

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0862216	<b>(X3) Date Survey Completed</b>  05/21/2021
<b>Name of Provider or Supplier</b>  Genetic Disease Laboratory	<b>Street Address, City, State</b>  850 Marina Bay Pkwy Ste G265, Richmond, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2009</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on a review of 3 of 3 Proficiency Testing (PT) attestation forms and interviews with laboratory director (LD) and technical supervisor (TS) #1, the LD failed to attest to the routine integration of the samples into the patient workload using the laboratory's routine method. Findings included: a. Review of the printed PT attestation statements on May 20th, 2021 for CAP FP-B-2020, (8/25/20), CAP FP-B-2020 (12/1/2020), and CAP-FP-A-2021 (4/6/2021) showed that the printed PT attestation statements were not signed by the LD, but were signed by TS#1 without appropriate delegation of duties in writing. b. Interviews with LD and TS (#1) on May 20th, 2021 at 12:05 PM confirmed that the printed PT attestation statements were not signed by the LD, but were signed by TS#1 without appropriate delegation of duties in writing. c. The laboratory reported testing 1,831,040 tests annually.</p>
<b>D5407</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on testing personnel and laboratory personnel interviews and Spinal Muscular Atrophy (SMA) procedures manual record review on May 20, 2021 at 2:40 pm, the</p>

laboratory failed to have SMA procedures that were approved, signed, and dated by the current laboratory director. Findings included: a. CLIA records indicate that the laboratory had updated its CLIA information to reflect a change of laboratory director to the laboratory's current laboratory director effective January 4, 2021. b. On May 20, 2021 at 2:40 pm, laboratory personnel confirmed that written procedures used in the section of the laboratory performing SMA testing did not include documentation indicating that these written procedures had been approved, signed, and dated by the current laboratory director. Laboratory documentation indicated that these procedures had been approved, signed, and dated by the former laboratory director only. c. According to laboratory records, the laboratory performed approximately 450,000 patient SMA tests annually.

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:  
Based on testing personnel and laboratory personnel interviews and Hamilton Microstar Plus maintenance record review on May 20, 2021 at 2:40 pm, the laboratory failed to perform Hamilton Microstar Plus maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. Findings included: a. In the Spinal Muscular Atrophy (SMA) section, the laboratory used two Hamilton Microstar Plus instruments to perform patient SMA tests. b. According to the manufacturer's operation manual, the manufacturer requires the performance of daily and weekly Hamilton Microstar Plus maintenance. c. On May 20, 2021 at 2:40 pm. testing personnel confirmed that daily and weekly manufacturer required maintenance were not performed and documented on either of the two Hamilton Microstar Plus instruments. d. According to laboratory records, the laboratory performed approximately 450,000 patient SMA tests annually.

**D5805**

**TEST REPORT**  
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:  
Based on laboratory director, technical supervisor, and laboratory personnel interviews and patient test reports record review on May 20, 2021 at 10:45 am, the laboratory failed to have patient test reports that indicated the names and addresses of the laboratory locations where the tests were performed. Findings included: a. The laboratory's patient test reports consisted of an aggregate of test results from tests

performed by the Genetic Disease Laboratory (GDL) and other laboratories. That is, all patient test reports included the reporting of patient test results which had been performed by GDL and at least one other laboratory. b. Although the patient test reports included GDL's and the other laboratory's names and addresses, the reports failed to indicate which laboratory performed and reported any particular test result. c. On May 20, 2021 at 10:50 am, laboratory personnel stated that the patient test report in use had been revised on June 24, 2020. In addition, laboratory personnel confirmed that from May 1 to 15, 2021, the laboratory issued approximately 12,000 patient test reports, including the reporting of approximately 200 patient T-cell Excision DNA (TREC) test results that were normally performed and reported by the other laboratory.

**D6076**

**LABORATORY DIRECTOR**  
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:  
Based on the number and severity of the deficiencies cited herein, the Condition: Laboratories Performing High Complexity Testing; Laboratory Director was not met. The laboratory director failed to ensure that the laboratory's quality assessment program was maintained (see D6094), testing personnel were qualified (see D6101), policies and procedures had been established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency (see D6103), and the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the testing process, was specified in writing (see D6107).

