Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0978965	02/28/2022
Name of Provider or Supplier	**Street Address, City, State**	
Grace Hematology & Oncology	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of 2020 and 2021 API(American Proficiency Institute) PT (proficiency testing) records, review of 2020 and 2021 hematology calibration records, and interview with TP(testing personnel #1) 2/28/22, the laboratory failed to test PT samples in the same manner it tests patients specimens for 3 of 3 PT events in 2021. Findings: Review of 2021 API PT records revealed 2021 Hematology /Coagulation 1st event was submitted 3/26/21, 2nd event was submitted 7/22/21, and 3rd event was submitted 11/11/21. Review of 2021 Hematology calibration records revealed the laboratory calibrated the Beckman Coulter AcT Diff analyzer on 3/19/21, 7/21/21, and 11/11/21. During interview at approximately 12:30 p.m., TP #1 confirmed she makes sure the analyzer is calibrated before she runs proficiency testing.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) 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. This STANDARD is not met as evidenced by: Based on review of manufacturer's operators manual, review of 2020 and 2021 hematology calibration records and the absence of documentation 2/28/22, the laboratory failed to retain all required Coulter AcT diff hematology calibration records. Findings: Review of the Beckman Coulter AcT Diff Operator's manual revealed for Auto-Calibration, "...3b. At the Setup screen, touch the Setup Report icon to print the old calibration factors...14. After 11 acceptable sample results, the Summary icon appears, touch the icon to view the summary screen. If Autoprint is ON and you are using a graphic printer a summary report prints automatically....Print the new calibration factors and place them in your log book...." 1. Review of Coulter AcT diff 2020 and 2021 calibration records revealed the laboratory failed to retain copies of all records for the following calibrations: a. 4/7/20: no documentation for the calibration summary with results of calibration and the S-cal calibrator assay sheet for the lot number used; b. 5/19/20: no documentation for the calibration summary with the results of calibration and the S-cal calibrator assay sheet for the lot number used; c. 8/25/20: no documentation for the new calibration factors printed post-calibration; d. 3/19/21: no documentation for the new calibration factors printed post-calibration and no S-cal calibrator assay sheet for the lot number used; e. 7/21/21: no documentation for the new calibration factors printed post-calibration; f. 11/11/21: no documentation for the new calibration factors printed post-calibration and no S-cal calibrator assay sheet for the lot number used.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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 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 review of the laboratory's policies and procedures and interview with TP (testing personnel) #4 on 2/28/22, the laboratory's procedure manual was not complete and current for the testing performed. Findings: The "Laboratory Manual" policy states "The Following Manufacturers' Instructions/Guides are Approved for use in the Laboratory ... Coag INR machine Coulter Ac T diff Hematology Analyzer ..." The

	"Quality Control Program" policy states "... Controls/Calibrations: At least 3 levels of controls must be tested daily and results must be in the expected ranges before patient test results are reported. ..." The procedure manual did not include a single, complete quality control policy for hematology which contained the type of quality control material used, the frequency, the criteria for acceptability, the steps to take if control results are unacceptable, and how assay sheets and control results are maintained. During interview at approximately 11:00 a.m., TP #4 stated that she found copies of old procedures in various places and put them in a notebook. She confirmed the laboratory did not have a comprehensive hematology quality control policy.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of 2020, 2021, and 2022 temperature and humidity logs, and review of quality assessment records 2 /28/22, the laboratory failed to monitor and document refrigerator temperature and room temperature and humidity daily for 6 of 12 months in 2020. The laboratory's "Standard of Practice Laboratory Temperature/Humidity Log" policy states "Acceptable temperature ranges have been established and they accommodate the highest 'low' and the lowest 'high' to satisfy proper storage requirements for the laboratory. ... We will also document the humidity of the laboratory on all working days ..." Review of 2019, 2020, and 2021 temperature and humidity logs revealed: 1. Logs for July, August, and September 2020 had no temperature or humidity readings documented. "WNL" (within normal limits) was written on the left side of the logs, and "staff change due to COVID-19" was written at the bottom of the logs. a. July - 23 of 23 days no temperatures or humidity documented; b. August - 21 of 21 days no temperatures or humidity documented; c. September - 22 of 22 days no temperatures or humidity documented. 2. On the October 2020 log, temperature and humidity readings were documented 7 of 19 days. There were no readings documented on the other 12 days. "WNL" (within normal limits) was handwritten on the left side of the log, and "staff change due to COVID-19" was written at the bottom of the log. 3. On the November 2020 log, only freezer and refrigerator temperature and humidity readings were documented on 11/1/20. Room temperature was not documented that day. There were no temperature or humidity readings documented for the rest of the month, 18 of 19 days. "WNL" (within normal limits) was written on the left side of the log, and "staff change due to COVID-19" was written at the bottom of the log. 4. On the December 2020 log, temperature and humidity readings were documented 11 of 20 days. "WNL" (within normal limits) was written on the left side of the log, and "staff change due to COVID-19" was written at the bottom of the log. Review of quality assessment records revealed the "Monthly Quality Assessment Checklist" for October 2020 included a review of temperature and humidity checks. The checklist states "... Affirm that temperature and humidity checks are done daily and documented. ..." A check mark was written beside this item on the checklist.

