Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0499104	08/20/2025
Name of Provider or Supplier	**Street Address, City, State**	
Peterson Regional Medical Center	551 Hill Country Drive, Kerrville, TX	

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	Based on a validation survey completed August 20, 2025, the laboratory was found to out of compliance with the CLIA regulations found at 42 CFR 493 CLIA requirements. The following conditions were n not met: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel;
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on a review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, the College of American Pathologist proficiency testing (PT) records, and confirmed in interview, the

	laboratory failed to achieve successful performance in two of two consecutive testing events for 2024 and 2025, resulting in unsuccessful performance for D (Rho) typing, refer to D2162, resulting in an overall unsuccessful performance for the specialty of ABO group and D(Rho) typing, see D2163.
D2162	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(f) (f) Failure to achieve satisfactory performance for the same analyte in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, the College of American Pathologist proficiency testing (PT) records for 2024 and 2025, the laboratory failed to achieve an overall testing event score of satisfactory performance (at least 100%) for two of two consecutive testing events for the D (Rho) typing. Two out of two testing event scores of unsatisfactory performance results in unsuccessful PT performance. The findings included: 1. A review of the CASPER Report 155 listed the following scores for D (Rho) typing: D (Rho) typing, 2024 Event 3 - 80% D (Rho) typing, 2025 Event 1 - 80% 2. A review of the College of American Pathologist records proficiency testing records for 2024 and 2025 confirmed that the laboratory received a D(Rho) typing score of less than 100% for D (Rho) typing for the 2024 3rd event and 2025 1st events. 3. In an interview on 8/19/2025 at 1435 hours, in the conference room, the blood bank supervisory confirmed the findings.
D2163	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(g) (g) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, the College of American Pathologist proficiency testing (PT) records for 2024 and 2025, the laboratory failed to achieve an overall testing event score of satisfactory performance (at least 100%) for two of two consecutive testing events for the specialty of ABO group and D(Rho) typing. Two out of two overall testing event scores of unsatisfactory performance results in unsuccessful specialty PT performance. The findings included: 1. A review of the CASPER Report 155 listed the following scores for the PT Program specialty: ABO/D(Rho), 2024 Event 3, 90% ABO/D(Rho), 2025 Event 1, 80% 2. A review of the College of American Pathologist records proficiency testing records for 2024 event 3, and 2025 event 1 confirmed that the laboratory received an ABO grouping and D(Rho) typing overall specialty scored less than 100% for the 3rd 2024 event and the 1st 2025 events. 3. In an interview on 8/19/2025 at 1435 hours, in the conference room, the blood bank supervisory confirmed the findings.
D3031	RETENTION REQUIREMENTS

	CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based upon review of Hematology quality control records, and interview of facility personnel, the laboratory failed to retain Hematology quality control records for 12 of 12 months in 2024. The findings included: 1. Review of Hematology quality control records found no quality control records available to review between January and December 2024. 2. During interview of the technical consultant for Core Lab conducted August 20, 2025 at 11:42 AM, she confirmed that she had discarded all records for 2024 after the survey conducted by the accredition agency on May 28, 2025.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) (d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on review of laboratory materials provided to laboratory clients, laboratory policy, direct observation, laboratory patient requisitions, and confirmed in interview, the laboratory failed to define acceptable storage and transport to ensure the specimen integrity of client referral specimens for 39 of 39 patients received for testing observed on 8/19/2025 and 8/20/2025. The findings included: 1. In a tour of the laboratory on 8/19/2025 at 09:20 hours, the laboratory administrative director confirmed client specimens were received for testing through out the day for testing. 