

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2037153	(X3) Date Survey Completed 01/26/2021
Name of Provider or Supplier Advanced Pathology Solutions Llc	Street Address, City, State 5328 Northshore Cove, North Little Rock, AR	
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
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: . Through a review of the Individualized Quality Control Plan (IQCP) for QuantStudio 12K Flex (Wound Panel) and the Biofire FilmArray Gastrointestinal Panel, lack of documentation and interviews with staff, it was determined the laboratory failed to include the Quality Assessment component in the developing of their IQCPs and failed to include the environment and testing personnel components as part of the Risk Assessment. Survey Findings Follow: A. A review of IQCP for the QuantStudio 12 K Flex and the Biofire FilmArray Gastrointestinal Panel (2 of 2 IQCPs) revealed the following components: 1) Quality Control Component and 2) Risk Assessment which included the Specimen, Test System and Reagent components. B. The surveyor requested the Quality Assessment component, and the Environment and Testing Personnel components as part of the Risk Assessment. None was provided. C. In an interview at 1300 on 01/26/2021, laboratory personnel #12 (as listed on Form CMS 209) confirmed the laboratory failed to include the Quality Assessment, environment and testing personnel components in the developing of the IQCPs.</p>