Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2179673	11/10/2022
Name of Provider or Supplier	**Street Address, City, State**	
Old Pueblo Healthcare Llc	3151 N Windsong Dr, Prescott Valley, AZ	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records from 2022 for testing performed by the laboratory and interview with the testing personnel, the laboratory director and testing personnel failed to sign the PT attestation statements. Findings include: 1. The laboratory performs testing in the specialties of Chemistry and Hematology, with an approximate annual test volume of 240,292. 2. The PT attestation statement presented for review for the first event of 2022 for Chemistry lacked the laboratory director's and testing personnel signature. 3. The PT attestation statements presented for review for the first, second and third event of 2022 for Hematology lacked the laboratory director's signature. 4. The testing personnel interviewed on 11/10/22 at 10:45am confirmed that the PT attestation statements indicated above were not signed by the laboratory director and testing personnel.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by:

	Based on review of patient test requisitions, review of patient test reports and interview with the facility personnel, the laboratory failed to establish policies and procedures to ensure positive identification of a patient's specimen from the time of collection through completion of testing and reporting of results. Findings include: 1. The laboratory began patient testing on May 4, 2020, with an approximate annual test volume of 240,292. The laboratory performs testing in the specialties of Chemistry and Hematology. 2. It is the practice of the laboratory to receive hand-labeled specimens. During the sample accessioning process, the laboratory matches the hand-labeled sample with the corresponding test requisition and generates a printed label. The printed label is then affixed to the sample prior to testing. The printed label is also affixed to the patient's test requisition. 3. The test requisition reviewed during the survey for patient P.L. (DOB 3/07/1947) - patient ID# 10177, contained the affixed printed label for patient S.B. (DOB 11/29/1946) - patient ID# 10177. 4. The testing personnel (TP-1) and accessioning personnel interviewed on 11/10/22 at 1:10pm stated that the specimens received by the laboratory with the test requisition referenced above belonged to patient P.L., however the specimens were mislabeled with S.B.'s patient label. They stated that both patients had the same patient ID number due to an error in the laboratory's patient record system, however the error was not identified during the sample accessioning process. 5. No documentation was presented for review during the survey to indicate the laboratory established policies and procedures to ensure positive patient identification on patient specimens from the time of collection or receipt of the specimen through completion of testing and reporting of results. 6. The TP-1 interviewed on 11/10/22 at 1:15pm confirmed that the laboratory failed to establish policies and procedures to ensure positive patient identification throughout the entire testing process.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (PT) records from 2022 and interview with the facility personnel, (A) the laboratory failed to document corrective action for unsatisfactory PT scores for testing performed in the specialty of Chemistry and (B) the laboratory failed to establish QA policies and procedures to monitor, assess, and when indicated, correct problems identified in the general laboratory systems. Findings include: A1. The laboratory received a score of 40% for the regulated analyte, Cholesterol Total, during the first PT event of 2022. A2. No corrective action documentation was presented for review during the survey to indicate the laboratory identified and corrected the error of the unsatisfactory PT score indicated above. A3. The facility personnel interviewed on 11/10/22 at 10:48am confirmed that the laboratory failed to document corrective action for the unsatisfactory PT score referenced above. B1. No QA documentation was provided for review during the survey conducted on 11/10/2022 to indicate the laboratory established policies and procedures to monitor, assess and, when indicated, correct problems identified in the general laboratory systems. B2. The testing personnel interviewed on 11/10/22 at 2:

	50pm confirmed the laboratory failed to provide documentation of an established QA policy and procedure to monitor, assess and correct problems identified with the general laboratory systems.
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 lack of written policies and procedures for review and interview with the testing personnel, the laboratory failed to establish policies and procedures for specimen labeling. Findings include: 1. The laboratory began patient testing on May 4, 2020, with an approximate annual test volume of 240,292. The laboratory performs testing in the specialties of Chemistry and Hematology. 2. No documentation was presented for review during the survey to indicate the laboratory had established, approved policies in place for specimen labeling. 3. The testing personnel and specimen accessioning personnel interviewed on 11/10/22 at approximately 11:40am stated that some specimens arrive at the laboratory which are hand-labeled by the person collecting the specimen. Upon arrival at the laboratory, the hand-labeled specimens are then labeled with a printed label. Some specimens which are hand-labeled include the date and time of collection, while others do not include this information. The testing personnel and accessioning personnel acknowledged that hand-labeled specimens are not consistently documented with the date and time of collection. 4. The testing personnel interviewed on 11/10/22 at 11:45am confirmed the laboratory failed to have the above referenced policy and procedure in place at the time of the survey.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on lack of quality assessment (QA) policies and procedures and interview with the testing personnel, the laboratory failed to establish QA policies and procedures to monitor, assess, and when indicated, correct problems identified in the preanalytic systems. Findings include: 1. No QA documentation was provided for review during the survey conducted on 11/10/2022 to indicate the laboratory established policies and procedures to monitor, assess and, when indicated, correct problems identified in the preanalytic systems. 2. The testing personnel interviewed on 11/10/22 at 2:50pm confirmed the laboratory failed to provide documentation of an established QA policy and procedure to monitor, assess and correct problems identified with the preanalytic systems.

