Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D1105892	08/23/2018
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 2016 and 2017 for testing performed in the specialties of Chemistry and Hematology and interview with the facility personnel, the laboratory director and the individual testing the samples failed to sign the PT attestation statement. Findings include: 1. The laboratory performs patient testing in the specialties of Chemistry and Hematology, with an approximate annual test volume of 12,502. 2. The PT attestation statements presented for review for the third event of 2016 for Chemistry and the first events of 2017 for Chemistry and Hematology lacked the director's signature and the testing personnel's signature. 3. The PT attestation statements presented for review for the second event of 2017 for Hematology and the third event of 2017 for Chemistry lacked the director's signature. 4. The facility personnel confirmed that the PT attestation statements indicated above were not signed by the laboratory director and testing personnel.
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 review of patient test reports, review of the laboratory's instrumentation and record system and interview with the facility personnel, the laboratory failed to verify the accuracy of calculations and results transmitted from the Laboratory Information System (LIS). Findings include: 1. The laboratory performs patient testing in the specialty of Chemistry and Hematology with an approximate annual test volume of 12,502. The laboratory implemented a LIS in November 2016 to interface test results from the analyzers to the electronic medical record (EMR). 2. No documentation was presented for review during the survey conducted on August 24, 2018 to indicate the laboratory verified the accuracy of patient test results and calculations generated by the LIS prior to integrating it into routine operation. 3. The facility personnel confirmed that they did not verify the accuracy and reliability of test results and calculations transmitted by the LIS prior to reporting patient results.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of calibration records for the Abbott Emerald hematology analyzer and interview with the facility personnel, the laboratory failed to perform and document calibration procedures as required. Findings include: 1. The laboratory utilizes the Abbott Emerald analyzer for Complete Blood Count (CBC) testing, with an approximate annual test volume of 5,838. 2. The laboratory's established calibration requirement is to perform calibration procedures on the analyzer every 6 months. 3. Review of the calibration records revealed the analyzer was calibrated on 10/20/17 and the next documented calibration occurred on 07/17/18. 4. No other documentation was presented for review during the survey to indicate the laboratory performed and documented calibration procedures for the Abbott Emerald analyzer every 6 months as required. 5. The facility personnel confirmed that the laboratory did not have documentation indicating calibration procedures were performed on the analyzer during the time period indicated above. 6. The number of patients tested on the analyzer during that time period could not be determined at the time of the survey.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification

	procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on lack of calibration verification documentation for the Ace Alera chemistry analyzer and interview with the facility personnel, the laboratory failed to perform and document calibration verification procedures as required. Findings include: 1. The laboratory uses an Ace Alera analyzer to conduct patient testing in the specialty of Chemistry, with an approximate annual test volume of 6,664. 2. No documentation was presented for review from 2016 and 2017 to indicate the laboratory performed calibration verification on the Ace Alera chemistry analyzer at least once every six months, including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results. 3. During the survey conducted on August 23, 2018 the laboratory produced documentation of calibration verification that occurred on August 15, 2018, but no other documentation was presented for review. 4. The facility personnel confirmed that the laboratory did not perform and document calibration verification procedures every six months as required from 2016 through the date of the survey.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of patient test reports, review of the laboratory's record system and interview with the facility personnel, the laboratory failed to maintain an information or record system that includes the identity of the personnel who performed each patient test. Findings include: 1. The laboratory performs testing in the specialties of Chemistry and Hematology, with an approximate annual test volume of 12,502. The

	laboratory utilizes an electronic medical record (EMR) system to maintain patient test reports. 2. No documentation was provided for review during the survey to indicate the laboratory maintained an information or record system that includes the identity of the testing personnel who performed the test. 3. The facility personnel confirmed that the laboratory did not have a system in place at the time of the survey to identify the testing personnel for each test that is performed by the laboratory.
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 March 2017. 2. The facility personnel confirmed that the laboratory did not have documentation of a semiannual competency evaluation for the 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 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. No 2017 annual competency evaluation documentation was presented for review for one testing personnel. 2. The facility personnel confirmed that the laboratory failed to provide documentation of an annual competency evaluation from 2017 for one testing personnel indicated above.