Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0410407	05/14/2026
Name of Provider or Supplier	**Street Address, City, State**	
St Peters Health	2475 Broadway, Helena, MT	

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 Montana CLIA Program conducted an announced CLIA recertification survey ending on May 14, 2026. The laboratory was found out of compliance with the following conditions: 493.1210 Condition: Routine chemistry. 493.1217 Condition: Immunohematology. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of College of American Pathology (CAP) proficiency testing records and interview with the general supervisor (GS1), the laboratory failed to have an attestation form signed by the laboratory director for 11of 36 proficiency testing events from June 25, 2024, to May 13, 2026. Findings: 1. A review of 2024 and 2025 CAP proficiency testing records for the blood bank sections revealed the absence of signed Attestation Statements by the laboratory director for the following events: AHIV-B 2024 Anti-HIV 1/2 DAT-B 2024 Direct Antiglobulin Test S-B 2024 Diagnostic Immunology HBF-B 2024 Fetal RBC Detection G-B 2024 Syphilis Serology G-C 2024 Syphilis Serology J-B 2024 Transfusion Medicine (Comp) RBCAT-B 2024 Red Blood Cell Antigen Typing S-A 2025 Diagnostic Immunology J-A 2025 Transfusion Medicine (Comp) RBCAT-A 2025 Red Blood Cell Antigen Typing 2. A review of the "Laboratory Designation of Authority" policy revealed the laboratory failed to have the laboratory director sign the attestation for blood bank as stated, "The Technical Supervisor is assigned as the designee for the entering and reviewing of proficiency testing results excluding Blood Bank". 3. An interview with

	GS1 on May 13, 2026, at 3:50 PM confirmed the laboratory did not obtain signed attestation forms from the laboratory director for the eleven events listed above from June 25, 2024, to May 13, 2026.
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on record review, laboratory procedure, and interview with technical supervisor (TS6) and general supervisor (GS1), the laboratory failed to ensure the requirements for the specialty of chemistry for the Point of Care Testing Department. Findings: 1. The laboratory failed to follow its procedure for conducting competency assessments. (Refer to D5209) 2. The laboratory failed to follow its Individualized Quality Control Plan (IQCP) to perform external quality control every month or with each new lot of reagents for three of three moderate complexity cartridges performed on the i STAT. (Refer to D5401). 3. The laboratory failed to perform comparison studies twice a year and define the relationship between the test results using seven of seven Abbott i-STAT analyzers. (Refer to D5775). 4. The laboratory failed to perform corrective action for missed external quality control checks to ensure patients tested and results reported with three of three cartridges performed on the i STAT were not adversely affected. (Refer to D5783).
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 observation, record review, laboratory procedure, and interview with general supervisor (GS2), the laboratory failed to ensure the requirements for the specialty of immunohematology. Findings: 1. The laboratory failed to follow its procedure for conducting competency assessments. (Refer to D5209) 2. The laboratory failed to verify the accuracy of the educational challenges for 14 of 14 proficiency testing events (Refer to D5215). 3. The laboratory failed to follow their procedures to have their emergency release forms signed by a physician (Refer to D5553). 4. The laboratory failed to follow its procedure to perform and document quarterly alarm checks for one of one blood bank refrigerator and freezer (Refer to D5555).
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

