Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0498371	02/07/2023
Name of Provider or Supplier	**Street Address, City, State**	
Clinical Pathology Laboratories, Inc	3131 University Drive East, Bryan, 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	The facility was found to be in COMPLIANCE with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on Center for Medicaid Services (CMS) 116 form, review of American Proficiency Institute (API) Proficiency Testing (PT) Immunohematology events in 2022 and confirmed in staff interview, the laboratory failed to have documentation of verifying the accuracy of analytes that were not graded by the proficiency testing program for 1 of 3 events in 2022 (2nd Event). Findings included: 1. Review of CMS-116 form, submitted at time of survey, revealed the laboratory performed 115 immunohematology samples annually. 2. Review of API Immunohematology 2022 PT (Events 1,2 and 3) revealed the following event with an ungraded performance: API Immunohematology 2nd Event Compatibility Sample: SER-06 Reported Result: Incompatible/AHG Expected Result: Incompatible Performance: Not Graded Further review of API PT Immunohematology 2nd event performance review revealed the following written statement: "Not required. Scored 100% on all samples tested on this survey." Signed by the Laboratory Director on 09/27/2022. The laboratory failed to

	have documentation of verifying the accuracy of analytes that were not graded by the proficiency testing program for 1 of 3 events in 2022 (2nd Event). 3. During an interview on 02/06/2023 at 10:15 p.m., with the General Supervisor (GS-1) in the laboratory office, GS-1 confirmed the above findings.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of Center for Medicare & Medicaid Services (CMS) 209 form, laboratory records and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessment for histology specimens for 2 of 2 events for testing person 1 (TP-1) in 2022. Findings Included: 1. Review of CMS-209 form submitted at time of survey, revealed 1 testing person (TP-1) for the specialty of histology (also the Laboratory Director). 2. Review of laboratory records from 2022 revealed no documentation of twice annual accuracy assessment performed in 2022 for TP-1. 3. During a telephone interview on 02/07 /2023 at 10:20 a.m., in the laboratory office with TP-1 (Laboratory Director), TP-1 confirmed the laboratory failed to have documentation of performing twice annual accuracy assessment for histology specimens for 2 of 2 events for testing person 1 (TP-1) in 2022.
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: I. Based on review of Center for Medicaid Services (CMS) 116 form, American Proficiency Institute (API) Proficiency Testing (PT) Immunohematology events in 2022, laboratory policy and confirmed in staff interview, the laboratory failed to follow their own policy for documentation of analytes that were not graded by the proficiency testing program for 1 of 3 events in 2022 (2nd Event). Findings Included: 1. Review of CMS-116 form revealed the laboratory performed 115 immunohematology samples annually. 2. Review of API Immunohematology 2022 PT (Events 1,2 and 3) revealed the following event with an ungraded performance: API Immunohematology 2nd Event Compatibility Sample: SER-06 Reported Result: Incompatible/AHG Expected Result: Incompatible Performance: Not Graded Further review of API PT Immunohematology 2nd event performance review revealed the following written statement: "Not required. Scored 100% on all samples tested on this survey." Signed by the Laboratory Director on 09/27/2022. 3. Review of laboratory policy, "CPLREG08SOP Regional Lab Proficiency Testing Policy and Procedure" (Approved by the Laboratory Director on 12/06/2022) revealed the following: "5.2.4 Review of Survey Results and Remedial Action, as indicated 5.2.4.6 If ungraded results are noted, they will be evaluated to include: Whenever possible, peer or

