

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 37D0050504	<b>(X3) Date Survey Completed</b> 06/26/2023
<b>Name of Provider or Supplier</b> Mary Mahoney Memorial Health Center	<b>Street Address, City, State</b> 12716 Ne 36th Street, Spencer, OK	
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>D0000</b>	The recertification survey was performed on 06/26/2023. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director and laboratory supervisor during an exit conference performed at the conclusion of the survey.
<b>D1001</b>	<p><b>CERTIFICATE OF WAIVER TESTS</b> CFR(s): 493.15(e)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation, and interview with the laboratory supervisor, the laboratory failed to follow the manufacturer's instructions for room temperature storage for 16 of 16 reagent cartridges for Hemoglobin A1c testing. Findings include: (1) On 06/26/2023 at 10:32 am, the laboratory supervisor stated Hemoglobin A1c testing was performed using the Siemens DCA Vantage analyzer; (2) Observation of the laboratory on 06/26/2023 at 10:35 am identified 16 DCA Systems Hemoglobin A1c reagent cartridges, lot #0078 stored at room temperature which had not been dated; (3) Review of the manufacturer's package insert under the heading "Cartridge Storage" stated, "Recommended storage is refrigerated at 2-8 C for maximum reagent life. Alternately, the cartridges can remain at room temperature (15-32 C) provided the expiration date on the carton is changed to three months from the date the carton is removed from the refrigerator"; (4) The findings were discussed with the laboratory supervisor who stated on 06/26/2023 at 10:35 am, the cartridges were being stored at room temperature and had not been dated with the three month room temperature expiration date.</p>

<p><b>D3031</b></p>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the laboratory failed to maintain analytic test records to include lot numbers and expiration dates for qualitative serum pregnancy testing for at least 2 years for 17 of 17 months reviewed. Findings include: (1) On 06/26/2023 at 10:40 am, the laboratory supervisor stated qualitative serum pregnancy testing was performed using the Consult Diagnostics hCG Combo Test Cassette; (2) A review of QC (quality control) and patient testing logs for testing performed from January 2022 through May 2023 identified the lot numbers and expiration dates of the test kits and QC materials used during the timeframe had not been documented on the logs; (3) Interview with the laboratory supervisor on 06/26/2023 at 02:00 pm, confirmed the following: (a) The testing logs were photocopied and the lot numbers on the logs were not reflective of the QC and test kits in use; (b) The laboratory did not have a method to maintain records of the lot numbers of QC materials and test kits used for testing during the review period.</p>
<p><b>D5217</b></p>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the laboratory failed to verify the accuracy of Wet Prep testing at least twice annually during the review period of August 2021 through the current date. Findings include: (1) On 06/26/2023 at 10:55 am, the laboratory supervisor stated Wet Prep testing was performed; (2) A review of records from August 2021 through the current date identified the testing had not been verified for accuracy at least twice annually as follows: (a) Prior to 02/22/2022; (b) Between 02/21/2022 and 03/30/2023. (3) The records were reviewed with the laboratory supervisor who stated on 06/26/2023 at 02: 20 pm, the laboratory had not verified the accuracy twice annually as stated above.</p>
<p><b>D5413</b></p>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p>

This STANDARD is not met as evidenced by:  
Based on a review of records, manufacturer's instructions, and interview with the laboratory supervisor, the laboratory failed to ensure the humidity was maintained as required by the manufacturer of the Sysmex XS-1000i analyzer for three of five months reviewed in 2023. Findings include: (1) On 06/26/2023 at 10:30 am, the laboratory supervisor stated CBC (Complete Blood Count) testing was performed using the Sysmex XS-1000i analyzer; (2) A review of the manual for the analyzer titled, "Instructions for Use" in Section 11.11 "Installation Environment" stated "Relative humidity should be in the range of 30-85%"; (3) A review of laboratory humidity records from January through May 2023 identified humidity readings were less than 30% for three of five months as follows: (a) January - One of 20 humidity readings were documented as less than 30%; (b) February - One of 20 humidity readings were documented as less than 30%; (c) March - Four of 23 humidity readings were documented as less than 30%. (4) The records were reviewed with the laboratory supervisor who stated on 06/26/2023 at 01:30 pm, the laboratory humidity had not been maintained as required by the manufacturer as shown 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, observation, and interview with the laboratory supervisor, the laboratory failed to ensure 11 of 11 Microalbumin/Creatinine reagent cartridges had not exceeded their room temperature expiration date. Findings include: (1) On 06/26/2023 at 10:32 am, the laboratory supervisor stated Urine Microalbumin /Creatinine testing were performed using the Siemens DCA Vantage analyzer; (2) Observation of the laboratory on 06/26/2023 at 10:35 am identified 11 DCA Systems Microalbumin/Creatinine reagent cartridges, lot #0065 stored at room temperature which had not been dated; (3) Review of the manufacturer's package insert for the testing under the heading "Use Life" stated, "Reagent cartridges can be kept for up to three months at room temperature anytime before the expiration date. Record on the carton, the date the carton was placed at room temperature"; (4) The findings were discussed with the laboratory supervisor who stated on 06/26/2023 at 10:35 am, the cartridges were being stored at room temperature and had not been dated with the three month room temperature expiration date.

