Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0210550	09/11/2025
Name of Provider or Supplier	**Street Address, City, State**	
Medstar Shah Medical Group Waldorf	10 St Patrick Dr Advance Access 1st Floor, Waldorf, MD	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the technical consultant (TC #1), the laboratory failed to ensure that the individual testing or examining the samples (TP) and the laboratory director (LD) or TC signed the PT attestation statements, attesting that PT specimens were run in the same manner as patient samples. Findings: 1. The laboratory had five TP listed on the "Laboratory Personnel Report" (CMS-209). Two TP performed hematology testing and three TP performed chemistry testing. 2. A review of hematology PT records from 2024 and 2025 showed that on five out of five attestation statements it appeared that the TP's names under the column "Analyst Performing Procedure" as well as the name of the LD in the spot labeled, "Director" were written in the same handwriting; and 3. A review of chemistry PT records from 2024 and 2025 showed that on four out of five attestation statements the names of the TP and the LD were typed onto the page and not signed. The second event of 2024 ("AQ-B 2024") was not available for review at the time of the survey. 4. During an interview on 09/11/2025 at 3:00 PM, TC #1 stated that they had written or typed the names of the TP and LD on the attestation statements and confirmed that the TP and LD had not personally attested to the routine integration of the PT samples into the patient workload using the laboratory's routine methods.
D3011	FACILITIES CFR(s): 493.1101(d)

	Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on surveyor observation and interview with laboratory staff and the technical consultant (TC #1), the laboratory did not ensure that an eye wash station was located in the laboratory area where testing occurs. Findings: 1. During a tour of the laboratory at 9:32 AM, it was observed that there was no eye wash station available in the laboratory where laboratory testing is performed. During an interview, laboratory staff stated that the eye wash station was located in another part of the office where they prepare chemotherapy medications. 2. During an interview on 09/11/2025 at 12: 30 PM, TC #1 confirmed that the eye wash station was not located in the room where laboratory testing is performed.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: I. Based on procedure manual review and interview with the testing personnel (TP) and the technical consultant (TC #1), the laboratory failed to follow manufacturer's instructions when running quality control (QC) and quality assurance (QA) on the "epoc Blood Analysis System" (epoc). Findings: 1. The laboratory performs blood urea nitrogen (BUN) and creatinine (creat) testing on the epoc and runs two levels of QC ("Eurotrol GAS-ISE Metabolites" "Level 1" and "Level 3") each day of patient testing. The QC is packaged in sealed, single-use glass ampules. 2. The procedure, "Epoc - BUN/Creat and Blood Gas Testing - Moderate" "Quality control fluids" stated that "if ampoules are taken from cool storage, equilibrate the ampoules to Room Temperature (20-25C). Equilibration time" is "one (1) hour for single ampoules outside of the box"; and 3. The "Sample Introduction" section of the procedure stated to "Immediately before use, shake the ampoule vigorously for at least fifteen seconds to re-equilibrate gasses with the solution." 4. During an interview on 09/11/2025 at 11: 00 AM, the TP stated that they allow the refrigerated ampules of QC material to sit at room temperature for 30 minutes (not one hour) and that they do not mix the ampules before testing the QC on the epoc. 5. According to the "Verification of Reader Performance" section of the procedure, "The epoc Reader contains a thermal control subsystem consisting of two (2) heater blocks each with an embedded factory calibrated precision chip-based temperature sensor." The procedure states that "Thermal QA should be performed twice a year for each Reader." 6. During an interview at 11:00 AM, TC #1 stated that the laboratory did not perform "Thermal QA" testing on the epoc twice a year as recommended by the manufacturer and confirmed that the laboratory failed to follow the manufacturer's instructions for how to perform QC and QA on the epoc. II. Based on procedure manual and quality control (QC) and patient log record review and interview with the technical consultant (TC #1), the laboratory failed to follow manufacturer's instructions for validating new

	lot numbers and shipments of test cards used for testing blood urea nitrogen (BUN) and creatinine (creat) with the "epoc Blood Analysis System" (epoc). Findings: 1. The laboratory runs two levels of QC on the epoc ("Eurotrol GAS-ISE Metabolites - Level 1" and "Eurotrol GAS-ISE Metabolites - Level 3") each day of patient testing. The printed QC results include the "Card lot" number of the test cards used to run the QC and are affixed to the "EPOC - QC testing Log" (QC log). 2. The procedure, "Epoc - BUN/Creat and Blood Gas Testing - Moderate" "Quality Control" "Verification of Newly Received Test Cards" states, "From each lot in each shipment of cards, analyze at least two (2) levels of fluid controls in duplicate using any verified Reader." 3. A review of QC and patient results logs from March through May 2024 showed that QC was run on a new lot number of test cards on 03/15/2024 (lot number 04-23352-20), however it was not run in duplicate to validate the new lot number per the manufacturer's instructions. This lot number of test cards was used to test a total of three patients on three days of testing (03/25/2024, 04/05/2024, and 04/09/2024); and 4. The laboratory ran QC on the next new lot number of test cards on 04/19/2024 (lot number 08-24042-20). The QC was not run in duplicate to validate the new lot number per the manufacturer's instructions. This lot number of test cards was used to test a total of 13 patients on nine days of testing between 04/17/2024 and 05/29/2024. 5. QC record review showed that the laboratory performed QC on 04/17/2024 using card lot number 04-23352-20, however they tested two patients on 04/17/2024 using a new lot number of test cards (card lot number 08-24042-20). The laboratory did not run QC on the new lot number of test cards until 04/19/2024. 6. During an interview on 09/11/2025 at 3:00 PM TC #1 confirmed that the laboratory failed to follow the manufacturer's instructions to validate all new lot numbers of test cards before being used for patient testing.
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 procedure manual and record review, and interview with the technical consultant (TC #1), the laboratory failed to define, monitor, and document laboratory room temperature and humidity where testing was performed and reagents were stored for the "epoc Blood Analysis System" (epoc) to ensure proper reagent storage and reliable test system operation. Findings: 1. The laboratory performs blood urea nitrogen (BUN) and creatinine (creat) testing on the epoc. 2. The "Epoc - BUN/Creat and Blood Gas Testing - Moderate" procedure stated that the "epoc Test Cards should be stored at room temperature (15-30 C) and that the "epoc Reader...must be used in relative humidity of less than 85% at 30 C, non condensing." 3. Record review showed that there were no temperature or humidity logs available for review at the time of the survey, documenting the temperature and humidity of the room where the epoc was used and where the test cards were stored. 4. During an interview on 09/11 /2025 at 11:15 AM TC #1 confirmed that there were no temperature and humidity

	logs and stated that the laboratory did not document the room temperature and humidity in the room where the epoc was operated and where test cards were stored.