

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 28D0455591	(X3) Date Survey Completed 07/27/2021
Name of Provider or Supplier Avera Creighton Hospital	Street Address, City, State 1503 Main Street, Creighton, NE	
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
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 surveyor review of Blood Bank General Procedure, surveyor review of investigation of suspected transfusion reaction paperwork, and interview with the laboratory general supervisor revealed the laboratory failed to follow its own procedure pertaining to transfusion reaction investigations. 1. Based on review of the laboratory's Blood Blank General Procedure, section Transfusion Reactions, the procedure indicates "The pathologist will provide written interpretation on the worksheet (Laboratory Transfusion Reaction Work Up Form), the interpretation may be verbalized to the attending physician, and the sheet is placed on patients chart. All transfusion reaction investigation will be reviewed by a pathologist and kept indefinitely." 2. Review of the Laboratory Transfusion Reaction Work Up form at time of survey revealed a transfusion reaction work up performed on 6/2/2021. The form had not been reviewed by a pathologist. 3. Interview with the general supervisor on 7/27/2021 at 2:50 PM confirmed the pathologist had not reviewed or been informed of the transfusion reaction investigation performed 6/2/2021.</p>
D6080	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(c)</p> <p>The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed.</p>

This STANDARD is not met as evidenced by:
The laboratory director failed to be accessible. Findings are: 1. The laboratory had their scheduled survey performed on 7/27/2021. The laboratory director was not present at time of survey. 2. At time of survey the general supervisor attempted to call the laboratory director around 2:00 PM. The laboratory director was unavailable. 3. Review of the Laboratory Transfusion Reaction Work Up Form revealed the laboratory director had not reviewed the transfusion reaction investigation performed on 6/2/2021.

D6113

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(a)

The technical supervisor must be accessible to the laboratory to provide on-site, telephone, or electronic consultation.

This STANDARD is not met as evidenced by:
The laboratory supervisor failed to be accessible. Findings are: 1. The laboratory had their scheduled survey performed on 7/27/2021. The laboratory supervisor was not present at time of survey. 2. At time of survey the general supervisor attempted to call the technical supervisor around 2:00 PM. The technical supervisor was unavailable. 3. Review of the Laboratory Transfusion Reaction Work Up Form revealed the laboratory supervisor had not reviewed the transfusion reaction investigation performed on 6/2/2021.