Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0472727	05/11/2021
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 05/10,11/2021 The findings were reviewed with the laboratory director, general supervisor, testing person #3, testing person #4, hospital administrator, manager of operations, and senior quality improvement services during an exit conference performed at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the general supervisor, the laboratory failed to following the manufacturer's instructions for specimen transport and storage for five of five patient specimens. Findings include: (1) On 05/10/2021 at 09:45 am, the laboratory manager stated the following to the surveyor: (a) The laboratory performed COVID-19 testing using the following instrument (i) Sofia SARS Antigen FIA - qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct anterior nasal swab specimens. (2) The surveyor reviewed the manufacturer's product insert titled, "Sofia SARS Antigen FIA" under the section, "USING SOFIA AND SOFIA 2" stated, "Critically important: Allow the test to develop for a FULL 15 minutes BEFORE placing it into Sofia or Sofia 2."; (3) The surveyor reviewed five test reports for patients tested on 11/23/2020, 12/14/2020, 02/01/2021, 03/08/2021, and 03/30/2021 and identified the following: (a) Patient Report #1 - Specimen collection date and time (11/23/2020 at 01:56 pm) and the result date and time (11/23 /2020 at 02:21 pm); (b) Patient Report #2 - Specimen collection date and time (11/23 /2020 at 01:56 pm) and the result date and time (11/23/2020 at 02:21 pm); (c) Patient

	Report #3 - Specimen collection date and time (02/01/2021 at 08:13 am) and the result date and time (02/01/2021 at 08:28 am); (d) Patient Report #4 - Specimen collection date and time (03/08/2021 at 11:48 am) and the result date and time (03/08 /2021 at 12:06 pm); (e) Patient Report #5 - Specimen collection date and time (03/30 /2021 at 02:52 pm) and the result date and time (03/30/2021 at 03:12 pm). (4) The surveyor was not able to determine if the test had developed for a full 15 minutes before placing it into the analyzer since the time between the specimen collection date and recieved time were identical; (5) The surveyor reviewed the records with the general supervisor. The general supervisor stated on 05/10/2021 at 04:45 pm the laboratory could not prove the test had developed for a full 15 minutes before placing it into the analyzer.
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, written policy, and interview with the general supervisor, the laboratory failed to have a written general supervisor and technical consultant competency policy based on the position responsibilities as listed in Subpart M. Findings include: (1) On 05/10/2021, the surveyor reviewed the competency assessment policy. It did not include guidance for assessing the competency of the general supervisor and technical consultant; (2) The surveyor then reviewed personnel records for competency assessments performed during 2019, 2020, and 2021. There was no evidence of competencies performed for the general supervisor and technical consultant based on their job responsibilities; (3) The surveyor asked the general supervisor if a written policy to evaluate the general supervisor and technical consultant based on job responsibilities was available. The general supervisor stated on 05/10/2021 at 02:21 pm a policy had not been written and competencies had not been performed.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the general supervisor, the laboratory failed to review and evaluate proficiency testing results for one of 34 events. Findings include: (1) On 05/10/2021, the surveyor reviewed 2019, 2020, and 2021 proficiency testing records. The following biases were identified (biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) First 2019 Chemistry Core Event (i) Cholesterol HDL (High Density Lipoprotein) - 3 of 5 results exhibited a positive bias (aa) Sample CH-02 - SDI of 3.1 (bb) Sample CH-04 - SDI of 2.2 (cc) Sample CH-05 - SDI of 2.0 (2) The surveyor could not locate evidence

