Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0890209	04/29/2024
Name of Provider or Supplier	**Street Address, City, State**	
Satish A Shah Md Laboratory	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of competency records and interview with the laboratory director (LD), the laboratory failed to establish and follow the competency of 11 of 12 testing personnel (TP) through internal blind testing or external proficiency testing (PT) samples for hematology testing performed from 08/11/2022 to the date of the survey. Findings include: 1. A review of the laboratory's competency evaluation policy revealed, the laboratory failed to include the following competency requirements- Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. 2. On the day of the survey, 04/29/2024 at 11:45 am, review of the laboratory's competency evaluation checklist revealed the TC failed to evaluate and document test performance of 11 of 12 testing personnel through internal blind sampling, external proficiency testing or previously analyzed samples for complete blood count testing performed from 08/11 /2022 to 04/29/2024. 3. TC #2 confirmed the finding above on 04/29/2024at 01:30 pm.
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, observation of the laboratory, and interview with the laboratory director (LD), the laboratory failed to monitor and document refrigerator and room temperatures to ensure operating conditions were met for the proper storage of hematology reagents and to ensure reliable test system operation of the Medonic M series analyzer from 8/11/2022 to the day of survey. Findings Include: 1. On the day of the survey, 04/29/2024 at 12:30 pm, review of 2 of 2 (07/2022, 08 /2023) months of laboratory's temperature logs revealed the laboratory failed to monitor and document refrigerator and room temperatures for weekends and holidays from 5/24/2022 to the day of survey. 2. During observation of the laboratory the surveyor discovered the following reagents to be stored in the laboratory. 1 of 1 Boule Con Diff quality control High- acceptable storage temperature: 2-10 degrees Celsius 1 of 1 Boule Con Diff quality control Normal- acceptable storage temperature: 2-10 degrees Celsius 1 of 1 Boule Con Diff quality control Low- acceptable storage temperature:2-10 degrees Celsius 2 of 2 Boule Con Diff Tri Level- acceptable storage temperature: 2-8 degrees Celsius. 1 of 1Medonic M Series Pack- acceptable storage temperature: 4-35 degrees Celsius. 3. The LD confirmed the findings above on 04/29 /2024 at 1:30 pm.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on observation of the laboratory, lack of records, and interview with the laboratory director (LD), the laboratory failed to provide documentation of maintenance activities that ensures equipment performance for 3 of 3 thermometers used for temperature monitoring in the laboratory from 08/11/2022 to the day of the survey. Findings include: 1. The laboratory's Maintenance Policy for Digital Thermometer stated, " Temperature and humidity on the primary thermometer should be verified against the secondary thermometer." 2. At the time of survey, 04/29/2024 at 12:30 pm, the laboratory failed to provide documentation of maintenance activities performed for following 3 of 3 thermometers from 08/11/2022 to the day of survey. BCR- refrigerator temperature ACU.RITE- room temperature and humidity THERMPRO- room temperature and humidity 3. The LD confirmed the findings above on 04/29/2024 at 01:30 pm.
D5805	TEST REPORT CFR(s): 493.1291(c)

	The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with the laboratory director (LD) the laboratory failed to include the location where hematology examinations were performed on the patient test report from 08/11/2022 to the day of survey. Findings include: 1. On the day of survey, 04/29/2024 at 11:30 am, review of 2 of 2 patient test report (07/18/2022 and 08/21/2023) revealed documentation of complete blood count test results that did not include the address of where the tests were performed from 08 /11/2022 to 04/29/2024. 2. The LD confirmed the above findings on 04/29/2024 at 01: 30 pm.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on observation of the laboratory, review of laboratory records, and interview with the laboratory director (LD), the LD failed to provide overall management and direction of the laboratory in accordance with 493.1407 for a moderate complexity laboratory from 08/11/2022 to 04/29/2024. Refer to 6004 and 6022.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on lack of personnel competency records and interview with the laboratory director (LD), the LD failed to evaluate the annual competency of 11 of 12 testing personnel (TP) who performed Hematology testing in 2023. Findings include: 1. According to the laboratory's competency evaluation policy, "evaluations will be

	performed annually for each laboratory tests a person performs." 2. On the day of survey 04/29/2024 at 11:50 am, review of the laboratory's personnel competency records revealed, the TC failed to evaluate the annual competency of 11 of 12 TP who performed complete blood count testing on the Medonic M series hematology analyzer in 2023. 3. The LD confirmed the findings above on 04/29/2024 at 01:30 pm.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and interview with the laboratory director (LD), the LD failed to ensure that quality control (QC) programs are established and maintained to identify failures as they occur for 4 of 10 analytes on 04 /26/2024 for the Medonic M series analyzer used to perform hematology testing from 08/11/2022 to 04/29/2024. Findings Included: 1. On the day of survey, 04/29/2024 at 01:01 pm, review of laboratory's QC records revealed that the following 4 of 10 hematology analytes failed to meet the laboratory's established acceptable QC criteria for the Medonic M series analyzer on 4/26/2024. - White Blood Cell High QC result 22.6 acceptable ranges 18.7-22.3 - Red Blood Cell High QC result 5.56 acceptable ranges 4.82-5.26 - Hemoglobin High QC result 17.4 acceptable ranges- 15.5-16.5 - Hematocrit High QC result 50.6 acceptable ranges- 42.9-49.9 2. The laboratory could not provide documentation of the corrective actions taken for QC performed on the Medonic M-series that did not meet the laboratory's established acceptable criteria on 04/26/2024. 3. The laboratory failed to provide a corrective action procedure for control results fail to meet the laboratory's established performance specifications. 4. The LD confirmed the findings above on 04/29/2024 at 01:30 pm.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of personnel qualification records and interview with the laboratory director (LD), the laboratory failed to ensure that 1 of 1 technical consultant (TC) met the minimum qualification requirements (493.1411) for moderate complexity hematology testing from 11/11/2022 to the date of survey. Refer to D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license

	issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on review of the CLIA laboratory personnel report (CMS 209), personnel credentials, quality control (QC) records, calibration verification records, and interview with the laboratory director (LD), the laboratory failed to ensure that the technical consultant (TC) who performed TC responsibilities for moderate complexity laboratory met the minimum requirements of 493.1489 from 08/11/2022 to 04/29 /2024. Findings Include: 1. On the day of the survey, 04/29/2024, review of personnel qualification records revealed the TC (CMS 209 testing personnel #2) did not meet the minimum qualifications to perform moderate complexity testing (493.1489) in Hematology from 08/11/2022 to 04/29/2024. 2. The laboratory provided the following personnel credentials for TP #2: - High School Diploma from Winters Hill High School graduation date- June, 2012. 3. A review of QC and calibration verification records revealed the TC reviewed QC and calibration verification records from 08/11 /2022 to 04/29/2024. 4. The LD confirmed the findings above on 04/29/2024 at 12:30 pm.