Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2162878	11/08/2023
Name of Provider or Supplier	**Street Address, City, State**	
Cancer Centers Of Southwest Oklahoma - Chickasha	2222 W Iowa Ave, Chickasha, OK	

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
D0000	The validation survey was performed on 11/08/2023. The laboratory was found out of compliance with the following CLIA Conditions 493.1409; D6033: Technical Consultant
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the technical consultant and testing person #1, the laboratory failed to follow their written policy for verifying the stated values of control materials prior to implementation for nine of 12 lot numbers used during the review period of 06/23/2023 through the current date. Findings include: (1) On 11/08/2023 at 10:20 am, the technical consultant stated the following: (a) The laboratory performed CBC (Complete Blood Count) testing using the Medonic M-series analyzer; (b) Three levels of Boule Con-Diff Tri-Level hematology QC (Quality Control) materials were performed each day of patient testing; (c) The manufacturer's provided ranges were used to determine acceptability of quality control results. (2) A review of the policy titled, "Quality Control Policies and Protocol" under "Evaluation of New Lot of QC" stated the following: (a) "When new lot of controls are received, QC correlation will be performed before the new lot of controls is put into use"; (b) "1. Run current lot of controls. If results are within acceptable range, proceed to step 2"; (c) "2. Run new lot of controls 2 times preferrably AM & PM": (d) "Repeat step 2 for 4 days". (3) A review of records for 12 control lot numbers used from 06/23/2023 through the current date identified the laboratory did not follow their policy for verifying new QC

	lot numbers as follows: (a) Lot #2230331, 2230332, and 2230333 used from 06/30 /2023 through 08/11/2023 - Tested one time on 06/27/2023 and one time on 06/28 /2023; (b) Lot #2230501, 2230502, and 2230503 used from 08/14/2023 through 09/25 /2023 - Tested one time on 08/11/2023; (c) Lot #2230731, 2230732, and 2230732 put into use on 10/31/2023 and was currently in use - Tested one time on 10/30/2023. (4) The findings were reviewed with technical consultant and testing person #1. Both stated on 11/08/2023 at 03:15 pm, the laboratory did not follow their written policy.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and interview with the technical consultant, the laboratory failed to ensure three of three expired materials were not available for use. Findings include: (1) On 11/08/2023 at 10:20 am, the technical consultant stated CBC (Complete Blood Count) testing was performed using the Medonic M-series hematology analyzer; (2) Observation of the contents of the laboratory refrigerator on 11/08/2023 at 10:20 am identified three levels of Boule Con-Diff Tri-Level hematology controls that had exceeded the manufacturer's expiration date as follows: (a) Lot #22306-01 with an expiration date of 10/26/2023 (b) Lot #22306-02 with an expiration date of 10/26 /2023 (c) Lot #22306-03 with an expiration date of 10/30/2023 (3) Interview with the technical consultant on 11/08/2023 at 10:35 am confirmed the controls had not been tested on the analyzer beyond the expiration date, however, they were in the refrigerator and available for use.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instruction manual, and interview with the technical consultant and testing person #1, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures on the Medonic M-series analyzer one of 15 months reviewed. Findings include: (1) On 11/08/2023 at 10:20 am, the technical consultant stated CBC (Complete Blood Count) testing was performed using the Medonic M-series hematology analyzer; (2) A review of the manufacturer's instruction manual titled, "Medonic M-series User's Manual", Chapter 8, section 8-2 required the following monthly maintenance procedures: (a) Monthly Cleaning (Hypochloride) (b) Clot Prevention (Enzymatic) (3) A review of maintenance logs from 08/01/2022 through 10/31/2023 identified monthly maintenance had not been documented as performed between 01/01/2023 and 03/31 /2023; (4) The records were reviewed with the technical consultant and testing person #1 who stated on 11/08/2023 at 01:26 pm monthly maintenance procedures had not been documented as performed as stated above.

D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H for five of six Hematology proficiency testing events reviewed in 2022 and 2023. Findings include: (1) A review of 2022 and 2023 Hematology proficiency testing events identified attestation statements had been signed up to two years after the samples had been tested for five of six Hematology events reviewed: (a) Third Event 2021 - The sample testing had been completed on 11/22/2021 and the attestation statement had not been signed until the current technical consultant (designee) signed it on 10/03/2023; (b) First Event 2022 - The sample testing had been completed on 03/29/2022 and the attestation statement had not been signed until the current technical consultant signed it on 10/03/2023; (c) Second Event 2022 - The sample testing had been completed on 08/02/2022 and the attestation statement had not been signed until the current technical consultant signed it on 10/03/2023; (d) Third Event 2022 - The sample testing had been completed on 11/23/2022 and the attestation statement had not been signed until the current technical consultant signed it on 08/11/2023; (e) First Event 2023 - The sample testing had been completed on 03 /24/2023 and the attestation statement had not been signed until the current technical consultant signed it on 08/11/2023. (2) The records were reviewed with the technical consultant who stated the following on 11/08/2023 at 11:30 am: (a) Employment as a technical consultant was effective 07/01/2023; (b) The five attestation statements had been signed during a retrospective review of proficiency testing records when it was identified they had not been signed by the laboratory director.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory director failed to ensure proficiency testing reports were reviewed for four of six Hematology events reviewed in 2022 and 2023. Findings include: (1) A review of 2022 and 2023 Hematology proficiency testing events identified the "Performance

	Evaluations" included a space for the laboratory director or designee signature and date (indicating review of the graded evaluation). The following was identified for four of six events: (a) Third 2021 Event - The graded results were received on 12/21 /2021 and the Performance Evaluation had not been signed until the current technical consultant signed it on 10/03/2023; (b) First 2022 Event - There was no evidence the Performance Evaluation had been signed and dated as reviewed by the laboratory director or designee; (c) Third 2022 Event - There was no evidence the Performance Evaluation had been signed and dated as reviewed by the laboratory director or designee; (d) First 2023 Event - The graded results were received on 04/17/2023 and the Performance Evaluation had not been signed until the current technical consultant signed it on 09/01/2023. (2) The records were reviewed with the technical consultant who stated the following on 11/08/2023 at 11:30 am: (a) Employment as a technical consultant was effective 07/01/2023; (b) The Performance Evaluations had either not been signed by the laboratory director or had been signed during a retrospective review of proficiency testing records when it was identified they had not been signed by the laboratory director.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records and interview with the technical consultant, the technical consultant failed to provide technical supervision in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant met the qualifications for one of two testing persons. Refer to D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated

	specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to ensure the individual who performed the duties and responsibilities of the technical consultant met the qualifications to perform competency evaluations for two of four competency evaluations reviewed during 2022 through the current date. Findings include: (1) On 11/08/2023, a review of records for two persons performing moderate complexity testing during 2022 through the current date identified the following for one of two testing persons: (a) Testing Person #2 - The 07/2022 and 07/31/2023 annual competency evaluations had been performed by an individual who did not meet the regulatory requirements of a technical consultant. (2) The records were reviewed with the technical consultant who stated on 11/08/2023 at 04:00 pm, the evaluations for testing person #2 had been performed by an individual who did not meet the qualifications of a technical consultant.