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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>19D1082041 | <b>(X3) Date Survey Completed</b><br><br>04/29/2024 |
| <b>Name of Provider or Supplier</b><br><br>Caldwell Memorial Hospital, Inc   | <b>Street Address, City, State</b><br><br>411 Main Street, Columbia, LA    |   |
| 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>   |
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| <b>D0000</b>              | A Recertification Survey was conducted on April 29, 2024 at Caldwell Memorial Hospital - CLIA # 19D1082041. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard level deficiencies were cited.  |
| <b>D2015</b>              | <p>TESTING OF PROFICIENCY TESTING SAMPLES<br/>CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of laboratory policy, proficiency testing records, and interview with personnel, the laboratory failed to ensure the Laboratory Director signed the performance review and attestation form for twelve (12) of twenty two (22) proficiency testing events reviewed in 2023 and 2024. Findings: 1. Review of the laboratory's "Proficiency Surveys" policy revealed "The Proficiency Testing Vendor's attestation statement must be signed by the Laboratory Director and the associates who performed any portion of the survey prior to submission of the results to API. Review of the evaluated survey results is conducted by the Laboratory Director". 2. Review of the laboratory's American Proficiency Institute (API) proficiency testing records for 2023 and 2024 revealed the performance review and attestation forms was</p> |

not reviewed by the Laboratory Director or designee for the following twelve (12) of twenty two (22) proficiency testing events: a) 2023 Chemistry Core 1st event - Performance Review and Attestation forms b) 2023 Chemistry Core 2nd event - Performance Review and Attestation forms c) 2023 Chemistry Core 3rd event - Performance Review and Attestation forms d) 2023 Hematology/Coagulation 1st event - Performance Review e) 2023 Hematology/Coagulation 2nd event - Performance Review f) 2023 Microbiology 1st event - Performance Review and Attestation g) 2023 Microbiology 2nd event - Performance Review and Attestation h) 2023 Immunology/Immunochemistry 1st event - Performance Review and Attestation i) 2023 Chemistry Miscellaneous 1st event - Performance Review j) 2023 Chemistry Miscellaneous 2nd event - Performance Review k) 2024 Hematology /Coagulation 1st event - Performance Review and Attestation l) 2024 Microbiology 1st event - Attestation 3. In interview on April 29, 2024 at 1:00 pm, the Laboratory Director confirmed the performance review and attestation forms were not signed as required in 2023 and 2024.

**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:

I. Based on review of the manufacturer's user manual, laboratory maintenance logs, and interview with personnel, the laboratory failed to perform the required maintenance procedures for the Beckman Coulter AU480 chemistry analyzer in 2022, 2023 and 2024. Findings: 1. Review of the manufacturer's user manual for the Beckman Coulter AU480 chemistry analyzer revealed the following maintenance procedures required: a) Weekly: \* Clean the Sample Probe and Mix Bars \* Perform a W2 \* Perform a Photocal \* Clean the Pre-Dilution Bottle \* Check Selectivity of the Na/K Electrodes (ISE optional unit) \* Enhanced Cleaning of ISE Electrode Line (ISE optional unit) b) Every Other Week or 3,000 Samples (ISE optional unit) \* Manually Clean ISE Mix Bar, Liquid Level Sensors, Sample Pot, and Sample Pot Tubing c) Monthly \* Clean the Sample Probe and Reagent Probe Wash Wells \* Clean the Mix Bar Wash Wells \* Clean the Wash Nozzle Unit and Check the Tube Mounting Joints \* Clean the DI Water Tank, DI Filter, and Sample Probe Filter d) Every Other Month or Every 20,000 Samples (ISE optional unit) \* Check and Add REF Electrode Solution e) Quarterly \* Clean the Air Filters \* Inspect and if needed, Replace the DI Water Filter and Sample Probe Filter \* Replace the Wash Solution Roller Pump Tubing f) Quarterly or Every 20,000 Samples (ISE optional unit) \* Replace the Mixture Aspiration and MID Standard Roller Pump Tubing \* Replace the Tubing between Sample Pot, Electrode Unit, and T-Connector \* Replace the REF Electrode Block-side Drain Tube and Pinch Valve Tubing \* Manually Clean the Drain Well and if needed, replace the Drain Tube g) Every 6 Months \* Clean the Cuvettes and the Cuvette Wheel h) Every 6 Months or Every 40,000 Samples (ISE optional unit) \* Replace the Na, K, or Cl Electrode i) Every Two Years or Every 150,000 Samples (ISE optional unit) \* Replace the ISE REF Electrode and Packing j) Yearly or As Needed \* Replace O-rings in the Water Supply Tube Mounting Joint \* Clean the Reagent Probe \* Replace a Sample and Reagent Probe \* Replace Mix Bars \* Replace the Wash Nozzle Joint \* Replace Packing in the Wash Nozzle Tube Mounting Joints \* Replace Syringes or Syringe Case Heads \* Clean the inside of the Reagent

