

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2063150	(X3) Date Survey Completed 05/13/2021
Name of Provider or Supplier Planned Parenthood Ncsnj - Flemington	Street Address, City, State 349 Route 31 South, Bldg B, Unit 503, Flemington, 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: Based on surveyor review of Proficiency Testing (PT) records and interview with the Vice President of Medical Administration (VP), the laboratory failed to ensure that the attestation statement for Rhesus (Rh) factor, Vaginal Wet Prep and Potassium Hydroxide (KOH) tests performed with the American Proficiency Institute (API) were signed by the Laboratory Director (LD) in the calendar year 2020 for events 1, 2 and 3. The VP confirmed on 5/13/21 at 1:30 pm that the that the LD did not sign the attestation statements listed above.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p>

This STANDARD is not met as evidenced by:
Based on surveyor review of the Quality Control (QC) records and interview with the Quality Risk Manager (QRM), the laboratory used expired QC material for Rhesus (Rh) factor tests from 12/25/20 to 4/23/21. The findings include: 1. Known Rh Positive Blood Control Lot # HMN503375 expired on 12/25/20 but the laboratory ran samples from 12/26/20 to 2/24/21 with expired control. 2. The laboratory performed and reported approximately 18 patient results during the above time frame. 3. The QRM confirmed on 5/13/21 at 10:35 am that the laboratory used expired QC.

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(g)

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.

This STANDARD is not met as evidenced by:
Based on surveyor review of the Quality Control (QC) records and interview with the Quality Risk Manager (QRM), the laboratory failed to verify the positive control used for Rhesus factor tests (Rh) from January 2020 to the date of the survey. The finding includes: 1. There was no documented evidence the patients' sample used for the positive control was verified to ensure it was positive prior to use. 2. The QRM confirmed on 5/13/21 at 10:30 am QC was not verified.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iii)

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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:
Based on surveyor review of Proficiency Testing (PT) records and interview with the Vice President of Medical Administration (VP), the Laboratory Director failed to ensure that all PT results received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action for Rhesus (Rh) factor, Vaginal Wet Prep and Potassium Hydroxide (KOH) tests performed with the American Proficiency Institute (API) in the calendar year 2020 for events 1, 2 and 3. The VP confirmed on 5/13/21 at 1:30 pm that the API PT results were not reviewed.