Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	50D0922744	07/22/2026
Name of Provider or Supplier	**Street Address, City, State**	
Karen I Fryberg Tulalip Health Clinic	7520 Totem Beach Road, Tulalip, 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
D0000	An on-site recertification survey was conducted on 07/22/26. Standard level deficiencies were cited.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of proficiency testing records and interview with the laboratory director and testing person #1, the laboratory failed to review and evaluate proficiency testing results for one of one hematology proficiency testing events. Findings include: 1. During a laboratory tour on 07/22/26 at 09:10 am, testing person #1 verified the laboratory performed Complete Blood Count (CBC) testing on the Beckman Coulter DxH. 2. A review of the 2026 Hematology 1st Event revealed the following failure with no corrective action. a. The laboratory received a score of 80% (failed one of five results - DXH-01 Red Cell Count). 3. During an interview on 07/22/26 at 12:05 pm, the laboratory director confirmed the findings above. 4. The laboratory performs approximately 13,900 CBC tests annually.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of

	results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of the laboratory's written procedures and interview with the laboratory director and testing person #1, the laboratory failed to have written procedures for one of six procedures. Findings included: 1. During a laboratory tour on 07/22/26 at 09:10 am, testing person #1 verified the laboratory performed Complete Blood Count (CBC) testing on the Beckman Coulter DxH analyzer. 2. A review of the laboratory's written procedures revealed no evidence of a written and approved CBC procedure. 3. During an interview on 07/22/26 at 11:15 am, the laboratory director confirmed the laboratory did not have a written and approved CBC procedure. 4. The laboratory performs approximately 13,900 CBC tests annually.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on the laboratory's written procedure, record review, and interview with the laboratory director, the laboratory failed to perform a complete function check for one of one urine centrifuges. Findings included: 1. On 07/22/26 at 10:50 am, the laboratory director confirmed the laboratory performed urine sediment examinations using the McKesson Variable Speed Centrifuge C856 (LT2007171). 2. A review of the laboratory's written procedure "Urinalysis" section "SEDIMENT PREPARATION" stated, "After completing the physicochemical tests, centrifuge the urine specimen for 5 minutes at 2,000 RPM". (RPM = Revolutions per minute). 3. A review of the laboratory's 11/06/25 centrifuge function check revealed the laboratory failed to check the centrifuge's timer of 5 minutes, per the laboratory's written procedure. 4. During an interview on 07/22/2026 at 11:51 am, the laboratory confirmed the findings above. 5. The laboratory performs approximately 3,575 urine sediment testing annually.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)

	(b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on the laboratory's written chemistry quality control (QC) procedure, review of chemistry QC records, and interview with the laboratory director and testing person #2, the laboratory failed to ensure two levels of QC were within acceptable range for two of two days of patient testing. Findings included: 1. During an interview on 07/22 /26 at 11:35 am, testing person #2 verified the laboratory performed chemistry testing on the Ortho Clinical Diagnostics Vitros system. 2. Review of the laboratory's written "Vitros 5600 Daily Quality Control Reference Guide" section "Daily QC Acceptance Criteria" stated, "QC results must fall within 2SD of the established mean". 3. Review of two laboratory's QC records on 06/18/296 and 06/30/26 revealed the following: a. 06/18/26 (MAS CR 1 Lot#27041) - Glucose Level 1 established mean 63.3 mg/dL with a 2SD acceptable range of (59.9 - 66.7 mg/dL). 1. On 06/18/26, QC value of 59.4 mg/dL was accepted by the laboratory (below the 2 SD acceptable limit). b. 06/18/26 (MAS CR 2 Lot#27042) - Calcium Level 2 established mean 9.51 mg/dL with a 2SD acceptable range of (9.05 - 9.97 mg/dL). 1. On 06/18/26, QC value of 9.99 mg/dL was accepted by the laboratory (above the 2 SD acceptable limit). c. 06/30/26 (MAS CR 1 Lot#2704)- Uric Acid Level 1 established mean 3.40 mg/dL with a 2SD acceptable range of (3.26 - 3.54 mg/dL). 1. On 06/30/26, QC value of 3.24 mg/dL was accepted by the laboratory (below the 2 SD acceptable limit). 4. During an interview on 07/22/26 at 01:15 pm, the laboratory director confirmed the findings above. 5. The laboratory performs approximately 10,725 chemistry tests annually.
D5807	TEST REPORT CFR(s): 493.1291(d) (d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of the laboratory's written procedure, patient's final report, and interview with the laboratory director and testing person #2, the laboratory failed to ensure the accuracy of normal reference ranges for one of 16 analytes. Findings included: 1. During an interview on 07/22/26 at 11:35 am, testing person #2 verified the laboratory performed chemistry testing on the Ortho Clinical Diagnostics Vitros system. 2. A review of the laboratory's written procedure, "INSTRUCTIONS FOR USE" section "Reference Interval" for serum creatinine testing stated the following: a. Male normal reference range of 0.66 - 1.25 mg/dL. 3. A review of one (male) final patient report revealed a different normal reference range for serum creatinine testing as follows: b. Male normal reference range of 0.70 -1.50 mg/dL. 4. During an interview on 07/22/26 at 12:00 pm, the laboratory director confirmed the laboratory's written procedure for serum creatinine normal reference range did not match the

	patient's final report. 5. The laboratory performs approximately 10,725 chemistry tests annually.