

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0210507	(X3) Date Survey Completed 04/01/2026
Name of Provider or Supplier Medstar Shah Medical Group Fort Washington	Street Address, City, State 952-A East Swann Creek Rd, Fort Washington, 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on procedure manual and proficiency testing (PT) record review and interview with the general supervisor (GS #4) and laboratory director (LD), the laboratory failed to have a written procedure for performing PT for the professional component (PC) of histopathology testing and failed to follow the approved procedure for performing PT for the technical component (TC) of histopathology testing. Findings: 1. The laboratory receives and processes patient histopathology specimens (TC) to make and stain slides for interpretation by the LD (PC). 2. During an interview on 04/01/2026 at 11:50 AM, GS #4 stated that the laboratory's PT program is a combination of peer review (second opinion) for patient cases and sending a peer review form and patient slides to a second pathologist for review. 3. A review of PT records from 2024 to 2026 showed that the laboratory utilized two different PT forms. The "MedStar Medical Group-Southern (SHAH Pathology) PROFICIENCY SCORE SHEET" (TC score sheet) documented PT performed for the TC of histopathology testing. The form required the reviewing pathologist to score from zero to three the "Fixation/Processing", "Microtomy", and "Staining" of submitted slides for "H&E" (hematoxylin and eosin), "PAS/AB" (Periodic Acid-Schiff), and "IHC (CD3)" (Immunohistochemical Cluster of Differentiation 3). The form included a "Scoring Key" and a space for the "Reviewing Pathologist" to sign and date. 4. The "Peer Review Form" (PC score sheet) documented PT performed for the PC of histopathology testing. The form recorded the "Reviewing Pathologist Diagnosis" for each case submitted for review. The reviewing pathologist noted the "Variation from</p>

Pathologist of Record" by placing a check mark next to columns labeled "None", "Minor 1", "Minor 2", "Major 1", and "Major 2" and signed and dated the form. 5. Procedure manual review showed that the laboratory had one PT procedure. During an interview on 04/01/2026 at 11:50 AM, GS #4 stated that the procedure, "TSA-ALL-HISTO-SOP-0001.001 Histology Alternative Proficiency Testing" (PT SOP) was the laboratory's procedure for performing PT for the TC of histopathology testing. They stated that PT for the PC of histopathology testing was performed by comparing and evaluating the results of patient cases which the LD sent to a second pathologist for a second opinion of their interpretation of the slides. GS #4 confirmed that there was no written procedure for how the laboratory performed PT for the PC of histopathology testing. 6. The PT SOP described how the laboratory should select and send patient slides to a second pathologist for review. It stated that "Proficiency Slide set samples must be reviewed and the Attestation Statement Form, TSA-ALL-HISTO-FRM-0001, signed and dated by the laboratory director prior to sending. The lab staff involved in any part of the slide preparation process is to sign and date the Attestation Statement." 7. Record review showed that there were no "TSA-ALL-HISTO-FRM-0001" PT forms available at the time of the survey. The TC score sheets used to document PT did not include the LD's signature or list the names of the laboratory staff who were involved in slide preparation. 8. The PT SOP also stated that "Upon receipt of the returned proficiency report and samples, the TSA Lab supervisor or Laboratory Director will review results with the lab staff. The Proficiency Review Form, TSA-ALL-HISTO-FRM-0001, must be completed" and "Any noted deficiencies will be noted on the form and reviewed for corrective actions with the technical staff and the general supervisor. These reports will be signed and dated by the the testing staff and Laboratory Director and retained". 9. Record review showed that the LD did not sign four out of four TC score sheets and four out of four PC score sheets from 2024 through 2026, documenting that they reviewed the PT results to determine PT success or failure. 10. During an interview on 04/01/2026 at 12:30 PM, the LD confirmed that the laboratory did not have a procedure for performing PT for the PC of histopathology testing, and that the laboratory failed to follow the approved procedure for performing PT for the TC of histopathology testing.