**D6094**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:  
Based on laboratory director and technical supervisor interviews and quality assurance record review on May 20, 2021 at 11:50 am and on May 21, 2021 at 10:30 am, the laboratory director, high complexity testing, failed to ensure that the laboratory's quality assessment program was maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Findings included:  
a. According to the laboratory's protocol titled "Quality Assurance & Assessment," it states: "Quarterly the TS or authorized designee with support from GDSP personnel randomly selects 25 patient test requisition forms received in the last quarter and reviews the entire testing process from specimen receipt through final reporting." b. According to the laboratory's quality assessment record titled "MSMS AAAC Quality Assessment Table," in 2020 and for the first quarter of 2021, the laboratory randomly

selected 5 patient test requisition forms received, and not 25 patient test requisition forms as required by the laboratory's protocol. c. According to laboratory records, the laboratory performed and reported 1,831,040 patient test results annually.

**D6101**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(11)

The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart.

This STANDARD is not met as evidenced by:

Based on a review of personnel folders for 6 of 6 technical supervisors (TS), 5 of 5 general supervisors (GS), and 45 of 45 testing personnel (TP) and interviews with the laboratory director (LD), the LD failed to employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests, and report test results. Findings included: a. Review of the available printed personnel information on May 20th, 2021 showed that 40 of 45 testing personnel did not have evidence showing that they met testing personnel requirements. b. Interview with the LD on May 21st, 2021 at 9:30 AM confirmed that for 40 of 45 testing personnel the laboratory did not have evidence showing that they met testing personnel requirements. See D6168. c. At the time of the survey on May 21st, 2021 the laboratory had indicated on the CMS-209 form that there were 6 TS, 5 GS, and 45 TP.

**D6103**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:

Based on a review of laboratory policies and procedures, and interviews with the laboratory director (LD), the LD failed to provide evidence that policies and procedures had been established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Findings included: a. Review of laboratory policies on May 20th, 2021 failed to show that that policies had been established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. b. Interview with the LD on May 21st, 2021 at 9:30 AM confirmed that policies and

procedures had not been established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills pursuant to 42 C.F.R. 493.1451(b)(8). c. At the time of the survey on May 21st, 2021 the laboratory had indicated on the CMS-209 form that there were 6 Technical Supervisors, 5 General Supervisors, and 45 Testing Personnel..

**D6107**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:  
Based on a review of personnel folders for 6 of 6 technical supervisors (TS), 5 of 5 general supervisors (GS), and 5 of 5 testing personnel (TP) and interviews with the laboratory director (LD), the LD failed to specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. Findings included: a. Review of the available printed personnel information on May 20th, 2021 showed that there were no written responsibilities and duties for consultants, supervisors, and testing personnel that had been approved by the LD. b. Interview with LD on May 21st, 2021 at 9:30 AM confirmed that there were no written responsibilities and duties for consultants, supervisors, and testing personnel that had been approved by the LD. c. At the time of the survey on May 21st, 2021 the laboratory had indicated on the CMS-209 form that there were 6 TS, 5 GS, and 45 TP.

**D6168**

**TESTING PERSONNEL**  
CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:  
Based on the number and severity of the deficiency cited herein, the Condition: Laboratories Performing High Complexity Testing; Testing Personnel was not met. The laboratory failed to have evidence indicating that testing personnel were qualified (see D6171).

## TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet

the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on a review of personnel folders for 45 of 45 testing personnel (TP) and interviews with the laboratory director (LD), the laboratory failed to provide evidence that 40 of 45 TP met personnel requirements by having earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution. Findings included: a. Review of the available printed personnel information on May 20th, 2021 showed that 40 of 45 testing personnel did not have evidence showing that they met testing personnel requirements. b. Interview with LD on May 21st, 2021 at 9:30 AM confirmed that for 40 of 45 testing personnel the laboratory did not have evidence showing that they met testing personnel requirements. c. At the time of the survey on May 21st, 2021 the laboratory had indicated on the CMS-209 form that there were 6 TS, 5 GS, and 45 TP.