation of the applicable training is maintained in employee training and competency files. |
| **Document Control** | • Each laboratory maintains a complete and current set of SOPs.<br>• Changes to SOPs occur in a systematic and controlled manner.<br>• SOPs are dated when put into use and dated when retired.<br>• In each laboratory, copies of retired SOPs are kept on file (paper or electronic) according to the requirements published in the Quest Diagnostics *Records Management Program Reference Guide.* |

# 11. Equipment

**Policy**

Quest Diagnostics maintains equipment in a manner appropriate to the proper collection, handling, preparation, testing and storage of specimens and generation of test results and patient reports.

**Definitions**

An instrument is a piece of equipment that is used for the purposes of analysis or measurement.

**Installation**

- Equipment is installed according to manufacturer's specifications.
- Equipment function is validated after installation and if the equipment is moved to another location.

**Function Checks**

- Function checks are performed to evaluate critical operating characteristics.
- For each type of equipment, written procedures specify the performance of function checks at required intervals.

**Tolerance Limits**

- Tolerance limits are established for each function and the acceptable range is documented in records stored near the instruments.
- When results exceed tolerance limits, documentation includes the corrective action taken.

**Preventive Maintenance Programs**

- Scheduled, routine Preventive Maintenance (PM) is performed to help prevent breakdowns or malfunctions, prolong the life of the equipment and maintain optimum operating characteristics.
- Additional repair work is performed as needed.

**Preventive Maintenance Procedures**

- The laboratory has written procedures for the PM of each instrument, device or test system, which meets or exceeds the manufacturer's specifications.
- When a service contract for PM from an outside vendor is used, there is a written description of the service to be performed and the frequency of service for each instrument.

**Equipment continued:**

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| **Frequency of Preventive Maintenance** | • Written procedures specify the schedule for routine PM, which at a minimum occurs at the frequency recommended by the manufacturer.<br>• Daily maintenance, as required, is performed before patient specimen testing. |
| **PM/Function Check Review** | PM records and function check documentation are routinely reviewed by a supervisor or supervisor designee. |
| **Temperature Dependent Equipment** | • Temperature dependent equipment is monitored and temperatures are recorded each day of use.<br>• When continuous monitoring is critical, recording thermometers and/or alarm systems are used. |
| **Thermometers** | Thermometers are checked against a standard thermometer of known accuracy [National Institute of Standards and Technology (NIST)-certified or guaranteed by the manufacturer to meet NIST standards]. |
| **Balances** | • Standard weights of the appropriate American National Standards Institute (ANSI)/American Society for Testing and Materials (ASTM) Class are used for checking the accuracy of analytical balances.<br>• Each balance is checked for accuracy consistent with its use. |
| **Timers** | Mechanical timers are checked semi-annually for accuracy or more frequently per department procedure. |
| **pH Meters** | pH meters are calibrated each day of use. |

**Equipment continued:**

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| **Centrifuges** | • Centrifuges used in testing procedures are calibrated at least every six months at each speed of intended use or as defined by the manufacturer.<br>• General use centrifuges (e.g., for specimen preparation) are calibrated at least annually at each speed of intended use or as defined by the manufacturer.<br>• Centrifuges are required to be kept clean by way of decontamination procedures.<br>• Tachometers (used to verify the speed of the centrifuges) are maintained and calibrated according to manufacturer specification. |
| **Pipettes/ Dilutors** | • Pipetting and diluting devices of all types (e.g., fixed volume, adjustable, autodilutors) are checked for accuracy, precision and carryover before being placed into service.<br>• Instruments that perform simultaneous fluid delivery into multi-well plates or tubes are checked for uniform delivery of reagents or solutions.<br>• Pipette calibration is performed at least quarterly, unless precision requirements of the assay indicate that more frequent evaluation is necessary. |
| **Spectro-photometers** | • Spectrophotometers are checked for absorbance, linearity, wavelength calibration and stray light at least annually or as recommended by the manufacturer.<br>• Filters are maintained in good condition, clean, and free of scratches. |
| **Gamma/ Scintillation Counters** | • Background counts for radioactivity counters are performed each day of use, including the background in each well of a multi-well counter.<br>• All gamma/scintillation counters are checked each day of use for counting efficiency using a sealed radioactive source. |
| **Densitometers** | Routine checks for linearity and precision are performed according to manufacturer specification or more frequently per departmental procedure. |

## Equipment continued:

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| **Autoclaves** | • Autoclaves have temperature and pressure gauges that are monitored for control of sterilization.<br>• The operating effectiveness of autoclaves is verified for each load using a chemical indicator.<br>• Autoclaves are checked weekly with a biological control. |
| **Microscopes** | • Microscopes are cleaned and serviced at regular intervals consistent with the degree of use, but no less frequently than annually.<br>• Ocular micrometers are calibrated for the microscopes with which they are used.<br>• Recalibration of ocular micrometers is performed whenever eyepieces or objectives are changed. |
| **Glassware** | Each laboratory has documented procedures for glassware handling and washing, including methods of testing for detergent removal. |
| **Room Temperature and Humidity** | • Each laboratory has an established system for monitoring room temperature and humidity in areas in which:<br>  • Temperature/humidity sensitive equipment, reagents and specimens are stored<br>  • Testing procedures that are sensitive to fluctuations in room temperature and/or humidity are performed<br>• If the operating temperature or humidity is not within established limits, corrective action is taken and documented. |
| **Equipment Records** | • Records of function checks, PM, service and repair are maintained for each piece of equipment. Any maintenance performed by the manufacturer or service contractor is also documented.<br>• Function checks are documented in a manner that allows for the detection of trends or malfunctions.<br>• Equipment records are maintained in accordance with the requirements published in the Quest Diagnostics *Records Management Program Reference Guide.* |