	This STANDARD is not met as evidenced by: Based on a record review, laboratory policy, the CMS 209 Laboratory Personnel Report and interviews with the General Supervisor (GS2) and Technical Supervisor (TS6), the laboratory failed to follow its procedure for conducting competency assessments for 72 out of 99 testing personnel (TP) from May 11, 2024 to May 14, 2026. Findings: 1. A review of the competency records for blood bank revealed GS2 failed to have annual competency assessment with the six required procedures for the years 2024 and 2025 2. An interview with GS2 on May 13, 2025, at 6:15 PM, confirmed their competency assessments were not performed for years 2024 and 2025. 3. A review of the Point of Care Testing (POCT) competency assessment records and the testing personnel (TP) listed on the CMS 209 Form revealed the following: For 2024, 63 of 71 POCT testing personnel did not have records of a competency assessment: TP18-TP27, TP32, TP35-TP41, TP43-TP57, TP61-TP70, and TP72-TP91. For 2025, 71 of 71 POCT testing personnel did not have records of a competency assessment: TP18-TP41 and TP43-TP91. 4. A review of the "Laboratory Quality Management" policy revealed the laboratory did not follow its stated requirements for competency assessment. The policy states "Competence assessment defined program for competence assessments for all personnel who perform laboratory testing" and requires "evidence of competence assessment for organization-wide POCT personnel." 5. An interview with TS6 on May 14, 2026, at 3:30 PM confirmed the laboratory did not perform competency assessments per their policy for 72 out of 99 testing personnel from May 11, 2024 to May 14, 2026.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of College of American Pathology (CAP) proficiency testing records for the blood bank section and interview with the general supervisor (GS1), the laboratory failed to verify the accuracy of the educational challenges for 14 of 14 proficiency testing events from March 12, 2024, to May 13, 2026. Findings: 1. A review of 2024 and 2025 CAP proficiency testing records for the blood bank section revealed no documented verification of the accuracy of the educational challenges for the following events: S-B 2024 Diagnostic Immunology S-C 2024 Diagnostic Immunology HBF-A 2024 Fetal RBC Detection J-A 2024 Transfusion Medicine (Comp) J-B 2024 Transfusion Medicine (Comp) J-C 2024 Transfusion Medicine (Comp) RBCAT-A 2024 Red Blood Cell Antigen Typing RBCAT-B 2024 Red Blood Cell Antigen Typing J-A 2025 Transfusion Medicine (Comp) J-B 2025 Transfusion Medicine (Comp)(J) J-C 2025 Transfusion Medicine (Comp)(J) J-C 2025 Transfusion Medicine (Comp)(JE1) S-A 2025 Diagnostic Immunology S-C 2025 Diagnostic Immunology 2. A review of the "Laboratory Quality Management" policy revealed no defined process for reviewing proficiency testing records to verify the accuracy of

	educational challenges. 3. An interview with GS1 on May 13, 2026, at 3:55 PM confirmed that the laboratory did not verify the accuracy of the educational challenges for the events listed above from March 12, 2024, to May 13, 2026.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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 record review, policy and interview with the technical supervisor (TS6), the laboratory failed to follow its Individualized Quality Control Plan (IQCP) to perform external quality control every month or with each new lot of reagents for three of three moderate complexity cartridges performed on the i STAT from January 1, 2025, to May 14, 2026. Findings: 1. A review of the IQCP's "Quality Control Plan: i STAT" stated, "External Controls: Two levels of control material are run monthly or upon start of a new lot of reagents." The point of care testing (POCT) department failed to have monthly external quality control for the following i-STAT cartridges: i STAT PT plus (Prothrombin Time) i STAT CHEM8+ (Sodium, Potassium, Chloride, Ionized Calcium, Glucose, Blood Urea Nitrogen, Creatinine, Total Carbon Dioxide, Hematocrit) i STAT CG4+ (pH, Partial pressure of oxygen, Partial pressure of carbon dioxide, Lactate) 2. A review of i STAT external quality control records in the Remote Access Laboratory System (RALS) interface engine revealed the lack of external quality control during the following periods: i STAT PT plus from January 1, 2025 to May 14, 2025 (17 of 17 months) i STAT CHEM8+ from January 1, 2025 to April 30, 2025, June 1, 2025 to January 31, 2026, and March 1, 2026 to April 30, 2026 (15 of 17 months) i STAT CG4+ from January 1, 2025 to April 30, 2025, June 1, 2025 to January 31, 2026, and March 1, 2026 to April 30, 2026 (15 of 17 months) 3. During an interview with TS6 on May 14, 2026, at 2:40 PM, TS6 confirmed the point of care testing staff did not perform external quality control monthly, or with each new cartridge lot from January 1, 2025 to May 14, 2026. During the same interview at 2:45 PM, TS6 stated 549 CHEM8+, 106 CG4+, and 201 PT/INR patient tests were performed from May 6, 2025 to May 6, 2026 .
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation, a review of the manufacturer's product insert, and an interview with the technical supervisor (TS5), the laboratory failed to label two of two vials of quality control (QC) material with the opened date and the open vial stability expiration date on May 12, 2026. Findings: 1. Observed during a tour of the

