

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D2107878	(X3) Date Survey Completed 03/29/2018
Name of Provider or Supplier Quest Diagnostics Llc	Street Address, City, State 54 Hazard Ave, Ste 90, Enfield, 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 specimen freezer temperature was out of range. Findings include: 1. Record review of the laboratory's "Appendix C/ Min/Max Temperature Monitoring Log" for the specimen freezer on 3/29/18 revealed the following: a. Freezer temperature was out of range on 11 of 26 working days in January 2018. b. Freezer temperature reading was overwritten on 5 of 26 days in January 2018. c. Freezer temperature was out of range on 5 of 24 working days in February 2018. d. Freezer temperature reading was overwritten on 2 of 24 days in February 2018. e. Freezer temperature reading was overwritten on 15 of 25 days in March 2018. 2. Staff interview with the technical consultant (TC) on 3/29/18 at 11:10 AM confirmed corrective action was not documented for each occurrence when the specimen freezer temperature was out of range. TC stated freezer temperature is unstable and corrective actions are not effective.</p>