Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0718167	03/07/2023
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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of Proficiency Testing (PT) reports from 2021 sent to the State Agency by the PT provider and interview with the facility personnel, the laboratory failed to successfully participate in a PT program for the regulated analyte, Urine Identification, for testing performed under the sub-specialty of Bacteriology. Findings include: 1. The laboratory's PT performance was unsatisfactory for the first event of 2021 for the regulated analyte, Urine Identification, with a score of 60%. 2. The laboratory's PT performance was unsatisfactory for the third event of 2021 for the regulated analyte, Urine Identification, with a score of 60%. 3. The facility personnel interviewed on March 7, 2023 at 10:05am confirmed the laboratory failed to

	successfully participate in PT for Urine Identification testing during 2021, as evidenced by the unsatisfactory PT scores listed above.
D2028	BACTERIOLOGY CFR(s): 493.823(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on information the Proficiency Testing (PT) provider furnished to the State Agency, the laboratory failed to achieve satisfactory performance for the regulated analyte, Urine Identification, for two out of three testing events (1st event of 2021 and 3rd event of 2021) resulting in unsuccessful PT performance. See D2016 for findings.
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: Based on lack of Quality Control (QC) documentation and interview with the facility personnel, the laboratory failed to perform and document control procedures using the number and frequency as required for testing performed in the specialty of Microbiology. Findings include: 1. The laboratory performs Urine Culture (growth/no growth) testing on patient specimens using the media, Blood Agar/MacConkey Bi-Plate. In addition, the laboratory performs DTM (Dermatophyte Test Media) testing on patient specimens. The laboratory's approximate annual test volume for Urine Culture and DTM testing is 858. 2. On the date of the survey, March 7, 2023, the laboratory's established QC procedure for Urine Culture testing includes testing a known positive (E. Coli) and a known negative (E. faecalis) on each new lot and/or shipment of media prior to using the media for patient testing. 3. Review of urine culture test results for patient ID# 7794 from testing performed on 5-02-2022 indicated the lot number of the media used was j32-5011722 (exp. 5/12/22). 4. No documentation was presented for review during the survey to indicate the laboratory performed QC as required on lot# j32-5011722, prior to testing patient specimens. 5. On the date of the survey, March 7, 2023, the laboratory's established QC procedure for DTM testing includes testing a known positive (C. albicans) and a known negative (P. aeruginosa) on each new lot and/or shipment of media prior to using the media for patient testing. 6. Review of DTM test results for patient ID# C.S. from testing performed on 4-28-2022 indicated the lot number of the DTM media used was x15-498296 (exp. 6/05/22). 7. No documentation was presented for review during the survey to indicate the laboratory performed QC as required on lot# x15-498296, prior

	to testing patient specimens. 8. No evidence was presented for review during the survey to indicate the laboratory maintains documentation of QC lot information for each lot/shipment of control materials used for Urine culture media and DTM media including, but not limited to, the control name, lot number, expiration date and date in use. 9. The facility personnel interviewed on March 7, 2023 at 11:25am confirmed the laboratory failed to perform and document external controls on each lot of media referenced above prior to testing patient specimens and confirmed the laboratory failed to maintain documentation of each lot of Urine culture and DTM control material used. 10. The number of patient tests performed using the media lot numbers indicated above could not be determined 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 Quality Control (QC) documentation for Microbiology plated media and interview with the facility personnel, the laboratory failed to check each batch of media for sterility. Findings include: 1. The laboratory performs Urine culture and DTM testing under the specialty of Microbiology, with an approximate annual test volume of 858. 2. It is the practice of the laboratory to perform a sterility check on each lot and/or shipment of media used for Urine culture and DTM testing. 3. No documentation was presented for review during the survey conducted on March 7, 2023 to indicate the laboratory performed and documented sterility checks on each of the following media lots used for patient testing: Urine culture media (lot# j32-5011722, exp. 5/12/22) and DTM media (lot# x15-498296, exp. 6/25/22). 4. The facility personnel interviewed on March 7, 2023 at 11:30am confirmed the laboratory failed to perform sterility checks on each lot of media referenced above. 5. The number of patient tests performed using the media from the lot numbers indicated above could not be determined at the time of the survey.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of Quality Assessment (QA) policies and procedures, analytic test records and interview with the facility personnel, the laboratory failed to follow established QA policies and procedures to monitor, assess and, when indicated, correct problems identified in the analytic systems. Findings include: 1. The

	laboratory's established QA policy titled 'Quality Assurance Plan' states, "The laboratory director will review all quality control charts and logs on a monthly basis. All controls exceeding the acceptable limits and not resolved by repeat testing will be reviewed by the laboratory director as soon as practical after the event. Corrective actions should be documented on the corrective action form and kept in the Laboratory Policy Manual...Quality assurance reviews should be conducted on a regular basis for the purpose of monitoring and improving the quality of the testing process. Our quality assurance reviews are conducted monthly." 2. No QA documentation or corrective action form was presented for review during the survey to indicate the laboratory monitored, assessed and, when indicated, corrected problems identified with a lack of Quality Control (QC) records and sterility testing records for Urine culture and DTM testing performed in the specialty of Microbiology. See D5445 and D5477 for findings. 3. No QA documentation was presented for review during the survey to indicate the laboratory performed and documented QA reviews on a monthly basis as indicated in laboratory policy during 2021, 2022 and through the date of the survey on March 7, 2023. 4. The facility personnel interviewed on 3/07/23 at 12:10pm confirmed that the laboratory's QA processes were not effective at monitoring, identifying and correcting problems found in the analytic systems and confirmed the laboratory failed to perform and document monthly QA reviews as indicated in laboratory policy.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with the facility personnel, the laboratory failed to have a system in place to ensure the accuracy of test results that are manually entered into the patient's Electronic Medical Record (EMR). Findings include: 1. The laboratory performs Urine culture and DTM testing under the specialty of Microbiology, with an approximate annual test volume of 858. 2. The Urine culture and DTM test results are manually entered by facility personnel into the laboratory's EMR (Office Practicum). 3. No documentation was presented for review during the survey conducted on March 7, 2023 to indicate the laboratory has a system in place to ensure the accuracy of patient test results that are manually entered into the EMR. 4. The facility personnel interviewed on March 7, 2023 at 11:50am confirmed that the laboratory failed to have a system in place to verify the accuracy of patient test results that are manually entered into the EMR.
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: Due to the number and severity of deficient practices identified during the survey conducted on March 7, 2023, the Condition of Laboratory Director was found to be not met as evidenced by: D6016 - ensuring that proficiency testing samples are tested as required under Subpart H; and D6022 - failure to ensure the quality control program and quality assessment program are maintained to assure the quality of laboratory services provided.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on information furnished to the State Agency by the Proficiency Testing (PT) provider, it was determined that the laboratory director failed to ensure that PT samples are tested in a manner that results in successful participation in a proficiency testing program for the regulated analyte, Urine Identification. See D2016 and D6000 for findings.
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 facility personnel interviews on March 7, 2023, quality control record review, quality assessment protocols and record review, the laboratory director failed to ensure that quality control and quality assessment programs were maintained to identify failures in quality as they occur. See D5445, D5477 and D5791 for findings.