

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 28D1000528	(X3) Date Survey Completed 06/15/2022
Name of Provider or Supplier Joshua Clinical Laboratory	Street Address, City, State 2419 M Street, Omaha, NE	
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 surveyor review of the laboratory's 2021 and 2022 American Association of Bioanalysts (AAB) proficiency testing (PT) records and interview with testing personnel #1, as listed on the CMS-209, on date of survey, 6/15/2022, it was determined the laboratory failed to successfully participate in proficiency testing for the analytes chloride and cholesterol, total. Refer to D2096.</p>
D2096	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p>

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 surveyor review of 2021 and 2022 proficiency testing (PT) results and interview with testing personnel #1, as listed on the CMS-209 the laboratory failed to achieve successful performance for the analytes chloride and cholesterol, total in two out of three testing events. Findings are: 1. Chloride, 2021 Event 2, score 0% 2. Chloride, 2022 Event 1, score 0% 3. Cholesterol, total, 2021 Event 2, score 0% 4. Cholesterol, total, 2021 Event 3, score 0% 5. Interview with testing personnel #1, as listed on the CMS-209, on 6/15/2022 confirmed the laboratory was unsuccessful in the PT events listed above.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

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.

This STANDARD is not met as evidenced by:

Based on surveyor record review and interview with testing personnel #1, as listed on the CMS-209 form, the laboratory failed to document monthly maintenance for the hematology analyzer for three out of six months reviewed. Findings are: 1. Review of hematology analyzer maintenance logs from January 2022 to June 2022 revealed no documentation of maintenance for January 2022, February 2022, and March 2022. 2. Interview with testing personnel #1, as listed on the CMS-209 form 6/15/2022 at 1:57 PM, confirmed the laboratory failed to document monthly maintenance for the hematology analyzer.