

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D1012328	(X3) Date Survey Completed 06/12/2023
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 06/12/2023. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the technical consultant and laboratory manager during an exit conference performed at the conclusion of the survey.
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant and laboratory manager, the laboratory failed to ensure a proficiency testing attestation statement had been signed by the laboratory director or designee for one of five events reviewed during 2021, 2022, and to date in 2023. Findings include: (1) A review of the third 2021; first, second, and third 2022; and first 2023 Hematology proficiency testing records identified the following for one of five events: (a) Third 2021 Event - The attestation statement had not been signed by the laboratory director or designee. (2) The findings were reviewed with the laboratory manager and technical consultant. Both stated on 06/12/2023 at 12:10 pm, the attestation statement had not been signed by the laboratory director or designee.</p>

<p>D2128</p>	<p>HEMATOLOGY CFR(s): 493.851(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to take corrective actions for unacceptable proficiency testing scores for one of five Hematology proficiency testing events reviewed. Findings include: (1) A review of Hematology Proficiency testing records for five events (Third 2021, First 2022, Second 2022, Third 2022, and First 2023) identified the following failure with no evidence that corrective action had been documented as performed: (a) Third 2021 Event - The laboratory attained a score of 0% for % Neutrophils. (2) The records were reviewed with the technical consultant who stated on 06/12/2023 at 12:00 pm, corrective action had not been taken and documented for the failure.</p>
<p>D5209</p>	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, written policies and procedures, and interview with the technical technical consultant, the laboratory failed to have a written policy to assess the competency of the technical consultant, based on the position responsibilities as listed in Subpart M, for one of one person serving as technical consultant. Findings include: (1) On 06/12/2023 a review of the laboratory policy and procedure manual identified no evidence of a policy for assessing the competency of the technical 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 March 2022 (when the technical consultant began employment) through the current date identified competencies, based on job responsibilities, had not been performed for one of one person listed as technical consultant; (3) The findings were reviewed with the technical consultant who stated on 06/12/2023 at 12:05 pm, a policy had not been written and competencies had not been performed.</p>
<p>D5211</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p>

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the technical consultant, the laboratory failed to review and evaluate proficiency testing results for one of five Hematology Proficiency testing events reviewed. Findings include: (1) A review of Hematology Proficiency testing records for five events (Third 2021, First 2022, Second 2022, Third 2022, and First 2023) identified the following failure with no evidence that corrective action had been documented as performed: (a) Third 2021 Event - The laboratory attained a score of 80% for % Monocytes. (2) The records were reviewed with the laboratory director who stated on 06/12/2023 at 12:00 pm, corrective action had not been taken and documented for the failure.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on a review of records, observation, and interview with the laboratory manager, the laboratory failed to ensure blood collection tubes were stored as required for ten of ten K2 EDTA tubes. Findings include: (1) On 06/12/2023 at 09:45 am, observation of the contents of the laboratory freezer identified the following materials: (a) Ten BD Vacutainer K2 EDTA 7.2 mg blood collection tubes, lot #2321388. (2) Interview with the laboratory manager confirmed the tubes were stored in the freezer to utilize when collecting blood samples that required the collection tube to be chilled and sent to the reference laboratory for testing (i.e., Ammonia testing); (3) A review of the manufacturer's storage requirement, which was located on the packaging of unopened containers of blood collection tubes, identified the storage temperature was 4-25 degrees C (Centigrade); (4) The findings were reviewed with the laboratory manager who stated on 06/12/2023 at 09:55 am, the blood collection tubes were not being stored as required by the manufacturer.

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 instructions, and interview with the laboratory manager, the laboratory failed to ensure the manufacturer's instructions were followed for performing quarterly maintenance procedures for one of one analyzer reviewed from September 2021 through May 2023. Findings include: (1) On 06/12/2023 at 09:40 am, the laboratory manager stated CBC (Complete Blood Count)

testing was performed using the Sysmex POCHi analyzer; (2) A review of the manufacturer's maintenance log showed the following required quarterly maintenance procedure: (a) "Clean Waste Chamber" (3) A review of maintenance logs from September 2021 through May 2023 identified no documentation the quarterly maintenance had been performed as follows: (a) Prior to 07/09/2022 (b) Between 07/09/2022 and 01/03/2023 (4) The records were reviewed with the laboratory manager who stated on 06/12/2023 at 10:35 am, the maintenance had not been documented as performed as shown above.

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 a review of records and interview with the technical consultant, the technical consultant failed to ensure competency evaluations for moderate complexity testing had been performed semiannually during the first year of testing for one of one testing person performing testing from March 2022 through the current date. Findings include: (1) On 06/12/2023 a review of personnel records for one person hired to perform moderate complexity testing after the previous recertification survey identified the following for one of one person: (a) Testing Person #1 - The initial training was complete on 03/22/2022. There was no evidence a competency evaluation had been performed through the current date. (2) The records were reviewed with the technical consultant who stated on 06/12/2023 at 12:15 pm, a semiannual competency evaluation had not been performed.

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 technical consultant, the technical consultant failed to ensure personnel performing moderate complexity testing had been evaluated at least annually for three of three persons during the review period of June 2021 through the current date. Findings include: (1) A review of personnel records for three persons performing moderate complexity testing during the review period of June 2021 through the current date identified no evidence an annual competency evaluation had been performed for three of three testing persons as follows: (a) Testing Person #1 - After initial training had been performed on 03/22/2022; (b) Testing Person #2 - Not performed between 06/01/2023 and 03/21/2023; (b) Testing Person #3 - Not performed between 06/01/2023 and 03/21/2023; (2) The records were reviewed with the technical consultant who stated on 06/12/2023 at 12:15 pm, the annual evaluations had not been performed.