	Hematology department on May 12, 2026, at 7:15 AM, two quality control vials (UF Control H and UF Control L) used on the Sysmex UF 5000 analyzer were not labeled with the opened date or the 30 day stability expiration date required by the manufacturer. 2. A review of the UF Control package insert showed, "Storage and shelf life after first opening. Once opened, product stability is 30 days at 2-8C." 3. An interview conducted on May 12, 2026, at 7:20 AM with TS5 confirmed the UF Controls were not labeled with the opened date or the open vial stability expiration date on May 12, 2026.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and an interview with Technical Supervisor (TS3), the laboratory failed to verify the normal reference ranges were appropriate for the laboratory's patient population for 32 of 32 analytes performed on the Atellica IM 1300 Analyzer prior to reporting patient test results from May 23, 2025, to May 13, 2026. Findings: 1. A review of performance verification records for two Atellica IM 1300 analyzers, signed by the laboratory director on May 23, 2025, did not include studies verifying the appropriateness of normal reference ranges for the following 32 analytes: Acetaminophen, Amphetamines, Barbiturates, Benzodiazepines, Cannabinoids, Carbamazepine, Cocaine Metabolite, Cortisol, Digoxin, Alcohol, Estradiol, Follicle Stimulating Hormone (FSH), Gentamicin, Luteinizing Hormone, Lithium, Methadone, Opiates, Parathyroid Hormone, Phenobarbital, Phencyclidine, Phenytoin, Progesterone, Prostate Specific Antigen (PSA), Salicylate, Testosterone, Theophylline, Thyroid Stimulating Hormone (TSH), Tobramycin, Tramadol, Tricyclic Antidepressants, Valproic acid , and Vancomycin. 2. A review of the Test Volume Sheet showed the following number of patient tests performed from May 6, 2025, to May 6, 2026: Acetaminophen (2117), Amphetamines (3257), Barbiturates (3257), Benzodiazepines (3257), Cannabinoids (3257), Carbamazepine (77), Cocaine Metabolite (3257), Cortisol (872), Digoxin (119), Alcohol (3634), Estradiol (3496), FSH (1426), Gentamicin (28), Lithium (859), Luteinizing Hormone (2467), Methadone (3257), Opiates (3257), Parathyroid Hormone (2467), Phenobarbital (14), Phencyclidine (3257), Phenytoin total (66), Progesterone (3496), PSA (8316), Salicylate (2049), Testosterone (1050), Theophylline (8), TSH (11,866), Tobramycin (2), Tricyclic Antidepressants (2), Valproic acid total (339), and Vancomycin (719). 3. During an interview on May 13, 2026, at 10:30 AM, TS3 confirmed the laboratory had not verified the normal reference ranges for the 32 analytes listed above from May 23, 2025, to May 13, 2026.
D5553	IMMUNOHEMATOLOGY CFR(s): 493.1271(b)(f) (b) Immunohematological testing and distribution of blood and blood products. Blood

	and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b). This STANDARD is not met as evidenced by: Based on record review of immunohematology and interview with the general supervisor (GS2), the laboratory failed to follow their procedures to have their emergency release forms signed by a physician for eleven of eleven patients transfused with nineteen of nineteen Packed Red Blood Cells (PRBC) units from August 13, 2024, to May 2, 2026. Findings: 1. A review of the "Emergency Release of Uncross Matched Blood" procedure stated, "the records must contain a signed statement from the requesting physician." The laboratory failed to obtain a physician ' s signature on the "Emergency Release/Massive Transfusion Documentation Form" or the "Emergency Release Form" for the following dates on which PRBC units were transfused: 1/16/2025 - One unit: W186624096449 2/2/2025 - One unit: W186625205014 3/1/2025 - One unit: W186625199016 5/7/2025 - One unit: W186625199329 6/18/2025 - Two units: W186625220477, W186625221404 6/25 /2025 - Two units: W186625231015, W186625225180 8/10/2025 - Three units: W186625260284, W186625256776, W186625212079 10/2/2025 - Two units: W186625275398, W186625275410 10/11/2025 - Two units: W186625266905, W186625266891 5/2/2026 - Two units: W186626359820, W186626390350 8/13 /2024 - Two units: W186624039324, W186624071495 2. An interview with GS2 on May 13, 2026 at 9:45 PM confirmed the laboratory failed to follow their procedure to have their emergency release forms signed by a physician for eleven patients transfused with nineteen Packed Red Blood Cells (PRBC) units from August 13, 2024, to May 2, 2026.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. This STANDARD is not met as evidenced by: Based on observation, record review of immunohematology, and an interview with the General Supervisor (GS2), the laboratory failed to follow its procedure to perform and document quarterly alarm checks for one of one blood bank refrigerator and freezer containing 86 units of blood and blood products intended for patient transfusion from May 13, 2024, to May 13, 2026. Findings: 1. Observed in the laboratory on May 13, 2026 at 6:30 PM, one Helmer refrigerator containing six group O Rh(D)-negative Red Blood Cells (RBC), twenty O Rh(D)-positive RBC, six A Rh (D)-negative RBC, fifteen A Rh(D)-positive RBC, two B Rh(D)-negative RBC and four B Rh(D)-positive RBC and one Helmer freezer containing eight O, A, and AB Fresh Frozen Plasma (FFP), six B FFP, two Frozen Cryoprecipitated Antihemophilic Factor and one Platelet. 2. A review of the "Freezer Maintenance and Alarm Testing" procedure revealed staff failed to perform and document the manual alarm test as stated: "Replace the alarm and temperature probes and note the temperature at which the alarm sounds, with a corresponding fluctuation on the temperature chart monitor," and "Record the results in the Blood Bank QC manual." 3. A review of the

