Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2158603	12/20/2019
Name of Provider or Supplier	**Street Address, City, State**	
H&M Molecular Diagnostics Llc	3770 Tansy St, Ste 101, San Diego, CA	

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
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of random patient testing records, quality control (QC) data, and interview with the laboratory director (LD)and testing personnel (TP); it was determined that the laboratory failed to include QC materials for each molecular amplification procedure performed. The laboratory must document all control procedures performed. The findings included: a. The laboratory uses Polymerase Chain Reaction (PCR) method to amplify extracted bacterial DNA for 15 organisms as well as resistant genes with no QC materials for all isolates performed. b. For five (5) out of five (5) patient test records reviewed covering period from 12/3/2019 to 12 /17/2019, three (3) of the fifteen (15) organisms isolated, the laboratory did not include positive QC controls which could have affected the results accuracy. c. The LD and TP confirmed (12/20/2019, 14:00) that the laboratory failed to include positive QC material used for molecular amplification for the organism (S. saprophyticus, M. morganii, and E. cloacae).
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

	This STANDARD is not met as evidenced by: Based on review of random patient testing records, quality control (QC) data, and interview with the laboratory director (LD)and testing personnel (TP); it was determined that the laboratory director failed to ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. See D5449.