

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0073136	(X3) Date Survey Completed 10/30/2019
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 recertification survey was conducted for the Lynnfield Pediatrics, LLC laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: . Based on proficiency testing (PT) record review and interview on 10/30/19, the laboratory did not maintain a copy of all PT records as evidenced by the following: AccuTest PT records for throat culture screens for presumptive identification of Group A Streptococci (GAS) for calendar years 2018 and 2019 were reviewed. The review revealed that a signed attestation statement provided by the PT program, signed by the analyst and the laboratory director, was not maintained for two years for all five events. Testing Person 2 (TP2) interviewed on 10/30/19 at 10:20 AM confirmed that attestation statements provided by the PT program were not signed by the analyst and the laboratory director, documenting that PT samples were tested in the same manner as patient specimens. The laboratory performs 377 throat culture screens annually. .</p>

D6018

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on record review and interview on 10/30/19, the laboratory director failed to ensure documentation of PT review as evidenced by the following: AccuTest PT records for throat culture screens for presumptive identification of GAS for calendar years 2018 and 2019 were reviewed. The review revealed that there was no documentation of review of PT reports for all five PT events. TP2 confirmed through interview on 10/30/19 at 10:20 AM that the PT reports from AccuTest did not document review by the appropriate staff in order to evaluate the laboratory's performance and to identify any problems that require corrective action. .

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on record review and interview on 10/30/19, the laboratory director failed to ensure that documentation was maintained to verify that testing personnel had the appropriate training for all aspects of the laboratory operation as evidenced by the following: The CMS 209 Laboratory Personnel Report was reviewed on 10/30/19. The report showed that there were three new testing persons hired and performing testing since the last CLIA recertification survey on 10/30/17. No documentation of training could be provided during the time of the survey for the three new testing persons to confirm that they were trained and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. Testing Person 1 (TP1) confirmed in an interview on 10/30/19 at 10:15 AM that there was no documentation maintained of initial training for the new testing persons. .

D6030

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(12)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform

test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

. Based on record review and interview on 10/30/19, the laboratory director failed to ensure that policies and procedures were established for individuals who conduct pre-analytical, analytical, and post analytical phases of testing to ensure their competency to process specimens, perform test procedures, and report test results promptly and proficiently as evidenced by the following: No documentation of competency assessments for 2018 and 2019 could be provided during the time of the survey for seven testing persons. The laboratory's policy and procedure manual was reviewed on 10/30/19. The review revealed that no policy was established on how to assess the competency of all individuals who conduct pre-analytical, analytical, and post analytical phases of testing. TP1 confirmed in an interview on 10/30/19 at 10:15AM that there were no policies and procedures established for monitoring and assessing the competency of all testing persons. .

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

. Based on lack of record review and interview on 10/30/19, the technical consultant failed to conduct competency assessments as evidenced by the following: No documentation of competency assessments for 2018 and 2019 could be provided during the time of the survey for seven testing persons assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. TP1 confirmed in an interview on 10/30/19 at 10:15 AM that competency assessments were not performed for seven testing persons for both 2018 and 2019. The laboratory performs 944 Bacteriology tests annually.