	in the records proving the biases had been identified and addressed; (3) The records were reviewed with the general supervisor. The general supervisor stated on 05/10 /2021 at 01:30 pm the biases had not been addressed.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of records and interview with the general supervisor, the laboratory failed to evaluate the accuracy of testing when proficiency testing results had not been graded by the proficiency program for two of 34 events reviewed. Findings include: (1) On 05/10/2021, the surveyor reviewed 2019, 2020, and 2021 proficiency testing records and identified the following for two of 34 events: (a) First 2020 Hematology Event: (i) For two of two results, the following was identified: (aa) EC1-01- Under "Expected Results" it stated, "See Commentary". There was no evidence the laboratory reviewed the commentary contained in the "Participant Summary Report" to evaluate their result; (bb) EC1-02 - Under "Expected Results" it stated, "See Commentary". There was no evidence the laboratory reviewed the commentary contained in the "Participant Summary Report" to evaluate their result. (b) Third 2020 Hematology Event for Urine Sediment: (i) For one of one result, the following was identified: (aa) US-06 - Under "Expected Results" it stated, "See Data Summary". There was no evidence the laboratory reviewed the commentary contained in the "Participant Summary Report" to evaluate their result. (2) The surveyor reviewed the records with the general supervisor who stated on 05/10/2021 at 01:40 pm, the laboratory had not evaluated the results that were not graded by the proficiency testing program.
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 general supervisor, the laboratory failed to follow the manufacturer's instructions for detecting the presence or absence of the expected ABO blood group antibodies anti-A and/or anti-B; Findings include: (1) On 05/10/2021 at 11:45 am, the general supervisor stated to the surveyor Crossmatch testing was performed in the laboratory which included ABO Typing using the tube method; (2) On 05/10/2021 at 11:55 am, the general supervisor stated the Ortho Affirmagen A1 cells and B Cells were used in reverse grouping to check for the presence or absence of the expected ABO blood group antibodies anti-A and/or anti-B; (3) The surveyor reviewed the manufacturer's

	instructions which stated, "3. Mix well and centrifuge. Suggested centrifugation: approximately 15 seconds at 3400 rpm (900-1000 rcf) or 1 minute at 1000 rpm (100-125 rcf)."; (4) The surveyor reviewed the blood bank centrifuge records and identified the Hettich EBA 280 centrifuge (serial number 0000709-02) used to processed blood bank specimens had been checked as follows: (a) 07/01/2020 at a speed of 5000 rpms and time of 30 seconds; (b) 06/16/2019 at a speed of 5000 rpms and time of 30 seconds. (5) On 05/11/2021, the surveyor reviewed the findings with the general supervisor. On 05/11/2021 at 09:35 am, the general supervisor stated to the surveyor the laboratory had not followed the manufacturer's instructions as indicated above.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a review of records and interview with the general supervisor, the laboratory failed to ensure reagents had not exceeded their expiration date for six of six days. Findings include: (1) On 05/10/2021 at 11:45 am, the general supervisor stated to the surveyor Crossmatch testing was performed in the laboratory which included ABO Typing using the tube method; (2) On 05/10/2021 at 11:50 am, the surveyor observed the following in the blood bank refrigerator: (a) Ortho Affirmagen A1 cells and B Cells lot #A437, expiration date 05/04/2021. (3) The surveyor asked the general supervisor what the materials were used for in the laboratory. On 05/10/2021 at 11:55 am, the general supervisor stated the Affirmagen A1 cells and B Cells were used in reverse grouping to check for the presence or absence of the expected ABO blood group antibodies anti-A and/or anti-B; (4) The surveyor showed the general supervisor the expired materials. On 05/10/2021 at 12:05 pm, the general supervisor stated the expired materials were available for use.
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 general supervisor, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures for two of three months. Findings include: (1) On 05/10/2021 at 11:35 am, the general supervisor stated to the surveyor that Arterial Blood Gas and Venous Blood Gas testing were performed on the Opti CCA-TS analyzer; (2) On 05/11/2021, the surveyor reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs. The requirement for weekly maintenance was as follows: (a) Clean Sample Measurement Chamber (3) The surveyor reviewed maintenance records for three months (February 2019, October 2019, and April 2020). There was no evidence the weekly maintenance had been performed: (a) Between 10/11/2019 and 10/25/2019 (b) Between 04/10/2020 and 04

