

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0095962	(X3) Date Survey Completed 04/29/2019
Name of Provider or Supplier Branford Pediatrics & Adolescent Medicine	Street Address, City, State 784 East Main St, Branford, 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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to ensure proper storage of culture media in the specialty of microbiology. Findings include: 1. Record review on 4/29/19 of the laboratory's refrigerator temperature log revealed lack of documentation for refrigerator temperature for the following period. 2018 2017 January: 1 of 31 days 4 of 31 days February: 1 of 28 days 4 of 29 days March: 1 of 31 days 4 of 31 days April: 4 of 30 days May: 4 of 31 days 6 of 31 days June: 1 of 30 days 2 of 30 days July: 3 of 31 days 5 of 31 days August: 3 of 31 days 4 of 31 days September: 2 of 30 days 4 of 30 days October: 1 of 31 days 5 of 31 days November: 1 of 30 days 5 of 30 days December: 2 of 31 days 9 of 31 days The refrigerator is used to store culture media. 2. Record review on 4/29/19 of the Healthlink Strep-select agar package insert revealed to store the media at 2-8 degrees C. 3. Record review on 4/29/19 of the laboratory's incubator temperature log revealed the lack of temperature documentation as follows: a. 11 of 16 days for the last two weeks in October 2017. b. 8 of 16 days for the last two weeks in December 2017. The incubator is used for microbiology cultures. 4. Staff interview with practice manager on 4/29/19 at 11:00 confirmed the above findings. 5. The laboratory performs 1,724 throat cultures and 374 urine cultures annually.</p>

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on record review and staff interview the laboratory failed to follow the quality assessment plan outlined in the Individualized Quality Control Plan (IQCP) for the specialty of microbiology. Findings include: 1. Record review of the laboratory IQCP plan for "Strep Throat Cultures" revealed the following. a. "Test System- Lab Director (LD) to monitor incubator temp logs weekly, initial monthly, inform practice manager of any concerns > staff member notified". b. "Environment- LD to monitor refrigerator temp logs weekly, initial monthly, inform practice manager of any concerns > staff member notified." c. "Environment- LD to monitor room temp logs weekly, initial monthly, inform practice manager of any concerns > staff member notified". d. "Media- Strep Select Agar (SSA): the practice will keep the certificate of analysis logged by date as they are received". 2. Record review on 4/29/19 of the laboratory's refrigerator temperature log for 2017 and 2018 revealed the lack of documentation for LD review or corrective action(s) when temperature was not recorded specifically as follows: a. 2017- missed temperature documentation for 54 of 364 days b. 2018- missed temperature documentation for 20 of 364 days 3. Record review on 4/29/19 of the laboratory's incubator temperature log for 2017 and 2018 revealed documentation of LD review or corrective action(s) when a temperature was not recorded was not available. 4. Record review of the laboratory's SSA plates log revealed the laboratory did not obtain manufacturer's certificate of analysis for each lot number and shipment of the SSA media received. The laboratory receives approximately 28 shipments of SSA media annually.