Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0185429	02/19/2020
Name of Provider or Supplier	**Street Address, City, State**	
Tan & Garcia Pediatrics Pc	2020 Good Hope Road, Suite 120, Enola, PA	

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 the review of the throat culture and urine culture examination policies and interview with the site manager, the laboratory failed to include quality control (QC) procedures in the throat culture and urine culture policies (2 of 2) from 2018 to the day of survey. Findings Include: 1. On the date of survey, 02/19/2020, review of the throat culture and urine culture examination policies (2 of 2) revealed, QC procedures were not indicated in both policies. 2. The site manager confirmed the finding above on 02/19/2020 around 11:05 am.

D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on review of the laboratory procedural manual and interview with the site manager, the laboratory failed to establish maintenance and/or function check protocols for 1 of 1 Acu-rite digital refrigerator/freezer thermometer when not provided by the manufacturer from 2018 to the day of survey. Findings Include: 1. The Acu-rite digital refrigerator/freezer thermometer package insert did not state maintenance and/or function check protocols for the thermometer. 2. One the day of survey, 02/19/2020, review of the laboratory procedure manual revealed, the laboratory did not establish a maintenance and/or function check protocols for 1 of 1 Acu-rite digital refrigerator/freezer thermometer from 12/07/2017 to 02/19/2019. 3. The refrigerator houses BD BBL selective streptococcus agar. 4. The site manager revealed the finding in above on 02/19/200 around 10:50 am.
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 review of the quality control (QC) records and interview of the site manager, the laboratory failed to document positive and negative reactivity QC for each lot or shipment of BD BBL Taxo disks when opened, in 2018. Findings include: 1. On the day of survey, 02/19/2020, the laboratory could not provide documentation of QC performed for BD BBL Taxo disks opened in 2018. 2. In 2018, 554 throat cultures were examined. 3. The site manager confirmed the findings above on 02/20 /2020 around 10:45 am.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that

	perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of temperature logs and interview site manager, the laboratory failed to document all corrective actions taken when acceptable refrigerator (11 of 12 months) and incubator temperatures (10 of 12 months) were out of range in 2018. Findings include: 1. The BD BBL Selective Streptococcus Agar package insert, storage instructions states "stores plates in the dark at 2-8 degrees Celsius (C)" (35.6-46.6 degrees Fahrenheit (F)). 2. The BD BBL Taxo disc package insert, storage instructions " store at 2-8 degrees C" (35.6-46.6 degrees F) 3. The temperature logs for multiple instruments states "report all problems, difficulties, or abnormalities concerning equipment to the supervisor and document the appropriate correction action". 4. On the day of survey, review of the temperature log for multiple instruments revealed, the acceptable refrigerator range of 35 - 46 degrees F and the acceptable incubator range of 35 - 37 degrees F, fell outside of the acceptable ranges and corrective actions were not documented when patient testing was performed for the following days in 2018: Refrigerator - 11 out of 12 months - 05 of 22 days in January. - 08 of 19 days in February. - 06 of 20 days in March. - 01 of 21 days in April. - 09 of 20 days in June. - 02 of 23 days in July. - 01 of 23 days in August. - 01 of 19 days in September. - 02 of 22 days in October. - 02 of 21 days in November. - 19 of 19 days in December. Incubator - 10 out of 12 months - 03 of 22 days in January. - 01 of 19 days in February. - 04 of 20 days in March. - 03 of 22 days in May. - 02 of 23 days in July. - 10 of 23 days in August. - 08 of 19 days in September. - 21 of 22 days in October. - 19 of 21 days in November. - 11 of 19 days in December. 5. The site manager confirmed the findings above on 02/19/2020 around 10:10 am.