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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 23D0036103 | (X3) Date Survey Completed 02/08/2021 |
| 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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| D5209 | <p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by:</p> <p>. Based on record review, lack of documentation, and interview with the Technical Consultant (TC), the laboratory failed to ensure written competency policies were followed for 14 (Testing Personnel (TP) #1 - #14) of 14 testing personnel performing the hematology complete blood cell count (CBC) for 2 years reviewed. Findings include: 1. A record review of the "Personnel Competency Policy/Procedure" lists the following 6 categories to be reviewed during a competency assessment as follows: a. Direct observations of routine patient test performance, patient preparation, specimen handling, processing, and testing. b. Monitoring the recording and reporting of patient test results. c. Review of test results, worksheets, quality control records, proficiency testing results, and preventive maintenance. d. Direct observation of performance of instrument maintenance and function checks. e. Assessment of test performance through testing previously analyzed samples. f. Assessment of problem solving skills. 2. A record review for 14 (TP #1 - #14) of 14 TP the competency assessment lacked documentation for the following in the assessments in 2019 and 2020: a. Direct observations of routine patient test performance, patient preparation, specimen handling, processing, and testing. b. Direct observation of performance of instrument maintenance and function checks. c. Assessment of problem solving skills. 3. A interview on 2/08/21 at 10:18 am, the TC confirmed the competency policy was not followed to assess all six requirements from Subpart M for the 2 years reviewed.</p> |