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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 11D2043843 | (X3) Date Survey Completed 07/22/2021 |
| Name of Provider or Supplier Wmg Urgent Care Acworth Health Park | Street Address, City, State 4550 Cobb Parkway, Nw, Suite 101, Acworth, 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 July 22, 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: |
| D5421 | <p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on document review and staff interview, the laboratory failed to ensure the ACT Diff II can obtain performance specifications comparable to those established by the manufacturer for Accuracy, Precision, Reportable range of test results, and reference intervals. Findings include: 1. Review of ACT Diff II quality control, calibration, and maintenance documents reveals the analyzer was installed November 2020. No validation documents were available at the time of survey. 2. Interview with the Quality Improvement Coordinator on 7/22/21 in the facility manager's office at approximately 12:30 p.m. confirmed the lack of the validation documents.</p> |
| D5441 | <p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures</p> |

that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on ACT Diff II quality control (QC) document review and staff interview, the lab failed to monitor over time the accuracy and precision of test performance. Findings include: 1. Review of QC documents reveals the lack of long term QC monitoring (Levey-Jennings charts) from November 2020 to July 2021. 2. Interview with the Quality Improvement Coordinator on 7/22/21 at approximately 11:00 AM in the facility manager's office, confirmed the lack of a long term QC monitoring system.

D5785

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(3)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:
Based on review of daily temperature and relative humidity records and staff interview, the lab failed to document corrective actions when temperatures and/ or relative humidity exceeded acceptable limits. Findings include: 1. Review of daily temperature and relative humidity records reveals Room temperature (RT) was out of range 9 of 29 days without corrective actions documented during February 2020. Refrigerator temperature was out of range 5 of 51 days and RT was out of range 4 of 31 days without corrective actions documented during August 2020. Room temperature (RT) was out of range 7 of 30 days without corrective actions documented during April 2021. 2. Interview with Quality Improvement Coordinator on 07/22/21 at approximately 11:45 AM in the office of the facility manager, confirmed the corrective actions were not documented.

D6028

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(10)

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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

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| | <p>This STANDARD is not met as evidenced by: Based on testing personnel (TP) document review and staff interview, the laboratory director (LD) failed to ensure that prior to testing patient's samples, all TP have the appropriate education. Findings include: 1. TP document review revealed the LD failed to ensure the TP had the minimal educational document on Staff #4, #5, #8, #11, #16 (CMS 209) in 2019, 2020, and 2021. 2. An interview with the Quality Improvement Coordinator in the ger's office on 7/22/21 at approximately 11:30 a.m. confirmed the lack of educational documents on the aforementioned TP.</p> |
| <p>D6029</p> | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</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)(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.</p> <p>This STANDARD is not met as evidenced by: Based on testing personnel (TP) document review and staff interview, the laboratory director (LD) failed to ensure that prior to testing patient's samples, all TP have the appropriate training. Findings include: 1. TP document review revealed the LD failed to ensure the TP had the appropriate training documented on 9 of 21 TP (CMS 209) in 2019, 2020 and/or 2021. 2. Interview with the Quality Improvement Coordinator in the facility manager's office on 7/22/21 at approximately 11:30 a.m. confirmed the lack of training documents on 9 of 21 TP (CMS 209).</p> |
| <p>D6053</p> | <p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) documents and staff interview, the technical consultant failed to perform semiannual competency on all testing personnel. Findings include: 1. Review of testing personnel (TP) competency documents reveals the lack of semiannual competency review for 15 of 21 TP (CMS 209) during the time period of 2019, 2020, or 2021. 2. Interview with the Quality Improvement Coordinator in the facility manager's office on 7/22/21 at approximately 11:30 a.m. confirmed the lack of trainig documents on 15 of 21 TP (CMS 209).</p> |
| <p>D6054</p> | <p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least</p> |

annually, after the first year.

This STANDARD is not met as evidenced by:

Based on review of testing personnel(TP) documents and staff interview, the technical consultant failed to perform annual competency on all testing personnel. Findings include: 1. Review of testing personnel (TP) competency documents reveals the lack of annual competency review for 15 of 21 TP (CMS 209) during the time period of 2019, 2020, or 2021. 2. Interview with the Quality Improvement Coordinator in the facility manager's office on 7/22/21 at approximately 11:30 a.m. confirmed the lack of annual competency documents on 15 of 21 TP (CMS 209).