Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2058341	11/10/2022
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
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 testing personnel, the laboratory failed to follow QA policies and procedures to monitor, assess, and when indicated, correct problems identified in the general laboratory systems. Findings include: 1. The laboratory's established QA policy titled, Quality Assurance Program & General Operating Procedures, states, "The laboratory will produce quarterly Quality Assurance reports." 2. No QA documentation was provided for review during the survey conducted on 11/10/2022 to indicate the laboratory documented QA activities on a quarterly basis during 2020, 2021 and 2022 (through the date of the survey) to monitor, assess and, when indicated, correct problems identified in the general laboratory systems. 3. The testing personnel interviewed on 11/10/22 at 2:50pm confirmed the laboratory failed to provide documentation of quarterly QA reports to monitor, assess and correct problems identified with the general laboratory systems.
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 review of patient test requisitions and interview with the testing personnel, three out of three test requisitions reviewed during the survey failed to include the date and time of specimen collection. Findings include: 1. The laboratory utilizes the Indiko Plus chemistry analyzer for the drug screen testing and the Shimadzu LC/MS 4080 analyzer for the drug confirmation testing; the Sysmex XN-350 hematology analyzer; and the Vitros 5600 chemistry analyzer for routine chemistry testing and testing performed in the sub-specialty of Endocrinology. The laboratory's approximate annual test volume is 436,667. 2. The test requisitions presented for review during the survey for specimen accession# 20220518153608, 20220512122858 and sample ID# 141097 failed to include the date and time of specimen collection. 3. The testing personnel interviewed at 11:45am on 11/10/2022 confirmed the date and time of specimen collection were not documented on the test requisitions referenced 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 review of established Quality Assessment (QA) policies and procedures and interview with the testing personnel, the laboratory failed to follow QA policies and procedures to monitor, assess, and when indicated, correct problems identified in the preanalytic laboratory systems. Findings include: 1. The laboratory's established QA policy titled, Quality Assurance Program & General Operating Procedures, states, "The laboratory will produce quarterly Quality Assurance reports." 2. No QA documentation was provided for review during the survey conducted on 11/10/2022 to indicate the laboratory documented QA activities on a quarterly basis during 2020, 2021 and 2022 (through the date of the survey) to monitor, assess and, when indicated, correct problems identified in the preanalytic laboratory systems. 3. The testing personnel interviewed on 11/10/22 at 2:50pm confirmed the laboratory failed to provide documentation of quarterly QA reports to monitor, assess and correct problems identified with the preanalytic laboratory systems.
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 testing personnel, 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. 2. The testing personnel interviewed on 11/10/22 at 2:20pm confirmed the laboratory failed to provide documentation of established corrective action policies and procedures.
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 review of established Quality Assessment (QA) policies and procedures and interview with the testing personnel, the laboratory failed to follow QA policies and procedures to monitor, assess, and when indicated, correct problems identified in the analytic laboratory systems. Findings include: 1. The laboratory's established QA policy titled, Quality Assurance Program & General Operating Procedures, states, "The laboratory will produce quarterly Quality Assurance reports." 2. No QA documentation was provided for review during the survey conducted on 11/10/2022 to indicate the laboratory documented QA activities on a quarterly basis during 2020, 2021 and 2022 (through the date of the survey) to monitor, assess and, when indicated, correct problems identified in the analytic laboratory systems. 3. The testing personnel interviewed on 11/10/22 at 2:50pm confirmed the laboratory failed to provide documentation of quarterly QA reports to monitor, assess and correct problems identified with the analytic laboratory 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 follow the policy and procedure in place to ensure the accuracy of test results and other patient specific information 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 performs patient testing with an approximate annual test volume of 436,667. The laboratory performs testing in the specialties of Chemistry and Hematology on the following analyzers: Sysmex XN-350, Vitros 5600, Indiko Plus and Shimadzu LC/MS 8040. 2. The test results generated from the laboratory's analyzers electronically interface into the laboratory's LIS (LabTrak), and then the results from the LIS electronically interface into the patients' EHR (e-ClinicalWorks). 3. During the survey conducted on 11/10/22, the policy and procedure reviewed by the surveyor, "Optima Medical Patient Result Accuracy Audit Policy and Procedure" listed steps to take to document a review of the accuracy of electronically interfaced results and patient-specific data. The policy states, "Locate a Patient Result Accuracy Front Sheet from the folder labeled as Patient Result Accuracy Audit Documentation. Fill in the date, initials and instrumentation that is being used. Select the first patient from the past 5 months...For each result reported, the accuracy of the number and the units of measure must be checked on each printout....For each printout, the accuracy of the patient ID number and sample date must be checked...For each printout, the accuracy of each analyte analyzed must be checked." 4. No documentation was presented for review during the survey to indicate the laboratory followed the above referenced policy and procedure to ensure the accuracy of patient test results and patient-specific information that are electronically interfaced from the analyzers to the LIS and from the LIS to the EHR. The laboratory last performed and documented a patient result accuracy review in November 2020. 5. The policy and procedure indicated above failed to include the frequency in which the laboratory is required to perform and document the review. 6. The testing personnel interviewed on 11/10/22 at 2:15pm confirmed the laboratory failed to follow the system in place to verify the accuracy of the patient test results and patient-specific information 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 performs patient testing in the specialties of Chemistry and Hematology, with an approximate annual test volume of 436,667. 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# 20220512122858 and 20220518153608) were missing the laboratory name and address where the testing was performed. 3. The test report maintained in the EHR for accession# 20220512122858 failed to indicate the correct received and report date. The received date was listed as 05/13/2022 13:26:10 and the reported date was listed as 05/11/2022 11:15:00. 4. The test report maintained in the EHR for accession# 20220518153608 failed to indicate the correct received and report date. The received date was listed as 05/18/2022 15:47:10 and the reported date was listed as 05/11/2022 16:21:00. 5. The testing personnel interviewed at 12:55pm 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.
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 review of established Quality Assessment (QA) policies and procedures and interview with the testing personnel, the laboratory failed to follow QA policies and procedures to monitor, assess, and when indicated, correct problems identified in the postanalytic laboratory systems. Findings include: 1. The laboratory's established QA policy titled, Quality Assurance Program & General Operating Procedures, states, "The laboratory will produce quarterly Quality Assurance reports." 2. No QA documentation was provided for review during the survey conducted on 11/10/2022 to indicate the laboratory documented QA activities on a quarterly basis during 2020, 2021 and 2022 (through the date of the survey) to monitor, assess and, when indicated, correct problems identified in the postanalytic laboratory systems. 3. The testing personnel interviewed on 11/10/22 at 2:50pm confirmed the laboratory failed to provide documentation of quarterly QA reports to monitor, assess and correct problems identified with the postanalytic laboratory systems.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must 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 one testing personnel who performs testing on the Sysmex XN-350 analyzer 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 one testing personnel who began patient testing on the Sysmex XN-350 hematology analyzer in January 2022. 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 testing personnel indicated above.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high 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 supervisor failed to evaluate and document the performance of one testing personnel, at least semiannually during the first year the individual tested patient specimens. Findings include: 1. No semiannual competency evaluation documentation was presented for review for one out of one testing personnel who began patient testing in July 2021. 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 testing personnel indicated above.