

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D1051703	(X3) Date Survey Completed 02/27/2024
Name of Provider or Supplier Desert View Hospital	Street Address, City, State 360 South Lola Lane, Pahrump, 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	
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on an interview with the laboratory manager, a review of the director approved procedure for emergency release of blood products, and the American Association of Blood Banks (AABB) Technical Manual (13th Edition), the laboratory failed to ensure that the director approved procedure for pre-transfusion testing was followed in the event of emergency release of blood products during the survey on February 27, 2024 between approximately 9:00 AM and 4:00 PM, and email correspondence received from the laboratory on February 29, 2024 at 5:29 PM. Findings include: 1. The laboratory manager stated during an interview on February 27, 2024 at approximately 10:30 AM that the laboratory had started performing emergency release of blood products for all patients, beginning January 1, 2024, without completing a crossmatch after release of the blood products. 2. The laboratory manager elaborated that the reasoning for completing only the antibody screen and not the crossmatch was because the laboratory implemented use of the Galileo Echo for the performance of ABO, Rh, Antibody Screen, and compatibility testing. The Echo did not have the capability of performing the immediate spin crossmatch, and the laboratory does not have the capability to perform an electronic crossmatch. 3. The older model of the Ortho MTS centrifuge and incubator for use with the Ortho MTS gel system previously in use was slated for revocation of FDA approval, effective January 1, 2024, forcing the facility to discontinue use of the instrumentation at that</p>

time. 4. There was no back up method established by the laboratory for the Ortho MTS gel system at the time that it was discontinued which would have allowed the performance of the immediate spin crossmatch when the use of the Echo was implemented. 5. These findings were confirmed via email correspondence received from the laboratory on February 29, 2024 at 5:29 PM. 6. The director approved procedure entitled, "Emergency Release or Special Issue of Components" stated in step 4, "Begin pre-transfusion testing IMMEDIATELY when the patient sample arrives (preferably collected before transfusion). 7. In the AABB Technical Manual (13th Edition), on page 386, under the section entitled, "Blood Administered in Urgent Situations," in the sub-section entitled, "Required Procedures" it states in step 3, "Begin compatibility tests and complete them promptly. If incompatibility is detected at any stage of testing, the patient's physician and the transfusion service physician should be notified immediately. Standard compatibility tests should be completed promptly for those units issued for initial replacement of patient's blood volume." The laboratory performs approximately 775 immunohematology tests annually.