

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D0523765	(X3) Date Survey Completed 04/23/2018
Name of Provider or Supplier Wasatch Women's Center	Street Address, City, State 715 E 3900 S Ste 203, Salt Lake City, 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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on procedure manual review and interview with staff, the laboratory director failed to sign and date as approved the Rh slide tests procedure. Findings include: 1. Procedure manual review included a newly revised Rh factor slide type procedure that did not include the signature and date of the director's approval. 2. In an interview conducted on 04/23/2018 at approximately 4:00 P.M. staff conformed the director had not approved the newly written procedure.</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on manufacturer's package insert instructions review, test record review, and interview with staff, the laboratory failed to follow Rh typing antisera manufacturer's instructions to incubate patient's cells with Rh anti-sera at 20 to 24 degrees Centigrade for 5 minutes. The laboratory performed approximately 5 tests per day. Findings include: 1. Quotient Anti D (Rh) typing sera reagent instructions stated the slide should be tested at 20 to 24 degrees Centigrade. 2. Temperature records review</p>

included documentation the laboratory performed testing on a 45 Degree Centigrade slide warming tray. 3. In an interview conducted on 04/24/2018 at approximately 4:15 P.M., testing personnel confirmed they used the 45 degree slide warmer to incubate the Rh slides.