

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 50D0670412	(X3) Date Survey Completed 02/20/2024
Name of Provider or Supplier Lummi Nation Health Ctr	Street Address, City, State 2608 Kwina Rd, Bellingham, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual, testing personnel (TP) competency records, and interview with the laboratory Manager/Testing Personnel #1 (LM/TP-1), the laboratory failed to follow policies and procedures for performing TP competency assessments. Findings include: 1. Review of the laboratory personnel Form CMS-209, identified five TP performing moderate complexity testing. The laboratory lacked documentation of a competency assessment for one (LM/TP-1) of five TP for 2023. 2. Review of the laboratory TP competency assessment records revealed that three of four competency assessments performed for 2023, were not reviewed or signed by the laboratory Director/Technical Consultant. 3. The LM/TP-1 confirmed the lack of competency assessment performance, and lack of review and signature of competency assessments for 2023. 4. The laboratory reports performing 3230 patient tests annually.</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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</p>

the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on request for and lack of documentation, and interview with the the laboratory Manager/Testing Personnel#1 (LM/TP-1), the laboratory failed to demonstrate that it could obtain the performance specifications established by the Cepheid GeneXpert manufacturer. Finding include: 1 The laboratory implemented the Cepheid GeneXpert Polymerase Chain Reaction (PCR) testing for respiratory pathogens on 12/02/2022. 2. A request for the laboratory's of verification of the manufacturers specification for the Cepheid GeneXpert analyzer, revealed a lack of performance and documentation of verification of the manufacturers specifications prior to performing and reporting patient testing. 3 The LM/TP-1 by interview confirmed the lack of performance of verification for the Cepheid GeneXpert manufacturers specifications for accuracy, precision, reportable range and reference intervals (normal values). 4. The laboratory reports performing 1200 Respiratory pathogen tests 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 a review of patient testing logs, the laboratory procedure manual for Urine Sediment and Wet Prep, and an interview with the laboratory Manager/Testing Personnel#1 (LM/TP-1), the laboratory failed to include a positive and negative control material for microscopic procedures each day of patient testing. Findings include: 1. Request for and lack of documentation of quality control (QC) records for microscopic testing for Urine Sediment, Wet Prep, and Skin scraping revealed the lack of performing a positive and negative control material each day of patient testing. 2. Review of tyhe laboratory Urinalysis Procedures, section "Microscopic Urinalysis-manual", does not include a process for quality control assessment each day of patient testing. 3. The LM/TP-1 confirmed by interview on 02/20/2024, at 11:30 a.m., the lack of QC procedures for microscopic testing. 4. The laboratory reports performing 40 microscopic examinations annually.

D6020

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 the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on a review of patient testing logs, the laboratory procedure manual for Urine Sediment and Wet Prep, and an interview with the laboratory Manager/Testing Personnel#1 (LM/TP-1), the laboratory Director failed to establish a quality control procedure for microscopic procedures performed each day of patient testing. Findings include: 1. Request for and lack of documentation of quality control (QC) records for microscopic testing for Urine Sediment, Wet Prep, and Skin scraping revealed the lack of performing a positive and negative control material each day of patient testing. See D5449. 2. Review of the laboratory's Microscopic Urinalysis- Manual procedure, lacked the instructions for performing positive and negative control procedures. 3. The LM/TP-1 confirmed by interview on 02/20/2024, at 11:30 a.m., the lack of QC procedures for microscopic testing. 4. The laboratory reports performing 40 microscopic examinations annually.