Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	50D0922744	05/06/2022
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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on record review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) performance results and interview with the Laboratory Director on May 06, 2022, the laboratory failed to verify the accuracy of ungraded potassium hydroxide (KOH) results when the proficiency testing program did not obtain the agreement required for scoring within their peer group. Findings include: 1. The laboratory's 2021 API event 3 for KOH, received an ungraded result for one (1) of five (5) specimen submissions. The laboratory did not perform or document review of the laboratories submitted results with API's expected results. 2. The laboratory's 2021 API event 3 for Cell ID for educational purposes, the laboratory received a 80% score. The laboratory had no documentation of review for the score received with testing staff or review of the PT providers results. 3. The laboratory Director confirmed by interview on May 06, 2022 at 10:00 a.m., the failure to document review of ungraded PT results, and those results that did not obtain agreement with the PT providers expected results. 4. The laboratory reports performing 535 KOH specimens annually.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an

	ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory director on May 06, 2022, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems. Finding include: 1. During record review of the Hematology quality control Levy-Jennings (LJ) graphs for March 22, 2021 to March 26, 2021, the platelets on control level 3 were below the laboratory's manufacturers established QC range. The laboratory's Levy-Jennings graph for August 2021 indicates the laboratory level 3 QC values for Platelets had again fell below the manufacturers established ranges. a. The laboratory has no documentation of corrective actions taken or assessment of the QC performance which resulted in a Service PM call in August. 2. The laboratory's QC LJ graphs for chemistry revealed the laboratory did not have documentation of review for QC values or corrective actions taken when shifts or trends occur from the established manufacturers means. a. Review of the LJ graph for for Total Bilirubin QC assay level 2, the fell below the manufacturers established mean by 2 SD on 02/08/2021. On 02/09/2021 the Total Bilirubin QC level 2 result was at the +3 SD range, (a change of 5 SD). The laboratory had no documentation of review or corrective actions taken for the 5 SD change in the Level 2 QC value from 02/08/2021- 02/09/2021. b. For the month of February 01, 02021 to March 01, 2021 the LJ graph revealed the Glucose values for abnormal QC (Level 2) consistently ran 2 SD below the manufacturers established mean. The laboratory had no documentation of review or corrective actions of the shift in the QC values. 3. The laboratory's LJ QC graphs for Microalbumin/Creatinine performed on the DCA analyzer, revealed a shift below the Manufactures established mean by 1 SD for a period of five days. The laboratory did not have documentation of evaluation or corrective actions taken for the shift from the manufacturers established mean. 4. The laboratory director confirmed by interview on May 06, 2022, that the laboratory does not documentation evaluation or corrective actions for QC values for shifts or trends when the assayed QC values differ from the manufacturers established ranges. 5. The laboratory reports performing 29,505 patient samples annually.
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 observation, record review and interview with the laboratory director on May 06, 2022, the laboratory failed to follow defined criteria for those conditions that are essential for proper storage of reagents and specimens. Findings include: 1. During the laboratory tour on May 6, 2022, this surveyor noted that the calibrated

	thermometers used for storing patient samples, controls and reagents, were past the manufacturers calibration experiation dates. S/N 192444333 calibrated thermometer expired 08/30/2021 S/N 80610192 calibrated thermometer expired 11/15/2008 S/N 80610166 calibrated thermometer expired 11/15/2008 2. The laboratory had unopened calibrated thermometers in the storage cabinet that expired on February 2022. 3. The laboratory director confirmed by interview on May 06, 2022 that the calibrated thermometers monitoring the laboratory reagents, and patient specimens were expired. 4. The laboratory CMS-116 record reports the laboratory performing 29,505 patient specimens annually.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory director on May 06, 2022, the laboratory failed to perform quality control at least once a day patient specimens are assayed or examined for each qualitative procedure, with a negative and positive control material. Findings include: 1. The laboratory CMS-116 testing report, and the laboratory's API PT testing documents indicate the performance of wet mounts and potassium hydroxide (KOH) testing. 2. The laboratory has no documentation of quality control being performed since the 2020 CLIA recertification survey to date of this survey 05/06/2022 for KOH. 3. The laboratory director confirmed by interview on May 06, 2022 at 2:00 p.m. that the laboratory does not perform QC for the moderately complex qualitative wet prep KOH specimens. 4. The laboratory CMS-116 records the laboratory performing 535 patient specimens 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 director on May 06, 2022, the laboratory director failed to ensure that quality assessment programs are established and maintained to ensure the quality of laboratory services provided. Findings include: 1. The laboratory director failed to review and document proficiency test scores that were ungraded or did not achieve 100% for each analyte submitted for PTevaluations. See D5215 2. The laboratory director failed to ensure that for each moderate complexity qualitative test performed, two levels of QC are performed each day of patient testing. See D5449 3. The laboratory director failed to

	ensure the laboratory's quality assessment systems were developed, reviewed for accuracy, and documention is performed, when quality performance fails to meet the manufacturers established parameters. See D5291