

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D1087302	(X3) Date Survey Completed 09/18/2018
Name of Provider or Supplier Quest Diagnostics Llc	Street Address, City, State 111 Salem Tpke, Norwich, CT	
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
D5781	<p>CORRECTIVE ACTIONS 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 take corrective action when the laboratory freezer temperature was out of range. Findings include: 1. Record review of the endocrinology laboratory freezer (SN#170718426) temperature log on 9/18/18 reveled: a. Acceptable freezer temperature range in 2018 was -20 to -70 C. b. Freezer temperature was out of acceptable range as follows in 2018: January 3 days February 1 day April 2 days May 7 days June 1 day July 8 days August 12 days September 9 days c. Corrective action documented for each occurrence outside the above range indicated "could not be determined" 2. Staff interview with technical consultant (TC) on 9/18/18 at 10:30 AM confirmed the freezer temperature was out of range as indicated above and corrective actions were not effective. TC also stated that the equipment is inconsistent in holding the recommended temperature of -20 to -70C.</p>