

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0561372	(X3) Date Survey Completed 02/28/2020
Name of Provider or Supplier William H Isacoff Md Inc	Street Address, City, State 10921 Wilshire Blvd Ste 505, Los Angeles, 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: 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 this standard was not met as evidenced by: Based on surveyor review on 2-28-2020 @ 12:30, of the 1st event (Q1/2019) of the American Proficiency Institute (API) proficiency testing records, interview with the laboratory manager and a testing person, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for: Hemoglobin (Hgb), White Blood Cell Differential, Granulocyte, Lymphocyte and Monocyte. The findings included: a. API reported the following unsatisfactory proficiency testing scores for the 1st event (Q1/2015) for the following analytes: Analyte: Score: Event/Year: Hgb 60% Q1/2019 WBC Differential 27% Q1/2019 Granulocyte 0% Q1/2019 Lymphocyte 60% Q1/2019 Monocytes 20% Q1/2019 b. The laboratory manager affirmed 02/28/2020 @ 12:30 pm that the laboratory received the above unsatisfactory proficiency testing scores. c. During the survey ten random patient samples from January 9, 2019 through February 7, 2019 were reviewed. The selected patients Complete Blood Counts (CBC) were analyzed and reported which include the failed analytes. Based on the laboratory test volume declaration, approximately 2,000 CBC tests were performed annually.</p>
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification</p>

procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on interview with testing personnel, lab manager 2/28/2020 @ 13:30 and review of laboratory calibration verification documentation, the laboratory failed to perform and document calibration at least once every six months. Findings include: a. Laboratory documents of Calibration revealed calibrations were performed on the Cell-Dyne as follows: Calibration 7/13/2018 Initial Calibration 5/2/2019 Calibration 9/25/2019 b. The laboratory was unable to provide additional documents verifying calibrations for the period between 7/13/2018 and 5/2/2019. c. Ten of ten randomly selected patient CBC s were reported from July 13, 2018 through May 2, 2019 with no evidence of Calibration Verification being performed. Based on the laboratory test volume declaration, approximately 2,000 CBC tests were performed annually