

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2160839	(X3) Date Survey Completed 08/29/2023
Name of Provider or Supplier Primary Pediatrics, Bonaire	Street Address, City, State 104 Bluff Chase, Suite A, Bonaire, GA	
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 performed on August 29, 2023. The facility was found to be NOT in compliance with all applicable CLIA requirements for specialties /subspecialties for 42 CFR. Condition Level D6000 - Director Oversight 149.1407
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: Based on review of the Daily Environmental Log (DEL) and staff interview, the laboratory failed to provide documentation of corrective action when the incubator temperature was outside of the acceptable reference range on the daily logs. Findings: 1. Review of the DEL from January 2023 to July 2023, the laboratory documented Incubator temperatures above the acceptable range of 34 to 39 degrees Celsius, with no documented Corrective Action performed to correct the out of range temp. Out of approximately 125 recorded Incubator temperatures, 92 were above the acceptable range. 2. Review of the patient test log for Urine Cultures revealed there was 28 Urine Cultures and 125 Throat Cultures performed during the time the incubator temperature was outside the acceptable range. 3. Interview with TP-1 and TP-2 (CMS form 209) on August 29, 2023 at approximately 1 pm, in the facility breakroom, confirmed the aforementioned statements above. Key: (TP)Testing Personnel (CMS) Center for Medicare and Medicaid Services (209 form) Testing Personnel List form 209</p>

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 document review and staff interview, the laboratory was not performing a negative Quality Control (QC) for Strep group A growth and verifying the Bacitracin disk on a blood agar plate for Throat Cultures. Both Positive and Negative QC was reported as being Positive from 5/2021 to 7/2023. On June 12, 2023, the laboratory resulted Negative for both the positive and negative QC. Findings: 1. Review of the Media QC, from May 2021 to June 2023, for Positive and Negative growth on the blood agar plate with a Bacitracin Disk for Strep group A from Throat cultures, the laboratory reported positive results for both the positive and negative QC. There were no QC negative results reported except for the lot that was tested on 6/12/2023 in which the positive and negative QC resulted as Negative. 2. A review of the patient testing log for 6/12/2023 revealed there were 25 Strep cultures reported between 6/12/2023 and the next lot of media on 07/17/2023 3. Interview with TP-1 and TP-2 (CMS form 209) on August 29, 2023 at approximately 12:30 pm in the facility breakroom confirmed the aforementioned statements. Key: (TP)Testing Personnel (CMS)Center for Medicare and Medicaid Services (209 form) Testing Personnel List form 209

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:

Based on review of the Quality Control(QC) documentation for the Media and Bacitracin Disk used for testing of Group Strep A cultures and review of the Environmental Log for temperatures of the Incubator used to incubate the Urine and Throat Cultures, the Laboratory Director failed to provide oversight and monitor and provide corrective action for errors in results for the Media QC, and failed to monitor and provide corrective action for out of range temperatures documented for the Incubator. Reference D6024

D6024

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(7)

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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified,

This STANDARD is not met as evidenced by:

Based on review of the Daily Environmental Log (DEL) and staff interview, the Laboratory Director (LD) failed to ensure that all necessary remedial actions were taken or documented when there were significant deviations from the laboratory's established performance specifications. The laboratory failed to provide documentation of corrective action when the incubator temperature was outside the reference range on the logs. Findings: 1. A review of the DEL revealed from January 2023 to July 2023, the laboratory documented incubator temperatures above the range of 34 to 29 deg Celsius, without corrective action performed. There were approximately 125 recorded incubator temperatures, 92 were above the acceptable range. 2. A review of the patient test log for Urine Cultures confirmed there was 28 Urine Cultures and 125 Throat Cultures performed during the time the incubator temperature was outside of the acceptable range. 3. Interview with TP-1 and TP-2 (CMS form 209) on August 29, 2023 at approximately 1 pm in the facility breakroom confirmed the aforementioned statements. Key: (TP)Testing Personnel (CMS)Center for Medicare and Medicaid Services (209 form) Testing Personnel List form 209

Based on document review and staff interview, the Laboratory Director failed to notice that the laboratory was not performing a negative Quality Control(QC) for Strep group A growth and verifying accuracy of the Bacitracin disk on the blood agar plate for Throat Cultures. Both positive and negative QC were reported as being positive for the last 24 months, with the exception of the new lot on June 12, 2023 which the lab reported both QC as negative. On June 12, 2023, the laboratory documented negative results for both the positive and negative QC. Findings: 1. Review of the Media QC for the last 24 months for Positive and Negative growth on the blood agar plate with a Bacitracin Disk for Strep group A from Throat cultures, the laboratory reported positive results for both the positive and negative QC on the media. There were no negative QC results reported except for the lot that was tested on 6/12/2023 which both the positive and negative QC were resulted as negative. 2. Review of the patient testing log for 6/12/2023, there were 25 Strep cultures reported between 6/12/2023 and the next lot of media on 07/17/2023 3. Interview with TP-1 and TP-2 (CMS form 209) on August 29, 2023 at approximately 12:30 pm in the facility breakroom confirmed the aforementioned statements. Key: (TP)Testing Personnel (CMS)Center for Medicare and Medicaid Services (209 form) Testing Personnel List form 209