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 2020, 2021, and 2022 Hematology QC(quality control) and calibration records and review of hematology manufacturer QC and calibrator package inserts 2/28/22, the laboratory failed to discard control and calibrator materials that had exceeded the expiration dates. Findings: 1. Random review of 2020, 2021, and 2022 Hematology QC records and Coulter 4C-ES cell control package inserts revealed the expired 4C-ES cell control lot numbers were in use on the following dates, and patient testing was performed: a. lot numbers 068700/078700 /088700 expired 1/18/21 and was in use for 28 days from 1/19/21- 3/1/21. Approximately 441 patients were tested from 1/19/21-2/25/21; b. lot numbers 069700 /079700/089700 expired 6/7/21 and in use for 36 days from 6/8/21-7/29/21. Approximately 617 patients were tested from 6/8/21-7/29/21. lot numbers 079700 and 089700 remained in use for 27 additional days from 8/2/21-9/9/21. Approximately 469 patients were tested from 8/2/21-9/9/21; c. lot numbers 068300/078300/088300 expired 11/8/21 and in use for 45 days from 11/9/21-2/2/22. Approximately 940 patients were tested from 11/9/21-2/2/22. 2. Review of 2020 and 2021 calibration records and S-cal calibrator package insert revealed the S-cal calibrator lot number 4723 expired 7/10/21 and was used for calibration on 7/21/21. Deficiency previously cited 9/11/19.
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 and review of 2019, 2020, and 2021 hematology records, the laboratory failed to perform and document shutdown of the Coulter as required. Review of manufacturer's instructions for the Coulter AcT diff hematology analyzer revealed the manufacturer specifies shutdown of the analyzer daily. Review of 2019, 2020, and 2021 hematology records revealed shutdown records for 2019 and 2021, but there were no records available to document the performance of shutdown for the Coulter AcT diff during 2020.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)

	(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of the manufacturer's calibration procedure and operator's manual, review of 2020 and 2021 Hematology calibration records and service reports, and interview with TP(testing personnel) 2/28/22, the laboratory failed to follow manufacturer's instructions for calibration of the Beckman AcT Diff with at least the frequency recommended by the manufacturer, failed to verify calibration by running 3 levels of controls after each calibration, and failed to perform all required activities prior to calibrating the hematology analyzer. Findings: Review of the Beckman Coulter AcT Diff calibration procedure revealed, "Calibration frequency. Calibrate at least once every six months or after replacing major components that involve the primary measurement characteristics(such as an aperture) or when control values are consistently out of expected assay range....Always verify calibration by running 3 levels of controls immediately after calibrating.....Before calibrating, you must first prepare the instrument by doing the Precalibration Checks, Reproducibility and Carryover Checks..." 1. The laboratory failed to follow the manufacturer's recommended frequency for calibration. Review of the Beckman Coulter AcT Diff Operator's manual stated, " Because the instrument is electronically stable, it should not require frequent recalibration when you operate it and maintain it according to the recommendations in this manual. Make the decision to recalibrate based on the performance of your quality control program. Beckman Coulter recommends that you calibrate your instrument according to the regulations required by your inspecting agency..." During interview at approximately 12:30 p.m., TP#1 stated that she performs the calibrations around the time that the proficiency testing is due. 2. The laboratory failed to calibrate the Beckman Coulter AcT Diff after replacing major components and when recommended by Beckman Coulter. Review of the service records from 12/23/20 revealed Beckman Coulter replaced parts, adjusted calibration factors for WBC(white blood cell), HGB(hemoglobin), PLT(platelet) and MPV(mean platelet volume) and suggested SCAL(calibration) to verify changes. Review of calibration records revealed there was no documentation that calibration was performed following the service until 3/19/21, a period of almost 3 months. Review of the service records from 2/2/22 revealed Beckman Coulter replaced suspect WBC bath and aperture assembly. There was no documentation that calibration was performed following the service and the replacement of the major components. 3. The laboratory failed to document the running of 3 levels of controls to verify calibration. Review of calibration records revealed no documentation that 3 levels of controls were run after the calibration on 7/22/20, 7/23/20, 7/29/20 and 3/19/21. 4. The laboratory failed to perform all required activities before calibrating the Beckman Coulter AcT Diff analyzer. Review of calibration records revealed there was no documentation that the laboratory had performed the Carryover checks before calibrating on 4/7/20, 5/19/20, 8/19/20 and 8/25/20 and no documentation that the laboratory had performed the reproducibility check on 8/25/20.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken