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 lack of performance specification documentation for the Sysmex XN 350 hematology analyzer and interview with the testing personnel, the laboratory failed to provide documentation indicating verification of performance characteristics for the instrument including accuracy, precision, reportable range and reference range. Findings include: 1. The laboratory began using the Sysmex XN350 hematology analyzer in January 2022. 2. During the survey conducted on 11/10/22, no documentation was presented for review to indicate the laboratory verified the manufacturer's performance characteristics of the Sysmex XN 350 analyzer including accuracy, precision, reportable range and reference range, prior to patient testing. 3. The testing personnel interviewed on 11/10/22 at 10:15am confirmed the laboratory began testing on the Sysmex XN 350 hematology analyzer in January 2022. The number of patient tests performed on the analyzer from January 2022 through the date of the survey could not be determined at the time of the survey.
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 quality assessment (QA) policies and procedures and interview with the testing personnel, the laboratory failed to establish QA policies and procedures to monitor, assess, and when indicated, correct problems identified in the analytic systems. Findings include: 1. No QA documentation was provided for review during the survey conducted on 11/10/2022 to indicate the laboratory established policies and procedures to monitor, assess and, when indicated, correct problems identified in the analytic systems. 2. The testing personnel interviewed on 11/10/22 at 2:50pm confirmed the laboratory failed to provide documentation of an established QA policy and procedure to monitor, assess and correct problems identified with the analytic systems.
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 reports and interview with the testing personnel, the laboratory failed to have a system in place to ensure the accuracy of test results that are electronically interfaced from the analyzers to the Laboratory Information System (LIS) and from the LIS to the patients' Electronic Health Record (EHR). Findings include: 1. The laboratory began patient testing on May 4, 2020, with an approximate annual test volume of 240,292. The laboratory performs testing in the specialties of Chemistry and Hematology. The laboratory utilizes the following analyzers: Sysmex XN-350, Vitros 5600 and Indiko Plus. 2. The test results generated from the laboratory's analyzers electronically interface into the laboratory's LIS, and then the results from the LIS electronically interface into the patients' EHR. 3. No documentation was presented for review during the survey to indicate the laboratory has a system in place to ensure the accuracy of patient test results that are electronically interfaced from the analyzers to the LIS and from the LIS to the EHR. 4. The testing personnel interviewed on 11/10/22 at 2:15pm confirmed the laboratory did not have a system in place to verify the accuracy of the patient test results that are electronically sent from the analyzers to the LIS and from the LIS to the EHR.
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 review of patient test reports generated from the EHR (Electronic Health Record) and interview with the testing personnel, the laboratory's test report failed to include the laboratory name and address where the testing was performed and failed to include the correct test report date. Findings include: 1. The laboratory began patient testing in the specialties of Chemistry and Hematology in May 2020, with an approximate annual test volume of 240,292. Final test reports are maintained in the EHR, e-Clinical Works. 2. The test reports maintained in the EHR and reviewed during the survey (accession# 20220317182101, 20221013153018 and 20220105164419) were missing the laboratory name and address where the testing was performed. 3. The test report maintained in the EHR for accession# 20220317182101 failed to indicate the correct received and report date. The received date was listed as 03/17/2022 18:22:06 and the reported date was listed as 03/15/2022 08:53:00. 4. The test report maintained in the EHR for accession# 20220105164419

