

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  17D2164374	<b>(X3) Date Survey Completed</b>  09/17/2021
<b>Name of Provider or Supplier</b>  Women's Health Group, Pa East, The	<b>Street Address, City, State</b>  8315 Positano Dr, Manhattan, KS	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5391</b>	<p>PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242.</p> <p>This STANDARD is not met as evidenced by: Due to a lack of policies, procedures, specimen rejection logs and interview with the Technical Consultant (TC), the laboratory failed to have written policies, procedures, and Quality Assurance (QA) documentation available for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic system. Findings: 1. A request was made to review the preanalytical policies and procedures. None were made available at the time of survey. 2. A request was made to review the specimen rejection log for QA documentation. None were made available at the time of survey. 3. Interview with the TC 9/17/21 at 12:00 p.m. confirmed, the laboratory failed to have written policies, procedures, and QA documentation available for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic system.</p>
<b>D5435</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>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</p>

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 certificates of accuracy, protocols for thermometer function checks and interview with the TC, the laboratory failed to define and perform a function check protocol for two of two thermometers. Findings: 1. Documentation made available for function checks on two of two thermometers were performed with another thermometer beyond its certificate of accuracy period. Accuracy was not verified. 2. No documentation was available for the certification of accuracy (NIST traceable) on two of two thermometers at the time of survey. 3. Protocols for function checks of the thermometers were not made available at the time of survey. 4. Interview with the TC on 9/17/2021 at 12:30 a.m. confirmed, the laboratory failed to define and perform a function check protocol for two of two thermometers.