Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2064571	12/19/2019
Name of Provider or Supplier	**Street Address, City, State**	
Browne Medical, Llc	464 Eagle Rock Avenue, Suite C, West Orange, 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
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to retain all PT records performed with the American Proficiency Institute for event 2 of 2018. The TP #4 listed on CMS for 209 confirmed on 12/19/19 at 1:30 pm that the laboratory failed to retain all PT records.
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 Testing Personnel (TP), the laboratory failed to follow the CA correctly for four out of seven Testing Personnel (TP) and two of two Technical Consultants (TC) in the calendar year 2018 to the date of the survey. The findings include: 1. The laboratory did not document review of records on TP #3 listed on CMS form 209. 2. Four of seven TP did not have a CA performed in the calendar year 2018. 3. Two of two TC did not have a CA performed in 2019 on the date of the survey. 4. The TP #4 listed on CMS form 209 confirmed on 12/19/19 at 1:20 pm that the CA procedure was not followed.

D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on surveyor review of the Maintenance Record (MR) and interview with the Testing Personnel (TP), the laboratory failed to perform and document monthly maintenance as specified by the manufacturer on the Medonic analyzer used in Hematology testing in April and June 2018 and January 2019. The TP #4 listed on CMS form 209 confirmed on 12/19/19 at 2:05 pm that there was no evidence of monthly maintenance as specified by the manufacturer.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a lack of a Quality Assurance (QA) plan and interview with the Testing Personnel (TP), the Laboratory Director failed to establish a QA plan from January 2018 to the date of the survey. The TP #4 listed on CMS from 209 confirmed on 12/19 /19 at 1:50 pm that a QA plan had not been established.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of Personnel Files and interview with the Testing Personnel (TP), the Laboratory Director failed to have training and education documented for TP in the calendar year 2018 to the date of the survey. The findings include: 1. There was no documented training for TP #7 listed on CMS form 209. 2. There was no diploma on

	file for TP #2 and Technical Consultants #1 and #2 listed on the CMS form 209. 3. The TP #4 listed on CMS form 209 confirmed on 12/19/19 at 1:00 pm that the records stated above were not available.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the Laboratory Director failed to have an approved procedure manual available for Hematology testing on the date of the survey. The TP #4 listed on CMS form 209 confirmed on 12/19/19 at 1:40 pm an approved PM was not available.