Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0926884	09/20/2021
Name of Provider or Supplier	**Street Address, City, State**	
Medstar Shah Medical Group Philip J Bean Med Ctr	24035 Three Notch Road, Hollywood, 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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) records and interview with the technical consultant (TC), the laboratory failed to record the PT sample results on the patient log in the same manner as the patient specimens. Findings: 1. The PT records from 2019 through 2021 were reviewed for a total of 8 events. 2. The manual PT testing results were recorded on a blank piece of paper used as a worksheet. The results of the PT specimens were recorded with the PT sample identification number along with the positive or negative results. The worksheet did not include the date of testing for the PT results recorded. 3. During the survey on 9/20/2021 at 2:00 PM TC #1 confirmed that the PT samples were not being recorded on the patient worksheet logs in the same manner as the patient specimens.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples.

	This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) records and interview with the technical consultant (TC), the laboratory did not test the coagulation PT samples the same number of times as the patient samples were tested. Findings: 1. The PT records from the 2020 through 2021 for a total of five events were reviewed. 2. The records showed that each of the coagulation PT samples were tested twice during each of the five events reviewed. 3. During the survey on 9/20/2021 at 2:00 PM, TC #1 confirmed that the coagulation PT samples had been tested twice for comparison and that the patient samples were only tested once.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) 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. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of maintenance logs, standard operating procedure (SOP), and interview with the technical consultant (TC), the laboratory's procedure manual failed to include written instructions for performing and documenting the monthly bacteria quality control (QC) check for the Millipore water purification system. Findings: 1. The Millipore maintenance worksheets from January 2020 through September 2021 were reviewed. 2. The Millipore maintenance worksheet requires the laboratory to perform and document a monthly bacteria QC check. The records showed the date the colony count was documented and who performed the test. 3. TC #2 confirmed that the SOP failed to include written instructions for how the laboratory collects the water sample, and tests and documents the results of the monthly bacteria QC check. 4. During the exit conference on 9/20/2021 at 3:50 PM TC #2 confirmed that the SOP failed to include written instructions for performing and documenting the monthly bacteria QC check for the Millipore water purification system.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: Based on procedure manual, laboratory reagent package insert, and patient log record review and interview with the technical consultant (TC) and laboratory director (LD), the laboratory did not follow the manufacturer's instructions for performing bacteriology testing. Findings: 1. The laboratory is performing presumptive identification of group A streptococcus on throat cultures, using Taxo A discs which are impregnated with low levels of Bacitracin. 2. During an interview at 10:15 AM on the day of the survey, TC #1 stated that the laboratory evaluates the culture plates at 24 and 48 hours after inoculation. This was confirmed with a review of the "Work In Progress Log" (patient log) from 9/14/2021. 3. The laboratory's "Throat Culture - Selective Strep Agar" procedure states, "All the smaples must be read within 24 to priliminary and 48 - 72 for the final reading." 4. Review of the package insert for the "BD BBL Taxo A Discs" showed that culture plates must be incubated "at 35 to 37 degrees C for 18 to 24 hours" before being read or interpreted. 5. During an interview on 9/20/2021 at 3:45 PM the LD confirmed that the laboratory did not follow the manufacturer's instructions for performing throat cultures.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on procedure manual, test kit manufacturer's instructions, and quality control (QC) record review and interview with the technical consultants (TC) and the laboratory director (LD), the laboratory did not run 2 levels of QC each day of patient testing and failed to establish an Individualized Quality Control Plan (IQCP) for performing serum pregnancy (HCG) and mononucleosis (mono) testing. Findings: 1. The laboratory performs urine and serum HCG testing using the "Henry Schein One Step + HCG Combo" testing kit. The test complexity is classified as waived when using urine as a specimen source and as moderate when using serum; and 2. The laboratory performs mono testing using the "Henry Schein One Step + Mononucleosis Rapid Test Device" testing kit. The test complexity is classified as waived when using whole blood as a specimen source and as moderate when using serum. 3. During an interview at 10:45 AM on the day of the survey, TC #1 stated that the laboratory uses both whole blood and serum to perform mono testing, and that external QC is performed monthly on the HCG and mono kits. This was confirmed with a review of QC logs from January to December, 2020. 4. At 12:30 PM TC #2 stated that they did not have an IQCP in place to reduce the amount of QC required when performing testing using the HCG and mono test kits. 5. During an interview on 9/20/2021 at 3:45 PM, the LD confirmed that the laboratory did not have an IQCP in place to reduce the

	amount of QC required when performing moderate complexity testing using the laboratory's HCG and mono testing kits.
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 record review and interview with technical consultant (TC) #1 and #2, TC #2 failed to evaluate the performance of TC #1 as a testing person (TP) performing moderate complexity testing. Findings: 1. Review of TC #1's personnel file determined that an evaluation of TC #1's competency as a TC had been performed annually. 2. TC #1 was also a TP performing moderate complexity testing. There was no documentation of annual competency evaluations for TC #1 as a TP performing moderate complexity testing. 3. During the exit interview on 9/20/2021 at 4:00 PM, TC #1 and TC #2 confirmed that annual competency evaluations of TC #1 as a TP performing moderate complexity testing were not being performed.