Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D1094000	01/25/2021
Name of Provider or Supplier	**Street Address, City, State**	
Ogden Clinic Utah Hematology Oncology Layton	2132 North 1700 West #301, Layton, 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
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on new instrument verification documentation review, lack of documentation, and interview with staff, the director failed to sign and date the new blood cell counter reportable range verification for Abbott Emerald serial number 008335 installed on 12 /29/2020. The laboratory performed approximately 20,000 complete blood count tests per year. Findings include: 1. The laboratory director failed to sign and date the reportable range study as approved for use prior to reporting patient test results. 2. In an interview conducted on 01/25/2021 at approximately 3:50 P.M. staff confirmed the director's signature was missing from the reportable range study.