Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 32D2029629	(X3) Date Survey Completed 06/30/2023
Name of Provider or Supplier Presbyterian Rust Medical Center Laboratory	**Street Address, City, State** 2400 Unser Blvd Se Room 0508, Rio Rancho, NM	
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	The facility was found to be NOT in compliance with the CLIA conditions for specialties/subspecialties surveyed for 42 CFR: 493.1240 Preanalytic systems 493.1409 Technical Consultant - Moderate Complexity 493.1421 Testing Personnel - Moderate Complexity 493.1447 Technical Supervisor - High Complexity 493.1459 General Supervisor - High Complexity
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on review of facility policy, patient blood transfusion records, and confirmed in interview, the facility failed to meet the requirements specified in 493.1103, as evidenced by: 1. The facility failed to document all transfusion related activities for 4 of 10 transfusions from June 2023. Refer D3015. 2. The facility failed to promptly identify and investigate transfusion reactions to the laboratory for 1 of 1 transfusion in October 2022. Refer to D3025.
D3015	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103

	A facility that provides transfusion services must meet all of the requirements of this section and document all transfusion-related activities. This STANDARD is not met as evidenced by: Based on review of facility policy, a random review of patient transfusion records (June 2023), and confirmed in interview, the facility failed to ensure all transfusion related activities were documented for administration of blood products to promptly identify and investigate transfusion reactions for 4 of 10 patients. Findings included: 1. The facility policy titled "Blood and Blood Product Administration" (Reference number PC.PDS.242, Effective date 08/12/2021) stated the following: " ...Policy ...10. Transfusion reactions can be life-threatening and occur with exposure to even a small amount of blood; therefore, transfusions should be started slowly unless the patient's condition requires a rapid, life-sustaining transfusion ...10.2 Obtain baseline vital signs within 15 minutes before the initiation of the transfusion, reassessed at the end of the first 15 minutes after starting the transfusion and hourly thereafter after starting the transfusion. Obtain a final set of vital signs at the completion of the transfusion ... Procedure ...2.10 Obtain and document pre-transfusion vital signs in the electronic health record (Blood pressure, heart rate, respiratory rate, temperature, and O2 saturation and assess for preexisting rash, chills, or itching) ...8. Suspected Transfusion Reaction 8.2.6 Document all vitals and reaction symptoms in the Blood Administration Flowsheet in the EHR ..." 2. A random review of patient transfusion records from June 2023 revealed the following 4 transfusions in which the facility failed to follow their own policy for documentation of vital signs during blood administration: a. Patient 4702600; Date of Transfusion 06/01/2023 "Pre-transfusion" vitals documented at 1110. "15 minutes into transfusion" vitals documented at 1140. No documentation was provided for hourly vital signs during the transfusion and at the completion of the transfusion. b. Patient 5090115; Date of Transfusion 06/02/2023 Transfusion started at 1655. No documentation of any vital signs after 1655 until 2010. c. Patient 1554385; Date of Transfusion 06/02/2023 "Pre-transfusion" vitals documented at 1609. "15 minutes into transfusion" vitals documented at 1624. No documentation was provided for hourly vital signs during the transfusion and at the completion of the transfusion. d. Patient 1696969; Date of Transfusion 06/03/2023 "Pre-transfusion" vitals documented at 1048. "15 minutes into transfusion" vitals documented at 1100. "Hourly vital signs" documented at 1215. No documentation was provided of vital signs at the completion of the transfusion. 3. In an interview on 06/28/2023 at 09:35 AM, during the review of patient transfusion records, the Interim Director for Patient Safety and Clinical Excellence confirmed the findings. Word Key: EHR=Electronic Health Record
D3025	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d) 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. This STANDARD is not met as evidenced by: Based on review of facility policy, patient records (October 29 - 30, 2022), and confirmed in interview, the facility failed to promptly identify and report a blood transfusion reaction to the laboratory for 1 of 1 patient transfused on October 30,

2022. Findings included: 1. The facility policy titled "Blood and Blood Product Administration" (Reference number PC.PDS.242, Effective date 08/12/2021) stated the following: " ...Policy ...10. Transfusion reactions can be life-threatening and occur with exposure to even a small amount of blood; therefore, transfusions should be started slowly unless the patient's condition requires a rapid, life-sustaining transfusion ...8. Suspected Transfusion Reaction 8.2.6 Document all vitals and reaction symptoms in the Blood Administration Flowsheet in the EHR. 8.2.7 Place a 'Transfusion Reaction Evaluation' order in the EHR. 8.2.8 Call and notify the Blood Bank of a suspected transfusion reaction ... Addendum C: Blood Transfusion Reactions Cause Hemolytic Reactions ...Signs & Symptoms Apprehension; Chills, Headache, fever; Pain in back, abdomen, or chest, or at infusion site; Respiratory distress, peripheral circulatory collapse, shock; Disseminated intravascular coagulation; hypotension, tachycardia; hemoglobinemia, hemoglobinuria. Specific Considerations Follow steps on 'Suspected Transfusion Reaction' ..." 2. Review of Patient 2059989 records from October 29, 2022, through October 30, 2022, revealed the following: 10/29/2022 17:01 through 21:02:36 Patient arrived in Emergency Department with a complaint of a gastrointestinal bleed. Orders were entered for laboratory testing and transfusion of packed red blood cells. 10/29/2022 21:15 "Quick Updates: ...Per blood bank, pt has + antibody and further testing will be needed prior to transfusion. Will continue to monitor." 10/30/2022 01:05 "Quick Updates: RN contacted blood bank in regard to needing blood for an emergent blood transfusion." 10/30/2022 01:46 Blood Bank issued units W401222033783 and W041222036674 per emergency release protocol to ED. Unit W041222033783 transfused to patient. 10/30/2022 02:27 "Quick Updates: Blood bank informed RN that the other RBC unit that has not been administered yet is not compatible. RN to return unit to blood bank." 10/30/2022 03:11:16 Blood Bank issued unit W068522042759 per emergency release protocol to ED. 10/30/2022 03:30 Unit W041222033783 completed. 10/20/2022 03:31 Transfusion of unit W068522042759 started. 10/30/2022 03:38 "Quick Updates: After first unit of blood was completed at 03:30 and VS obtained within 5-6 minutes patient started to moan and groan in pain reporting pain/cramping to his lower abdomen. Patient also c/o 'feeling cold' ..." 10/30/2022 03:46 "Quick Updates: Patient's second unit of blood was started. Patient continued to report severe abdominal cramping and feeling cold. Patient now becoming tachycardiac as well as tachypneic ..." At this time the patient was presenting with signs and symptoms of a hemolytic transfusion reaction per the facility policy (chills, pain in abdomen, respiratory distress, and tachycardia). 10/30/2022 03:53 "Quick Updates: Pt having an increase in pain and cramps ..." 10/30/2022 03:55 "Quick Updates: Patient continued to have chills and severe abdominal cramping after meds. Patient is still tachycardic and tachypneic. Provider notified and to bedside to evaluate the patient." The facility failed to recognize the signs and symptoms of a hemolytic transfusion reaction per the facility policy (chills, pain in abdomen, respiratory distress, and tachycardia). 10/30/2022 04:00 "Blood Administration: ...Reaction Symptoms: Chills/Rigors (Abdominal pain/cramping) ...Suspected Reaction?: Yes ...." 10/30/2022 04:04 "Quick Updates: Per provider stop transfusion as an allergic reaction is now suspected due to patient's signs and symptoms." At this time, the facility identified the transfusion reaction as an allergic reaction. 10/30/2022 04:04:31 "ED Notes: ...4:09 AM Given epinephrine and Benadryl ...5:35 AM discussed with [Pathologist on Call]. Advised patient has JKa antibody and this is likely the etiology of his acute reaction ..." 10/30/2022 04:20:09 "Lab Ordered TRANSFUSION REACTION EVALUATION" 10/30/2022 06:21:52 "Lab Resulted (Preliminary result) TRANSFUSION REACTION EVALUATION" Review of the "Transfusion Reaction Investigation Form-PHS" revealed "post-reaction visual hemolysis Positive". 10/30/2022 16:53 Patient Expired The facility failed to promptly identify the signs and symptoms of a hemolytic transfusion reaction

