

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2209126	(X3) Date Survey Completed 03/30/2022
Name of Provider or Supplier Bellin Health Escanaba	Street Address, City, State 610 S Lincoln Road, Escanaba, MI	
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
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Consultant #3 (TC3), the laboratory failed to ensure the risk assessment as part of the Individualized Quality Control Program (IQCP) assessed the potential risks within its own laboratory environment for the Biosite Triage Meter since it was put into use on 10/18/21. Findings include: 1. A review of the laboratory's IQCP revealed the laboratory director approved the plan on 10/18/21 for the laboratory's troponin and D-dimer testing. 2. A review of the laboratory's risk assessment for the Biosite Triage Meter revealed the data used in the risk assessment was from the verification study performed at a different laboratory. 3. An interview on 3/30/22 at 1:08 pm with TC3 confirmed the laboratory did not use data obtained in its own environment for the risk assessment in the IQCP for troponin and D-dimer testing.</p>
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials</p>

for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

. Based on record review and interview with Technical Consultant #3 (TC3), the laboratory failed to ensure the staining characteristics for peripheral blood smears were acceptable for 2 (11/22/2021 and 10/14/21) of 5 dates reviewed when patient peripheral blood smear evaluations were performed. Findings include: 1. A review of patient test records revealed the following patients had peripheral blood smears evaluated and no documentation of stain quality assessed that day: a. Patient 34357723 on 10/14/21. b. Patient 34944064 on 11/22/21. 2. The surveyor requested stain quality documentation for the dates listed above on 3/30/22 at 1:52 pm and it was not made available. 3. An interview on 3/30/22 at 2:27 pm with TC3 confirmed the laboratory did not have documentation of stain characteristics for the dates listed above.