

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0970932	(X3) Date Survey Completed 10/27/2025
Name of Provider or Supplier Lori Mcauliffe Md Pa	Street Address, City, State 405 S Pasadena Ave South, Saint Petersburg, FL	
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	An announced CLIA recertification survey was conducted at Lori McAuliffe MD PA on 10/27/2025. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited were as follows:
D5413	<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: Based on record review and interview, the laboratory failed to monitor the percent humidity of the room where testing was performed using the Cell-Dyn Emerald Hematology analyzer from 11/2024 to 09/2025. Findings included: 1. The Cell-Dyn Emerald Hematology analyzer validation study was reviewed. The analyzer was put into use 11/25/2024. 2. The Cell-Dyn Emerald Operator's Manual with a date of June 2010 was reviewed. The manual documented an operational maximum humidity of 80%. 3. Temperature Logs were reviewed for 02/2025 and 09/2025. There was no documentation that showed the laboratory monitored the percent humidity. 4. An interview with Laboratory Director on 10/27/2025 12:00 to 12:30 p.m. confirmed the above.</p>
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p>

(b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to--

This STANDARD is not met as evidenced by:

Based on record review and interview, the Technical Consultant failed to document and sign off on competency assessments for three of three testing personnel (TP) (TP #A, #B, #E) selected for review. Findings included: 1. TP #A's Job Description and Competency Evaluation Form was reviewed. Their date of hire was 12/27/2021. The records reflected and annual competency was due March 2024 and 2025. There was no annual competency evaluation for 2024 or 2025 completed or signed by the Technical Consultant. 2. TP #B's Job Description and Competency Evaluation Form was reviewed. Their date of hire was 01/02/2022. The records reflected and annual competency was due March 2024 and 2025. There was no annual competency evaluation for 2024 or 2025 completed or signed by the Technical Consultant. 3. TP #E's Job Description and Competency Evaluation Form was reviewed. Their date of hire was 01/20/2025. The initial competency was filled out but was not signed or dated by the Technical Consultant. The Form documented the 1st Review (competency) as 07/14/2025. 4. An interview with the Technical Consultant on 10/27/2025 from 12:00 to 12:30 p.m. confirmed the above.