

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0239484	(X3) Date Survey Completed 01/06/2022
Name of Provider or Supplier Cary Pediatric Center	Street Address, City, State 1001 Crescent Green Drive, Cary, NC	
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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2020 and 2021 laboratory Uricult media quality control (QC) records, review of 2020 and 2021 patient testing logs and interview with testing personnel (TP #1) 1/6/22, the laboratory performed patient testing using expired Uricult media from 8/25/20 until 9/28/20, a period of approximately 30 days in which 16 patients were tested and from 8/27/21 until 11/15/21 a period of approximately 75 days in which 25 patients were tested. Findings: 1. Review of laboratory QC records, "Uricult QC Log", revealed on 3/17/20 the laboratory received Uricult media Lot #1892940, expiration 8/24/20. The laboratory received the next shipment of Uricult media, Lot #1897050, on 9/24/20 approximately 29 days after expiration of Lot #1892940. Review of QC records also revealed Lot #1897050 was put into use and QC performed on 9/28/20, a period of approximately 30 days in which expired Uricult media was in use. Review of patient logs revealed 16 patients were tested 8/24/20 through 9/28/20. Interview with TP #1 at approximately 4:00 p.m. confirmed 16 patients were tested using expired Uricult media from 8/24/20 through 9/28/20. 2. Review of laboratory QC records, "Uricult QC Log" revealed on 3/9/21, the laboratory received Uricult media Lot #1899021, expiration date 8/27/21. The laboratory received the next shipment of Uricult media, Lot #1902570, on 11/12/21 approximately 72 days after expiration of Lot #1899021. Review of QC records also revealed Lot #1902570 was put into use and QC performed on 11/15/21, a period of approximately 75 days in which expired Uricult media was in use. Review of patient</p>

logs revealed 25 patients were tested 8/27/21 through 11/15/21. Interview with TP #1 at approximately 4:00 p.m. confirmed 25 patients were tested using expired Uricult media from 8/27/21 through 11/15/21.

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 laboratory procedure manual, 2021 BBL Strep Select Agar (SSA) quality control (QC) records and interview with testing personnel (TP #1) 1/6/22, the laboratory failed to perform QC on each new lot number of SSA media as required. Approximately 10 patients were tested when QC was not performed as required. Findings: Review of laboratory procedure, "BBL Strep Plate Quality Control", revealed "1. Quality Control is performed on all new BBL plate lot numbers and shipments." Review of SSA media QC records, "BBL Strep Select Agar (SSA) QC Log", revealed the laboratory received ten plates of SSA media, Lot #126730, on 10/5/21. Records also revealed QC was not performed on Lot # 126730 until 11/1/21, a period of approximately 29 days in which patient testing was performed. Interview with TP #1 at approximately 4:00 p.m. confirmed QC was not performed on SSA media, Lot #126730, as required. She also confirmed approximately 10 patients were tested prior to QC performance.