

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D1042991	(X3) Date Survey Completed 07/24/2020
Name of Provider or Supplier Lab Usa, Inc	Street Address, City, State 108r Merrimack Street, Haverhill, MA	
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
D0000	Based on evidence of unsuccessful proficiency testing performance for the Creatinine analyte, the following Condition level deficiency was deemed to be not met: Condition 42 CFR 493.803 - Proficiency Testing - Successful Participation. .
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 proficiency testing review for calendar years 2019 and 2020 (three testing events), the laboratory failed to successfully participate (achieve a score of 80 percent or more) in the American Proficiency Institute (API) proficiency testing program for the Creatinine analyte. Refer to D2093 and D2096. .</p>

D2093

ROUTINE CHEMISTRY

CFR(s): 493.841(d)

Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

This STANDARD is not met as evidenced by:

Based on record review of calendar years 2019 and 2020 proficiency testing results (three testing events), the laboratory failed to return proficiency testing results to the proficiency testing program within the time frame specified by the program as evidenced by the following: * Creatinine analyte. The laboratory achieved a score of 0 percent for the second testing event of 2020 (failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program). The failure to report proficiency testing results for the time period specified above was confirmed through a telephone interview with one technical supervisor on 7/23/2020. .

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 an off site desk review of the laboratory's 2019 and 2020 American Proficiency Institute (API) proficiency testing (PT) records the laboratory failed to achieve satisfactory performance for the Creatinine analyte for two out of three testing events resulting in unsuccessful performance for the analyte as evidenced by the following: 1. Desk review of the laboratory's 2019 and 2020 API PT records revealed the laboratory achieved a score for Creatinine of less than eighty percent for the following Routine Chemistry testing events: 2020 first testing event - Creatinine score of sixty (60) percent; and, 2020 second testing event - Creatinine score of zero (0) percent (failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program - refer to D2093). 2. Review of API reports for the two testing periods above confirmed that the PT scores were correct.