

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0678303	(X3) Date Survey Completed 12/07/2022
Name of Provider or Supplier Sant P Chawla Md Inc	Street Address, City, State 2811 Wilshire Blvd, Ste 414, Santa Monica, 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 the surveyor's review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, five (5) random patients sampling, and interview with the technical consultant (TC); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Hematology on the first event of 2022 (Q1-2022). The findings included: 1. The API proficiency program gave an overall unsatisfactory score of 40 % for Hematology for Q1-2022 which included: Sample Analyte Performance ABT-01 Lymphocyte Acceptable ABT-2 Lymphocyte Unacceptable ABT-3 Lymphocyte Unacceptable ABT-4 Lymphocyte Acceptable ABT-5 Lymphocyte Unacceptable 2. Based on the laboratory's annual testing declaration submitted on the day of the survey December 7, 2022; the laboratory analyzed and reported approximately 47,040 Hematology samples which included Lymphocytes counts during the time the laboratory had unsatisfactory proficiency testing results. 3. The TC confirmed on December 7 2022, at approximately 11:30 a.m. that the laboratory received the above proficiency score of 40% for Hematology as described in 1.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic</p>

examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on surveyor's review of the laboratory's policies & procedure manual, random patient samples, quality control (QC) and proficiency testing (PT) records for the years of 2021 and 2022, and interview with the laboratory technical consultant (TC) on December 7, 2022, the laboratory failed to have a step-by-step performance of the procedure and quality control procedure for the Cell- Dyne Abbott Emerald instrument. The findings include: 1. The laboratory uses the Cell- Dyne Abbott Emerald instrument Hematology analyzer for analyzing patient samples, however; the laboratory failed to have a step-by-step performance of the procedure and quality control procedures. 2. The TC affirmed the lack of a laboratory procedure manual stating a step-by-step performance of the procedure and quality control procedures for the Cell- Dyne Abbott Emerald instrument. 3. The laboratory's testing declaration form, signed by the laboratory 's director on 12,5/2022, stated that the laboratory performs 47,040 Hematology tests annually.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(13)

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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:

Based on direct observation and interview with the laboratory's technical consultant it was determined that the laboratory director failed to ensure that an approved procedure manual is available at all times to all personnel responsible for any aspect of the testing process. See D5403.