

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D0978965	<b>(X3) Date Survey Completed</b>  08/15/2024
<b>Name of Provider or Supplier</b>  Grace Hematology & Oncology	<b>Street Address, City, State</b>  3159 Hendersonville Rd, Fletcher, NC	
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>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2023 and 2024 hematology records, the absence of background records, and interview with testing personnel (TP) #3 on 8/15/24, the laboratory failed to retain DxH 500 hematology analyzer background counts for approximately 19 months from 1/26/23 to 8/15/24. Findings: Review of 2023 and 2024 hematology records revealed the laboratory started using the new DxH 500 hematology analyzer 1/26/23. The laboratory failed to retain background counts for the DxH 500 since the analyzer was put into use, a period of approximately 19 months. During interview at approximately 11:06 a.m., TP #3 stated the lab does not print backgrounds.</p>
<b>D5403</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or</p>

control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on policy and procedure review and interview with testing personnel (TP) #3 on 8/15/24, the laboratory's hematology policies and procedures had not been updated to reflect the current testing performed. Findings: Review of the laboratory's policies and procedures revealed the laboratory failed to update policies and procedures to remove the Coulter AcT diff hematology analyzer and include the DxH 500 hematology analyzer which the laboratory started using 1/26/23. For example, the laboratory policy, "PERFORMANCE IMPROVEMENT PLAN FOR LABORATORY SERVICES" stated "... 1. EQUIPMENT CALIBRATION, PREVENTIVE MAINTENANCE AND QUALITY CONTROL DATA- ... B. This evaluation will be based on whether appropriate calibration and preventive maintenance is performed when designated for the Act T Diff instrument. ... Laboratory Quality Assurance Program ... 2. Daily Quality Control The following is a list of all the waived/moderate testing that we perform. After each test, a description of the quality controls performed is included. ... Coulter ACT-Diff Hematology- ..."

Interview with TP #3 at approximately 9:39 a.m. confirmed the polices and procedures were not up to date. TP #3 stated the lab does not have a procedure for the DxH 500, but the lab follows the operators manual. This deficiency was cited on the previous survey 2/28/22.

**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 review of manufacturer's instructions, review of 2023 and 2024 maintenance records, and interview with testing personnel TP #3 on 8/15/24, the laboratory failed to perform and document the manufacturer's specified daily and monthly maintenance for the Hematology DxH 500 analyzer for approximately 19 months from 1/26/2023 to 8/15/2024. Findings: 1. Review of the DxH 520 "Instructions for Use" revealed procedures specified by the manufacturer to be performed daily. On page 3-3, "... Daily Checks Running Daily Checks ensures that the instrument is operational and ready to process samples. Daily Checks must be run every 24 hours either after a shutdown or at the beginning of the day before specimen processing. ..." On page 3-5, "... Running a Background Count Daily Checks includes background counts. ..."

Review of 2023 and 2024 maintenance records revealed the laboratory had documented startup and shutdown of the hematology analyzer each day of use from 1/26/2023 to 8/15/2024, but had not documented the performance of Daily Checks as required by the manufacturer or retained daily background counts (see D3031). 2. Review of the DxH 520 "Instructions for Use" revealed procedures specified by the

manufacturer to be performed monthly. On page 12-1 "... When, Why, and How to Perform Each Cleaning Procedure ..." the manufacturer specifies performing a bleach cycle "Every 1,000 cycles or monthly, whichever comes first". In addition, the manufacturer requires cleaning the WBC Bath Filter monthly. Review of 2023 and 2024 maintenance records revealed the laboratory failed to document performance of a bleach cycle or cleaning the WBC Bath Filter from 1/26/2023 to 8/15/2024. 3. The laboratory failed to utilize the "Cleaning and Replacement Procedures Log Sheet" provided by the manufacturer to document maintenance. During interview at approximately 11:06 a.m., TP #3 stated the only daily maintenance is the daily startup and shutdown, and what's on the current logsheet. TP #3 confirmed the laboratory had not retained daily background checks. TP #3 stated maintenance was completed but not documented for monthly and yearly items. This deficiency was cited on the previous survey 2/28/22.

