

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0095927	(X3) Date Survey Completed 01/22/2018
Name of Provider or Supplier Prohealth Physicians	Street Address, City, State 682 East Main Street, 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
D0000	The Branford/North Branfor Pediatrics Laboratory was surveyed pursuant to 42CFR Part 493 of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) on January 22, 2018.
D5471	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to check each new lot number and shipment of bacitracin disks for positive and negative reactivity in the subspecialty of bacteriology. Findings include: 1. Record review of manufacturer package inserts on 1/22/18 revealed the manufacturer package insert for the bacitracin discs was not available. 2. Record review of the Media Quality Control Record log for 2016 and 2017 on 1/22/18 revealed the following: a. The laboratory utilizes BBL Taxo A bacitracin discs. b. Eleven shipments of bacitracin discs were received during this timeframe. c. Bacitracin discs from each shipment were tested against a positive Strep Group A antigen test patient. d. Documentation of bacitracin discs from each shipment being tested with a positive and negative control was not available. 3. Staff interview with testing personnel #1 on 1/22/18 at 10:30 AM confirmed this finding. 4. The laboratory performs 569 throat cultures annually in the subspecialty of bacteriology.</p>