

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2045786	(X3) Date Survey Completed 02/24/2026
Name of Provider or Supplier American Health Associates	Street Address, City, State 39205 Country Club Drive Suite C30, Farmington Hills, MI	
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	<p>. The purpose of this unannounced survey was for complaint MI00155150. The Department of Licensing and Regulatory Affairs has evaluated this facility and determined that it is not in compliance with CLIA regulations (42 CFR Part 493, Laboratory Requirements) for the following condition: 493.1487 Condition: Laboratories performing high complexity testing; testing personnel .</p>
D6168	<p>TESTING PERSONNEL CFR(s): 493.1487</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: . Based on record review and interviews with the general supervisor (GS) and testing personnel (TP4), the laboratory failed to ensure 1 (TP4) of 4 testing personnel (TP) performing high complexity testing in hematology met educational requirements. Refer to D6171.</p>
D6171	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b)</p> <p>(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</p>

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 interviews with the general supervisor (GS) and testing personnel (TP4), the laboratory failed to ensure 1 (TP4) of 4 testing personnel (TP) performing high complexity testing in hematology met educational requirements. Findings include: 1. A review of the CMS-209 form revealed that TP4 was listed as personnel performing high complexity testing. 2. A review of the laboratory's test menu revealed that the complete blood count (CBC) with manual differential was categorized as high complexity testing. 3. A review of educational documentation revealed that TP4 earned a Bachelor of Arts in Liberal Arts and Sciences with a total of 24 semester hours of science coursework, as follows: a. BIO 1050 - Introduction to Life, 3 semester hours b. BIO 1510 - Basic Life Mechanisms, 4 semester hours c. BIO 2870 - Anatomy and Physiology, 5 semester hours d. BIO 3200 - Human Physiology, 3 semester hours e. CHEM 1020 - General Chemistry, 4 semester hours f. BIO 220 - Introduction to Microbiology, 5 semester hours A review of the laboratory's personnel records revealed TP4 did not meet educational requirements for high complexity testing. A Bachelor of Arts in Liberal Arts and Sciences and transcript was provided and lacked the minimum number of chemistry, biology, and combined biology, chemistry, and clinical laboratory science credits. 4. An interview conducted on 2/24/2026 at 4:16 pm with TP4 confirmed that TP4 was hired March 17, 2025. TP4 stated they began training in hematology for manual differentials from April 2025 to December 2025 and began working independently thereafter. 5. An interview conducted with the GS on 02/24/2026 at 4:30 pm confirmed that TP4 was performing manual differential testing in hematology.