

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  26D0871788	<b>(X3) Date Survey Completed</b>  08/29/2018
<b>Name of Provider or Supplier</b>  Womens Eastern Reception Diagnostic	<b>Street Address, City, State</b>  1101 East Highway 54, Vandalia, MO	
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>D6020</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(5)</p> <p>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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality control (QC) logs and QC plan and interview with the technical consultant, the laboratory director failed to ensure the QC program was maintained. Findings: 1. Review of the QC plan revealed the laboratory director approved a frequency of monthly external positive and negative controls for Troponin testing. 2. Review of the QC logs for Troponin testing revealed the laboratory failed to run a positive and negative control for months of January and February 2018. 3. Interview with the technical consultant on August 29, 2018 at 11 :00 AM confirmed the laboratory director failed to ensure the QC program was maintained throughout the testing process for the analyte, Troponin.</p>