**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 laboratory supervisor, the laboratory failed to ensure the manufacturer's instructions

were followed for performing maintenance procedures during the review period of August 2021 through May 2023. Findings include: (1) On 06/26/2023 at 10:30 am, the laboratory supervisor stated CBC (Complete Blood Count) testing was performed using the Sysmex XS-1000i analyzer; (2) A review of the manufacturer's maintenance log showed the following required maintenance procedures: (a) Weekly - "Power Down IPU" (b) Monthly - "Perform Monthly Rinse" (3) A review of maintenance logs from August 2021 through May 2023 identified no documentation maintenance had been performed as follows: (a) Weekly - Not documented as performed between: (i) 07/30/2021 and 10/01/2021 (ii) 12/03/2021 and 01/07/2022 (iii) 02/11/2022 and 02/25/2022 (iv) 08/19/2022 and 08/28/2022 (v) 03/17/2023 and 04/03/2023 (b) Monthly - Not documented as performed between: (i) 07/08/2021 and 10/14/2021 (ii) 04/25/2022 and 06/28/2022 (4) The records were reviewed with the laboratory supervisor who stated on 06/26/2023 at 01:50 pm, the maintenance had not been documented as performed as shown above.

**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 supervisor, the laboratory failed to follow their written protocol for ensuring the urine centrifuge was functioning properly for two of two function checks performed during the review period of August 2021 through the current date. Finding include: (1) On 06/26/2023 at 10:45 am, the laboratory supervisor stated the following: (a) Urine sediment examinations were performed; (b) The specimens were processed in the McKesson Unico centrifuge at a speed of 1500-2000 rpm (revolutions per minute) for 5 minutes; (2) A review of the centrifuge function check records confirmed the centrifuge speed and timer were checked annually; (3) A review of the procedure titled, "Steps in Preparing a Concentrated Urine Sediment" stated "Centrifuge at the speed and spin time specified in your laboratory's procedure. 1500-2000 rpms for 5 minutes"; (4) A review of centrifuge function check records during 2021 through the current date identified the centrifuge speed and timer had not been checked at the speed and time urines were processed for two of two checks performed as follows: (a) 10/30/2021 - The speed had been checked at 2200 rpm and the timer had been checked at ten minutes; (b) 10/28/2022 - The speed had been checked at 2200 rpm and the timer had been checked at ten minutes. (5) The records were reviewed with the laboratory supervisor who stated on 06/26/2023 at 03:30 pm, the laboratory had not followed their policy.

**D5479**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(e)(5)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e)

(5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of records, manufacturer's instructions, observation, and interview with the laboratory supervisor, the laboratory failed to follow the manufacturer's specifications for ensuring the correct control limits for the analyte platelets were programmed in the Sysmex XS-1000i analyzer for one of three levels of controls. Findings include: (1) On 06/26/2023 at 10:20 am, the laboratory supervisor stated: (a) CBC (Complete Blood Count) testing was performed using the Sysmex XS-1000i analyzer; (b) Three levels of Sysmex e-Check QC (quality control) materials were performed each day of patient testing; (c) When new lot numbers of QC materials were put into use the laboratory established their own means, and the limits of acceptability were calculated based on the manufacturer's Evidence Based Control Limits, that were programmed in the analyzers memory. (2) Observation of the Evidence Based Control Limits programmed into the analyzer on 06/26/2023 at 10:25 am, identified the limit for the analyte Platelets level one had been entered as 80%; (3) Review of the Sysmex "Product Information" sheet which provided the Evidence Based Control limits to be used for each analyte stated the limits for Platelets level one was 23%; (4) The findings were discussed with the laboratory supervisor who stated on 06/26/2023 at 10:30 am, the manufacturer's stated Evidence Based limit for Platelets level one had not been entered into the analyzer accurately.