Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D1012328	(X3) Date Survey Completed 08/31/2021
Name of Provider or Supplier Canadian Valley Family Care	**Street Address, City, State** 1491 Health Center Parkway, Yukon, 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 08/31/2021. NOTE: Hematology testing was not performed from 02/15/2021 through 08/26/2021 due to a flood in the laboratory. The laboratory continued to perform waived testing during this time. The laboratory was found out of compliance with the following CLIA regulation: 493.1409; D6033: Technical Consultant The findings were reviewed with the laboratory director and laboratory manager 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 a review of records and interview with the laboratory manager, the laboratory failed to follow the manufacturer's instructions for specimen transport and storage for 3 of 4 patient reports. Findings include: (1) On 08/31/2021 at 09:40 am, the laboratory manager stated to the surveyor the laboratory performed COVID-19 testing using the Abbott COVID-19 ID NOW test system using direct nasal swabs; (2) The surveyor reviewed the manufacturer's product insert under the section titled, "SPECIMEN TRANSPORT and STORAGE" the manufacturer stated, "For best performance, direct nasal, throat or nasopharyngeal swabs should be tested as soon as possible after collection. If immediate testing is not possible, and to maintain best performance, it is highly recommended the nasal, throat or nasopharyngeal swab is placed in a clean, unused tube labeled with patient information, and capped tightly at room temperature (15-30C) for up to one (1) hour prior to testing. Ensure the swab fits securely within the tube and the cap is tightly closed. If greater than one (1) hour delay occurs, dispose of sample. A new sample must be collected for testing." (3) The surveyor reviewed 4 test reports for patients tested on 08/31/2021 and identified the

	following: (a) Patient Report #1 - The specimen collection time and reported time were identical (09:08 am); (b) Patient Report #2 - The specimen collection time and reported time were identical (09:57 am); (c) Patient Report #3 - The specimen collection time and reported time were identical (10:05 am); (4) The surveyor was not able to determine if the results had been performed within (1) hour since the specimen collection time and reported times were identical; (5) The surveyor reviewed the records with the laboratory manager who stated on 08/31/2021 at 11:00 am, the laboratory could not prove the results had been performed within (1) hour since the reported time had not been recorded.
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 a review of records, and interview with the laboratory manager, the laboratory failed to ensure the demonstrated reportable range was utilized for a new analyzer. Findings include: (1) On 08/31/2021 at 09:30 am, the laboratory manager stated to the surveyor the laboratory began using the Sysmex POCH-100i analyzer to perform CBC (Complete Blood Count) testing on 08/27/2021; (2) The surveyor reviewed the performance specification records and identified the laboratory had demonstrated reportable ranges as follows: (a) Hemoglobin - 0-21.1 g/dl (b) Hematocrit - 0-58% (3) The surveyor requested the reportable range that was being utilized by the laboratory. The laboratory manager provided the surveyor with the manufacturer's reportable ranges contained in the installation manual which were: (a) Hemoglobin - 0.1-25.0 g/dl (b) Hematocrit - 10.0-60.0% (4) The surveyor reviewed the findings with the laboratory manager who stated on 08/31/2021 at 12:50 pm, the laboratory was not using the reportable ranges that had been demonstrated by the laboratory.
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 laboratory manager, the technical consultant failed to provide technical oversight 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. 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 laboratory director and laboratory manager, the laboratory failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications for 2 of 3 competency evaluations performed. Findings include: (1) The surveyor reviewed records for 3 persons performing moderate complexity testing in 2019, 2020 and to date in 2021 (laboratory manager, who is also listed as testing person #1, testing person #2, and testing person #3). The records showed the evaluation for 2 of 3 persons had been performed by an individual who did not meet the regulatory qualification requirements of the technical consultant: (a) Testing Person #2 - The 03 /01/2021 evaluation had been performed by the laboratory manager/testing person #1 (this person had earned a high school diploma); (b) Testing Person #3 - The 06/01 /2021 evaluation had been performed by the laboratory manager/testing person #1. (2) The surveyor reviewed the records with the laboratory director and laboratory manager and explained that all components of the competency evaluations must be performed by a person who qualifies as a technical consultant (an individual with a minimum of a bachelor's degree in a chemical, physical or biological science or

	medical technology from an accredited institution, and at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service). The laboratory director and laboratory manager stated to the surveyor on 08/31/2021 10:30 am, the above evaluations had been performed by an individual who did not meet the educational qualifications of a technical consultant.