	per the facility policy (chills, pain in abdomen, respiratory distress, and tachycardia) and failed to promptly report the reaction to the laboratory. 3. In an interview on June 27, 2023, at 3:00 pm, the Laboratory Director, after review of the documentation, confirmed the findings. 4. According to records, the laboratory had a year-to-date volume of 1,057 blood products transfused. Further review of blood bank records revealed 5 suspected transfusion reactions were evaluated from 01/01/2023 through 04 /19/2023. This was a 0.47 % transfusion reaction rate. Word Key: ED = emergency department + = positive RN = registered nurse RBC = red blood cells VS = vital signs c/o = complained of Jka = Kidd antibody a
D5026	IMMUNOHEMATOLOGY CFR(s): 493.1217 If the laboratory provides services in the specialty of Immunohematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1271, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of laboratory records, patient records, and staff interview, the laboratory failed to meet the requirements for the specialty of immunohematology, as evidenced by: 1. The laboratory failed to provide a policy (signed by the laboratory director) for the performance of 3 of 3 anti-human globulin (AHG) crossmatches performed at the laboratory. Refer to D5551. 2. The laboratory failed to promptly identify and investigate transfusion reactions in its facility for which it had investigational responsibility and make recommendations to medical staff regarding improvements in transfusion procedures for 1 of 1 blood transfusion reactions in October 2022. Refer to D5559. 3. The laboratory failed to ensure an effective quality assurance (QA) program was in place to monitor, assess, and correct problems in the laboratory for the specialty of immunohematology. Refer to D5793.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of manufacturer's instructions, laboratory procedure, patient test records, and staff interview, the laboratory failed to meet pre-analytic system requirements as evidenced by: 1. The laboratory failed to ensure lactate samples were centrifuged within 15 minutes of collection. Refer to D5311, I 2. The laboratory failed to ensure ammonia samples were analyzed within 60 minutes of collection. Refer to D5311, II
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:
I. Based on a review of the manufacturer's instruction, the laboratory's procedure manual, patient test records, and interview with staff, the laboratory failed to ensure 65 of 102 (sampling) patient lactate samples were centrifuged within 15 minutes of collection from March 2023 through June 2023. A) A review of the manufacturer's instructions ("LACT2 Gen.2", 0208057940190c503V2., 2022-10) for lactate analysis performed on the Cobas c503 analyzer revealed, "centrifuge within 15 minutes of collecting specimen." B) A review of the laboratory's procedure manual for lactate analysis ("Lactate by cobas c503 c303 Procedure", CHEM 600, 7/1/2022) performed on the Cobas c503 analyzer revealed, "precautions must be taken to retard glycolysis by keeping the whole blood on ice then separating the plasma from the cells within 15 minutes of collection." C) A review of the lactate patient test records revealed: Date of testing: 03/07/2023 1362751;3; collected 03/06/2023 00:45:00; received 03/07/2023 01:13:00; reported 03/07/2023 01:53:30; time from collection to receipt 28 minutes. 1693902;3; collected 03/07/2023 01:43:00; received 03/07/2023 02:16:00; reported 03/07/2023 03:01:08; time from collection to receipt 33 minutes. 1363512;3; collected 03/07/2023 02:36:00; received 03/07/2023 03:12:00; reported 03/07/2023 03:01:08; time from collection to receipt 36 minutes. 00160395;3; collected 03/07/2023 02:23:00 02:36:00; received 03/07/2023 03:23:00; reported 03/07/2023 03:51:57; time from collection to receipt 60 minutes. 00104838;3; collected 03/07/2023 04:28:00; received 3/07/2023 04:45:00; reported 03/07/2023 05:24:11; time from collection to receipt 17 minutes. 00501265;3; collected 03/07/2023 04:25:00; received 03/07/2023 04:52:00; reported 03/07/2023 05:34:20; time from collection to receipt 27 minutes. 1308055;3; collected 03/07/2023 04:50:00; received 03/07/2023 05:30:00; reported 03/07/2023 06:25:49; time from collection to receipt 40 minutes. 4815587;3; collected 03/07/2023 05:50:00; received 03/07/2023 06:25; reported 03/07/2023 06:54:51; time from collection to receipt 35 minutes. 00911644;3; collected 03/07/2023 05:08:00; received 03/07/2023 06:29:00; reported 03/07/2023 07:17:27; time from collection to receipt 79 minutes. 2071259;3; collected 03/07/2023 05:16:00; received 03/07/2023 06:50:00; reported 03/07/2023 07:24:10; time from collection to receipt 94 minutes. 4200413;3; collected 03/07/2023 05:53:00; received 03/07/2023 06:50:00; reported 03/07/2023 07:29:12; time from collection to receipt 57 minutes. 00522494;3; collected 03/07/2023 09:22:00; received 03/07/2023 10:08:00; reported 03/07/2023 10:45:19; time from collection to receipt 46 minutes. 00522494;3; collected 03/07/2023 09:22:00; received 03/07/2023 10:08:00; reported 03/07/2023 10:45:19; time from collection to receipt 46 minutes. 5139895;3; collected 03/07/2023 12:02:00; received 03/07/2023 12:20:00; reported 03/07/2023 12:52:14; time from collection to receipt 18 minutes. 1634180;3; collected 03/07/2023 12:29:00; received 03/07/2023 12:52:00; reported 03/07/2023 13:23:01; time from collection to receipt 23 minutes. 4658194;3; collected 03/07/2023 12:45:00; received 03/07/2023 13:10:00; reported 03/07/2023 13:35:55; time from collection to receipt 25 minutes. 00191410;3; collected 03/07/2023 14:16:00; received 03/07/2023 14:40:00; reported 03/07/2023 15:16:58; time from collection to receipt 24 minutes. Date of testing: 03/12/2023 1727244;3; collected 03/12/2023 03:26:00; received 03/12/2023 03:56:00; reported 03/12/2023 04:22:59; time from collection to receipt 30 minutes. 4694521;3; collected 03/12/2023

