

## **GENETIC PATERNITY TESTING SERVICES Contract Overview**

May 15, 2012-2015

### **Overview – Scope of Work and Deliverables**

DNA Diagnostics Center (DDC), the genetic testing contractor for the Michigan Office of Child Support (OCS), must arrange for specimen collection services in all counties, and provide, at a minimum, annual training (or otherwise as requested) to establishment personnel to do self-collection when requested by establishment staff. DDC must determine and arrange clinic schedules for the purpose of specimen collection. DDC must also provide staff or services for specimen collection outside the State of Michigan and in all types of prison and jail facilities.

DDC must provide all necessary supplies to the establishment staff (currently located in all 83 counties of the state).

DDC must arrange and pay for transportation of the samples between the collection location and the laboratory or testing facility.

DDC must provide the laboratory services necessary to determine or exclude paternity.

DDC must provide testing results within specified time limits via a confidential Web site and/or data file for the purpose of sharing case information with OCS or transferring data to the Michigan Child Support Enforcement System (MiCSES). DDC must provide hard copies of reports upon request.

DDC must provide consultation services related to test results, testing procedures, specific cases, and current genetic testing technology and methodology to the establishment staff.

DDC must provide expert witness testimony as requested in specific cases.

### **DDC Contract Provisions and Information**

Contract No: 071B0200129

Contract Period: May 15, 2012 through March 31, 2015 and allows for two (2) two-year extensions.

### **Contract Rate**

Per Individual Tested:     \$21.90  
Per Individual Collected:   \$ 5.00

- The contract rate will include:
  - Customer service;

- Specimen collection and supplies: collection kit, Client Authorization/Chain of Custody Form, camera and film;
- Scheduling of Uniform Interstate Family Support Act (UIFSA) services and jail draws;
- Collection of buccal samples or blood upon request;
- Transportation of the collected samples to the laboratory;
- Laboratory processing of samples;
- Generation of two reports (one with and one without genetic information);
- Expungement pursuant to Michigan statute, Public Act 31 of 2000;
- Expert witness services;
- Case file and specimen storage;
- Automated testing documentation; and
- Invoicing and statistical reporting.

**Amounts included in the child support orders by local offices for IV-D paternity testing and collection costs must reflect the contract rates.**

- DDC will invoice the state per person for each individual tested; therefore, additional children or additional alleged fathers will be charged at the per-person rate.
- DDC will only invoice for the additional party and will not charge for previously tested individuals if their previous samples/results can be used. If it is necessary to collect a new specimen at the request of the agency, then those samples will be invoiced at the per-sample rate.
- DDC will only invoice for the actual parties tested, so if the mother is not tested, then there will not be an extra charge (e.g., if one alleged father and one child are tested, the charge will be for two parties).
- If all samples are not collected at the same time for a particular case, DDC will invoice the state for partials upon receipt of the samples at the laboratory within the billing month they are received, and the charges will be included within the main invoice detail.
- Specimen collection either provided or arranged and paid for by DDC will be invoiced to:

Michigan Office of Child Support, Financial Management  
 Grand Tower Suite 1215  
 P.O. Box 30037  
 Lansing, MI 48909

**Customer Service Contact Information for IV-D Staff**

- DDC has assigned several Customer Service Associates to assist Michigan IV-D staff, and they will respond to all inquiries. The Customer Service Associates will be the point persons for all day-to-day needs. The group rotates phone calls, and a live representative will always answer the number 800-310-9868. Customers can also

leave a voice mail with any of the representatives. During absences, calls will be routed to a designated back-up staff member who is familiar with Michigan account specifics and will provide the same level of prompt service. Should an inquiry be forwarded to voice mail, it is DDC's policy to return all messages within four business hours. DDC's Customer Service Associates are available during standard business hours, though the department is staffed until 8 p.m. Eastern Standard Time (EST) in the event of an emergency. In addition, there are several Scheduling Associates who will handle all UIFSA and institutional scheduling for the state.

