Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2058341	08/22/2023
Name of Provider or Supplier	**Street Address, City, State**	
Prescott Healthcare Solutions, Llc Dba	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
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 number and severity of deficiencies cited for quality practices identified during the complaint investigation conducted on August 22, 2023, it was determined that the laboratory failed to 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. See D5203 and D5291 for findings.
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 and test reports from 2022 and 2023 and interview with the General Supervisor (GS), the laboratory failed to follow established 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 performs testing in the specialties of Hematology and Chemistry, with an approximate annual test volume of 436,667. 2. The laboratory's established policy 'Patient Identification' states, "Each patient will be correctly identified and entered in a computerized format into the Laboratory Information System (LIS). Each patient will receive a unique ID number (accession number) when he/she is processed, and this number will appear on all files, reports and correspondence regarding this patient sample." 3. During the sample accessioning process, the laboratory matches the labeled specimen with the corresponding test requisition and generates a printed label containing an assigned accession number. The printed label is then affixed to the sample prior to testing. The printed label is also affixed to the patient's test requisition. 4. 17 out of 17 patient test reports and corresponding test requisitions reviewed during the survey showed one unique ID number assigned to two separate patients. 5. 10 out of 10 patient test reports and corresponding test requisitions reviewed during the survey indicated the specimen was incorrectly identified during the accessioning process, resulting in mislabeled specimens and test results being reported on the incorrect patient. 6. The laboratory failed to follow established 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, as indicated above. 7. The GS interviewed on 08/22/23 at 10:56 AM confirmed the laboratory failed to follow established 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 established Quality Assessment (QA) policies and procedures and interview with the general supervisor (GS), the laboratory's QA policies and procedures failed to include 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. Findings include: 1. No QA documentation from 2022 and 2023 was provided for review during the complaint investigation conducted on 08/22/23 to indicate the laboratory has an ongoing mechanism to monitor, assess and, when indicated, correct problems identified with specimen and patient identification. See D5203 for specific findings. 2. The laboratory provided evidence of 3 separate email communications from the laboratory staff to the ordering provider (dated 01/12/23 at 1:08 PM, 06/28/23 at 9:58 AM and 06/28/23 at 10:20 AM) to notify the ordering provider of incorrect test results due to patient identification errors, however no documentation was presented for review to indicate how the laboratory monitored and assessed the issue to prevent the issue from recurring. 3. The GS interviewed on 08/22/23 at 12:00 PM confirmed the laboratory failed to provide QA documentation to indicate the laboratory has an ongoing mechanism to monitor, assess and correct problems identified with the general laboratory systems requirements specified at 493.1231 through 493.1236.
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 review of patient test reports, review of the laboratory's established policies and procedures and interview with the General Supervisor (GS), the laboratory failed to follow established policies for specimen storage and preservation and failed to establish policies and procedures for specimen acceptability and rejection and specimen referral. Findings include: 1. The laboratory performs testing in the specialties of Hematology and Chemistry, with an approximate annual test volume of 436,667. The laboratory refers certain specimens to other CLIA-certified laboratories for testing if the laboratory is unable to perform the test requested. 2. The laboratory's established policy for 'Specimen Stability and Processing' states, "Chemistries: serum SST tiger top tube: Refrigerated 7 days." 3. Review of final test reports for two out of two specimens sent to a referral laboratory for testing indicated the laboratory exceeded the specimen stability requirement of 7 days (refrigerated) as follows: - patient ID# 53671, specimen for Prostrate Specific Ag (PSA) collected on 07/21/23 10:12, received by referral laboratory on 08/01/23 06:20:05, test result reported by referral laboratory on 08/01/23 06:04:15. - patient ID# 91088, specimen for Complete Metabolic Panel (CMP) colleted on 07/19/23 14:43, received by referral laboratory on 07/31/23 18:04:03, test result reported by referral laboratory on 07/31/23 18:03:00 4. The 'Specimen Stability and Processing' policy presented for review failed to include information regarding the specimen stability and processing requirements of frozen specimens prior to sending to a reference laboratory for testing. \ 5. The laboratory failed to establish policies and procedures for specimen acceptability and rejection, including specimens which have exceeded the stability requirement, specimens not stored properly and specimens that are mislabeled or unlabeled. 6. The laboratory failed to establish policies and procedures for specimen referral. 7. The GS interviewed on 08/22/23 at 10:52 AM acknowledged the laboratory's policies and procedures for specimen storage and preservation, specimen acceptability and rejection, and specimen referral were not followed or not established as indicated above.
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) records and interview with the general supervisor (GS), the laboratory failed to establish QA 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. Findings

	include: 1. No QA documentation was provided for review during the complaint investigation conducted on 08/22/23 to indicate the laboratory established policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the preanalytic systems, including identified issues related to specimen referral and specimen stability. 2. The GS interviewed on 08/22/23 at 12:00 PM confirmed the laboratory failed to provide documentation of established QA policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified with the preanalytic systems specified at 493.1241 through 493.1242.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: **Based on lack of policies and procedures for review and interview with the general supervisor (GS), the laboratory failed to establish corrective action policies and procedures to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. Findings include: 1. No documentation was presented for review to indicate the laboratory established corrective action policies and procedures to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports, including but not limited to, patient identification errors and errors with testing samples past the specimen stability timeframe. 2. The laboratory failed to have a system in place to retrieve corrected test reports at the time of the complaint investigation conducted on 08/22/23. 3. The GS interviewed on 08/22 /23 at 10:52 AM confirmed the laboratory failed to provide documentation of established corrective action policies and procedures as referenced above, and was unable to retrieve corrected reports issued by the laboratory during the complaint investigation. **This is a repeat deficiency from the previous recertification survey conducted on 11/10/22.
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 lack of documentation for review and interview with the general supervisor (GS), the laboratory director failed to ensure that policies and procedures are established for monitoring individuals who perform preanalytical phases of testing to assure that they are competent and maintain their competency to process specimens accurately and proficiently and whenever necessary, identify needs for remedial

	training or continuing education to improve skills. Findings include: 1. No policies and procedures as described above were presented for review during the survey. 2. No evidence was presented for review to indicate the laboratory assessed the competency of individuals who process specimens to ensure the accessioning process is performed accurately and proficiently and whenever necessary, identify needs for remedial training or continuing education to improve skills. 3. The GS interviewed on 08/22/23 at 11:00 AM confirmed that the laboratory failed to provide evidence of established policies and procedures for monitoring individuals who perform preanalytical phases of testing. 4. The laboratory performs testing in the specialties of Hematology and Chemistry, with an approximate annual test volume of 436,667.