Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D2097807	07/26/2023
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
D0000	A recertification survey was completed on July 26, 2023. It was determined that Immediate Jeopardy (IJ) existed for the following condition level deficiencies: 42 C.F. R. 493.801 Condition: Enrollment and testing of [proficiency testing] 42 C.F.R. 493.1101 Condition: Facility Administration 42 C.F.R. 493.1230 Condition: General laboratory systems 42 C.F.R. 493.1240 Condition: Preanalytic systems; 42 C.F.R. 493.1250 Condition: Analytic systems; 42 C.F.R. 493.1290 Condition: Postanalytic systems; 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director 42 C.F.R. 493.1447 Condition: Laboratories performing high complexity testing; technical supervisor
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on the deficiencies cited here in, the Condition of Enrollment and Testing of Samples was not met. The laboratory failed to enroll in proficiency testing (see D2001), authorize the proficiency testing program to release proficiency testing results (see D2005), failed to test proficiency (see D2006), failed to maintain all documents in the handling, preparation, testing, and reporting of PT samples (see D2015).

D2001	ENROLLMENT CFR(s): 493.801(a)(1)(2)(i) The laboratory must-- (1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. (2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS; This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) and an interview with the laboratory manager, the laboratory failed to enroll in PT for the analytes gram stain, mycology identification, and human immunodeficiency virus (HIV) since the last survey on 12 /17/2020. Findings include: 1. A review of PT records from the American Proficiency Institute (API) revealed the laboratory failed to enroll in PT for gram stain, mycology, and HIV since the last survey on 12/17/2020. The laboratory performed approximately 750 microbiology tests and 30 HIV tests in 2022. 2. An interview with the laboratory manager on 07/20/2023, at approximately 5:05 PM, confirmed the laboratory failed to enroll in PT for gram stain, mycology, and HIV.
D2005	ENROLLMENT CFR(s): 493.801(a)(4) Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) and an interview with the laboratory manager, the laboratory failed to authorize American Proficiency Institute (API) to release the PT results to HHS for all analytes in the specialties of hematology, chemistry, immunology, and microbiology since the last survey on 12/17/2020. Findings include: 1. A review of PT records from the American Proficiency Institute (API) and a review of the Casper 0155D report, revealed the laboratory failed to authorize API to release the PT results to HHS for all testing performed in the specialties of hematology, chemistry, immunology, and microbiology since the last survey on 12/17/2020. 2. The laboratory performs approximately 125,000 patient tests per year. 3. An interview with the laboratory manager on 07/19/2023, at approximately 10:45 AM, confirmed the laboratory failed to notify API to release the PT results to HHS.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up

	until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT), laboratory PT records, and an interview with the laboratory manager, the laboratory failed to test the American Proficiency Institute (API) microbiology samples in the same manner as patient testing since the last survey on 12/17/2020. Findings include: 1. A review of PT records from the API and a review of laboratory PT records, revealed the laboratory failed to test the microbiology samples for organism identification and Clostridium difficile (CDiff) the same way as patient testing. 2. The laboratory performed testing on patient samples for CDiff by manual test kit method and also performed by molecular assay on the BD Max. There were no records or documentation in the laboratory that reflected which platform the PT samples were tested. 3. The laboratory performed approximately 750 microbiology tests per year. 4. An interview with the laboratory manager on 07/20/2023, at approximately 5:05 PM, confirmed the laboratory failed to test and report API microbiology samples the same manner as patient tests.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of Proficiency Testing (PT) records and an interview with the laboratory manager, the laboratory failed to maintain all documents in the handling, preparation, testing, and reporting of PT samples from the American Proficiency Institute (API), and the laboratory director failed to sign the attestation statements for API in the specialties of hematology, chemistry, and microbiology since the last survey on 12/17/2020. Findings include: 1. A review of the laboratory PT documents revealed the laboratory failed to maintain all documents from API, instrument printouts, and intermediate test records for the manual tests Clostridium difficile (CDiff), urine microscopy, and microbiology culture workups. 2. A review of the PT documents from API and the laboratory records, revealed the laboratory director failed to sign the API attestation statements and did not delegate the responsibility for the specialties of hematology, chemistry, and microbiology. 3. An interview with the laboratory manager on 07/20/2023, at approximately 5:05 PM, confirmed the laboratory failed to maintain PT sample testing records and the laboratory director failed to sign the attestation statements.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100

	Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on the deficiencies cited here in, the Condition of Facility Administration was not met. The laboratory failed be constructed and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized (see D3003), and retain quality control and patient test records, including instrument printouts, for at least 2 years (see D3031).
D3003	FACILITIES CFR(s): 493.1101(a)(2) The laboratory must be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized. This STANDARD is not met as evidenced by: Based on a record review, an observation, and an interview with the laboratory manager, the laboratory failed to ensure there was no patient specimen or environmental contamination in the laboratory where microbiology cultures and BD Max molecular tests were performed since the last survey on 12/17/2020. Findings include: 1. An observation on 7/19/2023, at approximately 10:30 AM, revealed the microbiology department failed to have a biological safely hood for the processing and testing of urine, stool, nasal, and sputum samples. 2. A record review of the BD Max reference manual revealed the necessity of the performance of wipe tests to determine whether there is environmental contamination or cross-over contamination. 3. An interview with the laboratory manager on 7/19/2023, at approximately 10:30 AM, confirmed the laboratory did not perform wipe tests to ensure there was no contamination.
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. This STANDARD is not met as evidenced by: Based on a review of the laboratory's records for the Vitek and BD Max analyzers, microbiology records, and an interview with the laboratory manager, the laboratory failed to retain documentation of instrument quality control, instrument maintenance,

	patient test printouts; quality control and patient microbiology culture workups, gram stains, and bacitracin susceptibility; patient worksheets for the manual test kit Clostridium difficile (CDiff), quality control, lot number and expiration dates for manual kits CDiff, Campylobacter, Human Immunodeficiency Virus (HIV), Candida, and Escherichia coli Shiga toxin kit (EHEC) since the last survey on 12/17/2020. Findings include: 1. A record review of the microbiology identification and sensitivity reports from the Vitek revealed the laboratory did not retain the Vitek 2 instrument printouts for patient microbiology specimens for identification and susceptibility testing, as well as quality control testing, and maintenance performance. The Vitek 2 did not contain a back-up system and the internal memory holds 30 days of activity. 2. A record review of the microbiology culture workups revealed the laboratory failed to document and retain testing records for gram stain quality control and patient testing, as well as culture workups to include the lot numbers and expiration dates of reagents, type of media, quality control, bacitracin sensitivity, dates of testing and personnel who performed the test. 3. A record review of the microbiology documents revealed the laboratory failed to document and maintain records that include quality control, lot numbers and expiration dates for the manual test kits for CDiff, HIV, and EHEC. 4. A review of the laboratory worksheet for CDiff revealed 4 out of 4 patients tested were not performed at the laboratory, but sent to another laboratory for testing on July 17, 2023. 5. The laboratory failed to document and retain any testing records for Candida species and there was no evidence the laboratory was testing for Candida, although results were reported with the BD Max urine panel assay since March 2023. The lab performed approximately 750 urine samples. 6. The laboratory performs approximately 750 microbiology tests per year. 7. An interview with the laboratory manager on 07/19/2023, at approximately 4:00 PM, confirmed the Vitek instrument reports and the BD Max results were not accessible or retained. The laboratory manager also confirmed that the laboratory failed to document and retain all testing records in the microbiology department, and that 4 patient stool samples for CDiff testing were performed at another laboratory and not at PCL. In addition, Candida was reported on all patient urine panel assays from the BD Max when no testing records were found in the laboratory.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the deficiencies cited herein, the Condition for General Laboratory Systems was not met. The laboratory failed to review and evaluate the results obtained on proficiency testing (see D5211) and failed to document proficiency testing evaluation and verification activities (see D5221) since the last survey on 12/17/2020.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing

	performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of the laboratory's written policies, proficiency testing (PT) records, and an interview with the laboratory manager, the laboratory failed to follow its procedure to document and review the evaluation of scores obtained from the American Proficiency Institute (API) for all tests performed in the specialties of hematology, chemistry, and microbiology since the last survey on 12/17/2020. Findings include: 1. Review of the laboratory's General and Safety Standard Operating Procedure (SOP) manual (GEN027 Proficiency Testing Protocol, effective 10/13/2022) and available American Proficiency Institute (API) records revealed that the laboratory failed to follow the SOP for evaluating and documenting the results evaluation for test scores which were not graded or scored. 2. The laboratory performs approximately 125,000 patient tests annually. 3. An interview with the laboratory manager on 07/19/2023, at approximately 11:30 AM, confirmed that the laboratory had no processes in place to review, evaluate, or document PT test sores.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of the laboratory's General and Safety Standard Operating Procedure (SOP) manual, proficiency testing (PT) records, and an interview with the laboratory manager, the laboratory failed to document the evaluation and verification of all unsatisfactory scores and the corrective action taken for the events in 2021 through 2023. Findings include: 1. Review of the laboratory's policy for proficiency testing in the General and Safety Standard Operating Policies (SOP) manual (GEN027 Proficiency Testing Protocol, effective 10/13/2022) and available PT records from the American Proficiency Institute (API) revealed that the laboratory failed to document the evaluation of PT scores that were graded less than 100% for: microbiology 2021, event 1 and 3; hematology and urinalysis 2021 event 3; reticulocyte count in 2022 events 2, and 3; urinalysis in 2022 event 2; Thyroid Stimulating Hormone, Valproic acid, Vancomycin, and Ferritin in 2022 event 2; and Testosterone and Total Iron Binding Capacity in 2022 event 3. 2. The laboratory performs approximately 125,000 patient tests annually. 3. An interview with the laboratory manager on 07/19/2023, at approximately 11:30 AM, confirmed the laboratory had no processes in place to review unsatisfactory PT scores, nor were there corrective actions taken when unsatisfactory score results were received.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The

