

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D0890209	<b>(X3) Date Survey Completed</b>  08/11/2022
<b>Name of Provider or Supplier</b>  Satish A Shah Md Laboratory	<b>Street Address, City, State</b>  Gettysburg Cancer Center, Gettysburg, 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>D5429</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> 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 the laboratory and interview with the Laboratory Director (LD), the laboratory failed to establish a maintenance policy to assess the maintenance /function for 1 of 1 Acu Rite digital thermometer used to monitor the room temperature and humidity for Medonic M series reagents from July 23, 2020 to the day of survey. Findings Include: 1. On the day of survey, 08/11/2022 at 11:22 AM, the laboratory failed to provide a maintenance policy for 1 of 1 Acu Rite digital thermometer. 2. The following reagent was stored at the room temperature 1 of 1 Medicin M seris pack( Lot# 2205-002, Exp- 2025-01-31). 3. No expiration date or serial number was observed on the Acu Rite digital thermometer. 4. LD confirmed the findings above on 08/11/2022 at 11:40 AM.</p>
<b>D6016</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(i)</p> <p>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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;</p>

	<p>This STANDARD is not met as evidenced by: Based on the review of American Proficiency Institute (API) proficiency test (PT) records and interview with the Laboratory Director (LD), the LD failed to ensure that 1 of 6 proficiency testing attestations were signed by the LD in 2022 for Hematology Coagulation PT. Findings include: 1. On the day of the survey 08/11/2022 at 10:08 AM, a review of the PT records revealed that the Laboratory Director failed to sign the API Event 1 2022 Hematology Coagulation proficiency attestations. 2. Interview with LD confirmed these findings above on 08/11/2022 at 11:40 AM.</p>
<b>D6051</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)(v)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of competency assessment records and interview with Laboratory Director (LD), the Technical Consultant (TC) failed to evaluate the test performance of 11 of 12 testing personnel (TP) through internal blind testing samples or external Proficiency Testing (PT) samples for Complete Blood Count (CBC) assay examinations from 07/23/2020 to 08/11/2022. . Findings Include: 1. At the time of survey, 08/11/2022 at 10:39 AM, a review of the competency assessment records revealed, the laboratory failed to establish a procedure to assess test performance of 11 of 12 TP through internal blind testing samples or external PT samples from 2020 to 2022 who performed CBC examinations on the Medonic M series analyzer. 2. A review of 11 of 12 TP competency assessments revealed that they were missing the following point "Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples;" 3. The LD confirmed the findings above on 06/08/2022 around 11:40 am.</p>
<b>D6063</b>	<p><b>LABORATORY TESTING PERSONNEL</b> CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of the CLIA ' s Laboratory Personnel Report (Form CMS-209), review of personnel qualification records, and interview with the Laboratory Director (LD) the laboratory failed to ensure that each individual performing Moderate Complexity testing 1 of 12 testing personnel is qualified. Refer to D6065.</p>
<b>D6065</b>	<p><b>TESTING PERSONNEL QUALIFICATIONS</b> CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology</p>

from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on review of the CLIA's laboratory Personnel Report (Form CMS-209), review of Personnel Qualification records, and interview with the Laboratory Director (LD), the laboratory failed to ensure that 1 of 12 performing moderate complexity testing from April, 2022 to August 11, 2022 is qualified. Findings include: 1. At the time of the survey (08/11/2022 at 09:50 am) the laboratory failed to provide the educational credential for 1 of 12 TP (CMS 209 personnel #2) who performed complete blood count (CBC) from april, 2022 to August 2022. 2. LD confirmed the findings above on 08/11/2022 at 11:40 am.