

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D2048185	<b>(X3) Date Survey Completed</b>  01/15/2019
<b>Name of Provider or Supplier</b>  International Pediatrics	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5415</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Note: This is a repeat deficiency. The laboratory was cited during the re-certification survey on 2/10/2017 for not recording the lot number and expiration date of Bacitracin discs. The plan of correction stated that this would be corrected. Based on quality control (QC) record review and interview with the laboratory director (LD), the laboratory failed to ensure that the lot numbers and expiration dates of control materials for Bacitracin QC were documented. Findings: 1. The laboratory documents Bacitracin Quality Control on a "Bacitracin Checklist." 2. A review of "Bacitracin Checklists" from 2/7/17 to 12/6/18 showed that lot numbers of Bacitracin discs were not documented 4 out of 11 times; and 3. Expiration dates of the Bacitracin discs were not documented 11 out of 11 times. 4. During an interview on 1/15/19 at 11:45 AM, the LD confirmed that there were no lot numbers or expiration dates recorded for the Bacitracin discs used for bacteriology testing.</p>
<b>D5445</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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</p>

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:

Based on standard operating procedure manual (SOPM) and quality control (QC) record review and interview with the laboratory director (LD), the laboratory did not run 2 levels of QC each day of patient testing and failed to ensure that the laboratory's Individual Quality Control Plan (IQCP) for performing throat culture testing was complete. Findings: 1. The procedure "Throat Cultures" in the SOPM states, "Bacitracin susceptibility tests are performed with each shipment & lot # to measure the quality of the culture results." 2. A review of QC records from 2/7/17 to 12/6/18 showed that bacitracin QC was performed 11 times, and not daily each day of patient testing. Bacitracin QC was not performed between 2/7/17 and 1/2/18. 3. Record review showed that the laboratory's IQCP for strep selective agar QC included a Risk Assessment, but did not include the Quality Control Plan (QCP) listing the number, type, frequency of testing, and criteria for acceptable results of the QC or the Quality Assessment (QA) plan to monitor the effectiveness of the laboratory's IQCP. 4. During an interview on 1/15/19 at 11:45 AM, the LD confirmed that the laboratory's IQCP was incomplete at the time of the survey.

**D6020**

**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 program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on quality control record review and interview with the laboratory director (LD), the LD failed to ensure that an Individual Quality Control Plan was completed for performing throat culture testing. Refer to D5445.

**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:

Based on review of the standard operating procedure manual (SOPM), quality assurance (QA) plan, and interview with the laboratory director (LD), the LD failed to

ensure that the QA plan was maintained to identify failures and corrective actions taken when failures are identified. Findings: 1. The procedure, "Throat Cultures" "Competency Control" in the laboratory's SOPM states, "In order to evaluate the personal competency, all daily and weekly logs will be reviewed and signed by the laboratory director every 3 months." "Furthermore, every 4 months five charts of patients who have been positive for strep will be pulled and inspected for any failure of the aforementioned procedures." 2. Record review showed that the "Bacitracin Checklist" which records results of bacitracin disc quality control was not signed by the LD for 2018; and 3. During an interview at 11:00 AM the LD stated that patient chart review "had not been done in the last 6 months or so" and that he had "not recorded" the reviews that were performed. 4. During an interview on 1/15/19 at 11:45 AM, the LD confirmed that the QA program had not been maintained as defined in the SOPM.