| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 11D0021848 | 11/05/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Dodge County Hospital Laboratory | 901 Griffin Avenue, Eastman, GA | |

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 |
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| **D0000** | A Clinical Laboratory Improvement Amendments (CLIA) Recertification survey was completed on November 5, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited: |
| **D5221** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(d)<br><br>All proficiency testing evaluation and verification activities must be documented.<br><br>This STANDARD is not met as evidenced by:<br>Based on proficiency test (PT) document review and staff interview, the laboratory failed to perform required corrective action for PT scores less than 100 percent. Findings include: 1. American Proficiency Institute (API) PT score review revealed the laboratory failed to perform corrective action for the following 2018 PT scores less than one hundred percent (100%): Microbiology Event Two (97 %) Core Chemistry Event Three -- Thyroid (80%), and T3 (Thyroid) Uptake - 80%. 2. An interview with the technical supervisor, in her office, on 11/5/2019, at approximately 3:30 p.m., confirmed the aforementioned lack of corrective action for PT scores less than 100 percent. |
| **D5291** | GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1239(a)<br><br>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. |

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| | This STANDARD is not met as evidenced by:<br>Based on review of the Standard Operating Policy (SOP) and Procedures, and staff interview, the laboratory did not have a Quality Assessment (QA) policy. Findings: 1. Review of the Laboratory SOP, confirmed that there was not a policy for an ongoing mechanism to monitor, assess, and when indicated, correct problems in the general laboratory system. 2. Interview with the Technical Supervisor, on November 5, 2019, at approximately 11:15 am, in the lab office, confirmed that the laboratory did not have a Quality Assessment Policy |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory policy and procedure manual (SOP) , calibration document review, and staff interview, the laboratory failed to followed established policies and procedures as required. Findings include: 1. SOP review and calibration document review revealed the laboratory failed to perform quality control (QC) for the bacteriology calibration loop for 2018 and 2019 thus far, as established in the SOP. 2. An interview with the technical supervisor in her office on 11/5/2019 at approximately 2:30 p.m. confirmed the aforementioned lack of adherence to the SOP policies and procedures. |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Thermo-Scientific Auto Cell Washer centrifuge(Cell Washer) maintenance logs, and staff interview, the laboratory failed to document performance of the weekly and monthly maintenance in Blood Bank.. Findings: 1. Review of the cell washer maintenance records, revealed that there was no documentation indicating that the weekly and monthly maintenance procedures were performed from March 2018 to October 2019. 2. Interview with the TS, on November 5, 2019, at approximately 11:10 am, in the lab office, confirmed that there was no documentation of the cell washer maintenance from March 2018 to October 2019. |
| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) |

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| | -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.<br><br>This STANDARD is not met as evidenced by:<br>Based review of the calibration records for both Unicel DxH800 Hematology Analyzers (DxH800), and staff interview, the laboratory failed to perform calibrations every 6 months. Findings: 1. Review of the calibration records for the two DxH800 machines showed that the analyzers were calibrated on the following dates: Serial # 29402 - 7/23/18, 5/27/19 (10 months), and 8/26/19 Serial # 29405 - 8/11/18, 5/20/19 (9 months), and 8/26/19 2. Interview with the TS, on November 5, 2019, at approximately 12:30 pm, in her office, confirmed that the DxH800 machines were not calibrated every 6 months. |
| **D6065** | TESTING PERSONNEL QUALIFICATIONS<br>CFR(s): 493.1423(b)(1)(2)(3)(4)(i)<br><br>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and<br><br>This STANDARD is not met as evidenced by:<br>Based on testing personnel (TP) document review and staff interview, the laboratory failed to employ qualified TP as required. Findings include: 1. TP document review revealed there was no educational documentation for Staff #26 (CMS 209) at the time of survey. 2. An interview with the technical supervisor in her office on 11/5/2019 at approximately 2:00 p.m. confirmed the lack of education documentation for Staff #26 (CMS 209). |
| **D6079** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(a)(b) |

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| | 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on testing personnel (TP) competency document review and staff interview, the laboratory director (LD) failed to delegate technical supervisor (TS) responsibilities to qualified individuals as required. Findings include: 1. TP competency document review revealed the following competencies were performed by an unqualified individual due to lack of educational qualifications: 2018 -- (CMS 209) Staff #15-17, 20-22, 24-25; 2019 -- (CMS 209) Staff # 15-17, 18-20, 22-24, 26. 2. TP competency document review revealed the following competency was performed by an unqualified individual due to lack of laboratory experience : 2018 -- (CMS 209) Staff #14. 3. An interview with the technical supervisor in her office on 11/5/2019 at approximately 3:00 p.m. confirmed the aforementioned competencies were performed by unqualified individuals. |
| **D6128** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(b)(9)<br><br>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.<br><br>This STANDARD is not met as evidenced by:<br>Based on testing personnel (TP) competency review and staff interview, the technical supervisor (TS) failed to ensure annual competencies were performed as required. Findings include: 1. TP competency document review revealed 2018 annual competency documents were not available at the time of survey for Staff #2 (CMS 209). 2. An interview with the TS in her office on 11/5/2019 at approximately 3:00 p. m. confirmed the aforementioned documentation was not available at the time of survey. |