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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 24D0406304 | (X3) Date Survey Completed 01/09/2021 |
| Name of Provider or Supplier Lake Region Healthcare - Elbow Lake | Street Address, City, State 1411 Hwy 79 E, Elbow Lake, MN | |
| 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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| D2016 | <p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: . Based on a review of Center for Medicare and Medicaid Services (CMS) reports and American Proficiency Institute (API) proficiency testing reports, the laboratory failed to successfully participate in proficiency testing (PT) in 2020 for White Blood Cell Differential and Lymphocytes, under the specialty of Hematology. Findings include: 1. The CMS CASPER Report 0155D and API PT Performance Summary, reviewed on January 9, 2021, indicated the the laboratory failed to successfully participate in White Blood Cell Differential and Lymphocytes testing in two testing events in 2020. Unsatisfactory PT performance in White Blood Cell Differential was obtained in the following events: -2020 1st event 28% -2020 3rd event 28% Unsatisfactory PT</p> |

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| | <p>performance in Lymphocytes was obtained in the following events: -2020 1st event 60% -2020 3rd event 60% 2. The CMS CASPER Report 0155D and API PT Performance Summary indicated the laboratory failed to obtain successful White Blood Cell Differential and Lymphocytes PT scores of at least 80 percent in two out of three consecutive testing events in 2020. See D2121 and D2130. .</p> |
| <p>D2121</p> | <p>HEMATOLOGY CFR(s): 493.851(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: . Based on review of proficiency testing (PT) reports from Center for Medicare and Medicaid Services (CMS) and the American Proficiency Institute (API), the laboratory failed to obtain a PT score for White Blood Cell Differential and Lymphocytes of at least 80 percent which resulted in unsatisfactory performance for each analyte. Findings include: 1. The CMS CASPER Report 0155D and API PT Performance Summary, reviewed on January 9, 2021, indicated the the laboratory failed to obtain White Blood Cell Differential and Lymphocytes PT successful scores of at least 80 percent in two testing events in 2020. 2. The API Performance Summary confirmed the laboratory failed to obtain a White Blood Cell Differential PT score of at least 80 percent in two testing events in 2020. -2020 1st event 28% -2020 3rd event 28% 3. The API Performance Summary confirmed the laboratory failed to obtain a Lymphocytes PT score of at least 80 percent in two testing events in 2020. -2020 1st event 60% -2020 3rd event 60% .</p> |
| <p>D2130</p> | <p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: . Based on review of proficiency testing (PT) reports from the Center for Medicare and Medicaid Services (CMS) and the American Proficiency Institute (API), the laboratory failed to achieve successful PT performance for White Blood Cell Differential and Lymphocytes testing in two of three consecutive PT events in 2020. Findings include: 1. The CMS CASPER Report 0153D, reviewed on January 9, 2021, indicated the laboratory failed to obtain White Blood Cell Differential and Lymphocytes PT successful scores of at least 80 percent in two out of three consecutive testing events in 2020. 2. The API Performance Summary confirmed the laboratory failed to obtain a White Blood Cell Differential PT score of at least 80 percent in two out of three consecutive testing events in 2020. -2020 1st event 28% -2020 3rd event 28% 3. The API Performance Summary confirmed the laboratory failed to obtain a Lymphocytes PT score of at least 80 percent in two out of three consecutive testing events in 2020. -2020 1st event 60% -2020 3rd event 60% .</p> |