

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 39D2028285	<b>(X3) Date Survey Completed</b> 04/27/2022
<b>Name of Provider or Supplier</b> Satish A Shah Md Pllc	<b>Street Address, City, State</b> 1 Presidential Blvd, Bala Cynwyd, PA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory quality control (QC) records and interview with the Testing Personnel (TP)#1, the laboratory failed to retain daily QC records for Medonic M Complete Blood Count (CBC) analyzer from 12/18/2019 to 12/31/2021. Findings include: 1. On the day of survey, 04/27/2022 at 10:30am, the laboratory could not to provide QC records for CBC examinations performed from 12/18/2019 to 12/31/2021. 2. The laboratory's annual test volume for CBC is 300 (CMS 116). 3. On 04/27/2020 at 10:33am, the TP#1 stated that all the QC for 2020 and 2021 was shredded and discarded. 4. The TP#1 confirmed the findings above on 04/27/2021 around 11:45am.</p>
<b>D3037</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) records and interview with the Testing Personnel (TP) #1, the laboratory failed to provide 1 of 3 API PT attestation statement in 2020, 1 of 3 API PT result records in 2020, and 1 of 3 API PT records in 2021 for Hematology/Coagulation events. Findings include: 1. On the day of survey, 04/27/2022 at 10:50am., the TP#1 could</p>

not provide the the following: - 2020: Attestation statement: Event #2. - 2020: PT results: Event #3. - 2021: PT records: Event #1. 2. The TP#1 confirmed the finding above on 04/27/2022 at 11:45am.

**D5211**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**  
CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:

Based a review of American Proficiency Institute (API) proficiency testing (PT) records and interview with the testing personnel (TP)#1, the Laboratory failed to review and evaluate the results obtained on proficiency testing for 3 of 3 (API) for Hematology/Coagulation in 2020 and 2021. Findings: 1. On the day of survey, 04/27 /2022 at 10:50 am., the records reviewed revealed that the laboratory could not provide records of the evaluation and review of the following: a. API Hematology: 2020 Event#2 and Event#3 b. API Hematology: 2021 Event#1. 2. The TP#1 confirmed the finding above on 04/27/2022 around 11:45 am.

**D5403**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(b)

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.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's procedure and interview with the Testing Personnel (TP)#1, the laboraotry written procedure manual did not include all pre analytical requirements applicable for the Complete Blood Count (CBC) analysis from 12/18/2019 to the day of survey. Findings include: 1. On the day of survey 04/27 /2022 at 10:15 am. review of the laboratory procedure manual revealed the manual did not include the following from 12/27/2019 to the day of survey: - Patient preparation. - Specimen collection and labeling,. - Processing - Criteria for specimen acceptability /rejection. 2. The TP#1 confirmed the finding above on 04/27/2022 at 11:45 am.

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**

CFR(s): 493.1252(b)

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.

This STANDARD is not met as evidenced by:

Based on review of temperature records and interview with the Testing Personnel (TP) #1, the laboratory failed to record daily temperatures for 1 of 1 refrigerator where the testing quality control reagents are store from 01/01/2020 to 12/31/2020. Findings Include: 1. On the date of survey 04/27/2022 at 10:00 am, the laboratory could not provided temperature records for 1 of 1 refrigerator from 01/01/2020 to 12/31/2020. 2. The TP #1 confirmed the findings above on 04/27/2022 at 11:45 am.

**D6051**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:

Based on review of American Proficiency Institute (API) proficiency testing (PT) records and interview with the testing personnel (TP)#1, the TC failed to evaluate the test performance of 1 of 2 testing personnel (TP) through internal blind testing samples or external PT samples for Complete Blood Count (CBC) assay examinations from 04/27/2020 to 04/27/2022. Findings Include: 1. On the day of survey, 04/27/2022 at 10:14 am., review of API PT records revealed, 1 of 2 TP (TP#1) performed the external PT samples for CBC assay examinations for 3 of 3 events in 2020 and 3 of 3 events in 2021. 2. The TP#1 could not provide documentation of internal blind testing evaluations performed for 1 of 2 TP (TP#2) for CBC assay examinations in 2020 and 2021. 3. The TP#1 confirmed the findings above on 04/27/2022 at 11:45 am.