

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 08D1026807	(X3) Date Survey Completed 01/27/2023
Name of Provider or Supplier Delaware Pediatrics	Street Address, City, State 3920 S Dupont Parkway, Suite A, Townsend, DE	
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
D0000	A Recertification Survey was conducted at approximately 9:00 am on January 27, 2023 at Delaware Pediatrics, Townsend DE. The laboratory was surveyed according to 42 CFR part 493 CLIA requirements. Specific deficiencies are as follows:
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by: observation and interview, the laboratory failed two consecutive Proficiency Tests (PTs) without documentation of corrective action or Laboratory Director (LD) review. 1. During document review at approximately 9:55 am on January 27, 2023 it was noted that the laboratory failed the Strep A Bacteriology PT Events 2 and 3 for 2021, No corrective action was documented for PT failure. Additionally, there was no</p>

evidence of LD review of PT results. 2. During the interview, the Clinic Manager (CM) stated that "the corrective action was written by the LD", however there is no documentation for PT failure. 3. At the end of the interview at approximately 10:57 am, no corrective action was provided for the failure of either 2021 PT event 2 or 3 for Strep A Bacteriology, nor is there evidence of LD review of PT results.

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:
document review and interview the laboratory failed to establish and follow written policies and procedures to monitor or assess problems in the laboratory. 1. During record review at approximately 9:43 am on January 27, 2023 it was determined that there was no Standard Operating Procedure (SOP) or evidence of an ongoing mechanism to monitor or assess problems or potential problems in the laboratory. 2. During the interview, the CM stated that the lab does monitor laboratory activities but they were not documented and that there was no SOP addressing Systems Quality Assessment. 3. At the end of the interview at approximately 10:57 am, no evidence of Systems Quality Assessment was provided.

D5441

CONTROL PROCEDURES
CFR(s): 493.1256(a)(b)(c)(g)

(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 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:
observation and interview the laboratory failed to perform Quality Control (QC) for Urine Dipsticks. 1. At approximately 10:06 am on January 27, 2023 during document review, the laboratory failed to provide any logs for Quality Control for Urine Dipsticks. The Pro Advantage Urine Reagent Strips package insert states, "Test commercially available positive and negative quality controls with each new lot, each new shipment of strips, and when you open a new bottle of reagent strips. Test the strips monthly that are stored for more than 30 days" However no QC for dipsticks was performed 2. During the tour of the lab no Urine Controls were observed., and the CM confirmed that the lab did not have controls for urine dipsticks. 3. At the end of the interview at approximately 10:57 am, no urine dipstick QC could be provided by the laboratory

D6030

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:
observation and interview. The laboratory failed to address Competency Assessment (CA) for Testing Personnel (TP). Additionally, there is no Standard Operating Procedure addressing CA. 1. At approximately 9:21 am on January 27, 2023 during document review, no CA could be found for 9 of 9 TP. There was a "Competency Checklist" for each TP, but none included the 6 required elements of Competency Assessment (CA) for 6 of 6 test procedures performed in the laboratory. 2. During the interview, Clinical Manager (CM) confirmed there was no Competency Assessment for the 9 TPs that address the six of the six minimal regulatory elements, nor an SOP for CA. 3. At the end of the interview at approximately 10:57 am no documentation for CA, nor an SOP addressing CA was provided for any of the six tests performed in the laboratory.