

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D0524216	(X3) Date Survey Completed 08/11/2022
Name of Provider or Supplier Intermountain Holladay Clinic	Street Address, City, State 6272 S Highland Dr, Murray, UT	
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 a review of the laboratory's proficiency/competency records, Standard Operating Procedure (SOP), the CMS-209, and interviews with staff, the laboratory failed to perform competency assessment for 2 of 12 Testing Personnel (TP). The laboratory performs approximately 11,000 tests annually. Findings include: 1. During a review of the biannual proficiency/competency testing records and the CMS-209 report revealed that the Provider Performed Microscopy (PPM) providers, failed to have completed 4 of 4 competency assessments for 2020 through August 2022 that addresses the six minimal regulatory requirements for the assessment of competency. 2. In an interview on 08/11/2022 at approximately 14:45, Technical Consultant 2 (TC2) confirmed that the laboratory does not assess the competency of PPM providers using the six minimal regulatory requirements.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p>

This STANDARD is not met as evidenced by:

Based on direct observation of laboratory equipment and interview with Technical Consultant 2 (TC2), the laboratory failed to recalibrate 1 of 1 timer once the calibration had expired. The laboratory performs approximately 11,000 tests annually. Findings include: 1. During a tour of the laboratory on 08/11/2022 at approximately 14:00, it was observed that a timer being used that indicated on the manufacturers sticker that the calibration had expired. 2. In an interview on 08/11/2022, TC2 confirmed that they do not calibrate timers when the calibration expires.