

| | | |
|--|---|---|
| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 26D2240325 | (X3) Date Survey Completed 08/02/2022 |
| Name of Provider or Supplier Cliniccare Laboratories, Llc | Street Address, City, State 1310 Papin Street Suite 107b, Saint Louis, MO | |
| 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 |
|---------------------------|---|
| 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 review of chemistry proficiency testing (PT) results for 2022 reported to the CLIA database by the PT provider and interview with the technical consultant (TC) on August 2, 2022, the laboratory failed to successfully participate in PT. Refer to D-tag 2096, unsatisfactory performance in two consecutive sodium PT challenges.</p> |
| D2096 | <p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test in two</p> |

consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on review of chemistry proficiency testing (PT) results for 2022 and interview with the technical consultant (TC), the laboratory failed to achieve satisfactory performance for sodium in two consecutive testing events. Findings: 1. Review of the chemistry PT results for the first event of 2022 showed the laboratory obtained an unsatisfactory score of 0 percent for the analyte sodium. 2. Review of the chemistry PT results for the second event of 2022 showed the laboratory obtained an unsatisfactory score of 0 percent for the analyte sodium. 3. Interview with the technical consultant on August 2, 2022 at 10:30 AM confirmed the laboratory failed to achieve satisfactory performance for sodium in two consecutive testing events.