

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0213730	(X3) Date Survey Completed 01/10/2019
Name of Provider or Supplier International Pediatrics	Street Address, City, State 10901 Connecticut Ave Suite 100, Kensington, 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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review, the lab did not record the name of the quality control organism for the Taxo A disc in a manner to assure positive identification and ensure that the quality control material has not deteriorated. Findings: 1. The laboratory states that it uses proficiency test material as the quality control reagent to check the positive and negative reactivity of the Taxo A disc; 2. The lab did not have a procedure to positively identify the quality control sample on the quality control documents. The individual proficiency test specimen number for the control was recorded in both 2017 and 2018, but the lab did not document the year the proficiency test specimen corresponded to; 3. On 1/4/18 the lab identified the source of the quality control organism as "SPGO GNPA" and did not positively identify the reagents source.</p>
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system</p>

performance and environmental conditions, and variance in operator performance. (g)
The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review the lab did not perform bacteriology quality control procedures as required for accurate and reliable patient test results. Findings: 1. The lab did not check both the positive and negative reactivity of Taxo A discs on October 20, 2017. The Taxo A quality control record for this date shows quality control results for two lot numbers of Taxo A discs. Lot 6295542 was checked for negative reactivity but not positive reactivity and lot 6295540 was checked for positive reactivity and not negative reactivity; and 2. The lab did not check both the positive and negative reactivity of Taxo A discs on October 11, 2018. The Taxo A quality control record for this date shows quality control results for two lot numbers of Taxo A discs. Lot 18005525 was checked for negative reactivity but not positive reactivity and lot 18005526 was checked for positive reactivity and not negative reactivity; 3. In January 2018, April 2018, May 2018, July 2018, August 2018 and September 2018 the lab reported two different lot numbers for each date and only reported a positive or negative reactivity result for each lot, but not both (positive and negative reactivity checks); and 3. The records for the Taxo A disc quality control were not available for the date 2/18/17 to 8/30/17.