Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0645546	09/14/2023
Name of Provider or Supplier	**Street Address, City, State**	
Department Of Health Bureau Of Public Health	3602 Spectrum Blvd, Tampa, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of laboratory staff competency assessment records, review of laboratory standard operating procedures (SOP) and interview with laboratory staff, the laboratory failed to perform competency assessments for technical and general supervisors and failed to follow their procedures. Findings included: 1. Review of personnel competency assessment records on September 13, 2023 and September 14, 2023 for years 2022 and 2023 found no competency assessment documentation for the technical supervisor and general supervisor in the microbiology section of the laboratory. 2. Review of the "Microbiology Departmentt [sic] Personnel Competency Assessment SOP" on September 13, 2023 revealed the following: Page 6: "C. Elements of Competency Applicable to Test System for Technical Supervisor 1. Supervisor ensures the laboratory section is enrolled and participating in an approved HHS approved proficiency testing program..." An appendix to the SOP contained a seven page form titled "Documentation of Competency (Technical Supervisor)". 3. During interview on September 13, 2023 at 4 PM, the microbiology technical supervisor confirmed competency assessments for the technical supervisor were not performed. She further confirmed the microbiology personnel assessment SOP did not include guidance for a competency assessment of the general supervisor or a timeframe for when the competency assessments for technical superior and general supervisor are performed.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)

	At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records, lack of testing documentation, and interview with Technical Supervisor for Virology, the laboratory failed to at least twice annually, verify the accuracy for Dengue 1-4 PCR and the Triplex assay: Zika, Dengue, Chikungunya for 2021 and 2022 as evidenced by: 1. In review of the laboratory's proficiency testing records, the laboratory couldn't provide documentation of proficiency testing or twice annual accuracy verification for Dengue 1-4 PCR and Triplex assay: Zika, Dengue, Chikungunya. 2. In interview with Technical Supervisor for Virology on 9/13/2023 at 1521 stated that they had not verify the accuracy for those assays in 2021 and 2022. He stated the last time they did any type of verification for accuracy was in 2019 with CDC proficiency testing.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory's patient test reports, and interview with the Technical Supervisor #3, the laboratory failed to follow manufacturer's instructions in regards to the limitations of not testing patients less than 14 years of age for the Aptima 2 combo gonorrhea and chlamydia from January 1, 2023 to the date of the survey as evidenced by: 1. In review of the manufacturer's instructions, Aptima 2 Combo assay, states under limitations, "The performance of the Aptima Combo 2 assay has not been evaluated in adolescents less than 14 years of age. 2. In review of the laboratory's patient test reports the following random sampling of patients were under the age of 14 at the time of testing: a. TSA23002914 report date 1/31/2023 DOB 12/12/2010 12 years of age. b. TSA23002915 report date 1/31 /2023 DOB 7/16/2009 13 years of age. c. TSA23002915 report date 1/31/2023 DOB 1 /22/2011 12 years of age. d. TSA23001054 report date 1/12/2023 DOB 5/27/2009 13 years of age. e. TSA23021005 report date 7/26/2023 DOB 10/22/2009 13 years of age. f. TSA23018548 report date 6/28/2023 DOB 8/19/2009 13 years of age. g. TSA23013538 report date 5/10/2023 DOB 6/3/2009 13 years of age. h.TSA23013545 report date 5/10/2023 DOB 7/18/2010 12 years of age. i.TSA23010730 report date 4 /12/2023 DOB 7/24/2009 13 years of age. j.TSA23007046 report date 3/8/2023 DOB 4/6/2009 13 years of age. k.TSA23006441 report date 3/2/2023 DOB 4/7/2011 11 years of age. The laboratory performed the assay on 35 patients in 2023 that were under the age of 14. 3. In interview with Technical supervisor #3 on 09/12/2023 at 1135 stated that they don't have policies in place or have a mechanism in their laboratory information system to reject those under the age of 14. He also stated that they did not have studies for those under the age of 14.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)

	The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation, interview with laboratory staff and review of user manual, the laboratory failed to monitor the temperature in the sample preparation area for the Bruker MALDI Biotype CA System. Findings included: 1. During the tour of the laboratory's Bruker MALDI sample preparation area on September 13, 2023 at 4 PM, the surveyor observed a room with a biological safety cabinet (BSC) in which MALDI sample preparation took place. The surveyor did not observe a thermometer or other device to monitor the temperature in the room or inside the BSC. 2. During interview on September 13, 2023 at 4 PM, the microbiology technical supervisor confirmed the temperature was not monitored in the Bruker MADLI sample preparation area. 3. Review of the Bruker MALDI Biotyper CA System User Manual Revision N found the following on page 19: "2.4 Environmental Requirements - Sample Preparation ... For best results, preparation of all solutions, Standard Solvent, and the entire sample preparation process including drying steps must be performed under controlled room temperature. In this User Manual, "room temperature" refers to this temperature range." The room temperature range referenced in the user manual was +20C (+68F) to +25C (+77F).