Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2079949	04/06/2021
Name of Provider or Supplier	**Street Address, City, State**	
Potomac Pediatrics	15204 Omega Dr Ste 100, Rockville, MD	

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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on remote review of the laboratory's procedure and phone interview with the testing person (TP), the laboratory's procedure failed to include instructions on how to interpret and report results for throat cultures. Findings: 1. The laboratory's "Strep Select Agar Procedure" detailed how to perform a throat culture in 9 steps. Steps 1-7 of the procedure explained how to label, inspect and inoculate the Strep Select Agar media and then add the bacitracin differentiation disc. 2. Step 8 stated "Place in Incubator on top shelf" and step 9 of 9 stated "Only Doctors are interpreting 24 hour and 48 hour results." 3. The procedure did not include the acceptable conditions for

	incubation (temperature, plate orientation, etc.) nor instructions for how to read, interpret and report the results of the throat culture. 4. During the phone conversation on 04/06/2021 at 4:07 PM, the TP confirmed that the throat culture procedure did not include instructions for how to read, interpret and report results of the test system.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on remote review of a final report and phone interview with the testing person (TP), the laboratory failed to report results for throat cultures as defined in the manufacturers' instructions for use (IFU). Findings: 1. The laboratory cultured throat swab specimens using Hardy Diagnostics Selective Strep Agar (catalog number A70) and Becton Dickinson (BD) BBL Taxo A Discs for differentiation of group A streptococci. 2. The "Intended Use" section of the manufacturer's IFU for the Selective Strep Agar (IFU-10426[A]) stated "Hardy Diagnostics Selective Strep Agar is a selective medium recommended for use in the primary isolation of all Streptococcus species, including streptococcal groups A (S. pyogenes), B (S. agalactiae), C, D, F, G, and S. pneumoniae, especially from respiratory specimens." The "Limitations" section stated "It is recommended that biochemical, immunological, molecular, or mass spectrometry testing be performed on colonies from pure culture for complete identification." 3. The "Intended Use" section of the manufacturer's IFU for the BD BBL Taxo A Discs (8800671JAA(02) 2015-04) stated "Taxo A discs are for the presumptive identification of group A beta-hemolytic streptococci based on susceptibility to a low level of bacitracin." The "Limitations of the Procedure" section stated the "Taxo A disc is presumptive, and a positive result should be followed with more specific physiological and/or serological tests." 4. The laboratory's final report stated "Lab: Strep Culture - Throat" and "Result: Positive." There was no indication on the final report that the testing performed was for presumptive identification of group A streptococcus. 5. During the phone interview on 03/23/2021 at 3:00 PM the TP confirmed that the laboratory did not report the results of a throat culture as presumptive positive for group A streptococcus.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

	This STANDARD is not met as evidenced by: Based on remote review of laboratory records and phone interview with the testing person (TP), the laboratory failed to establish performance specifications for testing specimen types that were not validated by the manufacturer using the Quidel Sofia Strep A+ FIA (fluorescent immunoassay), a FDA-cleared test system. Findings: 1. The laboratory used the Quidel Sofia Strep A+ FIA for rapid testing for group A streptococcus (GAS) organisms. The testing complexity of the Sofia Strep A+ FIA was categorized as CLIA waived when used with throat swab specimens. 2. Review of the patient logs for rapid and culture testing for GAS identified that a vaginal specimen was tested on 11/11/2020 using the Sofia Strep A+ FIA. 3. The laboratory procedure titled "Procedure for Physicians 48 Throat Cultures" stated that "All throat cultures that are older than 24 hours must be reevaluated if it grows any Group A Streptococci colonies. A rapid strep must be performed on those that appear positive after 24 hours to confirm a positive Group A Streptococci." 4. The "Intended Use" section of the Sofia Strep A+ FIA product insert (1347100EN01 01/18) stated that "The Sofia Strep A+ FIA detects Group A Streptococcal antigens from throat swabs from patients with signs and symptoms of pharyngitis, such as sore throat." 5. The surveyor contacted Quidel technical support via email regarding specimen types approved for use with the Sofia Strep A+ FIA. The response received on 04/01/2021 at 6:52 PM stated "the PI/clinical studies used human obtained throat swabs only (there just isn't any data for other sample types). The FDA only gives us approval for this one sample type: human throat swab." 6. The laboratory modified an FDA-cleared or approved test system by changing its intended use by testing specimen types that were not validated or approved by the manufacturer. A modified FDA-cleared or approved test system becomes a high complexity test. The laboratory did not establish performance specifications for accuracy, precision, analytical sensitivity and analytical specificity for testing the unapproved specimen types, vaginal and culture, using the Sofia Strep A+ FIA. 7. During the phone interview on 03/23/2021 at 3:00 PM the TP confirmed that the laboratory tested vaginal specimens using the Sofia Strep A+ FIA. During the phone conversation on 04/06/2021 at 4:07 PM, the TP confirmed that the laboratory tested culture specimens using Sofia Strep A+ FIA for confirmation of cultures positive at 48 hours.