

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D1092600	(X3) Date Survey Completed 06/06/2019
Name of Provider or Supplier Advanced Biomedical Db a United Diagnostic Lab	Street Address, City, State 2754 Veach Road, Owensboro, KY	
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
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of personnel records and staff interview on 06/06/2019, the laboratory director failed to ensure appropriate training for services offered was documented for Testing Personnel #2 listed on the Laboratory Personnel Report 209 prior to the start of patient testing 04/27/2019. Findings include: Analyzer 1. Review of personnel records revealed the hire date for Testing Personnel #2 was 03/26/2019. 2. There was no documentation of initial training on the Medonic Hematology Analyzer prior to 04/27/2019. 3. There was no documentation of initial training on the Instrumentation Laboratory ACL Coagulation Analyzer prior to 04/27/2019. 4. There was no documentation of initial training on the Beckman Coulter AU 480 Chemistry Analyzer prior to 04/27/2019. The Technical Supervisor acknowledged in an interview at 9:50 AM on 06/06/2019, the laboratory failed to have a system to ensure initial training was documented on each testing personnel prior to performing patient testing.</p>