

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0858508	(X3) Date Survey Completed 08/20/2020
Name of Provider or Supplier John D Sprandio Md Laboratory	Street Address, City, State 30 Lawrence Road, Suite 201, Broomall, PA	
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 the review of the manual differential examination policy and interview with testing personnel (TP) #1, the laboratory failed to include, quality control (QC) procedures in the manual differential examination policy from 2018 to the day of survey. Findings Include: 1. On the date of survey, 08/20/2020, review of the manual differential examination policy revealed, QC procedures were not stated in the manual from 02/26/2018 to 08/20/2020. 2. TP #1 confirmed the finding above on 08/20/2020 around 10:00 am.</p>

D5437

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based upon a review of the Ac T Diff analyzer calibration records and an interview with testing personnel (TP) #1, the laboratory failed to perform calibration on the Ac T Diff analyzer used to perform complete blood count (CBC) tests from 06/24/2019 to 02/28/2020. Findings Include: 1. The Coulter Ac T Diff analyzer operating procedure, calibration states, "Frequency also depends on regulatory requirements which for the instrument systems will be every 6 months". 2. On the day of survey, 08/20/2020, review of the Ac T Diff analyzer calibration records revealed, the laboratory did not perform the Ac T Diff analyzer calibration every 6 months, as per their policy. 3. TP #1 confirmed the finding above on 08/20/2020 around 09:45 am.