

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0316753	(X3) Date Survey Completed 03/22/2018
Name of Provider or Supplier Delta Health System - The Medical Center	Street Address, City, State 1400 East Union St - Laboratory, Greenville, MS	
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records for all events of 2016 and 2017 and the first event of 2018, the (CMS) Centers for Medicare & Medicaid Services 209 personnel form and confirmation by respiratory staff at 11:30am on 3/22/18, the Respiratory Department failed to rotate the proficiency testing events among all testing personnel responsible for performing patient blood gas testing.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Roche Cobas 501 chemistry analyzer (serial number 1394) maintenance form from 4/17/16 to 3/22/18, day of survey and interview with chemistry staff and Roche service representative at 4:00 pm on 3/22/18, the laboratory failed to document as performed the bi-monthly maintenance on the Cobas 501 chemistry analyzer as required by the manufacturer. The following maintenance was not documented as performed according to the required maintenance instructions of the manufacturer: Every 2 Months Maintenance: Replace ISE measuring cartridges</p>

D5449

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of manufacturer's instructions for the Alere Determine Human Immunodeficiency Virus (HIV) 1/2 Combo Test, quality control records, patient test log for HIV testing from 2-11-18 through 3-19-18, lack of documentation of an Individualized Quality Control Plan (IQCP), and confirmation by the technical consultant of serology, the laboratory failed to include a positive and negative control for HIV-1 antibodies, HIV-2 antibodies, and HIV-1 p24 antigen, each day of patient testing during this time frame. A total of sixteen patient HIV 1/2 specimens were tested and results reported on twelve days when controls were not documented as performed on the Alere Determine HIV 1/2 Combo Test. Findings include: Review of manufacturer's instructions for the Alere Determine HIV 1/2 Combo Test revealed the test kit is categorized as moderate complexity for venous whole blood specimens. The technical consultant of serology confirmed the laboratory uses venous whole blood specimens for testing with the Alere Determine HIV 1/2 Combo Test. Review of quality control records for the Alere Determine HIV 1/2 Combo Test and the patient test log from 2-11-18, when the test kit was put in use, through 3-19-18 revealed the laboratory failed to include a positive and negative control for HIV-1 antibodies, HIV-2 antibodies, and HIV-1 p24 antigen each day of patient testing for twelve days during this time frame when sixteen patient HIV 1/2 results were reported. The technical consultant of serology confirmed an IQCP was not established for the Alere Determine HIV 1/2 Combo Test.