Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0236987	07/14/2021
Name of Provider or Supplier	**Street Address, City, State**	
Grant Memorial Hospital	117 Hospital Drive, Petersburg, WV	

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, on site, recertification survey was conducted at Grant Memorial Hospital Laboratory on July 14, 2021, by the West Virginia Office of Laboratory Services. The laboratory was surveyed to assess compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to achieve a satisfactory score for the analyte Uric Acid in the American Proficiency Institute (API) 2021 1st proficiency testing (PT) event. Findings: 1. Review of API records identified an unsatisfactory score of 60% for the analyte #0515 Uric Acid for the 2021 1st testing event. 2. An interview with the general supervisor, 7/13/21 at approximately 9:30 AM, confirmed the findings.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

	This STANDARD is not met as evidenced by: Based on a tour of the laboratory and interview the laboratory failed to document expiration dates on quality control materials. Findings: 1. A tour of the Hematology department, 7/14/21 at approximately 10:00 AM, revealed no expiration date on 3 levels of Hematology quality control (QC) that is currently in use. The manufacturer instructions state opened QC vials are stable for 8 days. 2. A tour of the Chemistry department, 7/14/21 at approximately 9:40 AM, revealed 2 levels of Lipase calibrator (lot in use) that had no open or expiration date. The manufacturer instructions state reconstituted lipase calibrator is stable for 60 days at 2-8 C. 3. An interview with the technical supervisor, 7/14/21 at approximately 10:00 AM, confirmed the findings.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to perform and document all of the laboratory established maintenance protocol for 12 of 13 analyzers and ancillary equipment in the laboratory. Findings: 1. Review of monthly maintenance sheets for January 2021 thru June 2021 identified the following: Plasma Thawer Water Bath (serial #14035) 1/21 could not be located 2/21 no temperatures documented for 28 of 28 days, no weekly or monthly maintenance 3/21 no temperatures for 31 of 31 days, no weekly or monthly maintenance 4/21 no temperatures for 30 of 30 days, no weekly or monthly maintenance 5/21 no temperatures for 31 of 31 days, weekly documented 1 time, no monthly 6/21 no temperatures for 30 of 30 days, no weekly or monthly maintenance Platelet Rocker (serial #201608B) 1/21 could not be located 2/21 no temperatures for 28 of 28 days 3 /21 no temperatures for 31 of 31 days 4/21 no temperatures for 28 of 30 days 5/21 no temperatures for 31 of 31 days 6/21 no temperatures for 30 of 30 days Hematology Fridge (0908051) 1/21 no temperatures for 14 of 31 days, no monthly maintenance 3 /21 no monthly maintenance 4/21 no monthly maintenance Sorvall Cell Washer (9906106) 1/21 no weekly maintenance documented 2/21 no weekly maintenance documented 3/21 no weekly maintenance documented 4/21 no weekly maintenance documented 5/21 no weekly maintenance documented 6/21 no weekly maintenance documented Phlebotomy Fridge (model LR454A) 1/21 no monthly maintenance 3/21 no monthly maintenance Plasma Freezer (serial #XA107870) 1/21 no weekly or monthly maintenance 2/21 no monthly maintenance 3/21 no monthly maintenance 4 /21 no weekly or monthly maintenance 6/21 no monthly maintenance Allegra X-30 Centrifuge 1/21 no weekly maintenance 3/21 no weekly maintenance 4/21 weekly maintenance documented 3 times 5/21 weekly maintenance documented 1 time 6/21 no weekly maintenance documented Allegra X-22 Centrifuge 1/21 no weekly maintenance 2/21 no weekly maintenance Cell-Dyn Ruby 1/21 no weekly or monthly maintenance 2/21 weekly maintenance documented 1 time 3/21 weekly maintenance documented 2 times 5/21 weekly maintenance documented 1 time 6/21 weekly maintenance documented 1 time Access 2 (serial #572762) 1/21 daily documented 26

