

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0432460	(X3) Date Survey Completed 05/21/2026
Name of Provider or Supplier Hopedale Medical Complex	Street Address, City, State 107 S Tremont St, Hopedale, IL	
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
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>(b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: D5213 Based on review of laboratory policies and procedures, laboratory records, American Proficiency Institute (API) proficiency testing (PT) records, lack of documentation, and interview with Testing personnel (TP) #1; the laboratory failed to verify the accuracy for 26 of 26 analytes not evaluated by the PT provider for five of six PT events reviewed for the specialties of hematology, microbiology, and chemistry in 2024, 2025 and 2026. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled, "Proficiency Testing", which stated, under "Procedure", "For any missed test corrective action must be taken." 2. Review of API comparative evaluation summaries for the following PT events of 2024, 2025 and 2026 revealed the following un-graded PT samples: PT Event: Analyte : Sample: 2024 Event 2 Vaginal Wet Prep VA-02 2024 Event 2 Urobilinogen UA-04 2024 Event 2 Gram Stain GS-13 2024 Event 3 CK-MB CM-11 2024 Event 3 Myoglobin (CM) CM-11 2024 Event 3 Troponini I(CM) CM-11 2025 Event 2 BNP CM-07 2025 Event 2 D-dimer (CM) CM-07 2025 Event 2 D-dimer (CM) CM-08 2025 Event 2 Total Bilirubin CH-07 2025 Event 2 Total Bilirubin CH-09 2025 Event 2 Total Bilirubin CH-10 2025 Event 2 Triiodothyronine CH-06 2025 Event 2 Folate IA-07 2025 Event 2 Folate IA-09 2025 Event 2 Gram Stain GS-09 2025 Event 2 Susceptibility A UR-06 2025 Event 3 BNP CM-15 2025 Event 3 Total Bilirubin CH-12 2025 Event 3 Total Bilirubin CH-15 2025 Event 3 Blood Cell I.D. BCI-15 2025 Event 3 Reticulocyte CountRET-06 2025 Event 3 Susceptibility B UR-12 2026 Event 1 BNP CM-01 2026 Event 1 BNP CM-04 2026 Event 1 Total Bilirubin CH-05 3. Review of laboratory records found no documented review of the ungraded PT</p>

analytes in the specialties of hematology, microbiology, and chemistry in 2024, 2025 and 2026. 4. Interview with TP #1 on 05/21/26, at 10:59 am, confirmed the laboratory failed to verify the accuracy of analytes not evaluated by the PT provider for five of six applicable PT events.

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

(b)(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of laboratory's policy and procedure manual, testing personnel competency records, and interview with Technical Supervisor (TS) #1; the laboratory failed to have competency assessments performed semi-annually during the first year of patient testing for one of five testing personnel (TP) performing high complexity testing for the specialties of Diagnostic Immunology, Chemistry, Hematology, Immunohematology and Microbiology. Findings include: 1. Review of the laboratory policy titled, "Laboratory Competency", stated the following, "5. Competency and performance evaluations will be performed twice during the first year of employment and annually thereafter." 2. Review of testing personnel competency records revealed one of five TP (TP #5) performing high complexity testing failed to have two competency evaluations completed in their first year of high complexity testing. TP #5 completed their probationary evaluation on 05/01/2024. One competency evaluation for TP #5 was completed and signed off on 04/01/2025 during their first year of patient testing. 3. Interview with TS #1 on 05/21/2026, at 10:00 am, confirmed the laboratory failed to have completed competency assessments semi-annually during the first year of patient testing for one of five TP performing the high-complexity testing.