

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2065775	(X3) Date Survey Completed 09/22/2022
Name of Provider or Supplier Planned Parenthood Ncsnj - Hackensack	Street Address, City, State 575 Main Street, Hackensack, 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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Accession Log (AL), Test Records (TR) and interview with the Office Manager (OM), the laboratory failed to retain patient TR for KOH Wet Mount tests from 4/1/22 to the date of the survey. The finding includes: 1. From a random sample of five patients found in the AL one out of five TR were not available for review. 2. The OM confirmed on 9/22/22 at 10:40 am all patient TR were not retained.</p>
D5211	<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: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Office Manager (OM), the laboratory failed to review and evaluate PT results obtained from the American Proficiency Institute (API) for Hematology/Coagulation 3rd event 2021 and 2nd event of 2022. The findings include: 1. The laboratory did not evaluate "Not Graded" response from API for the following: a. Vaginal Wet</p>

Preparation sample VA-03 2021 3rd event b. Vaginal Wet Preparation sample VA-02 2022 2nd event 2. The OM confirmed on 9/22/22 at 10:30 am that the laboratory failed to evaluate the above mentioned coded results.