

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D1016329	<b>(X3) Date Survey Completed</b>  07/19/2022
<b>Name of Provider or Supplier</b>  Aw Dermatopathology Service	<b>Street Address, City, State</b>  3715 Prytania St, Suite 306, New Orleans, LA	
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>D0000</b>	A Certification survey was performed on July 19, 2022 at AW Dermatopathology, CLIA ID # 19D1016329. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, personnel records, CMS 209 form, and interview with personnel, the laboratory failed to establish written procedures to assess competency for one (1) of two (2) personnel serving as Clinical Consultant, Technical Supervisor, and General Supervisor. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Report) revealed the Laboratory Director and Clinical Consultant 2 served as Clinical Consultant, Technical Supervisor, General Supervisor, and Testing Personnel. 2. In interview on July 19, 2022 at 9:59 am, Testing Personnel 1 stated Clinical Consultant 2 was hired on November 29, 2021. 3. Review of the laboratory's policies revealed the laboratory did not have a written policy related to competency assessments for personnel serving as Clinical Consultant, Technical Supervisor, and General Supervisor, including, frequency of performance. 4. Review of the personnel records for Clinical Consultant 2 revealed a competency assessment; however, it did not include assessment for their duties related to Clinical Consultant, Technical Supervisor, and General Supervisor. 5. In interview on July 19, 2022 at 9:59 am, Testing Personnel 1 confirmed the laboratory did not have competency assessments for the duties of Clinical Consultant, Technical Supervisor, and General Supervisor for Clinical Consultant 2.</p>

**D6102**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on review of personnel records and interview with personnel, the Laboratory Director failed to ensure one (1) of five (5) Testing Personnel reviewed were approved to perform grossing of Histopathology samples. Findings: 1. In interview on July 19, 2022 at 9:59 am, Testing Personnel 1 stated Testing Personnel 3 was hired March 2021. 2. Review of personnel records for Testing Personnel 3 revealed an initial training was performed March 29, 2021; however, the laboratory did not have documentation of the Laboratory Director's approval/signature for patient testing. 3. In interview on July 19, 2022 at 9:59 am, Testing Personnel 1 confirmed the Laboratory Director did not approve/sign-off Testing Personnel 3 for testing after her initial training.

**D6103**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Findings: 1. The laboratory failed to establish written procedures to assess competency for one (1) of two (2) personnel serving as Clinical Consultant, Technical Supervisor, and General Supervisor. Refer to D5209. 2. The Technical Supervisor(s) failed to perform the semi-annual competency assessment for one (1) of five (5) testing personnel reviewed. Refer to D6127.

**D6127**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's CMS-209 form, personnel records, and interview with personnel, the Technical Supervisor(s) failed to perform the semi-annual

competency assessment for one (1) of five (5) testing personnel reviewed. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Report) form revealed the Laboratory Director and Clinical Consultant 2 serve as Technical Supervisors. 2. In interview on July 19, 2022 at 9:59 am, Testing Personnel 1 stated Testing Personnel 3 was hired March 2021. 3. Review of personnel records for Testing Personnel 3 revealed the competency assessment was performed at three (3) and six (6) months. The semi-annual competency assessment for Testing Personnel 3 was performed by Testing Personnel 2, not a Technical Supervisor. 4. In interview on July 19, 2022 at 9:59 am, Testing Personnel 1 stated Testing Personnel 2 performed the semi-annual competency assessment for Testing Personnel 3. Testing Personnel 1 confirmed the semi-annual competency for Testing Personnel 3 was not performed by a Technical Supervisor.