	when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and review of 2019, 2020, and 2021 temperature and humidity logs 2/28/22, the laboratory failed to take and document corrective action for temperature and humidity readings outside the acceptable limits. Findings: The laboratory's "Standard of Practice Laboratory Temperature/Humidity Log" policy states "... If the temperatures are found to be outside of the acceptable ranges, adjust the thermostat and read and record the temperature 1 hours later. If not resolved, make additional adjustments and document. If not resolved when re-evaluated 1 hour later (the laboratory director) will be made aware immediately and a repair person will be called. Corrective action will be documented on the back of the log and signed by staff responsible and by the lab director .... We will also document humidity...and if it falls outside the acceptable range, we will utilize a humidifier or dehumidifier to remedy the problem. Corrective action will be documented on the back of the Humidity Log and signed and dated by responsible personnel and by (the laboratory director)." Review of 2019, 2020, 2021, and 2022 temperature and humidity logs revealed: 1. No corrective action for humidity readings outside the acceptable limits on 3/8/21, 3/9/21, and 1/11/22; 2. No corrective action for refrigerator temperatures outside the acceptable limits on 7/29 /21, 12/8/21, and 12/13/21; 3. No corrective action for refrigerator temperatures not documented 5/6/21 and 7/19/21. The logs had been signed and dated by the laboratory director.
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 laboratory records and interview with testing personnel 2/28/22, the laboratory director failed to provide overall management and direction for the laboratory. Findings: 1. The laboratory director failed to ensure that proficiency testing samples were tested as required (see D6016). 2. The laboratory director failed to ensure that proficiency testing results were reviewed to evaluate the laboratory's performance and to identify any problems that required corrective action (see D6018). 3. The laboratory director failed to ensure a corrective action plan was followed when the laboratory received unacceptable proficiency testing results (see D6019). 4. The laboratory director failed to ensure the quality control program was established and maintained to assure the quality of the CBC(complete blood count) testing provided (see D6020). 5. The laboratory director failed to ensure the establishment and maintenance of an effective quality assessment program (see D6021). 6. The laboratory director failed to ensure that 3 of 4 testing personnel received the appropriate training for the Beckman Coulter AcT Diff hematology analyzer prior to testing patient specimens (see D6029). 7. The laboratory director failed to evaluate the competency of 3 of 3 testing personnel in 2021 (see D6046).
D6016	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of laboratory's records and interview with testing personnel 2/28/22, and deficiency cited at D2006, the laboratory director failed to ensure that proficiency testing samples were tested as required. Findings: The laboratory failed to test proficiency testing samples in the same manner it tests patients specimens for 3 of 3 PT events in 2021(see D2006).
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the laboratory's 2020, and 2021 API(American Proficiency Institute) PT(proficiency testing) records and absence of documentation 2/28/22, the laboratory director failed to ensure that PT results were reviewed to evaluate the laboratory's performance and to identify any problems that required corrective action. Findings: Review of 2020, and 2021 API PT records revealed there was no documentation that the laboratory director had reviewed or evaluated the graded PT results for the API Hematology/Coagulation 2020 3rd event, 2021 1st event, and 2021 3rd event.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of 2020, and 2021 API(American Proficiency Institute) PT (proficiency testing) records and absence of documentation 2/28/22, the laboratory

