Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0465364	05/20/2021
Name of Provider or Supplier	**Street Address, City, State**	
Delta Memorial Hospital	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
D2005	ENROLLMENT CFR(s): 493.801(a)(4) Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act. This STANDARD is not met as evidenced by: . Through a review of the Casper 0096D report, proficiency testing documentation, lack of documentation and interview with staff, it was determined the Respiratory laboratory failed to report proficiency testing results to Arkansas Department of Health (ADH) for three of three proficiency testing events in 2019 and 2020. Survey Findings follow: A. A review of Casper 0096D report for Delta Memorial Hospital Respiratory Laboratory revealed no proficiency testing scores for the analytes PH Blood Gas, PO2 Blood Gas and PCO2 Blood Gas in 2019 for three of three proficiency testing events. B. A review of Casper 0096D report for Delta Memorial Hospital Respiratory Laboratory revealed no proficiency testing scores for the analytes PH Blood Gas, PO2 Blood Gas and PCO2 Blood Gas in 2020 for three of three proficiency testing events. C. A review of the College of American Pathologist (CAP) for three of three proficiency testing events in 2019 and 2020 revealed the Respiratory laboratory participated in proficiency testing and received testing scores for three of three proficiency testing events in 2019 and 2020. D. Upon request the laboratory could not provide documentation that the proficiency testing results for three of three testing events in 2019 and 2020 had been reported to ADH. E. In an interview on 05/18/2021 at 10:30, the technical consultant confirmed Respiratory Laboratory participated in proficiency for 2019-2020 and the proficiency testing results were not reported to ADH.
D5445	CONTROL PROCEDURES

	CFR(s): 493.1256(d)(1)(2)(g) 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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Through a review of Hematology policy and procedure manual, Hematology Quality Control (QC) records for November 2019, March and July of 2020, laboratory patient log, lack of documentation as well as interview with staff it was determined the laboratory failed to document Hematology quality control when patients were tested. Survey Findings Follow: A. A review of the Hematology policy manual revealed the Quality Control policy: "Three levels of Sysmex XN-L controls will be tested once daily on the XN-550". B. A review of QC data for the month of November of 2020 (one of three months reviewed) revealed on 11/18/2020 (one of thirty days in November 2020) the laboratory had no documentation of acceptable Quality Control for Hematology. C. A review of laboratory patient log revealed on 11/18/2020, the laboratory resulted Complete Blood Counts on twenty-seven patients. D. In an interview on 05/19/2021 at 10:30, the technical consultant confirmed patients were tested and reported without acceptable QC for November 18,2020.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) 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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Through a review of ALCOR Erythrocyte Sedimentation Rate (ESR) package inserts, ESR Quality Control (QC), lack of documentation, as well as interviews with laboratory staff, it was determined the laboratory failed to establish the criteria for acceptability of ESR control as required by the manufacturer. Survey Findings Follow: A. ALCOR Mini-Sed Auto analyzer is utilized by the laboratory to perform ESR assay. A review of package insert for Alcor ESR controls for automated Sedimentation Rate revealed: "It is recommended that an individual laboratory establish its own mean and acceptable ranges and use those provided only as a guide."

	B. In a review of ESR quality control data, it was determined the mean and acceptable range in three of three months (January, April of 2021 and November 2020) reviewed matched the expected range as listed on the ALCOR ESR package insert. Level I control range (Lot # C138) (6-8 mm/hr) and Level II control range (Lot #C238) (40-94 mm/hr). C. The surveyor requested documentation of established ranges for ESR quality controls. None was provided. D. In an interview on 05/19/2021 at 10:00, laboratory employee #1 (as listed on CMS-209) confirmed that the laboratory has not established their own mean and range for ESR quality controls. The laboratory uses the manufactures ranges for the ESR control.