

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2081090	(X3) Date Survey Completed 02/03/2023
Name of Provider or Supplier Blair Gastro Pathology Lab	Street Address, City, State 810 Valley View Blvd, Altoona, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of documentation and an interview with the Executive Director (ED), the laboratory failed to verify twice annually the accuracy of grossing examinations performed from 09/17/2020 through the date of the survey. Findings include: 1. On the day of the survey, 02/03/2023, the laboratory could not provide documentation of verification of accuracy for grossing macroscopic examinations performed from 09/71/2020 to 02/03/2023. 2. The laboratory's annual test volume is 31778 (CMS 116) 3. The Executive Director confirmed the findings above on 02/03 /2022 around 11:00 am.</p>
D6141	<p>GENERAL SUPERVISOR CFR(s): 493.1459</p> <p>The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of the Laboratory Personnel Report (CLIA) (Form CMS-209), review of qualification documents, and interview with the Executive Director (ED), the laboratory failed to ensure 2 of 3 General Supervisors met the qualifications under 42 C.F.R. 493.1461. Refer to D6143. .</p>

GENERAL SUPERVISOR QUALIFICATIONS

CFR(s): 493.1461

(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 paragraph (b)(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 chemical, physical, biological or clinical 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)(2); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under 493.1462 on or before February 28, 1992. (c)(3)(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of 493.1462 on or before January 1, 1994. (c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995-- (c)(4)(i) Meet one of the following requirements: (c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS. (c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician). (c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or (c)(5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and-- (c)(5)(i) Be a high school graduate or equivalent; and (c)(5)(ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992. (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 493.1449(l)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l) or (2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(m).

This STANDARD is not met as evidenced by:
Based on review of the Laboratory Personnel Report (CLIA) (Form CMS-209), review of qualification documents, and interview with the Executive Director (ED), the laboratory failed to ensure 2 of 3 General Supervisors met the qualifications under 42 C.F.R. 493.1461 (e)(1) in 2021 and 2022. Findings Include: 1. On the date of the survey, 02/03/2023, reviewed of the credentials for GS#2 and GS#3 (CMS 209 personnel #2 and #3) who performed competency assessment for the testing personnel who performed grossing macroscopic examinations in 2021 and 2022 . 2. GS#2 did not meet the qualifications (493.1461 (e)(1)) to be a General Supervisor for the grossing macroscopic examinations. GS#2 received an Associate of Science in Medical Laboratory Technology in 1986 and a Bachelor of science in Health Sciences in 2023. 3. GS#3 did not meet the qualifications (493.1461 (e)(1)) to be a General Supervisor for the grossing macroscopic examinations. GS#3 received an Associate of Science in Medical Laboratory Technology in 1992. 4. The ED confirmed the findings above on 02/03/2023 around 11:00 am.