

Response to Bid Quotation

RFQ# DPS1041

Prepared For:

West Viriginia State Police

Offered by:

Cybergenetics Corp

Contact: Ria David cell: 412-901-9765

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May 25, 2010

Bid open: 5/25/10 Time: 1:30 PM RECEIVED

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LUMASING DIVISION STATE OF WV

Cybergenetics Expert System Bid Response

Cybergenetics TrueAllele® Technology is grouped into three main modules:

Analysis. The TrueAllele Analysis module transforms the raw sequencer data into quality-checked peaks for upload to the rule-based expert databanking system or the statistical casework system.

Databank. The high-throughput NDIS-approved TrueAllele Databank expert system processes convicted offender and reference samples. The system uses rules to separate data into 'Pass' and 'Edit/Reject' sets, organizing the data for efficient review.

Casework. TrueAllele Casework system is a statistical technology based on a detailed probabilistic modeling of the data. TrueAllele Casework infers genotypes up to probability, and reports the DNA match statistic as a likelihood ratio.

The three major tasks that this software must be able to perform are the following:

1. Accurately and efficiently evaluate convicted offender profiles, identify the samples which 'do not' meet the laboratory defined parameters and display the failed parameters, and allow for simple segregation of failed samples from passing samples and the export of passed samples in a CODIS accessible format.

The Databank module applies rules to quantitatively analyzed data, inferring genotypes for good data and flagging problematic data. The user interface displays the failed parameters for problematic data. The data is segregated both in the user interface and exported data files based on 'accept' or 'reject' (as well as 'edit'). Accepted data can be exported into a CODIS readable computer file format.

2. Perform quality control evaluations for every sample, offender, casework and controls generated or accepted by the laboratory and be able to display reports of the various quality checks.

The TrueAllele Analysis module checks the quality of the size standard tracking, allelic ladders, positive controls and negative controls. Analysis uses rules to flag problematic ladders and controls for a more detailed analyst review. The system records sample status (e.g., 'Pass' or 'Edit/Reject') in files. Analysis can generate and display reports showing its quality check results.

3. Evaluate casework samples both single source and mixtures, to assist the analyst in the interpretation of the sample DNA profile.

TrueAllele Casework can evaluate both single source and mixture DNA data. The system objectively infers genotypes using probability modeling and statistical search. Afterwards, the system compares inferred genotypes (e.g., evidence vs. suspect) to

determine the extent of match, reported quantitatively as a LR. These genotype and match results reside on a TrueAllele database, and are presented to an analyst in a Visual User Interface (VUIer™) software client program. To assist the analyst in their DNA interpretation, the VUIer provides text and graphical interfaces for key variables, such as genotypes, mixture weights, match strength and the original data.

The vendor must prove that their software was approved by NDIS as an expert system prior to 12/31/2009.

- The New York State Police have submitted and received approval for multiple NDIS the TrueAllele Databank validations on various STR kits and DNA sequencer platforms.
- The Massachusetts State Police submitted a TrueAllele Databank expert system validation for the ABI 3130XL sequencer and the ABI Identifiler kit, and received approval on 13-March-2008.
- The Maryland State Police submitted a developmental validation of their TrueAllele Databank expert system, which was approved in August 2008.

The software must be able to compare the run data generated from a specific run on a genetic analyzer to itself to identify possible cross contamination. The level of concordance (number of shared alleles) that is displayed must be a customizable parameter. The result of the comparison must be exportable in a report format.

The TrueAllele Databank identifies possible cross contamination by checking for duplicate samples, as well as comparing against staff profiles. The Databank system compares all of the samples on the plate to each other, and flags those that exceed the user-determined customizable number of matching alleles. These flagged samples are listed in a resulting tab-delimited duplicate check report file.

The software must be able to compare the run data generated on a genetic analyzer to a database of profiles that can be augmented as required meaning that all data of a similar type can be housed in a single database even if the analysis parameters which generated the DNA profile are not identical (e. g. analyst database, consumable contamination database). The level of concordance (number of shared alleles) that is displayed must be a customizable parameter. While not required, it is preferable that the software allow the databases to be populated by manual data entry as well as import from various genetic analyzer runs. The results of the comparison must be exportable in a report format.

The TrueAllele Casework database is capable of storing STR data generated from a variety of kits and analysis parameters. Inferred TrueAllele genotypes are automatically uploaded to this database. The Data module provides for manual profile database upload using text files. The level of match concordance is determined using the gold-standard LR match statistic. Comparison can be made between a set of evidence

genotypes and a set of suspect genotypes (e.g., within a case, or SDIS profiles). A user can customize the LR statistic by selecting a set of ethnic population databases, and by setting a coancestry coefficient value. The Report module enables DNA match comparison between any two genotype profiles, visually displays text and graphical results, and exports report files suitable for inclusion in a case folder or exhibiting in court.

The software must include customizable security that allows the administrator to define security levels for access to parameter settings, sample data or select software functionalities. The security settings must be easily identified and the administrator should be able to review an individual's access rights from a single screen.

TrueAllele Analysis, Databank and Casework all support multiple levels of customizable security. These allow an administrator to set permissions on levels ranging from specific case access to complete database access. The security settings for access rights can be set and reviewed on a single computer screen.

The software must be capable of tracing any changes to security definitions, analysis parameters and any overrides of system flags/rule firings as well as any edits to allele calls or artifact identification. The edit record should include identification by user name and event time, action taken, the original value and the changed value, if appropriate. The software must be password protected.

The TrueAllele Analysis and Databank systems maintain extensive computer log audit trails to record computer and human decisions. When users sign onto the system, their actions are recorded. The human readable log files are in computer readable form.

The Analysis software records all of an analyst's actions with a comprehensive audit trail. User interfaces require initial user log in. Log files record who performed what actions, and when. User allele call edits are recorded, along with the analyst who made the change.

