

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0643914	(X3) Date Survey Completed 09/11/2019
Name of Provider or Supplier Igenex Inc	Street Address, City, State 556 Gibraltar Dr, Milpitas, 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
D2121	<p>HEMATOLOGY CFR(s): 493.851(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: . Based on reviews of proficiency testing reports from CMS (report 155D, Individual Laboratory Profile) and CAP (College of American Pathologists), laboratory proficiency testing records, and patients tests records; and interview with the Laboratory Director, the laboratory failed to attain scores of at least 80% for RBC (Red Blood Cell count)and HCT (Hematocrit) using the Emerald hematology analyzer constituting unsatisfactory analyte performance for 2019, event 2. Findings included: a. CMS and CAP reported scores for 2019/event 2 based on the laboratory's unacceptable results as follows: Analyte Score Unacceptable results ----- RBC 20% 3 out of 5 HCT 40% 2 out of 5 b. The Laboratory Director affirmed (9/11/19 at 5pm) the aforementioned unsatisfactory proficiency testing scores. c. Based on annual test volumes information provided by the laboratory (9/10/19), the laboratory performed hematology testing on approximately 57 specimens each month since May 2019. .</p>
D2122	<p>HEMATOLOGY CFR(s): 493.851(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing reports from CMS (report 155D, Individual</p>

Laboratory Profile) and CAP (College of American Pathologists), laboratory proficiency testing records, and patients test records, and interview with laboratory personnel, it was revealed that the laboratory failed to attain an overall score of at least 80 percent indicating unsatisfactory performance in hematology testing for 2019, event 2. Findings included: a. CMS and CAP reported the overall score of 76% in hematology testing for the 2nd event of 2019 based on cumulative scores that included the following: Analyte Score ----- RBC (Red Blood Cell count) 20% HCT (Hematocrit)40% b. See D2121. .

D5775

COMPARISON OF TEST RESULTS
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:
Based on observation of 11 thermal cyclers, reviews of laboratory records, the lack of laboratory documents, and interview with laboratory personnel, the laboratory failed to have a policy and system that twice a year evaluated test results using the different thermal cyclers. Findings included: a. The laboratory provided a list (9/10/19) of 11 different thermal cyclers as follows: Make & Model , Serial numbers
----- Bio-Rad; C1000 Touch: RN033782 / CT0063789 RN033737 / CT006788 RN049053 / CT017415 RN048968 / CT017419 RN050659 / CT018085 C1000 Touch CFX96: 785BR11699 / CT014747 / RN045867 785BR12059 / CT015986 / RN047259 Eppendorf; Mastercycler: 533355480 533355484 5333Z4958784 5331-13611 b. The laboratory failed to provide for review a policy and records that twice a year documented comparisons of test results from all 11 thermal cyclers. c. Laboratory personnel affirmed (9/11/19 at 6pm) that all 11 thermal cyclers were used interchangeably for all assays and the lack of a written policy and system to compare test results from all of them. d. The reliability and quality of amplifications, and thus test results, from using all thermal cyclers interchangeably could not be assured in the absence of performing comparisons. Based on annual tests volumes (9/10/19), the laboratory reported more than 14,000 tests results using all thermal cyclers.