05:23:00; received 03/12/2023 05:46; reported 03/12/2023 06:35:59; time from collection to receipt 23 minutes. 1419222;3; collected 03/1212023 04:45:00; received 03/12/2023 14:21:00; reported 03/1212023 14:52:10; time from collection to receipt 36 minutes. 4623779;3; collected 03/12/2023 15:28:00; received 03/12/2023 16:09: 00; reported 03/12/202316:35:16; time from collection to receipt 41 minutes. 5264934; 3; collected 03/12/2023 15:25:00; received 3/12/2023 17:57:00; reported 03/12/2023 18:18:05; time from collection to receipt 152 minutes. 1312764;3; collected 03/12 /2023 16:48:00; received 03/12/2023 19:36:00; reported 03/12/2023 19:56:42; time from collection to receipt 48 minutes. 4292531;3; collected 03/12/2023 19:56:00; received 03/12/2023 20:15:00; reported 03/12/2023 20:44:05; time from collection to receipt 19 minutes. 00469929;3; collected 03/12/2023 19:58:00; received 03/12/2023 20:33:00; reported 03/12/2023 21:22:58; time from collection to receipt 35 minutes. 00469929;3; collected 03/12/2023 19:58:00; received 03/12/2023 20:33:00; reported 03/12/2023 21:22:58; time from collection to receipt 35 minutes. 5278684;3; collected 03/12/2023 21:25:00; received 03/12/2023 21:49:00; reported 03/12/2023 22:35:53; time from collection to receipt 24 minutes. 1353464;3; collected 03/12/2023 21:43:00; received 3/12/2023 21:42:00; reported 03/12/2023 22:35:53; time from collection to receipt 22 minutes. 00398203;3; collected 03/12/2023 21:09:00; received 03/12/2023 22:05:00; reported 03/12/2023 22:36:53; time from collection to receipt 54 minutes. 00249276;3; collected 3/12/2023 21:50:00; received 03/12/2023 22:16:00; reported 03 /12/2023 22:44:14; time from collection to receipt 26 minutes. 2359568;3; collected 03 /12/2023 22:14:00; received 03/12/2023 22:36:00; reported 03/12/2023 20:00:18; time from collection to receipt 22 minutes. Date of testing: 03/18/2023 5298328;3; collected 03/17/2023 23:35:00; received 03/18/2023 00:33:00; reported 03/18/2023 01:04:31; time from collection to receipt 58 minutes. 00114615;3; collected 03/18 /2023 00:45:00; received 03/18/2023 01:03:00; reported 03/18/2023 01:39:55; time from collection to receipt 18 minutes. 4762697;3; collected 03/18/2023 04:33:00; received 03/18/2023 05:00:00; reported 03/18/2023 05:24:38; time from collection to receipt 27 minutes. 00871407;3; collected 03/18/2023 07:50:00; received 03/18/2023 09:34:00; reported 03/18/2023 10:13:17; time from collection to receipt 46 minutes. 1874529;3; collected 03/18/2023 09:08:00; received 03/18/2023 09:36:00; reported 03 /18/2023 10:15:17; time from collection to receipt 18 minutes. 00445144;3; collected 03/18/2023 09:20:00; received 03/18/2023 10:10:00; reported 03/18/2023 10:50:47; time from collection to receipt 50 minutes. 4265112;3; collected 03/18/2023 11:40:00; received 03/18/2023 12:33:00; reported 03/18/2023 12:54:32; time from collection to receipt 53 minutes. 2457594;3; collected 3/18/2023 13:08:00; received 03/18/2023 13: 35:00; reported 03/18/2023 14:25:59; time from collection to receipt 27 minutes. 1589677;3; collected 3/18/2023 13:20:00; received 03/18/2023 13:50:00; reported 03 /18/2023 14:32:23; time from collection to receipt 30 minutes. 2251548;3; collected 03 /18/2023 14:45:00; received 03/18/2023 15:08:00; reported 03/18/2023 15:47:55; time from collection to receipt 23 minutes. 2251548;3; collected 03/18/2023 17:00:00; received 03/18/2023 17:17:00; reported 03/18/2023 17:48:56; time from collection to receipt 17 minutes. 1586654;3; collected 03/18/2023 19:04:00; received 03/18/2023 19:40:00; reported 03/18/2023 20:05:10; time from collection to receipt 36 minutes. 4658995;3; collected 03/18/2023 20:11:00; received 03/18/2023 20:34:00; reported 03 /18/2023 20:59:02; time from collection to receipt 23 minutes. 1825167;3; collected 03 /18/2023 20:48:00; received 03/18/2023 21:12:00; reported 03/18/2023 21:48:16; time from collection to receipt 24 minutes. 00610413;3; collected 03/18/2023 21:43:00; received 03/18/2023 22:31 :00; reported 03/18/2023 23:08:40; time from collection to receipt 48 minutes. 2071259;3; collected 03/18/2023 22:40:00; received 03/18/2023 22:56:00; reported 03/18/2023 23:20:02; time from collection to receipt 16 minutes. Date of testing: 06/27/2023 00963692;3; collected 06/26/2023 23:40:00; received 06 /26/2023 23:58:00; reported 06/27/2023 00:38:54; time from collection to receipt 18