All allele calls, edits, rule firings, data quality issues, system parameters, process timings, and other critical audit trail information is preserved in files. One optional feature helps ensure that all flagged allele calls are actually checked by the user, and records detailed audit files of this required review activity.

Casework data is protected by individual password protected user accounts.

The software must be able to compare samples identified as a positive control against a predefined profile(s) and flag that sample if the profile does not match or if other evaluation criteria are failed.

TrueAllele Analysis checks each positive control against the expected profile. The program flags positive controls that don't match the profile, or that exhibit other data artifacts.

The software must be able to evaluate ladders to determine if they are suitable for analysis purposes. This includes the correct identification of all manufacturer defined alleles and the correct identification of all the software defined artifacts.

TrueAllele Analysis applies four separate rules to flag allelic ladders that do not meet expected ladder quality standards. Ladders for all current Promega and Applied Biosystems kits are supported.

The software must be able to evaluate the samples identified as reagent controls and negative controls and flag the samples if any peaks or artifacts above the defined thresholds are identified.

TrueAllele Analysis uses a specific rule to check negative controls and reagent blanks for possible contamination, as defined by user-settable parameters.

The software must have the capacity to evaluate a single DNA profile generated by an Applied Biosystems genetic analyzer using manufacturer supplied collection softwares and at a minimum the criteria used in the ABI Genemapper 3.2 software as well as evaluate and identify stutter, -A and noise.

TrueAllele Databank has the capability of importing data from both GeneMapper® ID v.3.2 and v.3.2.1. TrueAllele Databank can also import data directly from the AB data collection software. The software can apply up to 27 specific rules that check for data artifacts and anomalies. These different data quality rules include checks for spikes, stutter, high n peak (-A), noise and failed samples. Moreover, the TrueAllele Casework system models stutter and other variables as part of its statistical inference process.

The software must be able to segregate samples that have passed all evaluation criteria from those samples that did not pass in a manner that allows the analyst to bypass the problem free samples completely if desired.

The TrueAllele Databank expert system separates the data into 'Pass' and sorted 'Edit/Reject' sets. Databank organizes the samples in a 'worst-first' ordering so that the analyst can concentrate their data review on the problematic data.

The software must allow the analyst to easily upload only those samples that have been identified as passing review.

TrueAllele Databank electronically records those samples that have been passed by the expert system or the analyst. The analyst uses the AutoResults module to create CMF output from these 'accepted' samples.

The software must be able to present the analyst with all the rule firings/flags for each sample together on a single screen.

When TrueAllele rules flag a data sample, the Databank user interface shows the specific rules that fired. The rule window appears next to the original STR data electropherogram signal. Other computer interfaces can explain to the analyst why these rules fired.

The software must allow all evaluation parameters to be customizable by the laboratory.

TrueAllele Analysis allows a site administrator to customize all rules, thresholds and parameters for application to its data and processes.

The software must allow for multiple sets of analysis parameters that are easily accessible for analysis purposes.

TrueAllele Analysis supports multiple process templates. Each template defines all the analysis parameters for one process. These templates can be automatically applied once they have been created.

The software must allow the analyst to view the raw data at any time within the system.

The raw electropherogram data obtained from the sequencer can be viewed at any time in the TrueAllele Analysis, Databank or Casework modules.

The software must be able to deconvolute a mixture of two unknowns of a ratio of 2:1 or greater into two separate profiles and display some type of quality evaluation to the résults. It is highly desirable for the software to be able to deconvolute mixtures containing one known profile and up to two unknown profiles.

TrueAllele Casework can infer genotypes from mixtures containing one, two, three or more unknown contributors. The VUIer software displays the results of the inference process, allowing an analyst to visually evaluate the quality of the inferred genotypes and mixture weight. The TrueAllele Casework interpretation process can also use known contributor genotypes (e.g., a victim reference).

The software must be server based and be able to handle at least ten client software connections simultaneously. The analyzed data should be available for viewing from any analysts workstation and not just the workstation where the data was originally generated or viewed.

TrueAllele Casework is based on a client-server database model. Based on Cybergenetics deployment experience and our understanding of the West Virginia State Police Forensic laboratory's requirements we estimate that your laboratory would require no more than six concurrent licenses. However, the TrueAllele database server can handle ten or more concurrent connections simultaneously, should that be desired. All data and results are stored on a central server that is securely accessible from any Viewstation or desktop computer connected to the network.

The vendor must provide support for the validation of the software to meet NDIS approval within a mutually agreed upon timetable not to exceed 12 months.

Cybergenetics provides validation training that enables the site to perform and submit a complete developmental validation rapidly and effectively. The TrueAllele Databank system includes the powerful AutoValidate™ module that facilitates automated scientific validation, and provides flexible reporting tools.

Cybergenetics has assisted each laboratory in its initial developmental validation. The New York State Police, with Cybergenetics assistance, have submitted five validations since 2001. Their landmark 2004 JFS validation paper became the foundation for the NDIS expert system validation process. Cybergenetics has also helped the Massachusetts State Police and the Maryland State Police complete and submit to NDIS their successful, approved developmental validations.

The vendor must provide the cost and components of available maintenance plans including upgrades, trouble shooting and correction of software defects. Price quotes for the first year, second year and third years must be included as well as any discounts for multiple year agreements. The vendor must also detail what, if anything would not be included in these maintenance plans. The vendor should also give details on wait times for service by phone or on site service calls including maximum time allowed before vendor response to initial contact and average time before a vendor response to initial contact.

Cost breakdown of the TrueAllele Casework and TrueAllele Databank bid package is in the attached spreadsheet.

TrueAllele support and maintenance (first year)

The first year support and maintenance is included in the TrueAllele Casework and Databank package.

