Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0645348	08/26/2019
Name of Provider or Supplier	**Street Address, City, State**	
Fdoh Bureau Of Public Health Laboratories - Miami	1325 Nw 14th Ave, Miami, FL	

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
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control records and interview with TS #1, the laboratory failed to check each shipment of microbial identification systems containing two or more substrates for both positive and negative reactivity. Findings: Review of quality control records revealed: a. API Coryne identification system quality control performed failed to include a positive control for the substrate "MAN" b. API RapID 20E identification system quality control performed failed to include a negative control for substrate "GLU" c. API 20E identification system quality control performed failed to include a positive control for "OX". d. API 20NE identification system quality control performed failed to include a negative control for "OX". e. API 20 Strep identification system quality control performed failed to include a negative control for substrates "BGUR", "LAP, "ADH", "RIB", "SOR", and "LAC", and failed to include a positive control for "BGAL" and "ARA". f. API 50 CH identification system quality control performed failed to include positive control for biochemicals located in cupules 3, 7, 9, 14, 16, 20, 33, 34, 38, 41, 42, 43, 46, and 49. API 50 CH identification system quality control performed failed to include negative controls for biochemicals located in cupules 11, 12, 32 and 22. During on August 29, 2019 at approximately 5pm, TS #1 confirmed the quality control testing of microbial identification systems failed to include positive and negative controls as listed above.

D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review and interview with TS #1, the laboratory failed to include all six competency assessment when performing competency assessments on testing personnel. Findings: 1. Review of testing personnel competency assessment records for the years 2017 and 2018 revealed proficiency testing records, observations of testing and a few records of problem solving, but did not include all six competency assessment criteria. 2. During interview on August 26, 2019 at approximately 5pm, TS #1 confirmed all six competency assessment criteria were not included in testing personnel competency assessment records.