Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	50D0669096	04/28/2021
Name of Provider or Supplier	**Street Address, City, State**	
Colville Tribes Health Laboratory Services	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review of American Proficiency Institute (API) proficiency testing (PT) documents, and interview with the acting laboratory manager, the laboratory failed to ensure that the individual testing or examining the samples and the laboratory director signed the attestation documents regarding the routine integration of the PT samples into the laboratory's routine workloads. Findings include: 1. Review of the 2020 API PT records revealed that the testing personnel (TP) and laboratory director (LD) did not sign the PT attestation form, attesting to the integration of PT samples into the laboratory's routine workload for six (6) of fifteen (15) PT testing events,. Event (1)-Hematology/Coagulation No signature-TP, LD Event (1)-Chemistry No signature-TP, LD Event (2)-Hematology/Coagulation No signature-TP, LD Event (2)-Microbiology No signature-TP, LD Event (2)-Chemistry No signature-TP, LD Event (3)-SARS CoV2 No signature-LD 2. Interviews with the acting laboratory manager and laboratory director on 4/28/2021 at 09:51 a.m., confirmed that the laboratory director and testing personnel did not attest to the integration of PT samples with patient testing on the API PT forms. 3. The laboratory reports performing 6210 patient tests annually.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--

	(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review for SARS CoV2 testing and interview with the acting laboratory manager, the laboratory failed to perform control procedures using the number and frequency specified by the manufacturer. Findings include: 1. The laboratory performs SARS CoV2 testing on an Abbott ID Now and Cepheid GeneXpert platforms. The manufacturers Emergency Use Authorization for both platforms requires controls to be ran for each new lot number, each shipment and each new testing personnel. 2. The laboratory has implemented non-laboratory personnel to perform SARS CoV2 testing at an ancillary location outside the laboratory on both analyzers. 3. The laboratory has no documentation of controls being performed by the non-laboratory testing personnel for three of four testing personnel who have been performing SARS CoV2 testing. 4. Interviews with the acting laboratory manager and the laboratory director on 4/28/2021 at 2:45 p.m. confirmed that the non-laboratory SARS CoV2 testing personnel have not performed control testing on the Abbott ID Now and Cepheid GeneXpert platforms. 5. The laboratory records indicate that the laboratory has performed 1440 SARS CoV2 tests since April 13, 2020 to 4/28/2021on the two testing systems
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on record review of the laboratory's test menu, personnel education and competency records and interview with the acting laboratory manager, the laboratory director failed to ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. Findings include: 1. The laboratory implemented SARS CoV2 testing on three waived Emergency Use Authorized (EUA) platforms utilizing laboratory and non-laboratory staff to perform the testing in April 13, 2020 (Abbott ID Now), November 2020 (Binax antigen test kit), and January 2021 (Cepheid GeneXpert Fourplex). 2. The laboratory did not have documentation of education for three (3) of five (5) of the testing personnel performing SARS CoV2 testing. 3. The laboratory did not have documentation of competency for five (5) of five (5) of laboratory testing personnel performing SARS CoV2 testing prior to testing and reporting patient result. 4. The acting laboratory

	manager and laboratory director confirmed by interview on 4/28/2021 at 2:45 p.m., the laboratory did not have documentation of education for 3 of 5 testing personnel and that the laboratory director did not perform competency assessment's for 5 of 5 testing personnel prior to testing and reporting patient SARS CoV2 results. 5. The laboratory reports performing and resulting 1,812 SARS CoV2 patient tests since April 13, 2020 to the date of survey 4/28/2021. 6. *This is a repeat dificiency identified in the previous recertification survey conducted on 05/15/2019. (Laboratory Director failed to ensure that traveling testing personnel had met the minimal education requirement to qualify as moderate complexity testing personnel).
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 record review of personnel training, and competency records, and interview with the acting laboratory manager, the laboratory director failed to specify, in writing, the responsibilities and duties of each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, and failed to identify 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. Findings include: 1. For two (2) of two (2) laboratory personnel performing patient testing, the laboratory had no documentation identifying and authorizing the responsibilities and testing each individual were allowed to perform. 2. The laboratory initiated SARS CoV2 testing and crossed trained non-laboratory administrative personnel to perform the patient testing. The laboratory director did not specify in writing the responsibilities and duties of three (3) of three (3) non-laboratory individuals, or whether supervision is required. 3. The laboratory acting manager and laboratory director confirmed by interview on 4/28/2021 at 2:45 p.m., the failure of the laboratory director to specify in writing the responsibilities and duties of each individual authorized to perform patient testing and whether supervision is required. 4. The laboratory reports performing and reporting 6210 patient tests annually. 5. *This is a repeat dificiency identified in the last survey conducted on 05/15/2019. Based upon review of proficiency testing, quality control, quality assurance and maintenance records and an interview with the Laboratory Supervisor, the Laboratory Director (LD) failed to assign in writing, the responsibilities of the Technical Consultant (TC) and testing personnel (TP) in all phases of the testing process.