minutes. 5295600;3; collected 06/27/2023 00:41:00; received 06/27/2023 01:02:00; reported 06/27/202301:26:33; time from collection to receipt 21 minutes. 00727416;3; collected 06/27/2023 02:41:00; received 06/27/2023 03:09:00; reported 06/27/2023 03:09:00; time from collection to receipt 28 minutes. 5299430;3; collected 06/27/2023 05:09:00; received 06/27/2023 05:40:00; reported 6/27/2023 06:22:15; time from collection to receipt 31 minutes. 00785572;3; collected 06/27/2023 06:11:00; received 06/27/2023 06:49:00; reported 06/27/2023 08:00:14; time from collection to receipt 38 minutes. 00168416;3; collected 06/27/2023 07:39:00; received 06/27/2023.07:56: 00; reported 06/27/2023 08:29:23; time from collection to receipt 17 minutes. 4728801;3; collected 06/27/2023 07:36:00; received 06/27/2023 08:05:00; reported 06 /27/2023 08:41:08; time from collection to receipt 29 minutes. 4376887;3; collected 06127/2023 08:09:00; received 06/27/2023 08:45:00; reported 06/27/2023 09:34:39; time from collection to receipt 36 minutes. 00435964;3; collected 06/27/2023 08:19: 00; received 06/27/2023 09:09:00; reported 06/27/2023 10:02:12; time from collection to receipt 50 minutes. 1841174;3; collected 06/27/2023 09:30:00; received 06/27/2023 10:11 :00; reported 06/27/2023 10:54:18; time from collection to receipt 41 minutes. 00762458;3; collected 06/27/2023 12:36:00; received 06/27/2023 13:00; reported 06/27/2023 13:35:52; time from collection to receipt 24 minutes. 1682803;3; collected 06/27/2023 08:31 :00; received 06/27/2023 13:11 :00; reported 06/27/2023 14:17:04; time from collection to receipt 280 minutes. 00124182:3; collected 06/27 /2023 14:30:00; received 06/27/2023 15:33:00; reported 06/27/2023"16:06:11; time from collection to receipt 63 minutes. 1534110;3; collected 06/27/2023 15:06:00; received 06/27/2023 15:32:00; reported 06/27/2023 16:06:12; time from collection to receipt 26 minutes. 5319653;3; collected 06/27/2023 17:10:00; received 06/27/2023 21:11:00; reported 06/27/2023 18:02:34; time from collection to receipt 19 minutes. 00616717;3; collected 06/27/2023 20:42:00; received 06/27/2023 21:11:00; reported 06/27/2023 21:48:00; time from collection to receipt 29 minutes. 00338427;3; collected 06/27/2023 20:54:00; received 06/28/2023 01:56:00; reported 06/28/2023 02:14:09; time from collection to receipt 62 minutes. D) In an interview on 6/29/23 at 01:08 PM, General Supervisor #5, as listed on the CMS-209, confirmed that samples were not centrifuged within 15 minutes of venipuncture. II. Based on a review of the manufacturer's instruction, the laboratory's procedure manual, patient test records, and interview with staff, the laboratory failed to ensure 3 of 24 (sampling) patient ammonia samples were analyzed within 60 minutes of collection from March 2023 through June 2023. A) A review of the manufacturer's manual for ammonia analysis ("NHL3L2", 0208058024190c503V3.0, 2022-09) performed on the Cobas c503 analyzer revealed, "place immediately on ice and centrifuge, preferably at 2-8C. Perform analysis within 60 minutes of venipuncture or freeze separated plasma immediately." B) A review of the laboratory's procedure manual for the ammonia analysis ("Ammonia by cobas c503 c303 Procedure", CHEM 544, 7/1/2022) performed on the Cobas c503 analyzer revealed, "place immediately on ice and centrifuge, preferably at 2-8C. Perform analysis within 60 minutes of venipuncture or freeze separated plasma immediately." C) A review of the ammonia patient test records revealed: 00330056;3; collected 03/10/2023 06:08:00; received 03/10/2023 07: 25:00; reported 03/10/2023 08:08:35; time from collection to receipt 77 minutes. 5264934;3; collected 03/12/2023 15:25:00; received 03/12/2023 16:30:00; reported 03 /12/2023 17:07:08; time from collection to receipt 65 minutes. E2324808; collected 06 /27/2023 23:40:00; received 06/28/2023 00:35:00; analyzed 06/28/2023 00:47:00; time from collection to analysis 67 minutes. D) In an interview on 06/28/23 at 10:13 AM, the laboratory staff member, identified as General Supervisor #1, as listed on the CMS-209, confirmed samples are accessioned into the laboratory information management system prior to centrifugation. In an interview on 06/29/2023 at 01:08 PM, General Supervisor #5, as listed on the CMS-209, confirmed that samples were

