Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0211709	05/24/2019
Name of Provider or Supplier	**Street Address, City, State**	
Children's National Pediatrician Assocs Chevy Chas	4601 North Park Avenue, Chevy Chase, 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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of the microbiology patient log and interview with the office manager, the laboratory failed record the proficiency testing (PT) samples on the patient log in the same manner as the patient specimens. Findings: 1. Review of the microbiology patient logs for 2017 through May 2019 showed that the laboratory was not listing the PT samples on the microbiology patient log in the same manner as the patient specimens. 2. During the survey on 05/24/19 at 11:15 AM the office manager confirmed that the PT samples were not listed on the microbiology patient log in the same manner as the patient specimens.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

	This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) records and interview with the office manager, the laboratory did not ensure that each testing person who performed the test signed the attestation worksheet showing that PT samples were reviewed in the same manner at the patients. Findings: 1. According to the office manager there are 3 physicians and one nurse practitioner who perform the final interpretation of the urine colony count testing. 2. The PT records from 2017 and 2018 (6 events) were reviewed. The PT attestation worksheets revealed that only the initials of the laboratory director was present. 3. The office manager explained that the PT interpretations are reviewed by the laboratory director along with the one of the physicians or the nurse practitioner prior to submission to the PT agency. 4. During the survey on 05/24/19 at 11:15 AM the office manager confirmed that the PT attestation worksheets failed to have the signature of each physicians or nurse practitioner involved in the interpretation of the PT result.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: I. Based on review of the Quality Assurance (QA) policy and interview with the office manager, the laboratory director failed to ensure that all QA activities were documented. Findings: 1. The pre-analytical portion of the QA policy that covers test tracking requires the laboratory to randomly select 10 requisitions on a quarterly basis for review. 2. The surveyor asked to review the documentation of the quarterly review. According to the office manager the patients listed on the patient log that are highlighted with yellow, pink or blue are the randomly selected patients for review. 3. The QA policy failed to include written instructions for how to identify the randomly selected 10 requisitions that were reviewed quarterly. The QA policy failed to identify where to document that the random review was 100% for each quarter and corrective actions taken when the minimal acceptable limits were not met. 4. During the survey on 05/24/19 at 11:15 AM the office manager confirmed that the QA policy did not include instructions for identifying and documenting the quarterly reviews. II. Based on review of the annual evaluation records and interview with the office manager, the laboratory director failed to ensure that the documentation identified initial training and six month evaluation of the testing personnel (TP) employed in the laboratory. Findings: 1. The annual evaluation records for 2018 and 2019 were reviewed. The annual review occurred during the month of April for each year. 2. When interviewed the office manager stated that in April 2019 one of the seven TP had actually started working in April 2019 and another TP had started in October 2018. 3. The evaluation records for the TP who started in April 2019 should have been identified as initial training. The evaluation records for the TP who started in October 2018 should have been identified as semi-annual evaluation. 4. The office manager confirmed that there were no initial training records available for the TP who started working in October

	2018. 5. During the survey on 05/24/19 at 11:15 AM the office manager confirmed that the evaluation records did not differentiate between initial training and semi-annual evaluation.