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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 13D2302318 | (X3) Date Survey Completed 07/23/2025 |
| Name of Provider or Supplier Proesis Biologics Westmoreland Llc | Street Address, City, State 3015 E Goldstone Way Ste 120, Meridian, ID | |
| 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 |
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| D0000 | A validation survey was conducted by the Idaho CLIA state agency at the facility on July 23, 2025. The laboratory was found out of compliance with the following condition: 42 CFR 493.1409, Technical Consultant, Moderate Complexity |
| D6004 | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, training and competency assessment records, educational documents and an interview with the Center Director and the Quality Assurance (QA) Manager on 7/23/2025, laboratory director failed to delegate initial training and annual competency assessment performance responsibilities to individuals that qualified as the technical consultant in 2024 and 2025. 1. A review of the CMS 209 identified one Technical Consultant (TC) and 12 testing personnel (TP). 2. A review of initial training and competency assessment documents identified that the TC failed to perform initial training and annual competency assessments. 3. A review of educational documents for the three Quality Assurance Specialists performing the training and annual competency assessments for the 12 testing personnel identified that they failed to meet the minimum educational requirements for a TC. 4. An</p> |

interview with the Center Director and QA Manager on 7/23/2025 at 10:02 am confirmed that they three QA specialists that were delegated to perform training and annual competency failed to qualify as a TC. 5. The laboratory reports performing 25,000 tests annually.

D6033

TECHNICAL CONSULTANT-MODERATE COMPLEXITY
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:
Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, educational documents and interviews with the Center Director and Quality Assurance Manager on 7/23/2025, the laboratory failed to have a technical consultant that qualified with the minimum educational and experience requirements. See D6035

D6035

TECHNICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or (b)(2)(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; AND (b)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and (b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this

section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b) (7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

This STANDARD is not met as evidenced by:

Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, educational documents and interviews with the Center Director and Quality Assurance (QA) Manager on 7/23/2025, the laboratory failed to have a qualified technical consultant (TC) since the facility opened in April 2024. The findings include: 1. A review of educational and associated documents for the Laboratory Director who was also listed as the TC on the CMS 209 identified that the laboratory failed to hire a technical consultant with the required testing experience in the specialty of chemistry. 2. An interview with the Center Director and QA Manager on 7/23/2025 at 9:46 am confirmed that the laboratory failed to have a qualified TC since testing began in April 2024. 3. The laboratory reports performing 25,000 tests annually.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

(b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, training and competency assessment records and an interview with the Center Director and Quality Assurance (QA) Manager on 7/23/2025, the laboratory failed to establish a procedure for six month competency assessments that included the six CMS CLIA required procedures. The findings include: 1. The CMS 209 identified 12 testing personnel (TP) performing moderate complexity testing. 2. A review of training and competency assessment records identified that the laboratory failed to have six month competency assessments that included the six CMS CLIA required procedures for two of two testing personnel in 2025. 3 An interview with the Center Director and QA Manager on 7/23/2025 at 10:16 am identified that the six month competency consisted of an acknowledgement of competency by the testing personnel and Laboratory Director and a knowledge check confirming that the facility failed to have a six month competency which included the six required procedures. 4. The laboratory reports performing 25,000 test annually.