Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D2299052	09/18/2024
Name of Provider or Supplier	**Street Address, City, State**	
Sincera Health Pllc	1518 Washington St, Pella, IA	

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
D5014	GENERAL IMMUNOLOGY CFR(s): 493.1208 If the laboratory provides services in the subspecialty of General immunology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of the laboratories policies and procedures, quality control (QC) records, verification of performance specification records, patient specimen logs, and confirmed by interview with the Laboratory Director (LD), the laboratory failed to: have procedures as specified in D5403; ensure approval of laboratory procedures with a date and signature by the LD as specified in D5407; verify the performance specifications of accuracy and precision for human immunodeficiency virus (HIV) 1/2 antigen/antibody testing as specified in D5421; perform two levels of QC at least once each day of patient testing as specified in D5449; ensure QC results meet the laboratory's criteria for acceptability before reporting patient test results as specified in D5481; take and document corrective action when QC results failed to meet the laboratory's established criteria for acceptability as specified in D5783; and ensure the accurate and reliable transcription of manual test results into the laboratory's electronic health record (EHR) as specified in D5801.
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1267, and 493.1281 through 493.1299.

	This CONDITION is not met as evidenced by: Based on review of the laboratories policies and procedures, quality control (QC) and calibration records, verification of performance specification records, patient specimen logs, and confirmed by interview with the Laboratory Director (LD), the laboratory failed to: have procedures as specified in D5403; ensure approval of laboratory procedures with a date and signature by the LD as specified in D5407; verify the performance specification of accuracy for chemistry testing as specified in D5421; perform two levels of QC at least once each day of patient testing as specified in D5447; ensure QC results meet the laboratory's criteria for acceptability before reporting patient test results as specified in D5481; and take and document corrective action when QC results failed to meet the laboratory's established criteria for acceptability as specified in D5783.
D5020	ENDOCRINOLOGY CFR(s): 493.1212 If the laboratory provides services in the subspecialty of Endocrinology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of the laboratories policies and procedures, quality control (QC) and calibration records, verification of performance specification records, patient specimen logs, and confirmed by interview with the Laboratory Director (LD), the laboratory failed to: have procedures as specified in D5403; ensure approval of laboratory procedures with a date and signature by the LD as specified in D5407; follow the manufacturer's instructions for performing QC after a valid calibration as specified in D5411; verify the performance specification of accuracy for endocrinology testing as specified in D5421; perform two levels of QC at least once each day of patient testing as specified in D5447; ensure QC results meet the laboratory's criteria for acceptability before reporting patient test results as specified in D5481; and take and document corrective action when QC results failed to meet the laboratory's established criteria for acceptability as specified in D5783.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the

	protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the Scopes of Service Policy, the laboratory's policies and procedures in the Teams application, and confirmed by interview with the Laboratory Director (LD) at 4:00 pm on 09/17/2024, the laboratory failed to have a procedure manual that included the following policies and procedures: requirements for patient preparation; specimen collection and labeling criteria; specimen processing, storage, and preservation; criteria for specimen acceptability and rejection; control procedures including the number, type, and frequency for each test system; and corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. The findings include: 1. The Scopes of Service policy included a section on Laboratory Document Control where it stated, "Teams is the document control system at Sincera. This system ensures that: All policies and procedures have been approved by the laboratory medical director or designee upon implementation and annually thereafter." 2. At the time of the survey, the LD confirmed that the Teams application did not include policies and procedures for: requirements for patient preparation; specimen collection and labeling criteria; specimen processing, storage, and preservation; criteria for specimen acceptability and rejection; control procedures including the number, type, and frequency for each test system; and corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the Scopes of Service Policy, policies and procedures in the Teams application, test system instructions for use (IFU), and confirmed by interview with the Laboratory Director (LD) at 12:49 pm on 09/17/2024, the LD failed to approve, sign, and date laboratory policies and procedures. The findings include: 1. The Scopes of Service policy included a section on Laboratory Document Control where it stated, "Teams is the document control system at Sincera. This system ensures that: All policies and procedures have been approved by the laboratory medical director or designee upon implementation and annually thereafter." 2. The Teams application included the following policies and procedures: Cepheid; Clinitek Status +; Critical Lab Reporting; Dimension EXL 200; HCG Combo; HIV- 1/2 Ag /Ab Combo; Infection Control; Laboratory Orientation, Training, and Education; Mono Test; Quality Assessment & QA; Quality Control; Rapid Strep A; Reference Lab Processing/Reporting; Scope of Services; Sofia Influenza A & B; and Sysmex XN-530. 3. Policies and procedures on the Teams application did not include written or electronic dates of approval and signature by the LD. 4. Interview with the LD indicated that the laboratory intended to use the IFUs as the procedures for the Cepheid GeneXpert, Qiagen QiaStat, and Alere Determine test systems. 5. Review of the Cepheid GeneXpert, Qiagen QiaStat, and Alere Determine test system IFUs did