	/24/2020 (4) The surveyor reviewed the records with the general supervisor, who stated on 05/11/2021 at 09:50 am the weekly maintenance had been performed as required but not documented.
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 general supervisor, the laboratory failed to follow their written protocol for ensuring the pipettes were functioning properly for four of four function checks. Findings include: (1) On 05/10/2021 at 01:00 pm, the general supervisor stated to the surveyor, coagulation testing was performed in the laboratory. The reagent preparation was processed using pipettes; (2) On 05/10/2021 at 10:45 am the surveyor observed the following pipettes in the laboratory: (a) MLA 1000 l serial number 951126; (b) Thermofisher Scientific Finnipipette adjustable 100-1000 l serial number 0624281. (3) The surveyor reviewed the pipette calibration policy titled, "WTG LABQ PIPETTE CALIBRATION". Under the section titled, "INTENDED USE" it stated, "Pipette calibration will be performed every 6 months."; (4) The surveyor ask the general supervisor for the 2019 and 2020 pipette maintenance records. The general supervisor stated on 05/10/2021 at 01:45 pm, the pipettes had not been checked in 2019 and 2020.
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 records and interview with the general supervisor, the laboratory failed to make appropriate reference ranges available for one of one reagent lot number change. Findings include: (1) On 05/10/2021 at 11:25 am, the general supervisor stated to the surveyor the laboratory performed PT/INR (Prothrombin Time /International Normalized Ration) testing on the STA Stago analyzer. In addition the following reagent was put into use on 10/15/2019: (a) Neoplastine PT reagent lot #257258 (2) On 05/10/2021, the surveyor reviewed the PT reagent implementation records and identified the laboratory had verified a PT normal reference interval of 11.8 - 14.3 seconds; (3) The surveyor then reviewed a patient PT report dated 12/09 /2019 at 10:49 am with a normal reference range of 12.2 -14.0 seconds; (4) On 05/11 /2021, the surveyor surveyor reviewed the findings with the general supervisor. On 05

	/11/2021 at 01:40 pm, the general supervisor stated that although the laboratory had established a PT normal reference interval with the PT reagent lot change, the laboratory had not implemented the change into the laboratory's computer information system.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of records and interview with the general supervisor, the laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H for 11 of 34 events. Findings include: (1) On 05/10/2021, the surveyor reviewed 2019, 2020, and 2021 proficiency testing events. For 11 of 34 events, the attestation statements had been signed approximately two to three months after the samples had been tested (not within a timeframe for the director to attest that, at the time of testing, the proficiency samples had been tested as required) as follows: (a) First 2019 Hematology/Coagulation Event - The sample testing had been completed on 04/01 /2019, and the attestation statement had not been signed by the laboratory director /designee until 07/23/2019; (b) Second 2019 Hematology/Coagulation Event - The sample testing had been completed on 07/26/2019, and the attestation statement had not been signed by the laboratory director/designee until 09/17/2019; (c) Second 2019 Microbiology Event - The sample testing had been completed on 06/28/2019, and the attestation statement had not been signed by the laboratory director/designee until 09 /17/2019; (d) First 2019 Immunohematology Event - The sample testing had been completed on 04/24/2019, and the attestation statement had not been signed by the laboratory director/designee until 07/23/2019; (e) First 2019 Chemistry Miscellaneous Event - The sample testing had been completed on 05/14/2019, and the attestation statement had not been signed by the laboratory director/designee until 07/23/2019; (f) First 2020 Hematology/Coagulation Event - The sample testing had been completed on 03/25/2020, and the attestation statement had not been signed by the laboratory director/designee until 06/23/2020; (g) Second 2020 Hematology /Coagulation Event - The sample testing had been completed on 07/27/2020, and the attestation statement had not been signed by the laboratory director/designee until 09 /22/2020; (h) First 2020 Microbiology Event - The sample testing had been completed on 03/02/2020, and the attestation statement had not been signed by the laboratory director/designee until 06/23/2020; (i) Second 2020 Microbiology Event - The sample testing had been completed on 07/03/2020, and the attestation statement had not been signed by the laboratory director/designee until 09/22/2020; (j) First 2020 Immunohematology Event - The sample testing had been completed on 04/10/2020, and the attestation statement had not been signed by the laboratory director/designee until 06/23/2020; (k) Second 2020 Chemistry Miscellaneous Event - The sample testing had been completed on 10/30/2020, and the attestation statement had not been signed by the laboratory director/designee until 01/08/2021. (2) The surveyor reviewed the findings with the general supervisor who stated on 05/10/2021 at 01:40

	pm the attestations had been signed approximately two to three months after the proficiency samples had been tested. The surveyor explained that attestation statements must be signed within a timeframe to definitively attest to the fact that proficiency samples were tested in the same manner as patient specimens.