

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 50D0669238	<b>(X3) Date Survey Completed</b> 04/18/2022
<b>Name of Provider or Supplier</b> David C Wynecoop Memorial Clinic	<b>Street Address, City, State</b> 6203 Agency Loop Rd, Wellpinit, WA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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 review of the laboratory's competency assessment records, the laboratory's policies and procedure manual and interview with the laboratory supervisor (TP#1) on April 18, 2022, the laboratory failed to establish and follow written policies and procedures to assess employee and consultant competency. Findings Include: 1. The laboratory hired a new laboratory supervisor (TP#1) start date May 23, 2021. The laboratory has testing records of a contracted Testing personnel (TP#2) on January 10, 2022. 2. The laboratory's Quality Assessment (QA) Policy (page 11) states "the Clinical Consultant or designee will conduct an ongoing evaluation of employee competence." 3. The laboratory has no documentation of ongoing evaluation of competency for TP#1 or TP#2, or annual competency for the Technical Consultant or Clinical Consultant. The laboratory does not have a designee identified for the Clinical Consultant responsibilities as listed in the QA Policy. 4. The laboratory's QA policy and procedures does not include annual consultant competency or six month competency assessment for new testing personnel. 5. The laboratory supervisor confirmed by interview on April 18, 2022 at 12:30 PM, the laboratory did not perform six month competency evaluation for TP#1 or TP#2. 6. The laboratory testing records identifies 18 test being performed annually by the laboratory.</p>
<b>D5293</b>	<p><b>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the</p>

effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's corrected reports folder, and interview with the laboratory Supervisor on April 18, 2022, the laboratory failed to have a quality assessment system to identify and correct problems that occur and an effective corrective actions process to identify, correct and revise policies and procedures to prevent recurrence of problems. Findings include: 1. A random selection of a patients DCA Microalbumin/Creatinine ratio report identified that the incorrect value was entered reported for Microalbumin. The patients result was performed on August 13, 2021 and corrected on October 08, 2021. 2. The laboratory had no documentation of corrective actions or discussion with appropriate staff for entering the correct values in accordance with the laboratory's manual reporting processes. 3. The laboratory supervisor confirmed by interview on April 18, 2022 at 1:00 PM the failure to perform corrective actions timely and to document quality assessment reviews with appropriate staff. 4. The laboratory reports performing 306 DCA Microalbumin /Creatinine ratio tests annually.

**D6021**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on record review and interview with the laboratory supervisor and laboratory Director on April 18, 2018, the laboratory director failed to ensure that the laboratory's Quality assessment programs are maintained. See D5209, D5293.

**D6032**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(14)

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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory CMS-209 personnel form and interview with the laboratory supervisor on April 18, 2022, the laboratory director failed to specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing. Findings include: 1. The laboratory CMS-209 identifies the laboratory supervisor as the laboratory technical consultant. The laboratory does not have documentation of the laboratory Director specifying the responsibilities and duties of the Technical consultant to the laboratory supervisor. 2. The laboratory director failed to specify in writing the duties of the laboratory supervisor or delegate the laboratory director responsibilities to the laboratory supervisor as a technical consultant or for the oversight of performance of the preanalytic, analytic, and postanalytic phases of testing. 3. The laboratory supervisor and laboratory director confirmed by interview on April 18, 2022 at 3:30 PM the lack of designation of responsibilities and duties for each consultant and each person engaged in performing patient testing. 4. The laboratory reports performing 430 patient tests annually.

**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 review of the laboratory's submitted CMS-209 testing personnel form, the testing personnel competency records, quality assessment records and interview with the laboratory supervisor on April 18, 2022, the laboratory Technical Consultant failed to perform six month and annual competency for two of two testing personnel. Findings include: 1. The laboratory's technical consultant listed on the CMS-209 form submitted for this survey, listed the laboratory supervisor as the Technical Consultant. 2. The laboratory supervisor is one of two testing personnel identified on patient testing work logs, quality control records, proficiency testing results and preventive maintenance records. 3. The testing personnel competency evaluations did not include review of performance listed, and was not performed six months for the laboratory supervisor (TP#1), and was not included in the evaluation of TP#2 (contract staff). 4. The laboratory supervisor confirmed by interview on April 18, 2022 that the laboratory six month competency was not performed on TP#1, and the evaluation of TP#2 was not documented for initial and six month evaluation period.