Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D0706920	09/17/2019
Name of Provider or Supplier	**Street Address, City, State**	
Fallon Paiute-Shoshone Tribe	1001 Rio Vista Dr, Fallon, NV	

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
D2003	ENROLLMENT CFR(s): 493.801(a)(2)(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1) This STANDARD is not met as evidenced by: Based on records review and interview with the laboratory consultant and testing personnel on September 17, 20119, for those tests performed by the laboratory that are not included in subpart I of this part, the laboratory failed to establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1). The findings included: a. Review of the laboratories testing menu and proficiency testing records, the laboratory had added the analyte Vitamin D in May of 2018 to the laboratory's testing menu. b. The laboratory had enrolled with American Proficiency Institute (API) for twice annual verification of accuracy, in accordance with 493.1236 (c)(1). The laboratory had missed the first event (out of 2 events) of 2018, due to lack of enrollment. c. The laboratory received a score of 0% on the 2018 2nd event, and 33% on 2019 1st event: Results submitted 2018 2nd event: 0% (results were to be submitted in whole numbers) IAT-04 129 unacceptable: Targeted results 13.0 IAT-05 416 unacceptable: Targeted results 42.0 IAT-06 335 unacceptable: Targeted results 34.0 Results submitted 2019 1st event:33% IAS-01 13 unacceptable Target results 25-54 IAS-02 13 unacceptable Target results 41-74 IAS-03 13 Acceptable Target results 11-35 d. The laboratory consultant and testing personnel confirmed by interview the failure of performance for the two consecutive API testing events. e. During the time of unsatisfactory results scores for the two API testing events 2018 2nd event, and 2019 1st event, (10/01/2018 -3/28/2019), the laboratory reports testing and reporting 92 Vitamin D patient results.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES

	CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the laboratory director, and the laboratory consultant on September 17, 2019, the laboratory failed to follow written policies and procedures to assess consultant competency. The Findings included: a. The laboratory consultant is contracted from out of state, by the laboratory. During the spring of 2018 through fall of 2019 the laboratory had undergone a change in laboratory director three times. b. For the year 2018 and 2019, there was no documentation of a competency assessment being performed on the laboratory consultant per the laboratory policy. c. The Technical consultant responsibilities as listed in 493.1413(b) specifically b(1)(3)(6)(7), during the implementation of a new analyte , were not evaluated for 2018 or for 2019. c. The laboratory consultant and laboratory director confirmed by interview on September 17, 2019 at approximately 04:00 p.m., that there had been no competency assessment performed on the laboratory consultant for the year 2018 or for 2019.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory records for correlational studies of the analyte Vitamin D, and interview with the laboratory consultant and testing personnel on Septemver 17, 2019, the laboratory failed to demonstrate that it could obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: Accuracy, Precision, and Reportable range of test results for the test system, and to verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population before reporting patient test results. The findings included: a The laboratory introduced the analyte Vitamin D in May of 2018, and had documentation of inititating correlation studies to validate the performance of the test system. However the laboratory had no documentation that the correlation studies had been completed prior to engaging in performing and reporting patient testing. b. The laboratory had purchased proficiency testing enrollment for Vitamin D through American Proficiency Institute (API) 2nd event (only two events per year). The results for event 2 of 2018 resulted in a 0%. See Dtag D2003 c. For event 1 of 2019 the laboratory received a 33% unacceptable final result. See D2003 d. During the time of PT failures, the laboratory had continued to test and result patient specimens for the analyte Vitamin D, without completing the correlation verification of the analyte performance characteristics. e. The

	manufacturers forms for verifcation of control ranges were incomplete and not signed off by the Technical consultant or the laboratory director as acceptable. (Qualigen Fastpack-Vitamin D Method Verifcation Kit pages 16-43). f. The laboratory director and laboratory consultant confirmed by interview on September 17, 25019 at approximately 3:00 p.m. that the laboratory did not have documentation that the laboratory could obtain the performance specifications established by the manufacturer and that the reference intervals were appropriate for the laboratory's patient population, before reporting the patient test results. g. The laboratory records indicated that the laboratory performed and reported 92 patient Vitamin D results from October 1, 2018 to March 3, 2019.
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 review of the laboratory's maintenance logs and interview with the laboratory consultant and testing personnel on September 17, 2017, the laboratory failed to perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. The findings included: a. The Qualigen Fast Pack test system is a moderate complexity system on which the laboratory performs Vitamin D Immunoassay. The manufacturers instructions lists daily, weekly, and monthly maintenance to be performed along with maintenance logs for documenting the maintenance performed. b The laboratory had no documentation of maintenance being performed for the months prior to December of 2018. The analyzer had been put into service for patient correlation testing in May of 2018 and documented patient test reporting on October 1, 2018. c. The laboratory failed their first proficiency testing (event 2 API 2018) during the time of undocumented maintenance (November 2018). d. The laboratory consultant and the laboratory testing personnel confirmed by interview on September 17, 2019 at approximately 4:00 p.m., the lack of performing and documenting the manufacturers maintenance required for the Qualigen Fast pack test system.