**D6021**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's policies and procedures, review of 2023 and 2024 laboratory records, and interview with TP #3 on 8/15/24, the laboratory director failed to ensure the quality assessment program was effective at identifying and correcting problems and preventing their recurrence. Findings: Review of the "Laboratory Quality Assurance Program" revealed "... The elements needed to comprise a good quality assurance program are: 1. Policy and Procedure Manual 2. Daily Quality Control 3. Proficiency Testing 4. Instrument Maintenance 5. Patient Test Management 6. Personnel/Continuing Education 7. Documentation/Record keeping ... The process of quality assurance is ongoing. ... The Laboratory Director is solely responsible for the maintenance of all PI activities ... 1. Policy and Procedure Manual ... Yearly, the Laboratory Director will review and sign off on each procedure as a check to see that updates are made where needed. ... 4. Instrument Maintenance ... Each instrument varies as for cleaning procedures, as well as daily, monthly, and yearly maintenance procedures. ... These preventive maintenance sheets have all the maintenance tasks listed that need to be checked off... These log sheets are checked for Quality Assurance purposes each month as well as each quarter for specific problems. They are reviewed and signed by the Laboratory Director on a monthly basis. ... Review of the "Laboratory Director Training" document signed and dated by the laboratory director 5/13/22 revealed the following laboratory director responsibilities: "... All oversight and responsibility for all lab functions ... Monthly review and signing of Preventive Maintenance logsheets ... Monitors and ensures the Laboratory Quality Assurance plan including all audits are completed in a timely manner ... Annual competency training of all lab staff ... Competency training of all new lab staff PRIOR to testing patient samples ... Annual review of Laboratory Manual and updating manual with any changes in lab procedures, forms, logsheets as needed. ..." The laboratory's quality assessment program included several checklists which could be used to document quality assessment activity on a routine basis. The laboratory had

not utilized the checklists during 2023 or 2024. The laboratory's quality assessment program failed to identify the following problems identified during the survey which were cited as deficiencies on the previous survey: 1. Procedure manual - not updated to include current instrument 2. Instrument Maintenance - daily and monthly maintenance not performed and documented as required 3. Testing personnel competency - competency evaluations not performed at the required frequency During interview at approximately 12:20 p.m., TP #3 stated the laboratory had not utilized the quality assessment checklists and had not performed and documented any quality assessment activities. This deficiency was cited on the previous survey 2/28/22.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:  
Based on review of personnel records, review of laboratory records, and interview with TP #3 on 8/15/24, the technical consultant (laboratory director) failed to perform and document annual competency evaluations for 3 of 3 testing personnel in 2023. Findings: Review of personnel records revealed no documentation of annual competency evaluation for 3 of 3 testing personnel (TP #1, TP #2, TP #3) in 2023. Review of the laboratory document "Laboratory Director Training" (signed and dated by the laboratory director 5/13/22) revealed the following laboratory director responsibilities: "... All oversight and responsibility for all lab functions ... Annual laboratory competency training of all lab staff..." During interview at approximately 9:40 a.m., TP #3 confirmed there were no competency evaluations performed in 2023 for any of the 3 testing personnel. This deficiency was cited on the previous survey 2/28/22.

**D6055**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results.

This STANDARD is not met as evidenced by:  
Based on review of personnel records and interview with TP #3 on 8/15/24, the technical consultant (laboratory director) failed to perform and document competency evaluations for 3 of 3 testing personnel after the installation of a new hematology analyzer in December 2022. Findings: Review of personnel records revealed 3 of 3 testing personnel (TP #1, TP #2, TP #3) were trained on a new Coulter DxH hematology analyzer in December 2022. There was no documentation that testing personnel competency was evaluated after the new Coulter DxH hematology analyzer was installed. During interview at approximately 9:40 a.m., TP #3 confirmed there had been no competency evaluations performed for any of the 3 testing personnel since the new hematology analyzer was installed.