# 12. Reagents

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| **Policy** | All reagents, calibrators, standards, controls, solutions, culture media, stains and other testing supplies are required to be labeled, stored and handled according to defined procedures, including being checked for acceptability prior to or concurrent with being placed into service. |
| **Reagent Preparation** | Written procedures are available and required to be followed by personnel who prepare reagents. |
| **Reagent Specifications** | • As necessary, procedures contain specifications such as supplier and catalog number, storage and handling instructions (including temperature and humidity requirements), precautions and other information necessary for handling or preparing reagents.<br>• Purchased chemicals used to prepare reagents are of American Chemical Society (ACS)-grade quality (or higher quality if required). |
| **Periods of Use** | • Outdated reagents are not used. Stability may only be extended by the manufacturer via written documentation.<br>• Contaminated or deteriorated reagents or other testing supplies are discarded regardless of expiration date. |
| **Reagent Kit Components** | Components of a reagent kit are not interchanged with like components from kits with different lot numbers, unless otherwise specified by the manufacturer. |

## Reagents continued:

**Reagent Labeling**

- Reagents and other testing supplies are labeled with the date of receipt (or an internal identification number) to differentiate between shipments of product with the same manufacturer's lot number.
- Additional information necessary to meet the minimum labeling requirements are:
  - Identity/description
  - Titer, strength or concentration, if applicable
  - Expiration date
  - Storage requirements
  - Date prepared or received
  - Initials of employee opening or preparing the reagent
  - Date placed into service
  - Safety hazard information, if applicable
  - Other pertinent information, such as precautions for use

**Reagent Verification**

- Written procedures specify the verification of each new batch, lot or shipment of reagent.
- Methods of reagent verification include:
  - Direct analysis with reference materials
  - Parallel testing of old vs. new lots of reagent
  - Checking against routine controls
- The results of verification testing are documented.
- Only those reagents that conform to established specifications are released for use.

**Package Inserts**

- All versions and updates of manufacturer package inserts are reviewed for changes.
- Current versions of package inserts for reagents/testing materials are available in the laboratory.
- Manufacturer assay information sheets for control and calibration materials are kept on file, in accordance with the Quality Control records requirements published in the Quest Diagnostics *Records Management Program Reference Guide.*

## Reagents continued:

**Microbiological Media**

- Each new batch or shipment of microbiological media is checked for:
  - Acceptable appearance (visual check)
  - Sterility (when labeled sterile)
  - The ability to support growth
  - Selectivity/inhibition and/or biochemical response (as appropriate)
- For certain media where the manufacturer has used QC checks that meet the National Committee for Clinical Laboratory Standards (NCCLS) guidelines for media Quality Control, laboratory staff document the physical characteristics of the media upon arrival and accept the manufacturer's control data. Any deterioration in the media is reported to the manufacturer.

**Water Quality**

- Each laboratory determines the NCCLS grade of water (Type I, Type II or Type III) necessary for each procedure and has a system for delivering adequate volumes of the required grade of water.
- Each laboratory that produces Type I water has a procedure and schedule for routine water production equipment maintenance and water quality testing.

**Reagent Storage**

- Reagents and other testing supplies are stored per manufacturer recommendations.
- Pure controlled substances (used as reagents) are secured, with limited access by laboratory personnel.
- Hazardous chemicals are stored according to standards determined by the Corporate Environmental Health and Safety department in compliance with federal, state and local regulations.

**Reagent Records**

Reagent records are maintained in accordance with the requirements published in the Quest Diagnostics *Records Management Program Reference Guide.*

# 13. Method Evaluation/Validation and Calibration

**Policy**

- Before a new test method or significant test modification is placed into service and test results are reported, test performance is evaluated and validated under routine laboratory conditions.
- Analytical instruments are calibrated when first installed and calibration is verified at regular intervals thereafter.
- For tests that are performed using different methodologies, on multiple instruments or at multiple sites, laboratory staff evaluate and define the relationship between the sets of test results.

**Definitions**

- Primary Evaluation is the initial, comprehensive study required to establish or verify the performance characteristics of a new test or test method.
  - When a new test or test method is to be standardized and implemented throughout Quest Diagnostics, a Primary Evaluation is performed under the direction of the corporate Technical Standards and Processes (TS&P) department.
  - For non-standard methods, staff in each laboratory adopting the new method are responsible for performing their own Primary Evaluation.
- Laboratory Validation is a confirmatory process performed at each site (except for the site that performed the Primary Evaluation, where local validation would be redundant) to help ensure that each site can achieve the expected accuracy, precision and reportable range of the new test or test method, as determined by the Primary Evaluation, and that the reference ranges are appropriate for the laboratory's patient population.
- Analytical Measurement Range (AMR) is the range of analyte concentration that can be measured with an undiluted specimen.
- Clinically Reportable Range (CRR) is the range of analyte concentration that can be measured beyond the AMR by diluting the specimen.
- Calibration is the initial process of adjusting an instrument or test system to achieve a known relationship between the measurement response and the concentration of the substance that is being measured.
- Calibration Verification is the process of assaying materials of known concentration in the same manner as patient specimens to substantiate the instrument or test system's calibration throughout the AMR for patient results.

## Method Evaluation/Validation and Calibration continued:

**Authorization**

- For Quest Diagnostics standard methods or test systems, approval of Primary Evaluation results by TS&P and other corporate staff is required.
- At the local level, the Laboratory Director approves the Laboratory Validation (or the Primary Evaluation, if performed locally) for all new tests/methods and changes to existing tests/methods.