	method comparisons will be performed. Findings will be documented on the Proficiency Test Evaluation Form for Ungraded Results and Educational Challenges. All PT results should be reviewed and evaluated by the Laboratory Director or designee in a timely manner." The inspector asked the General Supervisor (GS-1) to provide the Proficiency Testing Evaluation Form for Ungraded results, and no documentation was provided. 4. During an interview on 02/06/2023 at 10:15 p.m., with the General Supervisor (GS-1) in the laboratory office, GS-1 confirmed the laboratory failed to follow their own policy for documentation of analytes that were not graded by the proficiency testing program for 1 of 3 events in 2022 (2nd Event). II. Based on review of laboratory policy, chemistry quality control (QC) logs, QC corrective action documentation, patient records, and confirmed in interview, the laboratory failed to follow their own policy for evaluating all patient test results for QC failures and since the last acceptable QC run to ensure accurate and reliable test results for 9 of 9 CO2 patients tested on the Roche Cobas 6000 analyzer on 10/19 /2022. Findings Included: 1. Review of laboratory policy, "CPLREG11SOP Regional Laboratory Quality Control Policy" (Approved by the Laboratory Director on 12/06 /2022) revealed the following: "6.2.2 QC Failure Action 6.2.2.1 When possible, patient test results obtained in an analytically unacceptable test run or since the last acceptable test run must be evaluated to determine if there is a significant clinical difference in patient results." 2. Review of laboratory Roche 6000 Chemistry QC logs and corrective action documentation revealed QC failures for the following QC test event in October 2022: 10/20/2022 BioRad Liquid Assay Multiqual Quality Control Levels 1,2 and 3 Lot Number: 45930; Expiration: 07/31/2024 Analytes: CO2 (Bicarbonate) Review of the Chemistry Quality Control Problem Log revealed the following: 10/20/2022 Analyte: CO2 Level 2: 10.7 Expected Value: 10.77-18.77 Level 3: 18.3 Expected Value: 20.15-31.75 Actions Taken: Reran; Fresh Control Reran; Recalibrate Supervisor Review: Signed by TC-1 on 11/21/2022 3. The following 9 patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run when QC failures were documented on 10/20/2022: Performed on: 10/19/2022 Analyte: CO2 Unit Number: M098680;M093624; M086235;M010338;M096660;M092959;M098717;M064695;M098703 4. During an interview on 02/06/2023 at 12:20 p.m., with the Technical Consultant (TC-1) in the laboratory office, TC-1 confirmed the laboratory failed to follow their own policy for evaluating all patient test results for QC failures and since the last acceptable QC run to ensure accurate and reliable test results for 9 of 9 CO2 patients tested on the Roche Cobas 6000 analyzer on 10/19/2022.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: I. Based on direct observation, review of operator's manual, laboratory policy, laboratory environmental records, and confirmed in interview, the laboratory failed to ensure room temperature ranges were within operating specifications for the Roche

Cobas 6000 analyzer for 2 of 2 months in 2022 (random review 10/2022 and 11 /2022). Findings Included: 1. During a tour of the laboratory on 02/06/2023 at 08:00 a. m., the inspector observed 1 Roche 6000 analyzer (Serial Number: 2184-20) in the main laboratory area processing patient specimens. 2. Review of Roche Cobas 6000 Analyzer Series Operator's Manual (Version 8.2) revealed the following acceptable operating temperature range: "Environmental Conditions The following environmental conditions should be followed in order to ensure correct operation of this system: Ambient temperature During operation: 18 to 32 C with changes greater than or equal to 2 C" 3. Review of laboratory policy, "CPLREG21SOP Regional Lab Temperature and Humidity Monitoring Procedure" (Approved by the Laboratory Director on 12/06/2022) revealed the following: "Purpose: 1.1 Temperature and humidity monitoring helps ensure instruments, reagents, and specimens are meeting designated temperature specifications. The lab must ensure these specifications are met. Falling outside these ranges could compromise the integrity of results.. 3.3 Room Temperature 3.3.1 The acceptable temperature for room temperature areas will be based on the equipment and supplies located in the area. When calculating the range for the area, use the most restrictive range." 