

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 35D0408706	(X3) Date Survey Completed 08/14/2025
Name of Provider or Supplier Heart Of America Medical Center	Street Address, City, State 2975 Highway 2 East, Rugby, ND	
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
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on record review, policy review, and staff interview, the laboratory failed to verify the accuracy of results for 2 of 2 regulated analytes (N-terminal pro-B-type natriuretic peptide [NT Pro-BNP] and Folate) the American Proficiency Institute (API) assigned as not graded. The laboratory performed 421 NT Pro-BNP patient tests and 96 Folate patient tests in 2024. Findings include: 1. Reviewed on 08/13/25, the 1st Event 2025 Chemistry Core proficiency testing showed NT Pro-BNP samples CM-01 through CM-05 as not graded. The laboratory failed to evaluate the not graded results. 2. Reviewed on 08/13/25, the 2nd Event 2025 Chemistry Core proficiency testing showed Folate samples IA-07 and IA-09 as not graded. The laboratory failed to evaluate the not graded results. 3. During interview at 11:33 a.m. on 08/13/25, a technical supervisor (#1) confirmed the laboratory failed to evaluate the 1st Event 2025 NT Pro-BNP not graded results and 2nd Event 2025 Folate not graded results. 4. Reviewed on 08/13/25, the "Proficiency Testing Policy," effective 1/05, stated, ". . . Analytes not scored . . . need to be evaluated also. . . . document on survey report that you acknowledged result. . . . If results not comparable write up a 'Report of Analysis of unacceptable proficiency survey'. . . ."</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p>

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on observation, manufacturer's instructions review, and staff interview, the laboratory failed to store AUDIT MicroControls Linearity samples according to the manufacturer's instructions on 1 of 1 day observed (08/13/25). The laboratory performed 303 D-Dimer, 421 N-terminal pro-B-type natriuretic peptide (NT Pro-BNP), and 1,610 Hemoglobin A1C (Hgb A1C) patient tests in 2024. Findings include: 1. Observation of the laboratory's freezer occurred at 7:50 a.m. on 08/13/25. The freezer contained the following AUDIT MicroControls Linearity samples: one box Linearity FD D-Dimer, one box Linearity FD BNP (Extended), and one box Linearity FD HbA1c. The freezer temperature was -28 degrees (*) Celsius (C). 2. Reviewed at 7:50 a.m. on 08/13/25, the AUDIT MicroControls Instructions for Use stated, "Product should be stored at 2-8°C. . . . Use immediately or return to 2-8°C. During sampling, time outside 2-8°C should be minimized. . . ." 3. During interview at 7:50 a.m. on 08/13/25, a technical supervisor (#1) stated the laboratory used the AUDIT MicroControls Linearity samples for D-Dimer, NT Pro-BNP, and Hgb A1C and confirmed the laboratory should not have frozen the samples.

D5445

CONTROL PROCEDURES

CFR(s): 493.1256(d)(1)(2)(g)

(d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for:

This STANDARD is not met as evidenced by:

Based on record review, plan review, and staff interview, the laboratory failed to follow their Individualized Quality Control Plan (IQCP) for quality control performance for 1 of 7 months reviewed (March 2025) for D-Dimer testing on the Siemens Stratus. The laboratory performed 303 patient D-Dimers in 2024. Findings include: 1. Reviewed on 08/13/25, the QC records for D-Dimer performed on the Siemens Stratus indicated the laboratory failed to perform two levels of QC for the month of March 2025 as stated in the laboratory's IQCP. 2. Reviewed on 08/13/25, the laboratory's D-Dimer IQCP, last reviewed 07/10/25, stated to run two levels of QC monthly. 3. During interview at 2:50 p.m. on 08/13/25, a technical supervisor (#1)

confirmed the laboratory's IQCP for D-Dimers on the Siemens Stratus required performance of two levels of QC each month and the laboratory failed to perform two levels of QC in March 2025.