- Laboratory personnel and Ph.D.s are available for technical consultation and can be reached at the toll-free number listed above. Further, DDC's Specimen Collection Network provides immediate response in emergency situations and can be reached 24 hours a day at 800-310-9868 or 937-271-7041. All costs associated with providing and maintaining toll-free services are borne by DDC.
- DDC will provide customer support to IV-D staff through its Web site ([www.ddc-lab.com](http://www.ddc-lab.com)). Due to security considerations, use of electronic mail for case-specific communication is an exception and must be encrypted by both DDC and county establishment personnel.
- Fax numbers and email addresses to use for day-to-day communication with the local offices are listed below:

Fax number: 800-310-9728

Email: [epotter@dnacenter.com](mailto:epotter@dnacenter.com), [reckhart@dnacenter.com](mailto:reckhart@dnacenter.com)

Additional contact:

Lori Neff, Director of Customer Service  
Phone: 513-881-4031 or toll-free 800-310-9868  
Email: [lneff@dnacenter.com](mailto:lneff@dnacenter.com)

- Fax machines are located within the customer service and scheduling departments. Access to documentation received on fax machines is limited to the specific personnel manning those departments. In addition, due to DDC's strict confidentiality policies, information provided on any fax communication is considered to be confidential information and will not be disseminated to unauthorized personnel.
- All correspondence with DDC, including subpoenas, should be sent to the following address:

DNA Diagnostics Center  
Attn: Government Contracts  
One DDC Way  
Fairfield, OH 45014

## Specimen Collection

- Use of color-coded swabs, envelopes and chain of custody documentation protects against the possibility of inadvertently switching samples at the time of sample collection.
- Use of DDC's tamper-proof Secure-A-Gene Paks prevents any tampering with the specimen collection kits prior to sample collection as well as after samples are collected. Once samples are collected, they are placed back into the Secure-A-Gene Pak and the second seal is secured for shipping.
- The laboratory must obtain informed consent for all participating individuals to indicate they had knowledge of and granted consent for testing. This will be in the written authorization on the Client Authorization/Chain of Custody Form as required at the time of sample collection. If there is a court order ordering the test, that court order will suffice as the authorization and must be maintained in the case file.
- The collection process must be performed and witnessed by a competent person who has no interest in the testing outcome. A IV-D staff person who either collects or witnesses the genetic sample collection is not considered a person who has an interest in the testing outcome. The name of the specimen collector becomes part of the laboratory's permanent record.
- Identification of individuals: Proper photo identification is presented at the time of specimen collection. Adult parties must provide government-issued photo identification, which may include a driver's license, military ID, or other acceptable form of identification. The custodial party/legal guardian of the child(ren) is also instructed to bring a birth certificate. After the validity of the identification is verified by the specimen collector, the identification number is recorded on the Client Authorization/Chain of Custody Form along with Social Security numbers and dates of birth.
- Completion of the Client Authorization/Chain of Custody Form: The individual collecting the specimen will legibly complete this document, including the following information:
  - IV-D case number and court case number (if applicable);
  - Name of OCS requesting agency (county);
  - Collection site information (facility name);
  - Names of all parties in the case, even if all parties are not collected at the same time;
  - The Sample Collector's Statement on the back of the form, indicating the date and time of collection in addition to the collector's name and signature;
  - Race of mother and alleged father(s);
  - Sex of child;
  - Dates of birth for all parties;
  - Social Security numbers for all parties (if available);
  - Other ID number (government-issued photo identification);

- Transfusion and bone marrow transplant history; and
- Consent signatures of parties being collected or the guardian for a child being tested.
- Take photographs: The individual conducting the collections must take a photograph of all the parties to be collected. Photographs are then attached to the back of the chain of custody form in the space indicated.
- Take thumbprints: The collector will obtain a thumbprint by having parties press their thumb on the thumbprint pad and then press it on the appropriate section on the chain of custody form. *This is a routine procedure for DDC and is not a requirement of the Michigan contract.*

### **Specimen Collection Service Levels**

- Service Type 1: DDC works directly with the county to ensure that the needs of the account are being met and establishes an adequate collection schedule. Once the schedule is established, DDC provides a trained specimen collector to appear at the designated site at the appropriate time.
- Service Type 2: For those counties that choose to use the self-collection option, DDC will provide on-site, staff-managed collection training to county personnel.