Refrigerator or STAT Table Compartments \* Clean or Replace the Anti-static Brushes \* Replace Rack ID Labels \* Replace the Sample and Reagent Probe Tubing \* Perform a W1 \* Clean or Replace Individual Cuvettes \* Replace the Photometer Lamp \* Save Parameters

2. Review of the laboratory's maintenance logs from November 2022 through April 2024 revealed the following maintenance procedures were not performed as required for the following sixteen (16) of seventeen (17) months reviewed:

a) November 2022: Every Other Week or 3,000 Samples (ISE optional unit): \* Manually Clean ISE Mix Bar, Liquid Level Sensors, Sample Pot, and Sample Pot Tubing

b) December 2022: Every Other Week or 3,000 Samples (ISE optional unit) \* Manually Clean ISE Mix Bar, Liquid Level Sensors, Sample Pot, and Sample Pot Tubing

c) December 2022: Every Other Month or Every 20,000 Samples (ISE optional unit) \* Check and Add REF Electrode Solution

d) January 2023: Quarterly or Every 20,000 Samples (ISE optional unit) \* Clean the Air Filters \* Inspect and if needed, Replace the DI Water Filter and Sample Probe Filter \* Replace the Wash Solution Roller Pump Tubing \* Replace the Mixture Aspiration and MID Standard Roller Pump Tubing \* Replace the Tubing between Sample Pot, Electrode Unit, and T-Connector \* Replace the REF Electrode Block-side Drain Tube and Pinch Valve Tubing \* Manually Clean the Drain Well and if needed, replace the Drain Tube

e) February 2023: Every 6 Months or Every 40,000 Samples (ISE optional unit) \* Clean the Cuvettes and the Cuvette Wheel \* Replace the Na, K, or Cl Electrode

f) April 2023: Quarterly or Every 20,000 Samples (ISE optional unit) \* Clean the Air Filters \* Inspect and if needed, Replace the DI Water Filter and Sample Probe Filter \* Replace the Wash Solution Roller Pump Tubing \* Replace the Mixture Aspiration and MID Standard Roller Pump Tubing \* Replace the Tubing between Sample Pot, Electrode Unit, and T-Connector \* Replace the REF Electrode Block-side Drain Tube and Pinch Valve Tubing

g) May 2023: Every Other Week or 3,000 Samples (ISE optional unit): \* Manually Clean ISE Mix Bar, Liquid Level Sensors, Sample Pot, and Sample Pot Tubing

h) May 2023: Every Other Month or Every 20,000 Samples (ISE optional unit) \* Check and Add REF Electrode Solution

i) June 2023: Monthly \* Clean the Sample Probe and Reagent Probe Wash Wells \* Clean the Mix Bar Wash Wells \* Clean the Wash Nozzle Unit and Check the Tube Mounting Joints \* Clean the DI Water Tank, DI Filter, and Sample Probe Filter

j) July 2023: Every Other Week or 3,000 Samples (ISE optional unit): \* Manually Clean ISE Mix Bar, Liquid Level Sensors, Sample Pot, and Sample Pot Tubing

k) July 2023: Every Other Month or Every 20,000 Samples (ISE optional unit) \* Check and Add REF Electrode Solution

l) July 2023: Quarterly or Every 20,000 Samples (ISE optional unit) \* Clean the Air Filters \* Inspect and if needed, Replace the DI Water Filter and Sample Probe Filter \* Replace the Wash Solution Roller Pump Tubing \* Replace the Mixture Aspiration and MID Standard Roller Pump Tubing \* Replace the Tubing between Sample Pot, Electrode Unit, and T-Connector \* Replace the REF Electrode Block-side Drain Tube and Pinch Valve Tubing

m) August 2023: Every 6 Months or Every 40,000 Samples (ISE optional unit) \* Clean the Cuvettes and the Cuvette Wheel \* Replace the Na, K, or Cl Electrode

