Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 17D0889880	**(X3) Date Survey Completed** 07/26/2021
Name of Provider or Supplier Associates In Women's Health, Pa	**Street Address, City, State** 3232 E Murdock St, Wichita, KS	
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**
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 an absence of thermometer function check records or certificates of accuracy, protocols for thermometer function checks and interview, the laboratory failed to define and perform a function check protocol for 4 of 4 thermometers. Findings: 1. No documentation was available for function checks on 4 of 4 thermometers at the time of survey. 2. No documentation was available for the certification of accuracy (NIST traceble) on 4 of 4 thermometers at the time of survey. 3. Proctocols for function checks of the thermometers were not made available at the time of survey. 4. Interview with the technical consultant on 7/26/2021 at 1140 a.m. confirmed, the laboratory failed to define and perform a function check protocol for 4 of 4 thermometers.