Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D2097807	05/14/2021
Name of Provider or Supplier	**Street Address, City, State**	
Precision Clinical Laboratory	11275 E Mississippi Ave, Ste 2wi, Aurora, CO	

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
D3001	FACILITIES CFR(s): 493.1101(a)(1) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process. This STANDARD is not met as evidenced by: Based on direct observation, and Testing Personnel (TP) #2 interview, the laboratory failed to be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process. Findings include: 1. Direct observation of the laboratory space on May 10, 2021, at approximately 10:00 AM, showed untidy work areas and inadequate workbench space. 2. Observation of TP #2 test performance on May 10, 2021, at approximately 11:15 AM showed equipment tops being used as workbench space. 3. Interview with TP #2 on May 10, 2021, at approximately 11:30 AM confirmed that the laboratory failed to have adequate space and workbenches in all areas. 4. The laboratory performs approximately 131,160 tests annually.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by:

	Based on the number and severity of the deficiencies cited herein, the Condition: Analytic Systems was not met. The laboratory failed to have written microbiology procedure manuals available to laboratory personnel (see D5401), failed to follow the manufacturer's instructions for it's prothrombin time reagent used on the ACL Elite coagulation analyzer to test patient prothrombin time (PT) specimens (see D5411), failed to monitor and document the temperature of the refrigerator where patient samples were stored and failed to define the acceptable temperature ranges on the temperature document for the molecular testing laboratory (see D5413), failed to replace laboratory supplies when they had exceeded their expiration date (see D5417), failed to establish control procedures or develop an Individualized Quality Control Plan (IQCP) to check each batch or shipment of microbiology agar media before or concurrent with initial use (see D5445), failed to have documented quality control for its C. difficile, HIV, Influenza, and Strep A testing (see D5449), failed to check each lot number of gram-negative and gram-positive identification and susceptibility cards for the Vitek for positive and negative reactivity from the period reviewed since December 2020 (see D5471).
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 direct observation, and Testing Personnel (TP) #2 interview, the laboratory failed to have written microbiology procedure manuals available to laboratory personnel. Findings include: 1. On May 10, 2021, at approximately 1:00 PM the following tests kits, were observed: Alere C.difficile Tox A/B Quik Chek, Alere HIV-1/2 Ag/Ab Combo, McKesson Consult Influenza A & B Test, McKesson Rapid Test Kit Consult Strep A Test. 2. No procedure manuals were available for these tests upon request. 3. Interview with TP #2 on May 10, 2021, at approximately 2:00 PM, confirmed that the laboratory failed to have these procedure manuals available to laboratory personnel.
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 the manufacturer's instructions, observation, lack of laboratory records, and interview with Testing Personnel (TP) #2, the laboratory failed to follow the manufacturer's instructions for it's prothrombin time reagent used on the ACL Elite coagulation analyzer to test patient prothrombin time (PT) specimens. Findings include: 1. On May 10, 2021, at approximately 12:10 PM the PT reagent HemosIL RecombiPlasTin 2G (lot # N0504540) that expires on May 01, 2022, was observed

	being used on the ACL Elite analyzer. 2. Review of the reagent package insert for the PT reagent HemosIL RecombiPlasTin 2G (lot # N0504540) that expires on May 01, 2022, showed that the required International Sensitivity Index (ISI) value for the ACL Elite analyzer was 1.030. 3. On May 10, 2021, at approximately 12:12 PM the PT reagent HemosIL RecombiPlasTin 2G (lot # N0495565) that expired on January 01, 2021, with an ISI value of 1.020 was programed on the ACL Elite analyzer. 4. No normal patient prothrombin mean study was available upon request. 5. Interview with TP #2 on May 10, 2021, at approximately 12:20 PM, confirmed that the laboratory failed to performed a patient prothrombin mean study according to the manufacture's instructions and failed to update the lot # and ISI value on the ACL Elite analyzer for the current PT reagent being used.
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: Based on observation, record review, and interview with the Testing Personnel (TP) #4, the laboratory failed to monitor and document the temperature of the refrigerator where patient samples were stored and failed to define the acceptable temperature ranges on the temperature document for the molecular testing laboratory. Findings include: 1. On May 10, 2021, at 10:15 AM, an observation of the Accucold refrigerator revealed the refrigerator temperature was not monitored and was used for storing one patient urine specimen. 2. A record review of the molecular lab where Sars-CoV-2 test were performed revealed the laboratory failed to identify the appropriate temperature ranges for the test systems on the temperature recording document. 3. An interview on May 10, 2021, at 12:10 PM, with TP #4, confirmed that the temperature log failed to state the acceptable temperature ranges for the molecular test systems.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on the direct observation of supplies stored in the microbiology department refrigerator, and Testing Personnel (TP) #3 interview, the laboratory failed to replace laboratory supplies when they had exceeded their expiration date. Findings include: 1. Direct observation of the microbiology department refrigerator on May 10, 2021, at approximately 11:25 AM, showed a box with 6 sleeves (10 agar plates each) of MacConkey agar (lot #1021838) that expired on April 23, 2021. 2. Direct observation

