

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0896302	(X3) Date Survey Completed 08/07/2026
Name of Provider or Supplier Umass Memorial/ Dermatopathology Lab	Street Address, City, State 281 Lincoln Street, 4th Floor, Worcester, MA	
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
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on record review and confirmed through interview on 8/7/2026 with testing personnel (TP) 1, TP2, the Supervisor of Ambulatory Operations (SAO), and the Ambulatory Operations Manager of Dermatology (AOMD), the laboratory had one individual who did not meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed in the specialty of Histopathology. Findings revealed the following: One testing person did not meet the minimal educational requirements in order to perform high complexity testing. (Also refer to D6171)
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) 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 record review and confirmed through interview on 8/7/2026 with testing personnel (TP)1, TP2, the Supervisor of Ambulatory Operations (SAO), and the Ambulatory Operations Manager of Dermatology (AOMD), the laboratory had one testing personnel who did not meet the minimal education requirements in order to perform high complexity testing. Findings include: 1. On 8/7/2026 at 9:10 AM, CLIA surveyor observed TP1 and TP2 grossing tissue specimens in the laboratory. 2. Record review on 8/7/2026 of the laboratory's CMS form 209, signed by the laboratory director (LD) on 8/5/2026, as compared to the CMS form 209 from the previous survey signed by the LD on 7/10/2024 revealed that three new high complexity testing personnel have been added since the last survey. 3. Record review on 8/7/2026 of the laboratory's personnel files revealed that one of three new high complexity testing personnel, (TP2) did not meet the qualification requirements to perform high complexity testing, specifically: a. TP2 was performing gross examination on tissues for MOHS testing which is high complexity testing. b. The only documentation of qualifications for TP2 was a State of Massachusetts Nurse Aide Certification which does not meet the minimal qualification requirements for high complexity testing personnel. 4. Staff interview on 8/7/2026 at 10:36 AM with TP1, TP2, the SAO, and the AOMD revealed the following: a. TP1 stated that TP2 had been performing gross examinations for approximately 3 years, which was prior to the previous survey. TP1 also stated that TP1 was unsure why TP2 was not listed on the laboratory's 2024 CMS form 209. b. TP2 stated, "I am taking classes to earn my associates degree." c. The AOMD stated that TP2 was promoted from within and was trained on the job. d. The SAO confirmed the only credentials on file for TP2 was a State of Massachusetts Nurse Aide Certification. The SAO also stated TP2 does not have a college degree. 5. The laboratory performs 2,500 tests annually in the specialty of histopathology.