

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 33D0141347	<b>(X3) Date Survey Completed</b> 07/08/2024
<b>Name of Provider or Supplier</b> Bon Secours Medical Group	<b>Street Address, City, State</b> 70 Hatfield Lane, Suite 101, Goshen, NY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A federal surveyor from the Centers for Medicare & Medicaid Services (CMS) Survey Branch conducted an announced CLIA validation survey at Bon Secours Medical Group on July 8, 2024. The laboratory was surveyed under 42 CFR part 493 CLIA regulations. The laboratory was found to not be in compliance with all condition-level CLIA requirements. The following condition and standard-level deficiencies were found during CLIA exempt-state validation survey performed on July 8, 2024.
<b>D5301</b>	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of patient request records, review of laboratory procedures and interview with the laboratory supervisor, the laboratory failed to establish a written or electronic request (standing order policy) for complete blood (CBC) ordered from July 2022 to July 2024. Findings Include: 1. The laboratory supervisor stated, "the laboratory has a standing order to CBC ordered", but was unable to provide an established standing order procedure. 2. On July 8, 2024, review of laboratory records revealed the laboratory failed to provide written or electronic requests for patient CBCs ordered from an authorized person from July 2022 to July 2024. 3. The Clinical Laboratory Improvement Amendment (CLIA) Application for certification (Form CMS-116) states a total estimated annual test volume of 22,000. 4. The laboratory supervisor confirmed the findings above on 11:50 am.</p>
<b>D5429</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p>

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on review of maintenance records and interview with the laboratory supervisor, the laboratory failed to perform monthly maintenance on the Beckman Coulter DXH520 complete blood count (CBC) instrument for 8 out of 24 from July 2022 to June 2024. Findings Include: 1. The Beckman Coulter DXH520 manufactures manual under Table 12.1, Matrix of frequency for cleaning procedures: bleach cycle and cleaning the white blood cell (WBC) bath filter, Frequency - Monthly. 2. One the day of survey, July 8, 2024, the laboratory could not provide the monthly Beckman Coulter DXH520 maintenance records for the following 8 out of 24 from July 2022 to June 2024: 2022 - August. 2023 - January, April, June and October. 2024 - January, April and May. 3. The laboratory supervisor confirmed the findings above on July 8, 2024 at 11:15 am.

**D6033**

**TECHNICAL CONSULTANT-MODERATE COMPEXITY**

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 review of laboratory personnel educational credential records and interview with the laboratory supervisor, the technical consultant (TC) failed to qualify to perform their supervisory TC responsibilities in the laboratory from July 2022 to July 2024. Refer to 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 possess qualifications that are equivalent to those required for such certification; 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 one year of laboratory training or experience, or both in non-waived 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) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated

specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:

Based on review of laboratory personnel educational credential records and interview with the laboratory supervisor, the technical consultant (TC) failed to qualify to perform their supervisory TC responsibilities in the laboratory from July 2022 to July 2024. Finding Include: 1. On the Laboratory personnel report (Form CMS-209), the TC is the laboratory supervisor, which was signed by the laboratory director on June 20, 2024. 2. Review of laboratory records on July, 8, 2024 revealed the laboratory supervisor performs and signs off on testing personnel competency assessment records and signs off on monthly record reviews. 3. The laboratory supervisor provided a Associates Degree in Nursing, but was unable to provide an earned bachelors degree. 4. The laboratory supervisor confirmed the findings above on 12:00 pm.