2. Review of the laboratory materials provided to laboratory clients included a specimen requisition and the laboratory policy titled "Collection Manual/Specimen Requirements", that did not include instructions to clients for the acceptable storage and preservation of the specimen, or the conditions for specimen transport to the laboratory for testing. 3. During direct observation of specimen drop offs on 8/19 /2025 and 8/20/2025, included a cooler with the following patient specimens received into the laboratory for testing: 8/19/2025 at 16:50 hours; 19 patients including the following 6 patients: V Number; Tests Ordered V00309865814; urine culture V00309865665; glycohemoglobin, CBC, CMP, CK V00309865624; TSH, FT3 V00309865442; Hemoglobin solubility - Sickle cell V00309865582; CBC, CK, Lipid Panel, Iron, TIBC, TSH, T4F, CA125 V00309865178; ESR, CRP, ANA Titer, RF, Anti-CCP, Anti-SMXX, Glycohemoglobin 8/20/2025 at 10:10 hours; 20 patients including the following 6 patients: V Number; Tests Ordered V00309867521; PSA V00309867414; PSA V00309860831; Uric acid, CBC with manual differential, Folic Acid, Vitamin B 12 V00309867257; CBC, CMP, Urinalysis, Lipid, Microalbumin Creatinine, glycohemoglobin hemoglobin A1C V00309867281; CMP, CBC, Lipid panel V00309867125; PSA, Free PSA On 8/19/2025 at 1650 hours, in the laboratory receiving area, the surveyor asked if the coolers were monitored to maintain a specific temperature. The laboratory accession person stated the laboratory provided the

	coolers with two to three ice packs for specimen transport, but the temperature of the coolers or specimens were not monitored or confirmed. 4. In an interview on 8/20 /2025 at 11:25 hours, in the office, the laboratory administrative director confirmed that the laboratory collection policy and outpatient order requisitions did not define specimen storage and transport requirements for acceptability. Key: CBC - complete blood count CMP - comprehensive metabolic panel CK - creatinine kinase TSH - thyroid stimulating hormone FT3 - Triiodothryronine, Free T4F - Thyroxine, Free CA125 - Cancer Antigen 125 ESR - Erythrocyte sedimentation rate CRP - C reactive protein ANA - Anti-nuclear Antibody RF - Rheumatoid factor Anti-CCP - Anti-Cyclic Citrullinated Peptide Anti-SMXX, - Anti-Smith PSA - Prostate Specific Antigen
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 upon review of policies and procedures, review of manufacturer's instructions and interview of facility personnel, the laboratory failed to have a procedure to establish the mean normal prothrombin time (MNPT) with each new lot of Innovin used for international normalized Ratio (INR) calculations in 2024 and 2025. The findings included: 1. Review of policies and procedures found no written procedure available to testing personnel for establishing the MNPT with each new lot of Innovin used for calculation of the INR. 2. Review of the Dade Innovin instructions for use found on pages 2-3: "The mean normal prothrombin time (MNPT) is defined as the mean value of the normal range. It must be determined specifically for each thromboplastin lot using the method used for the analysis. Follow appropriate laboratory guidelines for establishing an MNPT, if applicable. For US customers the appropriate CLSI guideline is recommended." Further review found on page 5 under Interfering substances: "Many commonly administered drugs may affect the results obtained in prothrombin time testing. This should be kept in mind especially when unusual or unexpected abnormal results are obtained." 3. During interview of the technical consultant for the core lab conducted August 20 12:17 PM, she confirmed that the laboratory did not have a procedure for establishing an MNPT for each new lot of innovin, and did not have a means to gather donor age, sex and medication history to ensure they were not used in the MNPT establishment.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on review of laboratory blood bank policy, laboratory testing records, laboratory quality control records, and confirmed in interview, the laboratory failed to document QC for four of four patients with Fetal Cell Stains performed in 2024. The findings included: 1. Review of the laboratory blood bank procedure titled "Fetal Cell