	not include dates of approval and signature by the LD. 6. At the time of the survey, the LD had not approved, signed or dated the policies and procedures in the Teams application or the IFUs for the test systems listed above.
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 Siemens Dimension EXL 200 calibration and quality control (QC) records, the procalcitonin (PCT) Instructions for Use (IFU), and confirmed by interview with the Laboratory Director (LD) at 1:21 pm on 09/17/2024, the laboratory failed to follow the manufacturer's instructions for performing QC after a valid calibration for one out of five reagent calibrations reviewed from 08/16/2024- 09/17 /2024. The findings include: 1. The laboratory performed and accepted a valid calibration for PCT (lot number FC5022) on 09/01/2024. 2. The PCT IFU stated to perform QC at least once each day of use, following a valid calibration, with use of a new lot of reagent, and when troubleshooting test results that do not match clinical conditions or symptoms. 3. The laboratory performed procalcitonin testing on 1 patient after performing the calibration on reagent lot number FC5022. 4. At the time of the survey, the LD confirmed the laboratory did not perform QC after the valid calibration of PCT and prior to performing patient testing on 09/01/2024.
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: A. Based on review of performance specification records and confirmed by interview with the Laboratory Director (LD) at 1:21 pm on 09/17/2024, the laboratory failed to verify the performance specification of accuracy prior to testing and reporting patient specimens for 10 out of 32 analytes used to perform patient testing on the Siemens Dimension EXL 200 chemistry instrument. The findings include: 1. The laboratory began using the Siemens Dimension EXL 200 instrument to perform chemistry testing on 05/02/2024. 2. Review of the Siemens Dimension EXL 200 verification of performance specification records indicated the laboratory failed to verify accuracy for the following analytes: carbon dioxide, total protein, albumin, hemoglobin A1C, creatine kinase, magnesium, low-density lipoprotein, direct bilirubin, thyroid stimulating hormone, and uric acid. 3. At the time of the survey, the LD confirmed that the laboratory failed to have documentation of verification of the performance

	specification of accuracy for the analytes listed above. B. Based on lack of performance specification records and confirmed by interview with the Laboratory Director (LD) at 12:49 pm on 09/17/2024, the laboratory failed to verify the performance specifications of accuracy and precision prior to testing and reporting patient specimens for the Alere Determine HIV 1/2 Ag/Ab combo kit. The findings include: 1. The laboratory began using the Alere Determine HIV 1/2 Ag/Ab combo kit to perform human immunodeficiency virus (HIV) testing on 05/02/2024. 2. At the time of the survey, the LD confirmed the laboratory failed to have performance specification records for the Alere Determine HIV 1/2 Ag/Ab combo kit.
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 lack of Individualized Quality Control Plan (IQCP) records, review of quality control (QC) records, and confirmed by interview with the Laboratory Director (LD) at 3:25 pm on 08/28/2024, the laboratory failed to perform two levels of QC at least once each day of patient testing for the following test systems: Cepheid GeneXpert and Qiagen QiaStat. The findings include: 1. The laboratory began using the Cepheid GeneXpert and Qiagen QiaStat test systems to perform patient testing on 05/02/2024. 2. The laboratory performed QC with each new lot and shipment of tests for the Cepheid GeneXpert and Qiagen QiaStat test systems. 3. The LD indicated that the laboratory intended to follow the manufacturer's instructions for performing QC. 4. At the time of the survey, the laboratory did not have an IQCP for the Cepheid GeneXpert and Qiagen QiaStat test systems.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the Sincera Health Patient Specimen Log, Siemens Dimension EXL 200 quality control (QC) records, and confirmed by interview with the Laboratory Director (LD) at 1:21 pm on 09/17/2024, the laboratory failed to perform two levels of QC at least once each day of patient testing for 7 out of 31 days of patient testing reviewed from 08/16/2024- 09/17/2024. The findings include: 1. Review of Siemens Dimension EXL 200 QC records revealed that the laboratory did

