

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0705851	(X3) Date Survey Completed 08/11/2022
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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the calibration documents and interview with the technical consultant (TC), the laboratory failed to ensure that the manufacturer's instructions for calibration verification were followed on the hematology analyzer. Findings: 1. The calibration records that were reviewed showed that the calibration had been performed on 08/09/2022, 01/05/2021, and 05/20/2020. 2. The "Technical Consultant Duties and Responsibilities" state that the TC will validate the test performance. The manufacturer's instructions require that the calibration verification be performed every six months. The records show two nine month gaps between the performance of the calibration verification. 3. During the survey on 08/11/2022 at 11:15 AM, the TC confirmed that the calibration verification procedures were not performed as required by the manufacturer.</p>
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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.</p>

This STANDARD is not met as evidenced by:

Based on review of the evaluation records of the laboratory personnel and interview with the technical consultant (TC), the laboratory director did not ensure that the policies for monitoring the laboratory staff included the technical consultant.

Findings: 1. The laboratory's evaluation records were reviewed. The documentation did not include an evaluation of the technical consultant. 2. The laboratory's policies and procedures for training and evaluation of the laboratory staff did not include an evaluation of the TC. 3. During the exit interview on 08/11/2022 at 11:15 AM, the TC confirmed that the laboratory's policy and procedure manuals did not include evaluation of the technical consultant on an annual basis.