4. Review of laboratory environmental records for 10/2022 and 11/2022 revealed the main laboratory temperature range was 15-32 C. The laboratory failed to ensure room temperature ranges were within operating specifications for the Roche Cobas 6000 analyzer for 2 of 2 months in 2022. 5. During an interview on 02/06/2023 at 12:30 p.m., with the Technical Consultant (TC-1) in the laboratory office, TC-1 confirmed the above findings. Word Key: C-Celsius II. Based on direct observation, review of operator's manual, laboratory policy, laboratory environmental records, and confirmed in interview, the laboratory failed to ensure room temperature ranges were within operating specifications for the Roche Cobas e411 analyzer for 2 of 2 months in 2022 (random review 10/2022 and 11 /2022). Findings Included: 1. During a tour of the laboratory on 02/06/2023 at 08:00 a. m., the inspector observed 1 Roche e411 analyzer (Serial Number: 8719-01) in the main laboratory area processing patient specimens. 2. Review of Roche Cobas e411 Analyzer Series Operator's Manual (Version 3.3.1) revealed the following acceptable operating temperature range: "Environmental Conditions Temperature Operation: 18 to 32 C" 3. Review of laboratory policy, "CPLREG21SOP Regional Lab Temperature and Humidity Monitoring Procedure" (Approved by the Laboratory Director on 12/06 /2022) revealed the following: "Purpose: 1.1 Temperature and humidity monitoring helps ensure instruments, reagents, and specimens are meeting designated temperature specifications. The lab must ensure these specifications are met. Falling outside these ranges could compromise the integrity of results.. 3.3 Room Temperature 3.3.1 The acceptable temperature for room temperature areas will be based on the equipment and supplies located in the area. When calculating the range for the area, use the most restrictive range." 4. Review of laboratory environmental records for 10/2022 and 11 /2022 revealed the main laboratory temperature range was 15-32 C. The laboratory failed to ensure room temperature ranges were within operating specifications for the Roche Cobas e411 analyzer for 2 of 2 months in 2022. 5. During an interview on 02 /06/2023 at 12:30 p.m., with the Technical Consultant (TC-1) in the laboratory office, TC-1 confirmed the above findings. III. Based on direct observation, manufacturer's instructions, review of laboratory policy, laboratory environmental records, and confirmed in interview, the laboratory failed to ensure room temperature ranges were within manufacturer's specifications for the BioRad Liquid Assay Multiqual Quality Control for 2 of 2 months in 2022 (random review 10/2022 and 11/2022). Findings Included: 1. During a tour of the laboratory on 02/07/2023 at 11:00 a.m., the inspector observed 3 levels (1,2 and 3) of BioRad Liquid Assayed Multiqual Quality Control (Lot Number: 45930) in the laboratory refrigerator. 2. Review of BioRad Liquid Assay Multiqual Quality Control Instructions for Use (Lot Number: 45930;

Expiration: 07/31/2024) revealed the following acceptable room temperature range: "Procedure: If the product has been stored refrigerated, allow it to reach room temperature (18 to 25 C) before use." 3. Review of laboratory policy, "CPLREG21SOP Regional Lab Temperature and Humidity Monitoring Procedure" (Approved by the Laboratory Director on 12/06/2022) revealed the following: "Purpose: 1.1 Temperature and humidity monitoring helps ensure instruments, reagents, and specimens are meeting designated temperature specifications. The lab must ensure these specifications are met. Falling outside these ranges could compromise the integrity of results.. 3.3 Room Temperature 3.3.1 The acceptable temperature for room temperature areas will be based on the equipment and supplies located in the area. When calculating the range for the area, use the most restrictive range." 4. Review of laboratory environmental records for 10/2022 and 11/2022 revealed the main laboratory temperature range was 15-32 C. The laboratory failed to ensure room temperature ranges were within manufacturer's specifications for the BioRad Liquid Assay Multiqual Quality Control for 2 of 2 months in 2022. 