Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0400263	06/17/2021
Name of Provider or Supplier	**Street Address, City, State**	
Burnsville Family Physicians	1000 W 140th Street Suite 100, Burnsville, MN	

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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to ensure a Chemistry procedure (performance verification) was approved, signed, and dated by the laboratory director prior to use. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 06/17/21, at 9:05 a.m. 2. An Alfa Wassermann ACE Alera chemistry analyzer was observed as present and available for use during the tour of the laboratory. 3. Performance verification activities were completed and the laboratory began testing patient specimens using the analyzer on 04 /29/19, as confirmed by TP1. 4. The laboratory Director did not approve, sign, or date the Precision, Reportable Range, Accuracy and Expected Range performance verification documents prior to use of the analyzer. 5. In an interview on 06/17/21, at 12:30 p.m., TP1 confirmed the above finding. .
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: . Based on direct observation, document review and interview with laboratory personnel, the laboratory failed to verify the reference ranges for a chemistry analyzer prior to reporting patient test results. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 06/17/21, at 9:05 a.m. 2. An Alfa Wassermann ACE Alera chemistry analyzer was observed as present and available for use during the tour of the laboratory. 3. In an interview on 06/17/21, at 12:30 p.m., TP1 indicated the laboratory began testing patient specimens using the analyzer on 04/29/19. 4. By review of laboratory records, the laboratory failed to verify the reference ranges of the following chemistry analytes prior to testing patient samples: Cholesterol Triglycerides High Density Lipoprotein Low Density Lipoprotein Carbon Dioxide Creatinine Glucose Sodium Potassium Chloride Total Protein Albumin Alkaline Phosphatase Alanine Aminotransferase Aspartate Aminotransferase Total Bilirubin Direct Bilirubin Calcium 5. In an interview on 06/17/21, at 12:30 p.m., TP1 confirmed the above finding. .
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure reference intervals were consistent between a Chemistry procedure and a patient test report. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 06/17/21, at 9:05 a.m. 2. An Alfa Wassermann ACE Alera chemistry analyzer was observed as present and available for use during the tour of the laboratory. 3. Performance verification activities were completed and the laboratory began testing patient specimens using the analyzer on 04/29/19, as confirmed by TP1. 4. Reference intervals listed in the "Chemistry Analyzer - Alfa Wassermann ACE Alera" procedure, found in the Laboratory Policy & Procedure Manual, were not consistent with that included on a patient test report reviewed on date of survey as indicated below. Date of Service: 07/10/20 Patient: Female, 58 years Analyte Procedure Report Carbon dioxide 23.0 - 30.0 20 - 32 Creatinine 0.6-1.30 0.7 - 1.18 Glucose 70 - 99 60 - 99 Sodium 136.0 - 146.0 135 - 146 Blood Urea Nitrogen6 - 25 7 - 25 Calcium 8.5 - 10.4 8.6 - 10.3 5. In an interview on 06/17/21, at 12:30 p.m., TP1 confirmed the above finding. .