

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0909013	(X3) Date Survey Completed 08/22/2019
Name of Provider or Supplier Patriot Pediatrics	Street Address, City, State 74 Loomis Street, Bedford, 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 Patriot Pediatrics laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
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 interview, the laboratory failed to check each lot number and shipment of disks when opened for positive and negative reactivity as evidenced by the following: The laboratory performs throat culture screens for presumptive identification of Group A Streptococci (GAS) using Selective Strep Agar and Bacitracin disks. Quality control (QC) record review on 8/22/19 revealed that the laboratory did not check each lot and each shipment of Bacitracin disks with positive and negative organisms. There were no Bacitracin disks QC records available. Interview with the laboratory director on 8/22/19 at 1:30 PM confirmed that the laboratory failed to check each lot and shipment of Bacitracin disks using GAS positive and negative organisms.</p>