	of 31 days AU480 2/21 weekly maintenance documented 1 time, no monthly maintenance 4/21 weekly maintenance documented 3 times, no monthly 5/21 no monthly maintenance documented 6/21 weekly maintenance documented 2 times AU480 ISE 1/21 every other week maintenance documented 1 time 2/21 every other week maintenance documented 1 time, weekly documented 2 times 3/21 no weekly maintenance documented, no 3 month maintenance documented 6/21 weekly maintenance documented 1 time, every other week maintenance documented 1 time 2. An interview with the general supervisor, 7/13/21 at approximately 3:30 PM, confirmed the findings.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to ensure that (c) platelets and plasma thawing water bath temperatures were monitored. Findings: 1. Review of "Transfusion Log for Blood & Blood Products" from January 2020 thru July 13, 2021, identified 4 dates platelets were issued from the laboratory: 5/14/21,4/13/21, 4/14/21, and 3/1/21. 2. Review of Platelet Rocker monthly maintenance logs (January 2021 thru June 2021) revealed no room temperature recorded for 2 of 4 days platelets were issued; 3/1/21 and 5/14/21. 3. Review of "Transfusion Log for Blood & Blood Products" from January 2020 thru July 13, 2021 identified 1 date fresh frozen plasma (FFP) was issued from the laboratory: 1/14/21. 4. Review of the plasma thawing water bath maintenance logs (January 2021 thru June 2021) revealed that the log for January 2021 could not be located. 5. Interview with the general supervisor, on 7/14/21 at approximately 8:00 AM, confirmed the findings.
D5559	IMMUNOHEMATOLOGY CFR(s): 493.1271(e)(f) (e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to (f) document Immunohematology quality control (QC) for 2 of 194 days of patient testing in 2021.

	Findings: 1. Review of QC (1/1/21 thru 7/13/21) for Immunohematology revealed 2 days of patient testing that no QC was documented- 3/21/21 and 2/21/21. 2. Review of the Immunohematology testing log revealed the following: 3/20/21- 1 patient had 2 units crossmatched, 1 patient had a type and screen, 1 patient had 2 units crossmatched 2/21/21- 1 patient had a type and screen, 1 patient had a type/Rh 3. An interview with the general supervisor, 7/14/21 at approximately 8:00 AM, confirmed the findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to monitor and correct problems regarding the lack of documentation for maintenance, temperature logs, and specimen storage conditions as a part of the analytic systems quality assessment. Findings: 1. Review of maintenance logs identified 12 of 13 laboratory analyzers and ancillary equipment with incomplete documentation. Refer to D5433. 2. A tour of the laboratory identified quality control materials without an opened expiration date. Refer to D5415. 3. Review of Immunohematology quality control (QC) records identified 2 days no daily QC was documented. Refer to D5559. 4. Review of the Immunohematology log book identified 3 days platelets or fresh frozen plasma was issued to patients with no documentation of storage conditions. Refer to D5555. 5. An exit interview with the general supervisor, 7/14/21 at approximately 12:00 PM, confirmed the findings.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on record review and interviews the laboratory director failed to ensure the overall quality of the laboratory's analytic test systems. Findings: 1. A tour of the laboratory identified quality control materials with no opened expiration date. Refer to D5415. 2. A review of maintenance records identified a lack of documentation. Refer to D5433. 3. A review of the Immunohematology patient log identified 3 days temperatures were not documented and blood products issued from the laboratory. Refer to D5555. 4. A review of Immunohematology quality control (QC) records identified 2 days of patient testing that no QC was documented. Refer to D5559. 5. A review of analytic systems quality assurance identified no corrective actions for the lack of temperature and maintenance documentation. Refer to D5791.
D6175	TESTING PERSONNEL RESPONSIBILITIES

	CFR(s): 493.1495(b)(1) Each individual performing high complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on record review and interview the testing personnel failed to follow the established policies and procedures of the laboratory. Findings: 1. Review of analyzer maintenance logs identified a failure of testing personnel to document maintenance. Refer to D5433. 2. Review of quality control records for Immunohematology identified a failure to document daily quality control. Refer to D5559. 3. Review of temperature logs identified a failure to document temperatures for days platelets and fresh frozen plasma were issued. Refer to D5555. 4. Quality control materials were found that did not have an opened expiration date documented. Refer to D5415. 4. During an interview with the general supervisor, 7/14/21 at approximately 1:00 PM, confirmed the findngs.