

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0304310	<b>(X3) Date Survey Completed</b>  01/26/2022
<b>Name of Provider or Supplier</b>  Pediatric Healthcare	<b>Street Address, City, State</b>  4700 Woodmere Blvd, Montgomery, AL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5413</b>	<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 a review of temperature logs, a review of the manufacturer's storage requirements for Horiba Minotrol Quality Controls (QC), and an interview with Testing Personnel #1, the laboratory failed to ensure the refrigerator maintained temperatures required for the storage of items therein, as per manufacturer's specifications for 92 days from December 2019 through January 2022. The findings include: 1. A review of the refrigerator temperature logs revealed acceptable ranges of 35-45 degree Fahrenheit (F), however temperatures were below this range 5 days in December 2019, 53 days in 2020, 30 days in 2021, and 4 days in January 2022 (for a total of 92 days out of acceptable ranges in the review period). 2. On 1/26/2022 at 3:37 PM, the surveyor reviewed and confirmed the above noted findings with Testing Personnel #1. Contents of the refrigerator included the Horiba Minotrol Hematology QC, with storage requirements of 2-8 degrees Celsius (or 35-45 degrees F). Testing Personnel #1 confirmed the QC was stored at temperatures below the manufacturer's requirements. .</p>
<b>D5477</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g)</p>

(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 a review of Bacteriology records and an interview with Testing Personnel #1, the laboratory failed to perform and document quality control (QC) checks on each lot number of urine culture media to ensure the media supported growth of Gram Positive and Gram Negative organisms. The laboratory failed to document media QC on eight lot numbers of Urine Culture Bi-plates used in 2021. The findings include: 1. A review of the Bacteriology records revealed the laboratory performed visual inspections of all culture media, including Blood, Mueller-Hinton and Bi-plate (Blood /MacConkey) agar. The laboratory also performed QC checks on the bi-plates using Staph aureus (a Gram Positive organism) and Escherichia coli (or E. coli, a Gram Negative organism) to document the media's ability to support growth. However, when reviewing the records, the surveyor noted eight lot numbers of bi-plates with visual inspection between 7/13/2021 and 12/10/2021 with no documentation of media QC. 2. During an interview on 1/26/2022 at 3:40 PM, the surveyor reviewed the Bacteriology records with Testing Personnel #1 who confirmed the bi-plate media QC was performed, but the laboratory had failed to document the results for each lot number. .

**D5781**

**CORRECTIVE ACTIONS**

CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b) (1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on reviews of temperature logs, Quality Assurance (QA) records, the manufacturer's storage requirements for Horiba Minotrol Quality Controls (QC), and an interview with Testing Personnel #1, the laboratory failed to implement and document corrective actions when refrigerator temperatures exceeded the manufacturer's requirements for 92 days from December 2019 through January 2022. The findings include: 1. A review of the refrigerator temperature logs revealed acceptable ranges of 35-45 degree Fahrenheit (F), however temperatures were below this range 5 days in December 2019, 53 days in 2020, 30 days in 2021, and 4 days in January 2022 (for a total of 92 days outside of acceptable ranges in the review period). There was no documentation of corrective action on the temperature logs or the QA records. 2. On 1/26/2022 at 3:37 PM, the surveyor reviewed the temperature logs, QA

records and contents of the refrigerator with Testing Personnel #1. Contents of the refrigerator included the Horiba Minotrol Hematology QC, with storage requirements of 2-8 degrees Celsius (or 35-45 degrees F). Testing Personnel #1 confirmed the QC was stored at temperatures below the manufacturer's requirements, however the laboratory failed to implement and document corrective actions. SURVEYOR ID#32258 Licensure and Certification Surveyor