Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2048185	09/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
International Pediatrics	501 N Frederick Avenue Ste 212, Gaithersburg, 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: I. Based on review of the "International Pediatrics Bacitracin Checklist" worksheet, the procedure manual, and interview with the testing person (TP), the laboratory's procedure manual failed to provide written instructions for documenting the expiration date of the Bacitracin (sensitivity) disc when the quality control (QC) organisms are being testing with each new lot. Findings: 1. The "International Pediatrics Bacitracin Checklist" worksheet included the documentation of the date, lot number, result (positive or negative), source of bacteria (proficiency testing (PT) identification number), who plated the specimen, who read the results and was signed

	off of the laboratory director. 2. The "Bacitracin Susceptability Test" procedure found in the throat culture procedure stated "record the lot #'s- per our CLIA evaluators" but failed to include instructions for how to store, label and maintain the PT specimens while waiting to verify that the laboratory received a score of 100% prior to using as a QC organism. The procedure failed to include instructions for how to document the authenticated PT specimens as positive and negative QC for each new batch of Bacitracin discs prior to being used for patient testing. 3. During the survey on 09/21 /2021 at 1:00 PM, the TP confirmed that the procedure manual failed to include instructions for storing, labeling and using PT organisms as positive and negative QC for the Bacitracin discs used in the laboratory. II. Based on review of the throat culture procedure manual, and interview with the TP, the laboratory's procedure manual provided conflicting information. Findings: 1. The "Performance" section of the throat culture procedure states that the plate is incubated for 18-24 hours. The "Throat Culture Recording" section states that the culture is read after 24-48 hours. According to the manufacturer of the Bacitracin discs, the plates are to be read at 18-24 hours after incubation. 2. During the survey on 09/21/2021 at 1:00 PM, the TP confirmed that the procedure manual failed to include accurate instructions for the incubation of throat cultures. III. Based on review of the proficiency testing (PT) procedure manual, and interview with the TP, the laboratory's procedure manual failed to include the current PT agency used by the laboratory. Findings: 1. The procedure for successful PT states that the laboratory is enroll with "WSLH PT" (Wisconson State Laboratory of Hygiene). The laboratory's PT records show enrollment with Medical Laboratory Evaluation (MLE) PT. 2. During the survey on 09 /21/2021 at 1:00 PM, the TP confirmed that the procedure manual failed to include accurate instructions for PT enrollment. VI. Based on review of the procedure manual, and interview with the TP, the laboratory's procedure manual failed to include the written insturctions for entering the throat and urine cultures into the electronic medical record (EMR). Findings: 1. The procedure manuals that were reviewed failed to include written insturctions for entering the throat and urine cultures in to the EMR. 2. During the survey on 09/21/2021 at 1:00 PM, the TP confirmed that the procedure manual failed to include written insturctions for entering the throat and urine cultures in to the EMR.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of the "International Pediatrics Bacitracin Checklist" worksheet and interview with the testing personnel (TP), the laboratory failed to ensure that the Bacitracin (sensitivity) discs used for the presumptive identification and differentiation of beta-hemolytic group A streptococci had not expired while in use. Findings: 1. Review of the "International Pediatrics Bacitracin Checklist" worksheet from 2020 showed that the laboratory failed to include documentation of the expiration date of the lot numbers of Bacitracin discs used. There was no worksheet for 2021. 2. The TP stated that they were unaware of any other records showing the expiration date of the Bacitracin discs used by the laboratory. 3. During the survey on 09/21/2021 at 1:00 PM, the TP confirmed that the laboratory records that were available failed to include the expiration dates of the Bacitracin discs used in 2020.