5. During an interview on 02/06/2023 at 12:30 p.m., with the Technical Consultant (TC-1) in the laboratory office, TC-1 confirmed the above findings. IV. Based on direct observation, review of operator's manual, laboratory policy, laboratory environmental records, and confirmed in interview, the laboratory failed to ensure room temperature ranges were within operating specifications for the Sysmex XS-1000i automated hematology analyzer for 2 of 2 months in 2022 (random review 10/2022 and 11/2022). Findings Included: 1. During a tour of the laboratory on 02/06/2023 at 08:00 a.m., the inspector observed 1 Sysmex XS-1000i analyzer (Serial Number: 65233) in the main laboratory area processing patient specimens. 2. Review of Sysmex XS-1000i Automated Hematology Analyzer Instructions for Use (Last Revision: April 2009) revealed the following acceptable operating temperature range: "Installation Environment Operate the XS-100i/XS-800i within ambient temperature range of 15C-30C" 3. Review of laboratory policy, "CPLREG21SOP Regional Lab Temperature and Humidity Monitoring Procedure" (Approved by the Laboratory Director on 12/06/2022) revealed the following: "Purpose: 1.1 Temperature and humidity monitoring helps ensure instruments, reagents, and specimens are meeting designated temperature specifications. The lab must ensure these specifications are met. Falling outside these ranges could compromise the integrity of results.. 3.3 Room Temperature 3.3.1 The acceptable temperature for room temperature areas will be based on the equipment and supplies located in the area. When calculating the range for the area, use the most restrictive range." 4. Review of laboratory environmental records for 10/2022 and 11/2022 revealed the main laboratory temperature range was 15-32 C. The laboratory failed to ensure room temperature ranges were within operating specifications for the Sysmex XS-1000i automated hematology analyzer for 2 of 2 months in 2022. 5. During an interview on 02/06/2023 at 12:30 p.m., with the Technical Consultant (TC-1) in the laboratory office, TC-1 confirmed the above findings. V. Based on direct observation, review of manufacturer's instructions, laboratory policy, laboratory environmental records, and confirmed in interview, the laboratory failed to ensure room temperature ranges were within manufacturer's specifications for the Hemosil RecombiPlastin Prothrombin Time reagent for 2 of 2 months in 2022 (random review 10/2022 and 11/2022). Findings Included: 1. During a tour of the laboratory on 02/06/2023 at 08:00 a.m., the inspector observed 1 ACL coagulation analyzer (Serial Number: 955670) in the main laboratory area processing patient prothrombin time (PT) specimens. 2. Review of Hemosil Recombiplastin PT reagent instructions for use (Last Revision: 03/2019) revealed the following acceptable room temperature range: "Preparation: 1. Allow each vial of Recombiplastin 2G and Recombiplastin 2G Diluent to equilibrate at 15-25 C for at least 15 minutes before reconstituting the lyophilized reagent with the diluent." 3. Review of laboratory policy,

"CPLREG21SOP Regional Lab Temperature and Humidity Monitoring Procedure" (Approved by the Laboratory Director on 12/06/2022) revealed the following: "Purpose: 1.1 Temperature and humidity monitoring helps ensure instruments, reagents, and specimens are meeting designated temperature specifications. The lab must ensure these specifications are met. Falling outside these ranges could compromise the integrity of results.. 3.3 Room Temperature 3.3.1 The acceptable temperature for room temperature areas will be based on the equipment and supplies located in the area. When calculating the range for the area, use the most restrictive range." 4. Review of laboratory environmental records for 10/2022 and 11/2022 revealed the main laboratory temperature range was 15-32 C. The laboratory failed to ensure room temperature ranges were within manufacturer's specifications for the Hemosil RecombiPlastin Prothrombin Time reagent for 2 of 2 months in 2022. 