

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D1093324	(X3) Date Survey Completed 12/05/2018
Name of Provider or Supplier Bellin Health Fmc Bellevue	Street Address, City, State 3263 Eaton Rd, Green Bay, WI	
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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor review of the federal Certification and Survey Provider Enhanced Reports (CASPER) and College of American Pathologists (CAP) Proficiency Testing reports, the laboratory failed to participate successfully in proficiency testing for hematocrit in the Hematology Specialty in 2018. Findings include: 1. The laboratory had unsatisfactory scores for hematocrit testing for the first and third proficiency testing events in 2018. Unsatisfactory scores for a single analyte in two out of three proficiency testing events is unsuccessful participation. See D 2130.</p>
D2130	HEMATOLOGY

CFR(s): 493.851(f)

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on surveyor review of the federal Certification and Survey Provider Enhanced Reports (CASPER) and College of American Pathologists (CAP) Proficiency Testing (PT) reports, the laboratory failed to perform successfully in PT for the hematocrit analyte in the Specialty of Hematology. Findings include: 1. Review of the "Individual Laboratory Profile" PT report in the federal CASPER reporting system showed the laboratory performed unsatisfactorily in two out of three PT events for hematocrit testing in the Specialty of Hematology in 2018. 2018 Event one, score 40% and 2018 Event three, score 40%. 2. Review of the CAP PT evaluation reports confirmed the unsatisfactory 2018 PT scores for hematocrit for the first and third events in 2018. *Event FH4-A 2018: The laboratory submitted unacceptable results for samples FH4-01, 02 and 03. *Event FH4-C 2018: The laboratory submitted unacceptable results for samples FH4-13, 14 and 15. The resulting 40% scores for event one and event three in 2018 were unsatisfactory. Unsatisfactory performance for two out of three events is unsuccessful PT performance.

D5461

CONTROL PROCEDURES

CFR(s): 493.1256(d)(6)(g)

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-- Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on surveyor review of quality control and patient test records, and interview with the technical consultant, the laboratory did not perform quality control material testing before testing patient samples with a new lot of d-dimer reagents. Findings include: 1. Review of control records showed d-dimer lot number 64626 was first tested with control materials on November 21, 2018. 2. Review of patient test records showed d-dimer lot number 64626 was used for patient testing on November 18 and November 19, 2018. 3. Interview with the technical consultant, staff A, on December 5, 2018 at 1:45 PM confirmed d-dimer patient testing was performed with a new lot number of reagents prior to testing the new reagents with control materials.