

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0543719	(X3) Date Survey Completed 12/06/2022
Name of Provider or Supplier Privilege Dx Medical Laboratories, Inc	Street Address, City, State 10133 Riverside Dr, Toluca Lake, 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
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 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.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy and procedure, patient test results and interview with the laboratory technical supervisor on December 6, 2022, at 1:20 pm, the laboratory failed to have a policy & procedure when hematology instrument produced results with flagged IP messages. The findings include: 1. The laboratory used Sysmex 1000i automated CBC instrument to perform blood cell count. The instrument print out for the patient sample #168467 showed flagged IP message "Blasts?". A total of 15 patients data reviewed. The instrument manufacturer stated that when IP messages are flagged, the unit will judge that the analyzed data have low</p>

reliability. The purpose of the IP message is to inform the instrument operator of the possibility of the sample abnormality, so special measure or further analysis van be undertaken. However, the laboratory reported the patient's result without any further analysis. Therefore, the validity of the patients' test results rendered by the laboratory cannot be assured. 2. The laboratory technical supervisor on December 6, 2022, at 1:20 pm, affirmed that the laboratory did not have a policy in place to review all the IP messages. 3. The laboratory's testing declaration form, signed by the laboratory director on 12/5/2022, stated that the laboratory performs approximately 16,015 CBC differential tests, annually.

D6082

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(1)

The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's policy and procedure, patient test results and interview with the laboratory technical supervisor on December 6, 2022, at 1:20 pm, it was determined that the laboratory director failed to assure the quality of laboratory services provided. The findings include: See D5403.