

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D2103426	<b>(X3) Date Survey Completed</b>  07/01/2025
<b>Name of Provider or Supplier</b>  Bellin Health Generations	<b>Street Address, City, State</b>  720 Van Buren Street, Green Bay, WI	
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>D5403</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Item 1: Based on surveyor review of proficiency testing (PT) results, test procedures, and interview with the Technical Consultant (TC), one of one test procedures for potassium hydroxide (KOH) testing in the procedure manual did not address requirements for laboratory processing and referral based on specimen source. Findings include: 1. Review of PT results revealed testing personnel reported KOH PT results from vaginal source, and did not report KOH PT results from skin source. 2. Review of the procedure for KOH testing showed the laboratory accepted</p>

specimens from both vaginal and skin sources for onsite testing. 3. Interview with the TC on July 1, 2025, at 11:25 AM confirmed that KOH testing from skin source was not performed onsite, and confirmed the procedure did not include instructions for processing and referring samples from skin source to a reference laboratory for testing. Item 2: Based on surveyor observation in the laboratory, review of test procedures, and interviews with Testing Personnel (Staff A) and the Technical Consultant (TC), one of one test procedures for hematology slide staining in the procedure manual did not address requirements for preparation of in-use HEMA 3 stains for hematology slides. Findings include: 1. The surveyor observed unlabeled coplin jars containing liquids in the laboratory on July 1, 2025, at 10:15 AM. 2. Interview with Staff A on July 1, 2025, at 10:15 AM confirmed the coplin jars contained HEMA 3 stains used for staining hematology slides. 3. Review of the 'HEMA 3 Differential Stain' procedure showed the procedure did not address labeling of the coplin jars containing in-use stains transferred from original containers. 4. Interview with the TC on July 1, 2025, at 11:15 AM confirmed the 'HEMA 3 Differential Stain' procedure did not include instructions to label the coplin jars used to hold in-use stains for staining hematology slides.

**D5415**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(c)

(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:  
Based on surveyor observation of coplin stain jars in the laboratory and interview with Testing Personnel (Staff A), three of three solutions for hematology slide staining were not labeled to indicate identity, storage requirements, preparation, and expiration dates. Findings include: 1. The surveyor observed unlabeled coplin jars containing liquids in the laboratory on July 1, 2025, at 10:15 AM. 2. Interview with Staff A on July 1, 2025, at 10:15 AM confirmed the unlabeled coplin jars contained HEMA 3 stains for staining hematology slides.