

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2044746	(X3) Date Survey Completed 06/25/2026
Name of Provider or Supplier Satish A Shah Md Laboratory-Hanover Cancer Ctr	Street Address, City, State 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
D0000	A recertification survey was conducted by the Pennsylvania State Agency at Chesapeake Uro Asc LLC on 06/25/2026. The laboratory was found out of compliance with the following conditions: 493.1100 Condition: Facility administration 493.1250 Condition: Analytic systems 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). This CONDITION is not met as evidenced by: Based on record review and interview with the Laboratory Supervisor (LS), the laboratory failed to comply with the state of Pennsylvania code Chapter 5.22 for Responsibilities of owner and director, as required under 493.1101 for 2 of 2 years from 07/26/2024 to 06/25/2026. Refer to D3009.
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 record review, lack of documentation, and interview with the Laboratory

	Supervisor (LS), the laboratory failed to provide documentation of quality control (QC) and maintenance for 1 of 1 Contour glucometer from 07/26/2024 to 06/25/2026. Findings include: 1. The Contour glucometer instruction manual stated: "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." 2. Further review of the Contour glucometer instruction manual revealed, "Clean and disinfect your meter once a week." 3. On the day of survey, 06/25/2026 at 11:30 am, the laboratory failed to provide documentation of QC and maintenance performed for 1 of 1 Contour glucometer (S/N F993117) from 07/26/2024 to 06/25/2026. 4. The LS confirmed the above findings on 06/25/2026 at 12:45 pm. ***Repeat deficiency***
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of temperature records, observation of the laboratory, and interview with the Laboratory Supervisor (LS), the laboratory failed to monitor and document refrigerator and room temperatures as required under 493.1252 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 on weekends and holidays for 23 of 23 months from 07/26/2024 to 06/25/2026. Refer to D5413.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 Supervisor (LS), the laboratory failed to monitor and document refrigerator and room temperatures to ensure operating conditions were met for the proper storage of hematology reagents on weekends and holidays for 23 of 23 months from 07/26/2024 to 06/25/2026. Findings Include: 1. On the day of the survey, 06/25/2026 at 11:00 am, review the laboratory's temperature logs from revealed that the laboratory failed to monitor and document refrigerator and room temperatures on weekends and holidays for 23 of 23 months from 07/26/2024 to 06/25/2026. 2. During

	observation of the laboratory the surveyor discovered the following reagents stored in the laboratory: - Boule Con Diff quality control High- manufacturer's recommended storage temperature: 2-10 degrees Celsius - Boule Con Diff quality control Normal- manufacturer's recommended storage temperature: 2-10 degrees Celsius - Boule Con Diff quality control Low- manufacturer's recommended storage temperature: 2-10 degrees Celsius - Boule Enzymatic Cleaner- manufacturer's recommended storage temperature: 15-30 degrees Celsius 3. The LS confirmed the findings above on 06/25/2026 at 12:45 pm. ***Repeat deficiency***
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview with the Laboratory Supervisor (LS), the laboratory failed to establish and maintain a maintenance /function check policy to ensure equipment used in the laboratory for patient testing provided accurate and reliable test results for 2 of 2 years from 07/26/2024 to 06/25/2026. Findings include: 1. On the day of survey, 06/25/2026 at 12:25 pm, review of laboratory procedures revealed the laboratory failed to establish a policy for maintenance/function checks performed for equipment used in the laboratory for patient testing for 2 of 2 years from 07/26/2024 to 06/25/2026. 2. The laboratory failed to provide maintenance/function check records for the following 1 of 1 thermometer and 2 of 2 thermometer/hygrometers used to monitor reagent storage: - Durac thermometer - ThermPro thermometer/hygrometer - Meade Instruments thermometer/hygrometer 3. The LS confirmed the findings above on 06/25/2026 at 12:45 pm.
D6033	TECHNICAL CONSULTANT-MODERATE COMPLEXITY 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 record review and interview with the Laboratory Supervisor (LS), the Technical Consultant (TC) failed to provide technical oversight in accordance with 493.1413 for 2 of 2 years from 07/26/2024 to 06/25/2026. Refer to 6054.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually

	This STANDARD is not met as evidenced by: Based on policy and record review, lack of documentation, and interview with the Laboratory Supervisor (LS), the Technical Consultant (TC) failed to assess the annual competency of 7 of 12 Testing Personnel (TP) for hematology examinations performed in 2025. Findings Include: 1. The laboratory's CLIA Quality Management Policy stated, "Competency Evaluations: 1) Employees responsible for nonwaived testing in Satish A. Shah Laboratory will not perform testing until they have been certified by the laboratory director as being competent to perform testing. 2) Competency will be evaluated at least semiannually during the first year the employee tests patient specimens. 2a)Thereafter, evaluations will be performed every six (6) for each laboratory test a person performs." 2. On the day of survey, 06/25/2026 at 10:10 am, the laboratory failed to provide competency assessment records for 7 of 12 TP (CMS 209, TP#1, TP#2, TP#3, TP#4, TP#7, TP#8, TP#10, dated 06/24/2026), who performed complete blood count (CBC) examinations in 2025. 3. The laboratory performed 30,228 Hematology examinations in 2025 (CMS 116 estimated volume, dated 06/24/2026). 4. The LS confirmed the finding above on 06/25/2026 at 12:45pm. ***Repeat deficiency***
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 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. This CONDITION is not met as evidenced by: Based on review of personnel qualification records and interview with the Laboratory Supervisor (LS), the laboratory failed to ensure 1 of 12 TP (CMS 209, personnel #11, dated 06/24/2026) met the minimum educational requirements under 493.1423 to perform moderate complexity testing from 03/23/2026 to 06/25/2026. Refer to D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (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 (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of personnel qualification records and interview with the Laboratory

Supervisor (LS), the laboratory failed to ensure that 1 of 12 testing personnel (TP) met the minimum educational requirements to perform moderate complexity testing from 03/23/2026 to 06/25/2026. Findings Include: 1. On the day of survey, 06/25/2026 at 10:10 am, the laboratory failed to provide documentation for the equivalency evaluation performed for education obtained from a foreign institution for 1 of 12 TP (CMS 209 personnel #11, dated 06/24/2026) who performed moderate complexity (hematology) examinations from 03/23/2026 to 06/25/2026. 2. The LS confirmed the findings above on 06/25/2026 at 12:45 pm.