Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D1018905	04/16/2019
Name of Provider or Supplier	**Street Address, City, State**	
Family Medicine Associates Of Lincoln County, Pllc	1531 North Aspen Street, Lincolnton, NC	

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
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of a random patient test report, and interview with staff on 4/16/19, the laboratory director failed to ensure that the laboratory's Prostatic Specific Antigen (PSA) test reports included the identity of the assay used. Finding: The laboratory performed Prostatic Specific Antigen (PSA) testing using the Access Hybritech PSA intended for use on the Bachman Coulter Access 2 immunoassay analyzers. The manufacturer's product insert (A85067c, REF 3720) for this test reads in the section entitled, "WARNING: ...The concentration of PSA in a given specimen determined with assays from different manufacturers can vary due to differences in assay methods and reagent specificity. The results reported by the laboratory to the physicians must include the identity of the PSA assay used...". Review of a random computer generated patient report (#11489) revealed that the test report did not include the method used for PSA. During interview at approximately 2: 00 p.m., the laboratory manager and the technical consultant confirmed that the PSA method was not included in patient test reports.