- Support for the TrueAllele Casework and Databank technology includes telephone and email communication, trouble shooting, technology upgrades, and software patches.
- Except in emergencies, ongoing user support will be provided Monday through Friday during normal business hours of 9-5 EST.
- Cybergenetics usually responds within about 4 business hours to any query about a problem with the TrueAllele system by phone or email.
- Cybergenetics will respond to queries about any problems with the system not more than 1 business day by phone or email.
- The maintenance agreement includes any technical problems encountered during the maintenance period.
- Cybergenetics hardware comes with a three year manufacturer's warranty.

Cybergenetics will use email, telephone and remote access software to help maintain and support the TrueAllele Databank technology system. In the event that a problem cannot be solved with telephone, email, machine replacement, or remote access software, Cybergenetics will endeavor to solve the problem to the best of its ability with an on-site visit.

Cybergenetics offers three annual maintenance and support plans for the TrueAllele Casework and Databank package for the West Virginia State Police Forensic laboratory. Cybergenetics has included the cost of the Technical and Software support for the West Virginia State Police Forensic laboratory for years two and three in the attached spreadsheet price quote. Support and maintenance for the first year is included in the price of the Casework and Databank package.

Technical Support

Includes maintenance and user support. Full maintenance includes all routine system upkeep and software patches. Extensive user support includes documentation and tutorials as well as access to unlimited telephone and email communication for technology support and troubleshooting. User support is provided Monday through Friday during normal business hours (9-5 EST). The cost is 25% of the server and client modules.

Software Support (requires technical support)

Includes technology upgrades for server and client software components, including compute and database servers, match engine, ViewStations and data analysis. Requires Technical support. The cost is 25% of the server and client modules.

Scientific Support (requires technical and software support)

Includes Cybergenetics assistance in conducting validations, as well as user process and data monitoring, workflow and process planning. Requires Technical and Software support. The cost is 25% of the server modules.

The software must allow the export of profiles in multiple formats including CMF 1.0 and other CMF formats that are accepted by the CODIS software.

The TrueAllele software can export profiles into CMF 1.0 and CMF 3.2 files, as well as other formats.

The software must also be able to export multiple profiles with sample names under a header including the loci designations tested.

The TrueAllele software provides this export format.

The vendor must list any known technical issues with any currently available Microsoft Operating Systems or Office Software as well as known issues with any other commercially available software and delineate if these issues are with the full installs on the server only or with the software loaded on the individual workstations as well.

Cybergenetics is not aware of any such technical issues with any other commercially available software. The TrueAllele technology is compatible with Windows® operating systems and Microsoft® Office.

The software must be compatible with Genemapper 3.2 or use the same peak detection and sizing algorithms as Genemapper 3.2.

TrueAllele Analysis can access and import Genemapper results.

The software version offered must have been accepted by NDIS as a validated expert system for convicted offender analysis.

NDIS has accepted multiple TrueAllele Databank expert system validations.

Otherwise the vendor must demonstrate that the new version performs as expected and that none of the changes would cause the system to NOT meet NDIS standards for expert systems. The vendor must provide the most recent version of the NDIS accepted software if more than one version has been approved.

We recommend that each end-user site customize rule settings and other parameters for their own data and process. With Cybergenetics assistance, a developmental NDIS TrueAllele Databank validation can be accomplished in one week (though some groups elect to allocate more time than this).

The vendor must provide instructional manuals detailing all software functions and how to utilize each of the functions. Instructions should also detail how to export data and how to access and use the data files and reports generated by the software.

TrueAllele Databank and TrueAllele Casework each have instruction manuals that explain the software functions and how to use the technology. These instructions include explanations on how to export data, how to access and use the data files and reports. The instructions include written and visual information. Each Databank interface provides on-line access to the extensive software documentation. Other TrueAllele documentation is also available for the software modules.

All training must occur at the West Virginia State Police Forensic laboratory and the quote must include training for ten individuals. If the convicted offender and casework applications are separate then two individuals should be trained for the convicted offender component and up to ten individuals for the casework component.

Cybergenetics will provide 4 days of TrueAllele Casework training at the West Virginia State Police Forensic laboratory site for 10 TrueAllele Casework users. Training will include all documentation and materials necessary for the Casework training.

Cybergenetics will provide 4 days of training to 2 TrueAllele Databank users at the West Virginia State Police Forensic laboratory site for the TrueAllele Databank technology.

The version of the software offered by the vendor must be available for installation no later than March 30, 2010.

The TrueAllele Analysis, Databank and Casework technology versions offered in this bid are ready for immediate installation.

TrueAllele Technology Pricing Proposal	ricing Proposal			2
Item	Description	Quantity	Cost per Item	Cost
TrueAllele Technology				
TA Casework Package	::	1		\$120,000
	TA Compute and Database Server	Server		
	TA ViewStation with Client Software	Software		
	training, proficiency and support for 2	pport for 2 users		
	help with 1 process validation	on		
	1 yr support and maintenance	nce		
	1 concurrent license			
	2 additional concurrent licenses	nses		\$20,000
				5
Databank capability	capable of processing reference	S	and convicted offender samples	\$20,000
Databank user installation	Databank user installation set-up, optimization, 1 yr us	3		
	maintenance, help with NDIS	IS validation		
Casework & Databank Total	otal			\$165,000
Training				
On-site Casework training		6 students	\$2,500 per student	\$15,000
	2 day Casework training course	urse		
	(total of 8 students with 2 from Package)	from Package)		
On-site Databank training		2 students	\$2,500 per student	\$5,000
	2 day Databank training course	urse		
Training total				\$20,000
				-
Annual Support and Maintenance	intenance			\$25,000
Hardware and system support	port	-		
	Basic technical support and upgrades	upgrades	1.1	
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State of West Virginia Department of Administration Purchasing Division 2019 Washington Street East Post Office Box 50130 Charleston, WV 25305-0130