### **Collection Supplies Provided**

DDC's Specimen Collection Network personnel ensure that all specimen collectors and sites are adequately supplied with all necessary materials for collecting and shipping buccal swab specimens, including:

- Sterile, color-coded cotton buccal swabs;
- Color-coded sample envelopes;
- Packaging with tamper-proof seals to securely contain the samples and chain of custody documentation;
- Sterile, disposable gloves;
- An instant or digital camera and all necessary film and equipment to print the image at the time of collection;
- Fingerprint pads;
- Color-coded Client Authorization/Chain of Custody Form;
- Overnight courier or prepaid first-class postage envelopes;
- Prepaid air bills or mailers; and
- Miscellaneous office supplies.

### **Intergovernmental Cases**

If Michigan is the initiating state,<sup>1</sup> Michigan is not responsible for the payment of specimen collection and genetic testing costs for genetic test reports. The responding state, under 45 Code of Federal Regulations (CFR) 303.7(d)(6)(i), is required to establish paternity and therefore has jurisdiction to determine the specimen collection

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<sup>1</sup> Typically, the mother and child are in Michigan, and the alleged father resides in another state.

and genetic testing facilities/services to be used. In addition, the responding state will be responsible for payment of specimen collection and genetic testing costs.

If Michigan is the responding state,<sup>2</sup> and the responding county PA asks DDC to provide the specimen collection services for any of the parties to the case, those services, as well as genetic testing services, will be provided under the same terms of the DDC genetic testing contract as for a non-intergovernmental case.

### **Scheduling of Paternity Services Under UIFSA**

Scheduling of paternity services under UIFSA can be conducted via telephone, fax, and through DDC's interactive Web site: [www.ddc-lab.com](http://www.ddc-lab.com). DDC's secure, online scheduling tool is typically the most efficient, accurate, and convenient way to schedule appointments. DDC will provide any necessary training to facilitate the use of the online scheduling tool.

### **Scheduling of Jail/Prison Draws**

Scheduling of jail/prison draws can be conducted via telephone, fax, and through DDC's interactive Web site using its secure, online scheduling tool. DDC will provide any necessary training for using the online scheduling tool.

### **Transportation of Samples**

An overnight courier service will transport packages to DDC's laboratory in Fairfield, Ohio, and the United Parcel Service is currently the courier of choice for the State of Michigan. For those offices using the first-class prepaid postage envelopes, they will be delivered via the U.S. Postal Service.

Upon receipt at the laboratory, samples and chain of custody documents will be examined for accuracy and completeness. The integrity of sample shipping containers will be verified to ensure that no tampering occurred between the time of sample collection and the time the package arrived at the laboratory. The accessioning process involves signing and dating the Client Authorization/Chain of Custody Form as an affirmation that the form is complete and that all samples were correctly labeled and received intact. If the integrity of the packaging has been compromised, OCS will be notified and a second sample will be requested.

### **Probability of Paternity**

DDC must test alleged fathers who are not excluded to at least the 99.0 percent probability of paternity. If reaching this Michigan "rebuttable presumption" level requires testing beyond the routine battery of tests, the expense will be borne by the laboratory. Any additional testing at the request of the alleged father or the establishment personnel will be paid by the requester. All additional testing requested by the establishment personnel will require OCS approval. DDC's typical probability of paternity is greater than 99.99 percent for inclusionary cases.

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<sup>2</sup> Typically, the alleged father is in Michigan, and the mother and child reside in another state.

## **Probability of Exclusion**

DDC's testing of genetic markers must include the use of multiple systems which will, on average, result in a minimum cumulative probability of exclusion (CPE) of 99.9 percent for inclusion cases. DDC's testing battery and standard operating procedures offer an average probability of exclusion in excess of 99.99 percent.