	The laboratory failed to ensure that expired Bacitracin discs were not used when testing patient specimens.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Note: This is a repeat deficiency. The laboratory was cited during the re-certification survey on 01/15/2019 for not performing two levels of quality control (QC) each day of testing when performing throat and urine cultures. The laboratory's Individual Quality Control Plan (IQCP) failed to include a Quality Control Plan (QCP) section listing the number, type, frequency of testing and criteria for acceptability and a Quality Assessment (QA) section to monitor the effectiveness of the laboratory's IQCP. The plan of correction (POC) received by the state agency (SA) stated that the IQCP would be completed by 02/12/2019. Based on review of the standard operating procedure (SOP) manual, laboratory records, and interview with the testing person (TP), the laboratory failed to implement the POC that was submitted to the SA. Findings: 1. The SOP that was reviewed during the survey failed to include a written IQCP for throat and urine cultures. When interviewed the TP stated that they were unaware of what was included in an IQCP. 2. The laboratory records did not include documentation of two levels of QC each day of testing for throat and urine cultures. 3. The laboratory performs throat and urine cultures. The laboratory is required to test two levels of QC materials each day of testing unless they have a written Individualized Quality Control Plan (IQCP). An IQCP plan requires the laboratory to perform a risk assessment that included an evaluation of the specimen used; environment for testing; integrity of the reagent; components of the test system; and competency of the testing personnel. The quality assessment portion of the IQCP should include a review of the QC, proficiency testing records, patient results and all other records pertaining to testing throat cultures. 4. During the survey on 09/21/2021 at 1:00 PM, the TP confirmed that the SOP did not have a written IQCP and the laboratory did not test two levels of QC each day of testing for throat and urine cultures. The laboratory failed to implement the POC that was submitted to the SA.
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 observation of the Bacitracin (sensitivity) discs found in the freezer, review of the "International Pediatrics Bacitracin Checklist" worksheet and interview of the testing person (TP), the laboratory failed to perform quality control (QC) on the lot of Bacitracin currently in use in the laboratory. Findings: 1. The Bacitracin discs observed in the freezer had a lot number of 0084857 and an expiration date of 2021-10-31. 2. The "International Pediatrics Bacitracin Checklist" worksheet did not include this lot number. 3. During the survey on 09/21/2021 at 1:00 PM, the TP confirmed that lot number 0084857 was not on the worksheet and there were no records showing that the required QC had been performed and found to be acceptable for the discs prior to being used with patient specimens.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory director failed to ensure that quality control procedures were established for throat and urine cultures; failed to implement the plan of correction submitted for the 01/15/2019 recertification survey; failed to provide a written and approved Quality Assurance Manual; and failed to ensure that the corrective action log was being used when remedial actions were implemented to correct a problem discovered in the laboratory (D6022).
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: I. The laboratory director failed to ensure that quality control (QC) procedures were established for throat and urine cultures. Cross refer to D5445 for details. II. Based on review of the plan of correction (POC) from the previous recertification survey conducted on 01/15/2019, procedure manuals and interview with the testing person (TP), the laboratory director failed to implement the POC that stated the additional components of the Individual Quality Control Plan (IQCP) for throat and urine cultures would be completed and implemented. Findings: 1. The POC received by the state agency (SA) stated that the IQCP would be completed by 02/12/2019. The laboratory was cited during the recertification survey on 01/15/2019 for not performing two levels of QC each day of testing when performing throat and urine cultures. The laboratory failed to completed the Quality Control Plan (QCP) section

	listing the number, type, frequency of testing and criteria for acceptability and the Quality Assessment (QA) section to monitor the effectiveness of the laboratory's IQCP. 2. Review of the procedure manuals showed that there was no written and approved IQCP. 3. During the survey on 09/21/021 at 1:00 PM, the TP confirmed that the procedure manuals failed to include a written and approved IQCP for throat and urine cultures III. Based on review of the procedure manuals and interview with the TP, the laboratory director failed to provide a written and approved "Quality Assurance Manual" that was referred to in the Quality Assurance section of the "Laboratory Policy" procedure manual. Findings: 1. The document titled "Laboratory Policy" was reviewed. The section labeled "Quality Assurance" stated, "Please see the Quality Assurance Manual for further information." 2. The TP stated that at the time of the survey they had no knowledge of where the Quality Assurance Manual was stored. 3. The laboratory records included two completed "Laboratory Director Review" worksheets dated 1/6/21 and 1/9/20. The TP stated that they were responsible for completing the worksheets. According to CLIA the person performing the review requires a minimum of a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. The TP performing the review failed to meet the minimum requirements for performing the review. 4. During the survey on 09/21/021 at 1:00 PM, the TP confirmed that the Quality Assurance Manual was not available at the time of the survey and that the annual "Laboratory Director Review" worksheet was completed by the TP who did not meet the minimum qualification requirements. VI. Based on review of the procedure manuals and interview with the TP, the laboratory director failed to ensure that the corrective action log was being used when remedial actions were implemented to correct a problem discovered in the laboratory. Findings: 1. The document titled "Laboratory Policy" was reviewed. The section labeled "Corrective Action Log" stated, "Our office has a system in place to document problems that occur during the everyday operation of the lab, such as instrument malfunction, quality control problems or any other situation that requires remedial action." 2. During the survey on 09/21/021 at 1:00 PM, the TP confirmed that the laboratory records failed to include a corrective action log for documenting remedial actions.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the "Laboratory Policy" manual, employee evaluation records and interview with the testing person (TP), technical consultant failed to establish written policies and procedures for assessing the testing at six months. Findings: 1. The written "Laboratory Policy" manual failed to include instructions for the documentation and evaluation after the TP had been working for six months. 2. The employee evaluations forms showed that only one of the two TP listed on the "Laboratory Personnel Report (CLIA)" form had any documented competency evaluations. The other person listed had not documented evaluations. 3. During the survey on 09/21/2021 at 1:00 PM, the TP confirmed that the policies and procedure

	manual did not include a written program for the of the evaluation of TP after they had been working for six month.