

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 47D0091383	(X3) Date Survey Completed 02/21/2019
Name of Provider or Supplier Essex Pediatrics	Street Address, City, State 89 Main St, Essex Junction, VT	
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	Essex Pediatrics PC laboratory was surveyed for complaint allegations pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on observation, record review, and staff interview; the laboratory sent 5 bacteriology proficiency testing (PT) samples to another laboratory with a separate CLIA certificate in February 2019. Refer to tag D2013.</p>
D2013	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(4)</p> <p>The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested</p>

testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.

This STANDARD is not met as evidenced by:
Based on observation, record review, and staff interview; the laboratory sent 5 bacteriology proficiency testing (PT) samples to another laboratory in February 2019. Findings include: 1) Review on 2/21/2019 of an email sent to the State Agency (SA) on 2/14/2019 by Essex Pediatrics PC revealed on 2/5/2019 the laboratory sent 5 of 5 throat culture PT samples from the 2019 Medical Laboratory Evaluation (MLE) - M1 event to a reference laboratory. 2) Interview on 2/21/2019 at 11:15 AM with the Staff A (nurse manager) at Essex Pediatrics PC confirmed 5 of 5 throat culture PT samples from the 2019 MLE - M1 event to a reference laboratory on 2/5/2019. 3) Review on 2/21/2019 of an email sent to the SA on 2/14/2019 from a reference laboratory revealed it received 5 MLE PT samples from Essex Pediatrics PC on 2/5/2019. 4) Observation on 2/21/2019 at 1:45 PM at the reference laboratory revealed 5 MLE PT samples remained quarantined, unopened, and untested. MLE - PT samples observed were 2019 TC-1, 2019 TC-2, 2019 TC-3, 2019 TC-4, and 2019 TC-5. 5) Interview on 2/21/2019 at 1:45 PM with Staff B (technical specialist, microbiology) at the reference laboratory confirmed the 5 MLE PT samples came from Essex Pediatrics PC on 2/5/2019 and the PT samples have not been tested by the reference laboratory.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
Based on record review, observation, and staff interview the laboratory director failed to ensure bacteriology proficiency testing samples were tested in accordance with Subpart H. Refer to tag D6016.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(i)

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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on record review, observation, and staff interview the laboratory director failed to ensure bacteriology proficiency testing (PT) samples were not sent to another laboratory in 2019. Findings include: 1) Review on 2/21/2019 of an email sent to the State Agency (SA) on 2/14/2019 by Essex Pediatrics PC revealed on 2/5/2019 the laboratory sent 5 of 5 throat culture PT samples from the 2019 Medical Laboratory Evaluation (MLE) - M1 event to a reference laboratory. 2) Interview on 2/21/2019 at 11:15 AM with the Staff A (nurse manager) at Essex Pediatrics PC confirmed 5 of 5 throat culture PT samples from the 2019 MLE - M1 event to a reference laboratory on 2/5/2019. 3) Review on 2/21/2019 of an email sent to the SA on 2/14/2019 from a reference laboratory revealed it received 5 MLE PT samples from Essex Pediatrics PC on 2/5/2019. 4) Observation on 2/21/2019 at 1:45 PM at the reference laboratory revealed 5 MLE PT samples remained quarantined, unopened, and untested. MLE - PT samples observed were 2019 TC-1, 2019 TC-2, 2019 TC-3, 2019 TC-4, and 2019 TC-5. 5) Interview on 2/21/2019 at 1:45 PM with Staff B (technical specialist, microbiology) at the reference laboratory confirmed the 5 MLE PT samples came from Essex Pediatrics PC on 2/5/2019 and the PT samples have not been tested by the reference laboratory.