Cybergenetics Corporation 2555 Washington Road Suite 611

Pittsburgh PA 15241

Request for Quotation

SHIP

RFO NUMBER DPS1041

ADDRESS CORRESPONDENCE TO ATTENTION OF

KRISTA FERRELL 304-558-2596

WEST VIRGINIA STATE POLICE

4124 KANAWHA TURNPIKE

SOUTH CHARLESTON, WV 304-746-2141 25309

FO.B FREIGHT TERMS SHIP VIA DATE PRINTED TERMS OF SALE 05/05/2010 BID OPENING DATE: OPENING TIME 01:30PM 05/25/2010 CAT UNIT PRICE AMOUNT UOP ITEM NUMBER LINE QUANTITY LS 493-08 0001 DNA EXPERT SYSTEM REQUEST FOR QUOTATION (RFQ) THE WEST VIRIGNIA STATE PURCHASING DIVISION FOR THE AGENCY, THE WEST VIRGINIA STATE POLICE, IS SOLICITING BIDS TO PROVIDE THE AGENCY WITH A DNA EXPERT SYSTEM PER THE ATTACHED SPECIFICATIONS. TECHNICAL QUESTIONS CONCERNING THIS PROJECT MUST BE SUBMITTED IN WRITING TO KRISTA FERRELL IN THE WEST. VIRGINIA STATE PURCHASING DIVISION VIA MAIL AT THE ADDRESS SHOWN IN THE BODY OF THIS RFQ, VIA FAX AT 304-558-4115, OR VIA EMAIL AT KRISTA.S. FERRELLOWV.GOV. DEADLINE FOR ALL TECHNICAL QUESTIONS IS MAY 13, 2010. ANY TECHNICAL QUESTIONS RECEIVED WILL BE ANSWERED BY FORMAL ADDENDUM ISSUED BY THE PURCHASING DIVISION AFTER THE DEADLINE FOR TECHNICAL QUESTIONS HAS LAPSED. EXHIBIT 10 REQUISITION NO.: DPS 1041 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. SEE REVERSE SIDE FOR TERMS AND CONDITIONS TELEPHONE SIGNATURE

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

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KRISTA FERRELL 304-558-2596

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Cybergenetics
160 N. Cralg St. Suite 210
Pittsburgh PA 15213

WEST VIRGINIA STATE POLICE

4124 KANAWHA TURNPIKE SOUTH CHARLESTON, WV 25309 304-746-2141

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RFQ COPY TYPE NAME/ADDRESS HERE Cybergenetics

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ADDRESS CHANGES TO BE NOTED ABOVE

RFQ COPY TYPE NAME/ADDRESS HERE Cybergenetics Corp 160 N. Crais St, Suite 210 Pittsburgh, PA 15213

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- 1. Accurately and efficiently evaluate convicted offender profiles, identify the samples which do not meet the laboratory defined parameters and display the failed parameters, and allow for simple segregation of failed samples from passing samples and the export of passed samples in a CODIS acceptable format.
- 2. Perform quality control evaluations for every sample, offender, casework, and controls, generated or accepted by the laboratory and be able to display reports of the various quality checks.
- 3. Evaluate casework samples, both single source and mixtures, to assist the analyst in the interpretation of the sample DNA profile.

The vendor must prove that their software was approved by NDIS as an expert system prior 12/31/2009.

The software must be able to compare the run data generated from a specific run on a genetic analyzer to itself to identify possible cross contamination. The level of concordance (number of shared alleles) that is displayed must be a customizable parameter. The results of the comparison must be exportable in a report format.

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The software must allow all evaluation parameters to be customizable by the laboratory.

The software must allow for five or more sets of analysis parameters that are assessable for analysis purposes using one selection tool such as a drop-down list.

The software must allow the analyst to view the raw data at any time within the system.

The software must be able to deconvolute a mixture of two unknowns of a ratio of 2:1 or greater into two separate profiles and display some type of quality evaluation to the results. It is highly desirable for the software to be able to deconvolute mixtures containing one known profile and up to two unknown profiles.

The software must be server based and be able to handle at least ten client software connections simultaneously. The analyzed data should be available for viewing from any analyst's workstation and not just the workstation where the data was originally generated or viewed.

The vendor will install the software within ninety days of purchase.

The vendor must provide support for the validation of the software to meet NDIS approval.

The software must allow the export of profiles in multiple formats including CMF 1.0 and other CMF formats that are accepted by the CODIS software. The software must also be able to export multiple profiles with sample names under a header including the loci designations tested.

The vendor must list any known technical issues with any currently available Microsoft Operating Systems or Office software as well as known issues with any other commercially available software and delineate if these issues are with the full installs on the server only or with the software loaded on the individual workstations as well. The software must be compatible with Genemapper 3.2 or use the same peak detection and sizing algorithms as Genemapper 3.2.

The software version offered must have been accepted by NDIS as a validated expert system for convicted offender analysis. Otherwise the vendor must demonstrate that the new version performs as expected and that none of the changes would cause the system to NOT meet NDIS standards for expert systems. The vendor must provide the most recent version of the NDIS accepted software if more than one version has been approved.

The vendor must provide instructional manuals detailing all software functions and how to utilize each of the functions. Instructions should also detail how to export data and how to access and use the data files and reports generated by the software.

All training must occur at the West Virginia State Police Forensic Laboratory and the quote must include training for eight individuals. If the convicted offender and casework applications are separate then two individuals should be trained for the convicted offender component and eight individuals for the casework component.

The version of the software offered by the vendor must be available for installation no later than March 30, 2010.