## **Exclusion**

In DNA systems, DDC must obtain at least three exclusions to make a finding of non-paternity. DDC will conduct DNA testing using Polymerase Chain Reaction (PCR) methodology to achieve a minimum of three exclusions to support a conclusion of non-paternity. A determination that an alleged father is excluded will be made with no fewer than three inconsistencies, and in most cases, DDC will provide **four or more exclusions**.

## **DNA Testing**

DDC must have the ability to perform PCR testing methods on DNA samples collected by either buccal swabs or blood draws and must have the ability to perform Restriction Fragment Length Polymorphism (RFLP) testing when requested by establishment personnel.

For routine paternity cases, DDC will conduct DNA testing using PCR methodology and will report test results using autosomal Short Random Repeat (STR) testing. For every case, whether for exclusion or inclusion, DDC performs a duplicate independent quality control process to ensure 100 percent confidence in each final case result. This battery of tests contains overlapping confirmatory systems and a test for Amelogenin, the marker that verifies the gender of a sample. In addition, DDC will provide additional or extensive testing that is required at no additional charge to the State of Michigan for routine cases as necessary to meet contract specification requirements.

When samples are deemed acceptable for testing, the samples and chain of custody forms are bar coded with a unique numerical identifier and logged into the sample tracking database, and an accessioning associate enters the corresponding client data. Samples and chain of custody forms are then submitted to the laboratory for processing. DDC uses automated processes and equipment whenever possible. By using sophisticated robotic sample handling equipment, the potential for human error in manipulating the layout and placement of samples during the testing process is greatly reduced.

Final case review by DDC's Laboratory Director or Associate Laboratory Director ensures technical and scientific accuracy of paternity reports. Client names, collection dates, race, case numbers, and unique specimen bar code identifiers are all verified against the information on the Client Authorization/Chain of Custody Form as part of this final review. After the results have been issued, all samples and records are stored

according to the American Association of Blood Banks (AABB) and/or contractual prescribed procedures.

There is complete documentation for each case processed; this includes the individuals involved in accessioning the samples, testing the samples, data analysis, final review, and storage/archiving. Thus an intact chain of custody from the time of initial specimen collection to retention after testing and reporting is created, and these records will be maintained for a minimum of 10 years to meet Michigan's contractual requirements.

### **Report of Test Results**

DDC will submit reports, including an interpretation of test results for each individual case in accordance with AABB requirements and in accordance with Michigan Compiled Law (MCL) 722.711.

DDC must provide a written report of test results to the requesting establishment employee in accordance with MCL 722.711, and the report must contain the following information:

- a. The court case number (if applicable), the Department of Human Services (DHS) case number or IV-D case number, and the laboratory case number or identification number;
- b. The mother's name and race;
- c. The child's name;
- d. The alleged father's name and race;
- e. The collection dates and identification numbers of the genetic testing material;
- f. The cumulative paternity index;
- g. The probability of paternity;
- h. The conclusion as to whether the alleged father can or cannot be excluded as the biological father;
- i. The name, address, and telephone number of the contracting laboratory; and
- j. The name of the individual certifying the report.

In addition to the requirements of MCL 722.711, DDC must provide a statement as to whether or not the alleged parent(s) can be excluded.

- a. If an opinion of non-parentage is rendered, the basis for the opinion must be provided.
- b. If there is a failure to exclude, the report must include the following information:
  1. The individual parentage index for each genetic system reported;
  2. The type of system: When DNA, denote PCR or RFLP;
  3. The combined paternity index; and
  4. The probability of parentage expressed as a percentage. The prior probability(ies) used to calculate the probability of paternity must be stated.
- c. If the results are inconclusive or unusual, DDC must give an explanation as to the nature of the problem.



1. The laboratory must not render an opinion of non-parentage on the basis of a single indirect exclusion or on the basis of an exclusion at a single DNA locus; and
2. Results inconsistent with parentage testing detected at a single DNA locus must be reported and must be incorporated appropriately into statistical calculations.

The official reports of genetic test results will be posted electronically on DDC's Web site, and a hard copy will be provided only upon request. DDC's electronic reports will be available on its Web site starting the week of May 21, 2012.

