Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2044746	07/26/2024
Name of Provider or Supplier	**Street Address, City, State**	
Satish A Shah Md Laboratory-Hanover Cancer Ctr	195 Stock St, Suite 304, Hanover, 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
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on document review and interview with the laboratory director (LD) and testing personnel #1 (CMS 209 #1), the laboratory failed to provide a procedure manual, quality control documentation and manufacturer function tests for the Contour glucometer from 11/02/2022 to the day of survey. Findings include: 1. On the day of survey, 07/27/2024 the laboratory failed to provide a manufacturer provided instruction manual for the Contour glucometer. 2. The Contour glucometer instruction manual states: "You should perform a control test when: - Using your meter for the first time. - You open a new bottle or package of test strips. - You think your meter may not be working properly. - You have repeated, unexpected blood glucose results. 3. The laboratory failed to provide documentation of QC for Contour glucometer from 11/01/2022 to the day of survey. 4. The Contour glucometer instruction manual states: "Clean and disinfect your meter once a week." 5. The laboratory failed to provide documentation of manufacturer required function tests for the Contour glucometer from 11/02/2022 to the day of survey. 6. The LD confirmed the above findings on 7/27 /2024 at 2:45 pm.
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 lack of documentation and interview with the Laboratory Director (LD), the laboratory failed to establish and maintain a procedure to assess the competency of the laboratory's Technical Consultant (TC) for their supervisory responsibilities performed in 2024. Findings include: 1. On the day of survey, 07/26/2024, the laboratory failed to provide a written policy that reviews how to assess the competency of the laboratory supervisors for their regulatory responsibilities in 2024. 2. The LD confirmed the findings above on 07/26/2024 at 10:54 am.
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure and manufacturer's operator manuals, and interviews with the laboratory director (LD) and testing personnel #1 (TP), the laboratory failed to have a complete written procedure manual for hematology testing performed that met the requirements of 493.1251 from 11/02/2022 to the day of the survey. Findings include: 1. On the day of the survey, 07/26/2024 at 12:00 pm, review of the laboratory's procedure manuals revealed the operators manual were used to perform testing on the following from 11/02/2022 to day of survey: - CBC on the CDS Medonic M-Series.. 2. Review of the operators manual revealed that the test system instructions used failed to include the following requirements: - Step by step performance of the procedure including test calculations and interpretation of results. - Control procedures. - Corrective action to take when calibrations or control results fail to meet the laboratory criteria for acceptability. - 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. - Reference intervals (normal values). -The reportable range for test results for the test system as established or verified. 3. The LD confirmed the findings on 7/26/2022 at 2: 00 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 11/02/2022 to the day of survey. Findings Include: 1. On the day of the survey, 07/26/2024 at 1:30 pm, review the laboratory's temperature logs from January 2023 to July 2024 revealed that the laboratory failed to monitor and document refrigerator and room temperatures for weekends and holidays from 11/02/2022 to the day of survey. 2. During observation of the laboratory the surveyor discovered the following reagents to be stored in the laboratory. - Boule Con Diff quality control High- acceptable storage temperature: 2-10 degrees Celsius - Boule Con Diff quality control Normal- acceptable storage temperature: 2-10 degrees Celsius - Boule Con Diff quality control Low- acceptable storage temperature:2-10 degrees Celsius - Boule Con Diff Tri Level- acceptable storage temperature: 2-8 degrees Celsius. - Medonic M Series Pack- acceptable storage temperature: 4-35 degrees Celsius. 3. The LD confirmed the findings above on 7/26/2024 at 2:30 pm.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and interview with the laboratory director (LD), and testing personnel (CMS 209 TP #1)the LD failed to ensure that quality control (QC) programs are established and maintained to identify failures as they occur for 1 of 10 analytes on 07/26/2024 for the Medonic M series analyzer used to perform hematology testing from 11/02/2022 to day of survey. Findings Included: 1. On the day of survey, 07/26/2024 at 1:30 pm, review of laboratory's QC records revealed that the following 1 of 10 hematology analytes failed to meet the laboratory's established acceptable QC criteria for the Medonic M series analyzer on 07/26/2024. - Platelet result 96. Normal ranges for low control: 65 to 95. 2. The laboratory failed to document the corrective actions taken for QC performed on the Medonic M-series that did not meet the laboratory's established acceptable criteria on 07/26/2024. 3. The LD confirmed the findings above on 07/26/2024 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. Refer to D6018, D6022, D6029, and D6031.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; 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 Laboratory Director (LD), the laboratory director failed to ensure that the approved corrective action established for incorrect PT results was followed for 1 of 1 failed analytes in 2024. Finding include: 1. On the day of survey, 07/26/2024 at 10:30 am, review of the API PT records revealed that the laboratory received a 0 % score for RDW-CV for the 2024 Hematology/Coagulation - 1st Event. 2. The API Proficiency Testing Performance Evaluation states "laboratories should review the Performance Summary and Comparative Evaluation thoroughly for failures or 'not graded' analytes. Laboratories are responsible for documenting and performing corrective action for failures and must perform a self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded." 3. The laboratory's corrective action for the failed event failed to evaluate whether patients were affected. 4. LD confirmed the findings above on 07/26/2024 around 10:30 am.