n) September 2023: Every Other Month or Every 20,000 Samples (ISE optional unit) \* Check and Add REF Electrode Solution

o) October 2023: Every Other Week or 3,000 Samples (ISE optional unit): \* Manually Clean ISE Mix Bar, Liquid Level Sensors, Sample Pot, and Sample Pot Tubing

p) October 2023: Quarterly or Every 20,000 Samples (ISE optional unit) \* Clean the Air Filters \* Inspect and if needed, Replace the DI Water Filter and Sample Probe Filter \* Replace the Wash Solution Roller Pump Tubing \* Replace the Mixture Aspiration and MID Standard Roller Pump Tubing \* Replace the Tubing between Sample Pot, Electrode Unit, and T-Connector \* Replace the REF Electrode Block-side Drain Tube and Pinch Valve Tubing

q) November 2023: Weekly \* Clean the Sample Probe and Mix Bars \* Perform a W2 \* Perform a Photocal \* Clean the Pre-Dilution Bottle \* Check

Selectivity of the Na/K Electrodes (ISE optional unit) \* Enhanced Cleaning of ISE Electrode Line (ISE optional unit) r) November 2023: Every Other Week or 3,000 Samples (ISE optional unit): \* Manually Clean ISE Mix Bar, Liquid Level Sensors, Sample Pot, and Sample Pot Tubing s) November 2023: Every Other Month or Every 20,000 Samples (ISE optional unit) \* Check and Add REF Electrode Solution t) December 2023: Every Other Week or 3,000 Samples (ISE optional unit): \* Manually Clean ISE Mix Bar, Liquid Level Sensors, Sample Pot, and Sample Pot Tubing u) January 2024: Every Other Week or 3,000 Samples (ISE optional unit): \* Manually Clean ISE Mix Bar, Liquid Level Sensors, Sample Pot, and Sample Pot Tubing v) January 2024: Every Other Month or Every 20,000 Samples (ISE optional unit) \* Check and Add REF Electrode Solution w) February 2024: Every Other Week or 3,000 Samples (ISE optional unit): \* Manually Clean ISE Mix Bar, Liquid Level Sensors, Sample Pot, and Sample Pot Tubing x) February 2024: Every 6 Months or Every 40,000 Samples (ISE optional unit) \* Clean the Cuvettes and the Cuvette Wheel \* Replace the Na, K, or Cl Electrode y) March 2024: Every Other Week or 3,000 Samples (ISE optional unit): \* Manually Clean ISE Mix Bar, Liquid Level Sensors, Sample Pot, and Sample Pot Tubing z) March 2024: Every Other Month or Every 20,000 Samples (ISE optional unit) \* Check and Add REF Electrode Solution aa) April 2024: Every Other Week or 3,000 Samples (ISE optional unit): \* Manually Clean ISE Mix Bar, Liquid Level Sensors, Sample Pot, and Sample Pot Tubing 3. In interview on April 29, 2024 at 2:47 pm, the Laboratory Director confirmed the maintenance identified was not performed per manufacturer's requirements. II. Based on review of the manufacturer's user manual, laboratory maintenance logs, and interview with personnel, the laboratory failed to perform the weekly or monthly required maintenance procedures for the Sysmex XS 1000i hematology analyzer in 2023 and 2024. Findings: 1. Review of the manufacturer's user manual for the Sysmex XS 1000i hematology analyzer revealed the following maintenance procedures required: a) Weekly: Weekly Rinse b) Monthly: Monthly Rinse 2. Review of the laboratory's maintenance logs from November 2022 through April 2024 revealed the following maintenance procedures were not performed as required for the following two (2) of seventeen (17) months reviewed: a) February 2023: \* Weekly: Weekly Rinse b) June 2023: \* Monthly: Monthly Rinse 3. In interview on April 29, 2024 at 2:47 pm, the Laboratory Director confirmed the maintenance identified was not performed per manufacturer's requirements.