	Stain", section "Procedure" included the following instructions: "N. Meditech a. Go into the Laboratory > Worksheets > create. b. Create the FETSTAIN worksheet. Click OK. c. The Controls will automatically be ordered on the worksheet as well as the patient sample. d. Laboratory > Specimen Desktop. Click on Worklist > workbatch > L > FETSTAIN > T > F9 to look at number. Click OK. O. Control Slides 1. Look at Pos(itive) Control first. a. Verify that there are fetal bright pink cells in adult cells pale pink- ghostly looking. You need a good contrast between the two. b. In Meditech, on the FETSTAIN worksheet, check the control box and Enter Results. c. Result the KB-Pos ctrl with a "P" if the slide is appropriately stained and you see a good contrast between pink and ghost cells. d. Result with an "X" if the slide does not give a good contrast between the pink and the ghost cells and then re-stain all of your slides. 2. Look at the Neg(ative) Control slide next. a. Verify there are no fetal cells observed. No bright pink cells observed. b. Result the KB- neg control on the FETSTAIN worksheet with an "N" if the slide is appropriately stained and you see no fetal cells. Result with an "X" if the side does not give the correct result and then re-stain all of your slides." 2. Review of blood bank testing records for patients with Fetal Cell Stain testing performed in 2024 included the following four patients: Test Date: V-Number 04/24/2024: V00307625582 08/21/2024: V00307870998 10/02/2024: V00308280726 10/29/2024: V00308509223 Surveyor asked to see the quality control documentation for the above patients, and none could be provided. 3. In an interview on 8/20/2025 at 09:30 hours, in the blood bank, the blood bank supervisor confirmed that quality control had not been documented for the above patients in 2024.
D5543	HEMATOLOGY CFR(s): 493.1269(a)(d) (a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. This STANDARD is not met as evidenced by: Based upon review of policies and procedures, quality control records patient test records and interview of facility personnel, the laboratory failed to test quality control samples in duplicate when performing manual cell counts on 29 of 31 days in December 2024. The findings included: 1. Review of the laboratory's written policy titled Body Fluid Cell Count Automated and Manual (approved 04/10/2025) found on page 9: "Manual Body Fluid Quality controls will be run every 8 hours or by technologist." Further review found on page 15: "NOTE: Cell counts must be performed in duplicate." 2. Review of 29 Cell Count worksheets for December 2024 found the laboratory did not document two cell counts for quality control materials used for testing manual cell counts. 3. Review of patient test records found 30 patient specimens were tested for manual cell counts in December 2024. 4. During interview of the technical consultant for the core lab conducted August 19, 2025 at 2:37 PM, she confirmed the laboratory did not perform duplicate cell counts on quality control specimens by each technologist every 8 hours in December 2024.
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: Review of laboratory policy, patient records, personnel files, and confirmed in interview, the laboratory failed ensure four out of four testing personnel met the qualification requirements to perform the moderate complexity "Bleeding Time" procedure for patients tested from June 1, 2023, to June 1, 2025. See D6065 I.
