

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0920750	(X3) Date Survey Completed 11/16/2022
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
D5301	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: Based on lack of laboratory test requisition records and an interview with the Office Manager (OM) the laboratory failed to have a written or electronic test requisition for Complete Blood Count (CBC) patient testing from 10/27/2020 to 11/16/2022 (1 of 1 patient test report reviewed). Findings include: 1. On the day of the survey, 11/16/2022, the OM could not provide test requisitions for any CBC patient testing from 10/27/2020 to 11/16/2022. 2. According to the CMS 116, 20,001 CBC patient testing has been performed for the year 2021. 3. OM confirmed the above finding on 11/16/2022 at 12:31 PM.</p>
D5413	<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 observation of the temperature records, and an interview with the Office</p>

Manager (OM), the laboratory failed to document the Room Temperature (RT) ranges for the storage of Abbott Cell Dyn Hematology analyzer reagents for 2021 and 2022 (21 of 22 months). Findings include: 1. According to the laboratory's "Recording of temperature" manual, the acceptable ranges should be listed on the temperature log sheet. 2. On the day of the survey, 11/16/2022 at 11:40 AM, a review of the laboratory's RT temperature logs showed that the laboratory did not have an acceptable RT range for 21 of 22 months of temperature recorded. 3. According to the manufacturer's instructions Cell Dyn Emerald reagents should be stored at 4 to 35 degrees Celsius. 4. Interview with OM confirmed the findings above on 11/16/2022 at 12:31 PM.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

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.

This STANDARD is not met as evidenced by:
Based on observation of the laboratory and interview with the Office Manager (OM), the laboratory failed to perform and document maintenance on the 1 of 1 thermometer used for taking the temperature at which the Cell Dyn Emerald Hematology reagents were stored to ensure they were consistent with the manufacturer's instructions from 08/2022 to 11/16/2022. Findings Include: 1. On 11/16/2022 at 12:06 PM an observation of the laboratory revealed that the following thermometer was used for recording RT and expired. -S/N 33293 Expired on 08/2022. 3. Interview with OM confirmed the findings above on 11/16/2022 at 12:31 PM.

D6019

LABORATORY DIRECTOR RESPONSIBILITIES
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 the review of the American Proficiency Institute (API) records and interview with the Office Manager (OM), the Laboratory Director (LD) failed to identify and ensure that corrective actions were followed for 1 of 3 Hematology and Coagulation events for PT performance where the results were unacceptable or unsatisfactory in 2021. Findings include: 1. On the day of the survey, 11/16/2022 at 11:25 AM, a review of API PT records revealed, the laboratory did not document corrective actions for the following API PT event that received an unacceptable score in 2021. - API 1st Event Hematology and Coagulation 2021- Cell I.D or WBC Diff 0% - API 1st Event Hematology and Coagulation 2021- RBC 0% - API 1st Event Hematology and Coagulation 2021- HCT (Non-Waived) 0% - API 1st Event Hematology and Coagulation 2021- HGB (Non-Waived) 0% - API 1st Event Hematology and Coagulation 2021- WBC 0% - API 1st Event Hematology and

Coagulation 2021- Platelets 0% 2. The OM confirmed the above findings on 11/16 /2022 at 12:31 PM.