Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0478401	01/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
Ellis County Medical Associates, Pa	802 West Lampasas, Ennis, 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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . Based on review of laboratory documentation for the Bio-Fire FilmArray analyzer, confirmed by staff interview, the laboratory failed to document verification of accuracy and precision before reporting patient test results. Findings: 1. During the entrance conference for the survey on 01-24-2018, it was revealed that the laboratory had added a new instrument, the Bio-Fire FilmArray analyzer, for detection of gastrointestinal and respiratory pathogens, in December 2017. Testing person 1 (CMS form 209) stated the analyzer had been set up and verification performed by laboratory personnel under the supervision of the manufacturer's field service technician before patient testing began. 2. Documentation of the verification study was requested. Documents offered included information on possible protocols for assay verification supplied by the manufacturer and instrument result printouts showing repeat testing of samples on 12-18, 19 and 20 of 2017. No information regarding what protocol was employed or what conclusions were reached was available. No evidence of review or approval by the laboratory director was offered. .
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)

	(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: . Based on review of testing personnel competency verification documents for 2016 and 2017, confirmed by staff interview, the technical consultant failed to annually evaluate the competency of 2 of 3 testing personnel. Findings: 1. Competency verification documents were reviewed. Forms for testing persons 2 and 3 were signed by testing person 1. 2. Education and training documents were reviewed. It was determined that testing person 1 did not meet the education and training requirements for technical consultant. 3. In an interview at the site on 01-24-2018, testing person 1 stated she had performed the evaluations and signed competency verification documents for testing persons 2 and 3, and that she was unaware regulations precluded delegation of this duty to her. .
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: . Based on review of testing personnel training and evaluation documentation, confirmed by staff interview, the laboratory technical consultant failed to document performance evaluation for one of three testing personnel at least semiannually during the first year of patient testing. Findings: 1. Testing personnel training and evaluation documents were reveiwed. Documents for testing person 1, hire date 12-19-2016, included forms indicating completion of training and evaluation on 01-03-17. No documents indicating semiannual evaluation were made available. 2. In an interview at the site on 01-24-2018, testing person 1 stated that her performance had not been evaluated since the initial date of 01-03-2017. .