| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 11D0262297 | 04/21/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Adventhealth Medical Group Family Medicine | 824 Gi Maddox Parkway, Chatsworth, 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 April 21, 2021. 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: |
| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the policy and procedure manual (SOP) and staff interview, the laboratory failed to establish a competency policy for testing personnel (TP). Findings include: 1. SOP review revealed the laboratory failed to establish a policy and procedure for performing initial, six-month, and annual TP competencies. 2. An interview with Staff #1 (CMS 209) in the back medical office (outside the lab) on 04 /21/2021 at approximately 1:00 p.m. confirmed there was not a competency policy in the laboratory SOP. **REPEAT DEFICIENCY** |
| **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 review of the American Proficiency Institute (API) proficiency testing (PT) performance evaluation and staff interview, the laboratory failed to document |

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| | corrective action for an unacceptable analyte score. Findings include: 1. Review of the API PT evaluation documents for the 2020 event #3 for the analyte of platelet count (#0815) reveals a score of 80% with specimen HSY-12 being scored as unacceptable. No corrective action was noted for the unacceptable score. 2. An interview with Staff #1 (CMS 209) in the back medical office (outside the lab) on 04/21/2021 at approximately 1:00 p.m. confirmed there was not corrective actions documented for the unacceptable score. |
| **D5781** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(1)<br><br>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of temperature and humidity (RH) records and staff interview, the lab failed to document corrective actions when the RH or refrigerator temperature exceeded acceptable limits. Findings include: 1. Review of temperature and humidity records reveals RH was out of range 11 of 29 days in December 2019; 14 of 28 days in March 2020; and refrigerator temperature was out of range 4 of 21 days in August 2020 without corrective actions documented. 2. Interview with Staff #1 (CMS 209) in the back medical office (outside the lab) on 04/21/2021 at approximately 1:00 p.m. confirmed the corrective actions were not documented. |
| **D5807** | TEST REPORT<br>CFR(s): 493.1291(d)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on lab report review and staff interview, the laboratory failed to include all the required information on the in-house laboratory test reports. Findings include: 1. Review of in-house complete blood count (CBC) patient report #567179 reveals the lack of reference intervals and units of measurement. 2. An interview with Staff #1 (CMS 209) in back office (outside the lab) on 04/21/2021 at approximately 1:00 p.m. confirmed the lack of reference intervals and units of measurement. |
| **D6029** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(11)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform |

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| | 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory personnel records, CMS 209 personnel form, and staff interview, the laboratory director failed to ensure all testing personnel (TP) have the appropriate education by providing the high school diploma, GED, transcript, or college degree. Findings include: 1. Review of the CMS 209 personnel form, reveals 9 testing personnel listed. Review of the personnel records reveals TP #9 (CMS 209)did not provide proof of education in the records provided. 2. Interview with Staff #1 (CMS 209) in the back medical office (outside the lab) on 04/21/2021 at approximately 1:00 p.m. confirmed the lack of the required proof of education document for TP #9 (CMS 209). |
| **D6032** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(14)<br><br>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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory director (LD) failed to specify, in writing the duties and responsibilities of each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of laboratory testing. Findings include: 1. SOP review revealed the LD failed to specify in writing the duties and responsibilities of each person engaged in the performance of all phases of laboratory testing. 2. An interview with Staff #1(CMS 209) in back office (outside the lab) on 04/21/2021 at approximately 1:00 p.m. confirmed the SOP did not contain a duties and responsibilities policy and procedure. |
| **D6054** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. |

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| | This STANDARD is not met as evidenced by:<br>Based on review of testing personnel (TP) documents, review of the CMS 209 form, and staff interview, the lab director/technical consultant failed to perform annual competency on all testing personnel (TP). Findings include: 1. Review of the CMS 209 form reveals 9 staff listed as testing personnel. Review of the testing personnel competencies provided reveals no annual competency was performed on TP #4 (CMS 209) in 2019; no annual competency was performed on TP #5 (CMS 209) in 2019 or 2020. 2. Interview with Staff #1 (CMS 209) in back office (outside the lab) on 04/21 /2021 at approximately 1:00 p.m. confirmed the lack of the aforementioned annual competencies. |