Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 37D0883222	**(X3) Date Survey Completed** 08/23/2023
Name of Provider or Supplier Bearskin Health Center	**Street Address, City, State** 1 Turtle Drive, Wyandotte, 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 recertification survey was performed on 08/23/2023. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the clinic compliance officer, laboratory director, and testing person #1 during an exit conference performed at the conclusion of the survey.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on observation, review of manufacturer's package insert, and interview with the laboratory director and clinic compliance officer, the laboratory failed to ensure test kits were stored following the manufacturer's instructions for three of three areas observed. Findings include: SATELLITE LABORATORY (1) On 08/23/2023 at 12: 37 pm, the laboratory director stated Streptococcus A, RSV (Respiratory Syncytial Virus), SARS-CoV-2, and Influenza A& B testing were performed using the Abbott ID NOW instruments; (2) Observation of the satellite laboratory (located within the health facility complex) on 08/23/2023 at 12:37 pm, identified the following test kits: (a) Abbott ID NOW Strep A2 test kits; storage requirement of 2- 30 degrees Centigrade (C): (i) One box of lot #M221076; (ii) Seven boxes of lot #M232877; (iii) Three boxes of lot #M224048. (b) Abbott ID NOW RSV test kits; storage requirement of 2-30 C: (i) Four boxes of lot #M222500; (ii) Eight boxes of lot #M225698; (iii) 12 boxes of lot #M224961. (c) Abbott ID NOW COVID-19 2.0 storage requirement of 2-30 C: (i) Three boxes of lot #1100686 (d) Abbott ID NOW Influenza A&B 2 storage requirement of 2-30 C: (i) Five boxes of lot# M230024; (ii) One box of lot #M226138; (iii) Ten boxes of lot #M230024. (3) Interview with the laboratory director and clinic compliance officer on 08/23/2023 at 12:49 pm confirmed the

	temperature of the satellite laboratory was not being monitored. STORAGE CLOSET (1) On 08/23/2023 at 10:00 am, the laboratory director and testing person #1 stated Hemoglobin A1c testing was performed using the Siemens DCA Vantage analyzer; (2) Observation of the storage closet (adjacent to the phlebotomy room) on 08/23 /2023 at 10:20 am identified six boxes of DCA Systems Hemoglobin A1c reagent cartridges being stored at room temperature: (i) Three boxes of lot #0601063 which had not been dated; (ii) Three boxes of lot # 0576033 which had not been dated. (3) Review of the manufacturer's package insert under the heading "Storage and Use" stated, "Store reagent cartridges refrigerated at 2-8 C. Alternately, the cartridges can be kept for up to three months at room temperature any time before the expiration date"; (4) The findings were discussed with the laboratory director who stated on 08 /23/2023 at 10:20 am, the boxes had not been dated with the three month room temperature expiration date. LABORATORY (1) On 08/23/2023 at 10:00 am, the laboratory director and testing person #1 stated Hemoglobin A1c testing was performed using the Siemens DCA Vantage analyzer; (2) Observation of the laboratory on 08/23/2023 at 10:10 am identified six DCA Systems Hemoglobin A1c reagent cartridges (lot # 0576) which had not been dated; (3) Review of the manufacturer's package insert under the heading "Storage and Use" stated, "Store reagent cartridges refrigerated at 2-8 C. Alternately, the cartridges can be kept for up to three months at room temperature any time before the expiration date"; (4) The findings were discussed with the laboratory director and testing person #1. Both stated on 08/23/2023 at 10:10 am, the cartridges had not been dated with the three month room temperature expiration date.
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 a review of records and interview with the laboratory director and testing person #1, the laboratory failed to ensure all proficiency testing records had been maintained for a minimum of two years for one of five Hematology events reviewed in 2022 and 2023. Findings include: (1) A review of Hematology API (American Proficiency Institute) proficiency testing records for 2022 and 2023 identified the following for one of five events (Second 2022): (a) The attestation statement had not been maintained; (b) Copies of the Medonic M-Series instrument printouts could not be located; (c) Copy of the results submitted to the proficiency testing program could not be located. (2) The records were reviewed with the laboratory director and testing person #1. Both stated on 08/23/2023 at 11:50 am, the laboratory had not maintained the proficiency testing records as shown above.
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 a review of records, written policies and procedures, and interview with the laboratory director, the laboratory director failed to assess the competency of the clinical consultant based on the position responsibilities as listed in subpart M. Findings include: (1) A review of the laboratory policy and procedure manual identified no evidence of a policy for assessing the competency of the clinical consultant, including the frequency of the assessments; (2) A review of the Form CMS-209 (Laboratory Personnel Report) and personnel records for competency assessments performed during the review period of October 2021 through the current date identified competencies, based on job responsibilities, had not been performed for the clinical consultant listed on the CMS-209; (3) The findings were reviewed with the laboratory director who stated on 08/23/2023 at 11:00 am there was no policy and competencies were not performed for the clinical consultant during the review period of October 2021 to the current date.
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 laboratory director, 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 two of five Hematology proficiency testing events reviewed in 2022 and 2023. Findings include: (1) A review of 2022 and 2023 proficiency testing events identified attestation statements had been signed by the laboratory director approximately two months after the samples had been tested for two of five Hematology events reviewed: (a) First 2022 Event - The sample testing had been completed on 03/24/2022 and the attestation statement had not been signed by the laboratory director until 05/17/2022; (b) Third 2022 Event - The sample testing had been completed on 11/12/2022 and the attestation statement had not been signed by the laboratory director until 01/28/2023. (2) The records were reviewed with the laboratory director who stated on 08/23/2023 at 11:50 am, the attestation statements had not been signed until approximately two months after the proficiency samples had been tested.
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 a review of records and interview with the laboratory director, the technical consultant failed to ensure personnel performing moderate complexity testing had been evaluated at least annually for one of three persons during the review period from 08/19/2021 to 08/23/2023. Findings include: (1) A review of personnel records for three persons performing moderate complexity testing during the review period of 08/19/2021through 08/23/2023 identified no evidence an annual competency evaluation had been performed for one of three testing person as follows: (a) Testing Person #1 - No annual competency evaluation between 08/19/2021 and 08/23/2023. (2) The records were reviewed with the laboratory director who stated on 08/23/2023 at 11:00 am, the annual evaluation had not been performed.