Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D1105892	02/21/2024
Name of Provider or Supplier	**Street Address, City, State**	
Kingman Oncology Institute	890 Airway Ave, Kingman, 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 and 2023 for testing performed in the specialty of Hematology and interview with the testing personnel, the laboratory director and testing personnel failed to sign the PT attestation statements for three out of six testing events. Findings include: 1. The laboratory performs Complete Blood Count (CBC) testing in the specialty of Hematology, with an approximate annual test volume of 5,000. 2. The PT attestation statements presented for review for CBC testing for the 2nd event of 2022, 1st event of 2023 and 3rd event of 2023 lacked the signature of the laboratory director and the testing personnel. 3. The testing personnel interviewed on 2/21/2024 at 1:10 PM confirmed that the PT attestation statements indicated above were not signed by the laboratory director and testing personnel.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two

	years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records from 2023 and interview with the testing personnel, the laboratory failed to provide evidence of the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, and failed to maintain copies of the instrument printouts documenting that the PT samples were tested by the laboratory. Findings include: 1. The laboratory performs CBC testing in the speciality of Hematology on the Abbott Emerald analyzer, with an annual test volume of 5,000. 2. The laboratory failed to provide evidence of the signed attestation statement and the instrument printouts showing the PT samples were tested by the laboratory for the 2nd PT event of 2023. 3. The testing personnel interviewed on 2/21/2024 at 1:15 PM confirmed the attestation statement and instrument printouts for the PT event indicated above were not available for review at the time of the survey.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual for CBC testing and interview with the testing personnel, the laboratory failed to have the current laboratory director approve, sign and date the test procedure before use. Findings include: 1. The current laboratory director indicated in the CLIA Federal Database and assigned on the CMS-209, Laboratory Personnel Form presented for review during the survey has been listed as laboratory director since 04/20/2021. 2. The CBC policy and procedure manual presented for review during the survey conducted on 02 /21/2024 was not approved, signed and dated by the current laboratory director. 3. The testing personnel interviewed on 2/21/2024 at 1:35 PM confirmed that the policy and procedure manual indicated above was not approved, signed and dated by the current laboratory director. 4. The laboratory performs testing in the specialty of Hematology with an annual test volume of 5,000.