RFQ: DPS1041 COST SHEET

All inclusive cost for software, installation, training, and licensing For (1) DNA Expert System

s 185,060

Please list below the manufacturer and model of the system bid.

Model: True Allele Technology

^{**}Please provide literature/documentation illustrating that the system bid adheres to the specifications of this Request for Quotation.

Response to detailed questiens explaining technology

I have developed the list of points below that I would like each of your companies to respond too. If there are features that you feel are important and have not been addressed please contact me. If additional points are developed they will be forwarded to the other vendors for response. While many of these points have been covered in presentations this process will help finalize the development of the specifications for this project.

there are features that you feel are important and have not been addressed please contact me. If additional points are developed they will be forwarded to the other vendors for response. While many of these points have been covered in presentations this process will help finalize the development of the specifications for this project.

Dear Brent,

Thank you for the opportunity to respond to your informal questionnaire regarding the procurement of forensic DNA databank and casework interpretation systems.

I shall begin this response with a brief overview of the TrueAllele® (TA) systems, which will help to clarify the detailed responses which are provided below.

The TA technology that you are asking about can be grouped into three main modules:

- 1. Analysis. TA Analysis transforms the original electronic electropherotogram files into quality checked, quantified peak events. This module is executed prior to running either the Databank or Casework modules, and conducts much of the quality control.
- 2. Databank. Databank is an NDIS-approved expert system for the reliable processing of DNA reference samples, including convicted offender samples
- 3. Casework. TA Casework is statistical software based on a detailed probability model of the molecular biology. This module infers genotypes (up to probability) and reports DNA match statistics as likelihood ratios.

The TA Analysis and Databank modules are included in with every TA workstation, while TA Casework additionally requires a TA server for database and parallel computation.

Quality Control/Quality Assurance

Please explain how the laboratory would configure the software to perform the following functions:

The expert system must be able to compare the data generated for a particular run to a data set(s) of profiles with customizable features for identification. (contamination from supplies or analysts)

The TrueAllele system has a staff check feature that checks each plate for staff contaminations. How easy is it to add profiles to the staff database and can these be imported as Genemapper ID analyzed data?

Staff profiles are added by including them in a spreadsheet text file. Profiles in other file formats can be converted to this spreadsheet format.

TrueAllele also has other rules and features that check for contamination as well, including contamination from supplies. Examples are, the rules include 'duplicate' check which can pick up lab contamination. The 'low level peak' rule looks for minor contaminants and helps identify supplies contamination.

Can the laboratory set the number of alleles matching required to fire the "duplicate allele check" parameter as well as other parameters?

Yes; the system is customizable on many levels. You as the lab supervisor can set the number of matching alleles as desired by editing a text file. Other parameters can be changed in a similar manner.

How does the "low level peak "rule work?

The low level peak rule flags peaks that aren't flagged by other rules, such as stutter, but are above a lab-set RFU threshold.

Do both of these rules fire on the sample or is an easily identifiable note generated listing the samples which have duplicate alleles or shared low level results"

The duplicate check provides a list of samples (and corresponding lanes) in a specific 'duplicate sample' report. Independently, various reports show which rules fired for each locus of each lane.

The expert system must be able to compare the data generated for a run against itself to determine if there is contamination between samples with customizable features for identification and if possible using the sample name to exclude within a case matches. (sample to sample contamination)

Among the contamination check features, TrueAllele has a feature 'duplicate check' that looks for duplicate profiles within a plate.

Is a database of all samples analyzed by the system generated?

The TA Databank system puts its results into files that can then be uploaded to a database via a LIMS system.

If so, can the analyst query this database to determine if minor profiles are seen sporadically over a long period of time?

TA Databank produces the information through samples that can then be uploaded to a database that can then be queried for specific issues.

Software Analysis Features

List and describe the rules used to evaluate samples, ladders and controls.

Describe how the laboratory customizes the rules for their processes. (interface)

A laboratory can customize the rules for their process by running a set of data through TA Databank to check concordance. The lab can then modify the rules so that they can catch everything they need to catch and enable them to maintain an efficient process. These modifications can always be changed. The process takes a day or two depending on the data (and amount) that the lab prefers to put through. Cybergenetics offers the service of customizing the rules for clients, including running the samples in parallel with the lab to ensure that the software is running correctly as part of the set up, installation and optimization.

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How are the rule firings (flags) for a particular sample presented to the reviewer? Are they present on the main screen or accessed through the main screen or some other arrangement?

The rule firings are presented as a window with a table identifying all the rules and which fired. The rule firings are accessed through the main screen and are directly available to the analyst.

How user friendly is this?

Extremely. The entire situation is accessible to the user in one visual look at the screen, and any user action can be done in a single click.

% Allele rules

After stutter

Amelo

Check control

Conflict

Crossover

Dispersion

Dye to dye

Extra allele

High n peak

High signal

Lane to lane

Low homozygote

Low level peak

Low quality

Low signal

Negative

New allele

Noise

Off ladder

Off physical ladder

Off virtual ladder

Overlap

Peak morphology

Rare

Relative area

Relative height

Spike

Stutter

Third peak

Uncorrelated

Unexpected

% Plate rules

Ladder distance

Ladder interpolated

Ladder missing

Ladder overlay

Negative peaks

Outside marker window

Positive missing

Primer missing

How are samples presented to the reviewer if several samples have rule firings and some samples have none?

TrueAllele Databank is cued by the rule firings. This means that the samples are presented in a worst first

The sample issues are presented locus by locus correct?

Yes; the system organizes the data by locus. Typically, similar artifacts appear across the plate at specific loci, and by looking at these artifacts by locus, the review becomes more efficient. For example, Amelogenin can cause pull up in other loci, such as D19. The system will flag the lanes with D19 artifacts and organize them for review. When reviewing D19, the analyst will be presented with these artifacts in the lanes in which they occur one after the other. The cause of the artifact then is fresh in the analyst's mind, enhancing review.

