

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 08D0726548	(X3) Date Survey Completed 08/16/2022
Name of Provider or Supplier Brandywine Pediatrics, Pa	Street Address, City, State If Quillen Building, Concord Plaza, Wilmington, 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	D0000 A Recertification Survey was conducted at approximately 9:00 am on August 16, 2022 at Brandywine Pediatrics, PA. The Laboratory was surveyed according to 42 CFR part 493 CLIA requirements. Specific deficiencies are as follows:
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: lack of documentation, and interview the laboratory failed to monitor or record room temperatures to ensure reagents and test kits are at a proper testing temperature as required. Findings include: 1. At approximately 9:18 am on August 16, 2022 during documentation review of reagent and test kit storage, the laboratory was not able to provide evidence that room temperatures were being taken or recorded. The BD SARS-CoV-2 package insert states "Reagents and devices must be at room temperature (15-30C) when used for testing." In 0 of 2 laboratory spaces, there was no thermometer for monitoring room temperature. Additionally, there was no log sheet for recording room temperatures. 2. During the interview, the TS confirmed that they did not have a room temperature thermometer and did not monitor the temperature in either laboratory space. 3. By the end of the interview at approximately 10:45 am, no room temperature documentation was provided.</p>
D5507	BACTERIOLOGY

CFR(s): 493.1261(b)(c)

(b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

lack of documentation, and interview the laboratory failed to perform disc or media quality control for Streptococcus, or growth on urine cultures upon receipt in order to verify the integrity of the discs and plated media as required. The findings include: 1. During documentation review of Quality Control(QC) , at approximately 9:45 am on August 16, 2022, the laboratory was not able to provide documentation of Taxo A disc or media QC (Blood Agar Plates) upon receipt as required. 2. During the interview, the Technical Supervisor (TS) provided a Kwik Stick Control Test log sheet that indicated QC was performed on the media and Taxo A disc on June 30, 2022. The TS stated that the "QC is performed every 90 days". 3. By the end of interview at approximately 10:50 am, no other QC documents were provided for media or Taxo A discs.lack of documentation, and interview the laboratory failed to perform disc or media quality control for Streptococcus, or growth on urine cultures upon receipt.

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:

lack of documentation, and interview with the TS. The laboratory failed to address any of the six elements of Competency Assessment of Testing Personnel (TP). Additionally, there is no standard Operating Procedure (SOP) addressing CA. Findings include: 1. At approximately 9:46 am on August 16, 2022 during record review of Competency Assessment (CA), the TS provided a list of "Employee Proficiency Testing". 22 of 22 TP received proficiency testing, but 0 of 8 physician TP were listed on the proficiency testing documents, and did not participate in CA. There was also no documentation of initial training of 0 of 30 personnel. 2. During the interview, The TS stated that the Competency Assessment is performed but not documented specifically addressing the six minimal regulatory requirements for CA,

and that there was no SOP addressing proficiency or competency at all. 3. At the end of the interview, at approximately 10:50 am, the TS confirmed that CA is not performed using the six required CA criteria, and no SOP existed to address it.