**Test Performance Characteristics**

Test performance characteristics that are included in a Primary Evaluation/Laboratory Validation varies among quantitative, semi-quantitative and qualitative types of assays. The following specifications are established and/or verified, as applicable:

- Accuracy*
- Precision (including allowable total error, as applicable)*
- Analytic sensitivity
- Analytic specificity (including the effect of interfering substances)
- Analytical Measurement Range*
- Clinically Reportable Range
- Calibration procedure
- Quality Control procedure
- Allowable reagent lot to lot variability
- Instrument carryover
- Specimen stability
- Reference range verification*
- Critical Values

*Minimum requirements for Laboratory Validation of an unmodified, FDA cleared/approved test system

**Frequency of Calibration**

- Calibration is performed at intervals specified by the manufacturer or more frequently as determined by the laboratory.
- Calibration frequency is defined in each technical procedure.

## Method Evaluation/Validation and Calibration continued:

| | |
|---|---|
| **Frequency of Calibration Verification** | Calibration verification is performed:<br>• When there is a change in reagent lot number, unless it can be demonstrated that changing reagent lot numbers does not affect the reportable range and that QC results are not affected<br>• When there is major Preventive Maintenance or replacement of a critical instrument part that may affect test performance<br>• When QC results reflect an unusual trend or shift and other avenues of identifying and correcting the problem have not been successful<br>• At least every six months or more frequently if recommended by the manufacturer or according to the laboratory's established schedule |
| **Method and Instrument Comparison** | • Each laboratory has defined procedures to evaluate and define the relationship of test results when testing is performed on multiple instruments, using different methodologies or at multiple testing sites.<br>• Instrument and method comparisons are performed and documented at least every six months.<br>• When possible, patient specimens are used for comparison studies in order to avoid possible matrix effects. |
| **Corrective Action** | Corrective actions are taken and documented when calibration checks or method and instrument comparison checks exceed defined tolerance limits. |
| **Method Evaluation/ Validation and Calibration Records** | • Primary Evaluation, Laboratory Validation and calibration documentation is maintained in accordance with the requirements published in the Quest Diagnostics *Records Management Program Reference Guide*.<br>• For Primary Evaluations, the data remains at the Primary Evaluation site.<br>• For test methods or systems that are standardized, the Primary Evaluation data are housed and provided to all testing sites by TS&P.<br>• Laboratory Validation documentation is retained locally.<br>• All calibration, calibration verification and method and instrument comparison results are documented and retained locally. |

# 14. Laboratory Information System

| | |
|---|---|
| **Policy** | The Laboratory Information System (LIS) is established and maintained so that patient/testing data are secure, accurate and reliable. |
| **Environment** | The LIS is maintained in a secure, clean and adequately ventilated environment with protection against electrical power fluctuations. |
| **LIS Procedure Manuals** | Written procedures are maintained for the:<br>• Operation of computer equipment<br>• Preservation of data and equipment<br>• Use of LIS functions, as appropriate, for each authorized user |
| **System Security** | There are written procedures to help ensure that:<br>• Major computer programs are protected to prevent destruction or unauthorized alteration<br>• Only authorized personnel can enter or access patient/testing data |
| **Data Retrieval and Storage** | The LIS has capacity for:<br>• Storing sufficient amounts of data to meet the regulatory and patient care needs of Quest Diagnostics<br>• Providing a complete copy of archived patient results, including original reference intervals and interpretive comments |
| **Hardware and Software Documentation** | Quest Diagnostics maintains the following documentation:<br>• Hardware maintenance records<br>• Written record of all systems modifications<br>• Testing procedures for proper program function prior to initial implementation or subsequent changes<br>• Documentation of responses to error messages<br>• Approval for all changes, additions and deletions in programs, the test library and major computer functions |

## Laboratory Information System continued:

| | |
|---|---|
| **System Maintenance Documentation** | LIS maintenance records include:<br>• Reasons and corrective action taken for unscheduled downtime, system degradation or other computer problems<br>• All service and repair records |
| **Reporting Systems** | Each laboratory has adequate systems in place to report results in a timely, accurate and reliable manner. |
| **Report Format** | Each laboratory has a process for the annual review/approval by the Laboratory Director of patient report content and format. |
| **Report Accuracy** | • There are systems in place which aid in detecting clerical errors, analytical errors and unusual test results.<br>• These systems allow for the timely correction of errors.<br>• Manual and automated result entries are verified before final acceptance and reporting by the LIS.<br>• Where the laboratory employs auto-verification procedures for test results, there is documentation of validation of the process and Laboratory Director approval. |
| **Verification of Result Transmission** | LIS departments and technical departments are responsible for providing and implementing a written procedure to periodically verify that test results are accurately transmitted from the point of data entry (interfaced instruments and manual input) to all types of patient reports (both paper and electronic displays). |
| **Verification of Computer Calculations** | • Calculation routines are verified at least annually and after any changes to the database.<br>• The verification may be performed by staff in the department where the calculation is applied or by other designated individuals. |

# 15. Documentation

**Policy**

- Only controlled documents are used to describe and implement policies, processes and procedures.
- All steps in the pre-analytic, analytic and post-analytic phases of testing are documented.
- Records are generated, reviewed, and retained in accordance with regulatory, accreditation and corporate requirements.