	not analyzed within 60 minutes of venipuncture.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of laboratory policy, laboratory records, and confirmed in staff interview, the laboratory failed to complete blood bank pipette quarterly checks for 1 of 4 events in 2022. Findings included: 1. The laboratory policy titled "Gen 10 Pipette PCS2 Calibrator Procedure" (approved by the laboratory director on 03/03/2023) stated, "III. RESPONSIBILITY/SCOPE ... C ... 3. Pipettes used in blood bank testing require quarterly verification (see BB-SOP-0185)." 2. A review of the laboratory records titled "DG Pipette Quarterly Checks" revealed the following: a) Site RMC. Year 2022 Pipette serial number A20302151 "4th Quarter '*' * Not Done due to short staffing + staff turnover ..." b) Site RMC. Year 2022 Pipette serial number A20302511 "4th Quarter '*' * Not done due to staff turnover + short staffing ..." 3. In an interview on 06/28/2023 at 1400 in the laboratory, after a review of the above records, the Blood Bank Technical Specialist confirmed the above findings. Word key: PCS = pipette calibration system RMC = Rust Medical Center + = and
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) 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. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, reagent lot rollover studies, interview with staff, and observation, the laboratory failed to follow manufacturer's instructions for determining the therapeutic Activated Partial Thromboplastin Time (aPTT) range for monitoring unfractionated heparin therapy for two of two years reviewed (2021 and 2022). Findings follow: A) Review of the Hemostasis Performance Verification Manual for The Therapeutic aPTT range on the ACL Top 550 stated, "Due to differing sensitivities of APTT reagents to different heparins, it is important for laboratories to be able to demonstrate how their particular APTT reagent is responding to their pharmacy's type and brand of heparin." The frequency of these studies per the manufacturer stated, "...if necessary whenever there is a Change of lot number of aPTT reagent. Change of type of heparin. Change of instrument. If requested by your IL representative. As required by your regulatory agency." B) Review of reagent lot rollover studies for 2021 and 2022 included the heparin therapeutic range study performed at three other hospitals (not the laboratory being surveyed) and that data for a range was used for all hospitals. The brand of heparin was not included. The laboratory did not follow manufacturer's instructions for demonstrating how their particular APTT reagent was responding to their pharmacy's

	type and brand of heparin. C) During an interview on 06/28/23 at 11:00 am, Technical Consultant - 5 (TC-5) confirmed heparin curve/therapeutic range studies had not been "established at this site." D) During a tour of the pharmacy on 6/28/2023 at 08:43 a.m. B-Braun USA 20,000 Units Heparin in 5% Dextrose Injection, 40 Units mL, and 1,000 Units Heparin in 0.9% Sodium Chloride Injection, 2 Units mL were observed and confirmed the use of unfractionated heparin by the hospital.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure, manufacturer's instructions, stainer logs, and in interview with staff, the laboratory failed to define predictable staining characteristics for Wright's Stain when checking for intended reactivity in one of one written procedure. Findings follow: A. The laboratory document number: HEME 212, titled: HemaTek Slide Stainer Procedure, in section IV Quality Control step 4 states, "Stain is checked for intended reactivity each day of use and documented on the maintenance log." No definition given for the intended reactivity of types of cells and color stains will produce when performed. B. The HemaTek Stain Pak - Modified Wright's Stain instructions for use were reviewed. The instructions for use stated, "When a thin blood film is processed with this system and examined microscopically, the nucleus and the cytoplasm of neutrophils, lymphocytes, monocytes, eosinophils, and basophils show a characteristic blue or red coloration. Cells are then manually differentiated and quantified." This was not included in the laboratory's Wright's stain procedure. C. Review of the HemaTek Stainer Maintenance Log for May 2022, October 2022, and January 2023 did not include definition for the intended reactivity of types of cells and stain colors when checked daily. D. In an interview at 1326 on 6/29/2023 the Technical Consultant - 1 (TC-1) as listed on the form CMS-209 confirmed the laboratory did not define the intended reactivity in laboratory document number: HEME 212, titled: HemaTek Slide Stainer Procedure.
D5551	IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f) (a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (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 interview with staff, review of laboratory policies and patient records, the laboratory failed to provide a policy (signed by the laboratory director) for the performance of 3 of 3 anti-human globulin (AHG) crossmatches performed at the laboratory. Findings included: 1. In an interview on 06/27/2023 at 9:00 am in the laboratory, the laboratory manager stated that the facility performs electronic crossmatches only. If a patient has a positive antibody screen or a history of an antibody, the specimen is sent to the main hospital facility for antibody identification, unit antigen typing, and AHG crossmatching (if needed). 2. Review of Patient 2059989 records revealed Testing Person #14 performed 3 AHG crossmatches on 10 /30/2023. Units W401222033783 and W041222036674 were crossmatched at 02:09: 16. Unit W068522042759 was crossmatched at 02:57:29. 3. In an interview on 06/28 /2023 at 1:30 pm, the Associate Director for Presbyterian Laboratory System was asked to provide documentation of the AHG crossmatch orders and results in the laboratory information system (LIS) for those crossmatches performed on 10/30/2022. No documentation was provided. He was asked to provide an AHG policy for this facility signed by the laboratory director. No policy was provided. The Associate Director for Presbyterian Laboratory System confirmed that an AHG crossmatch was performed but was "a deviation from standard operating procedure."
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 review of facility and laboratory policies, laboratory forms, patient records (October 29 - 30, 2022), and confirmed in interview, the laboratory failed to promptly identify and investigate transfusion reactions in its facility for which it had investigational responsibility and make recommendations to medical staff regarding improvements in transfusion procedures for 1 of 1 blood transfusion reactions in October 2022. Findings included: 1. The facility policy titled "Blood and Blood Product Administration" (Reference number PC.PDS.242, Effective date 08/12/2021) stated the following: " ...Policy ...10. Transfusion reactions can be life-threatening and occur with exposure to even a small amount of blood; therefore, transfusions should be started slowly unless the patient's condition requires a rapid, life-sustaining transfusion ...8. Suspected Transfusion Reaction 8.2.6 Document all vitals and reaction symptoms in the Blood Administration Flowsheet in the EHR. 8.2.7 Place a 'Transfusion Reaction Evaluation' order in the EHR. 8.2.8 Call and notify the Blood Bank of a suspected transfusion reaction ... Addendum C: Blood Transfusion Reactions Cause Hemolytic Reactions ...Signs & Symptoms Apprehension; Chills, Headache, fever; Pain in back, abdomen, or chest, or at infusion site; Respiratory distress, peripheral circulatory collapse, shock; Disseminated intravascular