5. During an interview on 02/06/2023 at 12:30 p.m., with the Technical Consultant (TC-1) in the laboratory office, TC-1 confirmed the above findings. VI. Based on direct observation, review of manufacturer's instructions, laboratory policy, laboratory environmental records, and confirmed in interview, the laboratory failed to ensure room temperature ranges were within manufacturer's specifications for the Hemosil Routine Coagulation Quality Control (Levels 1 and 3) reagent for 2 of 2 months in 2022 (random review 10/2022 and 11/2022). Findings Included: 1. During a tour of the laboratory on 02/06/2023 at 08:00 a.m., the inspector observed 1 ACL coagulation analyzer (Serial Number: 955670) in the main laboratory area processing patient specimens. 2. Review of Hemosil Routine Coagulation Quality Control Levels 1 and 3 instructions for use (Last Revision: 2016) revealed the following acceptable room temperature range: "Preparation: Keep the control at 15-25 C for 30 minutes and invert to mix before use." 3. Review of laboratory policy, "CPLREG21SOP Regional Lab Temperature and Humidity Monitoring Procedure" (Approved by the Laboratory Director on 12/06/2022) revealed the following: "Purpose: 1.1 Temperature and humidity monitoring helps ensure instruments, reagents, and specimens are meeting designated temperature specifications. The lab must ensure these specifications are met. Falling outside these ranges could compromise the integrity of results.. 3.3 Room Temperature 3.3.1 The acceptable temperature for room temperature areas will be based on the equipment and supplies located in the area. When calculating the range for the area, use the most restrictive range." 4. Review of laboratory environmental records for 10/2022 and 11/2022 revealed the main laboratory temperature range was 15-32 C. The laboratory failed to ensure room temperature ranges were within manufacturer's specifications for the Hemosil Routine Coagulation Quality Control (Levels 1 and 3) reagent for 2 of 2 months in 2022. 5. During an interview on 02/06 /2023 at 12:30 p.m., with the Technical Consultant (TC-1) in the laboratory office, TC-1 confirmed the above findings. VII. Based on direct observation, review of laboratory policy, laboratory environmental records, and confirmed in interview, the laboratory failed to ensure room temperature ranges were within manufacturer's specifications for the Roche e411 ProCell and CleanCell reagents for 2 of 2 months in 2022 (random review 10/2022 and 11/2022). Findings Included: 1. During a tour of the laboratory on 02/06/2023 at 08:00 a.m., the inspector observed 1 Roche e411 analyzer (Serial Number: 8719-01) in the main laboratory area processing patient specimens. Further observation revealed bottles of ProCell and CleanCell reagents stored on the shelf underneath the e411 analyzer. ProCell Amount: 9 bottles Lot Number: 66071701 Expiration: 02/29/24 Storage Temperature: 15-25 C CleanCell Amount: 9 bottles Lot Number: 63802101 Expiration: 02/29/24 Storage Temperature: 15-25 C 2. Review of laboratory policy, "CPLREG21SOP Regional Lab Temperature and Humidity Monitoring Procedure" (Approved by the Laboratory Director on 12/06 /2022) revealed the following: "Purpose: 1.1 Temperature and humidity monitoring helps ensure instruments, reagents, and specimens are meeting designated temperature

	specifications. The lab must ensure these specifications are met. Falling outside these ranges could compromise the integrity of results.. 3.3 Room Temperature 3.3.1 The acceptable temperature for room temperature areas will be based on the equipment and supplies located in the area. When calculating the range for the area, use the most restrictive range." 3. Review of laboratory environmental records for 10/2022 and 11 /2022 revealed the main laboratory temperature range was 15-32 C. The laboratory failed to ensure room temperature ranges were within manufacturer's specifications for the Roche e411 ProCell and CleanCell reagents for 2 of 2 months in 2022 (random review 10/2022 and 11/2022). 4. During an interview on 02/06/2023 at 12:30 p.m., with the Technical Consultant (TC-1) in the laboratory office, TC-1 confirmed the above findings.