**Responsibility**

Managers and supervisors are responsible for:

- Ensuring that personnel have current copies of the documents they need to perform their work
- Promptly removing outdated documents from the workplace
- Complying with the Quest Diagnostics *Records Management Program Reference Guide.*

**Document Types**

Four types of documents are used in the clinical laboratory:

| Type | Description |
|---|---|
| Quality policies and other policy documents | Statement of the policies in place to satisfy quality and other requirements |
| Process documents | Descriptions of what is done to meet the policy requirements |
| Standard operating procedures | Detailed work instructions that outline how processes are to be implemented |
| Forms and records | • Forms are used to capture data or information resulting from procedures being carried out.<br>• A form on which data has been recorded becomes a record. |

**Documentation continued:**

| | |
|---|---|
| **Testing Personnel Documentation** | • Records reflect the identification of the personnel performing essential steps in the testing and results release process, including:<br>  • Test set-up<br>  • Test performance<br>  • Results data entry<br>  • Results review and verification<br>  • Results release<br>• Initials, signatures and/or personnel identification codes are used in the documentation process. |
| **Results Verification and Release** | • Each laboratory has written procedures describing the steps involved in results verification and release.<br>• These procedures support the timely detection of:<br>  • Clerical errors<br>  • Analytical errors<br>  • Unexpected test results |
| **Test Records** | Test records are maintained in accordance with the requirements published in the Quest Diagnostics *Records Management Program Reference Guide.* |
| **Documentation Technique** | Appropriate documentation technique is used for records when data/information is:<br>• Recorded<br>• Voided<br>• Changed |
| **Records Review** | • Managers and supervisors review records according to established schedules.<br>• Records review is documented. |

**Documentation continued:**

| | |
|---|---|
| **Document Availability and Storage** | Controlled copies of documents are:<br>• Available to personnel as required<br>• Stored in such a manner that integrity is maintained and retrieval is facilitated<br>• Retained according to the Quest Diagnostics *Records Management Program Reference Guide* |

# 16. Communications

**Policy**

- Quest Diagnostics has systems and processes for effective internal and external communications.
- The confidentiality of all patient related information is maintained in accordance with Health Insurance Portability and Accountability Act (HIPAA) guidelines.

**Test Orders**

- Tests are performed only per documented orders from licensed physicians or other authorized individuals.
- Written authorization is requested for all tests ordered verbally (e.g., by telephone).
- Test request records are retained according to the Quest Diagnostics *Records Management Program Reference Guide.*
- Test request forms must include, at a minimum, the following information for processing the order:
  - Patient name or other identifier
  - Name and address of the ordering authorized individual
  - Name or identifying code of test(s) ordered

**Directory of Services**

The Quest Diagnostics *Directory of Services* (in print and also available electronically), provides the basic information needed by customers ordering tests, including:

- Patient preparation (if required)
- Specimen requirements
- Specimen collection instructions
- Test names
- Order codes
- Specimen transport information

## Communications continued:

**Patient Reports**

- The patient report is confidential and sent only to a licensed physician or other authorized individual(s).
- The patient report contains, at a minimum, the following information:
  - Unique specimen/accession number
  - Patient name or other identifier
  - Patient age/date of birth and sex (when provided)
  - Date of specimen collection and time of collection (when provided)
  - Date of receipt of the specimen in the laboratory
  - Date of the report
  - Test name
  - Test result and unit of measure
  - Reference range, if available
  - Explanatory or qualifying messages, when applicable
  - Name and address of the laboratory performing the test
  - Customer account number or equivalent

**Timely Reporting**

- Patient reports are sent to the authorized individual or laboratory requesting the test(s).
- Procedures are available that outline the actions to be taken if timely reporting of test results cannot occur.
- If the laboratory cannot report test results within its established time frame, it will, depending on the length of the delay and/or the clinical urgency of receiving the requested test result, notify the ordering authorized individual/laboratory of the delay in reporting.

**Critical Values**

- Quest Diagnostics has developed and follows written procedures for reporting Critical Values.
- Critical Values are promptly communicated to the ordering authorized individual/laboratory.
- Each laboratory maintains documentation of these communications.

**Unacceptable Specimens**

Information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability is indicated on the patient report.

**Communications continued:**

| | |
|---|---|
| **Test Methods and Changes** | • The laboratory will make information on test methods, performance specifications, and test interferences available to customers upon request.<br>• When the laboratory changes an analytical method, such that test results or their interpretations may be significantly affected, the change is communicated to customers. |
| **Revised Reports** | • In the event that a reported test result needs to be revised, the customer is promptly contacted with the new result.<br>• The change in results is clearly indicated on the revised report.<br>• Quest Diagnostics has a standard procedure whereby each laboratory tracks the number and type/cause of revised reports. |
| **Customer Complaints and Problems** | • Complaints and problems reported to the laboratory are documented. Investigations of complaints are made and, as necessary, corrective actions are taken.<br>• Each laboratory has a system in place to document problems that occur as a result of communications breakdowns with customers.<br>• Corrective actions are documented. |
| **Internal Communication** | Each laboratory has a system to communicate and document externally and internally identified problems. |
| **Government Agency Reporting** | Test results are released to government agencies as defined by state and local regulations. |

Quest Diagnostics®

## NICHOLS INSTITUTE, CHANTILLY, VIRGINIA

# QUALITY & PERFORMANCE

| Key Indicators | Target 2007 | 2006 Achieved | 2007 Achieved<br>December Inclusive |
|---|---|---|---|
| **Formally Evaluated CAP External Proficiency Testing**<br>DPMO non conformances | 7,000 DPMO | 12,370 DPMO | 5,607 DPMO |
| **Lost Specimens**<br>DPMO per # of accessions | 25 DPMO | 13 DPMO | 13 DPMO |
| **Turn-around Times**<br>DPMO non-conformance (missed TAT) | 100,000 DPMO | 113,622 DPMO | 122,729 DPMO |
| **Telephone Responsiveness-All departments**<br>% picked up in ≤ 30 seconds<br>% abandoned<br>Average wait time in seconds | 90%<br>4%<br>15 seconds | 93%<br>4%<br>8.7 seconds | 90 %<br>4 %<br>10.9 seconds |
| **Revised Reports**<br># revised in DPMO accessions | 200 DPMO | 185 DPMO | 121 DPMO |

