| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 42D0867853 | 08/27/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Cmc Immediate Care Gaffney | 840 West Floyd Baker Blvd, Gaffney, SC | |

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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| **D2010** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(2)<br><br>The laboratory must test samples the same number of times that it routinely tests patient samples.<br><br>This STANDARD is not met as evidenced by:<br>During an onsite validation survey on 08/27/2018, based on procedure manual review, proficiency testing review, and testing personnel review, the laboratory failed to ensure that proficiency testing (PT) samples for complete blood count (CBC) testing were routinely tested the same number of times as patient samples for 2 of 6 PT events reviewed from 2016 to 2018 (2017, Event 3, and 2018, Event 1). Findings include: 1. The procedure manual stated that all panic values would be rerun to ensure accuracy. The laboratory procedure defined the following as panic values: a. WBC (white blood cell count) less than 3 or greater than 15 b. Hgb (hemoglobin) less than 8 or greater than 18 c. Plt (platelet count) less than 80 or greater than 600 2. Review of the Medical Laboratory Evaluation (MLE) proficiency testing events from 2016 to 2018 revealed the following proficiency testing events with critical values that were reported and not repeated according to laboratory policy. a. 2017, Event 3: i. sample HD-11- WBC 21, Hgb. 18.7 ii. sample HD-12- WBC 1.9, Hgb 5.9, Plt 54 iii. sample HD-14- WBC 19.9, Hgb 18.3 iv. sample HD-15-WBC 1.9, Hgb 5.9, Plt 59 b. 2018, Event 1: i. sample HD-1- WBC 19.9, Hgb 18.4 ii. sample HD-2- WBC 1.8, Hgb 6.1, Plt 63 iii. sample HD-4- WBC 1.7, Hgb 6.1, Plt 63 iv. sample HD-5- WBC 20.0, Hgb 18.4 3. Testing personnel confirmed during an onsite interview on 08/27/2018 at 2: 30pm that the laboratory failed to ensure that proficiency testing samples were routinely tested the same number of times as patient samples. |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1) |

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| | 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>During an onsite validation survey on 08/27/2018, based on instrument operator manual review, instrument maintenance record review and testing personnel interview, it was determined that the laboratory failed to document daily maintenance on the Medonic hematology instrument for three of three years reviewed from 2016 through 2018. Findings include: 1. Review of the Medonic hematology analyzer operator's manual revealed that all operators should routinely perform scheduled maintenance to ensure optimum performance of the instrument including a daily cleaning of the aspiration and pre-dilute probes. 2. Review of the laboratorys Medonic hematology analyzer maintenance logs revealed that daily maintenance had not been documented for three of three years reviewed from 2016 through 2018. 3. Testing personnel confirmed during an onsite interview on 08/27/2018 at 1:30pm that the daily maintenance had not been performed for the reviewed years. |
| **D5777** | COMPARISON OF TEST RESULTS<br>CFR(s): 493.1281(b)(c)<br><br>(b) The laboratory must have a system to identify and assess patient test results that appear inconsistent with the following relevant criteria, when available: (b)(1) Patient age. (b)(2) Sex. (b)(3) Diagnosis or pertinent clinical data. (b)(4) Distribution of patient test results. (b)(5) Relationship with other test parameters. (c) The laboratory must document all test result comparison activities.<br><br>This STANDARD is not met as evidenced by:<br>During an onsite validation survey on 08/27/2018, based on lack of documentation and testing personnel interview, the laboratory failed to ensure that a system to identify and assess patient test results that appear inconsistent was established in the laboratory. Findings include: 1. Documentation of the laboratory's system to identify and assess patient test results that appear inconsistent with the following relevant criteria, when available: a: Patient age. b: Sex. c: Diagnosis or pertinent clinical data. d: Distribution of patient test results. e: Relationship with other test parameters was unavailable for review on the day of the survey. 2. Testing personnel confirmed during an onsite interview on 08/27/2018 at 1:30pm that the laboratory had failed to ensure that a system to identify and assess patient test results that appear inconsistent with the relevant criteria was established in the laboratory. |