	source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on laboratory records and test requisition review, and an interview with the laboratory manager, the laboratory failed to ensure a test requisition was completed for four out of four specimens collected for Clostridium difficile (CDiff) testing which were sent to another laboratories for testing on 07/17/2023. Findings include: 1. A review of the laboratory CDiff worksheet revealed 4 of 4 patient specimens were tested for CDiff at another laboratory, and there was no test requisition provided to the testing laboratory. 2. An interview with the laboratory manager on 07/20/2023, at approximately 12:30 PM, confirmed there were no test requisitions for 4 out of 4 patient specimens that were delivered to another laboratory for CDiff testing.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on laboratory records review and an interview with the laboratory manager, the laboratory failed to have written policies and procedures for patient specimen submission, handling, and referral to other laboratories. Findings include: 1. A review of the laboratory's General and Safety Standard Operating Procedures (SOP) manual revealed the laboratory failed to have written policies for stool, urine, sputum, nasal, and blood specimen collection, labeling, storage and preservation, conditions for specimen transport, and specimen acceptability and rejection criteria, as well as referral to another laboratory for testing. 2. A review of 4 out of 4 patient test reports for Clostridium difficile testing performed on 07/17/2023, revealed patient specimens were sent to an outside laboratory without a reference order sent to the laboratory. The samples were hand-delivered by an employee who worked at both laboratories and tested at the other facility without orders or acceptable specimen handling. 3. An interview with the laboratory manager on 07/20/2023, at approximately 12:30 PM, confirmed that 4 of 4 patient specimens had been tested for Clostridium difficile at another laboratory, and there were no written policies for specimen submission, handling, or referral to another laboratory.
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 deficiencies cited herein, the Condition of Analytic Systems was not met. The laboratory failed to have written procedure manuals available to laboratory personnel (see D5401), failed to follow the manufacturer's instructions for the Sysmex XN hematology analyzer and the Sysmex CA600 coagulation analyzer (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 verify the performance of the molecular assays on the BD Max, the Vitek microorganism identification assay, and the Exctye M Estimated Sedimentation Rate (ESR) to include the accuracy, precision, and interpretative reportable range (see D5421), failed to establish and verify the performance of the laboratory developed molecular BioGx urine panel performed on the BD Max (see 5423), failed to ensure the maintenance and routine function checks for the BD Max, Vitek, and Siemens Dimension was performed and documented (see 5429), failed to establish control procedures or establish an alternative quality control program for tests performed in microbiology (see D5445).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory manager, the laboratory failed to have written procedures or manufacturer's reference information available to laboratory personnel for testing performed in the specialties of hematology, coagulation, chemistry, microbiology, mycology, and immunology. Findings include: 1. A review of the laboratory tests performed revealed there were no step-by-step or complete procedures written and available to personnel for the Sysmex XN hematology analyzer, Siemens Dimension chemistry analyzer, Tosoh Hemoglobin A1C, Exctye M Automated Erythrocyte Sedimentation Rate (ESR), BD Max, Vitek 2, microbiology cultures, urine microscopy, and manual test kits for Campylobacter, Clostridium difficile, Human Immunodeficiency Virus (HIV), Candida, gram stains, and Escherichia coli Shiga toxin kit (EHEC). 2. An interview with the laboratory manager on 07/19/2023, at approximately 5:00 PM, confirmed that the laboratory failed to have these procedure manuals or other reference material available. 3. The laboratory performs approximately 125,000 patient tests annually. This is a repeat deficiency from the complaint survey performed on 05/14/2021.
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 a record review, an observation, and an interview with the laboratory manager and testing personnel #1 (TP 1), the laboratory failed to follow the manufacturer ' s instructions for testing hematology and coagulation specimens on the Sysmex XN and Sysmex CA600 since the last recertification survey on 12/17/2020. Findings include: 1. A record review revealed the laboratory failed to document the verification for establishing the normal patient Prothrombin mean study for the current Innovin reagent in use for the Sysmex CA600. 2. An observation on 07/19 /2023, at approximately 3:40 PM, revealed the laboratory failed to input the lot number of the Innovin (#59797 expiration date: 05/11/2024) in the analyzer or maintain records of prior lots used for patient testing. 3. An observation of a heat block in the hematology section of the laboratory on 07/19/2023, at approximately 3: 10 PM, showed 2 patient specimens were being incubated at approximately 92 degrees Fahrenheit. 4. TP1 stated on 07/19/2023, at approximately 3:15 PM, that the samples were being incubated at around body temperature because the initial complete blood test (CBC) results indicated critical hemoglobin and hematocrit values and she was trained to incubate the samples if testing needed to be repeated. 5. An observation on 7/20/2023, at approximately 3:35 PM, revealed that TP1 failed to perform quality control on the Sysmex XN hematology analyzer after replacing the Cellpack reagent. 6. A record review revealed there was no hematology procedure available and the manufacturer ' s instructions did not state to incubate patient specimens for critical values or rerun criteria. This is a repeat deficiency from the last complaint survey on 05/14/2021.
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 a record review, an observation, and an interview with the laboratory manager, the laboratory failed to establish acceptable environmental conditions, as well as monitor and document the temperature of the microbiology lab where the Vitek and incubator were located, and the adjacent laboratory where the BD Max was used for patient specimen organism identification, as well as storage for the BD Max kits and manual test kits for Campylobacter, Clostridium difficile, and Escherichia coli Shiga toxin (EHEC) since the last recertification survey on 12/17/2020. Findings include: 1. A record review of the microbiology laboratory documents revealed the lab failed to establish and document acceptable temperature ranges for the incubator; the Vitek laboratory space where manual culture workups and sensitivities for urine,

