

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0107979	(X3) Date Survey Completed 10/10/2019
Name of Provider or Supplier Planned Parenthood	Street Address, City, State 240 Mulberry St, Newark, NJ	
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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <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.</p> <p>This STANDARD is not met as evidenced by:</p> <p>a. Based on surveyor review of the Proficiency Testing (PT) records and interview with the Director of Risk and Quality (DRQ), the laboratory failed to maintain the Attestation Statements (AS) signed by the analyst and laboratory director for Immunohematology (IH) tests performed with the American Proficiency Institute (API) in 1-2019 at the Montclair location. The DRQ confirmed on 10/10/19 at 11:15 am that the laboratory did not maintain all AS records. b. Based on surveyor review of PT records and interview with the DRQ, the laboratory failed to retain all PT result records performed with API for Vaginal Wet Preparation (KOH) in the 1-2019 and 2-2109 events for the Patterson, Iron Bound, and East Orange locations. The DRQ confirmed on 10/10/19 at 11:40 am that all PT records were not retained. c. Based on surveyor review of PT records and interview with the DRQ, the laboratory failed to retain all PT work records performed with API for IH in 1-2019 and 2-2019 events for all locations. The DRQ confirmed on 10/10/19 at 11:45 am that the laboratory did not maintain all work records.</p>

<p>D5209</p>	<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: Based on surveyor review of the Competency Assessment (CA) records and interview with the Director of Risk Manger (DRQ), the laboratory failed to perform a CA on seven out of seven Testing Personnel (TP) reviewed in the calendar year 2018. The DRQ confirmed on 10/10/19 at 10:50 am that CA was not performed on TP in 2018.</p>
<p>D5211</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: a. Based on surveyor review of the Proficiency Testing records and interview with the Director of Risk and Quality (DRQ), the laboratory failed to evaluate "Not Graded" results obtained for Vaginal Wet Prep (KOH) proficiency testing performed with the American Proficiency Institute (API) for sample VKP-01 in the 2-2019 event at the Mulberry Site. The DRQ confirmed on 10/10/19 at 11:20 am that the laboratory failed to evaluate coded results. b. Based on the surveyor review of the Proficiency Testing (PT) records and interview with the DRQ, the laboratory failed to review and evaluate Immunohematology PT results obtained from API for all events in 1-2019 and 2-2019. The findings include: 1. Results were not evaluated for D(Rho) type as follows: a. 2-2019 - Montclair b. 1-2019 and 2-2019 - East Orange 2. The DRQ confirmed on 10/10/19 at 11:30 am that the laboratory did not review and evaluate all PT results.</p>
<p>D5221</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Director of Risk and Quality (DRQ), the laboratory failed to evaluate results when they received an unacceptable score for analyte Rh-08 in 2-2019 Immunohematology tests performed with the American Proficiency Institute (API) in the 2-2019 event performed in East Orange. The findings include: 1. The laboratory received an "Unacceptable" result in 2-2019 for D(Rho) Type sample Rh-08. 2. There was no documented evidence that the laboratory investigated the failure. 3. The DRQ confirmed on 10/10/19 at 11:10 am that the laboratory did not perform and document an evaluation of unacceptable PT result.</p>
<p>D5411</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p>

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

Based on surveyor observation of Eldon Cards, review of the Manufactures Package Insert (MPI), Quality Control log (QC) and interview with the Director of Risk and Quality (DRQ), the laboratory failed to follow the MPI for Rhesus (Rh) factor test from 10/18/17 to the date of survey. The findings include: 1. The MPI stated Eldon Cards "expires six month after first opening" but the laboratory did not put a new expiration date on the Eldon cards at the time of the survey. 2. the MPI stated to "upon receipt of Eldon cards check for possible damage by testing with red cells with and without the RhD antigen" but there was no documented evidence this was done. 3. The DRQ confirmed on 10/10/19 at 12:10 pm the laboratory failed to follow the MPI.

D5805

TEST REPORT

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Final Reports (FR) and interview with the Director of Risk Manager (DRQ), the laboratory failed to ensure that the Test Report Date (TRD) was indicated on the FR from 10/18/17 to the date of survey. The DRQ confirmed on 10/10/19 at 12:20 pm that the TRD was not on the FR.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on surveyor review of Personnel Files and interview with the Director of Risk Manager (DRQ), the Laboratory Director failed to have education documented for one

out of seven Testing Personnel reviewed from 10/18/17 to the date of the survey. The DRQ confirmed on 10/10/19 at 10:40 am that all education records were not available.