

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D0972209	<b>(X3) Date Survey Completed</b>  06/17/2025
<b>Name of Provider or Supplier</b>  Parochial Medical Center Lab	<b>Street Address, City, State</b>  1065 West Main Street, New Holland, PA	
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 CLIA validation survey was conducted by the Pennsylvania Department of Health at the Parochial Medical Center Lab, that was concluded on June 17, 2025. Conditions cited under 42 CFR part 493 CLIA Regulation: D6033 -42 CFR. 493.1409 Technical Consultant-Moderate Complexity.
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by:                      A. Based on observation in the laboratory, review of laboratory temperature records, and interview with Testing Personnel (TP) #1, the laboratory failed to monitor room temperatures to ensure proper storage of reagents and operating conditions of the laboratory were met for 238 of 731 days from 6/17/2023 to 6/17/2025. Findings include: 1. On the day of survey, 6/17/2025, at 11:00 am, during the tour of the laboratory, the surveyor observed the following supplies stored in the laboratory: - Various Vacutainer Collection Supplies Storage requirements 39.2F to 77F. - Abbott Cell-Dyn Emerald Instrument Reagents. Storage requirements 39.2F to 95F. 2. Review of the laboratory's temperature records revealed the laboratory failed to monitor and document room temperatures for 238 of 731 days from 6/17/2023 to 6/17/2025 when the laboratory was closed. 3. TP #1 confirmed the findings above on 6/17/2025 at 11:30 am. B. Based on observation in the laboratory, lack of documentation,</p>

and interview with Testing Personnel (TP) #1, the laboratory failed to monitor refrigerator temperature to ensure reagent stability and proper operating conditions of the supplies used for hematology testing stored there for 731 of 731 days from 6/17/2023 to 6/17/2025. Findings include: 1. On the day of survey, 6/17/2025, at 11:00 am, during the tour of the laboratory, the surveyor observed the following hematology reagents stored in the laboratory refrigerator: - Cell-Dyn Emerald Quality Control. Storage requirements 35.6F to 46.4F. 2. The laboratory could not provide documentation of temperature monitoring for the refrigerator where Cell-Dyn Emerald Quality Control was stored for 731 of 731 days from 6/17/2023 to 6/17/2025. 3. TP #1 confirmed the findings above on 6/17/2025 at 11:30 am.

**D6018**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(iii)

(e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; and

This STANDARD is not met as evidenced by:

Based on review of the laboratory's proficiency testing results from the Wisconsin State Laboratory of Hygiene (WSLH) Proficiency Testing (PT) and interview with testing personnel (TP) #1, the laboratory director (LD) failed to ensure that all PT reports received were reviewed by the appropriate staff to evaluate and identify problems that required corrective action for 1 of 1 WSLH testing event for Hematology in 2025. Findings include: 1. On 6/17/2025, at 10:00 am, review of the Laboratory's policy titled, "Proficiency Testing Policy", stated, "After PT samples are received, they will be promptly reviewed by the Laboratory Director or a qualified designee. The review will be documented, and the results of the evaluation will be shared with the Lab Testing Personnel." 2. Review of WSLH testing reports revealed the LD or a qualified designee failed to evaluate 1 of 1 WSLH PT HemeReg 1 2025 reports to ensure acceptable results and investigate failures to identify problems that required corrective action in 2025.. 3. TP#1 confirmed the findings on 6/17/2025 at 11:30 am.

**D6020**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:

Based on lack of documentation, and interview with Testing Personnel #1 (TP), the laboratory director (LD) failed to ensure that a Quality Assurance (QA) program was established and maintained to ensure the quality of services provided and to identify failures in quality as they occur for testing performed in Hematology for 2 of 2 years from 6/17/2023 to 06/17/2025. Findings Include: 1. On the day of the survey, 6/17/2025, the laboratory failed to provide documentation that the LD had reviewed and approved the QA program reports for 2 of 2 years from 6/17/2023 to 6/17/2025. 2. TP#1 confirmed the findings above on 6/17/2025 at 12:30 pm.

**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 review of personnel qualification records and interview with Testing Personnel #1 (TP), the laboratory failed to ensure that 1 of 1 TP (CMS 209 TP#1 dated 6/17/2025) performing the duties of a technical consultant met the qualification requirements (493.1411) for moderate complexity hematology testing from 6/17/2023 to 6/17/2025. Refer to D6034.

**D6034**

**TECHNICAL CONSULTANT QUALIFICATIONS**

CFR(s): 493.1411

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.

This STANDARD is not met as evidenced by:

Based on record review and interview with Testing Personnel #1 (TP), the laboratory failed to ensure that 1 of 1 TP (CMS 209 TP #1) performing the duties of a technical consultant met the qualification requirements (493.1411) for moderate complexity hematology testing from 6/17/2023 to 6/17/2025. Findings include: 1. On the date of survey, 6/17/2025 at 11:30 am, review of laboratory records revealed that TP#1 was performing the duties of a TC from 6/17/2023 to 6/17/2025. a.) Performing personnel competency assessment records in 2023 and 2024 b.) Maintaining and documenting Quality Assessment in 2023 and 2024. 2. The laboratory provided the following credentials for TP#1 on 6/17/2025: -Associate in Science degree, Nursing. 3. Further review of the CMS 209 on the date of survey revealed TP#1 was not listed as a TC. 4. TP #1 confirmed the above findings on 6/17/2025 at 12:30 pm.