	coagulation; hypotension, tachycardia; hemoglobinemia, hemoglobinuria. Specific Considerations Follow steps on 'Suspected Transfusion Reaction' ..." 2. The laboratory policy titled "Transfusion Reaction Investigation Procedure-PHS" (Approved by the laboratory director 05/31/2022) stated, "V. Procedure Instructions ...C ...If it's a mild allergic reaction (i.e., only itching, hives, flushing), the implicated blood product is not required to be brought back to the blood bank ...". This laboratory policy failed to define any other signs and symptoms of a transfusion reaction to be consistent with the facility policy. 3. Review of Patient 2059989 records from October 29, 2022, through October 30, 2022, revealed the facility failed to promptly identify the signs and symptoms of a hemolytic transfusion reaction per the facility policy (chills, pain in abdomen, respiratory distress, and tachycardia) and promptly report the reaction to the laboratory. See D3025, #2. 4. In an interview on June 27, 2023, at 3:00 pm, the Laboratory Director, after review of the documentation, confirmed the findings.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedures, quality control (QC) records, and interview with Testing Person #9 and General Supervisor #5 , as listed on the CMS-209, the laboratory failed to evaluate patient test results back to the last acceptable QC run, for 7 of 31 days in April 2023. A) A review of the laboratory policy and procedure ("General Quality Control Policy", QUAL 30, 12/14/2022) revealed that "patient test results obtained in an analytically unacceptable test run or since the last acceptable test run must be re-evaluated to determine if there is a significant clinical difference in patient results by the Laboratory/Medical Director." B) A review of the laboratory's quality control record revealed the following: Date /Time; Control Name; Flags 04/07/2023 13:08; for brain natriuretic peptide (BNP); recalibration Last acceptable quality control 04/06/2023 09:12. Total volume of specimens analyzed 8; identified as numbers 360-367 on a separate patient identification list. 04/07/2023 22:29; creatinine (CREJ); recalibration Last acceptable quality control 04/15/2023 08:40. Total volume of specimens analyzed: 291; identified as numbers 5-295 on a separate patient identification list. 04/08/2023 17:10; human chorionic gonadotropin (HCG); recalibration Last acceptable quality control 04 /07/2023 at 09:01. Total volume of specimens analyzed: 4; identified as numbers 1-4 on a separate patient identification list. 04/10/2023 16:35 pm; lipase (LIP); recalibration Last acceptable quality control 04/09/2023 10:14. Total volume of specimens analyzed: 23; identified as numbers 334-357 on a separate patient identification list. 04/16/2023 02:43; troponin (TNT); recalibration Last acceptable quality control 04/06/2023 at 09:12. Total volume of specimens analyzed: 37; identified as numbers 296-333 on a separate patient identification list. 04/18/2023 22: 33; vancomycin (VANK); recalibration Last acceptable quality control 04/17/2023 19: 56. Total volume of specimens analyzed: 2; identified as numbers 368-369 on a separate patient identification list. 04/19/2023 14:44; HCG; recalibration Last

	acceptable quality control 04/18/2023 19:54. Total volume of specimens analyzed: 2; identified as numbers 358-359 on a separate patient identification list. C) The laboratory was asked to provide documentation of patient evaluation back to the last acceptable QC. No documentation was provided. D) In an interview on 06/28/2023 at 12:48, Testing Person #9, as listed on the CMS 209 form, confirmed that no patient assessments were performed for chemistry in April of 2023. In an interview on 06/29 /2023 at 13:08, General Supervisor #5, as listed on the CMS-209, stated that patient assessment following recalibration of the chemistry instrumentation was not performed as required for the above events and dates.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory policy, transfusion audit records, and confirmed in interview, the laboratory failed to ensure an effective quality assurance (QA) program was in place to monitor, assess, and correct problems in the laboratory for the specialty of immunohematology. Findings included: 1. Review of the laboratory policy titled "Blood Bank-Nursing Transfusion Audit Procedure" stated the following: "Purpose/Purpose/Principal A. In order to maximize transfusion safety and promote interaction and opportunity for education between nursing and blood bank, blood bank personnel will monitor transfusions on a periodic basis. B. Documentation of transfusion monitoring will be evaluated to identify areas needing improvement ...IV. Procedure Instructions A. Blood Bank staff will accompany a dispensed blood component to the ward or unit on which it will be transfused. B. The blood bank employee will sign off on the 'Blood Bank/Nursing Transfusion Audit' check list item by item, indicating if and what corrective action was necessary and/or taken ..." 2. Review of the "Blood Bank Nursing Transfusion Audit Form" revealed the following lines with a box for "Y" (yes) and "N" (no): "Transfusion Audit Checklist: 1. Order in computer 15. Evidence of adverse reaction If yes, a. Transfusion stopped (for symptoms other than urticaria/hives/skin rash) b. Transfusion reaction protocol completed." Date of Audit: 08/26/2022; Patient1384218 Transfusion Audit Checklist: "1. Order in computer" Neither Y nor N was checked in the box for this line. "15. Evidence of adverse reaction " Neither Y nor N was checked in the box for this line. "If yes, a. Transfusion stopped (for symptoms other than urticaria/hives/skin rash)" This box was checked as Y (yes). "b. Transfusion reaction protocol completed." This box was checked as Y (yes). This audit form was signed as reviewed by the Blood Bank Supervisor on 09/21/2022 with a score of 100% and submitted to the unit charge nurse on 09/30/2022. Date of Audit: 12/28/2022; Patient 2425774 Transfusion Audit Checklist: "15. Evidence of adverse reaction" This box was checked as Y (yes). "If yes, a. Transfusion stopped (for symptoms other than urticaria/hives/skin rash)" This box was checked as Y (yes). "b. Transfusion reaction protocol completed." This box was checked as Y (yes). This audit form was signed as reviewed by the Blood Bank Supervisor on 01/17/2023 with a score of 100% and submitted to the unit charge nurse on 01/17/2023. Date of Audit: 03/31/2023; Patient 1694442 Transfusion Audit Checklist: "15. Evidence of adverse reaction" Neither Y nor N was checked in the box

