

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0465364	(X3) Date Survey Completed 06/01/2023
Name of Provider or Supplier Delta Memorial Hospital	Street Address, City, State 811 Highway 65 S, Dumas, AR	
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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Through a review of proficiency test documentation for 2022, it was determined the laboratory director or designee failed to sign attestation statements for ten of fourteen proficiency testing events in 2022. Survey findings follow: A) A review of the Attestation Statements for 1st, 2nd, and 3rd API Hematology/Coagulation Testing Events of 2022 revealed that the laboratory director or designee failed to sign the Attestation Statements. B) A review of the Attestation Statements for 1st and 2nd API Chemistry Miscellaneous Proficiency Testing Events of 2022 revealed that the laboratory director or designee failed to sign the Attestation Statements. C) A review of the Attestation Statements for 1st, 2nd, and 3rd API Immunology/Immunochemistry Proficiency Testing Events of 2022 revealed that the laboratory director or designee failed to sign the Attestation Statements. D) A review of the Attestation Statements for 1st and 2nd API Microbiology Proficiency Testing Events of 2022 revealed that the laboratory director or designee failed to sign the Attestation</p>

Statements. E) In an interview at 2:02 p.m. on 5/30/23, laboratory employee #3 (as listed on the form CMS-209) confirmed that the laboratory director or designee failed to sign Attestation Statements for ten proficiency testing events in 2022.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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:
Through observation, review of temperature records, lack of documentation and interview it was determined that the laboratory failed to monitor the temperature on each day of operation in one of five rooms in which supplies with storage temperature requirements were stored. Findings follow: A) During a tour of the laboratory on 5/30/23 at 9:50 a.m., five separate rooms (main lab, phlebotomy blood drawing area, microbiology lab, storage room, and arterial blood gas lab) containing items with a temperature storage requirement were observed. B) During a review of the laboratory's temperature records it was noted that no temperature records were presented for the storage room. C) During a tour of the laboratory on 6/1/23 at 8:40 a.m. thirteen 2L bottles of Procell M lot # 65858301 expiration date 2024-5-31 and twelve 2L bottles of CleanCell M lot # 90122102 expiration date 2024-09-31, both products with a storage temperature requirement of 15 to 25 degrees C., were observed in the storage room. D) Upon request, the laboratory could not present the temperature records for the storage room in which the supplies identified above were stored. E) In an interview on 5/31/23 at 3:00 p.m., the laboratory staff member (# 4 on the CMS 209) stated " no we don't have temperatures for the storage room".

D5551

IMMUNOHEMATOLOGY
CFR(s): 493.1271(a)(f)

(a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Through a review of blood bank patient and quality control logbook, as well as interviews with laboratory staff, it was determined the laboratory failed to perform quality control each day of testing patient samples. Survey findings follow: A) The

blood bank patient and quality control logbook includes documentation of a crossmatch performed for one unit of blood on 1/26/2022 on Patient MR # 3174 and one unit of blood on 1/31/22 on Patient MR # 2671 There was no documentation in the blood bank patient and quality control log of blood bank quality control for 1/26/2022 or 1/31/2022. B) In an interview, at 2:20 p.m. on 5/31/23, laboratory employee #3 (as listed on the form CMS-209) confirmed the lack of documented quality control on the dates listed above.