

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2109711	(X3) Date Survey Completed 03/04/2020
Name of Provider or Supplier Personalized Genetics Llc	Street Address, City, State 607 College Ave, Pittsburgh, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and interview with the technical supervisor (TS) #2, the TS failed to ensure verification of accuracy was performed twice annually for the Quantstudio12K Real Time PCR system in 2018 and 2019. Findings Include: 1. The Laboratory Procedural manual under, section E., proficiency testing and verification of methods states, "PT is not available for the tests run in the laboratory. Accuracy of methods will be verified twice annually using internal blinded controls samples, and the results will be independently analyzed by Translation Service. Results will be reviewed and evaluated by the laboratory director or his/her designee. The results of these evaluations are documented and maintained". 2. On the day of survey, 03/04/2020, the TS #2 could not provide records of the verification performed for the Quantstudio 12K Real Time PCR system in 2018 and 2019. 3. The TS #2 confirmed the findings above on 3/04/2020 around 10:35 am.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory and interview with the technical supervisor</p>

(TS) #2, the laboratory failed to perform maintenance protocols for 1 of 1 Thermo Scientific traceable thermometer used to monitor temperatures of a chest freezer storing controls for the Quantstudio 12K Real Time PCR system analyzer from 2018 to the day of survey. Findings Include: 1. On the day of survey, 03/04/2020, the surveyor observed a sticker with a maintenance due date of 07/16/2017 on the Thermo Scientific traceable thermometer, used to monitor the temperature of a chest freezer. 2. The chest freezer stored controls for the Quantstudio 12K Real Time PCR system analyzer. 3. The laboratory could not provide any other maintenance performed on the thermometer after 07/16/2017. 4. The TS #2 confirmed the findings above on 03/04/2019 around 11:15 am.

D6125

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:

Based on review of testing personnel (TP) competency assessment records and interview with the technical supervisor (TS) #2, the TS failed to assess the competency of TP through external proficiency testing samples or internal blind testing samples for 1 of 1 TP in 2018 and 2 of 4 TP in 2019 for the Quantstudio 12K Real Time PCR system analyzer. Findings Include: 1. On the day of survey, 03/04/2020, review of TP competency assessment records revealed, annual competency performed in 2018 and 2019 did not include the assessment of external proficiency testing samples or internal blind testing samples for the Quantstudio 12K Real Time PCR system analyzer for 1 of 1 TP in 2018 and 2 of 4 TP in 2019. 2. The TS #2 confirmed the finding above on 03/04/2020 around 9:45 am.