	director failed to ensure corrective action plan was followed when the laboratory received unacceptable PT results. Findings: Review of 2020 2nd API event revealed there was no corrective action documented for the 80% score for Monocytes and 80% score for MCV(mean corpuscular volume). Review of 2021 1st event revealed a API PT statistics summary on file for MCV and RDW(red cell distribution width) but no corrective action documented for the 80% score for MCV and 80% score for RDW. Deficiency previously cited on 9/11/19.
D6020	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 the quality control program is 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 QC(quality control) and calibration records, review of temperature and maintenance documentation, and interview with TP(testing personnel) 2/28/22, the laboratory director failed to ensure the quality control program was established and maintained to assure quality of the CBC(complete blood count) testing provided. Findings: 1. The laboratory failed to retain all required Beckman Coulter AcT diff hematology calibration records (see D3031). 2. The laboratory failed to have a comprehensive quality control policy in place for hematology (see D5403). 3. The laboratory failed to monitor and document the temperature and humidity as required for accurate and reliable test performance (see D5413). 4. The laboratory failed to discard control and calibrator materials that had exceeded the expiration dates (see D5417). 5. The laboratory failed to perform and document shutdown of the Beckman Coulter AcT Diff as required (see D5429). 6. The laboratory failed to follow manufacturer's instructions for calibration of the Beckman Coulter AcT Diff (see D5437). 7. The laboratory failed to take and document corrective action for temperature and humidity readings outside the acceptable limits (see D5785).
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 and review of 2020 and 2021 quality assessment documentation, the laboratory director failed to ensure the establishment and maintenance of an effective quality assessment program designed to identify and correct problems and monitor and evaluate the ongoing and overall quality of the total testing process. Review of the laboratory's policies and procedures

	revealed the only quality assessment policy available for review was a new policy which had not been used as of the date of the survey. Review of 2020 and 2021 quality assessment documentation revealed the laboratory used a monthly checklist to document quality assessment reviews. The monthly checklists failed to identify problems identified during the survey in the following areas: 1. Proficiency testing (see D2006, D6016, D6018, D6019); 2. Record retention (see D3031); 3. Procedure manual (see D5403); 4. Temperature and humidity monitoring (see D5413, D5785); 5. Expired supplies (see D5417); 6. Maintenance (see D5429); 7. Calibration (see D5437); 8. Testing personnel qualifications, training, and competency (see D6029, D6046, D6063, D6065).
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with testing personnel 2/28/22, the laboratory director failed to ensure that 3 of 4 TP(testing personnel) received the appropriate training for the Beckman Coulter AcT Diff hematology analyzer prior to testing patient specimens. Findings: Review of personnel records revealed TP #1 was hired in September 2020, TP #2 in October 2020, and TP #3 in December 2020. Personnel records revealed an initial training checklist that was completed by the TP and referred them to resources as the procedure manual, installation and training guide, and package inserts. During interview at approximately 3:30 p.m, the testing personnel confirmed they trained by reading the manufacturer's operators manual and trying to figure out what to do.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of TP(testing personnel) competency records and interview with testing personnel 2/28/22, the Technical Consultant(laboratory director) failed to evaluate the competency of 3 of 3 TP in 2021. Findings: 1. Review of 2021 TP competency records revealed TP #1 performed the semiannual competency assessments for TP #2 and TP #3, and TP #2 performed the semiannual competency assessments for TP #1 in February 2021. Review of personnel records revealed TP #1 only had a nursing license on file and TP #2 had an associates degree on file and they do not meet the technical consultant qualifications to perform competency

	assessments. 2. Review of 2021 TP competency records also revealed an annual "Competency Validation Skills Checklist" completed for TP #1 in September 2021, for TP #2 in October 2021, and for TP #3 in December 2021. It was unclear who performed the evaluations. The "Competency Validation Skills Checklist" did not include the 6 elements of competency assessment and only included "knowledge of CLIA" and "Testing: Equip/updating logs" on the form. During interview at approximately 3:30 p.m., TP #1 confirmed the TP perform competency assessments on each other. She stated they are observing each other run the CBC(complete blood count) samples.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of personnel records 2/28/22 and the deficiency cited at D6065, the laboratory failed to verify that 2 of 4 testing personnel (TP #1 and TP #3) met the minimum education requirements for performing moderate complexity testing. (see D6065)
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of personnel records and absence of documentation 2/28/22, the laboratory failed to verify that 2 of 4 testing personnel (TP # 1 and TP #3) met the minimum education requirements for performing moderate complexity testing. Findings: Reveiw of personnel records revealed that TP #1 had a nursing license and TP #3 had a Certified Medical Assistant certificate on file. There was no additional education documentation on file for TP #1 and TP #3.