

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0684771	(X3) Date Survey Completed 10/05/2018
Name of Provider or Supplier Nanda Biswas Md	Street Address, City, State 12677 Hesperia Rd Ste 170, Victorville, 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 review of the laboratory's proficiency testing (PT) result reports, and interview with the testing personnel, It was determined that the laboratory failed 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. The findings included: a. The laboratory performed Complete Blood Cells Count (CBC) including Hematocrit (Hct), and enrolled its PT program with American Proficiency Institute (API) to ensure the accuracy of the testing system and fulfill the CLIA requirements. b. The laboratory attained a score of 60% for Hct in the 2nd 2016 PT event was unsatisfactory analyte performance for the testing event. c. The laboratory performed in approximately 83 patient samples each month. d. The laboratory testing personnel affirmed (10/05/18 @ 11:30 am) that the laboratory attained a score of 60% for Hct in the 2nd 2016 PT event was unsatisfactory analyte performance for the testing event.</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 the laboratory's proficiency testing (PT) result reports, and interview with the testing personnel, It was determined that the laboratory failed to</p>

attain an overall testing event score of at least 80 percent was unsatisfactory performance. The findings included: a. The laboratory performed Complete Blood Cell Counts (CBC) which including WBC with automated cell differentials, RBC, Hemoglobin (Hgb), Hematocrit, and Platelet count. b. The laboratory enrolled its PT with American Proficiency Institute (API) to ensure the accuracy of its CBC testing system and fulfil the CLIA requirements. c. The laboratory attained an overall testing event score of 62% for CBC in the 2nd 2017 PT event was unsatisfactory performance. d. The PT testing scores were as follows: 2017 2nd PT Score (%) Automated Cell diff 73 RBC 60 Hct 60 Hgb 60 WBC 60 Platelets 60 Overall 62 e. The laboratory performed in approximately 83 patient samples each month. f. The laboratory testing personnel affirmed (10/05/18 @ 11:30 am) that the laboratory attended an overall testing event score of 62% for CBC in the 2nd 2017 PT event was unsatisfactory performance.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(i)

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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:
Based on review of the laboratory's proficiency testing results reports, and interview with the laboratory testing personnel, it was determined that the laboratory director failed to ensure that the proficiency testing samples were tested as required under Subpart H of 42 CFR part 493. The findings included: See D-2121 and D-2122