

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0671931	(X3) Date Survey Completed 11/21/2019
Name of Provider or Supplier Chelmsford Pediatrics	Street Address, City, State 7 Village Square, Chelmsford, 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 Chelmsford Pediatrics, LLC laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: . Based on proficiency testing (PT) review and interview with the Testing Person (TP) on 11/21/19, the laboratory director failed to effectively review and evaluate PT results obtained on proficiency testing performed as specified in subpart H of this part as evidenced by the following: The surveyor reviewed American Association of Bioanalysts (AAB) PT records for calendar years 2018 and 2019 (5 testing events). The review revealed that the laboratory director failed to review and evaluate 3 out of 5 results for the following testing events: 1. AAB Nonchemistry Microbiology 2018 Event Q3. 2. AAB Nonchemistry Microbiology 2019 Event Q1. 3. AAB Nonchemistry Microbiology 2019 Event Q2. The TP interviewed on 11/21/19 at 11:01 AM confirmed that the laboratory director failed to review and evaluate AAB PT results for 3 testing events in 2018 and 2019.</p>
D6019	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv)</p> <p>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</p>

director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

. Based on proficiency testing (PT) review and interview with the Testing Person (TP) on 11/21/19, the laboratory director (LD) failed to ensure a corrective action plan was followed when any proficiency testing (PT) results are found to be unacceptable as evidenced by the following: The surveyor reviewed the American Association of Bioanalysts (AAB) PT records for calendar years 2018 and 2019 (5 testing events). The review revealed the laboratory received an unacceptable testing score of 60% for 2019 PT Nonchemistry Microbiology Event Q2 and no corrective action was conducted for unacceptable analyte results. The TP interviewed on 11/21/19 at 11:01 AM confirmed that the laboratory did not have documentation indicating that the laboratory investigated the unacceptable results. The laboratory performs 1,721 Throat Culture tests annually.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Testing Person (TP) on 11/21/19, the Technical Consultant (TC) failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least annually, after the first year as evidenced by the following: The surveyor asked the TP for personnel competency records on 11/21/19. The TP stated that there were no records and the annual competency evaluations were not performed and documented for the one testing person for calendar years 2018 and 2019. The TP interviewed on 11/21/19 at 9:55 A.M. confirmed that the TC failed to perform and document annual competency evaluations for the TP.