

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0920750	(X3) Date Survey Completed 10/27/2020
Name of Provider or Supplier Satish A Shah Md Pllc	Street Address, City, State 207 N Broad Street, Philadelphia, 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 review of the laboratory procedures and interview with the Medical Assistant (MA), the laboratory failed to establish a complete Hematology complete blood count (CBC) procedure from 4/25/2018 to the day of survey. Findings include: 1. On the date of survey, 10/27/2020, review of the laboratory's procedures revealed, the laboratory did not establish a complete CBC procedure manual that included the following from 4/25/2018 to 10/27/2020: - Requirements for patient preparation; specimen collection, labeling and storage. - Step-by-step performance of the procedure. - Calibration and calibration verification procedures. - The reportable</p>

	<p>range for test results for the test system as established. - Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. - The laboratory's system for entering results in the patient record and reporting patient results including. 2. The MA confirmed the findings above on 10/27/2020 around 10:15 am.</p>
<p>D5413</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's temperature records and interview with Medical Assistant (MA), the laboratory failed to monitor and document the condition for storage of the Abbott Cell- Dyn Emerald complete blood count (CBC) analyzer reagents stored at room temperature from 2018 to the date of survey. Findings include: 1. The "The Cell-Dyn Emerald Cleaner and CN-Free Lyse bottles state to be stored at, "4 to 35 degrees Celsius". 2. On the date of survey 10/27/2020, review of the laboratory's temperature records revealed, the laboratory did not monitor or document the room temperature where the following Abbott Cell- Dyn Emerald complete blood count (CBC) analyzer reagents were stored from 4/25/2018 to 10/27/2020: - 2 of 2 bottles of Cell-Dyn Emerald Cleaners Lot# 1196 Exp 01/04/202. - 2 of 2 bottles of CN-Free Lyse Lot# 1012 Exp 05/21/2021. 3. The MA confirmed the findings above on 10/27/2020 around 10:00 am.</p>
<p>D5429</p>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on observation of service stickers and interview with the Medical Assistant (MA), the laboratory failed to perform and document service maintenance for 1 of 1 Fisher Scientific Traceable thermometer from 4/25/2018 to the day of survey. Findings include: 1. On the day of survey, while on tour of the laboratory, observation of 1 of 1 Fisher Scientific Traceable thermometer, used to measure internal temperatures of the mini Sanyo refrigerator revealed, the thermometer was due for service on 03/31/2016. 2. The Laboratory was unable to provide documentation of service performed on the Fisher Scientific Traceable thermometer after 03/31/2016. 3. The Mini Sanyo refrigerator housed, 3 of 3 boxes of Cell-DYN controls, Lot# 0265, Exp 01/08/2021. 4. The MA confirmed the findings above on 10/27/2020 at 08:50 am.</p>
<p>D6019</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES</p>

CFR(s): 493.1407(e)(4)(iv)

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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on surveyor review of American Proficiency Institute (API) Proficiency Testing (PT) records and interview with the Medical Assistant (MA), the laboratory director failed to ensure an approved corrective action plan was documented for the unsatisfactory result for the API 1st event for Hematology Platelet Count in 2020. Findings include: 1. On the day of survey, 10/27/2020, review of API PT records revealed, the laboratory did not document a correction action plan for the following API event in 2020: - Event 1, Platelet counts, score of 80%. 2. The MA confirmed the finding above on 10/27/2020 at 9:40 am.