

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2097795	(X3) Date Survey Completed 05/18/2018
Name of Provider or Supplier Diagnostic Solutions Laboratory, Llc	Street Address, City, State 5895 Shiloh Road, Suite 101, Alpharetta, GA	
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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on May 18, 2018. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on document review and an interview with the Facility's Technical Supervisor (TP) # 1 (CMS 209), the laboratory failed to monitor Relative Humidity (RH) daily as recommended by manufacturer (between 15 - 80%) for the QuantStudio 3 and 5 Real-Time PCR Systems Analyzer. Findings include: 1.) Document review revealed no documentation for (RH) in 2016, 2017 and January through May of 2018. 2.) An interview with the Facility's Technical Supervisor TP # 1(CMS 209) at approximately 12:30 pm on May 18, 2018 in the staff conference room confirmed Relative Humidity (RH) was not monitored throughout the laboratory.</p>