	not perform any QC and reported patient test results on the following dates for the specified analytes: *08/29/2024- thyroid stimulating hormone (TSH)- 1 patient reported *08/30/2024- sodium (NA), potassium (K), chloride (CL), carbon dioxide (CO2), calcium (CA), total bilirubin (TBIL)- 1 patient reported *09/01/2024- procalcitonin (PCT)- 1 patient reported *09/07/2024- NA, K, CL, CO2, glucose (GLU), CA, albumin (ALB), total protein (TP), alkaline phosphatase (ALP), alanine aminotransferase (ALT), aspartate aminotransferase (AST), TBIL, blood urea nitrogen (BUN), creatinine (CREA)- 1 patient reported *09/08/2024- NA, K, CL, CO2, CA, TBIL, PCT- 1 patient reported *09/09/2024- NA, K, CL, CO2, CA, TBIL, magnesium (MG)- 3 patients reported *09/10/2024- troponin (TROP)- 1 patient reported 2. At the time of the survey, the LD confirmed that the laboratory failed to perform two levels of QC at least each day of patient testing for 7 out of 31 days of patient testing reviewed from 08/16/2024- 09/17/2024.
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 review of quality control (QC) records, the Alere Determine HIV 1/2 Ag/Ab combo kit Instructions for Use (IFU), and confirmed by interview with the Laboratory Director (LD) at 12:49 pm on 09/17/2024, the laboratory failed to perform a negative and positive control at least once each day of patient testing for human immunodeficiency virus (HIV) 1/2 antigen/antibody testing for two out of two days of patient testing reviewed from 07/01/2024- 09/17/2024. The findings include: 1. The laboratory performed HIV 1/2 antigen/antibody testing using the Alere Determine HIV 1/2 Ag/Ab combo kit. 2. Patient A had HIV 1/2 antigen/antibody testing performed on 07/16/2024. 3. Patient B had HIV 1/2 antigen/antibody testing performed on 08/06/2024. 4. The LD indicated the laboratory uses the Alere Determine HIV 1/2 Ag/Ab combo kit (IFU) insert as the procedure. The IFU did not specify the frequency with which QC must be performed. 5. The LD verbally indicated the laboratory intended to perform QC each day of patient testing. 6. At the time of the survey, the LD confirmed that the laboratory did not have HIV 1/2 antigen /antibody QC records for testing performed on 07/16/2024 or 08/06/2024.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of Siemens Dimension EXL 200 quality control (QC) records, the Sincera Health Patient Specimen Log, and confirmed by interview with the Laboratory Director (LD) at 1:21 pm on 09/17/2024, the laboratory failed to ensure

