

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D1069749	(X3) Date Survey Completed 11/25/2025
Name of Provider or Supplier Hackensack Meridian Health Network	Street Address, City, State 2 Hospital Plaza, Old Bridge, 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>(a)(4) 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 lacked copies of all PT records for testing performed with the American Proficiency Institute (API) for the 2nd Hematology PT event of 2025. The findings include: 1. The laboratory lacked the work records and the attestation page for the 2nd Hematology PT event of 2025. 2. TP #1 as listed on the CMS 209 form confirmed on 11/25/25 at 11:30 am, all PT records were not retained.</p>
D6030	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</p> <p>(e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Competency Assessment (CA) records, the lack of a Procedure Manual (PM) and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to have complete established procedures for assessing</p>

the competency of TP from 6/18/24 to 11/25/25. The findings include: 1. The laboratory did not have a complete written CA procedure that included the following: a) How the competency of new TP will be initially assessed. b) How the competency of new TP will be assessed 6 months after the initial assessment. c) The frequency for competency assessment of TP. d) How TP will be assessed for the six required CA procedures. 2. TP #1 as listed on the CMS 209 form confirmed on 11/25/25 at 10:30 am, the LD failed to establish written policies and procedures for CA. *Note: This deficiency was previously cited on the survey performed on 6/18/24.