Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2107461	05/11/2022
Name of Provider or Supplier	**Street Address, City, State**	
Temple Genetics Laboratory	3500 North Broad Street, Philadelphia, PA	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of laboratory procedure manuals and interview with the laboratory Director (LD), the laboratory failed to establish a competency assessment procedure to assess 1 of 2 Technical Supervisor (TS) and 1 of 2 General Supervisor (GS) for their supervisory responsibilities from 12/10/2019 to the day of survey. Findings Include: 1. On the day of survey, 05/11/2022 at 10:24 am, the laboratory could not provide a competency assessment procedure to assess the competency 1 of 2 TS and 1 of 2 GS (CMS 209 Personnel #2) from 12/10/2019 to 05/11/2022. 2. The LD could not provide competency assessment documentation for 1 of 2 TS and 1 of 2 GS from 12/10/2019 to 05/11/2022. 3. The LD confirmed the findings above on 05/11/2022 around 12:10 pm.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by:

	Based on lack of documentation and interview with the Laboratory Director (LD), the laboratory failed to evaluate and document the relationship between 2 of 2 QuantStudio 7 Flex Real-Time PCR test result at least twice in 2021. Findings Include: 1. On the day of survey, 05/11/2022 at 11:27 am, the laboratory could not provide documentation for the comparison of test results between 2 of 2 QuantStudio 7 Flex Real-Time PCR analyzers for the SARS-CoV-2 RNA twice annually from 12 /19/2020 to 05/11/2022. 2. The laboratory performed 73,912 SARS-CoV-2 RNA examinations in 2021. 3. The LD confirmed the findings above on 05/11/222 around 12:00 pm.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory competency assessment records and interview with the Laboratory Director (LD), the Technical Supervisor (TS) failed to evaluate the semiannual competency assessment for 7 of 10 Testing Personnel (TP) who performed SARS-CoV-2 RNA PCR examinations from 12/19/2020 to the day of survey. Findings include: 1. On the day of survey 05/11/2022 at 10:01 am, the TS could not provide semiannual competency assessment record for 7 of 10 TP (CMS 209 personnel #3, #4, #5, #6, #7, #8, and #11) who performed SARS-CoV-2 RNA PCR examinations from 12/19/2020 to the day of survey. 2. The laboratory performed 73,912 SARS-CoV-2 RNA PCR examinations in 2021. 3. The LD confirmed the findings above on 05/11/2022 at 12:09 pm.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of the laboratory competency assessment records and interview with the Laboratory Director (LD), the Technical Supervisor (TS) failed to evaluate the annual competency assessment for 7 of 10 Testing Personnel (TP) who performed SARS-CoV-2 RNA PCR examinations from 12/19/2020 to the day of survey. Findings include: 1. On the day of survey 05/11/2022 at 10:01 am, the TS could not provide competency assessment record for 7 of 10 TP (CMS 209 personnel #2, #3, #4, #5, #6, #7, and #11) who performed SARS-CoV-2 RNA PCR examinations from 12 /19/2020 to the day of survey. 2. The laboratory performed 73,912 SARS-CoV-2 RNA PCR examinations in 2021. 3. The LD confirmed the findings above on 05/11 /2022 at 12:09 pm.
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 review of the CLIA ' s Laboratory Personnel Report (Form CMS-209), review of personnel qualification records, and interview with the Laboratory Director (LD), the laboratory failed to ensure that each individual who performed High Complexity testing (1 of 10) met the CLIA requirement 493.1489b. Refer to D6171
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 review of the CLIA ' s Laboratory Personnel Report (Form CMS-209), review of personnel qualification records and interview with the Laboratory Director (LD), the laboratory failed to ensure that 1 of 10 Testing Personnel (TP) who performed Virology testing from 12/08/2020 to 05/11/2022 met the CLIA requiremnt 493.1489b. Findings Include: 1. On the day of inspection, 05/11/2022 at 09:35 am, the laboratory could not provide documentation of credentials for 1 of 10 TP (CMS 209 TP #3) who performed High complexity tests. 2. On 5/13/2022 at 02:43 pm. The laboratory provided the following documents for TP#3: - Temple University Bachelor of Science Diploma. - Temple University Master of Education Diploma. -Temple University Bachelor of Science (Electrical Engineering) Transcripts. - Temple University Master of Education Transcripts. 3. On 05/13/2022, review of the credentials revealed that TP#3 did not have the minimum qualifications. 4. The laboratory performed 73,912 SARS-CoV-2 RNA examinations in 2021. 5. The LD confirmed the findings above on 05/16/2022 at 08:41 am.