| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 23D0371506 | 04/16/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Macomb Medical Clinic Pc | 2405 E 14 Mile Road, Sterling Heights, MI | |

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 |
|---|---|
| **D5431** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(2)<br><br>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview, the laboratory failed to document for four (#1, #2, #4, and #6) of 11 patient charts audited the daily background count for the Medonic hematology instrument as defined by the manufacturer. Findings include: 1. On April 16, 2018 at 1:18 p.m., record review for four of 11 patient charts audited revealed there was no documentation of the instrument background count on the day of testing. 2. On April 16, 2018 at 1:18 p.m. when queried, the technical consultant as listed on the CMS-209 was unable to provide the surveyor the documentation requested. 3. During the interview on April 16, 2018 at 1:18 p.m., the technical consultant confirmed acceptable background counts were not documented before patient testing. |
| **D5801** | TEST REPORT<br>CFR(s): 493.1291(a)<br><br>The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt |

| | |
|---|---|
| | from outside referral laboratories, satellite or point-of-care testing locations.<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview, the laboratory failed to establish a system to ensure the Laboratory Information System (LIS) calculated glomerular filtration rate (GFR) was monitored for accuracy from the point of entry to the final patient's electronic medical record (EMR) for two (April 12, 2016 to April 12, 2018) of two year. Findings include: 1. On April 16, 2018 at 1:20 p.m., record review for two of two years revealed the laboratory had no documentation to show the LIS calculated chemistry GFR test was monitored for accuracy from the point of entry to the final patient's EMR. 2. During the interview on April 16, 2018 at 1:20 p.m., the technical supervisor as listed on the CMS-209 confirmed the LIS glomerular filtration calculation was not checked for accuracy. |