Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D1093627	04/29/2019
Name of Provider or Supplier	**Street Address, City, State**	
Valley Pediatrics Of Greenwich, Llc	25 Valley Dr, Greenwich, 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
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: A. Based on surveyor observation, record review and staff interview, the laboratory failed to check each lot number and shipment of media for its ability to support growth and, as appropriate, select or inhibit specific organisms in the subspecialty of bacteriology. Findings include: 1. Surveyor observation on 4/29/19 at 11:50 AM of the Healthlink Strep Select Agar (SSA), Catalog #1146 media revealed the following lot numbers and quantities currently in use: Lot Number Quantity 1905800 1 plate 1906408 10 plates 2. Record review on 4/29/19 of the medical supplier packing slips for the Healthlink SSA media revealed the following quantities were received by the laboratory. Lot Number Received Quantity 1905800 4/9/19 60 plates 1906408 4/11 /19 20 plates 3. Record review on 4/29/19 of the 'SSA media Sterility Check quality control (QC) log' revealed the laboratory failed to document the ability of the media to support growth, select or inhibit specific organisms for the 2 of 2 lot numbers noted above. 4. Staff interview with practice manager on 4/29/19 at 11:50 AM confirmed the above findings. 5. The laboratory performs 500 throat cultures annually in the subspecialty of bacteriology. This is a repeat deficiency. B. Based on record review and staff interview, the laboratory failed to check each lot number and shipment of media for its ability to select or inhibit specific organisms in the subspecialty of bacteriology. Findings include: 1. Record review on 4/29/19 of the laboratory's Throat

	Culture procedure revealed the laboratory failed to specify quality control organisms to be used to document the ability of the media to support growth, select or inhibit specific organisms for each lot number and shipment. 2. Record review on 4/29/19 of the 'SSA media Sterility Check quality control (QC) log' revealed the laboratory failed to specify the organisms utilized for the 'positive QC and negative QC' for 37 of 37 shipments received between 1/2/18 and 4/6/19. 3. Record review on 4/29/19 of the HealthLink Product Information and QC Sheet for SSA revealed expected results utilizing the following control organisms will yield the following results: Streptococcus pneumoniae-growth, alpha hemolysis; Streptococcus pyogenes-growth, beta hemolysis, Staphylococcus aureus-inhibition (partial) and Escherichia coli inhibition (partial to complete). 4. Staff interview with medical assistant #1 (MA1) on 4/29/19 at 11:50 AM confirmed the above. The MA1 stated the control organisms utilized by the laboratory are Group A Strep for the 'positive QC' and Group B Strep for the 'negative QC'. MA1 was unaware of the manufacturer's recommendation for control organisms to inhibit growth. 5. The laboratory performs 500 throat cultures annually in the subspecialty of bacteriology.