

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D1069494	(X3) Date Survey Completed 04/04/2019
Name of Provider or Supplier Uinta Basin Medical Center Manila Clinic	Street Address, City, State 100 West 96 North, Manila, 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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation, test records review, and confirmation by the laboratory director, the laboratory failed to retain the complete blood count (CBC) quality control assay sheets to determine quality control ranges set for each lot number of quality control (QC) materials was accurately printed on the QC test reports for 3 of 11 QC lot numbers reviewed from 04/20/2017 to 12/03/2018 when the laboratory temporarily discontinued testing.. Findings include: 1. The laboratory failed to retain the QC manufacturer's assay sheets for QC lot numbers: 7240 in use on 10/31/2017 for patient 113307; and 11/16/2017 for patient 125544; 8015 in use on 03/16/2018 for patient 126271; 8071 in use on 05/25/2018 for patient 2161994 and on 06/21/2018 for patient 212999; 8127 on 07/09/2018 for patient 47028; 8183 in use on 10/08/2018 for patient 05181959 (date of birth); and 8239 in use on 12/03/2018 for patient 99625. 2. In an interview conducted on 04/04/2019 at approximately 12:25 P. M., the laboratory director confirmed the testing person failed to retain assay sheets for QC materials in use after 01/04/2018,</p>