

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0506831	<b>(X3) Date Survey Completed</b> 12/07/2022
<b>Name of Provider or Supplier</b> Parkview Hospital	<b>Street Address, City, State</b> 901 S Sweetwater Street, Wheeler, TX	
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>D0000</b>	Noted deficiencies were discussed with the laboratory representatives at the exit conference. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
<b>D3025</b>	<p><b>REQUIREMENTS FOR TRANSFUSION SERVICES</b> CFR(s): 493.1103(d)</p> <p>Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities.</p> <p>This STANDARD is not met as evidenced by: Based on interview, review of reference material, nursing policies and procedures, vital signs on transfusion record, interview, and email, the facility failed to take post transfusion vital signs used to identify blood and blood product transfusion reactions for six out of six units reviewed. Findings follow. A. Interview with the director of nursing on December 1, 2022, at 1445 in the conference room acknowledged an end of transfusion and 1-hour post transfusion vital signs should be taken. B. Review of the AABB Technical Manual, 18th ed, American Association of Blood Banks, 2014, on Chapter 9, Storage, Processing, Distribution, and Inventory, under Documentation stated, "The patient's medical record must include proper documentation of all transfusions. For each transfusion, this documentation must contain the transfusion order, consent for transfusion, component name, donation identification number, date, and time of transfusion, pre-and posttransfusion vital signs, volume transferred, identification of the transfusionist, and, if applicable, any transfusion related adverse events." On Chapter 21 Administration of Blood Components under Monitoring the Transfusion, stated "Vital signs should be taken within 5 to 15 minutes of beginning the transfusion and then according to institutional policy. There is little evidence to support a best practice related to the frequency of vital-sign monitoring other than at</p>

baseline, soon after the start of transfusion, and after transfusion. AABB standards requires that the medical record must include pre- and posttransfusion vital signs. Vital signs should be taken at once if there is a suspected transfusion reaction." C. Review of the nursing policy titled "Blood and Blood Product, Administration of" (reviewed 2/22) under Procedure on page 2 stated, "7. The patient's temperature, pulse, respirations, and blood pressure should be recorded on the Nurses Notes at the beginning of the transfusion. Take vital signs as required on the Transfusion Record and record in spaces allotted." The policy and procedure did not define when vitals should be taken. D. Review of the Blood Transfusion Record showed "VITAL SIGNS: Before Transfusion, 15 minutes after, 30 minutes after, 45 minutes after, 1 hour after, 2 hours after, end of transfusion." The Blood Transfusion Record does not require vital signs post transfusion. E. Random review of six of six units transfused reviewed were missing post transfusion vital signs: 1. Patient Hospital # 10001872 on 11/07/22 Unit # W091022354181 packed red blood cells 2. Accession # 10000720 on 07/26/22 Unit # W091022218178 packed red blood cells 3. Patient Hospital # 4139-0034 on 05/08/22 Unit # W091022193018 packed red blood cells 4. Patient Hospital # 19944-0002 on 04/18/22 Unit # W091022180891 packed red blood cells 5. Patient Hospital # 19711 on 12/17/21 Unit # W091021413471 packed red blood cells 6. Patient Hospital # 19348-0005 on 08/18/21 Unit # W0910213296298 platelets F. Interview with the director of nursing on December 1, 2022, at 1515 in the conference room confirmed the findings. Phone interview with testing personnel #2 on December 7, 2022 at 1120 hours acknowledged they used the AABB Technical Manual as a reference in Immunohematology. G. In an email on December 7, 2022, from testing personnel #2, the estimated annual test volume for transfusions was reported at 7.

**D5441**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on review of the quality control records, interview, and email, the laboratory failed to monitor accuracy and precision using the Alere EPOC for blood gases with the Siemens Healthineers Eurotrol GAS-ISE Metabolites Level 1 & 3 for 11 of 11 months reviewed. Findings follow. A. Review of the quality control records from Jan - Nov 2022 showed accuracy and precision were not monitored. Statistical calculations were requested on December 1, 2022, at 10:05 but not provided. B. Interview with technical consultant #2, as listed on the CMS form 209, on December 1, 2022, at 10:05 in the conference room confirmed they do not do statistical calculations on their blood gas controls. C. In an email on December 7, 2022, from testing personnel #2, the estimated annual test volume for blood gasses was reported at 37.

**D5445**

**CONTROL PROCEDURES**

CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--  
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the quality control (QC) records, IQCP (Individualized QC plan), patient testing records, and interview, the laboratory failed to perform external QC once a week on the BD MAX used to test SARS-CoV-2 for 2 out of 29 patients tested over a four-month period. Findings follow. A. Review of the IQCP plan, implemented 09/01/21, showed external quality control was to be performed "weekly and with reagent lot change". B. Review of QC records from 07/29/22 - 11/24/22 showed external QC was performed 8/26/22 and not performed again until 9/09/22. C. Review of patient testing records showed patient testing was performed on 1. 9/02/22 MR# 16027 and 2. 9/06/22 MR# 18640. D. Interview with testing personnel #3, as listed on the CMS form 209, on December 1, 2022, at 1145 in the laboratory confirmed the findings.

**D5545**

**HEMATOLOGY**

CFR(s): 493.1269(b)(d)

(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on review of the quality control (QC) records, patient testing, and interview, the laboratory failed to perform QC every eight hours of testing for Prothrombin Time (PT) tested on the Sysmex CA-600 for two out of 26 patients tested in Oct 2022. Findings follow. A. Review of the quality control log against the documentation of patient testing for the month of Oct 2022 showed on 10/10/22 two patients were tested without prior QC: QC was last performed on 10/09/22 at 15:02 1. MR # 12344 was analyzed on 10/10/22 at 09:00. The time between the last quality control run and the patient analysis was 17 hours and 52 minutes. 2. MR # 440 was analyzed on 10/10/22 at 09:25. The time between the last quality control run and the patient analysis was 18 hours and 23 minutes. B. Interview with testing personnel #2, as listed on the CMS form 209, on November 30, 2022, at 1200 in the conference room confirmed the findings.