

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1102394	(X3) Date Survey Completed 06/05/2019
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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: . Based on review of laboratory policy for use of the BioFire FilmArray GI panel, the laboratory failed to document a change in procedure required by the manufacturer into lab policy; in addition this change showed no evidence of having been approved by the laboratory director. Findings: 1. On 03-05-2019, an Urgent Medical Device Recall notice was sent out to users of the BioFire FilmArray GI panel advising that, due to elevated rates of false positives using the system, positive Campylobacter and Cryptosporidium results should be confirmed by other methods before reporting. This was followed by another notice from the manufacturer on 03-13-2019, advising that positive results for Campylobacter and Cryptosporidium be confirmed by retesting with a new GI Panel pouch or an alternate assay, and that only results for confirmatory testing for those analytes should be reported. The notice affected panels with expiration dates of 10-23-2019 onward. 2. Review of laboratory policy showed no documentation reflecting addition of the notice or changes to policy reflecting the manufacturer's recommendations. 3. In an interview at the site on 06-05-2019, the laboratory technical consultant (CMS form 209) stated that testing personnel were aware of the notice, but it had yet to be addressed in laboratory policy. She further stated that since the time the notice was issued no patient specimens had tested positive for Campylobacter or Cryptosporidium. .</p>
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations</p>

Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

. Based on review of laboratory quality control documentation for 2018 and 2019 confirmed by staff interview, the laboratory failed to perform controls at the required frequency when testing patient samples using the BioFire FilmArray Gastrointestinal (GI) panel. Findings: 1. Quality control records for 2018 and 2019 were reviewed. The laboratory was performing quality controls on the BioFire FilmArray GI panel according to manufacturer's recommendations; monthly and at lot change. According to materials provided the laboratory tests an average of 360 patient specimens a year using the system. 2. In an interview at the site on 06-05-2019, testing person 1 (CMS form 209) stated she was unaware of the regulatory requirement to perform controls on qualitative procedures at least once per day of patient testing if the laboratory has not developed an individual quality control plan (IQCP). .