Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2169892	12/08/2020
Name of Provider or Supplier	**Street Address, City, State**	
Pediatrics Of Arlington, Plc	1635 North George Mason Drive # 185, Arlington, VA	

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	An announced on-site CLIA initial survey was conducted at Pediatrics of Arlington on December 8, 2020 by the Virginia Department of Health's Office of Licensure and Certification. The survey included an entrance interview on November 16, 2020 and virtual record review conducted on December 3, 2020. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiency is as follows:
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's media logs, urine culture patient logs, and interview, the laboratory failed to document the ability to support and inhibit growth, and produce a specific biochemical response for five (5) of five (5) lot numbers of Hardy Diagnostics Blood/EMB Biplates utilized for twelve (12) patient urine cultures from March 12, 2020 to December 3, 2020. Findings include: 1. Review of the laboratory's patient test logs revealed the laboratory utilized Hardy Diagnostics Blood /EMB Biplate media for 12 patient urine cultures from March 12, 2020 to December 3, 2020. 2. Review of the laboratory's media logs revealed the laboratory received and utilized the following lot numbers Hardy Diagnostics Blood/EMB Biplate media for patient urine cultures from March 12, 2020 until December 3, 2020: Lot 455082, Lot 455773, Lot 460261, Lot 463500, Lot 468740. A total of 5 lot numbers. Review of the

	media logs revealed no documentation of the ability of each lot number of Hardy Diagnostics Blood/EMB Biplate media to support or inhibit specific organism growth, and produce a specific biochemical response. The surveyor requested to review the quality control documentation for the Hardy Diagnostics Blood/EMB Biplate media. The laboratory provided no documentation to review. 3. In an interview with the Laboratory Director (LD) on December 3, 2020 at approximately 9:15 AM, the findings were confirmed.