

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2039282	(X3) Date Survey Completed 01/18/2018
Name of Provider or Supplier Personal Genome Diagnostics Inc	Street Address, City, State 3600 Boston Street #10, Baltimore, MD	
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
D5293	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of the written procedure manual, observation of the laboratory, and interview with the quality assurance (QA) supervisor, the laboratory did not maintain general laboratory quality assessment procedures for documenting potential communication problems involving laboratory equipment. Findings: 1. At the time of the survey and observation of the laboratory refrigerators around 10:20 AM in the reagent room and 10:50 AM in the sample room showed yellow sticky notes on the temperature logs that were hanging on the refrigerators. 2. The sticky notes stated a to do list for June 2018. 3. The QA supervisor stated that the sticky notes were not suppose be on the refrigerators and laboratory personnel was informed to not attached sticky notes on the refrigerators for maintenance procedures that needed to be performed in the future. 4. The laboratory did not communicate or document laboratory messages utilizing the laboratory communication log and notification sheets for messages involving interlaboratory communication. 5. The QA supervisor confirmed that general laboratory quality assessment procedures for documenting potential communication problems involving laboratory equipment was not maintained.</p>
D5391	<p>PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a)</p>

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242.

This STANDARD is not met as evidenced by:

Based on review of the written procedure manual, observation of the processing area, and interview with the quality assurance (QA) supervisor, the laboratory did not ensure that policies and procedures were in place to identify and correct problems when processing patient specimens for DNA testing. Findings: 1. At the time of the survey and observation of the processing area refrigerator around 10:45 AM showed a clear bin with two different patient serum tubes in a plastic bag. 2. The QA supervisor stated that the specimens are quarantined and was unsure the reason the samples were placed in the bin. The bin did not have a quarantine label. 3. The QA supervisor interviewed the accessioners and found that one sample was received with no requisition for testing and one specimen had a sticky note attached with received date and collection date. The QA supervisor stated that the specimens had been in the refrigerator bin since the beginning of January. 4. The laboratory did not investigate and document corrective action procedures for the quarantined specimens. The QA supervisor stated that policies and procedures needed to be updated to ensure that accessioners are performing the correct procedures when preanalytic problems occur.

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 review quality assessment procedures and interview with the quality assurance (QA) supervisor, the laboratory director did not maintain quality assurance procedures for the overall criteria of laboratory acceptability. Findings: 1. The QA supervisor performs a monthly internal quality audit of laboratory operations. 2. The laboratory director did not review and sign the monthly quality audit for the year 2016. 3. The QA supervisor confirmed that the laboratory director did not review and sign the laboratory quality audits for the year 2016.

D6112

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451

The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section.

This STANDARD is not met as evidenced by:

Based on review of the written procedure, observation of the processing area, interview with the accessioner, and the quality assurance supervisor, the technical supervisor did not ensure that all accessioners processing patient specimens for DNA testing were following the laboratory's written procedures. Findings: 1. At the time of

survey and observation of the clinical processing area around 10:30 AM showed an opened package on the counter with specimens and a requisition. 2. The accessioner stated that she opens all the packages and line all specimens, packaging, and requisitions on the counter and then enter all specimens into the database for testing. 3. The written procedure states that the accessioner should open one package at a time for processing. 4. The quality assurance supervisor confirmed that the accessioner was not following the written procedure and that retraining will be performed.