Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0410407	10/03/2018
Name of Provider or Supplier	**Street Address, City, State**	
St Peters Health	2475 Broadway, Helena, MT	

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	Based on an on-site initial survey conducted on 10/1/18-10/3/18, deficiencies were cited for St Peters Health in Helena, MT.
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 observation, record review, and interview, the laboratory failed to retain the quality control (QC) data for urine drug screens (UDS) performed on the Siemens Vista from 5/23/18 to 10/2/18. The findings include: 1. On 10/1/18 at 10:45 a.m., two Siemens Vista analyzers were observed in the laboratory. 2. A review on 10/1/18 at 10:45 a.m. of the list of tests performed on each analyzer included UDS performed on the second Vista analyzer. 3. A review on 10/2/18 at 12:15 p.m. of the QC for UDS was not located in Meditech. QC for only the nine previous calendar days was retained on the Siemens Vista analyzer. QC data older than nine calendar days was not located. 4. On 10/2/18 at 12:15 p.m., staff member A stated the QC data was not printed or retained electronically.
D5553	IMMUNOHEMATOLOGY CFR(s): 493.1271(b)(f) (b) Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b). (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

	This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to document visual inspection of blood during storage from 5/23/18 through 10/2/18. The findings include: 1. On 10/2/18 at 1:00 p.m., blood was observed in the laboratory blood bank refrigerator. 2. A review on 10/2/18 at 1:00 p.m. of the blood bank review logs lacked documentation of visual inspection of the blood during storage. 3. On 10/2/18 at 1:00 p.m., staff member B stated the units are counted daily but are not visually inspected.