

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 48D0699866	(X3) Date Survey Completed 03/07/2022
Name of Provider or Supplier Clinical Laboratory Inc	Street Address, City, State Island Med Ctr Suite 6, Sunny Isle, St Croix, VI	
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	An unannounced CLIA off-site proficiency testing (PT) desk review for Clinical Laboratory Inc. was conducted on March 7, 2022 by a federal surveyor from the Centers for Medicare and Medicaid Services, CLIA New York Operation Branch. The laboratory was inspected under 42 CFR Part 493 CLIA regulations. Specific deficiencies cited are as follows:
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 off-site review of the CASPER 0153D report (Unsuccessful proficiency testing (PT) report), CASPER 0155D report (Individual Laboratory Profile the laboratory) and performance evaluations from the proficiency testing organization</p>

	<p>American Association of Bioanalysts (AAB), the laboratory failed to achieve satisfactory performance of at least 80% for three consecutive events for Parasitology and total bilirubin for the second and third testing events in 2021. Findings include: Please refer to: - D2055. - D2096.</p>
<p>D2055</p>	<p>PARASITOLOGY CFR(s): 493.829(e)</p> <p>Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on off-site review of the CASPER 0153D report (Unsuccessful proficiency testing (PT) report), CASPER 0155D report (Individual Laboratory Profile the laboratory) and performance evaluations from the proficiency testing organization American Association of Bioanalysts (AAB), the laboratory failed to achieve satisfactory performance of at least 80% for two out of three consecutive events in the specialty of Parasitology for the second and third testing events in 2021. Findings include: 1. Based on an offsite PT desk review performed on 03/07/2022 at 10:30 am and review of the CASPER 0153D, 0155D, and AAB performance evaluation reports, the laboratory failed to achieve satisfactory scores for the following two out of three consecutive events in 2021: a. Analyte: 0035 Parasitology - i. AAB 2021 2nd event 60%. ii. AAB 2021 3rd event 60%.</p>
<p>D2096</p>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p> <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.</p> <p>This STANDARD is not met as evidenced by: Based on off-site review of the CASPER 0153D report (Unsuccessful proficiency testing (PT) report), CASPER 0155D report (Individual Laboratory Profile the laboratory) and performance evaluations from the proficiency testing organization American Association of Bioanalysts (AAB), the laboratory failed to achieve satisfactory performance of at least 80% for two out of three consecutive events for the analyte Total Bilirubin which is in the specialty of Chemistry for the second and third testing events in 2021. Findings include: 1. Based on an offsite PT desk review performed on 03/07/2022 at 10:30 am and review of the CASPER 0153D, 0155D, and AAB performance evaluation reports, the laboratory failed to achieve satisfactory scores for the following two out of three consecutive events in 2021: a. Analyte: 0305 Total Bilirubin - i. AAB 2021 2nd event 20%. ii. AAB 2021 3rd event 60%.</p>