

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 41D2093720	<b>(X3) Date Survey Completed</b> 04/08/2026
<b>Name of Provider or Supplier</b> Miriam Hospital, The	<b>Street Address, City, State</b> 1180 Hope Street, Bristol, RI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An onsite validation survey was conducted on 04/08/2026. The laboratory was found to be in compliance with condition-level deficiencies. The following standard-level deficiencies were cited.
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> 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. In addition, retain the following:</p> <p>This STANDARD is not met as evidenced by: Based on laboratory observation, review of quality control records, and interview with the General Supervisor (GS), the laboratory failed to retain chemistry quality control records for 8 of 8 months from November 1, 2024 to June 30, 2025. Findings: 1. During a tour of the laboratory, the following instrument was observed in use for chemistry testing: Abbott Alinity Serial Number: AC06367 2. A random date, 12/12 /2024, was selected for chemistry quality control (QC) record review for the analyte Magnesium. The Testing Personnel (TP) searched the Laboratory Information System (LIS) and the Abbott Alinity instrument data base but could not find the QC data. Further investigation by the TP revealed there was no QC data for Magnesium between November 1, 2024 to June 30, 2025. 3. In an interview on 04/08/2026 at 4:20 PM, the GS confirmed the findings stated above for Magnesium, BioRad Quality Control Level 1 and 3 (Lot # 56750).</p>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish</p>

and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies, review of personnel competency records and interview with the General Supervisor (GS), the laboratory failed to establish written policy for competency assessment of the GS and did not complete one of two annual competency assessments for the GS from 2024 to 2025. Findings: 1. A review of the laboratory policy, LABADM 2.1-Lab Testing Personnel, Training, Competency & Proficiency Testing revealed competency assessment for a GS was not included. 2. A review of the 2024 and 2025 laboratory personnel competency records revealed there was no assessment completed for the GS in 2024. 3. In an interview on 04/08/2026 at 12:55 PM, the GS confirmed the findings stated above.