

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D0965574	<b>(X3) Date Survey Completed</b>  11/30/2022
<b>Name of Provider or Supplier</b>  Englewood Women's Services	<b>Street Address, City, State</b>  200 Grand Avenue, Englewood, 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>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), observation of the Quality Control (QC) material and interview with the Testing Personnel (TP), the laboratory failed to follow all procedures written for "To Obtain Control Samples for Daily Quality Control Testing:" from 7/5/22 to the date of the survey. The findings include: 1. The procedure "To Obtain Control Samples for Daily Quality Control Testing:" stated "Samples should be kept in a test tube (Purple top) with anti-coagulant (E.D.T. A)". 2. Both Positive and Negative QC were kept in a Red Top serum test tube. 3. The TP confirmed on 11/30/22 at 1:30 pm that the laboratory did not follow the PM.</p>