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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 23D0036103 | (X3) Date Survey Completed 06/06/2018 |
| Name of Provider or Supplier Rochester Medical Group | Street Address, City, State 633 E South Blvd #1200, Rochester Hills, 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 |
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| D5429 | <p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to perform and document the weekly maintenance for the hematology Cell-Dyn Emerald instrument for 13 (November - December 2016, January - February, and April to December 2017) of 18 months reviewed. Findings include: 1. On June 6, 2018 at 10:20 AM, record review of the "Cell-Dyn Emerald Maintenance Log" listed one task to be performed weekly: "Perform weekly Checklist Reviews". 2. On June 6, 2018 at 10:20 AM, record review of the "Cell-Dyn Emerald Maintenance Log" revealed there was no documentation to show the weekly maintenance had been performed and documented for 13 (November - December 2016, January - February, and April to December 2017) of 18 months reviewed. 3. During the interview on June 6, 2018 at 10:20 AM, the laboratory liaison confirmed the weekly maintenance had not been performed and documented.</p> |
| D5437 | <p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible,</p> |

traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

. Based on record review and interview, the laboratory failed to perform the calibration procedures for the Cell-Dyn Emerald hematology analyzer at least every six months for one (first six months in 2017) of two years reviewed. Findings include:

1. On June 6, 2018 at 11:35 AM, review of the calibration data for the hematology Cell-Dyn Emerald analyzer revealed the laboratory did not perform and document the calibration procedure every six months for one (first six months in 2017) of two years reviewed.
2. On June 6, 2018 at 11:35 AM when queried, the office liaison was not able to provide the surveyor with the documentation to demonstrate the calibrations had been performed every six months in 2017.
3. During the interview on June 6, 2018 at 11:35 AM, the office liaison confirmed the calibrations for the hematology analyzer were not performed and documented every six months in 2017.