	stool, and sputum samples were examined; and the BD Max laboratory room for molecular testing of enteric and viral organism identification. As well as storage for the BD Max kits and manual test kits for Campylobacter, Clostridium difficile (CDiff), and Escherichia coli Shiga toxin (EHEC). 2. An observation on 7/20/2023, at approximately 11:50 AM, revealed the temperature of the BD Max room was 28.5 degrees Celsius. There were 2 BD Max molecular Enteric Bacterial kits, 2 BD Max CTGCTV2 kits, 3 BD Max CDiff kits, 1 BD Max GBS kit, and 6 ExK-DNA 1 urine kits with storage requirements of 2 - 25 degrees Celsius. 3. An interview with the laboratory manager on 07/20/2023, at approximately 11:55 AM, confirmed that the temperature of the microbiology incubator and BD Max room were not established or documented. 4. The laboratory performs approximately 750 microbiology tests annually. This is a repeat deficiency from the last complaint survey on 05/14/2021.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 a review of the laboratory records and an interview with the laboratory manager, the laboratory failed to verify the performance for each specimen type (urine, stool, sputum and nasal) for the molecular assays on the BD Max (Enteric bacterial and extended panel, viral and extended panel, Clostridium difficile (CDiff)), the Vitek microorganism identification assay, and the Exctye M Estimated Sedimentation Rate (ESR) that include the accuracy, precision, and interpretative reportable range since the last recertification survey on 12/17/2020. Findings include: 1. A review of the laboratory records revealed no documentation to demonstrate that the laboratory had verified the test performance specifications for the BD Max CDiff, Enteric Bacterial and Viral assays, or the Excyte M (ESR) instrument. 2. The laboratory performs approximately 750 BD Max assays and 190 ESRs per year. 3. An interview with the laboratory manager on 07/20/2023, at approximately 4:00 PM, confirmed that the establishment and verification for these assays were not performed.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

	This STANDARD is not met as evidenced by: Based on a review of the laboratory records and an interview with the laboratory manager, the laboratory failed to establish and verify the performance of the laboratory-developed molecular BioGx urine panel performed on the BD Max to include the limitations, interfering substances, and interpretative reporting since the start of patient testing in March 2023. Findings include: 1. A review of laboratory records revealed no documentation to demonstrate that the laboratory had verified the test performance specifications for the laboratory developed molecular test BioGx urine panel performed on the BD Max. 2. The laboratory performed approximately 450 urine assays on the BD Max. 3. An interview with the laboratory manager on 07 /20/2023, at approximately 4:00 PM, confirmed that the verification of the BioGx verification did not include all performance specifications.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a record review, an observation, and an interview with the laboratory manager, the laboratory failed to ensure the maintenance and routine function checks for the BD Max, Vitek, and Siemens Dimension was performed and documented since the last recertification survey on 12/17/2020. Findings include: 1. A review of the laboratory records revealed no documentation to demonstrate that the laboratory had performed routine function checks, as well as, daily and weekly maintenance and decontamination on the BD Max and Vitek since the last recertification survey on 12 /17/2020. 2. An interview with the laboratory manager on 07/19/2023, at approximately 4:35 PM, confirmed the laboratory failed to have maintenance and function records available for the BD Max and Vitek. The Labatory manager also confirmed that on 05/24/2023, the Dimension main computer had a major system failure and had to be replaced, which there were no maintenance activities documented.
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 the laboratory manager, the laboratory

