

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0679767	(X3) Date Survey Completed 04/18/2023
Name of Provider or Supplier Hackensack Meridian Health Network	Street Address, City, State 1030 St Georges Ave, Avenel, 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
D3037	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to retain graded results for Hematology /coagulation PT events 3-2022, 2-2022 1-2022 performed with the American Proficiency Institute. The TP confirmed on 4/18/22 at 10:45 am that all PT graded results were not retained.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), monthly Quality Control (QC) and interview with the Testing Personnel (TP), the laboratory failed to have a procedure for failed QC for Hematology testing from 8/2/5/19 to the date of survey. The findings include: 1) Two out of three levels of QC on controls failed on 2/23/22. 2) Control lot # 2221031 was run six times. 3) There were no corrective action procedures for failed QC in the PM. 4) The TP confirmed on 4/18/22 at 10:30 am that the laboratory failed to have the aforementioned procedure.</p>