

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  26D2240325	<b>(X3) Date Survey Completed</b>  04/03/2023
<b>Name of Provider or Supplier</b>  Cliniccare Laboratories, Llc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2004</b>	<p><b>ENROLLMENT</b> CFR(s): 493.801(a)(3)</p> <p>For each specialty, subspecialty and analyte or test, participate in one approved proficiency testing program or programs, for one year before designating a different program and must notify CMS before any change in designation;</p> <p>This STANDARD is not met as evidenced by: Based on review of chemistry proficiency testing (PT) results reported to the CLIA database by the PT provider for 2022 and interview with the technical consultant (TC), the laboratory failed to participate in one approved proficiency testing program or programs, for one year before designating a different program. Findings: 1. Review of PT results for the first and second events of 2022 showed the laboratory enrolled with College of American Pathologists (CAP). 2. Review of PT results for the third event of 2022 showed the laboratory enrolled with American Proficiency Institute (API). 3. Interview with the technical consultant (TC) on March 28, 2023 at 8:15 AM confirmed the laboratory failed to participate in one approved proficiency testing program or programs, for one year before designating a different program.</p>
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> 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-</p>

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.

This CONDITION is not met as evidenced by:

Based on review of chemistry proficiency testing (PT) results reported to the CLIA database by the PT provider for 2022/2023 and interview with the technical consultant (TC) on March 28, 2023 at 8:15 AM , the laboratory failed to successfully participate in PT. Refer to D-tag 2096, unsatisfactory performance in three out of four consecutive sodium PT challenges.

**D2096**

**ROUTINE CHEMISTRY**

CFR(s): 493.841(f)

Failure to achieve satisfactory performance for the same analyte or test in two 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 reported to the CLIA database by the PT provider for 2022/2023 and interview with the technical consultant (TC), the laboratory failed to achieve satisfactory performance for sodium in three out of four consecutive testing events. Findings: 1. Review of the chemistry- core 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- core PT results for the second event of 2022 showed the laboratory obtained an unsatisfactory score of 0 percent for the analyte sodium. 3. Review of the chemistry- core PT results for the first event of 2023 showed the laboratory obtained an unsatisfactory score of 60 percent for the analyte sodium. 4. Interview with the technical consultant (TC) on March 28, 2023 at 8:15 AM confirmed the laboratory failed to achieve satisfactory performance for sodium in three out of four consecutive testing events.