Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0315452	02/11/2019
Name of Provider or Supplier	**Street Address, City, State**	
Jackson Urological Associates Pc	28 Medical Center Drive, Jackson, TN	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual, employee personnel records for 2017, 2018, and 2019, and interview with the lead testing personnel, the laboratory failed to have a procedure to include all six criteria for assessing personnel competency. The findings include: 1) Review of the laboratory procedure manual revealed the following six criteria were not included in the procedure and competency documentation: direct observation of routine patient test performance; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results and preventative maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and assessment of problem solving skills. 2) Review of the 2017, 2018, and 2019 employee personnel records revealed no documentation of competency assessment for the six required criteria. 3) Interview on February 11, 2019 at 1:30 p.m. with the lead testing personnel confirmed the testing personnel competency procedure did not include the six criteria for testing personnel competency assessment required by the Centers for Medicare and Medicaid Services (CMS). _____
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)

	(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of patient test reports, record review and interview with the lead testing personnel, the laboratory's quality assessment was ineffective when it failed to detect incorrect quality control (QC) limits for the Prostate Specific Antigen (PSA) were used in 2017. The findings include: 1) Review of patient number nine test report revealed patient testing for PSA on 06.01.2017. 2) Review of the laboratory's QC records revealed the following for the PSA analyte: Range Manufacturer in use Range Lot # 40901 .23 - .43 .29 - .424 Lot # 40902 3.14 - 4.56 2.96 - 4.28 Lot # 40903 23.6 - 32.8 20.2 - 31.4 Units of measure are in ng/mL. The incorrect ranges were in use from 2.6.2017 to 7.7.2017. The quality control reports were reviewed by both the lead testing personnel and the laboratory director on a monthly basis during this period with no corrective action documented. 3) Interview with the lead testing personnel on February 11, 2019 at 1:30 p.m. confirmed the laboratory's quality assessment process was ineffective it failed to detect incorrect QC limits were in use from 2.6.2017 to 7.7.2017 patient testing performed and no corrective action documented.