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 Center for Medicare & Medicaid Services (CMS) 116 form, Daily Quality Control (QC) logs, patient requisitions and confirmed in staff interview, the laboratory failed to test staining materials for intended reactivity to ensure the predictable staining characteristics for Hematoxylin & Eosin (H&E) prior to patient analysis for 2 of 2 patients reviewed in 2021. Findings Included: 1. Review of CMS-116 for submitted at time of survey revealed 4 histology specimens are performed annually. 2. Review of Daily QC logs and patient requisitions revealed the following dates H&E QC was not documented prior to patient testing: 01/15/2021 Unit Number: M089876 Stain Performed: H&E Stain QC Adequacy: Not documented 08/16/2021 Unit Number: M093867 Stain Performed: H&E Stain QC Adequacy: Not documented The laboratory failed to test staining materials for intended reactivity to ensure the predictable staining characteristics for Hematoxylin & Eosin (H&E) prior to patient analysis for 2 of 2 patients reviewed in 2021. 3. During a telephone interview on 02/07 /2023 at 10:20 a.m., in the laboratory office with TP-1 (Laboratory Director), TP-1 confirmed the above 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 laboratory policy, chemistry quality control (QC) logs, QC

	corrective action documentation, patient records, and confirmed in interview, the laboratory failed to evaluate all patient test results after performing test system adjustments for QC failures and since the last acceptable QC run to ensure accurate and reliable test results for 9 of 9 CO2 patients tested on the Roche Cobas 6000 analyzer on 10/19/2022. Findings Included: 1. Review of laboratory policy, "CPLREG11SOP Regional Laboratory Quality Control Policy" (Approved by the Laboratory Director on 12/06/2022) revealed the following: "6.2.2 QC Failure Action 6.2.2.1 When possible, patient test results obtained in an analytically unacceptable test run or since the last acceptable test run must be evaluated to determine if there is a significant clinical difference in patient results." 2. Review of laboratory Roche 6000 Chemistry QC logs and corrective action documentation revealed test system adjustments performed for the following QC test event in October 2022: 10/20/2022 BioRad Liquid Assay Multiqual Quality Control Levels 1,2 and 3 Lot Number: 45930; Expiration: 07/31/2024 Analytes: CO2 (Bicarbonate) Review of the Chemistry Quality Control Problem Log revealed the following: 10/20/2022 Analyte: CO2 Level 2: 10.7 Expected Value: 10.77-18.77 Level 3: 18.3 Expected Value: 20.15-31.75 Actions Taken: Reran; Fresh Control Reran; Recalibrate Supervisor Review: Signed by TC-1 on 11/21/2022 3. The following 9 patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run when test system adjustments were performed (10/19/2022): Analyte: CO2 Unit Number: M098680; M093624;M086235;M010338;M096660;M092959;M098717;M064695;M098703 4. During an interview on 02/06/2023 at 12:20 p.m., with the Technical Consultant (TC-1) in the laboratory office, TC-1 confirmed the laboratory failed to evaluate all patient test results after performing test system adjustments for QC failures and since the last acceptable QC run to ensure accurate and reliable test results for 9 of 9 CO2 patients tested on the Roche Cobas 6000 analyzer on 10/19/2022.
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 Center for Medicare & Medicaid Services (CMS) 209 form, laboratory policy, personnel records, and confirmed in staff interview, the technical supervisor (TS) failed to evaluate and document the annual competency for 1 of 3 Testing Persons (TP-2) responsible for high complexity testing in 2022. Findings Included: 1. Review of CMS 209 form submitted at time of survey, revealed the specialty of Immunohematology was performed by Testing Persons 1 (TP-1) through TP-3. 2. The laboratory policy, "CPLSW450567POL LabGen Competency Assessment Protocol" (Approved by the Laboratory Director on 12/06/2022) revealed the laboratory failed to include a policy for annual competency assessment. 3. Review of TP-2 personnel records revealed the following competency assessment dates for Immunohematology (Blood Bank): Initial Competency Assessment: 06/16/2021 6 Month Competency Assessment: 12/27/2021 Annual Competency Assessment: 07/07 /2022 Days passed annual competency due date: 21 Days The Technical Supervisor (TS-1) failed to evaluate competency annually in 2022 for 1 of 3 Testing Persons (TP-2) who perform high complexity testing in Immunohematology in 2022. 4. During a

	phone interview on 02/07/2023 at 01:00 p.m., with the Technical Supervisor (TS-1) in the laboratory office, TS-1 confirmed the above findings.