	that results of control materials for general immunology, routine chemistry, and endocrinology testing met the laboratory's test system criteria for acceptability prior to reporting patient test results for 19 out of 31 days of patient testing reviewed from 08 /16/2024- 09/17/2024. Refer to D5783.
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 Siemens Dimension EXL 200 quality control (QC) records, the laboratory's Quality Control policy, and confirmed by interview with the Laboratory Director (LD) at 1:21 pm on 09/17/2024, the laboratory failed to take and document corrective action when chemistry QC fell outside the laboratory's established criteria for acceptability for 19 out of 31 days of patient testing reviewed from 08/16/2024- 09 /17/2024. The findings include: 1. The laboratory performs chemistry testing on the Siemens Dimension EXL 200 instrument. 2. Review of the laboratory's Quality Control policy revealed no written instruction for performing and documenting corrective action for out of control QC results. 3. Review of chemistry QC records revealed out of range results for level 1 QC for the following dates and analytes: * 08 /20/2024- carbon dioxide (CO2), glucose (GLU), calcium (CA), albumin (ALB), alkaline phosphatase (ALP), alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin (TBIL), blood urea nitrogen (BUN), creatinine (CREA), and uric acid (UA) * 08/22/2024- GLU, CA, ALB, ALP, ALT, AST, BUN, CREA, and c-reactive protein (CRP) * 08/24/2024- GLU, CA, ALT, AST, BUN, and CREA * 08/26/2024- CA, ALT, AST, TBIL, BUN, CREA, and troponin (TROP) * 08 /29/2024- CA, ALB, AST, TBIL, BUN, CREA, and TROP * 08/30/2024- ALP * 08 /31/2024- GLU, CA, ALB, ALP, ALT, AST, TBIL, BUN, and CREA * 09/01/2024- GLU, CA, ALB, ALT, AST, TBIL, BUN, and CREA * 09/03/2024- sodium (NA), GLU, AST, TBIL, BUN, and CREA * 09/05/2024- ALP, BUN, GLU, and thyroid stimulating hormone (TSH) * 09/08/2024- ALP, ALT, and BUN * 09/09/2024- ALT and TSH * 09/10/2024- ALB, ALT, amylase (AMY), AST, BUN, CA, CREA, GLU, triglycerides (TRIG), lipase (LIP), TSH, and n-terminal pro brain natriuretic peptide (ProBNP) * 09/11/2024- ALT, GLU, and TSH * 09/12/2024- TBIL * 09/13/2024- TBIL and procalcitonin (PCT) * 09/14/2024- TBIL and TSH * 09/16/2024- ALT, AMY, AST, BUN, CA, CREA, TBIL, and GLU * 09/17/2024- TBIL 4. Review of chemistry QC records revealed out of range results for level 3 QC for the following dates and analytes: * 08/20/2024- ALT, AST, BUN, CA, CREA, UA, TBIL, and potassium (K) * 08/22/2024- GLU, CA, ALB, ALP, ALT, AST, BUN, CREA, total protein (TP), TBIL, NA, K, chloride (CL), and CO2 * 08/24/2024- GLU, CA, ALT, ALB, BUN, TBIL, K, and CREA * 08/26/2024- CA, ALT, AST, TBIL, BUN, CREA, ALB, and GLU * 08/29/2024- CA, ALB, AST, TBIL, BUN, CREA, ALP, ALT, and GLU * 08/30/2024- CREA and LIP * 08/31/2024- GLU, CA, ALB, ALP, ALT, AST, K, BUN, and CREA * 09/01/2024- GLU, CA, ALB, ALT, AST, K, BUN, and CREA * 09/03/2024- GLU, ALB, CA, ALP, ALT, BUN, and CREA * 09/05/2024- ALB,

	ALP, ALT, BUN, CA, CREA, TBIL, GLU, and TSH * 09/08/2024- ALP, CREA, and BUN * 09/09/2024- LIP * 09/10/2024- ALB, ALT, AMY, BUN, CA, total cholesterol (CHOL), CREA, GLU, high-density lipoprotein (HDL), TRIG, low-density lipoprotein (LDL), LIP, magnesium (MG), TSH, and ProBNP * 09/13/2024- AST, TBIL, and PCT * 09/14/2024- TBIL * 09/16/2024- ALB, AMY, BUN, CA, CREA, TBIL, GLU, and LIP * 09/17/2024- AST, TBIL, and BUN 4. The laboratory reported results for a total of 27 patients during the dates listed above. 5. At the time of the survey, the LD confirmed that the laboratory did not have documented corrective action for the unacceptable QC results listed above. In addition, the LD confirmed that the laboratory's QC policy did not include instructions for performing and documenting corrective action for out of control QC results.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of patient test logs, patient electronic health records (EHR), and confirmed by interview with the Laboratory Director (LD) at 12:49 pm on 09/17 /2024, the laboratory failed to have a system in place to ensure the accurate and reliable transcription of manual test results into the laboratory's EHR for two out of two patients reviewed having human immunodeficiency virus (HIV) 1/2 antigen /antibody testing performed from 07/01/2024- 09/17/2024. The findings include: 1. Review of the laboratory's Patient Specimen Log indicated Patient A had HIV 1/2 antigen/antibody testing performed on 07/16/2024 with a negative result. 2. Patient A's EHR chart did not include a record of the HIV 1/2 antigen/antibody testing performed on 07/16/2024. 3. Review of the laboratory's Patient Specimen Log indicated Patient B had HIV 1/2 antigen/antibody testing performed on 08/06/2024 with a negative result. 4. Patient B's EHR chart did not include a record of the HIV 1 /2 antigen/antibody testing performed on 08/06/2024. 5. At the time of the survey, the LD confirmed that the laboratory did not have a system in place to ensure the accurate and reliable transcription of manual test results into the EHR.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of performance specification records, quality control (QC) records, patient specimen logs, policies and procedures, personnel records, and confirmed by

