

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1102394	(X3) Date Survey Completed 12/01/2021
Name of Provider or Supplier Texarkana Gastroenterology Consultants Pa	Street Address, City, State 1920 Moores Ln Ste A, Texarkana, TX	
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
D0000	The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. .
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: . Based on laboratory procedure, review of the CMS116, and confirmed in interview, the laboratory failed to perform a water rinse following disinfection of the FilmArray Pouch Loading station. The laboratory reported an estimated testing volume of 360 BioFire FilmArray Gastrointestinal panel tests, annually. 1. Review of the laboratory procedure titled 'FilmArray Gastrointestinal Panel' (FLM1-MKT-0071-02) Section 'Procedure', subsection 'Prepare Pouch' stated: "1. Thoroughly clean the work area and FilmArray Pouch Loading Station with freshly prepared 10% bleach (or suitable disinfectant) followed by a water rinse." 2. Review of the CMS116 section VII 'Non-Waived Testing' list and estimated annual test volume for the Microbiology specialty at approximately 360. 3. At 1350 hours on 12/1/2021, in the laboratory, the surveyor queried for the water used for the water rinse as listed in the procedure. The primary testing person stated that no water rinse was done after cleaning for the FilmArray Pouch Loading station. .</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other</p>

supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

. Based on surveyor's observation and confirmed in interview, the laboratory failed to label aliquoted staining reagents with storage requirements, preparation, and expiration dates for ten of ten reagents used for the staining histopathology specimens.

1. Surveyor observed the partially labeled reagents in aliquoted containers, under a hood, for staining in the laboratory at 1400 hours on 12/1/2021: Xylene Alcohol Water Hematoxylin Eosin Bluing Clarifier Acetic Acid Alcian Blue Perodic Acid 2. In an interview at 1500 hours on 12/1/2021 in the laboratory, the primary testing person confirmed that the reagents were in use for histopathology staining, and that they were unaware each aliquoted container needed to be labeled with storage requirements, preparation, and expiration dates. .