Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0386471	07/03/2025
Name of Provider or Supplier	**Street Address, City, State**	
Cross Medical Laboratories Llp	321 E Market Street, Suite 102, Iowa City, IA	

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 review of laboratory personnel records, the US Food and Drug Administration (FDA) Clinical Laboratory Improvement Amendments (CLIA) test system categorization database, and confirmed by telephone interview with the Office Manager at 9:30 am on 07/03/2025, the laboratory failed to meet the testing personnel requirements by providing documentation to qualify the testing personnel who perform high complexity testing as specified in standard 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 review of laboratory personnel records, the US Food and Drug Administration (FDA) Clinical Laboratory Improvement Amendments (CLIA) test system categorization database, and confirmed by telephone interview with the Office Manager at 9:30 am on 07/03/2025, the laboratory failed to ensure one out of two testing personnel met the educational requirements for performing high complexity testing. The findings include: 1. The laboratory began using the Ventana Benchmark Ultra Plus system for patient testing in March 2024. The following immunohistochemical (IHC) antibody stains are performed by the laboratory on the instrument: anti-Keratin (34BetaE12), anti- P40 (BC28), anti-p504s (SP116), anti-Ki-67 (30-9), P16, anti-PRAME (EPR20330), anti-MART-1/ melan A (A103), anti-S100 (4C4.9), Sox 10 (SP267), anti-Cytokeratin 20 (CK 20), Myosin, smooth muscle (SMMS-1), NKX3.1 (EP356), GATA-3 (L50- 823), and anti-Helicobacter pylori (SP-48). 2. Review of the FDA CLIA test system categorization database indicated that the anti-Ki-67 (30-9) and anti-Helicobacter pylori (SP48) assays are both categorized as high complexity. The remaining assays are not listed in the database and have not been categorized; therefore, they default to high complexity. 3. Testing personnel (TP) #1 and #2 both perform IHC antibody staining on the Ventana Benchmark Ultra Plus system. 4. Review of educational documentation and transcripts for TP #1 revealed they did not meet the minimum semester hours required to perform high complexity testing. 5. At the time of the survey, the laboratory did not provide adequate educational documentation to qualify TP #1 for high complexity testing.