	of the microbiology department Narco 1000 CO2 incubator on May 10, 2021, at approximately 11:30 AM, showed 4 patients have been plated using the expired MacConkey media. 3. Interview with TP #3 on May 10, 2021, at approximately 2:20 PM, confirmed that the laboratory failed to discard the expired media before its expiration date and use it for patient testing.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a record review and interview with Testing Personnel (TP) #3, the laboratory failed to establish control procedures or develop an Individualized Quality Control Plan (IQCP) to check each batch or shipment of microbiology agar media before or concurrent with initial use. Findings include: 1. A review of microbiology documents revealed the laboratory failed to have quality control procedure or IQCP for the quality control checks of the MacConkey and Blood Agar media before using on patient specimens. 2. On May 10, 2021, at 12:30 PM, an interview with TP #3 confirmed the laboratory failed to have a quality control procedure or IQCP for the microbiology media. 3. The laboratory performs approximately 360 patient urine specimens a year.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on direct observation, and Testing Personnel (TP) #2 interview, the laboratory failed to documented quality control for its C. difficile, HIV, Influenza, and Strep A testing. Findings include: 1. On May 10, 2021, at approximately 1:00 PM the following tests kits, were observed in the laboratory: Alere C.difficile Tox A/B Quik Chek, Alere HIV-1/2 Ag/Ab Combo, McKesson Consult Influenza A & B Test, McKesson Rapid Test Kit Consult Strep A Test. 2. No quality control records were available for these tests upon request. 3. Interview with TP #2 on May 10, 2021, at approximately 2:05 PM, confirmed that the laboratory failed to have these quality control records available.
D5471	CONTROL PROCEDURES

	CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with Testing Personnel (TP) #3, the laboratory failed to check each lot number of gram-negative and gram-positive identification and susceptibility cards for the Vitek for positive and negative reactivity from the period reviewed since December 2020. Findings: 1. The laboratory failed to demonstrate a positive and negative reaction for each gram-negative and gram-positive identification and susceptibility card since December 2020. 2. An interview on May 10, 2021, at 12:30 PM, with TP #3, confirmed the laboratory failed to perform quality control procedures that demonstrated a positive and negative reaction for each gram-positive and gram-negative identification and susceptibility card used on the Vitek. 3. The laboratory performed 17 patient urine specimens on the Vitek Identification and Antibiotic Susceptibility Testing instrument since April 23, 2021.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory directory, the laboratory director failed to ensure quality control procedures were established for the Vitek Identification and Antibiotic Susceptibility Testing instrument, Alere test kits, Clostridium difficule and HIV Ag/Ab Combo, McKesson Consult Streptococcus and Influenza A/B test kits, microbiology agar media, and the Prothrombin time /International normalized ratio (INR) performed on the ACL Elite instrument. Findings: 1. A record review of the quality control documents in the microbiology department revealed the laboratory failed to maintain quality control procedures for test systems in microbiology. 2. A record review of quality control records for the Vitek revealed the laboratory failed to perform quality control on the gram-negative and gram-positive cards for Vitek identification and susceptibility system, microbiology agar media, HIV test kit and the Clostridium difficile test kit. 3. A record review revealed the laboratory director failed to ensure the correct International Sensitivity Index (ISI) value for the ACL Elite analyzer. 4. An interview on May 10, 2021, at 1:20 PM, with the laboratory director confirmed procedures for the quality control systems were not established.