	failed to indicate the correct received and report date. The received date was listed as 01/05/2022 16:45:03 and the reported date was listed as 01/04/2022 15:32:00. 5. The test report maintained in the EHR for accession# 20221013153018 failed to indicate the correct received and report date. The received date was listed as 10/13/2022 15:32:04 and the reported date was listed as 10/04/2022 14:19:00. 6. The testing personnel interviewed at 12:53pm on 11/10/22 confirmed the laboratory's test reports maintained in the EHR failed to include the name and address of the laboratory where the testing was performed, and failed to include the correct report date and the correct date of specimen receipt.
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 review of patient test results and interview with the testing personnel, the laboratory failed to promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of errors identified during the reporting process and failed to issue corrected reports to the authorized person ordering the test. Findings include: 1. Review of the test requisition for patient, P.L. (DOB 03/17/1947) revealed the patient's specimens were mislabeled with a label for patient, S.B. (DOB 11/29/1946). See D5203 for specific findings. 2. The test requisition referenced above indicated orders for the following tests: TSH Reflex (FT4, FT3), Comprehensive Metabolic Panel (CMP), and CBC W/DIFF, W/PLT. 3. The laboratory received the above referenced specimens on 10/04/22 14:19:00. The tests were performed by the laboratory and the test results were reported in the Electronic Health Record (EHR) for patient S.B. on 10/07/22 at 14:23:54 for the CBC W/DIFF, W/PLT; on 10/07/22 at 14:24:05 for the CMP; and on 10/07/22 at 14:24:39 for the TSH Reflex. 4. No evidence or documentation was presented for review during the survey to indicate the laboratory promptly notified the authorized person who ordered the tests of reporting errors, in which clinically significant test results were reported on the wrong patient. 5. The reported test results were transmitted to the EHR for patient, P.L. on 10/13/22 at 15:32:04, upon identification of the error by laboratory staff. 6. No evidence was presented for review during the survey to indicate the laboratory issued a corrected report to the authorized person who ordered the tests once the error was identified. There was no documenation maintained in the LIS or EHR to indicate why the test results were corrected and whether or not a corrected report was issued to the authorized person who ordered the tests. 7. The testing personnel interviewed on 11/10/22 at 1:35pm confirmed that the laboratory failed to promptly notify the authorized person who ordered the tests of errors identified with the test results and the laboratory failed to issue a corrected test report to the authorized person who ordered the tests once the error was identified.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on lack of quality assessment (QA) policies and procedures and interview with the testing personnel, the laboratory failed to establish QA policies and procedures to monitor, assess, and when indicated, correct problems identified in the postanalytic systems. Findings include: 1. No QA documentation was provided for review during the survey conducted on 11/10/2022 to indicate the laboratory established policies and procedures to monitor, assess and, when indicated, correct problems identified in the postanalytic systems, including but not limited to, policies related to corrected test reports. 2. The testing personnel interviewed on 11/10/22 at 2:50pm confirmed the laboratory failed to provide documentation of an established QA policy and procedure to monitor, assess and correct problems identified with the postanalytic systems.
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 lack of quality assessment documentation for review, the laboratory director failed to ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. See D5291, D5391, D5791 and D5891 for findings.
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 initial training documentation for two testing personnel and interview with the testing personnel, the laboratory director failed to ensure that prior to testing patients' specimens, all personnel have the appropriate training for the type and complexity of services offered. Findings include: 1. No initial training documentation was presented for review for two out of two testing personnel who

	began patient testing in May 2020. 2. During the survey conducted on 11/10/22 at approximately 9:50am, the testing personnel confirmed the laboratory failed to provide documentation of initial training for the two testing personnel indicated above. 3. The laboratory began patient testing on May 4, 2020 in the specialties of Chemistry and Hematology, with an approximate annual test volume of 240,292.
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 performance evaluation documentation and interview with the testing personnel, the technical consultant failed to evaluate and document the performance of two testing personnel, at least semiannually during the first year the individuals tested patient specimens. Findings include: 1. No semiannual competency evaluation documentation was presented for review for two out of two testing personnel who began patient testing in May 2020. 2. The testing personnel interviewed on 11/10/22 at 9:51am confirmed that the laboratory failed to have documentation of a semiannual competency evaluation for the two testing personnel indicated above.
D6054	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 annually, after the first year. This STANDARD is not met as evidenced by: Based on lack of competency evaluation documentation for review from 2021 and 2022 and interview with the facility personnel, the technical consultant failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least annually. Findings include: 1. During the survey conducted on 11/10/22, no annual competency evaluation documentation from 2021 and 2022 was presented for review for two out of two testing personnel who perform testing in the specialties of Chemistry and Hematology. Each testing personnel began patient testing on May 4, 2020. 2. At 9:51am on 11/10/22, the facility personnel confirmed that the laboratory failed to provide documentation of an annual competency evaluation from 2021 and 2022 for the testing personnel indicated above.