Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D0665552	11/01/2022
Name of Provider or Supplier	**Street Address, City, State**	
Northern Nevada Public Health	1001 E Ninth St Bldg B, Reno, 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
D0000	This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on 11/01/2022. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.
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 review of the Medical Laboratory Evaluation (MLE) proficiency testing (PT) evaluation for 2021 MLE-M1 and interview with the Advanced Practice Registered Nurse (APRN), the laboratory failed to verify the accuracy of the Gram Stain for PT sample GS-3 and Gram Stain morphology for samples GS-2 and GS-4 which were not graded due to lack of participant consensus and the Gram Stain morphology for GS-3 due to the result not being submitted to MLE. Findings include: 1. Review of the 2021 MLE-M1 Gram Stain and Gram Stain morphlogy PT results revealed that sample GS-3 was not graded for Gram Stain reaction due to lack of referee consensus and for Gram Stain morphology due to the result not being submitted to MLE. Samples GS-2 and GS-4 were not graded for Gram Stain morphology due to lack of participant consensus. 2. The laboratory did not have the participant summaries printed to compare the laboratory's PT results to the other participants' results. During the CLIA survey on 11/01/2022, the APRN interviewed at

	approximately 11:00 AM, accessed the MLE website and discovered the participant summaries available for printing. 3. The laboratory director signed the MLE evaluation on 5/19/2021 and failed to verify the accuracy of the ungraded PT samples. The laboratory performs approximately 300 microbiology tests annually.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the Afinion HbA1c External Quality control logs from January to November 2022, review of the manufacturer's acceptable ranges, and interview with the APRN, the laboratory quality assessment process failed to identify and take corrective action for the wrong acceptable range noted on the control log for October-November 2022 for the level two control, lot number 10216857 for hemoglobin A1c. Findings include: 1. The quality assessment program failed to identify that the acceptable range printed on the control log sheet used by the testing personnel to determine acceptability of the control result was incorrect and failed to take corrective action. 2. The manufacturer's acceptable range for the hemoglobin A1c level two control for lot number 10216857 is 7.2-8.8 %. 3. The acceptable range noted on the external control log for the level two control, lot number 10216857, is 7.3-8.9%. 4. The APRN interviewed on 11/01/2022 at approximately 11:30 AM confirmed the incorrect acceptable range on the control log. The laboratory performs approximately 76 hemoglobin A1c tests annually.