

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0190807	(X3) Date Survey Completed 11/25/2020
Name of Provider or Supplier Planned Parenthood Keystone-Allentown	Street Address, City, State 29 N 9th Street, Allentown, 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	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p> <p>A. Based on review of the Laboratory's competency policy, competency assessment records and interview with the manager, the laboratory failed to establish a complete competency assessment procedure to assess the competency of 1 of 1 Technical Consultant (TC) (on the CMS 209 form, listed as personnel #2) for their supervisory responsibilities in 2018, 2019 and 2020. Findings include: 1. On the day of survey, 11/25/2020, the manager could not provide a complete competency assessment policy that reviews how to assess the competency for 1 of 1 TC for their supervisory responsibilities in 2018, 2019 and 2020. 2. The manager confirmed the finding above on 11/25/2020 around 10:15 a.m. B. Based on review of competency assessment records and interview with the manager, the laboratory failed to perform competency assessments for 1 of 1 Testing Personnel (TP) (on the CMS 209 form, listed as personnel #2) who performed Potassium hydroxide (KOH) and wet mount microscopic examinations in 2018, 2019 and 2020. Findings include: 1. On the day of survey, 11/25/2020, the manager could not provide competency assessment records for 1 of 1 TP who performed KOH and wet mount microscopic examinations in 2018, 2019 and 2020. 2. The manager confirmed the finding above on 11/25/2020 around 10:15 a.m.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an</p>

ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on review of Quality Assessment (QA) records and interview with the manager, the Laboratory failed to ensure QA programs were maintained and documented to ensure the quality of laboratory services provided in 2019 (01/01/2019 to 12/31/2019). Findings Include: 1. On the day of survey, 11/25/2020, the manager could not provide QA documentation for the periodic evaluation of the laboratory's pre-analytical, analytical, and post-analytical processes in 2019 (01/01/2019 to 12/31/2019). 2. The manager confirmed the findings above on 11/25/2020 at 12:10 p.m.

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 observation of the laboratory and interview with the manager, the laboratory failed to ensure the maintenance/function for 1 of 1 thermometer used to monitor the temperature of the laboratory refrigerator where the Rhesus (Rh) testing controls were store in 2018, 2019 and 2020. Findings Include: 1. On the day of survey, 11/25/2020, the surveyor observed 1 of 1 refrigerator thermometer in use to monitor the temperatures where the Rh testing controls were store in 2018, 2019, and 2020. 2. The laboratory could not provide documentation of maintenance/function checks performed on the thermometer in 2018, 2019 and 2020. 3. The laboratory could not provide a maintenance/function policy for the thermometer. 4. The manager confirmed the findings above on 11/25/2020 at 12:15 p.m.

D6051

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(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 Medical Laboratory Evaluation (MLE) proficiency testing (PT) records and interview with the manager, the Technical Consultant (TC) failed to evaluate the test performance of 1 of 4 testing personnel (TP) through internal blind testing samples or external PT samples for Rhesus (Rh) D factor assay examinations performed in 2018, 2019 and 2020. Findings Include: 1. On the day of survey, 11/25/2020, review of MLE PT records revealed, 1 of 4 TP (TP#3) did not perform in external PT samples for Rh D factor assay examinations for 3 of 3 events in 2018, 3 of 3 events in 2019, and 3 of 3 events in 2020. 2. The manager could not provide

documentation of internal blind testing evaluations performed for 1 of 4 TP (TP# 3) for Rh D assay examinations performed in 2018, 2019 and 2020. 3. The manager confirmed the findings above on 11/25/2020 at 10:49 a.m.