Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D2161177	10/24/2019
Name of Provider or Supplier	**Street Address, City, State**	
Avera Merrill Pioneer	1100 S 10th Avenue, Rock Rapids, IA	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of calibration records and confirmed by laboratory personnel #2 (refer to the Laboratory Personnel Report) at approximately 3:30 pm on 10/23/2019, the laboratory failed to retain daily calibration records for the analytes: sodium, potassium, and chloride for 146 out of 146 days (5/1/2019 - 9/23/2019). The findings include: 1. On 5/1/2019, the laboratory began performing patient testing for the analytes: sodium, potassium and chloride. 2. The chemistry analyzer required the laboratory calibrate the analytes: sodium, potassium and chloride each day of patient testing. 3. The laboratory retained the calibrations electronically on the chemistry analyzer. 4. At the time of the survey, the laboratory discovered the chemistry analyzer only retained the calibrations for the analytes: sodium, potassium, and chloride for 30 days. 5. The laboratory did not have calibration records for the analytes: sodium, potassium and chloride from 5/1/2019 - 9/23/2019.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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.

	This STANDARD is not met as evidenced by: Based on review of immunohematology policies and procedures and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 9:15 am on 10/24/2019, the laboratory failed to have a procedure for performing transfusion reaction investigation(s) and a procedure for the screening and dosing for Rh immune globulin (Rhogam).
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) on 10/24/2019 at approximately 11:00 am, the laboratory director failed to ensure that the laboratory established a written quality assessment procedure that included the four quality systems: general laboratory, pre analytical, analytical, and post analytical.