

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0669516	(X3) Date Survey Completed 03/21/2019
Name of Provider or Supplier Avon Pediatrics Llc	Street Address, City, State 34 Dale Rd, Avon, CT	
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
D5203	<p>SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation and staff interview, the laboratory failed to ensure positive identification of a patient's specimen from the time of collection through completion of testing. Findings include: 1. Surveyor observation on 3/21/19 at 11:00 AM of the laboratory work bench area revealed the following: a. A cone shaped piece of styrofoam located on the laboratory work bench. b. Testing personnel #2 (TP2) performed a rapid strep test and stuck the stick side of the patient's throat swab into the side of the styrofoam cone. The swab was not labeled. TP2 set a timer and walked away from the bench while the rapid strep test was in progress. c. Testing personnel #3 (TP3) performed a rapid strep test and stuck the stick side of the patient's throat swab into the top of the styrofoam cone. The swab was not labeled. TP3 set a timer and walked away from the bench while the rapid strep test was in progress. 2. Staff interview on 3/21/19 at 11:05 AM with the testing personnel #1 (TP1) confirmed swabs are not labeled with any patient identifier and they are left unattended in the styrofoam cone until planted. TP1 confirmed at times multiple unlabeled swabs can be left in the styrofoam cone until planted. 3. The laboratory performs 582 throat cultures annually in the subspecialty of bacteriology.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the</p>

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.

This STANDARD is not met as evidenced by:

Based on surveyor observation, record review, and staff interview, the laboratory failed to follow established laboratory safety procedures. Findings include: 1. Surveyor observation on 3/21/19 at 11:00 AM revealed, testing personnel #2 (TP2) performed a rapid strep test and planted a throat culture without wearing gloves. 2. Record review on 3/25/19 of the laboratory's, 'Model Exposure Control Plan For Avon Pediatrics,' procedure revealed: a. Form 5.1, 'General Requirements on Personal protective Equipment', #3, "Employees shall wear appropriate gloves when it can be reasonable anticipated they may have hand contact with Blood, or other infectious materials, mucous membranes, non-intact skin, and when handling or touching contaminated items or surfaces." b. Form 5.3, Employer Policy Statement for Use of Gloves', #1, "Gloves are to be worn at any time when there is potential for direct contact with blood or other potentially infectious body fluids or materials." 3. Staff interview with testing personnel #1 at 11:05 AM confirmed the findings in #1 above.

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

Based on surveyor observation, record review and staff interview, the laboratory failed to follow the manufacturer's instructions in the subspecialty of bacteriology. Findings include: 1. During observation on 3/21/19 at 11:30 AM of the bacteriology testing area, surveyor observed testing personnel #2 planting a throat swab on a Strep Select Agar (SSA) plate. 2. During observation on 3/21/19 at 11:30 AM of the incubator used for throat culture testing, surveyor noted the following: a. Three SSA plates were located inside the incubator. b. Two of the 3 plates referenced above were cold to the touch. 3. Record review on 3/21/19 of the manufacturer's package insert for SSA media revealed: a. "Allow unopened plates to warm to room temperature prior to inoculation." b. "The ability to detect microorganisms by culture techniques can be affected by the following factors: improper specimen collection, storage and inoculation, initiation of antiinfective therapy prior to specimen collection, improper culture incubation temperatures and atmospheres, improper length of culture incubation, and improper storage and handling of culture media." 4. Staff interview with testing personnel #1 on 3/21/19 at 11:30 AM confirmed the above findings.

D5781

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that

perform outside of established operating parameters or performance specifications; (b) (1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to take corrective action when the laboratory incubator temperature was out of range in the subspecialty of bacteriology. Findings include: 1. Record review on 3/21/19 of the laboratory incubator temperature logs from 1/24/17 through 3/21/19 revealed: a. Acceptable incubator temperature range is 33 to 37 degrees Celsius. b. Corrective action when the incubator temperature was out of range was not documented for 134 of 462 working days from 1/24/17 through 3/21/19 . 2. The temperature charts were not reviewed by the technical consultant to ensure corrective action was carried out when the temperatures were out of range. 3. Record review on 3/21/19 of the package insert for the Strep Select Agar revealed: a. "Incubate the plates at 33 - 37 degrees Celsius." b. "The ability to detect microorganisms by culture techniques can be affected by the following factors: improper specimen collection, storage and inoculation, initiation of antiinfective therapy prior to specimen collection, improper culture incubation temperatures and atmospheres, improper length of culture incubation, and improper storage and handling of culture media." 4. Staff interview on 3/21/19 at 11:00 AM with testing personnel #1 confirmed the above findings. 5. The laboratory performs 582 throat cultures annually in the subspecialty of bacteriology.