DPMO - Defects Per Million Opportunities

3/21/2008

| Chantilly Test Code | Seq | Chantilly Test Description | Vendor Test Description | Chantilly Place of Service |
|---|---|---|---|---|
| 333 | 1 | ACETAMINOPHEN | Acetaminophen | Nichols Institute - Chantilly |
| 104 | 2 | ACID-FAST BACILLI CULTUREPROGRESSIVE | AFB cu | Nichols Institute - Chantilly |
| 890 | 3 | AMITRIPTYLINE | Amitriptyline (Elavil) serum | Nichols Institute - Chantilly |
| 55098 | 4 | AMMONIA, (P) | Ammonia, Plasma | Nichols Institute - Chantilly |
| 27 | 5 | AMYLASE, SERUM | Amylase, Serum | Nichols Institute - Chantilly |
| 18137 | 6 | ANACHOICE(TM)SCREEN W/REFLEX TO TITER, IFA | Antinuclear antibodies (ANA) | Nichols Institute - Chantilly |
| 6470 | 7 | THROAT CULTURE BETA STREPGROUP A ONLY | Beta-Hemolytic Strep A | Nichols Institute - Chantilly |
| 47 | 8 | BILIRUBIN, TOTAL | Bilirubin Total | Nichols Institute - Chantilly |
| 46 | 9 | BILIRUBIN, TOTAL + DIRECT & INDRECT, SERUM | Bilirubin, Total/Direct, serum | Nichols Institute - Chantilly |
| 329 | 10 | UREA NITROGEN (BUN) | BUN | Nichols Institute - Chantilly |
| 500 | 11 | CLOSTRIDIUM DIFFICILETOXINS A & B | C. diff. Toxin A | Nichols Institute - Chantilly |
| 65 | 12 | C-REACTIVE PROTEIN SCREEN | C-Reactive Protein | Nichols Institute - Chantilly |
| 425 | 13 | CALCIUM, TOTAL | Calcium, serum | Nichols Institute - Chantilly |
| 393 | 14 | CARBAMAZEPINE | Carbamazepine (Tegretol) | Nichols Institute - Chantilly |
| 74 | 15 | CBC WITH DIFFERENTIAL | CBC w/diff-platelet | Nichols Institute - Chantilly |
| 581 | 16 | CHLORPROMAZINE | Chlorpromazine, (Thorazine) | NMS |
| 2040 | 17 | CLOMIPRAMINE | Clomipramine (Anafranil) s. | Nichols Institute - Chantilly |
| 15687 | 18 | CLOZAPINE(CLOZARIL) | Clozapine (clozaril) serum | Nichols Institute - Chantilly |
| 112818 | 19 | CORTISOL,TOTAL,LC/MS/MS | Cortisol serum/plasma | Nichols Institute - SJC |
| 642 | 20 | CK (CPK) ISOENZYMES, SERUM | Creatinine Kinase (CK) MB/Total | Nichols Institute - Chantilly |
| 99 | 21 | CREATINE KINASE (CK) | Creatinie Kinase, serum | Nichols Institute - Chantilly |
| 97 | 22 | CREATININE WITH eGFR | Creatinine, Serum | Nichols Institute - Chantilly |
| 893 | 23 | DESIPRAMINE | Desipramine, serum | Nichols Institute - Chantilly |
| 659 | 24 | DIGITOXIN | Digoxin (Lanoxin) | Nichols Institute - Chantilly |
| 2803 | 25 | ESTROGENS, TOTAL | Estrogen | Nichols Institute - Chantilly |
| 44389 | 26 | ETHANOL | Ethanol serum/blood | Nichols Institute - Chantilly |
| 385 | 27 | ETHOSUXIMIDE | Ethosuximide (Zarontin) serum | Nichols Institute - Chantilly |
| 859 | 28 | FERRITIN | Ferritin | Nichols Institute - Chantilly |
| 2540 | 29 | FLUOXETINE | Fluoxetine (Prozac) serum | Nichols Institute - SJC |
| 265 | 30 | FOLIC ACID | Folates (Folic Acid) | Nichols Institute - Chantilly |
| 5220 | 31 | GABAPENTIN | Gabapentin (Neurotin) serum | Nichols Institute - Chantilly |
| 5220 | 32 | GABAPENTIN | Gabritril serum | Nichols Institute - Chantilly |
| 148 | 33 | GLUCOSE | Glucose, 2hr P.P. | Nichols Institute - Chantilly |
| 148 | 34 | GLUCOSE | Glucose serum | Nichols Institute - Chantilly |
| 148 | 35 | GLUCOSE | Glucose plasma | Nichols Institute - Chantilly |
| 5310 | 36 | THIN PREP, PAP SMEAR | Gynecologic Mono-Layer PAP | Nichols Institute - Chantilly |
| 670 | 37 | HALOPERIDOL | Haloperidol serum | Nichols Institute - SJC |
| 25 | 38 | GLYCOHEMOGLOBIN, HBA1C | Hemoglobin A1C | Nichols Institute - Chantilly |
| 235 | 39 | HCG, QL, URINE | HCG Beta subunity, Qual (s) | Nichols Institute - Chantilly |
| 3341 | 40 | HELICOBACTER PYLORI ANTIBODY (IGG) | Heliobacter Pylori, Igg | Nichols Institute - Chantilly |
| 2068 | 41 | T CELLS, HELPER/INDUCER SUBSET | helper T-Lymph-CD4 | Nichols Institute - Chantilly |
| 1003 | 42 | HEPATITIS A (IGM),ACUTESTATUS | Hepatitis A AB Igm | Nichols Institute - Chantilly |
| 1002 | 43 | HEPATITIS A TOTAL AB,IMMUNE STATUS | Hepatitis A AB, Total | Nichols Institute - Chantilly |
| 718 | 44 | HEPATITIS B SURF AB QL | Hepatitis B Surface AB | Nichols Institute - Chantilly |
| 453 | 45 | HEPATITIS B SURFACEANTIGEN (HBsAG) | Hepatitis B Surface Ag | Nichols Institute - Chantilly |
| 4628 | 46 | HEPATITIS A,B & C PANEL | Hepatitis Panel-A,B,C | Nichols Institute - Chantilly |
| 892 | 47 | IMIPRAMINE, QUANT. (INCLUDES DESIPRAMINE) | Imipramine (tofranil) serum | Nichols Institute - Chantilly |
| 805 | 48 | IRON, URINE | Iron | Nichols Institute - Chantilly |
| 175 | 49 | IRON AND IRON-BINDING CAPACITY | Iron/TIBC | Nichols Institute - Chantilly |
| 5896 | 50 | LAMOTRIGINE | Lamotrigine (Lomictal) serum | Nichols Institute - Chantilly |
| 186 | 51 | LEAD, BLOOD(S.A. 14394) | Lead (Adult) blood | Nichols Institute - Chantilly |
| 1350 | 52 | FSH & LH | LH & LSH | Nichols Institute - Chantilly |
| 187 | 53 | LIPASE | Lipase serum | Nichols Institute - Chantilly |
| 466 | 54 | LITHIUM | Lithium | Nichols Institute - Chantilly |
| 1961 | 55 | LIPOPROTEIN ELECTROPHORESIS | LP Lipo El | Nichols Institute - Chantilly |
| 195 | 56 | MAGNESIUM | magnesium, serum | Nichols Institute - Chantilly |
| 2687 | 57 | MICROALBUMIN | Microalbumin, 24 hour urine | Nichols Institute - Chantilly |
| 2687 | 58 | MICROALBUMIN | Microalbumin, Random urine | Nichols Institute - Chantilly |
| 891 | 59 | NORTRIPTYLINE | Nortriptyline (Aventyl) Serum | Nichols Institute - Chantilly |
| 2364 | 60 | OCCULT BLOOD, STOOL3 SPECIMENS | Occult Blood (Stool) | Nichols Institute - Chantilly |
| 432 | 61 | OSMOLALITY | Osmolality serum | Nichols Institute - Chantilly |
| 2243 | 62 | OSMOLALITY, URINE | Osmolatity, urine | Nichols Institute - Chantilly |
| 212 | 63 | OVA AND PARASITES | Ova and Parasite | Nichols Institute - Chantilly |
| 1989 | 64 | PERPHENAZINE(NMS TC-3440) | Perphenazine (Trilafon) | NMS |
| 214 | 65 | PHENOBARBITAL | Phenobarbital serum | Nichols Institute - Chantilly |
| 56 | 66 | PHENYTOIN | Phenytoin (Dialantin) | Nichols Institute - Chantilly |
| 222 | 67 | PHOSPHATE (AS PHOSPHORUS) | Phosphorus | Nichols Institute - Chantilly |
| 231 | 68 | POTASSIUM | Potassium, serum | Nichols Institute - Chantilly |
| 730 | 69 | HCG,TOTAL,QN | Pregnancy Serum | Nichols Institute - Chantilly |
| 235 | 70 | HCG, QL, URINE | Pregnancy Test (Urine) | Nichols Institute - Chantilly |
| 4075 | 71 | PRIMIDONE | Preimidone (Mysoline) | Nichols Institute - Chantilly |
| 245 | 72 | PROLACTIN (PRL) | Prolactin | Nichols Institute - Chantilly |
| 1054 | 73 | PROSTATE SPECIFIC ANTIGEN TOTAL | Prostate-specific AG, Serum | Nichols Institute - Chantilly |
| 237 | 74 | PROTEIN, TOTAL | Protein serum | Nichols Institute - Chantilly |
| 241 | 75 | PROTHROMBIN TIME (PT) | Prothrombin time | Nichols Institute - Chantilly |
| 213+241 | 76 | PT & PTT | PT & PTT | Nichols Institute - Chantilly |
| 251 | 77 | RETICULOCYTE COUNT | Reticulocyte count | Nichols Institute - Chantilly |
| 8316 | 78 | HIV 1 RNA QN PCR V1.5 | RNA-PCR-Quant | Nichols Institute - Chantilly |
| 2377 | 79 | RPR, PROGRESSIVE | STS | Nichols Institute - Chantilly |
| 259 | 80 | SEDIMENTATION RATE, RBC | Sedimentation rate | Nichols Institute - Chantilly |
| 271 | 81 | SODIUM | Sodium serum | Nichols Institute - Chantilly |

