

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0252931	(X3) Date Survey Completed 01/17/2025
Name of Provider or Supplier Camille Mason, Md, Pa	Street Address, City, State 2526 Hwy 72 E, Abbeville, SC	
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
D0000	An onsite CLIA recertification survey was conducted at Camille Mason, MD, PA on January 17, 2025, by the South Carolina Department of Public Health's Bureau of Nursing Homes and Medical Services. The laboratory was found to be out of compliance with 42 CFR Part 493, CLIA Requirements for laboratories.
D3013	<p>FACILITIES CFR(s): 493.1101(e)</p> <p>Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, lack of documentation, and staff interview, the laboratory failed to maintain acceptable room temperature for the preservation of histology slides. Findings include: 1. During a tour of the laboratory storage room on 01/17/2025 at 3:00 pm, the surveyor directly observed slide storage in a room that lack a temperature monitoring device. 2. Review of the laboratory's temperature records revealed that the laboratory failed to monitor the slide storage room. The laboratory failed to provide documentation of any monitoring device to preserve slide storage. 3. In an interview on 01/17/2025 at 2:33 pm in the breakroom with testing personnel (TP1) the above findings were confirmed.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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>

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, lack of laboratory records, and interview with staff, the laboratory failed to establish written policies and procedures to assess the competency of testing personnel for three of three years reviewed 2021, 2022, 2023. Findings include: 1. The surveyor requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process for assessing the competency of one of one testing personnel. 2. The surveyor requested and the laboratory failed to provide records of competency assessment of one of one testing personnel who process specimens unsupervised. 3. During an interview on 01/17/2025 at 2:33pm with testing personnel in the breakroom, the above findings were confirmed.

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(2)

(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:
Based on direct observation, lack documentation, and testing personnel interview, the laboratory failed to document the performance specifications for the lab equipment (Avantik QS12) Cryostat & Microtome prior to use. Findings include: 1. The surveyor observed a new cryostat & microtome in the Moh's lab during a tour of the lab on 01/17/2025 at 11:10am. 2. The surveyor requested and the laboratory failed to provide records of performance verification as applicable. 3. In an interview on 01/17/2025 at 2:33 pm in the break room with TP1 confirmed the Cryostat & Microtome was install in 2024.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(12)

(e)(12) 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:
Base on records reviewed, lack of documentation and staff interviewed, the laboratory failed to document prior to testing patient's specimens all personnel have the appropriate education and experience and received the appropriate training for high complex services offered and have demonstrated that they can perform all testing operations reliably to provide and report accurate results for Moh's surgery for four of four (2020, 2021, 2022, 2023) years reviewed. Findings include: 1. A review of CMS

209 laboratory personnel report form identified one laboratory director as technical supervisor and one testing personnel. 2. A review of patient records: M20-008, performed 01/08/2020; M21-002, performed 01/18/2021; M22-011, performed 01/10/2022; M23-057, performed 01/24/2023; documented (TP1) as the lab person assisting in the Moh's surgery. 3. The surveyor requested education and training records for TP1, and the laboratory failed to provide records for education or training on day of survey, 01/17/2025. 4. In an interview with TP1 on 01/17/2025 at 2:33 pm in the break room, the above findings were confirmed.

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(7)(8)

(b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
During an onsite recertification survey on 01/17/2025, testing personnel record review, and testing personnel interview, the laboratory director/technical supervisor failed to ensure that competency assessments were performed annually as required (see D5209).

D6171

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) (A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were

qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on records review and staff interview, the laboratory failed to document testing personnel's qualifications for high complexity testing. Findings include: 1. Review CMS 209 laboratory personnel report form listed one person as testing personnel (TP1) for high complexity testing. 2. A review of personnel files reveals no documentation of qualifications, no training records available on 01/17/2025, day of survey for TP1. 3. In an interview with TP1 on 01/17/2025 at 2:33 pm in the break room the above findings were confirmed.