

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2048767	(X3) Date Survey Completed 12/08/2021
Name of Provider or Supplier Hope Health Center	Street Address, City, State 24100 Calabasas Rd, Calabasas, CA	
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 Surveyor review of laboratory's patients', quality control, proficiency testing and analytic system records, and interview with the laboratory technical consultant on December 8, 2021 at 3:00 pm, the laboratory failed to retain its test analytic system records. The findings include: 1. The laboratory used an automated ABX Micros 60 instrument to do CBC test in 2019. During that year the instrument broke down and then the laboratory used a Cell Dyn CD1800 instrument to test patient sample. However, the laboratory did not document and retain any records of the test analytic system. 2. The laboratory technical consultant on December 8, 2021 at 3:00 pm, affirmed that the laboratory did not save the test system analytic records. 3. The laboratory's testing declaration form, signed by the laboratory Director on 12/6/2021, stated that the laboratory performs approximately 6,000 tests, annually.</p>
D3033	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i)</p> <p>In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's documents, lack of test verification records</p>

and interview with the laboratory technical consultant on December 8, 2021 at 2:50 pm, the laboratory failed to retain its complete blood count (CBC) test verification records for ABX Micros 60 instrument. The findings include: 1. The laboratory used the ABX Micros 60 and Cell Dyn CD1800 instruments to do CBC test in 2019. However, it failed to retain the test verification records for both instruments. Therefore, it can not be assured that the verification was performed, and the reported CBC test results were accurate, and thus may have caused patient harm. a) The laboratory used an automated ABX Micros 60 instrument to do CBC test in 2019. During that year the instrument broke down and then the laboratory used a Cell Dyn CD1800 instrument to test patient sample. Patient # 1 was found tested on 10/7/2019 on CD1800. The laboratory did not have CBC test verification records on CD1800. b) After it received the repaired ABX Micros 60 instrument, the laboratory verified the accuracy of its CBC test on the instrument, however it failed to keep the verification records. 2. The laboratory technical consultant on December 8, 2021 at 2:50 pm, affirmed that the laboratory did not save the CBC test verification results. 3. The laboratory's testing declaration form, signed by the laboratory Director on 12/6/2021, stated that the laboratory performs approximately 6,000 tests, annually.

D6004

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappropriates performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's documents, test reports, lack of test verification and analytic system records and interview with the laboratory technical consultant on December 8, 2021 at 3:00 pm, the laboratory director failed to ensure compliance with the applicable regulations. The findings include: See D3031 and D3033.