

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 50D0669096	<b>(X3) Date Survey Completed</b> 03/26/2025
<b>Name of Provider or Supplier</b> Colville Tribes Health Laboratory Services	<b>Street Address, City, State</b> 19 Lakes Street, Nespelem, 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 laboratory personnel competency records, Laboratory Personnel Initial Training and Continued Competency Assessment policy, and interview with the Testing Personnel (TP) #2 on the CMS-209, the laboratory failed to follow their own policy to assess competency of the Technical Consultant (TC) for two of two years. Findings included: 1. A review of laboratory personnel competency records revealed there were no records of annual competency assessments for the TC for the years 2023 and 2024. 2. A review of the Laboratory Personnel Initial Training and Continued Competency Assessment policy revealed the statement, "The purpose of this policy and procedure is to define how all new laboratory staff, both employees and contractors, will be trained, as well as define how continued assessment will be monitored for all laboratory staff, including both laboratory testing personnel and Laboratory Supervisor/Technical Consultant (as defined in the QA/QI laboratory policy and procedure)." 3. In an interview on March 26, 2025, at 10:15 AM, the TP #2 confirmed annual competency assessments for the Technical Consultant were not completed for the years 2023 and 2024.</p>
<b>D5415</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(c)</p> <p>(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage</p>

requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:  
Based on laboratory observation, review of the GeneXpert Chlamydia trachomatis (CT)/Neisseria gonorrhoeae (NG) and the GeneXpert Xpress SARs-CoV-2 (COV-2)/Influenza (FLU)/Respiratory Syncytial Virus (RSV) Plus test kit labels and package inserts, review of the laboratory Daily Temperature Check log sheets, and interview with the Testing Personnel (TP) #2 on the CMS-209, the laboratory failed to ensure the room temperature ranges were within the manufacturer's test kit storage specifications for five of five CT/NG test kits and two of two COV-2/FLU/RSV Plus test kits from March 2023 to March 2025. Findings included: 1. Laboratory observation on March 26, 2025 at 2:30 pm revealed five CT/NG test kits (Lot # 1001429812) with 10 tests cartridges per kit and two COV-2/FLU/RSV test kits (Lot # 1001465028) with 10 tests cartridges per kit stored in the cupboard above the Cepheid GeneXpert Xpress instrument in the laboratory. 2. A COV-2/FLU/RSV test kit package insert and test kit labels for both COV-2/FLU/RSV and CT/NG stated storage temperature requirement of 2-28C. 3. A review of Daily Temperature Check log sheets from March 2023 to March 2025, revealed an acceptable Room Temperature Range of 18-30C. 4. In an interview on March 26, 2025, at 2:35 PM, the TP #2 confirmed the room temperature range set by the laboratory was 2-28C on the Daily Temperature Check log sheets from March 2023 to March 2025.

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(a)(1)

(a)(1) 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 review of the Operator Manual for the Cepheid GeneXpert Xpress instrument, a review of the GeneXpert Xpress System Maintenance Log sheets, and interview with the Testing Personnel (TP) #2 on the CMS-209, the laboratory failed to document the monthly maintenance of archiving tests, purging tests, and replacing the fan filters as specified by the manufacturer for nine out of twenty-four months of use. Findings included: 1. A review of the Operator Manual and the GeneXpert Xpress System Maintenance Log sheets for the Cepheid GeneXpert Xpress instrument, serial number 907628, revealed monthly maintenance tasks of Archive Tests, Purge Tests, and Replace fan filters. 2. A review of the GeneXpert Xpress System Maintenance Log sheets from March 2023 to February 2025 revealed no recording of monthly maintenance being completed for the following nine out of twenty-four months: August 2023 November 2023 December 2023 January 2024 February 2024 June 2024 August 2024 Sept 2024 December 2024 3. In an interview on March 26, 2025, at 2:45 PM, the TP #2 confirmed that the laboratory failed to document completion of the monthly maintenance for the Cepheid GeneXpert instrument, serial number 907628, for nine of twenty-four months from March 2023 to February 2025.

