

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0190807	(X3) Date Survey Completed 09/16/2024
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
D2006	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records and interview with the Quality Manager (QM), the laboratory failed to examine 5 of 5 AAB-MLE PT immunohematology testing events in the same manner as patient specimens in 2023 and 2024. Findings include: 1. On the day of survey, 09/16/2024 at 11:12 am, review of the laboratory's AAB-MLE PT records and Rh testing Attestation forms revealed that the laboratory failed to examine the ABO Group and D (Rho) typing PT samples in the same manner as patient specimens in 2023 (events #1-3) and 2024 (events #1 and #2). 2. Interview with the QM on 09/16/2024 at 12:00 pm confirmed the PT samples for Rh testing were analyzed by each testing personnel (CMS 209 personnel #4, #5, #6, #7, #8) and the final result reported was based on the group consensus. 3. The laboratory could not provide documentation stating the Rh testing was included in the laboratory's patient repeat criteria. 4. The QM confirmed the findings above on 09/16/2024 at 12:45 pm</p>
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p>

(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records and interview with the Quality Manager (QM), the laboratory failed to provide 2 of 3 AAB-MLE PT attestation statements for immunohematology testing events performed in 2023. Findings include: 1. On the day of the survey, 09/16/2024, the laboratory failed to provide attestation statements for the 1st and 2nd event of ABO Group and D (Rho) typing proficiency testing performed in 2023. 2. The QM confirmed the findings above on 9/16/2024 at 12:45 pm.

D3009

FACILITIES

CFR(s): 493.1101(c)

The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.

This STANDARD is not met as evidenced by:

Based on document review and interview with the Quality Manager (QM), the Laboratory Director (LD) failed to be present for a reasonable period of each working day in each laboratory for which he was director from 11/01/2018 to 09/16/2024 as required by Pennsylvania (PA) state regulations. Findings include: 1. The PA State regulation 5.22 (g) states: "A director shall be present for a reasonable period of each working day in each laboratory for which he is director." 2. Review of the Application for Approval to Direct more than Two Clinical Laboratories (Exception to 5.22) form, revealed the LD currently oversees 7 compliance laboratories (39D0190807) throughout multiple sites in the state of PA. 3. The Planned Parenthood Keystone laboratory manual states, "The Lab Director will annually assess competencies of APCs (Advanced Practice Clinicians) for moderate complexity tests. Additional quality assurance standards in place for moderately complex laboratory procedures on-site include annual review of laboratory logs and daily controls by Laboratory Director or designee." 4. During an interview on 09/16/2024 at 12:45 pm, the QM confirmed the Lab Director is on-site as needed but failed to provide the date of his last on-site visit.

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 competency assessment records, lack of documentation, and interview with the Quality Manager (QM), the laboratory failed to establish a competency assessment procedure to assess 2 of 2 technical consultants (TC) for their supervisory responsibilities in 2022 and 2023. Findings Include: 1. On the day of survey, 09/16/2024 at 11:05 am, the laboratory failed to provide a competency assessment procedure to assess the competency of 2 of 2 TC (CMS 209 personnel #2 and #3) for their supervisory responsibilities in 2022 and 2023. 2. The laboratory failed to provide competency assessment documentation for 2 of 2 TC (CMS 209 personnel #2 and #3) for 2022 and 2023. 3. The QM confirmed the findings above on 09/16/2024 at 12:45 pm.