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 the Medonic calibration records and interview with the Laboratory Director (LD) and testing personnel (CMS-209 TP #1), the laboratory director failed to review the calibration records and quality records for the Medonic series. Findings include: 1. The laboratory's Laboratory Director "Duties and Responsibilities" procedure states "the Laboratory Director must ensure that quality control and quality assurance programs are established and maintained, and remedial actions are taken (and documented) when tests/tasks are not perform to specifications." 2. On the date

	of the survey, 07/26/2024 at 1:00 pm, the laboratory failed to provide documentation of LD reviewed calibrations or quality control records. 3. The LD confirmed the above findings on 07/26/2024 at 1:00 pm.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of testing personnel records, lack of documentation, and interview with the Laboratory Director (LD) the LD failed to ensure testing personnel (TP) received the appropriate training for performing complete blood cell counts (CBC) examinations prior to testing patient specimens from 11/02/2022 to the day of the survey. Findings include: 1. On the day of survey, 07/26/2024, the laboratory failed to provide training records for 2 of 15 TP, (CMS 209 TP #14, and #15), performing CBC intepretation of results and result verification. 2. The LD confirmed the finding above on 07/26/2024 at 2:30 pm.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on laboratory procedure review and interviews with the laboratory director (LD), and testing personnel #1 (TP), the LD failed to ensure that the procedure manual in use was approved. Findings include: 1. On the day of the survey, 07/26 /2024 at 12:00 pm, the laboratory provided a the manuafucturer provided instruction manual for the CDS-Medonic series. 2. The laboratory failed to provide documentation that the manufacturer provided instruction manual was approved for use as the procedural manual. 3. LD confirmed the findings on 07/26/2024 around 2: 30 PM.
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 competency assessment records and interview with Laboratory Director (LD), the Technical Consultant (TC) failed to evaluate the test performance of 6 of 15 testing personnel (TP) through internal blind testing samples or external Proficiency Testing (PT) samples for Complete Blood Count (CBC) assay examinations for 2023 and 2024. . Findings Include: 1. On the day of survey, 07/26 /2024 at 11:00 AM, review of the competency assessment records revealed, the laboratory failed to evaluate the following 6 of 15 testing personnel with assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples in 2023 and 2024: - 2024 CMS 209 TP #4 and TP #5 - 2023 CMS 209 TP #1, TP #2, TP #3 and TP #9 2. The LD confirmed the findings above on 07/26/2024 around 11:00 am.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on lack of competency assessment (CA) records and interviews with the laboratory director (LD) and testing personnel #1 (TP), the technical consultant (TC) failed to assess the annual competency of 2 of 15 TP for hematology examinations performed in 2023. Finding Include: 1. On the day of the survey, 07/27/2024 at 10:00 am, the laboratory failed to provide CA records for 2 of 15 TP (CMS 209 personnel #4, and #5) that performed complete blood cell counts on the CDS Medonic series hematology analyzer in 2023. 2. The laboratory performed 10,167 Hematology examinations in 2023 (CMS 116 estimated annual volume). 3. The LD confirmed the findings above on 07/27/204 at 02:30 pm.