Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0471956	05/10/2022
Name of Provider or Supplier	**Street Address, City, State**	
Mercy Hospital Healdton, Inc	3462 Hospital Rd, Healdton, 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 on 05/09,10/2022 The findings were reviewed with the laboratory director, laboratory consultant #1, laboratory consultant #2, technical consultant, testing person #4, and hospital administrator during an exit conference performed at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with laboratory consultant #1, the laboratory failed to follow the manufacturer's instructions for Lactic Acid testing for one of six test reports. Findings include: (1) On 05/10/22 at 10:15 am, laboratory consultant #1 stated Lactic Acid testing was performed on the Cobas C311 analyzer; (2) A review of the manufacturer's instructions for the analyzer stated: (a) "Specimen collection and preparation" (i) "Centrifuge within 15 minutes of collecting the specimen."; (b) "cobas c 311 test definition" (i) "Reaction time" 10 minutes (3) A review of patient testing records on 04/04/22, 04/15/2022, 04/20/2022, 04/21/2022, 04/24/2022, and 05/07/2022 revealed the following for one of six patient test reports (NOTE: Result time correlates to time sample tested): (a) Patient Report #22HD-114C0003 - The collection date and time were documented as 04/24/2022 at 08:35 am and the result date and time were 04/24/2022 at 09:19 am (44 minutes later). (4) The findings were reviewed with laboratory

	consultant #1 who stated on 05/10/22 at 02:30 pm, the laboratory could not prove the specimens were collected and centrifuged within the timeframe required by the manufacturer.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant and laboratory consultant #1, the laboratory failed to follow the written technical consultant competency policy based on the job responsibilities as listed in Subpart M for one of one technical consultant. Findings include: (1) On 05/09/2022, a review of personnel records for competency assessments performed during 2020 and 2021 revealed no evidence competencies had been performed for the technical consultant based on job responsibilities since 12/17/2019; (2) A review of the laboratory's written policy titled, "Competency Assessment Policy" required an annual evaluation of the technical consultant; (3) The records were reviewed with laboratory consultant #1 and the technical consultant who stated on 05/09/2022 at 02:10 pm, the technical consultant competency, based on job responsibilities, had not been documented as performed in 2020 and 2021.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the 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 the policy and procedure manual and interview with laboratory consultant #1, the laboratory failed to follow written procedures for implementing new PT(Prothrombin Time) and PTT (Partial Thromboplastin Time) normal reference ranges for one of one lot reagent change. Findings include: (1) On 05/10/2022 at 03: 00 pm, laboratory consultant #1 stated the following: (a) PT (Prothrombin Time) and PTT (Partial Thromboplastin Time) testing were performed using the Stago STA Satellite analyzer; (b) The following reagents were put into use on 05/27/21: (i) STA-Neoplastine C1 Plus lot #257595; (ii) STA- Automate lot# 257957 (2) A review of the electronic laboratory procedures stated the following (a) "Stago PT Procedure" (i) "REFERENCE INTERVAL" (aa) "Normal values may vary depending on local conditions. Therefore, it is necessary that each laboratory establish its own normal ranges and acceptable control values for their particular local patient population. In general, values are considered normal if they fall within the range of: mean 2 standard deviations (X 2 SD)". (b) "Stago PTT Procedure" (i) "REFERENCE INTERVAL" (aa) "Normal values may vary depending on local conditions. Therefore, it is necessary that each laboratory establish its own normal ranges and acceptable control values for their particular local patient population. In general,

