Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0920451	05/15/2018
Name of Provider or Supplier	**Street Address, City, State**	
Bellin Hfmc Howard	2714 Riverview Dr, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the Technical Consultant, the laboratory has not evaluated the accuracy of Post Vasectomy Semen testing twice annually. Findings include: 1. Review of laboratory records from 2016 and 2017 show no evidence of twice annual accuracy evaluation for Post Vasectomy Semen testing. 2. Interview with the Technical Consultant on May 15, 2018 at 1:30 PM confirmed accuracy of test results had not been verified in 2016 and 2017. This is a repeat deficiency previously cited on March 23, 2010 and March 25, 2014.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor review of performance verification records, laboratory information system (LIS) records, patient test reports, and interview with the technical consultant, the laboratory director failed to provide overall management and direction in accordance with 493.1407 of this subpart. Findings include: 1. The laboratory director did not ensure that the new reference range obtained from verification procedures for the Thyroid Stimulating Hormone (TSH) analyte was implemented prior to patient

	result reporting with the new TSH methodology. See D6024. 2. The laboratory director did not ensure that patient test reports had the correct reference range for TSH test results. See D6026.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on surveyor review of performance verification records for the Dimension EXL chemistry analyzer, review of the laboratory information system (LIS) records, and interview with the technical consultant, the laboratory director failed to ensure appropriate actions were taken when the reference range for Thyroid Stimulating Hormone (TSH) changed on December 6, 2016. Findings include: 1. Review of performance verification records for the new Dimension EXL chemistry analyzer show that the new TSH LOCI methodology does not have the same reference range as the Dimension Expand chemistry analyzer which was being replaced by the Dimension EXL analyzer. The new TSH LOCI methodology reference range for the Dimension EXL chemistry analyzer was approved by the laboratory director and was 0.36-3.74 uIU/mL. Review of verification records show the new Dimension EXL chemistry analyzer was implemented for patient testing on December 6, 2016. 2. Review of current LIS records show that TSH results are reported with a reference range of 0.34-4.82 uIU/mL. 3. Interview with the technical consultant on May 15, 2018 at 3:30 PM confirmed the laboratory director failed to ensure that the new reference range for the TSH analyte was implemented.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on surveyor review of performance verification records for the Dimension EXL chemistry analyzer, review of patient test reports, and interview with the technical consultant, the laboratory director failed to ensure the correct reference range for Thyroid Stimulating Hormone (TSH) is provided on patient reports. Findings include: 1. Review of performance verification records for the new Dimension EXL chemistry analyzer show that the new TSH LOCI methodology does not have the same reference range as the Dimension Expand chemistry analyzer which was being replaced by the

	Dimension EXL analyzer. The new TSH LOCI methodology reference range for the Dimension EXL chemistry analyzer was approved by the laboratory director and was 0.36-3.74 uIU/mL. Review of verification records show the Dimension EXL chemistry analyzer was implemented for patient testing on December 6, 2016. 2. Review of patient test reports show that TSH results are reported with a reference range of 0.34-4.82 uIU/mL. 3. Interview with the technical consultant on May 15, 2018 at 3:30 PM confirmed the laboratory director failed to ensure that the correct reference range for TSH testing was on patient reports.