Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0926884	02/14/2019
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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of the microbiology, hematology, and chemistry proficiency testing (PT) records and interview with the laboratory supervisor, the laboratory did not ensure that the PT records identified which testing person performed the tests in each discipline. Findings: 1. The PT records from 2017 and 2018 (6 events) were reviewed. 2. Each event included PT samples for the disciplines of microbiology, hematology, and chemistry. 3. The attestation worksheet for each event included the initials of 2-3 testing personnel. The worksheet failed to identify which specialty each of the testing personnel performed. 4. During the survey on 02/14/2019 at 2:45 PM the laboratory supervisor confirmed that the PT worksheets did not identify who performed the PT tests for each of the disciplines of microbiology, hematology, and chemistry.
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 observation in the combined Microbiology/Coagulation laboratory and interview with the laboratory supervisor, the laboratory did not have an eyewash in the Microbiology/Coagulation laboratory where testing was being performed. Findings: 1. The laboratory is required to implement safety policies and procedures to ensure safety in the testing personnel. The Occupational Safety and Health Administration (OSHA) and Environmental Protection Agency (EPA) provide guidelines for laboratory safety. 2. The area where the laboratory was performing microbiology and coagulation testing was toured during the survey. Observation of the room showed that there was no eyewash attached to the sink to aid in flushing out the eyes of the testing personnel if they were to have been splashed with any chemicals or specimens during testing. 3. During the survey on 02/14/2018 at 2:45 PM the laboratory supervisor confirmed that there was no eyewash station in the microbiology and coagulation laboratory where testing was being performed.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the hematology patient summary records and interview with the laboratory supervisor, the laboratory did not ensure that post analytic system records, e.g., patient reports/results were maintained for at least 2 years. Findings: 1. Review of the hematology patient summary records showed that when an abnormal or critical value was repeated for verification the original result was overridden with the new result. The original and repeated results were not within the hematology analyzer system or the computer system. 2. During the exit interview at 2:45 PM the testing person confirmed that the laboratory's hematology analyzer and computer system did not maintain original results after an abnormal or critical value was repeated for confirmation.
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 the standard operating procedure manual (SOPM) and interview with the technical consultant (TC), the laboratory failed to update the "QC & Equipment Function Testing Policy" to reflect the actual practice of the laboratory. Findings: 1. The laboratory performs lot to lot testing of hematology quality control (QC) before using the new lot number of QC. The section, "Reagent Testing" of the "QC & Equipment Function Testing Policy" in the SOPM states that "All reagents used within the laboratory are checked for proper reactivity prior to being placed into use. A lot of reagent being placed into use has been checked against the prior lot or quality control." 2. During an interview at 2:00 PM on the day of the survey, the TC stated that they "run the new and old lot number of complete blood count (CBC) controls to verify that the new lot is within parameters before using" and that they run the old and the new lot numbers 3 times each. The SOPM did not include a procedure for how to perform the lot to lot comparison; and 3. In the section, "Calibration," "Hematology and Coagulation," the procedure states that calibration is performed "quarterly" on the Pentra XL 80. During an interview at 2:00 PM on the day of the survey, the TC stated that the CBC analyzer is calibrated every 6 months. Record review showed that the analyzer was calibrated twice a year. 4. During an interview on 2/14/19 at 2:50 PM, the TC confirmed that the "QC & Equipment Function Testing Policy" in the SOPM was not updated to reflect the current practice of the laboratory.
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: I. Based on standard operating procedure manual (SOPM) and quality control (QC) record review and interview with the technical consultant (TC), the laboratory did not ensure that all corrective actions were documented when hematology QC was unacceptable. Findings: 1. The laboratory utilizes the Horiba ABX Pentra XL 80 hematology analyzer to perform hematology testing. 2. SOPM review showed that the procedure, "Handling Out of Range QC values" states that if QC fails that testing personnel should "record QC outlier on 'Redial Action Log' or 'Laboratory Daily Checklist'" and that "All the corrective actions must be followed and documented in 'Redial Action Log' or 'Laboratory Daily Checklist.'" 3. According to the TC, all out of range QC results are documented on the "Remedial Action Out of QC Log Form." QC record review showed that on 9/19/17 the white blood count was out of range

