Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0524732	08/21/2019
Name of Provider or Supplier	**Street Address, City, State**	
Brigham Medical Clinic	600 W Hospital Rd, Brigham 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
D3029	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(2) Test procedures. Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance. This STANDARD is not met as evidenced by: Based on procedure manual review, lack of documentation and interview with staff, the laboratory failed to include the date AcT Diff II test procedure was discontinued. Findings include: 1. The laboratory started complete blood cell count testing using the Sysmex XN 330 12/18/2018. 2. The laboratory failed to record the date of discontinuance for the previous AcT Diff II instrument. 3. In an interview with staff on 08/21/2019 at approximately 12:30 P.M. staff confirmed they did not record the date AcT Diff II procedure was discontinued.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on new Sysmex XN 330 complete blood count procedure review, lack of documentation and interview with staff, the laboratory director failed to sign and date the new instrument procedure as approved. The laboratory tested approximately 5 specimens per day. Findings include: 1. The laboratory new procedure for the Sysmex XN 330 failed to include the director's signature and date of approval. 2. In an interview with testing personnel on 08/21/2019 at approximately 11:55 A.M. staff

	stated the director had not approved the XN 330 complete blood count testing procedure prior to testing patient samples in December 2018.