Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D2250646	08/16/2022
Name of Provider or Supplier	**Street Address, City, State**	
Pioneer Healthcare, Llc	6766 Hwy 98 W Ste 102, Hattiesburg, MS	

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
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 review of the Centers for Medicare and Medicaid Services (CMS) data system for proficiency testing, a lack of proficiency testing (PT) records, and confirmation by the lab director/technical consultant (LD/TC) as listed on the CMS-209 personnel form, the laboratory failed to enroll in an HHS approved proficiency testing program for complete blood count testing (CBC) performed on the Sysmex XN-330. Testing began on January 28, 2022. Findings include: 1. Review of the CMS data system for proficiency testing revealed no documentation of the performance of proficiency testing for CBC testing on the Sysmex XN-330 since it was put into use on 1/28/22. 2. There was no documentation available for review on the day of survey for proficiency testing. 3. The LD/TC confirmed in an interview at 12:30 p.m. that the laboratory had not enrolled in proficiency testing for CBC's performed on the Sysmex XN-330. Approximately 81 CBC's had been performed between 1/28/22 and 8/16/22.
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 review of quality control (QC) records for the Sysmex XN-330 hematology analyzer from 1/28/22 through 8/16/22 and manufacturer's assay sheets for the XN-L Check controls, the laboratory failed to retain the manufacturer's assay sheet for the lot number of XN-L Check controls, in use from 1/28/22 through 6/21/22, for at least 2 years. Findings include: 1) A quarterly QC report for lot #1351 (in use between 12 /16/21 and 3/29/22) was reviewed--no assay sheet was retained for this lot. 2) A quarterly QC report for lot #2070 (in use between 3/16/22 and 6/21/22) was reviewed--no assay sheet was retained for this lot. 3) The laboratory director/technical consultant and TP #1 confirmed in an interview at 11:00 a.m. that no quality control assay sheets had been retained.
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 review of patient test logs, interview with the laboratory director/technical consultant (LD/TC) on 8/16/22 at 11:15 a.m., and lack of a written procedure manual, the laboratory failed to establish a written procedure manual for performing CBC (Complete Blood Count) testing with the Sysmex XN-330 Hematology analyzer, in use for patient testing from 1/28/2022 through 8/16/22 when a total of 81 patient specimens were tested. Findings include: 1. Review of patient test logs revealed approximately 81 patient CBC's were tested from 1/28/22 through 8/16/22. 2. There was no procedure manual available for review on 8/16/22 for performing patient CBC's on the Sysmex XN-330 Hematology analyzer. 3. The LD/TC confirmed in an interview on 8/16/22 at 11:00 a.m. that there was no written procedure for performing CBC's.
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 Laboratory Policy and Procedure Manual, the laboratory failed to establish written procedures for complete blood counts (CBC's) performed on the Sysmex XN-330 hematology analyzer for the following: 1) Calibration procedures, including type of calibrator and frequency of performing calibration, 2) The reportable range for test results, 3) Control procedures, including type of control, number and frequency of testing controls, control limits, and criteria to determine acceptable control results, 4) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability, 5) Reference intervals (normal values), 6) Panic or alert values for complete blood counts (CBC), 7) The laboratory's system for entering results in the patient record and reporting patient results, including reporting panic or alert values, 8) The verification of CBC results when patient results are flagged by the Sysmex XN-330 hematology analyzer, and 9) The steps to follow if the system becomes inoperable.
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 quality control (QC) quarterly records for the Sysmex XN-330 hematology analyzer from 1-28-22 through 8-16-22, lack of QC results available for review, and billing reports for complete blood counts (CBC) on patients, the laboratory failed to document at least two levels of control material each day of patient CBC testing on 46 days during this time frame when a total of 69 patient CBC's were performed and reported. Findings include: 1. No hard copies of QC results were retained for each daily run. 2. Quarterly QC reports only contained QC runs for sporadic days. 3. Testing Personnel #1 confirmed that daily QC results had not been retained. 3. Review of quality control records (quarterly reports) for the Sysmex XN-330 hematology analyzer from 1-28-22 through 8-16-22 and billed CBC's revealed on the following days the laboratory failed to document at least two levels of control material for CBC testing when a total of 69 patient CBC's were performed and reported: 2/7/22: Patient #15490 2/18/22: Patient #15608 2/21/22: Patient #15339 2/24/22: Patient #15105, #9274 3/3/22: Patient #14456, #13284 3/7 /22: Patient #14486 3/9/22: Patient #15752 3/10/22: Patient #15767, #15689, #8168 3 /25/22: Patient #7663 3/28/22: Patient #15913, #15132 4/6/22: Patient #11716 4/8/22: Patient #7105 4/9/22: Patient #16011 4/14/22: Patient #14586 4/22/22: Patient #16140, #16144 4/23/22: Patient #15688 4/26/22: Patient #16004 4/30/22: Patient #16217 5/9/22: Patient #5488 5/10/22: Patient #15419 5/22/22: Patient #16634 5/23 /22: Patient #10444 5/28/22: Patient #7253, #16724 6/1/22: Patient #5796 6/16/22:

	Patient #15362, #5317 6/17/22: Patient #15433 6/20/22: Patient #7192 6/25/22: Patient #16729, #17163 6/27/22: Patient #14216, #12011, #16312 6/30/22: Patient #15442 7/11/22: Patient #17546 7/13/22: Patient #14720 7/15/22: Patient #16727 7/16 /22: Patient #15869 7/19/22: Patient #15317, #17753 7/22/22: Patient #4962 7/23/22: Patient #17549, #17850, #17851 7/26/22: Patient #17897, #6267 7/27/22: Patient #17913 7/28/22: Patient #17930 7/31/22: Patient #9679, #7755, #4588, #7027, #3840, #3581, #5094 8/1/22: Patient #17172 8/2/22: Patient #8161 8/3/22: Patient #4632, #15803 8/5/22: Patient #9770, #36 8/8/22: Patient #18060
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on lack of documents available for review, the laboratory failed to establish a comprehensive Quality Assessment (QA) program designed to monitor and evaluate the overall quality of the complete blood count total testing process (general laboratory, preanalytic, analytic and postanalytic systems) to assure the quality of the laboratory services provided. There was no QA system in place the day of survey for the Sysmex XN-330 used to perform complete blood counts (CBC's).
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 lack of personnel records to review, the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, installation records for the Sysmex XN-330 hematology analyzer, and lack of documentation of training, the laboratory director failed to ensure that testing personnel (TP) #1 and #2, listed on the CMS 209 personnel form, had appropriate education and received appropriate training for performing complete blood count (CBC) testing with the Sysmex XN-330 hematology analyzer, prior to testing patient specimens. Findings include: 1) There were no personnel records available for review on the day of survey. 2) Both testing personnel have Licensed Practical Nursing licenses and are presumed to have appropriate education, but no proof of education was available for review. 3) Review of the installation records for the Sysmex XN-330 hematology analyzer revealed the hematology analyzer was installed in November 2021 and put in use for patient testing in January 2022. Review of these installation records for the Sysmex XN-330

	hematology analyzer and personnel records for the testing personnel listed on the CMS 209 personnel form revealed no documentation of training on the Sysmex XN-330 for the two individuals responsible for CBC testing, prior to testing patient specimens. 4) The laboratory director confirmed in an interview at 12:30 p.m. on 8/16 /22 that there was no documentation of training on the Sysmex XN-330 or proof of education for TP #1 and #2.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on review of laboratory testing records from 1/28/22 through 8/16/22 and interview with the technical consultant/laboratory director (TC/LD) as listed on the CMS-209 form (Centers of Medicare & Medicaid Services) at 11:00 a.m. on 8/16/22, temperature records had not been documented as reviewed by the TC. Findings Include: 1. Review of the laboratory records from 1/28/22 through 8/16/22 revealed the following records were not documented as reviewed by the TC: a. Temperature records (room, refrigerator). 2. Interview with the TC/LD at 11:00 a.m. on 8/16/22 confirmed there was no documented review of these records by the TC.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on lack of personnel records available for review, review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, and interview with the laboratory director/technical consultant (LD/TC) at 12:30 p.m. on 8/16/22, the technical consultant failed to evaluate and document the performance of Testing Personnel (TP) #1 and #2, responsible for moderate complexity testing since January 2022, at least semiannually during the first year this individual tested patient specimens. 1. There were no personnel records available for review on the day of survey. 2. The LD/TC confirmed in an interview at 12:30 p.m. that no semiannual (6 month) competency/evaluation had been performed on TP #1 and #2.