	(high) at 2.9 (acceptable range 2.0 - 2.8). The repeat QC was in range at 2.7. A review of the "Remedial Action Out of QC Log Form" from September, 2017 showed that on 9/19/17 the testing person wrote "QC-Low" and "Reran OK." The testing person did not document which analyte was out of range on the form; and 4. On 9/22/17 the hemoglobin was out of range (low) at 13.3 (acceptable range 13.3 - 14.3). The repeat QC was in range at 13.5. A review of the "Remedial Action Out of QC Log Form" from September, 2017 showed that on 9/22/17 the testing person wrote "QC Normal QC" and "Reran OK." The testing person did not document which analyte was out of range on the form. 5. During an interview on 2/14/19 at 2:50 PM, the TC confirmed that corrective action had not been documented when hematology QC was out of range. II. Based on standard operating procedure manual (SOPM) and quality control (QC) record review and interview with the technical consultant (TC), the laboratory did not ensure that all corrective actions were documented when chemistry QC was unacceptable. Findings: 1. The laboratory utilizes the Siemens Dimension EXL chemistry analyzer to perform chemistry testing. 2. SOPM review showed that the procedure, "Handling Out of Range QC values" states that if QC fails that testing personnel should "record QC outlier on 'Redial Action Log' or 'Laboratory Daily Checklist'" and that "All the corrective actions must be followed and documented in 'Redial Action Log' or 'Laboratory Daily Checklist.'" 3. According to the TC, all out of range QC results are documented on the "Remedial Action Out of QC Log Form." QC record review showed that on 5/10/18 the carbon dioxide (CO2) was out of range (high) at 43.4 (acceptable range 21.8 - 31.8) and the total bilirubin (Tbil) was out of range (low) at 5.70 (acceptable range 6.00 - 8.00). Review of instrument print outs showed that the control was rerun twice before the CO2 was acceptable at 26.8 and the Tbil was acceptable at 6.51. 4. A review of the "Remedial Action Out of QC Log Form" from May, 2018 showed that on 5/10/18 the testing person wrote, "QC L2 TBI Low, ECO High" and "Reran OK." The testing person did not document corrective actions taken before the QC was acceptable. 5. During an interview on 2/14/19 at 1:15 PM the testing person stated that they "don't write down everything" and at 2:50 PM, the TC confirmed that corrective action had not been documented when chemistry QC was out of range.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: I. Based on review of the "Quality Assurance & Performance Improvement Plan", quality assurance (QA) records and interview with the laboratory supervisor, the laboratory director did not ensure that the "Laboratory Weekly Checklist" was completed each week. Findings: 1. The "Laboratory Weekly Checklist" is used on Mondays to document calibration needs, reagent supply status, review of the Levey Jennings quality control reports for all moderate complexity and waived tests performed in the laboratory, maintenance records and completion of pending corrective actions resolutions. 2. Random review of the daily and weekly QA records showed that for the month of May 2017 the weekly review was only performed once;

	in July and August 2017 the weekly review was performed three times; in October 2017 the weekly review was only performed twice; and in December 2018 the weekly review was performed three times. 3. During the survey on 02/14/2018 at 2:45 PM the laboratory supervisor confirmed that the weekly checklist was not being used each week to ensure that the laboratory QA was being performed and document. II. Based on review of the "Protime/INR-MLA Electra 800" coagulation procedure manual, the "PT/INR Lot Comparison" summary worksheets and interview with the laboratory supervisor, the laboratory director did not ensure that lot to lot comparison was being performed per the instructions in the procedure manual and that the lot to lot quality control (QC) comparison was part of the "PT/INR Lot Comparison" summary report. Findings: 1. The "PT/INR Lot Comparison" summaries from 04/13/17, 08/13/18 and 01/07/19 were reviewed. The summary from 04/13/17 showed that 15 normal patients were tested to determine the new "Mean of Normal Patient" and the results of the QC materials used during the lot to lot comparison. The summary from 08/13/18 showed that 13 normal patients were tested to determine the new "Mean of Normal Patient" and there were no QC results listed on the summary. The summary from 01/07/19 showed that 15 normal patients were tested to determine the new "Mean of Normal Patient" and there were no QC results listed on the summary. 2. When interviewed the laboratory supervisor stated that the procedure required the use of 10 normal patient's to recalculate the "Mean of Normal Patient" for the new lot of thromboplastin. Review of the approved "Protime/INR-MLA Electra 800" coagulation procedure showed that 20 normal patients or more are required to recalculate the "Mean of Normal Patient" for the new lot of thromboplastin. 3. The procedure did not include an example of the worksheet that should be used to capture all the required information for the "PT/INR Lot Comparison" summary. 4. The "Test Procedure" section of the "Protime/INR-MLA Electra 800" coagulation procedure states that the laboratory is to "1. Pre-incubate the reconstituted PT-HS with the Calcium reagent to 37C for at least 10 minutes." The procedure did not identify what the abbreviation "PT-HS" represented. 5. During the survey on 02/14/2018 at 2:45 PM the laboratory supervisor confirmed that the "Protime/INR-MLA Electra 800" coagulation procedure was not being followed; the procedure did not include a standard "PT/INR Lot Comparison" summary worksheet to document the required information; and the abbreviation "PT-HS" had not been defined in the procedure.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the laboratory supervisor, the laboratory director did not specify in writing, the responsibilities and duties of each person engaged in the performance of the pre-analytic, analytic and

	post analytic phases of testing, that identifies which examination and procedure each individual is authorized to perform, and whether supervisory or director review is required prior to reporting patient test results. Findings: 1. According to the testing person that was interviewed the laboratory has two technical consultants. One is an on-site testing person/technical consultant and the other is a part-time technical consultant. 2. The procedure manual does not include written instructions that differentiate between the duties and responsibilities of the two technical consultants. 3. During the survey on 02/14/19 at 2:45 PM the testing person confirmed that the laboratory's procedure manual did not specify in writing the duties and responsibilities for each of the two technical consultants.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: I. The testing personnel did not document all quality control (QC) activities performed on the hematology and chemistry analyzers, including corrective actions performed when QC was out of range. Cross-refer to D5783. II. The testing personnel did no follow the "Protime/INR-MLA Electra 800" when performing lot to lot comparisons. Cross-refer to D6021.