	interview with the Laboratory Director (LD), the LD failed to ensure that procedures for verification of performance specifications are adequate as specified in D6013; ensure a quality control program is established and maintained as specified in D6020; ensure a quality assessment program is established and maintained as specified in D6021; ensure the laboratory takes and documents corrective action when QC fails to meet the laboratory's established criteria for acceptability as specified in D6024; ensure that prior to testing patient specimens, personnel are trained as specified in D6029; and ensure the laboratory has all of the necessary policies and procedures as specified in D6031.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) 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 lack of Alere Determine HIV 1/2 Ag/Ab combo kit performance specification records, review of Siemens Dimension EXL 200 performance specification records, and confirmed by interview with the Laboratory Director (LD) at 12:49 and 1:21 pm on 09/17/2024, the laboratory director failed to ensure the verification of the performance specifications of accuracy and precision for the Alere Determine HIV 1/2 Ag/Ab combo kit, and the performance specification of accuracy for 10 out of 32 analytes used to perform patient testing on the Siemens Dimension EXL 200 chemistry instrument prior to testing and reporting patient test results. Refer to D5241.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratories policies and procedures, lack of Individualized Quality Control Plan (IQCP) documents, calibration and quality control (QC) records, patient specimen logs, and confirmed by interview with the Laboratory Director (LD) at 1:21 pm on 09/17/2024, the LD failed to ensure the establishment and maintenance of an effective quality control program from 05/02/2024- 09/17/2024. The findings include: 1. The LD did not ensure the laboratory followed the manufacturer's instructions for performing QC after a valid calibration. Refer to D5411. 2. The LD did not ensure performance of two levels of QC at least once each day of patient

	testing for the Cepheid GeneXpert or Qiagen QiaStat test systems. Refer to D5445. 3. The LD did not ensure performance of two levels of QC at least once each day of patient testing for the Alere Determine HIV 1/2 Ag/Ab combo test kit. Refer to D5447. 4. The LD did not ensure performance of two levels of QC at least once each day of patient testing for the Siemens Dimension EXL 200 instrument. Refer to D5449. 5. The LD did not ensure that results of control materials for general immunology, routine chemistry, and endocrinology testing met the laboratory's test system criteria for acceptability before reporting patient test results. Refer to D5481. 6. The LD did not ensure the laboratory took and documented corrective action when chemistry QC fell outside the laboratory's established criteria for acceptability. Refer to D5783.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and confirmed by interview with the Laboratory Director (LD) at 4:00 pm on 09/17/2024, the LD failed to ensure the laboratory established and maintained a quality assessment program which covered the four quality systems: general, pre-analytic, analytic, and post-analytic. The findings include: 1. The laboratory used the Teams application as a document control system to house policies and procedures. 2. Within Teams, the laboratory had a policy called "Quality Assessment & QA." 3. At the time of the survey, the LD failed to ensure the Quality Assessment and QA policy defined the laboratory's quality assessment activities related to the general, pre-analytic, analytic, and post-analytic quality systems. In addition, the LD failed to ensure the laboratory documented quality assessment activities.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on review of Siemens Dimension EXL 200 quality control (QC) records, the laboratory's Quality Control policy, and confirmed by interview with the Laboratory Director (LD) at 1:21 pm on 09/17/2024, the LD failed to ensure the laboratory documented corrective action when QC failed to meet the laboratory's established

	criteria for acceptability for 19 out of 31 days of patient testing reviewed from 08/16 /2024- 09/17/2024. Refer to D5783.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of personnel records, lack of training records, and confirmed by interview with the Laboratory Director (LD) at 9:39 am on 09/17/2024, the LD failed to ensure that prior to testing patient specimens, all testing personnel performing moderate complexity testing received the appropriate training for one out of two testing personnel [Testing Personnel (TP) #2]. The findings include: 1. Review of training records for TP #2 did not include the Sysmex XN-530 test system or the Alere Determine HIV 1/2 Ag/Ab combo kit. 2. At the time of the survey, the LD confirmed that the LD failed to ensure training records for TP #2 included the Sysmex XN-530 and Alere Determine HIV 1/2 Ag/Ab test systems.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) 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 review of the laboratory's policies and procedures and confirmed by interview with the Laboratory Director (LD) at 4:00 pm on 09/17/2024, the LD failed to ensure the availability of an approved procedure manual that included: the requirements for patient preparation; specimen collection and labeling criteria; specimen processing, storage, and preservation; criteria for specimen acceptability and rejection; control procedures including the number, type, and frequency for each test system; and corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. Refer to D5403.