DDC will submit reports including an interpretation of test results as listed for each individual case in accordance with AABB requirements and in accordance with MCL 722.711. A scanned copy of the final paternity test report will include the Ph.D.'s signature, report of findings, conclusions, and chain of custody documentation. Authorized staff will be able to download and print these documents from DDC's secure Web site. In addition, DDC will provide hard copy documentation as required by the state.

Results must be issued within 10 days or less after the receipt of the final specimen, with the exception of difficult cases. These are cases for which it may take longer to obtain results (e.g., cases with possible recombination or mutation, testing two parties only, testing for extended family studies, testing first-degree male relatives, or low probability of paternity). If the stated turnaround time is not met in at least 95 percent of the cases in a month, payment on late cases will not be made to the laboratory unless authorized by the requesting establishment personnel. For routine casework, DDC's turnaround time will be four days for 95 percent of the cases from the date of sample arrival at the laboratory until the date the report is issued.

Orchid (the previous vendor/contractor), at one time, had posted on its Web site billing information that could be used to determine if the state was billed for the cost of the specimen collection and/or the genetic testing. Using this information, the PA could identify what costs should be included in the child support order. The PA could also identify when the state was not billed because of reuse of samples/results. However, posting of the billing information was discontinued until the amounts billed to OCS could be properly displayed for ongoing cases where the alleged father had been excluded and a new alleged father had been named. Currently, the billing information will not be posted. OCS will send an announcement when the correct billing information will be posted.

### **Expungement**

In accordance with MCL 722.716a, DDC must have the ability to destroy specimens and isolated genomic DNA on excluded individuals. The data must be removed from all of DDC's computer and physical files. An authorized individual must witness and sign off on these processes. This must be a routine procedure completed in 90 days. DDC must notify the excluded alleged father by certified return receipt when genetic material and records are destroyed (last-known address will be supplied by the establishment

personnel). DDC must procure an annual independent audit verifying the laboratory's compliance with the required expungement procedure, and the audit report must be supplied to the contract manager.

### **Expert Witness Service**

DDC personnel will testify as experts in court as to the procedures used for collecting DNA samples, processing DNA samples, and analyzing and interpreting test results. DDC's highly qualified doctoral staff provides litigation support to our customers, including pre-trial preparation and in-court explanation of genetic paternity testing procedures and subsequent results. DDC will also testify as the custodian of records in providing specific parentage probability data for an individual case. DDC has a set of support documents such as diagrams and slides available for court presentations. These visual aids assist in clearly explaining the concept of DNA testing and its use in paternity determination. DDC's expert witnesses will provide the following services to Michigan at no additional charge:

- Provide expert testimony for trials and hearings;
- Assist in the cross-examination of defense experts;
- Provide written and/or telephone technical consultation;
- Provide telephonic/video depositions;
- Provide pattern trial questions for expert testimony;
- Assist counsel in preparation for the presentation of scientific evidence at trials and in depositions;
- Fill requests for document production; and
- Provide affidavits regarding specific case events.

### **Specimen Storage**

AABB requirements mandate the storage of documents/records used for genetic testing for a minimum of five years. DDC will accommodate the 10-year retention requirements as requested by the State of Michigan.

Reuse of stored samples/results: In cases where genetic samples have previously been collected and retesting or a new referral is made, upon request, DDC will use the existing genetic samples for testing comparison and conclusion if acceptable and authorized by the particular county. When any individual has been previously tested (on the current case or on another case) and the previous results are reused, but additional testing is neither required nor conducted, DDC will not invoice for the reuse of test results. DDC consistently uses previous results without issue and is able to produce a profile. It is part of the daily routine to retrieve stored samples/data from previous cases. DDC must have proper signed consent on file from the party being tested if these samples are to be utilized for another case not originally listed on the chain of custody form. Therefore, any establishment personnel requests to reuse specimen testing results on an unrelated case must be accompanied by a written consent signed by the party(ies) or a copy of the court order. The required consent form will be provided by DDC and posted on their Web site.

