Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2058341	08/08/2018
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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on lack of employee competency policies and procedures for review and interview with the facility personnel, the laboratory failed to establish policies and procedures to assess employee competency. Findings include: 1. The laboratory began testing patient specimens in July 2017 in the sub-specialties of Routine Chemistry and Toxicology. 2. No documentation was presented for review to indicate the laboratory established policies and procedures to assess the competency of individuals who perform testing on patient specimens and to assess the competency of the Technical Consultant. 3. The facility personnel confirmed that the laboratory did not have policies established to assess the competency of testing personnel and the technical consultant.
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 direct inspection of patient specimens, review of the laboratory's policy and procedure manual and interview with the facility personnel, the laboratory failed to follow established policies for specimen identification and collection. Findings include: 1. The laboratory performs urine drug screen testing in the sub-specialties of Routine Chemistry and Toxicology, with an approximate annual test volume of 31,462. 2. The laboratory's established policy specific to Patient Identification states, "Patient information will include: ...Date and Time of Specimen Collection Clinically". 3. Direct inspection by the surveyor of the laboratory's collected specimens on August 8, 2018 revealed that the laboratory failed to consistently include the date and time of specimen collection on the collection cup. 4. The facility personnel confirmed that the laboratory personnel were not following laboratory policy by including the date and time of specimen collection on each specimen tested by the laboratory.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on lack of documentation for review and interview with the facility personnel, the laboratory failed to document the humidity of the laboratory where patient testing is performed. Findings include: 1. The laboratory began patient testing in July 2017 under the sub-specialties of Routine Chemistry and Toxicology, with an approximate annual test volume of 31,462. 2. The laboratory performs patient testing on the Indiko Plus Chemistry analyzer which has a humidity requirement of 40% - 80%, as stated in the manufacturer's operating manual. 3. No documentation was presented for review during the survey to indicate the laboratory documented the humidity of the laboratory where patient testing was performed. 4. The facility personnel confirmed that the laboratory was monitoring the humidity of the room where patient testing is performed, but failed to document the humidity measurements.
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 facility personnel, the laboratory failed to have a system in place to ensure the accuracy of test results that are electronically interfaced into the laboratory's information system (LIS). Findings include: 1. The laboratory performs approximately 31,462 patient tests annually under the sub-specialty of Routine Chemistry and Toxicology. 2. The laboratory performs testing on the Indiko Plus analyzer, and the test results are electronically interfaced from the analyzer to the LIS, Paracelsus. 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 interfaced from the Indiko Plus analyzer to the LIS (Paracelsus). 4. The facility personnel confirmed that the laboratory did not have a system in place to verify the accuracy of the patient test results that are sent from the analyzer to the LIS.
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 and interview with the facility personnel, the laboratory failed to include on the test report the name of the laboratory where the testing was performed. Findings include: 1. The laboratory performs patient testing in the specialty of Chemistry, with an approximate annual test volume of 31,462. 2. Two out of two test reports reviewed during the survey, patient #100002545 and 10000309, were missing the laboratory name where the testing was performed. 3. The facility personnel confirmed that the laboratory name where the testing was performed was not included on the test reports referenced above.
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 facility personnel, the technical consultant 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 testing personnel who

	began patient testing in July 2017. 2. The facility personnel confirmed that the laboratory did not have documentation of a semiannual competency evaluation for the testing personnel indicated above.