	for this line. "If yes, a. Transfusion stopped (for symptoms other than urticaria/hives /skin rash)" This box was checked as Y (yes). "b. Transfusion reaction protocol completed." This box was checked as Y (yes). This audit form was signed as reviewed by the Blood Bank Supervisor on 04/23/2023 with a score of 100% and submitted to the unit charge nurse on 05/08/2023. 2. A review of the three patients' transfusion records was performed with the Interim Director for Patient Safety and Clinical Excellence on 06/28/2023 at 3:00 pm. The patient records were reviewed for documentation that the transfusions were stopped, and that transfusion reaction protocol was completed. No documentation was provided. The laboratory failed to ensure an effective quality assurance (QA) program to assess problems related to transfusion medicine. 3. In an interview with on 06/29/2023 at 1:30 pm, the Associate Director for Presbyterian Laboratory System, after review of the documentation, confirmed the findings.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid (CMS) 209 personnel form, review of personnel records, and confirmed in an interview, the laboratory failed to ensure that 2 of 13 technical consultants met the qualification requirements of 493.1411. Refer to D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived

	testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid (CMS) 209 personnel form, review of personnel records, and confirmed in an interview, the laboratory failed to ensure education and experience requirements for 2 of 13 technical consultants (TC) for moderate complexity testing. Findings included: 1. Review of the CMS 209 form revealed the laboratory listed two technical consultants (TC-6 & TC-7) for the specialties of Chemistry and Hematology 2. Personnel records for the individual listed as TC-6 revealed educational documents provided did not meet the qualifications for a TC. 3. Personnel records for the individuals listed as TC-6 and TC-7 were not provided to meet experience requirements for serving as a TC. 4. In an interview on 6/29/2023 at 1:55pm in the conference room, TC-7 confirmed the above findings.
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 the Centers for Medicare and Medicaid (CMS) 209 personnel form, review of personnel records, and confirmed in staff interview, the laboratory failed to ensure that testing personnel met the qualification requirements specified at 493.1421 for 11 of 64 personnel performing moderate complexity testing. Refer to 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 the Centers For Medicare and Medicaid (CMS) 209 personnel form, review of personnel records, and confirmed in an interview, the laboratory failed to ensure that testing personnel met the qualification requirements specified at 493.1423 for 11of 64 testing personnel. Findings included: 1. Review of the CMS 209 form revealed the following patient testing personnel (TP): a) TP#24 b) TP#31 c) TP#34 d) TP#40 e) TP#41 f) TP#49 g) TP#50 h) TP#56 i) TP#57 j) TP#58 k) TP#59 2. The laboratory was asked to provide education records for the above personnel. No records were provided. 3. In a staff interview on 6/28/2023 at 1:10pm in the conference room, human resources representatives confirmed the above findings.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory and facility's policies, patient transfusion records, and confirmed in interview, the laboratory director failed to provide overall management and direction. The laboratory director failed to ensure immunohematology systems provided quality services. Refer to D6082.
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 review of policies/procedures, patient records, and confirmed in interview, the laboratory director failed to ensure immunohematology systems provided quality services, as evidenced by: 1. The laboratory failed to provide a policy (signed by the laboratory director) for the performance of 3 of 3 anti-human globulin (AHG) crossmatches performed at the laboratory. Refer to D5551. 2. The laboratory failed to promptly identify and investigate transfusion reactions in its facility for which it had investigational responsibility and make recommendations to medical staff regarding improvements in transfusion procedures for 1 of 1 blood transfusion reactions in October 2022. Refer to D5559. 3. The laboratory failed to ensure an effective quality assurance (QA) program was in place to monitor, assess, and correct problems in the laboratory for immunohematology. Refer to D5793.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification

	requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on review of the CMS-209, the laboratory failed to have a technical supervisor who met the qualification requirements of 493.1449 of this subpart. Refer to D6111.
D6111	TECHNICAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1449 (a) The technical supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor-- (b)(1) Is a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or Possesses qualifications that are equivalent to those required for such certification. (c) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of bacteriology, the individual functioning as the technical supervisor must-- (c)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (c)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (c)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (c)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (c)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (c)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; and (c)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology. (d) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycobacteriology, the individual functioning as the technical supervisor must-- (d)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (d)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or

possess qualifications that are equivalent to those required for such certification; or (d)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor or podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (d)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (d)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (d)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (d)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology. (e) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycology, the individual functioning as the technical supervisor must-- (e)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (e)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (e)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (e)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (e)(3)(ii) Have at least 1 year of laboratory training or experience, or both in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (e)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (e)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology. (f) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of parasitology, the individual functioning as the technical supervisor must-- (f)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (f)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic

Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (f)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (f)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; (f)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (f)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or (f)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (f)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or (f)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (f)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology. (g) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of virology, the individual functioning as the technical supervisor must-- (g)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (g)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (g)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (g)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (g)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (g)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (g)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology. (h) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of diagnostic immunology, the individual functioning as the technical supervisor must- (h)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (h)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic

Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (h)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (h)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or (h)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (h)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of diagnostic immunology; or (h)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (h)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or (h)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (h)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology. (i) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of chemistry, the individual functioning as the technical supervisor must-- (i)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (i)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (i)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (i)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or (i)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (i)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of chemistry; or (i)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (i)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or (i)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (i)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry. (j) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of hematology, the individual functioning as the technical supervisor must-- (j)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (j)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (j)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (j)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of hematology (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (j)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (j)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of hematology; or (j)(4)(i) Have earned a master's degree in a chemical,