	laboratory's alarm check documents revealed staff failed to perform the quarterly manual alarm check for one refrigerator and one freezer and failed to document the temperature at which the alarm sounds from May 13, 2024, to May 13, 2026. 4. An interview with GS2 on May 13, 2026, at 7:00 PM confirmed the laboratory is required to perform quarterly alarm checks and that staff did not manually check the temperature at which the alarm sounds for the freezer or refrigerator for years 2024 and 2025. 5. No procedure for the refrigerator's alarm check was available for review. 6. A review of the Test Volume Report revealed 756 compatibility tests were performed from May 6, 2025 to May 6, 2026 (12 months).
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on record review, policy review, and interview with technical supervisor (TS6), the laboratory failed to perform comparison studies twice a year and define the relationship between the test results using seven of seven Abbott i-STAT analyzers from May 14, 2024, to May 14, 2026. Findings: 1. A review of records showed no comparison studies between the seven Abbott i-STAT for the i STAT PT plus (Prothrombin Time); i STAT CHEM8+ (Sodium, Potassium, Chloride, Ionized Calcium, Glucose, Blood Urea Nitrogen, Creatinine, Total Carbon Dioxide, Hematocrit); and i STAT CG4+ (pH, Partial pressure of oxygen, Partial pressure of carbon dioxide, Lactate) were available for review for years 2024 and 2025. 2. A review of the "Laboratory Quality Management" policy failed to include instructions for comparison studies, including written criteria for acceptable differences in test values between the seven Abbott i STAT analyzers. 3. An interview with TS6 on May 14, 2026, at 2:50 PM confirmed the laboratory failed to perform comparison studies twice a year and define the relationship of test results between seven Abbott i-STAT analyzers from May 14, 2024, to May 14, 2026. 4. The 2025 test volume from May 6, 2025, to May 6, 2026, included 549 CHEM tests, 106 CG4 tests, and 201 PT/INR tests.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (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 quality control records, policies, and interview with technical supervisor (TS6), the laboratory failed to perform corrective action for missed external quality control checks to ensure patients tested and results reported with three

	of three cartridges performed on the i STAT were not adversely affected from January 1, 2025 to May 14, 2026. Findings: 1. A review of records lacked corrective action documents for the Abbott i STAT PT plus (Prothrombin Time); i STAT CHEM8+ (Sodium, Potassium, Chloride, Ionized Calcium, Glucose, Blood Urea Nitrogen, Creatinine, Total Carbon Dioxide, Hematocrit); and i STAT CG4+ (pH, Partial pressure of oxygen, Partial pressure of carbon dioxide, Lactate) missed monthly external quality control checks. (Cross Refer D5401) 2. A review of records showed no evaluation of patient test results to ensure patients were not adversely affected since the last acceptable external quality control was available for review. 3. A review of the "Laboratory Quality Management" policy, signed by the laboratory director, revealed the policy did not define corrective action for missed external quality controls or review of patient results since the last acceptable external control. 4. An interview with TS6 on May 14, 2026, at 2:45 PM, confirmed the laboratory did not perform corrective action for missed external quality control checks or an evaluation to ensure patients tested on the i-STAT were not adversely affected from January 1, 2025, to May 14, 2026. 5. The 2025 test volume from May 6, 2025, to May 6, 2026, included 549 CHEM tests, 106 CG4 tests, and 201 PT/INR tests.
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 record review, and interview with technical supervisor (TS6) and general supervisor (GS1), the laboratory failed to ensure six of six testing personnel met the qualification requirements for performing moderate testing for the Point of Care Testing Department. (Refer to 6065)
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 (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on record review, laboratory procedure, and interviews with technical supervisor (TS6) and general supervisor (GS1), the laboratory failed to ensure that six