	failed to perform control procedures or develop an equivalent quality control program to check each batch or shipment of four types of microbiology agar media (MacConkey, chocolate, Trypticase soy agar (TSA) with sheep blood, and MacConkey /Sheep blood biplate), bacitracin disks, the BD Max molecular assays for urine, Enteric bacterial and extended panel, Viral and extended panel, Clostridium difficile (CDiff) assay, Candida, the Vitek organism identification and sensitivity assays, manual test kits that included Campylobacter, Human Immunodeficiency Virus Ag /Ab Combo (HIV) test kit, Enterohemorrhagic Escherichia coli (EHEC), CDiff manual test kit, Candida, and gram stains before or concurrent with each day of patient testing since the last recertification survey on 12/17/2020. Findings include: 1. A review of the microbiology documents revealed the laboratory failed to perform quality control activities each day of patient testing and failed to establish an equivalent quality program or Individualized Quality Control Plan (IQCP) for the microbiology agar media, bacitracin disks, the BD Max molecular assays for urine, Enteric bacterial and extended panel, Viral and extended panel, CDiff assay, Candida, the Vitek organism identification and sensitivity assays, Campylobacter, HIV, EHEC, CDiff manual kit, and gram stains. 2. A review of the laboratory procedures revealed the laboratory failed to establish an IQCP for the microbiology agar media, bacitracin disks, the BD Max molecular assays for urine, Enteric bacterial and extended panel, Viral and extended panel, CDiff assay, Candida, the Vitek organism identification and sensitivity assays, Campylobacter, HIV, EHEC, CDiff, and gram stains. 3. An interview with the laboratory manager on 07/20/2023, at approximately 5:35 PM, confirmed the laboratory failed to establish equivalent quality testing or quality control and failed to perform quality control activities on the assays at least once each day of patient testing. 4. The laboratory performs approximately 800 tests per year. This is a repeat deficiency from the last complaint survey on 05/14/2021.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a record review, an observation, and an interview with the laboratory manager, the laboratory failed to document corrective actions when the BD Max test system failed to meet acceptable criteria for patient testing, the refrigerator where patient microbiology specimens were stored exceeded temperature range, and the BD Max room where the reagents used for patient testing exceeded the maximum temperature. Findings include: 1. An observation on 07/19/2023, at approximately 3:45 PM, revealed the refrigerator where patient microbiology specimens were stored for microbiology culture workup and molecular testing was recorded at 10 degrees Celsius for the month of July. The refrigerator acceptable range was stated at 2 - 8 degrees Celsius. There was no documentation or evidence of correction. 2. An observation on 07/19/2023, at approximately 3:45 PM, revealed the BD Max room

	where the BD Max reagents (urine, enteric bacterial and extended panel, viral and extended panel, and Clostridium difficile panel) was 28.8 degrees Celsius, which exceeded the manufacturer's acceptable maximum temperature of 25.0 degrees Celsius. 3. A record review of the Vitek, BD Max, hematology Sysmex XN, chemistry Dimension EXL, Sysmex CA600 coagulation analyzer, and Tosoh Glycated Hemoglobin (A1C) analyzer, revealed the laboratory failed to document corrective actions for when there was an issue with test performance or instrument problems since the last recertification survey on 12/17/2020. 4. An interview with the laboratory manager on 07/20/2023, at approximately 5:30 PM, revealed the chemistry analyzer main computer had a major system failure and there were no corrective actions taken to document equipment failures, exceeded temperatures, or problems with the analyzers.
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 a record review and an interview with the laboratory manager, the laboratory failed to take corrective actions for patient microbiology culture tests performed on the BD Max and the Vitek that were unacceptable and not rerun before reporting results since the last recertification survey on 12/17/2020. Findings include: 1. A review of 4 out of 15 patient test reports from the BD Max revealed the internal positive control for the urine panels failed to be acceptable or the molecular run was invalid and not corrected or reran prior to reporting the final results. 2. The laboratory failed tp perform external quality control tests for the BD Max and the Vitek to be able to determine the acceptable of the test performance. 3. A review of 3 out of 3 patient test reports from the Vitek organism identification and antibiotic sensitivity assay revealed the laboratory reported a gram-negative organism but reported sensitivities for a gram-positive organism, Vitek instrument printout for the patient result reported an inconclusive result with an organism identified, and an organism was entered manually into the Vitek without any testing records available which showed the tests performed to identify the organism. 4. An interview with the laboratory manager on 07/19/2023, at approximately 4:50 PM, confirmed he was unable to provide an explanation about why the patient tests were reported when the molecular tests were invalid, when the Vitek reported inaccurate results, or why the testing personnel was manually entering an organism identification without any testing records. This is a repeat deficiency from 5/14/2021.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of

	specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory manager, three out of three testing personnel failed to document and maintain patient testing records performed for manual microbiology culture workups, molecular testing for urine, enteric, viral, Clostridium difficile, Candida, gram stains, and manual microbiology test kits since the last recertification survey on 12/17/2020. Findings include: 1. A review of the microbiology patient logbook revealed the laboratory failed to record each step of culture workup from the initial setup, incubation, morphology, gram stain, bacitracin sensitivity, and molecular setup on the BD Max or Vitek to include the date and time of testing, the personnel who performed the test, specimen source, and lot numbers and expiration dates of reagents and test kits. 2. A review of the laboratory records in microbiology revealed there were no records of tests performed for Candida performed in the laboratory, but the patient test reports indicated results for Candida on the BD Max urine panel assays since March 2023. 3. A review of a Clostrium difficile (CDiff) worksheet in the laboratory revealed it was a worksheet from another laboratory for CDiff testing and results on four out of four patients on July 17, 2023, which were performed by an testing personnel #3 who worked at both laboratories. 4. The laboratory performed approximately 750 microbiology tests annually. 5. An interview with the laboratory manager on 07/19/2023, at approximately 1:35 PM, confirmed the testing personnel failed to document all testing performed in microbiology and that the four CDiff samples were not performed at the laboratory, but at another laboratory by the same individual.
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290 Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 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 postanalytic systems and correct identified problems as specified in 493. 1299 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the deficiencies cited herein, the Condition of Postanalytic Systems was not met. The laboratory failed to include the name and address of the laboratory location where the test was performed on the patient test report (see D5805), and issue corrected reports to the authorized person ordering the test, and maintain duplicates of the original and corrected reports (see D5821). This is a repeat deficiency from the last complaint survey on 05/14/2021.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where

	the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a review of patient test reports and laboratory records, and an interview with the laboratory manager, the laboratory failed to include the name and address of the laboratory location where tests were performed, as well as include the specimen source for microbiology specimens, and provide interpretation of test results when applicable on the patient test report since the last recertification survey on 12/17/2020. Findings: 1. A review of patient test reports and Clostridium difficile (CDiff) worksheets revealed the laboratory failed to have the correct name and address of the laboratory location where 4 of 4 patient specimens were tested for CDiff. 2. A review of five out of twelve patient test reports revealed the specimen source for microbiology culture/identification and antibiotic sensitivity was not stated on the patient's final report. 3. A review of twelve out of twelve patient test reports revealed the reports for molecular testing for urine, enteric, viral pathogens and CDiff indicated in the 'Notes' section that the identification and sensitivity was performed at another reference lab location in another state, but records showed the testing was performed at PCL. 4. A review of patient test reports revealed the reports for molecular urine pathogen results failed to include an interpretative reference range. 5. A review of one out of one patient report for Human Immunodeficiency Virus (HIV) revealed the lab reported "Positive". The manufacturer package insert indicated a positive result should be reported as a "Preliminary Positive". 6. An interview with the laboratory manager on 7/20/2023, at approximately 3:30 PM, confirmed that the laboratory discontinued using the stated reference laboratory on the molecular urine panel assays, but failed to change the canned statement on all the patient reports. The lab manager also confirmed that the laboratory failed to have the correct name and address of the laboratory where CDiff testing was performed at another laboratory and not at PCL.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on a review of the amended test reports and an interview with the laboratory manager, the laboratory failed to issue a corrected report for one out of one urine culture reports to the authorized person ordering the test and maintain duplicates of the original and corrected reports on 06/21/2023. Findings include: 1. A review of one out of one amended patient test report revealed that there was no documentation of when or how the authorized person was notified of the result correction for a urine culture on 06/21/2023. 2. A review of one out of one amended patient test reports revealed that the laboratory did not maintain duplicates of the original report. 3. A

	review of one out of one amended patient test report revealed that the corrected results were entered manually into the electronic laboratory information system and the original result was deleted. 4. An interview with the laboratory manager on 07/20 /2023, at approximately 3:10 PM, confirmed that the laboratory does not document on the reports or on a separate log when or to whom the notification of the corrected report was given, and also that the laboratory does not maintain copies of the original reports.
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 the deficiencies cited herein, the Condition of Laboratories Performing High Complexity Testing; Laboratory Director was not met. The laboratory director failed provide overall operation and administration for the laboratory (see D6079), failed to ensure that each of the tests performed in the laboratory provide quality services for all aspects of test performance (See D6082), that verification procedures used are performed to determine accurate test performance for each method (See D6086), proficiency testing samples provided by American Proficiency Institute (API) were tested as required under subpart H of this part (See D6089), quality control programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur (See D6093), quality assessment programs were established and maintained, and to identify failures in quality as they occur (See D6094), failed to ensure that test reports include the specimen source, location of testing, methodology of test performance, and the interpretation of test results (see 6098), failed to ensure that policies and procedures were written to monitor testing personnel and to assure they were trained and competent (See D6103), failed to ensure policies and procedures for all testing in the laboratory were made available to all testing personnel (see D6106).
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on reviews of laboratory training and competency documents, as well as reviews of the procedure manuals, laboratory records, and patient test reports, and an

