

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2171722	(X3) Date Survey Completed 01/07/2025
Name of Provider or Supplier Pennsylvania Hospital Mohs Surgery Lab	Street Address, City, State 235 South 8th Street, Philadelphia, PA	
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
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> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Mohs laboratory manager, the laboratory failed to establish a competency assessment procedure to assess 1 of 1 Technical Consultant (TC) for their supervisory responsibilities performed in 2023 and 2024. Findings Include: 1. On the day of survey, 1/7/2025 at 11:17 am, the laboratory failed to provide a competency assessment procedure to assess the competency of TC #1 (CMS 209 personnel #3) for their supervisory responsibilities performed in the laboratory in 2023 and 2024. 2. The laboratory failed to provide competency assessment documentation for the supervisory responsibilities of TC #1 when overseeing microbiology testing performed in 2023 and 2024. 3. The Mohs laboratory manager confirmed the findings above on 01/07/2025 at 12:45 pm.</p>
D6143	<p>GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461</p> <p>(a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or (2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(i) 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 have earned a doctoral, master's, or bachelor's degree in a</p>

chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(3); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3) Meet the requirements at 493.1443(b)(3) or 493.1449(c)(4) or (5); or (c)(4) Notwithstanding any other provision of this section, an individual is considered qualified as a general supervisor under this section if they were qualified and serving as a general supervisor in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3) (i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or (f)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(f)(2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(f)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or (g).

This STANDARD is not met as evidenced by:

Based on review of the laboratory's designee delegation policy, competency assessments, personnel qualification records (credentials) and interview with the Mohs laboratory manager (MLM), the laboratory failed to ensure that 1 of 2 General Supervisors (GS) met the requirements to provide supervision of testing personnel (TP) who performed macroscopic histopathology examinations in 2024. Findings include: 1. The Laboratory Director's Designee Delegation for Pennsylvania Hospital Mohs Lab states, "The lab manager has my permission to perform all log checks for equipment and temperature maintenance. In the absence of the lab manager, the site Practice Manager, Nurse Manager or Lab Compliance and Operations Manager is to sign off on all logs, safety auditing, instrument maintenance management, and competency assessments in the lab. The histotechs are responsible for filling out all logs as needed." 2. On the day of survey, 01/07/2025 at 11:17 am, review of competency assessment records revealed the MLM (CMS 209 personnel # 14) assessed the competency of TP #1 and TP #2 (CMS 209 personnel #1 and #2) who performed macroscopic examinations (grossing and inking) in the Mohs laboratory in 2024. 3. The laboratory provided the following personnel credentials for the MLM: - Stockton University Bachelor of Science degree in Biology/Chemistry awarded on December 9, 2009. 4. Review of personnel credentials revealed the laboratory failed to ensure that 1 of 2 GS (CMS 209 GS #2) met the required qualifications (493.1449) to perform supervision of high complexity dermatopathology testing in 2024. 5. During an interview on 01/07/2025 at 12:20 pm, the MLM confirmed that they perform the observation of the histotechs to assess competency and provide the day-to-day supervision of the Mohs laboratory.