

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  25D0029591	<b>(X3) Date Survey Completed</b>  10/15/2021
<b>Name of Provider or Supplier</b>  Trace Regional Hospital	<b>Street Address, City, State</b>  1002 E Madison St, Houston, MS	
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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory personnel records and interview with the laboratory manager/technical consultant #2, listed on the Centers of Medicare &amp; Medicaid Services (CMS) 209 form at 4:00 p.m. on 10/12/15, the Laboratory Director failed to follow written policies to assess competency of the technical consultant (TC) at least annually. There was no evaluation for the Technical Consultants on the day of survey for the years 2019, 2020 or 2021. Findings include: 1. Interview with TC#2 confirmed there were no competency evaluations documented by the laboratory director for the TC since the last survey on 5/30/19. 2. Based on review of the personnel records on 10/15/21, the laboratory director failed to follow policies and evaluate the technical consultant at least annually for the years 2019, 2020 and 2021. THIS IS A REPEAT DEFICIENCY</p>
<b>D5439</b>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit</p>

of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on review of chemistry laboratory records from 5/30/19 through 10/15/21 and confirmation with the laboratory manager at 4:00 p.m. on 10/15/21, the laboratory failed to perform calibration verification on the Siemens Dimension EXL-LM chemistry analyzer every 6 months for sodium, potassium and chloride and a seven (7) drugs of abuse panel (including cocaine, THC, barbiturates, benzodiazapine, opiates, PCP and amphetamines). Findings include: 1. Review of Siemens Dimension EXL LM calibration verification records revealed no records of calibration verification on Sodium (NA), Potassium (K), and Chloride (CL) or the 7 drugs of abuse panel for 2019, 2020 or 2021. These chemistry tests have only 1 or 2 calibration points. Calibration verification is required every 6 months. 2. The laboratory manager in an interview at 4:00 p.m. on 10/15/21 confirmed that calibration verifications for NA, K, CL and the drugs of abuse panel were not performed in 2019, 2020, and 2021. THIS IS A REPEAT DEFICIENCY

**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 quality control (QC) logs, patient testing logs and interview with both technical consultants as listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form on 10/15/21 at 2:00 p.m., the laboratory failed to include a positive and negative control on each day of patient testing for the Quidel Quick Vue Combo hCG Pregnancy test when performed using serum between 11/24/19 and 9/18/21. Findings Include: 1. Interview with the technical consultants on 10/15/21 at 2:00 p.m. confirmed that testing personnel (TP) were not performing two levels of QC (positive and negative) each day of patient testing with serum with the Quick Vue Combo hCG test kit. Use of serum as a sample on the Quick Vue Combo hCG kit makes it a moderate complexity test which requires QC on each day of use. 2. There was no IQCP (Individualized Quality Control Plan) available for review on the day of survey. An IQCP is required after 1/1/16 if two levels of quality control (QC) are not performed each day of use for moderate/high complexity testing. 3. Review of the

	<p>Quick Vue Combo hCG patient test log and QC log from 11/24/19 through 9/18/21, revealed that on the 6 days listed below, pregnancy tests were performed on serum samples. No QC was performed on these days: 11/24/19- 1 patient tested 1/1/20 - 1 patient tested 7/20/20 - 1 patient tested 10/13/20 - 1 patient tested 1/13/21 - 5 proficiency testing samples 9/18/21 - 5 proficiency testing samples</p>
<p><b>D5555</b></p>	<p><b>IMMUNOHEMATOLOGY</b> CFR(s): 493.1271(c)(f)</p> <p>(c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on review of immunohematology (blood bank) records and Jewett temperature graphs from 6/1/19 through 10/15/21, the laboratory failed to follow the manufacturer's instructions for equipment operation. Review of the Jewett recorder graphs revealed the laboratory failed to change the temperature recorder graphs every seven days (according to manufacturer's instructions) as follows: 5/19/20 through 6/1/20 6/23/21 through 7/1/20 8/22/20 through 9/1/20 10/3/21 through 10/13/20 10/13/20 through 10/25/20 11/17/20 through 11/25/20 11/25/20 through 12/3/20 12/19/20 through 12/28/20 1/12/21 through 1/21/21 1/28/21 through 2/5/21 2/12/21 through 2/20/21 2/20/21 through 3/1/21 3/1/21 through 3/9/21 3/16/21 through 3/24/21 4/15/21 through 4/24/21 4/24/21 through 5/3/21 5/3/21 through 5/11/21 5/24/21 through 6/3/21 6/3/21 through 6/11/21 6/11/21 through 6/22/21 6/22/21 through 7/2/21 8/3/21 through 8/11/21 8/19/21 through 8/28/21 8/28/21 through 9/6/21 9/15/21 through 9/23/21 9/6/21 through 9/15/21 9/30/21 through 10/8/21</p>
<p><b>D6054</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory personnel records including the Centers of Medicare and Medicaid Services (CMS) 209 personnel form and interview with the both technical consultants (TC) listed on the CMS 209 form, on the day of survey (10/15/21), the TC failed to evaluate annually and document the performance of testing personnel (TP) #2 for the years 2019 and 2020. Findings include: 1. Based on laboratory personnel records available for review on 10/15/21, there were no annual evaluations/competencies performed by the technical consultant on TP #2 for 2019 and 2020. 2. Interview with the TC on 10/15/21 at 4:00 p.m. confirmed that annual evaluation/competencies had not been documented as performed for TP #2 for 2019 or 2020.</p>
<p><b>D6128</b></p>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b></p>

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on review of laboratory personnel records including the Centers of Medicare and Medicaid Services (CMS) 209 personnel form and interviews with the technical consultants (TC) on 10/15/21, the technical supervisor failed to evaluate annually and document the performance of the TP #1, #2 and #3 who are responsible for immunohematology (blood bank) testing. Findings include: 1. Based on the laboratory personnel records available for review on 10/15/21, there were no annual evaluations /competencies on high complexity testing performed by the technical supervisor for TP #1, #2 and #3 since the last survey on 5/30/19. 2. Interview with both TC/TP on 10 /15/21 at 4:00 p.m. confirmed the annual evaluation/competencies for immunohematology had not been documented as performed by the technical supervisor for TP #1, #2 and #3 for 2020 and 2021.