Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0705851	01/09/2020
Name of Provider or Supplier	**Street Address, City, State**	
Medstar Shah Medical Group/ Greenbelt	7501 Greenway Center Dr Suite 500, Greenbelt, 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
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the hematology quality control (QC) procedure, interview with the technical consultant (TC), and the testing person (TP), the laboratory did not document all corrective action procedures when hematology QC did not meet the laboratory's criteria of acceptability. Findings: Refer to D6072 1. On June 28, 2019 the high QC was repeated 8 times. The reason for the numerous repeats was not documented. The QC was reviewed by the TC on 7/10/19. 2. The TP stated that service was contacted and a technician came onsite but a service report was not available the day of the survey and the TC was unaware that the technician was on site.
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services

	performed; This STANDARD is not met as evidenced by: Based on review of the hematology quality control (QC) procedure and interview with the technical consultant (TC), the TC failed to identify training needs when testing personnel did not followed QC procedures when hematology QC did not meet the laboratory's criteria of acceptability. Findings: Refer to D6072 1. The "Quality Control Procedure" states that when QC is unacceptable the testing person (TP) should rerun the patient sample with fresh controls. 2. If controls are still not within acceptable range the TP should troubleshoot the analyzer and the test method. 3. If after troubleshooting the QC is still unacceptable the TP should notify the laboratory director and patient samples should be sent to a reference lab. All corrective actions should be documented. 4. TP did not follow the written QC procedures when QC failed to meet the laboratory's criteria of acceptability. 5. The TC confirmed that TP did not follow the written QC procedure for unacceptable QC when performing hematology testing and retraining was not performed.
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: Based on review of the hematology quality control (QC) procedure, interview with the technical consultant (TC), and the testing person, testing personnel (TP) failed to follow QC procedures when hematology QC did not meet the laboratory's criteria of acceptability. Findings: 1. The "Quality Control Procedure" states that when QC is unacceptable the TP should rerun the patient sample with fresh controls. 2. If controls are still not within acceptable range the TP should troubleshoot the analyzer and the test method. 3. If after troubleshooting the QC is still unacceptable the TP should notify the laboratory director and patient samples should be sent to a reference lab. All corrective actions should be documented. 4. On January 11, 2019 the high QC was not within acceptable range for RBC'S and repeated 5 times. The repeat of patient samples with fresh controls was not documented. Troubleshooting the analyzer and the test method was not documented. The QC was reviewed by the TC on 2/1/19. 5. On January 28, 2019 the high control was not within acceptable range for platelets and repeated 5 times. The repeat of patient samples with fresh controls was not documented. The QC was reviewed by the TC on 2/1/19. 5. On January 30, 2019 the high QC was not within acceptable range for platelets and repeated 4 times. The repeat of patient samples with fresh controls was not documented. Troubleshooting the analyzer and the test method was not documented. The QC was reviewed by the TC on 2/1/19. 6. On January 31, 2019 the high QC was not within acceptable range for platelets and repeated 6 times. The repeat of patient samples with fresh controls was not documented. Troubleshooting the analyzer and the test method was not documented. The QC was reviewed by the TC on 2/1/19. 7. On February 5th and 6th 2019 the normal QC was not within acceptable range for RBS's and platelets. The QC was repeated 7 times on both days. The repeat of patient samples with fresh controls was not documented. The QC was reviewed by the TC on 3/3/19. 8. On May 31, 2019 the high QC was not within acceptable range and repeated 5 times. The repeat of

	patient samples with fresh controls was not documented. Troubleshooting the analyzer and the test method was not documented. The QC was reviewed by the TC on 6/10 /19. 9. On June 27, 2019 the normal QC was not within acceptable range for RBC'S and granulocytes and repeated 4 times. The high QC was not within acceptable range for RBC'S, WBC'S, platelets, hemoglobin, hematocrit, and granulocytes and repeated 9 times. The repeat of patient samples with fresh controls was not documented. The QC was reviewed by the TC on 7/10/19. 10. On June 28, 2019 the high QC was repeated 8 times. The reason for the numerous repeats was not documented. The QC was reviewed by the TC on 7/10/19. 11. The TC confirmed that TP did not follow the written QC procedure for unacceptable QC when performing hematology testing.