

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0472705	(X3) Date Survey Completed 07/02/2021
Name of Provider or Supplier Okeene Municipal Hospital	Street Address, City, State 207 East F Street, Okeene, OK	
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
D0000	The recertification survey was performed 06/30/2021 through 07/02/2021. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory manager at the conclusion of the survey.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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 a review of records, written policy, and interview with the laboratory manager, the laboratory failed to have a written technical consultant and general supervisor competency policy based on the position responsibilities as listed in Subpart M. Findings include: (1) On 06/30/2021 the surveyor reviewed the competency assessment policy. It did not include guidance for assessing the competency of the technical consultant and general supervisor; (2) The surveyor then reviewed personnel records for competency assessments performed during 2019, 2020, and to date in 2021. There was no evidence of competencies performed for the technical consultant #2, general supervisor #1, and general supervisor #2 based on their job responsibilities; (3) The surveyor asked the laboratory manager if a written policy to evaluate the technical consultant and general supervisor based on job responsibilities was available. The laboratory manager stated a policy had not been written and the above competencies had not been performed.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the</p>

laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on a review of written policies and procedures, and interview with the laboratory manager, the laboratory failed to have a written procedure for Urine Microscopic testing. Findings include: (1) On 06/30/2021 at 03:25 pm, the laboratory manager stated to the surveyor Urine Microscopic testing was performed in the laboratory; (2) On 07/01/2021 the surveyor reviewed the manual titled, "Urinalysis Manual" and was unable to locate a written procedure for Urine Microscopic testing; (3) The surveyor reviewed the procedure manual with the laboratory manager, who stated on 07/01/2021 at 11:55 am, the procedure had not been written.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on a review of records, procedure manual, and interview with the laboratory manager, the laboratory failed to ensure the verified reportable ranges were used by the laboratory for a new test method. Findings include: (1) On 06/30/2021 at 03:43 pm, the laboratory manager stated to the surveyor the laboratory began performing pH, pCO₂, and pO₂ testing using the OPTI CCA TS2 analyzer on 08/22/2019; (2) On 07/01/2021 the surveyor reviewed the performance specification records and identified the laboratory had demonstrated the following reportable ranges: (a) pH - 6.919-7.614 (b) PCO₂ - 15.3-88.4 (c) PO₂ - 60-510.2 (3) The surveyor requested the reportable ranges that were being utilized by the laboratory. The laboratory manager provided the surveyor with the manual titled, "Blood Gas Procedure Manual" with showed the laboratory was using the manufacturer's reportable ranges as follows: (a) pH - 6.6-7.8 (b) pCO₂ - 10-200 (c) pO₂ - 10-700 (4) The surveyor reviewed the findings with the laboratory manager, who stated on 07/01/2021 at 05:50 pm the laboratory was not using the reportable ranges that had been demonstrated by the laboratory.

D5435

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(2)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or

baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on a review of records, policies and procedures, and interview with the laboratory manager, the laboratory failed to follow their written protocol for ensuring the urine centrifuge was functioning properly. Findings include: (1) On 06/30/2021 at 03:20 pm, the laboratory manager stated to the surveyor, urine sediment examinations were performed in the laboratory. The specimens were processed in the Select Medical Products PSS Select 602 centrifuge at a speed of 1500 rpm (revolutions per minute) for 5 minutes; (2) On 07/01/2021 the surveyor reviewed the policy titled "Centrifuge Maintenance" which stated, "All centrifuge RPM's will be calibrated at least every 6 months"; (3) The surveyor reviewed the centrifuge maintenance records. The records showed the centrifuge speed and timer checks had not been performed every six months as required by policy. The checks had not been performed between 11/27/2019 and 03/03/2021; (4) The surveyor reviewed the findings with the laboratory manager who stated on 07/01/2021 at 11:50 am the centrifuge speed and timer had not been checked as shown above.

D5441

CONTROL PROCEDURES

CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory manager, the laboratory failed to have control procedures that monitored the accuracy and precision of the complete analytic process for Free T4 testing for 2 of 2 lot numbers. Findings include: (1) On 06/30/2021 at 03:50 pm, the laboratory manager stated the following to the surveyor: (a) Free T4 (Thyroxine) testing was performed on the Ortho Vitros ECiQ analyzer; (b) Two levels of MAS Liquimmune QC (quality control) materials (level 1 and level 2) were performed each day of patient testing; (c) Established ranges were used for determining acceptability of QC results. (2) On 07/02/2021, the surveyor reviewed QC records which included documentation of establishing QC ranges, Levey-Jennings graphs, and cumulative data for level 1 lot #LIA22031 and level 2 lot #LIA 22032 used during the review period of January through May 2021. The documentation showed the ranges that had been utilized by the laboratory to determine acceptability of QC results were wider than the established QC ranges as follows: (a) MAS Level 1 - The laboratory had established a 2 standard deviation (SD) range of 1.378-1.022, but a range of 0.86-2.54 had been used; (b) MAS Level 2 - The laboratory had established a 2 SD range of 3.618-4.122, but a range of 3.08-4.62 had been used. (3) The surveyor reviewed the records with the laboratory manager

who stated on 07/02/2021 at 11:30 am, ranges wider than the laboratory established 2 SD ranges, as shown above, had been used to evaluate QC results.

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:

Based on a review of records and interview with the laboratory manager, the laboratory failed to perform quality control as stated in the IQCP for PTT testing for 1 of 17 months. Findings include: (1) On 06/30/2021 at 03:22 pm, the laboratory manager stated the following to the surveyor: (a) PTT (Partial Thromboplastin Time) testing was performed using the Hemochron Signature Elite Jr. analyzer; (b) Two levels of QC (quality control) materials were tested monthly, according to the laboratory IQCP (Individualized Quality Control Plan); (2) On 07/01/2021 the surveyor reviewed PTT QC records for testing performed from 01/13/2020 through 05/12/2021 and identified the following for 1 of 17 months: (a) One level of QC (level 2) had been performed on 10/12/2020 (3) The surveyor reviewed the records with the laboratory manager who stated on 07/01/2021 at 05:45 pm, one level of QC had been performed instead of two levels as required.

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 a review of records and interview with the laboratory manager, the laboratory failed to perform a positive AHG control 16 of 16 days of blood bank testing. Findings include: (1) On 06/30/2021 at 03:40 pm, the laboratory manager stated to the surveyor the laboratory utilized the AHG (Anti-Human Globulin) reagent to perform Antibody Screen and Compatibility testing using the tube method; (2) The surveyor reviewed records for blood bank testing performed from 01/06/2020 through 06/18/2021 and identified a positive AHG control had not been performed 16 of 16 days of patient testing. The specific days were 01/06/2020; 02/27/2020; 03/30/2020; 04/01/2020; 05/04,21/2020; 06/01,28/2020; 07/17/2020; 01/18/2021; 02/09,17/2021; 03/30/2021; 04/19,22/2021; and 06/18/2021; (3) The surveyor reviewed the records with laboratory manager who stated a positive AHG control was not being performed.