Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D2315547	10/29/2025
Name of Provider or Supplier	**Street Address, City, State**	
Healix Diagnostics	1680 Elk Creek Dr 2nd Fl, Idaho Falls, ID	

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
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. This STANDARD is not met as evidenced by: Based on a review of quality control (QC) documents, manufacturer certificate of analysis (COA) and an interview with the technical supervisor (TS) on 10/29/2025, the laboratory failed to check each lot of prepared plated medium for its ability to support growth and/or inhibit growth prior to patient testing since beginning testing in April 2025. The findings include: 1. A review of microbiology QC and COA records identified that the laboratory failed to perform and document quality control (QC) to show the ability of the prepared plated medium to support growth on Columbia CNA /MacConkey II split plate agar lot number 5237874 (BD BBL), Trypticase Soy Agar with 5% Sheep Blood Agar lot number 5262235 (BD BBL), Chocolate II Agar lot number 309501 (Remel) and to inhibit growth on the Columbia CNA/MacConkey II split plate agar lot number 5237874 (BD BBL). 2. An interview with the TS on 10/29 /2025 at 11:14 am confirmed that the laboratory failed to perform and document QC on each lot of prepared plated medium. 3. The laboratory reports performing 1150 microbiology tests annually.
D5507	BACTERIOLOGY CFR(s): 493.1261(b)(c) (b) For antimicrobial susceptibility tests, the laboratory must check each batch of

	media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of the laboratory's Phoenix 50 quality control (QC) documents and an interview with the technical supervisor (TS) on 10/29/2025, the laboratory failed to perform QC each day of patient testing since beginning testing in April 2025. The findings include: 1. A review of the Phoenix 50 QC for the following antimicrobial susceptibility test panels; NMIC-306, PMIC-110, SMIC-101 identified that the laboratory performed QC weekly failing to perform QC each day of patient testing. 2. An interview with the TS on 10/29/2025 at 11:05 am confirmed that the laboratory failed to have QC for each day of patient testing. 3. The laboratory reports performing 1,300 antimicrobial susceptibilities annually.