

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  09D0645021	<b>(X3) Date Survey Completed</b>  08/05/2021
<b>Name of Provider or Supplier</b>  Gwu Medical Faculty Associates	<b>Street Address, City, State</b>  2150 Pennsylvania Avenue, Nw 2-121 Mohs Lab, Washington, DC	
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>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the clinical lab around 12 noon and interview with the office manager, the lab failed to ensure reagents used to perform fungal testing was not used beyond the manufacturers expiration date. Findings: 1. The laboratory performs Tzanck testing. 2. Observation of the reagents used for patient testing showed that four of the reagents expired during the year 2019 and 2017 and on 8/16/2018 and 11 /2017. 3. The office manager asked the physicians were they aware that the reagents had expired and the response was yes they were aware. 4. The office manager stated that she was unsure if the reagents were used for patient testing, 5. The office manager confirmed that the Tzanck reagents had expired.</p>
<b>D5435</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p>

This STANDARD is not met as evidenced by:  
Based on review of the written procedure manual and interview with the testing person, the laboratory failed to document the autoclave sterilization process of instruments used to perform patient procedures and to ensure the acceptability of patient testing. Findings: 1. The laboratory performs Histopathology testing. 2. The laboratory performed and documented the autoclave steam sterilization of instruments up to the year 2017. 3. After the year 2017 the documentation stopped. 4. The testing person stated that he was unaware of the procedures and documentation for sterilization of instruments used during patient procedures. 5. The testing person confirmed that the instrument sterilization procedures stopped during the year 2017.

**D6124**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(b)(8)(iv)

The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks.

This STANDARD is not met as evidenced by:  
Based on review of the written procedure manual and interview with the testing person, the laboratory director acting as the technical supervisor (TS) failed to perform Histopathology observations of the testing person skills during competency procedures. Findings: 1. The testing person begin Histopathology testing in September 2019. 2. The testing person has been educated and trained to perform tissue grossing, inking, and prepare slides for review by the physician. 3. Review of the competency performed during the year 2021 did not show that observation procedures were performed by the TS. 4. The testing person stated that the competency form was changed and observations were included on the previous form. 5. The testing person confirmed that observation procedures were not performed during competency assessment by the TS.