physical, biological or clinical laboratory science or medical technology from an accredited institution; and (j)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology; or (j)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (j)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology. (k)(1) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of cytology, the individual functioning as the technical supervisor must-- (k)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (k)(1)(ii) Meet one of the following requirements-- (k)(1)(ii)(A) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (k)(1)(ii)(B) Be certified by the American Society of Cytology to practice cytopathology or possess qualifications that are equivalent to those required for such certification; (l) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of histopathology, the individual functioning as the technical supervisor must-- (l)(1) Meet one of the following requirements: (l)(1)(i)(A) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (l)(1)(i)(B) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (l)(1)(ii) An individual qualified under 493.1449(b) or paragraph (l)(1) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (l)(1)(i)(B) of this section, the responsibility for examination and interpretation of histopathology specimens. (l)(2) For tests in dermatopathology, meet one of the following requirements: (l)(2)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (l)(2)(i)(B) Meet one of the following requirements: (l)(2)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(i)(B)(2) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(i)(B)(3) Be certified in dermatology by the American Board of Dermatology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(ii) An individual qualified under 493.1449(b) or paragraph (l)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (l)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens. (l)(3) For tests in ophthalmic pathology, meet one of the following requirements: (l)(3)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (l)(3)(i)(B) Must meet one of the following requirements: (l)(3)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(3)(i)(B)(2) Be certified by the American Board of Ophthalmology or possess qualifications that are equivalent to those required for such certification and have successfully completed at least 1 year of formal post-residency fellowship training in ophthalmic pathology; or (l)(3)(ii) An individual qualified under 493.1449(b) or paragraph (1)(3)(i) of this section may delegate to an individual who is a resident in a

training program leading to certification specified in paragraphs (b) or (1)(3)(i)(B) of this section, the responsibility for examination and interpretation of ophthalmic specimens; or (m) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of oral pathology, the individual functioning as the technical supervisor must meet one of the following requirements: (m)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (m)(1)(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (m)(2) Be certified in oral pathology by the American Board of Oral Pathology or possess qualifications for such certification; or (m)(3) An individual qualified under 493.1449(b) or paragraph (m)(1) or (2) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (m)(1) or (2) of this section, the responsibility for examination and interpretation of oral pathology specimens. (n) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of radiobioassay, the individual functioning as the technical supervisor must-- (n)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (n)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (n)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (n)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or (n)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (n)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of radiobioassay; or (n)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (n)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or (n)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (n)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay. (o) If the laboratory performs tests in the specialty of histocompatibility, the individual functioning as the technical supervisor must either-- (o)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (o)(1)(ii) Have training or experience that meets one of the following requirements: (o)(1)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (o)(1)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(1)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility; or (o)(2)(i) Have an earned doctoral degree in a biological or clinical laboratory science from an accredited institution; and (o)(2)(ii) Have training or experience that meets one of the following requirements: (o)(2)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (o)(2)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(2)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility. (p) If the laboratory performs tests in the specialty of clinical

	cytogenetics, the individual functioning as the technical supervisor must-- (p)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (p)(1)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or (p)(2)(i) Hold an earned doctoral degree in a biological science, including biochemistry, or clinical laboratory science from an accredited institution; and (p)(2)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics. (q) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of immunohematology, the individual functioning as the technical supervisor must-- (q)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (q)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (q)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (q)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of immunohematology. Note: The technical supervisor requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service. For example, an individual, who has a doctoral degree in chemistry and additionally has documentation of 1 year of laboratory experience working concurrently in high complexity testing in the specialties of microbiology and chemistry and 6 months of that work experience included high complexity testing in bacteriology, mycology, and mycobacteriology, would qualify as the technical supervisor for the specialty of chemistry and the subspecialties of bacteriology, mycology, and mycobacteriology. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS 209, review of personnel records, and confirmed in an interview, the laboratory failed to employ a technical supervisor (TS) who met the qualifications to provide technical oversight of high complexity testing. Findings included: 1. A review of the CMS 209 form included two individuals listed as the TS (TS-4 & TS-5) for providing oversight of high complexity testing (subspecialties of Chemistry and Hematology). 2. Personnel records for the individual listed as TS-4 revealed educational documents provided did not meet the qualifications for a TS. 3. Personnel records for the individuals listed as TS-4 and TS-5 were not provided to meet experience requirements for a TS. 4. In an interview on 6/29/2023 at 1:55pm in the conference room, TS-5 confirmed the above findings
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by:

	Based on review of Centers for Medicare and Medicaid (CMS) 209 form, personnel records, and interview with staff, the Technical Supervisor (TS-5) failed to perform the annual competency evaluations for 1 of 64 testing persons (TP-61) in the specialty of Chemistry. Findings included: 1. Review of the submitted CMS 209 form revealed Testing Person 61 listed to perform chemistry testing. 2. Review of personnel records from 2021 through 2022 revealed the following: a. Testing Person #61 No documentation of annual competency assessment for 2021 was provided. The Technical Supervisor did NOT document competency assessment for TP-61 to include: a) Direct observation of routine patient test performance, including patient preparation, specimen handling, processing and testing. b) Monitoring the recording and reporting of patient test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens or external proficient testing samples. f) Assessment of problem solving skills. 3. In an interview on 06/29/2023 at 1033 hours in the conference room, Technical Supervisor 5 was asked to provide documentation of 2021 annual competency for Testing Person #61. No documentation was provided. This confirmed the above findings.
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by: Based on review of CMS-209, personnel records, and confirmed in an interview, the laboratory failed to ensure 2 of 9 general supervisors met the qualification requirements. Refer to D6143.
D6143	GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461 (a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry 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; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(2); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under 493.1462 on or before February 28, 1992. (c)(3)(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December

31, 1987, qualifies as a general supervisor if he or she meets the requirements of 493. 1462 on or before January 1, 1994. (c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995-- (c)(4)(i) Meet one of the following requirements: (c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS. (c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. 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). (c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or (c)(5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and-- (c)(5)(i) Be a high school graduate or equivalent; and (c)(5)(ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3)(i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l) or (2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(1)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(m).

This STANDARD is not met as evidenced by:
Based on review of CMS 209, personnel records and confirmed in an interview, the laboratory failed to ensure 2 of 9 General Supervisors (GS-6 & GS-7) met the education and experience requirements to provide day-to-day supervision of testing personnel and reporting of test results for high complexity testing. Findings included: 1. Review of the CMS 209 form revealed the laboratory listed two General Supervisors (GS-6 and GS-7) for providing day-to-day supervision of testing personnel and reporting of test results. 2. Review of personnel records for GS-6 revealed the educational documents provided by the laboratory did not meet the qualifications for a GS. 3. Personnel records for the individuals listed as GS-6 and GS-7 were not provided to meet experience requirements for a GS. 4. In an interview on 6/29/2023 at 1:55pm in the conference room, GS-7 confirmed the above findings.