

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0073136	(X3) Date Survey Completed 11/13/2020
Name of Provider or Supplier Lynnfield Pediatrics, Llc	Street Address, City, State 628 Salem Street, Lynnfield, 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	A CLIA paper desk review of proficiency testing was conducted for the Lynnfield Pediatrics laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. Based on evidence of unsuccessful proficiency testing performance for the Bacteriology subspecialty, 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 year 2020 (two testing events) of American Proficiency Testing (API) proficiency testing results, the laboratory failed</p>

to successfully participate (achieve a score of 80 percent or more) in a proficiency testing program for the Bacteriology subspecialty as evidenced by the following: Refer to D2020 and D2028. .

D2020

BACTERIOLOGY
CFR(s): 493.823(a)

Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

This STANDARD is not met as evidenced by:

Based on record review of calendar year 2020 American Proficiency Institute (API) proficiency testing results, the laboratory failed to attain a testing event score of at least 80 percent for all Bacteriology analytes resulting in unsatisfactory performance as evidenced by the following testing event scores: Bacteriology (throat cultures): 1. 2020 API testing event 1 - score of 60 %. 2. 2020 API testing event 2 - score of 40 %. The results were confirmed with API on 11/10/20 at 3:52 PM.

D2028

BACTERIOLOGY
CFR(s): 493.823(e)

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.

This STANDARD is not met as evidenced by:

Based on proficiency testing review of American Proficiency Institute (API) proficiency testing results for calendar year 2020 (two testing events), the laboratory failed to achieve an overall testing event score of satisfactory performance for the subspecialty of Bacteriology as evidenced by the following testing event scores: Bacteriology: 1. 2020 API testing event 1 - score of 60 %. 2. 2020 API testing event 2 - score of 40 %. The results were confirmed with API on 11/10/20 at 3:52 PM.