

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D0210507	<b>(X3) Date Survey Completed</b>  08/15/2018
<b>Name of Provider or Supplier</b>  Medstar Shah Medical Group Fort Washington	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5781</b>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(b)(1)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory manager, the laboratory failed to document corrective action when an error was found in the histology laboratory. Findings: 1. The laboratory utilizes the "Histology Error Identification Form" to record errors found in the histology laboratory. 2. A review of "Histology Error Identification Forms" from 2016 to 2018 was performed. The review showed that an error form, dated 12/25/16, documented an error involving the wrong patient's tissue being found on a slide on 12/21/16. No corrective action had been documented. 3. At the time of the survey the laboratory manager and laboratory director documented the corrective action that had been performed at the time of the error. 4. During an interview on 8/15/18 at 2:15 PM, the laboratory manager confirmed that there was no documentation of corrective action performed at the time the error was discovered.</p>