	interview with the laboratory manager, the laboratory director failed to ensure that three out of three testing personnel were trained and competent to perform testing and reporting of tests performed in the microbiology lab, as well as ensure that three out of three technical supervisors were competent to perform laboratory oversight and testing since the last survey recertification survey on 12/17/2020. Findings include: 1. A review of training and competency records revealed there were no records for three out of three testing personnel who worked in the microbiology lab and performed tests on the BD Max, Vitek, manual cultures, and microbiology test kits. 2. A review of competency records revealed there were no records for three out of three technical supervisors who performed patient testing and failed to provide technical oversight of the microbiology lab in the specialties for chemistry, hematology, immunology, and microbiology. 3. An interview with the laboratory manager on 07/20/2023, at approximately 5:20 PM, confirmed the laboratory director failed to ensure the staff were trained and competent to provide lab testing, reporting, and technical supervision and oversight.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on review of the laboratory documents and an interview with the laboratory manager, the lab director failed to ensure that the Excyte M ESR, BD Max molecular assays for urine, Enteric bacterial and extended panel, viral and extended panel, Clostridium difficile assay, Candida, the Vitek organism identification and antibiotic sensitivity assays, manual test kits that include Campylobacter, Human Immunodeficiency Virus (HIV), and enterohemorrhagic Escherichia coli (EHEC), gram stains, and microbiology culture workups were developed in all aspects of test performance, which included the preanaltyic, analytic, and post analytic phases of testing since 12/17/2020. Findings include: 1. The laboratory failed to meet the applicable requirements under 493.1101 through 493.1105 for facility administration. (See D3000) 2. The laboratory failed to meet the requirements specified in 493.1251 through 493.1283, 493.1289. (See D5400) 3. The laboratory failed to meet the requirements specified in 493.1231 through 493.1236, 493.1239. (See D5200) 4. The laboratory failed to meet the requirements specified in 493.1291 through 493.1299. (See D5800)
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on a review of the laboratory verification data and an interview with the laboratory manager, the laboratory director failed to ensure that the verification

	procedures used to validate the molecular assays for each specimen type (urine, stool, sputum and nasal) on the BD Max (urine, Enteric bacterial and extended panel, viral and extended panel, Clostridium difficile), Candida, the Vitek microorganism identification assay, and the Exctye M Estimated Sedimentation Rate (ESR) were adequate to determine performance characteristics of each method prior to testing patient specimens since the last recertification survey on 12/17/2020. The findings include: 1. The laboratory director failed to ensure that the verification for test performance specifications for microorganism identification on the Vitek, BD Max, and Excyte ESR test system were acceptable prior to patient testing. (See D5421) 2. An interview with the laboratory manager on 07/20/2023, at approximately 5:30 PM, confirmed the laboratory director failed to ensure the test systems were verified prior to patient testing.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records from the American Proficiency Institute (API) and an interview with the laboratory manager, the laboratory director failed to ensure PT samples from API were tested in the same manner as patient testing since the last recertification survey on 12/17/2020. Findings include: 1. The laboratory director failed to ensure that the microbiology samples from API for organism identification were tested in the same manner as patient specimens. (See D2006). 2. An interview with the laboratory manager on 07/20/2023, at approximately 5:10 PM, confirmed the laboratory director failed to ensure that PT samples were tested appropriately.
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 a review of quality control records and the lack of laboratory procedures, as well as an interview with the laboratory manager, the laboratory director failed to ensure the quality control program was established for the BD Max molecular test system, the Vitek organism identification and antibiotic susceptibility testing , Candida, Human Immunodeficiency Virus (HIV) test kit, Clostridium difficile, Enterohemorrhagic Escherichia coli (EHEC), microbiology agar media, and gram stains since the last recertification survey on 12/17/2020. Findings include: 1. A record review of the quality control documents and the lack of procedures in the microbiology department revealed the laboratory failed to establish and perform quality control procedures or equivalent quality testing for test systems in microbiology above. (See D5445) 2. An interview with the laboratory manager on 07 /20/2023, at approximately 5:15 PM, confirmed the laboratory director failed to ensure that the quality control programs were established and performed for the test

	systems in microbiology. This was a repeat deficiency from the last complaint survey on 05/14/2021.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment 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 review of patient test results, lack of quality control (QC) records, lack of quality assessment (QA) records, and lack of procedure manuals, as well as an interview with the laboratory manager, the laboratory director failed to ensure that an effective QA program was established and maintained to identify failures in quality as they occur for test performed in the specialties of chemistry, immunology, microbiology, mycology, and hematology since the last recertification survey on 12/17 /2020. The findings include: 1. The laboratory director failed to establish and maintain written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems, analytic system, post-analytic system, facilities systems, and proficiency testing. 2. An interview with the laboratory manager on 07/20/2023, at approximately 5:15 PM, confirmed the laboratory director failed to ensure that quality assessment programs were established and maintained.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review of patient test reports and an interview with the laboratory manager, the laboratory director failed to ensure that test reports include the specimen source, location of testing, methodology of test performance, and the interpretation of test results since the last recertification survey on 12/17/2020. Findings include: 1. A review of twelve out of twelve patient test reports revealed that another laboratory was stated on the patient test reports for the microbiology molecular urine panel tests performed. 2. A review of five out of twelve patient test reports revealed that the specimen source was not stated and the test methodology for Clostridium difficile (CDiff) was not stated correctly on the patient test reports. The patient specimens were tested by molecular method on the BD Max, but the report indicated the method was a manual test kit. 3. A review of patient test reports and CDiff worksheets revealed the laboratory failed to have the correct name and address of the laboratory where 4 out of 4 patient specimens were tested for CDiff. 4. A review of patient test reports revealed the patient test reports failed to include an interpretative reference range for molecular urine pathogen results. 5. An interview with the laboratory manager on 07/20/2023, at approximately 5:35 PM, confirmed the laboratory director failed to ensure that patient test reports included the laboratory where the tests were performed, the method of test performance, the source of cultures, and the interpretation for molecular tests.

