

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0705851	(X3) Date Survey Completed 02/07/2018
Name of Provider or Supplier Medstar Shah Medical Group/ Greenbelt	Street Address, City, State 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the technical consultant (TC), the laboratory did not ensure that all the testing personnel that tested patient samples performed the PT. Findings: 1. The laboratory currently has 4 testing personnel listed on the "Laboratory Personnel Report (CMS-209)." 2. A review of hematology PT attestation worksheets from 2016 and 2017 showed that PT was performed by the same testing person in 5 of 6 events. 3. During an interview on 2/7/18 at 12:45 PM, the TC confirmed that PT samples were not tested each year by all the staff that perform patient testing to ensure accurate and reliable patient test results.</p>
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the technical consultant (TC), the laboratory failed to ensure that the laboratory director (LD) signed PT attestation statements, attesting that PT specimens were run in the same way as patient samples. Findings: 1. A review of hematology PT records from 2016 to</p>

2017 showed that the LD did not sign the attestation statements for 6 out of 6 events.
2. During an interview on 2/7/18 at 12:45 PM, the TC confirmed that the attestation statements were not signed by the LD.

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:

I. Based on surveyor observation and interview with the laboratory staff, 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 11:05 AM, it was observed that there was no eye wash station available in the laboratory where laboratory testing is performed. 2. During an interview on 2/7/18 at 12:45 PM, the laboratory staff confirmed that the laboratory did not have an eye wash station in the laboratory. II. Based on standard operating procedure manual review (SOPM), surveyor observation, and interview with the technical consultant (TC), the laboratory did not ensure that testing personnel followed established laboratory safety procedures while performing laboratory testing. Findings: 1. A review of the SOPM showed a procedure, "Laboratory Safety" which states, "wear gloves for each phlebotomy or fingerstick and when handling laboratory specimens." 2. During a tour of the laboratory at 11:05 AM, the surveyor observed a testing person perform laboratory testing on a blood specimen without wearing gloves. 3. During an interview on 2/7/18 at 12:45 PM, the TC confirmed that the testing person was not wearing gloves while performing laboratory testing on blood specimens.

D5311

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL
CFR(s): 493.1242(a)

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

Based on standard operating procedure manual review (SOPM), surveyor observation, and interview with the technical consultant (TC), the laboratory did not ensure that testing personnel followed established policies and procedures for specimen labeling. Findings: 1. A review of the SOPM showed a procedure, "Laboratory Labeling Policy" which states that "Every patient blood sample will be labeled with the patient's first and last name, the date and the initials of the person drawing the blood." 2. During a tour of the laboratory at 11:05 AM, the surveyor observed that hematology specimens in a rack near the analyzer were labeled only with the patient's first and last name. 3. During an interview on 2/7/18 at 12:45 PM, the TC confirmed that the testing personnel were not following the laboratory's policy for specimen labeling.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 surveyor observation and interview with the technical consultant (TC), the laboratory did not ensure the accuracy of the thermometer used in the laboratory refrigerator. Findings: 1. The thermometer that the laboratory staff use to determine the temperature of the laboratory refrigerator hangs from one of the wire shelves in the refrigerator. 2. The laboratory did not have a certificate of calibration for the refrigerator thermometer. 3. The laboratory did not have a procedure to check the thermometer's accuracy and did not check the accuracy of the thermometer in a scientific way. 4. During an interview on 2/7/18 at 12:45 PM, the TC confirmed that the accuracy of the laboratory refrigerator thermometer had not been checked or established by certification.

D6070

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1425(b)(1)

Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:

Based on surveyor observation, laboratory staff did not follow established safety procedures for performing laboratory testing. See D3011