

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 12D0646230	(X3) Date Survey Completed 12/03/2018
Name of Provider or Supplier Clinical Labs Of Hawaii-Kohala Psc	Street Address, City, State 54-383 Hospital Rd, Kapaau, HI	
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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation and an interview with the testing personnel and outreach laboratory manager on 12/03/2018 at 11:00 a.m., it was determined that the laboratory failed to ensure its Modified Wrights stain was not used beyond its expiration date. The findings include: 1. A bottle of Sigma Aldrich Modified Wrights stain, lot SLBT6367, opened on 04/29/2018 and expired on 10/01/2018 was available for use in the laboratory. 2. 22 patient hematology blood smears were stained with the expired reagent in October. 3. 23 patient hematology blood smears were stained with the expired reagent in November.</p>
D6093	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation and an interview with the testing personnel and outreach laboratory manager on 12/03/2018 at 11:00 a.m., it was determined that the laboratory failed to assure the quality of the Modified Wrights stain it used to stain 45 patient blood smears. Refer to D5417.</p>