

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0995726	(X3) Date Survey Completed 05/06/2020
Name of Provider or Supplier Clinlab, Inc	Street Address, City, State 763 S New Ballas Road, Ste 160, 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 2019 and 2020 syphilis serology proficiency testing (PT) results reported to the CLIA database by the PT provider, the laboratory failed to successfully participate in PT. See D-tag 2074, unsatisfactory performance in two out of three consecutive syphilis serology PT challenges.</p>
D2074	<p>SYPHILIS SEROLOGY CFR(s): 493.835(e)</p> <p>Failure to achieve an overall testing event score of satisfactory performance for 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 2019 and 2020 syphilis serology proficiency testing (PT) results, the laboratory failed to achieve an event score of satisfactory performance for syphilis serology in two out of three testing events. Findings: 1. The laboratory obtained an unsatisfactory score of sixty percent for syphilis serology in the second testing event of 2019. 2. The laboratory obtained an unsatisfactory score of sixty percent for syphilis serology in the first testing event of 2020.