| Chantilly Test Code | Seq | Chantilly Test Description | Vendor Test Description | Chantilly Place of Service |
|---|---|---|---|---|
| 248 | 82 | T3 UPTAKE | T3-uptake | Nichols Institute - Chantilly |
| 634 | 83 | T-4 (THYROXINE), TOTAL | T4 | Nichols Institute - Chantilly |
| 18094 | 84 | T CELLS CD3 | T-Cell (T-Lymphocyte CD3 Cells) | Nichols Institute - Chantilly |
| 15983 | 85 | TESTOSTERONE,TOTAL LC/MS/MS | Testosterone Serum | Nichols Institute - Chantilly |
| 631 | 86 | THEOPHYLLINE | Theophylline Serum | Nichols Institute - Chantilly |
| 8761 | 87 | TOPIRAMATE (TOPAMAX) | Topiramate (Topamax) serum | Nichols Institute - Chantilly |
| 62 | 88 | FTA-ABS | T-Pallidum Ab (FTA-Ab) | Nichols Institute - Chantilly |
| 297 | 89 | TREPONEMA PALLIDIUM AB(TP-PA) | T-Pallidum Antibodies (TP-PA) | Nichols Institute - Chantilly |
| 321 | 90 | TRIGLYCERIDES | Triglycerides | Nichols Institute - Chantilly |
| 6229 | 91 | TSH,3RD GENERATION | TSH | Nichols Institute - Chantilly |
| 6229 | 92 | TSH,3RD GENERATION | TSH 3rd Generation | Nichols Institute - Chantilly |
| 2542 | 93 | URINALYSIS, COMPLETE, W/REFLEX TO CULTURE | UA Culture reflex | Nichols Institute - Chantilly |
| 665 | 94 | CULTURE,URINE,ROUTINE | Culture reflex @ additional cost | Nichols Institute - Chantilly |
| 331 | 95 | URIC ACID | Uric Acid | Nichols Institute - Chantilly |
| 564 | 96 | URINALYSIS, CHEMICAL WITH MICROSCOPIC EXAMINA | Urinalysis, Complete | Nichols Institute - Chantilly |
| 712 | 97 | VALPROIC ACID | Valporic acid serum | Nichols Institute - Chantilly |
| 2306 | 98 | VARICELLA-ZOSTER VIRUSIGG ANTIBODY | Varicella Zoster IGG | Nichols Institute - Chantilly |
| 264 | 99 | VITAMIN B12 | Vitamin B-12 | Nichols Institute - Chantilly |
| 264 | 99 | VITAMIN B12 | | Nichols Institute - Chantilly |
| 278 | 100 | VITAMIN B12 AND FOLIC ACID | Vitamin B-12 and Folates | Nichols Institute - Chantilly |
| 737 | 101 | HEALTH PROFILE #1 | Diagnostic Multi-Chem (28 tests) | Nichols Institute - Chantilly |
| 792 | 102 | HYPOTHYROID GROUP | Thyroid Profiles Includes: (4 Tests) | Nichols Institute - Chantilly |
| 610 | 103 | ELECTROLYTES, URINE | Electrolyte Panel Includes: (3 Tests) | Nichols Institute - Chantilly |
| 13210 | | UNCONFIRMED DRG PROF #58URINE | Drug Abuse Screen (7) Urine, w/o confirmaton | Nichols Institute - Chantilly |
| 11209+80+221+ 587 | 104 | HFP7 & 3 AC | HFP7 & 3 AC | Nichols Institute - Chantilly |
| 37 | 105 | LIPID PANEL | Lipid Profile Four Includes: (3 Tests) | Nichols Institute - Chantilly |
| 2991 | 106 | TOXICOLOGY SCREEN, BLOOD, SERUM OR PLASMA | Drug Abuse Screen, Total-w/o Confirmation | Nichols Institute - Chantilly |
| 5594 | | RESPIRATORY CULTURE | Lower Respiratory Culture | Nichols Institute - Chantilly |
| 5594 | | RESPIRATORY CULTURE | Upper Respiratory Culture | Nichols Institute - Chantilly |
| 663 | | WOUND CULTURE(ABSCESS OROTHER SITES | General Bacterial Culture | Nichols Institute - Chantilly |
| 103 | | BLOOD CULTURE | Blood Culture | Nichols Institute - Chantilly |
| 664 | | CULTURE,FECES | Stool Culture | Nichols Institute - Chantilly |
| 665 | | CULTURE,URINE,ROUTINE | Urine Culture | Nichols Institute - Chantilly |
| 14205 | | SPUTUM CULTURE | Sputum Culture | Nichols Institute - Chantilly |
| 261 | | ANTIBIOTIC SENSITIVITY(AEROBIC) | Sensitvity Organism | Nichols Institute - Chantilly |
| 599 | 108 | HEAVY METALS PANEL, BLOOD | Heavy Metal Profile (Blood) | Nichols Institute - Chantilly |
| 718+813 | 109 | Hepatitis Profile (Diagnostic follow up) | Hepatitis Profile (Diagnostic follow up) | Nichols Institute - Chantilly |
