

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0663439	(X3) Date Survey Completed 04/11/2023
Name of Provider or Supplier Drs Murphy And Staats	Street Address, City, State 5212 Lyngate Court, Burke, VA	
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	An announced CLIA recertification survey was conducted at Drs Murphy and Staats on April 11, 2023 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies are as follows:
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on a tour, review of the laboratory's policy and procedure manual, maintenance logs, hematology analyzer's operator's guide, quality control (QC) records, log sheets, patient records and interviews, the laboratory failed to follow manufacturer's instructions for specimen requirements for fifteen (15) days from January 3, 2023 to April 1, 2023 while analyzing one hundred thirty-three (133) patients. The findings include: 1. In a tour of the laboratory with the primary testing personnel on April 11, 2023 at approximately 9:00 AM, the inspector noted the laboratory utilizes a Coulter ACT diff analyzer to perform Complete Blood Cell (CBC) counts on patient specimens. 2. Review the "Patient Lab Logsheets" from January 2023 to March 2023 revealed patient Complete Blood Cell (CBC) counts were collected on the following dates: January 2023-1/3/2023 to 1/5/2023, 1/7/2023, 1/9/2023 to 1/13/2023, 1/16/2023 to 1/20/2023, 1/23/2023 to 1/27/2023, 1/30/2023, 01/31/2023. February 2023-2/1/2023 to 2/3/2023, 2/6/2023 to 2/10/2023, 2/13/2023 to 2/17/2023, 2/20/2023 to 2/24/2023, 2/27/2023, 02/28/2023. March 2023-3/1/2023 to 3/3/2023, 3/6/2023 to 3/10/2023, 3/13/2023 to 3/17/2023, 3/22/2023, 3/29/2023 and 3/31/2023. 3. Review of the daily Coulter AcT Diff QC records revealed QC was performed on the following</p>

days: January 2023-1/4/2023, 1/6/2023, 1/11/2023, 1/13/2023, 1/14/2023, 1/18/2023, 1/20/2023, 1/25/2023, 1/29/2023. February 2023-2/1/2023, 2/3/2023, 2/8/2023, 2/10/2023, 2/15/2023, 2/17/2023, 2/22/2023, 2/24/2023. March 2023-3/1/2023, 3/3/2023, 3/8/2023, 3/10/2023, 3/12/2023, 3/15/2023, 3/19/2023, 3/22/2023, 3/25/2023. 3/31/2023. The inspector requested to review the Coulter QC records for the days when patient CBC specimens were collected. The laboratory provided no documentation for review. In an interview with the primary testing personnel (TP) on April 11, 2023 at approximately 10:30 AM, the TP stated they work on Wednesdays and Fridays. The TP stated patient CBCs are held and run when they work. 4. Review of the Coulter AcT diff's Operator's Guide revealed a statement, "Beckman Coulter suggests that you analyze a whole blood sample within 24 hours of collection." 5. Review of patient test records revealed the following dates when samples were run after 24 hours of collection: January 2023-1/9/2023-8 patients, 1/16/2023-7 patients, 1/23/2023-15 patients. 1/27/2023-6 patients, 1/30/2023-11 patients. February 2023-2/6/2023-14 patients, 2/13/2023-11 patients, 2/20/2023-17 patients, 2/27/2023-11 patients. March 2023-3/6/2023-3 patients, 3/13/2023-7 patients, 3/16/2023-5 patients, 3/17/2023-13 patients, 3/22/2023-4 patients, 3/29/2023-1 patient. A total of 133 patients were run 24 hours after collection. 6. In an exit interview with the Laboratory Director (LD) on April 11, 2023 at approximately 12:45 PM, the above findings were confirmed. The LD stated, "I thought CBCs could be analyzed up to 48 hours after collection."

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
 CFR(s): 493.1252(d)

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.

This STANDARD is not met as evidenced by:
 Based on review of the laboratory's policy and procedure manual, culture media logs, patient log sheets and interviews, the laboratory failed to ensure that culture media for throat and urine cultures were not used past their expiration date for seven (7) days from January 12, 2023 until January 19, 2023 while performing fifty (50) throat cultures and eleven (11) urine cultures. The findings include: 1. Review of the laboratory's policy and procedure manual revealed the laboratory utilizes Hardy Diagnostics 5% Blood Agar for throat and urine cultures. 2. Review of the laboratory's culture media logs revealed the laboratory received the following shipments of Hardy Diagnostics 5% Blood Agar plates: lot# 148258 expiration date 01/11/2023 was received on 11/22/2022. Quality Control was performed on 11/24/2022. The media was put in use for throat and urine cultures on 11/24/2022. lot# 149490P expiration date 03/09/2023 was received on 01/17/2023. Quality Control was performed on 01/19/2023. The media was put in use for throat and urine cultures on 01/19/2023. The inspector requested to review documentation of receipt of additional shipments of Hardy Diagnostics 5% Blood Agar plates received between 11/22/2022 and 01/19/2023. The laboratory provided no documentation to review. 3. Review of patient culture logs from January 12, 2023 until January 19, 2023 revealed 50 throat cultures and 11 urine cultures were set up and reported utilizing the expired lot number (#148258) of 5% Blood Agar plates. 4. In an exit interview with the Laboratory Director on April 11, 2023 at approximately 12:45 PM, the above findings were confirmed.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's policies and procedures, maintenance records, lack of documentation, and an interview, the laboratory failed to document the required Beckman Coulter AcT Diff hematology analyzer's weekly maintenance for ten (10) of eighty-four (84) weeks and monthly maintenance for sixteen (16) of twenty (20) months reviewed from August 2021 until March 31, 2023. Findings include: 1. Review of the laboratory's procedures and maintenance log revealed the following instructions: Quality Assurance Monthly Checklist - under Analytic Systems, "All required instrument maintenance is performed and documented"; Coulter AcT Diff Maintenance Log - "Perform Weekly: Bleach; Monthly: Clean baths". 2. Review of the laboratory's available Coulter AcT Diff Maintenance log records from August 2021 until March 2023 revealed a lack of documentation of the "Weekly: Bleach" maintenance for the following weeks: September 2021-1 week; December 2021-1 week; January 2022-2 weeks; February 2022-1 week; March 2022-1 week; April 2022-2 weeks; May 2022-1 week and July 2022 1 week. A total of 10 weeks with no documented weekly maintenance. The inspector requested to review documentation of the above listed weekly maintenance. The laboratory provided no documentation to review. 3. Review of the laboratory's available Coulter AcT Diff Maintenance log records from August 2021 until March 2023 revealed a lack of documentation of the "Monthly: Clean Bath" maintenance for the following months: August 2021, October 2021, December 2021, January 2022, February 2022, March 2022, April 2022, May 2022, June 2022, July 2022, August 2022, September 2022, October 2022, December 2022, February 2023 and March 2023. A total of 16 months with no documented monthly maintenance. The inspector requested to review documentation of the above listed monthly maintenance. The laboratory provided no documentation to review. 4. In an exit interview with the Laboratory Director on April 11, 2023 at approximately 12:45 PM, the above findings were confirmed.