Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0472727	01/20/2023
Name of Provider or Supplier	**Street Address, City, State**	
Mercy Hospital Watonga, Inc	500 N Clarence Nash Blvd, Watonga, 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 01/19,20/2023. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the hospital administrator, senior quality improvement specialist, director of nursing, laboratory director, operational manager, lead technologist, testing person #2, testing person #3, and testing person #5 during an exit conference performed at the conclusion of the survey.
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, manufacturer's instructions and interview with the lead technologist and testing person #3, the laboratory failed to follow the manufacturer's instructions for implementing one of three coagulation reagents. Findings include: (1) On 01/19/2023 at 09:45 am, the lead technologist stated the Stago STA Satellite analyzer was used to perform PT/INR (Prothrombin Time/International Normalized Ratio) testing; (2) On 01/20/2023 at at 11:00 am, testing person #3 stated the current PT reagent, STA Neoplastine CI Plus lot #260019, was put into use on 04/02/2022; (3) A review of the manufacturer's instructions titled, "Protocol Quick User Guide", contained instructions for implementing new reagents and in Section 4 "Total Precisions (for each analyte reported)" it stated, "Total precision studies should be performed with the new lot of reagents" and provided the following instructions: (a) "Use control material that will be used for the assay"; (b) Run each level six (6) times per day over five (5) days"; (c) Data will be used to create 'site specific' quality control range". (4) A review of the implementation records for the PT reagent

	identified the laboratory did not use control materials to perform the total precisions as stated in the manufacturer's instructions; (5) The records were reviewed with testing person #3 who stated on 01/20/2023 at 11:35 am the total precision studies had not been performed with the PT reagent lot change.
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 and interview with the lead technologist and testing person #2, the laboratory failed to utilize the demonstrated reportable range for one of one new analyte added to the Roche Cobas c311 analyzer. Findings include: (1) On 01/19/2023 at 09:35 am, the lead technologist stated the laboratory added the analyte CRP (C-Reactive Protein) to the test menu for the Roche Cobas c300 analyzer on 11/17/2021; (2) On 01/20/2023 a review of the performance specification records identified the laboratory had demonstrated a reportable range of 3.0-334.4 mg/L for CRP: (3) A review of the reportable range programmed into the LIS (Laboratory Information System) and interview with the lead technologist and testing person #2 on 01/20/2023 at 01:50 pm, confirmed the laboratory was using a reportable range of 3.0-350 mg/L instead of the reportable range that had been demonstrated by the laboratory.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) 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. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the lead technologist, testing person #2, and testing person #3, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures for three of four instruments reviewed from 06/01/2021 through 12/31/2022. Findings include: QUICKSLIDE HEMA PRO SLIDE STAINER (1) On 01/19/2023 at 09:30 am, the lead technologist stated the Hardy Diagnostics Quick Slide Hemapro slide stainer was used to stain patient blood smears to perform manual differentials; (2) A review of the Hemapro "Users Operation Manual" on page 22 under the title, "Tubing Kit Replacement" stated, "The orange pump tubes and the clear lines with color coded cannulas must be replaced every six (6) months to ensure the Hemapro is operating under normal operating conditions"; (3) A review of records from 06/01/2021 through 12/31/2022 identified no documentation to prove the tubing kit replacement procedure had been performed before or after 04/29/2022; (4) The records were reviewed with

	the lead technologist and testing person #2. Both stated on 01/19/2023 at 02:40 pm the maintenance procedure had not been performed as stated above. SYSMEX XS-1000i (1) On 01/19/2023 at 09:35 am, the lead technologist stated CBC (Complete Blood Count) testing was performed using the Sysmex XS 1000i analyzer; (2) On 01/20 /2022, a review of the manufacturer's maintenance log showed the following required weekly maintenance procedure: (a) "Power Down IPU" (3) A review of maintenance logs from 06/01/2021 through 12/31/2022 identified weekly maintenance had not been documented as performed between: (a) 07/23/2021 and 08/02/2021 (b) 10/24 /2022 and 11/07/2022 (4) The records were reviewed with the lead technologist and testing person #3. Both stated on 01/20/2023 at 10:00 am, the weekly maintenance had not been documented as performed as shown above. STAGO STA SATELLITE (1) On 01/19/2023 at 09:45 am, the lead technologist stated PT/INR (Prothrombin Time/International Normalized Ratio) and D-dimer testing were performed using the Stago STA Satellite analyzer; (2) On 01/20/2022, a review of the manufacturer's maintenance log showed the following required weekly maintenance procedures: (a) Decontaminate needle and washing well (b) Clean Shield (Soak 0.37% fresh decontamination solution 10 min) (c) Clean Carousels (warm water) (d) Clean sample and product compartments (warm water) (e) Clean rail (warm water) (f) Clean rail glass (STA leaner solution) (g) Clean rail, sample and product covers with 0.37% fresh decontamination solution (h) Clean optical sensor (STA Cleaner solution) (i) Clean the cover and monitor (with 20%ethanol) (j) Save Test configurations to Disk /Saveall Disc (k) Decontaminate stir bars as per package insert (3) A review of maintenance logs from 06/01/2021 through 12/31/2022 identified weekly maintenance had not been documented as performed between: (a) 08/25/2021 and 09/08/2021 (b) 12/22/2021 and 01/06/2022 (c) 06/21/2022 and 07/06/2022 (4) The records were reviewed with testing person #3 who stated on 01/20/2023 at 11:00 am, the weekly maintenance had not been documented as performed as shown above.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of a patient report and interview with the lead technologist and testing person #3, the laboratory failed to make appropriate reference ranges available for one of one coagulation reagent lot number change. Findings include: (1) On 01/19 /2023 at 09:45 am, the lead technologist stated the Stago STA Satellite analyzer was used to perform PT/INR (Prothrombin Time/International Normalized Ratio) testing; (2) On 01/20/2023 at at 11:00 am, testing person #3 stated the current PT reagent, STA Neoplastine CI Plus lot #260019, was put into use on 04/02/2022; (3) A review of PT reagent implementation records identified the PT normal reference interval had been verified as 11.7-13.6; (4) A review of one random PT patient report identified the testing had been performed on 01/18/2023 at 07:33 pm with a normal reference range of 12.2-14.0; (5) The reports and implementation records were reviewed with the lead technologist who stated on 01/20/2023 at 01:40 pm, the laboratory had not updated the normal reference range into the laboratory's computer information system.