Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 22D0075947	**(X3) Date Survey Completed** 09/07/2021
Name of Provider or Supplier West Cambridge Pediatric And Adolescent Medicine	**Street Address, City, State** 575 Mount Auburn St Ste 101, Cambridge, 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 West Cambridge Pediatric and Adolescent Medicine laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (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. This STANDARD is not met as evidenced by: . Based on record review and interview with the laboratory director (LD), 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 surveyor asked to review the quality control (QC) records for the Bacitracin (Taxo A) disks on 9/7/2021. The laboratory performs throat cultures for presumptive identification of Group A Streptococci (GAS) using Selective Strep Agar and Taxo A disks. The review revealed that the laboratory did not check each lot and each shipment of Taxo A disks with positive and negative organisms. There were no Taxo A disks QC records available to review for calendar years 2020 and 2021. The LD confirmed in an interview on 9/7/2021 at 12:26 P.M. that the laboratory failed to check each lot and shipment of Taxo A disks using GAS positive and negative organisms for calendar years 2020 and 2021. The laboratory performs 401 throat culture tests annually.