The analyst can always see all the data but TrueAllele presents the data that specifically needs to be reviewed. Once the analyst reaches acceptable data, they can skip to the next step, or choose to view all the data. There are also interfaces specifically for viewing large amounts of good data very rapidly (ie. a plate in about 1-2 minutes)

What "pre-processing" does the reviewer need to do with a sample set before the expert system can begin the analysis?

The analyst spends a minute per plate reviewing the size standard tracking and then another minute reviewing the controls. This is done in an easy to read visual interface where the entire plate is presented to the analyst for a cursory overview check.

Can more than 1 tray of data be analyzed as a set? Are there limits to the number of trays that can be analyzed as a set? How are the migrational differences that can be generated by temperature variation occurring over the time period necessary for several trays to be run handled?

Yes, multiples trays can be analyzed as a set. There are no limits to the number of trays that can be analyzed as a set, but for efficiency, Cybergenetics recommends not more than about 5 be analyzed at a time. Handling temperature variation within plate or across plates is not an issue in TrueAllele Databank, dependent on the plate layout.

How does TA handle the ladders especially with multiple plates?

To preserve the integrity of ladder analysis to the data, TA Databank looks at the ladders within their own plate.

Are all ladder values averaged for the entire dataset or by plate or by some other method?

Ladders are not averaged. TrueAllele Databank checks the ladders on the plate and provides a visual report for the analyst to review. When the analyst confirms the ladders, the system uses the ladder closest in time and space to the sample for calling alleles. For example, for the AB 3100, the system will use a ladder within an injection (which, presumably, was run most like the data), and if there's not one in the injection, will find and use the ladder in the next injection, closest in time.

The software should possess the ability to have separate customizable sets of parameters for casework analysis and convicted offender analysis.

TA Databank (for convicted offenders) has many user configurable custom parameters. These parameters include peak height cutoff, minimums and maximums for ladders, positive and negative controls, what output is generated, kits, panels, market windows, thresholds, automated pdf files, table outputs. The key parameters are usually set by Cybergenetics for the end user prior to system validation.

TA Casework To operate TA Casework the user can adjust the duration of sampling conducted by the statistical software. Typical control parameters include the number of burn-in cycles, the number of read-out cycles, and the number of Markov Chains. What is meant by these 3 terms? If the parameters used to analyze the casewok data are more stringent than with databank data how is that setup with TA.

These terms all refer to the duration of statistical search. Cybergenetics provides it users with standard operating procedures for setting these parameters. The TA casework and TA databank are separate systems, and their parameters are different.

The expert system should be network capable. The system should allow different analysts to see the same analyzed data.

The TA Databank system can be remotely viewed and controlled over a network. The TA Casework system comprises a client/server network architecture where cases residing on the central TA Database server can be accessed by TA ViewStations or client software over a network. The system will allow different analysts to see the same analyzed data. Since the same case analysis is stored on the TA Database server, the system should allow different analysts to see the same analyzed data.

The analyst should be able to view the raw data easily anywhere in the system.

The original electropheretogram data is viewable in every module of the TA Databank and Casework systems.

The expert system should be able to handle a mixture containing up to three unknowns.

The TA Casework system has been used successfully on cases containing at least three unknown contributors.

Demonstrate features of your software compared to the other two systems that emphasize the efficiency and ease of use for the reviewer of convicted offender samples.

TA Databank is a more fully automated system than either GMID or I3. Every aspect of the system is audited, and can integrated with a LIMS system. For example: Reasons feature allows analysts to flag problem samples with user customizable reasons and associated actions. Lab feedback report provides the lab with concise list of problems samples and actions. This can easily integrated with LIMS for automated rerun reports. Lab feedback is a pull down window where a lab designates some of the specific reasons that according to their protocol would trigger reworking a sample. This helps reduce analyst error and maintain consistency in sample analysis. This also eliminates the need to manually set up samples for reprocessing, as well as keeping a complete automated audit trail of the reasons for deciding to rework the samples. TA Databank allows the lab to create multiple templates that are used for analysing the samples, based on sequencer, chemical kits etc, further reducing the chance of human error. TA Databank enables batching of multiple plates for ease and efficiency of processing the data. AutoResults™ module automates the creation of CMF files from interpreted data TA Databank also enables remote access of the software. The original electropherogram data is always accessible and viewable in TrueAllele Databank for the analyst to compare with the analysis and interpretation. The Electropherogram interface as zoom and scroll features for enabling close visualization of potentially problematic areas. TrueAllele Databank also has a feature for viewing large amounts of data very quickly in a single window.

An analyst should be able to access the system output on their current workstation. Please list the minimum and recommended computer workstation requirements for your software. The system should be compatible with Genemapper ID or be able to demonstrate that the same algorithms are used as in Genemapper ID.

The requirements for a PC computer are the following: Windows XP, service pack 3, 2 gigahertz processor or greater, 1 gigabyte per processor -if have core duo, window. The TA Analysis module reads directly from the original Genemapper ID .fsa data acquisition files.

How are the results of the expert system casework modules organized for printing to a case file?

The TA Casework user can open tab text tables in the Viewer interface that provides genotype output

that can be cut and paste into reports.

Is there any software available today that the expert system software is known to conflict with or requires a certain loading sequence? This should include the CODIS software from the FBI and any of the major LIMS systems that are available. JusticeTraks, The Beast and Labvantage. If there are any, then that information must be available prior to the specifications being released. Otherwise, the specifications will state that no known software conflicts are permitted.

There are no known software conflicts between TA and other conventionally used DNA software. Moreover, Cybergenetics provides LIMS integration services to insure maximum compatibility.

