Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2064568	05/22/2018
Name of Provider or Supplier	**Street Address, City, State**	
Browne Medical, Llc	907 Oak Tree Avenue, Suite H, South Plainfield, NJ	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on surveyor review of the Competency Assessment (CA) records and interview with the Technical Consultant (TC), the laboratory failed to perform CA correctly on nine out of nine TP in 2017. The findings include: 1. The laboratory did not document what records were reviewed and how CA was assessed. 2. The laboratory did not document assessment was for which tests. 3. The TC confirmed on 5/22/18 at 1:00 pm that CA was not performed correctly.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on surveyor observation of the Quality Control (QC) material, review of the Manufacturer Package Insert and interview with the Technical Consultant (TC), the laboratory failed to follow the MPI instructions for hematology Boule Con-Diff Tri-level controls on the day survey. The findings include: 1. The MPI stated "Open QC vial stability 14 days after opening". a. The laboratory did not record new expiration

	date on vials. 2. The TC confirmed on 5/22/18 at 1:10 pm the laboratory failed to follow the MPI instructions.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on surveyor review of Temperature Records (TR) and interview with the Technical Consultant (TC), the laboratory failed to records room and refrigerator temperature accurately in April 2018. The findings include: 1. A review of TR revealed that refrigerator temperature was recorded in freezer column and vise versa but the Quality assurance reviewer did not noticed and signed off on it. 2. The TC confirmed on 5/22/18 at 2:00 pm that room and refrigerator temperatures was not recorded accurately.