**D5469**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on observation by surveyor, review of the manufacturer's package inserts, laboratory policy and quality control records as well as interview with personnel, the laboratory failed to establish their own mean and ranges for Quality Control (QC) material utilized for chemistry testing as required by the manufacturer. Findings: 1. Observation by surveyor during laboratory tour on April 29, 2024 at 2:14 pm revealed the laboratory utilizes the following quality control (QC) material for the Beckman Coulter AU480 chemistry analyzer: a) BioRad Liquid Assayed Multiqual Control: Lot 45960 Exp 10/31/2025 Sodium (NA), Potassium (K), Chloride (CL), Blood Urea Nitrogen (BUN), Glucose (GLUC), Calcium (CA), Total Protein (TP), Albumin (ALB), Magnesium (MG), Aspartate Transferase (AST), Creatinine (CREA), Alanine Transaminase (ALT), Total Bilirubin (TBIL), Amylase (AMY), Alkaline Phosphatase (ALP), Lipase (LIP), Cholesterol (CHOL), High Density Lipoprotein (HDL), Triglyceride (TRIG) b) BioRad Liquichek Urine Chemistry Control: Lot 97440 Exp 09/30/2025 Urine Sodium (UR NA) 2. Review of the BioRad QC package inserts under "Assignment of Values" section revealed "It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides". 3. Review of the laboratory's policy manual revealed the laboratory did not have a policy for establishment of quality control materials for chemistry testing. 4. Review of the laboratory's quality control records revealed the laboratory was utilizing the manufacturer's mean and ranges. 5. In interview on April 29, 2024 at 2:14 pm, the Laboratory Director stated the laboratory uses the manufacturer's ranges and the ranges are monitored by the Unity BioRad tracking system. The Laboratory Director confirmed the laboratory does not establish their own means and ranges for chemistry quality control materials.

**D6018**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(iii)

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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:  
Based on review of laboratory proficiency testing records and interview with personnel, the Laboratory Director failed to ensure proficiency testing attestation statements were signed by the appropriate personnel. Refer to D2015.

**D6020**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(5)

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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

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|                     | <p>This STANDARD is not met as evidenced by:<br/>Based on review of the laboratory's quality control records and interview with personnel, the Laboratory Director failed to ensure that a quality control program was established to assure the quality of laboratory testing. Refer to D5469.</p>   |
| <p><b>D6023</b></p> | <p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b><br/>CFR(s): 493.1407(e)(6)</p> <p>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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of laboratory policies, maintenance records, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance. Refer to D5429 I and II.</p>  |
| <p><b>D6030</b></p> | <p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b><br/>CFR(s): 493.1407(e)(12)</p> <p>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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of laboratory policy and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D6046.</p> |
| <p><b>D6036</b></p> | <p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b><br/>CFR(s): 493.1413</p> <p>The technical consultant is responsible for the technical and scientific oversight of the laboratory.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of laboratory policies and records as well as interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Refer to D5429.</p>   |
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**D6042**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(4)

(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

This STANDARD is not met as evidenced by:

Based on review of the laboratory's quality control records and interview with personnel, the Technical Consultant failed to ensure that a quality control program was established to assure the quality of laboratory testing. Refer to D5469.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policy, CMS 209 form (Laboratory Personnel Report), personnel records, and interview with personnel, the Technical Consultant failed to perform annual competency in 2023 for three (3) for five (5) testing personnel reviewed. Findings: 1. Review of the laboratory's "Validation of Competency of Laboratory Personnel" policy under "Annual Evaluation" revealed "The competency and performance of all laboratory employees will be assessed annually. Documentation will include: Laboratory Validation of Competency Checklist, Performance Evaluation, and Current License Verification". 2. Further review of the "Validation of Competency of Laboratory Personnel" policy under "Competency Assessment Criteria" revealed "The determination of the successful competency assessment is based on any combination of the following elements: \* Direct observation of instrument maintenance, function checks and proper documentation \* Direct observation of specimen handling, processing, testing skills, and result reporting \* Accurate performance of quality control, QC reporting, and troubleshooting \* Accurate testing of proficiency testing samples, internal blind samples, and retesting of patient samples \* Problem-solving skills \* Knowledge (verbalized) regarding the location of reference materials (procedures, operator manuals, logs, website, etc.) \* Demonstration of phlebotomy skills, if applicable \* Verbalization of processes for things not routinely ordered The Laboratory Director will be responsible for indicating the element used to assess competency". 3. Review of the CMS 209 (Laboratory Personnel Report) form revealed the following three (3) of five (5) serve as Testing Personnel: \* Personnel 3 \* Personnel 4 \* Personnel 5 4. Review of the laboratory's personnel records revealed the Technical Consultant did not perform competency assessments in 2023 for the following three (3) of five (5) testing personnel: \* Personnel 3 \* Personnel 4 \* Personnel 5 5. In interview on April 29, 2024 at 11:40 am, the Technical Consultant confirmed the competency assessments in 2023 were not performed as required by the laboratory policy.