The system should include modules that assist in the performance checks and validation requirements required by NDIS.

TA Databank includes the AutoValidate™ Module which facilitates rapid and accurate NDIS validation of convicted offender expert systems. TA Casework contains built-in likelihood ratio match and multiple database worlds that similarly enable rapid scientific validation. These tools can also be used for performance checks.

Security

Customizable security levels should be available to set the rights of individuals who have access to the software?

Customizable security measures are implemented in the Analysis, Databank and Casework

components.

What auditing features does the software have to track the actions of individuals on the software?

TA Analysis and Databank maintain log files of all user actions. The TA Casework database maintains an audit trail with user name and time stamp of key data and request actions.

What auditing features does the software have to track the changes performed within the software to a sample?

The auditing features include tracking edits, analyst annotations of samples, which ladders were used to designate a sample, logs of each analysts user interface (keeps track of who was where, and for how long), a similar feature for the Datadisk (data processing unit) tracks who opened it and when, anytime any result is generated a log is created. The set of data that the analyst has to review by protocol is tracked to verify that the analyst completed the job or not. How is this accomplished?

The system keeps a list of the samples that have fired one or more rules. By protocol, these samples require analyst review. During analyst review, the system records which samples are reviewed – ticking them off the list.

Each file is also time and date stamped, including logs that can not be used by the user but can be accessed through the software.

The software should be password protected.

The computers, software and databases are password protected at multiple levels.

Implementation

The optimization of the system for convicted offenders and casework must occur on site.

Cybergenetics generally conducts initial optimization for the user group. Following user training an end user supervisor can refine these settings. I am going to require that all work be performed on site.

The optimization can be done on site.

The training must occur on site or at MUFSC if arrangements can be made.

Cybergenetics offers on-site training for both Databank and Casework systems.

Costs

The different levels of maintenance must be clearly described and the cost structure must be available.

The system should be designed to handle the following efficiently:

Installed on eight analyst workstations with the analysts divided into two teams of four for

the casework component workflow

The TrueAllele Casework client software can be downloaded from Cybergenetics and placed on as many computers as the lab wishes. Is this the software that an analyst would use to make requests for sample comparisons and then view the results of each request?

Yes

The number of concurrent TrueAllele Casework licenses will limit how many analysts can access the TrueAllele Database server to upload, request and review data for interpretation and match activities.

Two analysts will need the convicted offender component as well and must be available at all times for both analysts. times for both analysts.

The TrueAllele Databank technology is installed on the TrueAllele Casework ViewStations. The TrueAllele Databank technology does not interact with the TrueAllele Database server computer. Therefore, analysts who need to use the TrueAllele Databank technology can use it on the TrueAllele ViewStations concurrently with analysts using the TrueAllele Casework at their desk computers without impacting on the concurrent licenses for TrueAllele Casework usage. (This means that 6 analysts can be working at the same time -2 on TrueAllele Databank and 4 on TrueAllele Casework). If you think that you need more TrueAllele Casework concurrent licenses, you can add them. Does this mean that the analysts working with the database samples can work from their desktops or do they have to go to another workstation.

They can work from their desktops.

If individuals are reviewing the results of casework requests and using all of the functions available to evaluate the analyzed results does that require use of the license to handle these functions?

Yes

Please see the attached excel spreadsheet for a breakdown of the various costs associated with the TrueAllele Casework and Databank systems as well as annual support and maintenance

Technology Description



Cybergenetics

TrueAllele Technology

Clients

VUIer'TM Software

TA-VUIer software helps the forensic analyst solve their cases. The easy-to-use VUIer Software user interface enables the analyst to set up their samples via the request interface. Once the computer has processed the data, the analyst views the results in the context of their original DNA and the original electropherogram data for quality checking. A wide range of useful TA-VUIer interfaces allow the user to zoom in and out to view the data and results from many perspectives, including DNA profiles, matches and mixture weights.

ViewStation

A ViewStation provides the ideal 24" color screen environment for the VUIer client software. The TrueAllele ViewStation computer enables the user to make requests, upload data to the database, download the results and review the DNA cases.

Servers

Quantum Compute Server

TrueAllele Casework provides an easy upgrade path as a laboratory's production requirements increase. Featuring eight core processors, the TrueAllele Casework Quantum compute server increases capacity in increments of 400 casework samples per week. Available in tower or rack configurations.

Quantum Database Server

The Quantum Database server is the central electronic filing cabinet and coordinator for the TrueAllele system. The server is a repository for all DNA data, interpretation questions and STR profile answers. It also provides a customizable DNA match capability. The Quantum Database server communicates over a network with the user's client computers and the problem solving computer server.



TrueAllele® Databank Standard Package

The TrueAllele Databank Standard Package

Includes:

Technology:

- Two TrueAllele Databank Workstations for unlimited single source DNA samples.
- NDIS approved expert system that reviews 1,000,000 single source DNA samples/year.
- From sequencer file to DNA profile: complete 5 minute human review of a 96 well plate.
- TrueAllele Databank set-up includes: software, hardware (two TrueAllele Databank Workstations), network connections and extensive documentation.
- Out of the box productivity before validation: a full review takes only 10 minutes/plate

Training:

- TrueAllele Databank training (2 day training for two users) at Cybergenetics, Pittsburgh, PA*
- User training enables one trained TrueAllele forensic analyst to review 1,000,000 samples a year.

Technology integration services:

- Basic integration planning including process evaluation and work flow review needed to introduce TrueAllele Databank into the laboratory.
- set up support including regular communication, user support, quality assurance and control, and technology monitoring.
- Cybergenetics sets up automatic transformation of DNA sequencer files into DNA profiles (e.g., as CODIS CMF files).
- 1 day LIMS support to set-up text results for input directly into LIMS systems.