| 3165 | 110 | COMPREHENSIVE HBV & HCVPROFILE | Hepatitis Profile B & C | Nichols Institute - Chantilly |
| 925 | 111 | COMPREHENSIVE HAV & HBV PROFILE #2 | Hepatitis Profile A & B | Nichols Institute - Chantilly |
| 1004 | 112 | COMPREHENSIVE HAV PROFILE | Hepatitis A Profile | Nichols Institute - Chantilly |
| 973 | 113 | VIRAL HEPATITIS B PROFILE | Hepatitis B Profile | Nichols Institute - Chantilly |
| 3571 | 114 | HEPATITIS C VIRUS AB,EIA | Hepatitis C Virus Antibody | Nichols Institute - Chantilly |
| 148 | 115 | GLUCOSE | 4 hr. GTT | Nichols Institute - Chantilly |
| 5890 | 116 | ALBUMIN | Albumin | Nichols Institute - Chantilly |
| 142 | 117 | ALKALINE PHOSPHATASE FRACTIONATION | Alkaline phos panel | Nichols Institute - Chantilly |
| 319 | 118 | ALANINE AMINOTRANS-FERASE (ALT) | ALT | Nichols Institute - Chantilly |
| 320 | 119 | ASPARTATE AMINOTRANS-FERASE (AST) | ALT-SGOT | Nichols Institute - Chantilly |
| 319 | 120 | ALANINE AMINOTRANS-FERASE (ALT) | ALT-SGPT | Nichols Institute - Chantilly |
| 1990 | 121 | AMIODARONE | Amiodarone | Nichols Institute - Chantilly |
| 10939 | 122 | NEUTROPHIL CYTOPLASMIC ABSCREEN/REFLEX TO TI | ANC | Nichols Institute - SJC |
| 320 | 123 | ASPARTATE AMINOTRANS-FERASE (AST) | AST | Nichols Institute - Chantilly |
| 2413 | 124 | BASIC METABOLIC PANEL | Basic Metabolic Panel | Nichols Institute - Chantilly |
| 11206 | 125 | BASIC METABOLIC PANELW/E GFR | BMP | Nichols Institute - Chantilly |
| 2138 | 126 | CA 125 | CA125 | Nichols Institute - Chantilly |
| 10924 | 128 | VON WILLEBRAND FACTOR COLLEGEN BINDING ASSAY | CBA | Nichols Institute - SJC |
| 79 | 129 | CHLORIDE | Chloride | Nichols Institute - Chantilly |
| 80 | 130 | CHOLESTEROL, TOTAL | Cholesterol, Total | Nichols Institute - Chantilly |
| 8870 | 131 | COMPREHENSIVE METABOLIC PANEL | Comp metabolic panel 13 | Nichols Institute - Chantilly |
| 1491 | 132 | COMPREHENSIVE METABOLIC PANEL - 1999 | Comp metabolic panel 14 | Nichols Institute - Chantilly |
| 99 | 133 | CREATINE KINASE, TOTAL | CPK | Nichols Institute - Chantilly |
| 96 | 134 | CREATINE | Creatine | Nichols Institute - Chantilly |
| 712 | 135 | VALPROIC ACID | Depakote | Nichols Institute - Chantilly |
| 56 | 136 | PHENYTOIN | Dilantin | Nichols Institute - Chantilly |
| 634 | 137 | T-4 (THYROXINE), TOTAL | Free T4 | Nichols Institute - Chantilly |
| 494 | 138 | FSH, SERUM | FSH | Nichols Institute - Chantilly |
| 7092 | 139 | GENTAMICIN, SERUM | Gentamiacin | Nichols Institute - Chantilly |
| 587 | 140 | GAMMA GLUTAMYL TRANSFERASE (GGT) | GGT | Nichols Institute - Chantilly |
| 10249 | 141 | HEREDITARY HEMOCHROMATO-SIS DNA MUTATION AN | H&H | Nichols Institute - Chantilly |
| 157 | 142 | HEMATOCRIT | Hematocrit | Nichols Institute - Chantilly |
| 158 | 143 | HEMOGLOBIN | Hemoglobin | Nichols Institute - Chantilly |
| 841 | 144 | HERPES SIMPLEX VIRUS CULTURE | HSV Culture | Nichols Institute - Chantilly |
| 241 | 145 | PROTHROMBIN TIME (PT) | INR | Nichols Institute - Chantilly |
| 113 | 146 | LACTATE DEHYDROGENASE(LD) | Ldh | Nichols Institute - Chantilly |
| 11209 | 147 | HEPATIC FUNCTION - 2000 | LFT | Nichols Institute - Chantilly |
| 2084 | 148 | MUMPS AB IGG, EIA | Mumps IgG | Nichols Institute - Chantilly |
| 5310 | 149 | THIN PREP, PAP SMEAR | PAP | Nichols Institute - Chantilly |
| 15579 | 150 | PROBNP, N-TERMINAL(S.A. 14647) | Pro BNP | Nichols Institute - Chantilly |
| 17183 | 151 | PROGESTERONE LC/MS/MS | Progesterone | Nichols Institute - Chantilly |
| 14176 | 152 | INTACT PTH WITH CALCIUM | PTH (Intact) | Nichols Institute - Chantilly |
| 19867 | 153 | ANACHOICE(TM) RA PANEL | RA Panel | Nichols Institute - Chantilly |

