

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  04D0469373	<b>(X3) Date Survey Completed</b>  02/06/2019
<b>Name of Provider or Supplier</b>  Mercy Waldron	<b>Street Address, City, State</b>  1341 W 6th St, Waldron, AR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5469</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(10)(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Through a review of the laboratory policy and procedure manual, monthly Levey-Jennings graphs for Protime, APTT (activated partial thromboplastin time), and D-dimer, and quality control package inserts, and through interviews with laboratory staff, it was determined the laboratory failed to determine statistical ranges for the establishment of control ranges. Survey findings include: 1. The laboratory used package insert ranges instead of establishing it's own ranges for the Protime and APTT which used STA-COAG CONTROL (N + ABN) PLUS as the control material. A. The package insert for the STA-COAG CONTROL (N + ABN) PLUS states that the control ranges given in the package insert are intended only as a guideline and it is recommended that each laboratory establish its own target values and acceptance ranges. The ranges listed in the package insert as guidelines are as follows: Normal Protime 12.5 to 15.5; Normal APTT 30 - 41; Abnormal Protime 20 - 32; and Abnormal APTT 79 - 103. B. Instrument quality control printouts for QC lot 252679,</p>

which the laboratory began using as a control on 11/1/2018, list the following current (2/6/2019) control ranges used as acceptance ranges: Normal Protime 12.5 to 15.5; Normal APTT 30 - 41; Abnormal Protime 20 - 32; and Abnormal APTT 79 - 103. These ranges are the exact ranges listed in the package insert which are intended only as guidelines. C. In an interview on 2/5/2019 at 3:18/2019, laboratory employee #2 (as listed on the form CMS-209) confirmed the ranges programmed into the instrument as acceptable ranges were taken from the package insert of the control material. 2. The laboratory failed to use calculated standard deviation in setting acceptable ranges for quality control for the D-dimer assay. A. The laboratory policy and procedure manual includes a policy for quality control daily review that states the laboratory uses quality control failure rules, 1-3s; 2-2s; and R-4s where "s" is standard deviation. The 1-3s rule is defined as a failure of one control level outside of three standard deviations from the mean. The 2-2s rule is defined as a failure of two controls outside of the same two standard deviations from the mean. The R-4s rule is defined as two controls in the same run being separated by four standard deviations (one control outside of plus two standard deviations and another control outside of minus two standard deviations in the same run). In order to use these control rules the laboratory must calculate standard deviations. B. A review of the current Levey-Jennings graph for D-dimer dated 2/6/2019 revealed the calculated standard deviation for D-dimer Level 1 Control (Lot # 35669700) at the time of the survey was documented as 0.056 (rounded 0.06). The plus or minus two standard deviation range for D-dimer Level 1 Control, listed on quality control daily printouts, is -.408 to 2.052. This is calculated from an approximate 0.6 standard deviation instead of the 0.06 calculated by the quality control software. The standard deviation in use for calculation of the range is ten times the actual standard deviation that the test system is experiencing. C. In an interview on 2/5/2019 at 3:18/2019, laboratory employee #2 (as listed on the form CMS-209) confirmed the current ranges in use for the D-dimer Level 1 Control (Lot # 35669700) are not the appropriate and do not correlate with the instrument calculations.

**D5481**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Through a review of Individual QC Charts for September 2018, November 2018, and January 2019, a review of patient test reports, and an interview with laboratory staff, it was determined the laboratory reported AST (aspartate aminotransferase) before quality control was within the laboratory's acceptable range. Survey findings include:  
A. The Individual QC Chart for September 2018 shows that on 9/30/2018 Level 1 quality control Lot #47983 (acceptable range for the control was 38.1 to 42.9) results for AST were unacceptable when initially performed at 2:20 a.m. (result listed as 33) and was repeated thirteen times before the control was acceptable on the 14th repeat at 12:08 p.m. (acceptable result 39). B. A review of patient chemistry test reports for 9/30/2018 revealed that one of four patients with AST reported on 9/30/2018 was reported before the quality control was acceptable at 12:08 p.m.. Patient #31966785 had an AST result reported on 9/30/2018 at 11:14 (54 minutes before the acceptable control).

C. In an interview at 10:12 on 2/6/2019, laboratory employee #2 (as listed on the form CMS-209) confirmed an AST result was reported on Patient #31966785 before the quality control was acceptable.

**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 immunohematology quality control records for 2018 through January 2019 and Blood Bank Worksheets for 2018 through the date of the survey, as well as interviews with laboratory staff it was determined the laboratory failed to perform and document quality control for immunohematology testing on one day of patient testing. Survey findings follow: a. A review of quality control records for January 2018 through January 2019 revealed the laboratory failed to document immunohematology (blood bank) quality control on 1/18/2019. b. A review of the Blood Bank Worksheet for 1/18/2019 showed a blood type and Rh and a crossmatch for two units of blood was performed on Patient #E1402198693. c. At 12:46 p.m. on 2/6/2019 laboratory employee #2, from the Form CMS-209, reviewed quality control records and confirmed the lack of documented quality control on a day of blood bank patient testing.