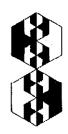
Technology validation service:

- TrueAllele Databank system optimization and internal validation for two processes.
- Cybergenetics assistance with one full NDIS developmental validation
- AutoValidate[™] module that enables rapid validations and concordance studies for internal technology upgrades, proficiency testing and audits.

Technology support services:

• One year of technology and user service and support.





Cybergenetics 160 N. Craig St. Ste 210 Pittsburgh, PA 15213 USA 412.683.3004 412.683.3005 FAX http://www.cybgen.com

Date:

25 May 2010

To:

Krista Ferrell/ State of West Virginia

Purchasing Division

Fax Number: 304-558-3970

Phone Number:

From: Ria David, Cybergenetics

Re: Notarized State of West Virginia Purchasing Division - Purchasing Affidavit RFQ# DPS 1041

Number of Pages: 2, including cover page

Message:

Good morning, Krista Ferrell.

I am sending the signed notarized State of West Virginia Purchasing Division Purchasing Affidavit for the TrueAllele Genetic Calculator as a caseworking software system to assist with DNA mixture interpretations and statistical analysis.

Please let me know if you need anything further from me.

Sincerely,

Ria David, PhD President

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Cybergenetics

State of West Virginia

VENDOR PREFERENCE CERTIFICATE

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

1.	Application is made for 2.5% resident vendor preference for the reason checked: Bidder is an individual resident vendor and has resided continuously in West Virginia for four (4) years immediately preceding the date of this contification; or
	ing the date of this certification; or , Bidder is a partnership, association or corporation resident vendor and has maintained its headquarters or principal place of business continuously in West Virginia for four (4) years immediately preceding the date of this certification; or 80% of the ownership interest of Bidder is held by another individual, partnership, association or corporation resident vendor who has maintained its headquarters or principal place of business continuously in West Virginia for four (4) years immediately preceding the date of this certification; or , Bidder is a nonresident vendor which has an affiliate or subsidiary which employs a minimum of one hundred state residents and which has maintained its headquarters or principal place of business within West Virginia continuously for the four (4) years immediately preceding the date of this certification; or ,
2.	Application is made for 2.5% resident vendor preference for the reason checked: Bidder is a resident vendor who certifies that, during the life of the contract, on average at least 75% of the employees working on the project being bid are residents of West Virginia who have resided in the state continuously for the two years immediately preceding submission of this bid; or,
3.	Application is made for 2.5% resident vendor preference for the reason checked: Bidder is a nonresident vendor employing a minimum of one hundred state residents or is a nonresident vendor with an affiliate or subsidiary which maintains its headquarters or principal place of business within West Virginia employing a minimum of one hundred state residents who certifies that, during the life of the contract, on average at least 75% of the employees or Bidder's affiliate's or subsidiary's employees are residents of West Virginia who have resided in the state continuously for the two years immediately preceding submission of this bid; or,
4.	Application is made for 5% resident vendor preference for the reason checked: Bidder meets either the requirement of both subdivisions (1) and (2) or subdivision (1) and (3) as stated above, or,
5.	Application is made for 3.5% resident vendor preference who is a veteran for the reason checked: Bidder is an individual resident vendor who is a veteran of the United States armed forces, the reserves or the National Guard and has resided in West Virginia continuously for the four years immediately preceding the date on which the bid is submitted; or,
6.	Application is made for 3.5% resident vendor preference who is a veteran for the reason checked: Bidder is a resident vendor who is a veteran of the United States armed forces, the reserves or the National Guard, if, for purposes of producing or distributing the commodities or completing the project which is the subject of the vendor's bid and continuously over the entire term of the project, on average at least seventy-five percent of the vendor's employees are residents of West Virginia who have resided in the state continuously for the two immediately preceding years.
require agains	understands if the Secretary of Revenue determines that a Bidder receiving preference has failed to continue to meet the ments for such preference, the Secretary may order the Director of Purchasing to: (a) reject the bid; or (b) assess a penalty such Bidder in an amount not to exceed 5% of the bid amount and that such penalty will be paid to the contracting agency acted from any unpaid balance on the contract or purchase order.
authori the req	mission of this certificate, Bidder agrees to disclose any reasonably requested information to the Purchasing Division and zes the Department of Revenue to disclose to the Director of Purchasing appropriate information verifying that Bidder has paid uired business taxes, provided that such information does not contain the amounts of taxes paid nor any other information d by the Tax Commissioner to be confidential.
and ac	penalty of law for false swearing (West Virginia Code, §61-5-3), Bidder hereby certifies that this certificate is true curate in all respects; and that if a contract is issued to Bidder and if anything contained within this certificate es during the term of the contract, Bidder will notify the Purchasing Division in writing immediately.
Bidder	:Signed:
Dafe:	Title:

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

RFQ No. DPS 1041

STATE OF WEST VIRGINIA Purchasing Division

Cybergenetics

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 pald 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 countles 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.

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

	·
WITNESS THE FOLLOWING SIGNATURE	
Vendor's Name: Cybergenetics Co	<u>vp</u>
Authorized Signature: Re Decrel	Date: 5 25 10
State of Pennsylvania	' '
County of Allegheny, to-wit:	
Taken, subscribed, and sworn to before me this 35^{T_1} day of	<u>May</u> , 2010.
My Commission expires 7704 30	, 20 <u>1'3</u> .
AFFIX SEAL HERE NO	OTARY PUBLIC Donna J. Scheuble
	COMMONWEALTH OF PENNSYLVANIA Notarial Seal Donna J. Scheuble, Notary Public City of Pittsburgh, Allegheny County My Commission Expires May 30, 2013 Member, Pennsylvania Association of Proceedings Affidayit (Revised 12/15/09)