Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	50D0922744	11/23/2020
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
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document 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 a record review and an interview with the laboratory director, the laboratory failed to perform and document maintenance on the Vitros 5600 integrated chemistry and immunoassay analyzer Findings: 1. A record review of the chemistry maintenance logs revealed that the laboratory failed to document monthly maintenance as prescribed by the manufacturer on the Vitros 5600 integrated analyzer from September 2019 thru January 2020. 2. The laboratory performs approximately 15,000 chemistry tests and approximately 180 immunoassay tests on the analyzer annually. 3. In an interview on November 23, 2020 at 9:30 AM, the laboratory director confirmed the laboratory failed to document monthly maintenance on the Vitros 5600 analyzer..
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following

	occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory director, the laboratory failed to perform calibration verification at least every six (6) months, as required for multiple analytes tested on the Vitros 5600 integrated chemistry and immunoassay analyzer. Findings: 1. A review of calibration and calibration verification records for the Vitros 5600 analyzer revealed that the laboratory failed to perform calibration verification for Vitamin D, Hepatitis A Antibody (HAV), HBsAg, Anti-HBc and Hepatitis C Antibody (HCV) every six (6) months as required. 2. In an interview on November 23, 2020 at 10:30 AM, the laboratory director confirmed the laboratory failed to perform calibration verification for Vitamin D, HAV, HBsAg, Anti-HBc and HCV at least every six (6) months and that these analytes have 2 or less calibrators.
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 a record review and an interview with the laboratory director, the laboratory failed to run at least 2 levels of quality control materials for the LifeSign MI test cartridges each day of patient testing since the last survey. Findings: 1. A review of the quality control records for the LifeSign MI Cardiac Test Panel, which tests Myoglobin, CKMB and TNI, revealed the laboratory failed to test at least 2 levels of quality control material each day of patient testing since the last survey on February 27, 2018. 2. The laboratory performs approximately 33 Cardiac Risk Panels per year. 3. In an interview on November 23, 2020 at approximately 10:10 AM, the laboratory director confirmed the laboratory failed to perform or document quality control each day of patient testing for Myoglobin, CKMB and TNI.