| Chantilly Test Code | Seq | Chantilly Test Description | Vendor Test Description | Chantilly Place of Service |
|---|---|---|---|---|
| 11208 | 154 | RENAL FUNCTION PANELW/EGFR | Renal Panel | Nichols Institute - Chantilly |
| 2173 | 155 | MEASLES IGG AB (RUBEOLA) | Rubeola IGG | Nichols Institute - Chantilly |
| 393 | 157 | CARBAMAZEPINE | Tegratol | Nichols Institute - Chantilly |
| 1123 | 158 | 1,25-DIHYDROXYVITAMIN D | Vit. D, 1-125 Dihydroxy | Nichols Institute - Chantilly |
| 17306 | 159 | VITAMIN D,25-HYDROXY,LCMSMS | Vit. D, -25- hydroxyl | Nichols Institute - Chantilly |
| 2318 | 160 | WBC COUNT ONLY | WBC | Nichols Institute - Chantilly |

Quest Diagnostics

# Selection of Referral Laboratories

Quest Diagnostics has established a Referral Testing Service department that is responsible for all testing services not performed by Quest Diagnostics and to assist customers in the identification of testing site(s) for unusual or esoteric tests. To ensure quality and service of subcontracted labs, the Referral Testing Service department has developed high-level criteria based on quality of laboratory service, efficiency of service, and cost effectiveness. More specifically, the following information is gathered and reviewed before selecting a reference laboratory:

## Licensing and Certification

Quest Diagnostics WILL NOT contract with a laboratory unless that laboratory holds valid certificates and licenses covering all applicable testing performed and meets the following criteria:

- The laboratory must meet the licensure and certification standards that are compatible with the type of testing performed. The laboratory must provide a copy of a current CLIA or equivalent certificate of accreditation with documentation of specialty and subspecialty certifications.
- In those states that are CLIA exempt, the laboratory must hold and provide a copy of a state license or a state approval certificate.
- As applicable, the laboratory must demonstrate licensure to perform testing on specimens from other states.

## Quality of Laboratory Service

Any subcontracted laboratory must supply:

- Previous external inspection information.
- Data from External Proficiency testing.
- Information to support/describe its Quality Improvement program.
- Information describing the breadth of testing, including specimen requirements and reference ranges.
- Documentation that supports the employment of qualified testing personnel.

## Efficiency of Laboratory Service

Any subcontracted laboratory must:

- Supply information that supports its ability to meet turnaround times for request tests.
- Supply information that documents adequate reporting capability.
- Meet Quest Diagnostics' result reporting connectivity needs
- Supply information that demonstrates it can meet Quest Diagnostics' service standards