	values are considered normal if they fall within the range of: mean 2 standard deviations (X 2 SD)". (3) A review of the reagent lot change revealed the following normal reference ranges: (a) PT - Normal Reference Range (11.9 - 14.2) seconds (b) PTT - Normal Reference Range (24.3 - 37.0) seconds (4) A review of one patient report from 04/23/2022 at 05:26 pm revealed the following normal reference ranges: (a) PT - Normal Reference Range (11.7 - 14.4) seconds (b) PTT - Normal Reference Range (23.9 - 36.0) seconds (5) The patient record was reviewed with laboratory consultant #1 who stated on 05/10/2022 at 01:10 pm, the normal reference ranges had not been changed with the reagent lot change as indicated above.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of records and interview with laboratory consultant #1 and the technical consultant, the laboratory failed to follow the manufacturer's instructions for two of two coagulation reagent lot changes; and failed to follow manufacturer's instructions for one of one quality control lot changes. Findings include: REAGENT LOT CHANGE (1) On 05/10/2022 at 03:00 pm, laboratory consultant #1 stated the following: (a) PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing were performed using the Stago STA Satellite analyzer; (b) The following reagents were put into use on 05/27/21: (i) STA-Neoplastine C1 Plus lot #257595; (ii) STA- Automate lot# 257957; (2) A review of the manufacturer's instructions for reagent lot changes stated the following: (a) "Current Lot vs. New Lot Correlation" (i) "Collect 40 samples spanning across the reportable range, of which 20 of these samples should be normal samples" (b) "Criteria for reference range 'normal' donors" (i) "Sex-Equal numbers of males and females"; (ii) "Drug History-Patients should be excluded if taking birth control or estrogen containing products, Coumadin, Heparin (UFH, LMWH or heparinoid), Direct Thrombin Inhibitors and antibiotics". (3) A review of the records for the reagent lot changes revealed following: (a) For the Current Lot vs. New Lot Correlation (i) The laboratory tested 25 samples, nine males and 18 females (not equal number males and females); (ii) The medical history documentation for one donor sample included birth control; (iii) The medical history documentation for two donor samples included anticoagulants; (4) The records were reviewed with laboratory consultant #1, who stated on 05/10/2022 at 11:45 am the manufacturer's instructions had not been followed as indicated above. QUALITY CONTROL LOT CHANGE (1) On 05/10/2022 at 03:00 pm, laboratory consultant #1 stated the following: (a) PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing were performed using the Stago STA Satellite analyzer; (b) The following QC (quality control) materials were put into use on 08/30/21: (i) STA-Coag Control Normal lot #257810 (iv) STA-Coag Control Abnormal lot #257810 (2) A review of the manufacturer's instructions for QC lot changes which stated the following: (a) "Total Precisions" (i) "Use control materials that will be used for the assay" (ii) "Run each level six (6) times per day over five (5) days" (iii) "Data will be used to create 'site specific' quality control range" (iv) "Total 30 data points per analyte is recommended for routine assays. This is to verify that the new reagent is

	working within the manufacturer's specifications. It is acceptable to use the assigned control range for a short period of time (30 days) while the control data is being collected". (4) A review of the records for the QC lot change revealed no evidence the QC material had been performed according to manufacturer's instructions; (a) For the Total Precisions (i) PT Normal QC included 21 data points (not the recommended 30 data points) (ii) PT Abnormal QC included 21 data points (iii) PTT Normal QC included 24 data points (iv) PTT Abnormal QC included 21 data points (5) The records were reviewed with laboratory consultant #1 and the technical consultant. The technical consultant stated on 05/10/2022 at 01:00 pm the laboratory could not locate the documentation to prove the manufacturer's instructions had been followed.
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, written policy, and interview with laboratory consultant #1, the laboratory failed to follow their written protocol for ensuring the centrifuge used to process urine sediment samples was functioning properly for one of one function checks performed. Findings include: (1) On 05/09/2022 at 01:15 pm, laboratory consultant #1 stated the following: (a) The laboratory processed urine specimens using the Cardinal Horizon 6 Flex at 1500 rpm (revolutions per minute) for five minutes. (2) A review of the laboratory's written procedure titled, "Microscopic Urinalysis and Culture Criteria" under the section "III. Procedure Steps" stated the following: (a) "5. Place tube in balanced centrifuge. Centrifuge for 5 minutes @ 1500.". (3) A review of 2022 centrifuge records revealed the following for one of one checks performed: (a) The centrifuge had been checked at 1900 rpm on 02/20/2022. (4) The findings were reviewed with laboratory consultant #1 who stated on 05/09 /2022 at 02:00 pm, the centrifuge function checks had not been performed according to laboratory policy as indicated 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 laboratory consultant #1, the laboratory failed to have control procedures that monitored the accuracy and precision of the complete analytic process for Aspartate Aminotransferase for one of one lot numbers. Findings include: (1) On 05/10/22 at 10:15 am, laboratory consultant #1 stated: (a) AST (Aspartate Aminotransferase) testing was performed on the Cobas C311 analyzer; (b) Two levels of Liquicheck Unassayed Chemistry 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) QC records were reviewed which included documentation of establishing QC ranges, Levey-Jennings graphs, and cumulative data for level 1 lot #92911 and level 2 lot #92912 used during the review period of 12/28/2021 through the second day of the survey (05/10/22). The documentation showed the ranges that had been utilized by the laboratory to determine acceptability of QC results for level 2 were wider than the established QC ranges as follows: (a) AST (i) Level 2 - On 12/28/2022, the laboratory had changed the established mean and standard deviation (SD) to a mean of 190 and SD of 1.5 (range of 187 - 193); (ii) Level 2 - The Levey Jennings documentation showed a mean of 190 and SD of 15.0 (range of 160 - 220). (3) The records were reviewed with laboratory consultant #1 who stated on 05/10/2022 at 01:45 pm the laboratory ranges wider than the established ranges, as shown above, had been used to evaluate QC results.