Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0668205	(X3) Date Survey Completed 01/03/2025
Name of Provider or Supplier Planned Parenthood Ncsnj - Shrewsbury	**Street Address, City, State** 69 East Newman Springs Road, Shrewsbury, 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
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Office Manager (OM) the laboratory failed to review coded results for potassium Hydroxide (KOH) Testing performed with the American Proficiency Institute (API) in the second event of 2024 and third event of 2023. The findings include: 1. The laboratory received a coded result (Code 2 -No Consensus) "See Data Summary" for Vaginal Wet Preparation as follows: a) 2nd event 2024 sample VA-02 b) 3rd event 2023 sample VA-03 2. There was no documented evidence that coded PT result was reviewed. 3. The OM confirmed on 1/3/25 at 11:15 am that the laboratory did not review coded PT results.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters.

	This STANDARD is not met as evidenced by: Based on the lack of Quality Control Verification (QCV) records and interview with the Office Manager (OM)), the laboratory failed to verify QC material before patient testing for Rhesus factor performed on Eldoncard test system from May 2024 to the date of survey. The findings include: 1) There was no documented evidence that QCV was performed on the aforementioned test system. 2) The OM confirmed 1/3/25 at 11: 00 am there was no documented evidence that QC material was verified before patient testing.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with Office Manager (OM), the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems from 9/20/23 to the date of survey. The finding includes: 1. The laboratory lacked a Quality Control Verification (QCV) procedure for all Rhesus factor (Rh) testing performed by the laboratory. 2. The OM confirmed on 1/3/25 at 11:45 am that the laboratory failed to have a QCV procedure for Rh testing.