

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 09D0645021	(X3) Date Survey Completed 09/09/2019
Name of Provider or Supplier Gwu Medical Faculty Associates	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with laboratory (lab) staff, the lab did not document all proficiency reviews conducted. Findings: 1. In order for the lab to check the staining and MOHS procedures for accuracy and reliability, the lab submits 6 cases annually for peer review; 2. The reviewer returns the slides and reports and comments on agreement or disagreement for the submitted cases; 3. On October 8, 2017 and December 18, 2018 the lab reported that it submitted 6 cases on each date for peer review, but the report from the reviewer stated that 5 and not 6 cases were reviewed and found to be in agreement, there was no documented corrective action regarding the missing reviews; and 4. This was confirmed during interview with the histotechnician on the day of survey.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in</p>

493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on record review, the laboratory (lab) written procedures did not include a key showing the relationship of the dye colors used to orient the patient tissue and the markings made on the MOHS map showing how the dyes were applied to the tissue.

D5407

PROCEDURE MANUAL

CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

A. Based on record review and interview with laboratory (lab) staff, the director did not sign and date the written procedures showing that they were reviewed and approved by the current director. Findings: 1. During interview with staff on the day of survey, the lab director began performing director duties in August 2019; and 2. The labs written procedures were not signed by the current lab director showing that they were reviewed and approved.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(d)

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.

This STANDARD is not met as evidenced by:

Based on record review and interview with laboratory (lab) staff, the lab did not document the histology stain and zylene maintenance (cleaning, changes and filtering) to ensure they are not substandard quality. Findings: 1. The lab's written procedure (worksheet to document stain maintenance) states that the stain cups are cleaned each day of use and this activity is documented on the worksheets; 2. During interview with staff on the day of survey, it was determined that the lab changes and cleans the alcohol cups each day of MOHS surgery, but replaces stains (hematoxylin and eosin) every 2 weeks and replaces zylene every three weeks and this activity was not documented; 3. The written procedure did not include instructions for changing the stains and zylene, including frequency and documentation requirements; and 4. The worksheet did not show that the stains and zylene are changed with the frequency described by staff and the dates that the stain and zylene changes were actually made.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on record review and interview with laboratory (lab) staff, the lab did not oil the cryostat with the frequency stated in the written procedure. Findings: 1. The written procedure states that the cryostat is oiled weekly. Cryostat maintenance records for 2019 did not show that the cryostat was oiled weekly; and 2. During interview with the histotechnician, it was determined that the cryostat is oiled every 6 months due to frequency of use.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on observation and interview, the laboratory (lab) did not hold quarterly laboratory quality assurance meetings as stated in the written procedure. Findings: 1. The lab's written procedure states that it will hold quarterly quality assurance meetings; In 2018 and 2019 there was no documentation that quarterly quality assurance meetings were held; 2. On the day of survey, the quarterly quality assurance minutes was requested, but the lab did not provide meeting minutes; and 2. The finding was confirmed with the histotechnician on the day of survey.

D6106

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(14)

The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.

This STANDARD is not met as evidenced by:

A. Based on record review and interview with laboratory (lab) staff, the lab did not ensure that the written procedure was organized in a reliable manner. Findings: 1. A section of the MOHS written procedure was attached to the end of the KOH prep procedure; 2. Two additional procedures for MOHS surgery were separated, one procedure was in the MOHS manual and another was in the lab manual; and 3. This was confirmed during interview with the histotechnician on the day of survey. B. Based on record review and interview with laboratory (lab) staff, the lab did not have current written procedures for MOHS surgery. The written procedures referred to the previous director and not the current director. Findings: 1. Procedure 8.4 refers to the previous directors; 2. Duties and responsibilities policy refers to the previous director as the lab director, clinical consultant, technical supervisor, general supervisor and testing person; and 3. This was confirmed during interview with the histotechnician on the day of survey.