

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2276117	(X3) Date Survey Completed 07/14/2023
Name of Provider or Supplier Advanced Biomedical	Street Address, City, State 224 S Peters Rd Ste 206, Knoxville, TN	
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
D3009	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, request of documentation and staff interview, determined the laboratory failed to obtain a State of Tennessee Medical Laboratory license required and issued by the State of Tennessee, Department of Health, for operation of a reference laboratory since patient testing began on 03.10.2023. The findings include: 1. Observation of the laboratory on 07.14.2023 at approximately 10:00 am revealed the following instruments in use for patient testing that began on 03.10.2023: Germain Flu A&B screen, Quick Vue Strep A Screen, Hemmoccult fecal occult blood, Henry Schein urine drug screen, Globe Scientific erythrocyte sedimentation rate, Clinitek 500 Urinalysis, Beckman Coulter AU480 Chemistry analyzer, Sysmex CA500 Coagulation analyzer, Sysmex XT-1800 complete blood count analyzer, and urine microscopics. 2. Request for the State of Tennessee Medical Laboratory license revealed there was not one available for surveyor review. 3. Interview on 07.14.2023 at approximately 10:30 am with the on-site Clinical Consultant confirmed the laboratory was functioning as a reference laboratory and had not applied for a State of Tennessee Medical Laboratory license resulting in the laboratory not following the State of Tennessee, Department of Health's laboratory requirements for patient testing that began 03.10.2023.</p>