

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0977077	(X3) Date Survey Completed 08/24/2026
Name of Provider or Supplier Idaho Urologic Institute	Street Address, City, State 2855 E Magic View Dr, Meridian, 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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a direct observation, review of manufacturer instructions for use (IFU), lack of temperature documentation, and an interview with the technical supervisor, the laboratory failed to monitor room temperature in the patient draw room, the storage room and microbiology laboratory where testing reagents and blood collection tubes were stored prior to use. The findings include: 1. A direct observation of the patient draw room and storage room identified the following blood collection tubes: Becton Dickinson (BD) 5 ml SST tubes, Greiner Bio-One 3 ml K2 EDTA tubes, Becton Dickinson (BD) 3 ml lithium heparin tubes. 2. A direct observation of the microbiology laboratory identified the following reagents: Microscan Kovacs, Microscan 10% ferric chloride, Microscan indole, Microscan sulfanilic acid, Microscan mineral oil, Microscan Voges-Proskauer A, Microscan Voges-Proskauer B, Microscan prompt vials and Hardy Oxistrips. 3. A review of the manufacturer IFUs for Greiner and BD blood collection tubes list a storage temperature of 4-25 C. A review of the Microscan reagent and Hardy Oxistrip IFU's list a storage temperature of 15-30 C. The Microscan prompt IFU list a storage temperature of 2-27 C. 4. A review of laboratory temperature logs identified that the laboratory failed to monitor and document storage temperatures of blood collection tubes and microbiology

	reagents as required by the manufacturers daily for 5 of 5 months in 2024, 12 of 12 months in 2025 and 8 of 8 months in 2026. 5. An interview with the technical supervisor on 8/24/2026 at 1:07 pm confirmed that the laboratory failed to monitor storage temperatures. 6. The laboratory reports performing 66,999 tests annually.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (1) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. This STANDARD is not met as evidenced by: Based on a direct observation, review of quality control (QC) documentation, and an interview with the technical supervisor, the laboratory failed to perform QC for oxidase testing strips since the previous inspection on 7/15/2024. The findings include: 1. A direct observation in the microbiology laboratory identified Hardy Oxistrips, oxidase testing strips. 2. A review of laboratory QC documentation identified that the laboratory failed to perform QC on Hardy Oxistrips for the 2 years since the last inspection. 3. An interview with the technical supervisor on 8/24/2026 at 2:09 pm confirmed that the laboratory failed to perform QC on oxidase testing. 4. The laboratory reports performing 66,999 tests annually.