

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D2064568	<b>(X3) Date Survey Completed</b> 12/05/2019
<b>Name of Provider or Supplier</b> Browne Medical, Llc	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3037</b>	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Technical Consultant (TC), the laboratory failed to retain graded results received from the American Proficiency Institute for event 1-2019. The TC #2 listed on CMS form 209 confirmed on 12/5/19 at 12:45 pm that all PT records were not retained.</p>
<b>D5221</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Technical Consultant (TC), the laboratory failed to review and evaluate results when they received an unacceptable score in Hematology tests performed with the American Proficiency Institute for the first event in the calendar year 2019. The findings include: 1. The laboratory received an 80% Grade for Erythrocyte Count, Hematocrit, Hemoglobin, and Leukocyte Count for 2019 event 1. 2. There was no documented evidence that the laboratory investigated the failures. 3. The TC #2 listed on CMS form 209 confirmed on 12/5/19 at 1:10 pm that the laboratory did not review and document an evaluation of unacceptable PT results.</p>
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p>

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual (PM), Quality Control records and interview with the Technical Consultant (TC), the laboratory failed to follow their PM policy for "Corrective Actions for Out-of-Control Situations" for Hematology tests on 5/8/19 and 10/7/19. The findings include: 1) The PM stated "If control results indicate a problem appropriate action(s) must be taken and documented in the remedial action log". 2) High Controls were run three times on 5/8/19 there was no documented remedial action. 3) Normal controls were run five times and High controls eight times on 10/7/19 with no documented remedial action. 4) The TC #2 confirmed on 12/5/19 at 1:05 pm the above mentioned procedure was not followed.