

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0899963	(X3) Date Survey Completed 05/08/2025
Name of Provider or Supplier Miami Beach Community Health Center	Street Address, City, State 1221 71st St, Miami Beach, 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
D0000	An announced CLIA validation survey was conducted at MIAMI BEACH COMMUNITY HEALTH CENTER on 05/08/2025. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory Director (LD) failed to sign attestation for seven out of seven events of Proficiency Testing (PT) reviewed in 2023, 2024 and 2025 for Urinalysis and Microscopy (Urine Sediment, Vaginal Wet preparation and Vaginal Wet preparation KOH) and for the 3rd event of 2024 the Testing Personnel (TP) for Microscopy section failed to sign the attestation. Findings included: 1-Review of Form CMS-209 signed by the LD on 05/08/2025, revealed that the LD was the Clinical Consultant (CC) and Technical Consultant (TC). The laboratory had 5 TP (TP#1, TP#2, TP#3, TP#4 and TP#5). 2- Review of PT records revealed that: TP1, TP2, and TP#3 did the urinalysis test and TP#4 and TP#5 did the Microscopy tests. 2-Review of PT records from American Proficiency Testing (API) for 2023(1st, 2nd, 3rd events), 2024 (1st, 2nd, 3rd events) and first event of 2025 for Urinalysis and Microscopy (Urine sediment, Vaginal Wet preparation and Vaginal Wet preparation (Potassium Hydroxide)(KOH)), revealed that the attestations were not signed by the LD instead were signed by a Lead Technologist (TP#1). There was no designee letter. 3-Review of PT records from API for the 3rd event of 2024 revealed that TP#4 who did the test based on records reviewed failed to sign the attestation on 10/30/2024 4-During the interview on 05/08/2024 at 11:20 AM, the</p>

TP#3 confirmed that the LD failed to sign the attestation and TP#4 failed to sign attestation for 3rd event of 2024 for the Microscopy tests.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b)(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. The procedures for evaluation of the competency of the staff must include, but are not limited to--

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the Technical Consultant (TC) failed to perform the competency for three out of three Testing Personnel (TP) doing Urinalysis and for two out of two doing direct mount and Wet preparation with Potassium Hydroxide (KOH) in 2023, 2024 and 2025. Findings included: 1-Review of FORM-209 (01/2021) signed and dated by the Laboratory Director (LD) on 05/08 /2025, revealed that the LD, Clinical Consultant (CC), and TC was the same person and there were five TP (TP#1, TP#2, TP#3, TP#4 and TP#5) 2-Review of personnel records revealed the following: a) TP#1, TP#2 and TP#3 performed Urinalysis test. b) TP#4 and TP#5 performed the Urine Sediment, Direct Mount, KOH test. c) Competencies for the five TP were signed by a Lead Technologist for 2023, 2024 and 2025. 3-During an interview on 05/08/2025 at 11:30 AM, TP#3 confirmed that the TC failed to do the competencies for all TP.