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: I. Review of laboratory policy, patient records, personnel files, and confirmed in interview, the laboratory failed to have four out of four testing personnel qualified to perform the moderate complexity "Bleeding Time" procedure for 29 of 29 patients tested from June 1, 2023, to June 1, 2025. The findings included: 1. Review of the laboratory phlebotomy manual included the following moderate complexity procedure using the Surgicutt device: "LAB-PHLEB Bleeding Time" Review of the laboratory test include the bleeding time on the laboratory test menu as a moderate complexity test. 2. Surveyor asked for the list of testing personnel performing the test and their qualifications. The laboratory administrative director provided the following list of personnel performing bleeding times, along with their personnel files: Testing Personnel (TP) 34 TP35 TP36 TP37 Review of the above testing personnel files did not include education, training, and competencies. 3. Review of patient testing from June 1, 2023 to June, 1, 2025 included 29 patients where the bleeding time procedure had been performed and reported to include the following: Date Performed V Number Testing Person 07/19/2023 V00306384298 TP34 08/02/2023 V00306442757 TP34 08 /15/2023 V00306509498 TP36 08/17/2025 V00306520925 TP35 08/18/2025 V00306526484 TP37 08/29/2023 V00306570466 TP35 08/31/2023 V00306582362 TP35 10/09/2023 V00306748286 TP34 08/18/2023 V00306756933 TP35 11/28/2023 V00306974080 TP35 12/06/2023 V00307015578 TP35 01/22/2024 V00307206839 TP35 01/29/2024 V00307243881 TP35 02/01/2024 V00307213900 TP34 03/13/2024 V00307450684 TP35 04/25/2024 V00307642884 TP35 05/15/2024 V00307738880 TP35 05/30/2024 V00307804609 TP34 06/13/2024 V00307828202 TP35 06/27/2024 V00307933655 TP34 06/28/2024 V00307940023 TP34 07/30/2024 V00308088285 TP35 09/09/2024 V00308277938 TP34 09/11/2024 V00308289776 TP34 10/21/2024 V00308476225 TP35 10/29/2024 V00308484658 TP35 11/26/2024 V00308651595 TP34 04/25/2025 V00309335263 TP34 05/21/2025 V00309458958 TP35 4. In an

	interview on 8/20/2025 at 10:50 hours, in the conference room, the laboratory administrative director confirmed the above. II. Based on review of laboratory policy, personnel records, and confirmed in interview, the laboratory failed to ensure one of five testing personnel met minimum qualifications for moderate point of care testing reviewed from October 2023 through May 2025. The findings included: 1. Review of the laboratory policy titled "LAB-GEN Personnel Orientation, Files, Records, Training and Competency" included the following instructions: "N. Personnel records are maintained in the laboratory and/or Human Resources; the records include: 1. Summary of training and experience 2. Copy of academic degree or transcript 3. License, if required by State 4. Certification, if required by State.." 2. Random review of laboratory personnel performing moderate complexity point of care testing (POCT) on the Hemochrom Signature Elite analyzer (ACT Testing), and the NOVA Prime Pulse (O2 sat and Hgb testing) included the following POCT testing personnel (TP) who's personnel file did not include documentation of education: POCT TP 8 Surveyor asked for education documentation to support the testing personnels performance of moderate complexity testing and none was provided. 3. Review of testing records included the following 24 patients, and 39 tests, performed by POCT TP 8 from October 2023 through May 2025: Date Performed V Number Test 10/04 /2023 V00306720004 ACT 10/04/2023 V00306720004 ACT 10/04/2023 V00306720004 ACT 11/10/2023 V00306892019 ACT 05/14/2024 V00307556571 ACT 08/14/2024 V00308148360 ACT 08/14/2024 V00308148360 ACT 09/04/2024 V00308192293 ACT 09/04/2024 V00308192293 ACT 10/09/2024 V00308417823 ACT 11/16/2024 V00308596105 O2 and Hgb 11/16/2024 V00308602218 ACT 12/07 /2024 V00308695758 ACT 12/25/2024 V00308779651 ACT 12/26/2024 V00308779941 ACT 12/26/2024 V00308779941 ACT 01/23/2025 V00308898469 ACT 01/23/2025 V00308898469 ACT 02/03/2025 V00308944685 ACT 02/04/2025 V00308947936 ACT 02/04/2025 V00308947936 ACT 02/04/2025 V00308947936 ACT 02/09/2025 V00308974336 ACT 02/23/2025 V00309036879 ACT 02/23/2025 V00309038222 ACT 02/23/2025 V00309038222 ACT 03/24/2025 V00309176253 ACT 04/02/2025 V00309221174 ACT 04/04/2025 V00309238350 ACT 04/13/2025 V00309274967 ACT 04/19/2025 V00309306850 ACT 04/19/2025 V00309306850 ACT 04/19/2025 V00309306850 ACT 04/19/2025 V00309306850 ACT 04/24/2025 V00309236809 ACT 05/22/2025 V00309455236 ACT 05/25/2025 V00309473239 ACT 05/25/2025 V00309473239 ACT 05/30/2025 V00309491728 ACT 4. In an interview on 8/20/2025 at 16:00, in the conference room, the point of care coordinator confirmed the laboratory did not have education records for the above point of care testing personnel.