**D6032**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(14)

(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 Directors Job Description, Laboratory Personnel Initial Training and Continued Competency Assessment policy, and interview with the Testing Personnel (TP) #2 on the CMS-209, the Laboratory Director failed to specify, in writing, the responsibilities and duties for two of two consultants, the Clinical Consultant (CC) and the Technical Consultant (TC). Findings included: 1. A review of the Laboratory Directors job description revealed the following statement, "Duty: The responsibilities and duties of each consultant and each person engaged in the testing process are specified in writing ..." 2. A review of the Laboratory Personnel Initial Training and Continued Competency Assessment policy revealed the following statement, "The Laboratory Director must specify, in writing, the responsibilities and duties of each consultant ..." 3. In an interview on March 26, 2025, at 1:55 PM, the TP #2 confirmed there were no written responsibilities and duties available for the CC and TC.

**D6033**

**TECHNICAL CONSULTANT-MODERATE COMPLEXITY**  
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 review of laboratory personnel records and interview with the Testing Personnel (TP) #2 on the Centers for Medicare and Medicaid Services (CMS)-209, the laboratory failed to provide personnel records for one of one Technical Consultant (TC) for technical oversight of the moderate complexity laboratory. Findings: 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 (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 1 year of laboratory training or experience, or both, in nonwaived 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)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and (b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b)(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

This STANDARD is not met as evidenced by:  
Based on review of laboratory personnel records and interview with the Testing Personnel (TP) #2 on the CMS-209, the laboratory failed to provide personnel records for one of one Technical Consultant (TC) for technical oversight of the moderate complexity laboratory. Findings included: 1. Review of the laboratory personnel records revealed the laboratory failed to provide personnel records with credentials for TC of the moderate complexity laboratory. 2. In an interview on March 26, 2025, at 10:15 AM, the TP #2 confirmed the laboratory did not have personnel records and credentials of the TC and the laboratory was not able to produce the records by the survey exit time.

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

(b)(9) 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 laboratory personnel competency records, Laboratory Personnel Initial Training and Continued Competency Assessment policy, and interview with the Testing Personnel (TP) #2 on the CMS-209, the Technical Consultant (TC) failed to complete and document one of one initial competency assessment for Testing Personnel # 3 on the CMS-209 form, during the first year of moderate complexity testing. Findings included: 1. A review of laboratory personnel competency records

revealed an initial competency assessment was completed and documented for TP #3 by TP #2. 2. A review of the Laboratory Personnel Initial Training and Continued Competency Assessment policy revealed the statement, "A. New staff: prior to being assigned any laboratory duties in the Coleville Service Unit and prior to obtaining or testing patient specimens, all new laboratory staff will: Have present in the laboratory under the care of the Laboratory Supervisor/Technical Consultant, a file for each staff member that contains ... evidence of competency ..." 3. In an interview on March 26, 2025, at 10:15 AM, the TP #2 confirmed the initial competency was completed in December 2024 by TP# 2 who is not qualified, and not by the Technical Consultant.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

(b)(9) Thereafter, evaluations must be performed at least annually

This STANDARD is not met as evidenced by:  
Based on review of laboratory personnel competency records, Laboratory Personnel Initial Training and Continued Competency Assessment policy, and interview with the Testing Personnel (TP) #2 on the CMS-209, the Technical Consultant (TC) failed to complete and document five of five annual competency assessments for three testing personnel. Findings included: 1. Review of three testing personnel competency records revealed the following: Testing personnel number based on the sequence on the CMS-209 form a. TP# 1: Annual competency assessment not completed by TC for the years 2023 and 2024. b. TP# 2: Annual competency assessment not completed by TC for the year 2024. c. TP# 4: Annual competency assessment not completed by TC for the years 2023 and 2024. 2. A review of the Laboratory Personnel Initial Training and Continued Competency Assessment policy revealed the statement, "D. Testing Personnel: each laboratory employee requires yearly direct observation by the Laboratory Supervisor of proficiency in each test performed in the CSU laboratory and documented as proficient in each test independently." 3. In an interview on March 26, 2025, at 10:15 AM, the TP #2 confirmed that the TC did not complete and document annual competency assessments for TP#1 (2023 and 2024), TP#2 (2024) and TP# 4 (2023 and 2024).