

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0940011	(X3) Date Survey Completed 12/06/2023
Name of Provider or Supplier Advanced Breath Diagnostics, Llc	Street Address, City, State 105 Westpark Dr, Suite 150 C, Brentwood, 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
D5317	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d)</p> <p>If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, patient test report review, and staff interview, the laboratory failed to provide instructions to clients that collect patient specimens to include patient preparation, specimen collection, specimen labeling, specimen storage, preservation, or conditions for transportation on the date of the survey (12/06/2023) for serum human chorionic gonadotropin (hCG) testing. The findings include: 1. Observation of the laboratory on 12/06/2023 at 10:00 am revealed an OSUM combo test kit in use for serum hCG patient testing. 2. Review of a patient test report revealed a serum hCG reported on 11/16/2023 for patient #C23016 that was collected from an outside client. 3. During an interview with the laboratory director on 12/06/2023 at 10:30 am, the laboratory director was asked to provide a copy of instructions provided to the outside client(s) that included the requirements for patient preparation, specimen collection, specimen labeling, specimen storage, preservation, or conditions for transportation for the serum hCG patient testing. No document was available. This confirmed the survey findings.</p>