D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on a review of the laboratory ' s procedure manual, testing personnel training and competency documents, and an interview with the laboratory manager, the laboratory director failed to ensure that policies and procedures were written to monitor testing personnel and to assure they were trained and competent in order to perform testing in chemistry, hematology, immunology, mycology, and microbiology since the last recertification survey on 12/17/2020. Findings include: 1. A review of training and competency records revealed there were no competency records for three out of three testing personnel for the testing and reporting of patient results for the tests performed in microbiology and mycology. 2. A review of the laboratory's procedure manual revealed that there were no Standard Operating Procedures (SOP) for the Sysmex XN hematology analyzer, Siemens Dimension chemistry analyzer, Tosoh Hemoglobin A1C, Exctye M Automated Erythrocyte Sedimentation Rate (ESR), BD Max, Vitek, microbiology cultures, and manual test kits for Campylobacter, Clostridium difficile, Human Immunodeficiency Virus (HIV), gram stains, Candida, and Escherichia coli Shiga toxin kit. 3. An interview with the laboratory manager on 07/20/2023, at approximately 5:20 PM, confirmed the laboratory director failed to ensure that policies and procedures were written and that testing personnel were trained and competent to provide lab testing and reporting.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on a review of laboratory documents and an interview with the laboratory manager, the laboratory director failed to ensure that policies and procedures for all tests in the laboratory were made available to all testing personnel since the last recertification survey on 12/17/2020. Findings include: 1. A review of the laboratory tests performed and the lack of procedures revealed the laboratory director failed to ensure procedures were available to personnel for the Sysmex XN hematology analyzer, Siemens Dimension chemistry analyzer, Tosoh Hemoglobin A1C, Exctye M Automated Erythrocyte Sedimentation Rate (ESR), BD Max, Vitek, microbiology cultures, Candida, and manual test kits for Campylobacter, Clostridium difficile, Human Immunodeficiency Virus (HIV), gram stain, and Escherichia coli Shiga toxin kit. (See 5401) 2. An interview with the laboratory manager on 07/20/2023, at approximately 5:35 PM, confirmed the laboratory director failed to ensure that policies and procedure were available to all personnel.

D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on the deficiencies cited herein, the Condition of Technical Supervisor for Laboratories Performing High Complexity Testing was not met. The laboratory failed to perform verification and establish test performance characteristics of each test and test system (see D6115) and failed to enroll in proficiency testing for all services offered (see D6116) since the last recertification survey on 12/17/2020.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on the review of verification documentation and an interview with the laboratory manager, three of three Technical Supervisors (TS) failed to verify the performance, which include the accuracy and precision of the molecular assays on the BD Max (urine, Enteric bacterial and extended panel, viral and extended panel, and Clostridium difficile), Vitek microorganism identification assay, Exctye M Automated Erythrocyte Sedimentation Rate (ESR), and Candida, since the last recertification survey on 12/17/2020. Findings include: 1. A review of laboratory records revealed no documentation to demonstrate that three out of three TSs had verified the test performance specifications for the Excyte M Estimated Sedimentation Rate (ESR), molecular assays on the BD Max Clostridium difficile (CDiff), Enteric Bacterial and Viral, and urine. The laboratory performs approximately 750 BD Max and Vitek assays and 190 ESR tests annually. (See D5421 and D5423) 2. A review of laboratory records revealed there were no records for testing being performed for Candida, although the laboratory was reporting out results from documents review from March 2023. 2. An interview with the laboratory manager on 07/20/2023, at approximately 4: 00 PM, confirmed that the establishment and verification for the BD Max, Vitek, Candida, and Excyte M ESR assays were not performed to establish the precision, accuracy, and other specifications.
D6116	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(3) The technical supervisor is responsible for enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) documentation and an interview with the laboratory manager, the laboratory failed to enroll in an approved PT program for

	the analytes gram stain, Candida, and Human Immunodeficiency Virus (HIV) since the last recertification survey on 12/17/2020. 1. A review of PT records from the American Proficiency Institute (API) revealed the laboratory failed to enroll in PT for gram stains, Candida identification, and HIV. 2. The laboratory performs approximately 750 bacteriology tests and 30 HIV tests annually. (See D2000) 3. An interview with the laboratory manager on 07/20/2023, at approximately 5:05 PM, confirmed the laboratory failed to enroll in PT for gram stain, Candida identification, and HIV.