

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 07D2086844	<b>(X3) Date Survey Completed</b> 03/15/2019
<b>Name of Provider or Supplier</b> Medical Laboratory Diagnostics -Vernon	<b>Street Address, City, State</b> 281 Hartford Tpke, Suite 204, Vernon, CT	
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>D5781</b>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document corrective action when the laboratory freezer temperature was out of range. Findings include: 1. Record review of the laboratory specimen freezer temperature logs on 3/15 /19 revealed: a. Acceptable freezer temperature range is -25 C. to -15 C. b. Corrective action was not documented for 43 working days from January 12, 2017 through March 15, 2019 when the temperature was outside of the above range. c. Temperature logs were signed as reviewed by the laboratory director. 2. Staff interview with the phlebotomy supervisor, phlebotomist #1, and testing personnel #1 on 3/15/19 at 9:30 AM confirmed the above findings.</p>
<b>D6024</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(7)</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</p>

and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified,

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory director failed to ensure corrective action(s) were documented by the laboratory when the specimen freezer temperature was out of range. Findings include: 1. Record review of the laboratory specimen freezer temperature logs on 3/15/19 revealed: a. Acceptable freezer temperature range is -25 C. to -15 C. b. Corrective action was not documented for 43 working days from January 12, 2017 through March 15, 2019 when temperature was outside of the above range. c. Temperature logs were signed as reviewed by the laboratory director. 2. Staff interview with the phlebotomy supervisor, phlebotomist #1, and testing personnel #1 on 3/15/19 at 9:30 AM confirmed the above findings.