## **Statistical Reporting**

DDC will provide the following reports on a monthly basis:

- Invoice/Billing Statement Summary
- Monthly Work Product Detail

DDC will also provide a monthly report of repeated test statistics and a comprehensive quarterly report to DHS that outlines the work accomplished during the reporting period, work to be accomplished during the subsequent reporting period, any problematic issues, and notification of any significant deviation from previously agreed-upon work plans. DDC will also provide ad hoc statistical reports as required by DHS, OCS, or their designate. If, at any time for the duration of the contract, Michigan wishes to include additional information on its reports or would like to amend their format, DDC will make customized modifications in its Laboratory Information Management System (LIMS) specifically to meet these requests.

## **Service Level Agreements (SLAs)**

DDC will monitor and track all SLAs on a routine basis to evaluate the laboratory's performance and compliance with contractual requirements. Such data will be presented in an agreed-upon format. DDC will also use third-party audits as required to measure the following service-level standards:

- Repeat testing occurs in no more than 5 percent of contract cases in a month – compliance percentage of 95 percent;
- Expungement is accomplished as required by law;
- Expungement audit is conducted and is completed within the time limits;
- Expert witness testimony is provided as required;
- Report of test results is provided within 10 days – compliance percentage: 95 percent;
- Report of test results – Test results are found to be accurate and reliable, including meeting the integrity of the chain of evidence and probability standards; and
- AABB certification is not lost.

## **Special Situations**

- **When a party insists the test results are incorrect:**

The first step is to have the parties review the photos that were taken at the time of collection to ensure that the proper individuals were collected for testing. If all is in order with the photos, and establishment personnel have determined that the complaint is legitimate, a request can be made to DDC to perform an additional case review. This second analysis will consist of confirmation that all chain of custody and laboratory documentation is in order. Upon completion of this analysis, the findings will be documented and communicated to the party. If preferred, a DDC employee can discuss these findings directly with the party. If the party is still dissatisfied with the results, establishment personnel will obtain additional specimens and tests, but

the contesting party will be required to pay for the collection and testing costs in advance.<sup>3</sup> Send the payment to DHS at:

Michigan Department of Human Services  
Cashier's Office  
Grand Tower Suite 1100  
P.O. Box 30037  
Lansing, MI 48909

The following information must be written on the payment check stub:

Pre-payment  
IV-D Case Number: \_\_\_\_\_  
Index: 50700  
PCA: 83205  
AOC: 6155  
Appn: 83200

- **If a “no photo” situation occurs:**

It is a requirement of the AABB as well as a Michigan contract requirement to have an original or legible photocopy of a government-issued photo identification or a photograph that is suitable for positive identification for all tested parties. In the event that there is no photo obtained for test results prior to this contract, it will be necessary to have the individuals retested and invoiced per contract terms.

There may be occasions when a correctional facility or institution may not allow cameras into the facility. If this is the case, DDC will attempt to obtain a copy of the booking photo and/or verify the identity from the person's identification badge. If the photo cannot be obtained, DDC will have the collector use the DDC Identity Verification Form. This form will indicate that it was not possible to obtain a photo.

- **Additional testing beyond contract requirements:**

If a party requests additional testing and all contract requirements have been met, the testing will be at the expense of the testing parties and will be handled through the DDC call center. Payment must be made directly to DDC.

- **If testing parties are minors:**

Minor mothers may give consent for paternity testing of their children or themselves unless a circuit court judge has required a next friend or guardian ad litem be appointed for paternity proceedings for the minor mother. Michigan law on paternity specifies that “It is unnecessary in any proceedings under this act commenced by or against a minor to have a next friend or guardian ad litem appointed for the minor unless required by the circuit judge. A minor may prosecute or defend any

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<sup>3</sup> Ref: CFR 303.5(e)(3).

proceedings in the same manner and with the same effect as if he or she were of legal age.” (MCL 772.714[9])

- **Request to use a previous alleged father sample that is due for expungement:**

Alleged father samples that are due for expungement will not be reused in another case.