Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0718167	05/23/2018
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Associates Pc	7720 N 16th St #110, Phoenix, AZ	

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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (PT) records for 2017 and 2018 and interview with the facility personnel, the laboratory failed to provide a documented review of the PT results for testing events in the specialty of Bacteriology and Mycology. Findings include: 1. No documentation of a review, either by written comment or signature, was presented during the survey to indicate the laboratory director or designee reviewed the PT results for all three events in 2017 and the first event of 2018. 2. There must be evidence of PT results reviewed even if the laboratory received 100% 3. The facility personnel confirmed that the PT results indicated above were not reviewed by laboratory director or designee.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory manual presented during the survey and interview with the facility personnel, the laboratory failed to have a procedure manual that was approved, signed, and dated by the current laboratory director. Findings include: 1. The laboratory's procedure manual presented for review during the survey failed to include the approval, signature and date of the laboratory director. 2. The laboratory

	manual (revised May 3, 2016) had a cover sheet with a section for the laboratory director to sign and date, but there was no signature and date. The revision date of the manual was the same day as the previous survey date of May 3, 2016. 2. The facility personnel acknowledged that the procedure manual was not signed and dated by the laboratory director at the time of the survey.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of (A) plate media sterility checks done by the laboratory for urine cultures, (B) DTM media for positive and negative reactivity, (C) lack of packing slips to review for comment on media inspection and interview with the facility personnel, the laboratory failed to include lot numbers for sterility checks, failed to indicate that quality control (QC) was performed for specific lot numbers and failed to present all of the media packing slips with comments regarding media acceptability. Findings include: A 1. There was no evidence of lot numbers and expiration dates for the plate media sterility checks performed on 05/04/18 for patient ID #42126 with a date of service 05/18/18. B 1. QC lot numbers were missing in the patients' medical records sporadically for both DTM and urine culture media. Media QC records could not be consistently matched to each patient tested including Patient ID #44461 with a date of service of 11/30/2017 for a urine culture and patient #11160 with a date of service on 02/05/18 for a DTM culture. C 1. Some media packing lists were not presented for review to indicate that the media received from the supplier was checked by the laboratory before use and the specific lot was checked for sterility and quality control. The laboratory personnel acknowledged that certain information was missing and/or not documented including the items reference above.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on lack of signature and date of the laboratory director on the signature page of the procedure manual, the director failed to ensure an approved procedure manual was available for personnel (See D5407 for findings)

D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on lack of documentation presented for review and interview with the facility personnel, the technical consultant failed to have annual competency assessment of 7 out of 7 testing personnel that perform DTM testing and Urine culture testing for growth/no growth. Findings include: 1. The procedure manual contains an assessment list for DTM and Urine Cultures that is titled "non-waived competency annual testing". No completed documents of competency was presented for any of the testing personnel. The document was revised on 05/03/2016. 2. Each testing personnel has a sheet indicating if competency assessment was performed. The last assessment date indicated was in 2014. 3. The facility personnel acknowledged that there were no completed documents for review.