

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 41D0082225	(X3) Date Survey Completed 11/05/2020
Name of Provider or Supplier East Bay Pediatrics And Adolescent Medicine	Street Address, City, State 234 Maple Avenue, Barrington, RI	
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of specimen processing, record review, interview with the Testing Personnel (TP1), the laboratory failed to document a procedure for the specialty of Hematology. Findings include: 1. Record review of the laboratory procedure manuals on 11/5/2020 revealed a Cell-Dyn operators manual and no additional written procedure for Hematology. 2. Interview with TP1 on 11/5/2020 at 9:30 AM revealed that TP1 believed that the director approved Cell-Dyn operator's manual was sufficient as a procedure manual for the Hematology specialty.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: D5407 Based on surveyor observation of specimen processing, record review, interview with the Testing Personnel (TP1), the laboratory failed to document procedure manual changes and record director approval those changes. Findings include: 1. Record review of the laboratory procedure manual on 11/5/2020 revealed a Strep A Taxo disc package insert to be used as a procedure supplement and noting</p>

plate incubation to be "35 to 37" degrees Celsius for "18 to 24" hours. The approved procedure manual noted plat incubation to be "33-37" degrees Celsius for "24-48" hours. 2. Interview with TP1 on 11/5/2020 at 9:00 AM revealed that TP1 is using the current procedure as noted by the manufacturer and that changes were not reflected in the laboratory manual approved as of 5/2/2018.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(13)

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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:

Based on surveyor observation of specimen processing, record review, interview with the Testing Personnel (TP1), the laboratory director failed to provide a procedure manual for the specialty of Hematology. Findings include: 1. Record review of the laboratory procedure manuals on 11/5/2020 revealed a Cell-Dyn operators manual and no additional written procedure for Hematology. 2. Interview with TP1 on 11/5/2020 at 9:30 AM revealed that TP1 believed that the director approved Cell-Dyn operator's manual was sufficient as a procedure manual for the Hematology specialty.