

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 39D0190807	<b>(X3) Date Survey Completed</b> 01/25/2023
<b>Name of Provider or Supplier</b> Planned Parenthood Keystone-Allentown	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> 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's proficiency testing (PT) records, and interview with the risk quality management manager, the laboratory failed to ensure that the verification of accuracy of wet mount and potassium hydroxide (KOH) microscopic examinations were performed at least twice annually as required from 11/25/2020 to 01/25/2023. Findings Include: 1. On the day of the survey, 01/25/2023 at 11:06 am, the laboratory could not provide documentation that the verification of accuracy for KOH and wet mount microscopic examinations were performed at least twice annually from 11/25/2020 to the the date of the survey. 2. The risk quality management manager confirmed the finding above on 01/25/2023 around 02:00 pm.</p>
<b>D5449</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality control (QC) records, and interview with the risk quality management manager, the laboratory failed to include a negative and positive control</p>

	<p>material each day of patient testing for Rhesus factor (Rh) Group testing from 12/21/2021 to the date of the survey . Findings Include: 1. On the day of survey, 01/25/2023 at 01:00 pm, review of the Rh QC records revealed the laboratory performed external quality controls on the Eldon Rh typing cards weekly from 12/21/2021 to 01/25/2023. 2. The risk quality management manager confirmed the findings above on 01/25/2023 around 02:00 pm.</p>
<p><b>D5463</b></p>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(7)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Over time, rotate control material testing among all operators who perform the test. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality control records and interview with the risk quality management manager, the laboratory failed to over time rotate control material testing between 5 of 5 testing personnel (TP) who perform Rhesus factor (Rh) Group testing on the Eldon Rh typing card from 12/21/2021 to the date of the survey. Findings include: 1. On the date of the survey, 01/25/2023 at 01:00 pm, review of the laboratory's weekly Rh Control test log revealed that 4 of 5 TP (CMS 209 personnel # 5, 6, 7, and 9) did not perform QC from 12/21/2021 to 01/25/2023 for Rh testing performed on the Eldon Rh typing cards. 2. The risk quality management manager confirmed the finding above on 01/25/2023 around 02:00 pm.</p>
<p><b>D6021</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on the review of laboratory health center assessment and infection control audit records and interview with the risk quality management manager, the laboratory director failed to ensure quality assessment (QA) programs were maintained and documented to assure the quality of laboratory services provided from 11/25/2020 to the date of survey. Findings Include: 1. On the day of survey, 01/25/2023 at 12:35 pm, a review of the laboratory's health center assessment records revealed no documented review was performed by the LD for the following from 11/25/2020 to 01/25/2023. - 07/06/2022: health center assessment performed by risk quality management manager - 09/14/2022: health center assessment performed by risk quality management manager - 08/16/2021: health center assessment performed by risk quality management manager 2. The risk quality management manager confirmed the findings above on 01/25/2023 around 02:00 pm.</p>
<p><b>D6046</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b></p>

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's personnel competency records, lack of documentation, and interview with the risk quality management manager, the technical consultant failed to evaluate the competency assessment of 6 of 6 testing personnel (TP) that performed potassium hydroxide (KOH) and wet mount microscopic examinations in 2021 and 2022. Findings include: 1. On the day of survey, 01/25/2023 at 10:16 am, the laboratory could not provide documentation of the competency assessments for 6 of 6 TP (CMS 209 personnel # 2, 3, 4, 10, 11, 12) that performed KOH and wet mount microscopic examinations in 2021 and 2022. 2. The risk quality management manager confirmed the finding above on 01/25/2023 around 02:00 PM.