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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 11D0910844 | (X3) Date Survey Completed 07/25/2023 |
| Name of Provider or Supplier Evans Medical Group | Street Address, City, State 1205 Town Park Lane, Evans, 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 |
|---------------------------|--|
| D0000 | On August 30, 2023 an off site follow-up review was completed. The report revealed that the plan of correction was found to be acceptable. The facility is now in compliance with CLIA regulations. A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on July 25, 2023. 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: |
| D3011 | <p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on document review and interview with the staff, it was determined the laboratory failed to document inspection and flush of the eyewash equipment on a weekly basis as required from 2021 to July 2023. Finding: 1. The review of maintenance records revealed that the laboratory failed to document inspection on and flush of the eyewash equipment, as required on a weekly basis, according to the procedure manual from 2021 to the day of survey 7/25/2023. 2. An interview with the clinic administrator, Technical Consultant (TC) and TP#4 (CMS-209) at 1:05 PM on 07/25/2023 confirmed the laboratory failed to document inspection of the Eyewash equipment from 2021 to the day of survey 7/25/2023.</p> |
| D6049 | <p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records,</p> |

proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:

Based on review of monthly Quality Assurance (QA) documents and interview with staff, the Technical Consultant(TC) failed to review all (QA) documents on a monthly basis as required by Clinical Laboratory Improvement Amendments (CLIA) from 2021 to 2023. Findings include: 1. Quality Assurance (QA) documents review revealed the (TC), did not review ALL quality assurance documents (including Eyewash maintenance log) from 2021 to 07/25/2023. 2. An interview with the Technical Consultant (TC) TP#3 (CMS 209) in the conference room on 07/25/2023 at approximately 12:40 PM, confirmed the (TC) did not review ALL (QA) documents as required from 2021 till the day of survey 07/25/2023.

D6070

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1425(b)(1)

Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:

Based on review of the policy and procedure manual (SOP), observation during the lab tour and staff interview, the laboratory failed to follow the policy for labeling specimens. Finding: 1. Observation during the lab tour at 11:30 AM revealed 6 urine specimens on the lab counter , to the left of the sink labeled ONLY with the patient's first and last name. A second patient's unique identifier was NOT on the labeled specimens. 2. Review if the SOP reveals the lab policy requires specimens to be labeled with at least two (2) unique identifying factors such as name, date of birth, or patient ID (identification) number. 3. Interviews with the Technical Consultant (TC) TP#3 (CMS 209) and TP # 4 (CMS 209) on 07/25/2023 in the laboratory at approximately 11:37 AM confirmed the urine specimens were not labeled with at least two (2) unique identifiers.