	of six testing personnel met the qualification requirements to perform moderate complexity testing on the i STAT analyzer in the Point of Care Testing Department from May 14, 2024, to May 14, 2026. Findings: 1. No educational records were available for testing personnel TP45, TP46, TP48, TP50, TP51, and TP69. 2. A review of the "Laboratory Quality Management" policy showed, "7. Personnel files - Development and maintenance of lab personnel files: c. Documentation of highest level of education received for those doing moderately and highly complex testing. The laboratory failed to have documentation of the highest level of education for testing personnel performing moderate tests on the i-STAT analyzer. 3. During an interview with TS6 and GS1 on May 14, 2026, at 1:30 PM, TS6 and GS1 confirmed they failed to obtain the six testing personnel's educational documentation prior to testing from May 14, 2024 to May 14, 2026.
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 record review, procedures, and interviews with technical supervisor (TS6) and general supervisors (GS2), the laboratory director failed to provide overall management and direction in accordance with 493.1445. Findings: 1. The laboratory director failed to ensure the requirements for the specialty of Chemistry for the Point of Care Testing Department. (Refer to D5016) 2. The laboratory director failed to ensure the requirements for the specialty of Immunohematology. (Refer to D5026) 3. The laboratory director failed to ensure six of six testing personnel met the qualification requirements for performing moderate testing for the Point of Care Testing Department. (Refer to 6065) 4. The laboratory director failed to ensure blood bank documentation was reviewed and all necessary remedial action were taken and documented. (Refer to 6096)
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratorys established performance characteristics are identified, and This STANDARD is not met as evidenced by: Based on record review of immunohematology and interview with general supervisor (GS2), the laboratory director failed to ensure blood bank documentation was reviewed and all necessary remedial action was taken and documented from May 13, 2024 to May 13, 2026. Findings: 1. A review of the laboratory ' s "Emergency Release /Massive Transfusion Documentation Form" and "Emergency Release Form" showed no documented remedial action for missing physician signatures for eleven patients who received PRBC transfusions (Cross-Reference D5553). 2. A review of the patient ' s (X006956854) Emergency Release/Massive Transfusion Documentation form, dated 1/16/2025, showed the justification, "unit given after previous transfusion reaction." No remedial action for the transfusion reaction was documented. 3. A

	record review of the Emergency Release/Massive Transfusion documentation for patient X007628745 revealed discrepant information was identified for two units (W1866 26 366525 and W1866 26 356053), and the records lacked remedial action and review. A. For unit W1866 26 366525, the first Emergency Release/Massive Transfusion record documented, "W1866 26 366525 JH @ 1750 - RETURNED (UNUSED, EMS had in pocket)" with a crossed out entry dated 02/11/26 referencing the first set of blood. A second document recorded, "W186626366525 JH @ 1750 - 02 /10/2026 1845 (partial) EMS EN ROUTE". SoftBank data listed the same unit as issued on 02/10/2026 at 18:36 to patient X006782745. B. For unit W1866 26 356053, the first Emergency Release/Massive Transfusion record documented, "W1866 26 356053 JH @ 1750 2/10/26 1845," and the second document recorded, "W186626356053 JH @ 1750 RETURNED UNUSED (Temp = 3-7C / 02 10 2026) @ 2134." SoftBank data listed two separate issue events for this unit: a final issue on 02/11/2026 at 07:03 to patient X007628745 and an additional issue on 02/11/2026 at 10:17 to patient X006986263. 4. An interview with GS2 on May 13, 2026, at 10:00 PM confirmed the laboratory director failed to ensure blood bank documentation was reviewed and all necessary remedial action was taken and documented from May 13, 2024 to May 13, 2026.