Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0315452	06/06/2022
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
D0000	493.51 Notification requirements for laboratories issued a certificate of compliance Laboratories issued a certificate of compliance must meet the following conditions: (a) Notify HHS or its designee within 30 days of any change in-- (1) Ownership; (2) Name; (3) Location; (4) Director; or (5) Technical supervisor (laboratories performing high complexity only). (b) Notify HHS no later than 6 months after performing any test or examination within a specialty or subspecialty area that is not included on the laboratory ' s certificate of compliance, so that compliance with requirements can be determined. (c) Notify HHS no later than 6 months after any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate of compliance. This requirement is not met as evidenced by: Based on review of the Centers for Medicaid and Medicare Services Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116), Aspen Web 116, laboratory procedure manual, and interview with the laboratory supervisor, the laboratory failed to notify of change in specialties within six months of the change in 2021. The findings include: 1. Review of the CMS Form 116 completed as part of the survey revealed current specialties did not include histopathology or cytology. 2. Review of the laboratory's specialties in Aspen Web 116 revealed histopathology and cytology listed as specialties. 3. Review of the laboratory procedure manual revealed histopathology and cytology were discontinued effective 12.31.2020. 3. Request to the laboratory supervisor on 06/06/2022 at 9 am for documentation of the State Agency notification of change in specialties revealed no documentation was available. 4. Interview with the laboratory supervisor on 06/06/2022 at 3 pm confirmed the laboratory failed to notify the State Agency of the deletion of specialty for histopathology and cytology within six months of the change in 2021.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check

	protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the manufacturer instructions for use, document request, interview with the laboratory supervisor,and review of email communication, the laboratory failed to verify the accuracy of the urine centrifuge timer and speed (revolutions per minute (rpm)) 2020, 2021, and 2022. The findings include: 1. Observation of the laboratory on 06/06/2022 at 8:30 am revealed a centrifuge in use for spinning down urine specimens in preparation for urine microscopic exam. 2. Review of the manufacturer instructions for use revealed the following: "Centrifuge for 5 minutes at 400 rcf (1500 rpm)." 3. Request made to the lab supervisor on 06/06/2022 at 11:00 for documentation of verification of accuracy for the urine centrifuge timer and rpm revealed no documentation was available for 2020, 2021. and 2022. 4. Interview with the laboratory supervisor on 06/06/2022 at 3 pm confirmed the laboratory failed to verify the accuracy of the urine centrifuge timer and rpm in 2020, 2021, and 2022. 5. Review of additional information received via email from the laboratory supervisor on 06/13/2022 revealed approximately 16, 186 patient were tested between June 1, 2020 until May 31, 2022 during the period when the accuracy of the timer and rpm of the urine centrifuge had not been verified.