| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 10D2141888 | 08/29/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Clermont Urgent Care | 1675 Hancock Rd Ste 300, Clermont, FL | |

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 recertification survey was conducted on August 29, 2019. Clermont Urgent Care clinical laboratory was found not in compliance with 42 CFR 493, requirements for clinical laboratories. |
| **D3031** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(3)<br><br>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, interview and record review, the laboratory failed to retain instrument printouts from the Sysmex XP-300 hematology analyzer for at least two years. Findings: Review of the Sysmex XP-300 hematology analyzer's instrument printouts of the daily quality control records showed that the first date of testing was 5 /4/18. Observation of documents stored in the hematology analyzer's memory showed that patient test results were not saved for 2018 and that the patient test results for 2019 were available for only recent patients. During an interview on 8/29/19 at 11:56 AM, the Laboratory Director stated the patient test result printouts were discarded after the results were entered into the computer. During an interview on 8/29/19 at 11: 59 AM, the Laboratory Director stated she did not know how long patient test results were maintained in the analyzer's memory. |
| **D5211** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(a)<br><br>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. |

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| | This STANDARD is not met as evidenced by:<br>Based on record review and interview, the Laboratory Director failed to document the review and evaluation of proficiency testing for 2018, (events A, B, and C), and 2019 (events A, and B). Findings: Review of the American Academy of Family Physicians (AAFP) proficiency testing documentation showed that the Laboratory Director had not signed and dated the results forms for 2018 events A, and 2019 events A, and B. The laboratory also failed to have the documentation of the results for 2018 events B and C until the Laboratory Director printed the results from AAFP's website. The procedure titled "Proficiency Testing" signed by the Laboratory Directory on 3/4/19 stated "Proficiency testing results will be reviewed within 30 days of receipt of results." During an interview on 8/29/19 at 9:40 AM, the Laboratory Director acknowledged that the forms were not signed and dated, and she did not know where the results for events B and C for 2018 were located. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview, the laboratory's written procedure manual was incomplete. Findings: 1. Review of the laboratory's procedure manual, signed by the Laboratory Director on 3/4/19, showed the procedure manual did not include a procedure on Quality Assessment. During an interview on 8/29/19 at 12:10 PM, the Laboratory Director acknowledged that there was no procedure on Quality Assessment. 2. Review of the laboratory's procedure titled "Critical Values" signed by the Laboratory Director on 3/4/19, showed that the alert (critical) values for hematology testing were not listed in the procedure. During an interview on 8/29/19 at 12:10 PM, the Laboratory Director acknowledged that she could not find the list of the critical values. |