

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0645343	(X3) Date Survey Completed 09/12/2024
Name of Provider or Supplier University Of Miami Immunology And	Street Address, City, State 1600 Nw 10th Ave Rmsb 8149, 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
D0000	A recertification survey was conducted on 9/9/2024 to 9/12/2024. University of Miami Immunology and Histocompatibility clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D3005	<p>FACILITIES CFR(s): 493.1101(a)(3)</p> <p>Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to have a uni-directional workflow for Polymerase chain reaction (PCR) testing. Findings Included: During a tour of the laboratory on 09/12/2024 at 11:00 AM , it was a revealed that the laboratory did not have uni-directional work flow for PCR reagents. The fridges and freezers are located in a corner of the laboratory so reagents and specimen cross through an open space by PCR Elite instrument, Bench top and a accessioning table. Review of ELITe InGenius manual read," The ELITe InGenius system operates in CLOSED or OPEN mode. The CLOSED mode enables the user to run only IVD assay protocols. The CLOSED mode is also considered as a depository including all the IVD validated assay protocol according to the IFUs of the ELITe MGB assays in use. Modification of assay protocols or creation of a new assay protocol are not allowed in the CLOSED mode. The OPEN mode enables the user to run also additional non-IVD user-defined assay protocols developed by the laboratory to fit their specific needs. Review of HISTO MOL 5 VIR BK, CMV & EBV PCR Testing on the EliTech ELITE InGenius System signed by laboratory director on 6/2/2024 read, " Login when prompted (in OPEN mode). Review of HISTO MOL 10 VIR Zika PCR Testing on the EliTech InGenius System signed by laboratory director on 4/13 /2024 read,"Thaw at room temperature the tubes containing the Positive and Negative</p>

Controls, 20X Zika PreMix, PCR MasterMix and MS2 RNA Internal Control. Mix by vortexing and centrifuge the tubes to bring the contents to the bottom. Prepare the Zika ELITE MGB Monoreagent sufficient for the required number of reactions, including the positive and negative controls according to Table 1 (see below). 8.7.1 Prepare and label a 2.0 mL Sarstedt tube for the Zika ELITE MGB Monoreagent. 8.7.2 Mix by vortexing, centrifuge the tube to bring the content to the bottom, and then keep in orange cooler until ready to transfer to the ELITE InGenius (Trademark) instrument. Prepare the Ready-to-Use MS2 RNA Internal Control Mix sufficient for the required number of reactions, including the positive and negative controls. 8.8.1 Prepare and label a 0.5 mL Sarstedt tube for the Ready-to-Use MS2 RNA Internal Control Mix. 8.8.2 First add the nuclease-free water (not included) and then the MS2 RNA Internal Control template. After transferring the MS2 RNA Internal Control mix the solution several times to ensure complete transfer. Mix by vortexing, centrifuge the tube to bring the contents to the bottom, and then keep the Ready-to-Use MS2 RNA Internal Control mix in the orange cooler until ready to transfer to the ELITE InGenius (Trademark) instrument. Interview on 09/12/2024 at 11:00 PM the Technical Supervisor confirmed PCR testing did not have a uni-directional workflow.

D5441

CONTROL PROCEDURES
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the laboratory failed to run quality controls the same day of Zika Virus polymerase chain reaction (PCR) testing for one day out of three months reviewed (September 2022, June 2023 and February 2024). Findings include: 1-Review of policy "HISTO MOL10 VIR Zika PCR Testing on the EliTech InGenius System." Last approval by Laboratory Director on 04/13/2024 revealed that it stated on page 3: "7. QUALITY CONTROL 7.1 Positive and Negative control from kit must be used daily, with expected results. 7.2 Daily, weekly, and monthly maintenance must be performed on the InGenius." 2- Review of Zika quality controls records for September 2022, June 2023 and February 2024 revealed that on 09/15/2022 there was no quality control records, review of a instrument printout of 09/15/2022 at 10:28 PM, revealed that the laboratory tested four samples without a quality control. During an interview on 09/11/2024 at 04:30 PM, the Virology Supervisor confirmed that the laboratory did not run controls on the same testing date of the samples of reference.

D5781

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken

when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on observation, review of temperature logs, and interview, the laboratory failed to document corrective action for temperatures that were out of range for the reagents stored in refrigerator D, and freezers #22, #24, #31 and #36 from 01/03/2023 to 09/10/2024. Findings: Refrigerator D Observation on 09/09/2024 at 4:15 PM, revealed the temperature range was 15-30 degrees Celsius (C) for the Michel Wash Solution. Review of the Refrigerator D Preventive Maintenance log listed the temperature range was 2 to 8 degrees C. On 09/09/2024 at 4:15 PM General Supervisor A acknowledged the Michel Wash Solution was incorrectly stored. Freezer #22 Observation on 09/11/2024 at 11:22 AM, showed the temperature range was -20 to -65 degrees C for Freezer #22 for SSP Class I & Class II Wipe Test. Review of the temperature logs for Freezer #24 showed that the freezer was warmer than -65 degrees C for 18 of 424 days the temperatures were recorded. Freezer #24 Observation on 09/10/2024 at 4:10 PM, showed the temperature range was range was -65 to -85 degrees C for the following reagents: LymphoTrack IGK Assay S5/PGM, LymphoTrack FR1/2/3 Assay S5/PGM, and LymphoTrack TRG Assay S5/PGM Review of the temperature logs for Freezer #24 showed that the freezer was warmer than -65 degrees C for 424 of 424 days the temperature was recorded. Freezer #31 Observation on 09/09/2024 at 4:10 PM, showed the temperature range was less than or equal to -10 degrees C for the following reagents in Freezer #31: MGB Alert Internal Control Set IC2-B, MGB Alert Internal Control Set IC1, SARS-CoV RUA, and MGB Alert HSV 1&2 Probe Mix ASR Review of the temperature logs for Freezer #31 showed that the freezer was warmer than -10 degrees C for 7 of 424 days the temperature was recorded. Observation on 09/09/2024 at 4:10 PM, showed the temperature range was -15 to -25 degrees C for the following reagents in Freezer #31: LightCycler FastStart DNA Master HybProbe, Real-Time PCR Systems Spectral Calibration Kit II 96-Well, RealStar HEV RT-PCR Kit 2.0, and Invitrogen Yeast RNA. Review of the temperature logs for Freezer #31 showed that the freezer was warmer than -15 degrees C for 66 of 425 days the temperature was recorded. Observation on 09/09/2024 at 4:10 PM, showed the temperature range was -20 degrees C or below for the following reagents in the Freezer #31: Adenovirus Low Run Control, Adenovirus High Run Control, Adenovirus Verification Panel, BKV Low Run Control, BKV High Run Control, BKV Verification Panel, CMV Low Run Control, CMV High Run Control, CMV Verification Panel, EBV High Run Control, EBV Low Run Control, EBV Verification Panel, HHV-6B Verification Panel, HSV-1 Low Run Control, HSV-1 High Run Control, HSV-1 Verification Panel, Parvovirus B19 Low Run Control, Parvovirus B19 High Run Control, Parvovirus B19 Verification Panel, PQ Elite MGB Kit, and Negative Run Control. Review of the temperature logs for Freezer #31 showed that the freezer was warmer than -20 degrees C for 411 of 424 days the temperature was recorded. Freezer #36 Observation on 09/11/2024 at 11:30 AM, showed the temperature range was less than or equal to -20 degrees C in Freezer #36 for All Type Fastplex NGS 11 Loci Kit. Review of the temperature logs for Freezer #36 showed that the freezer was warmer than -20 degrees C for 195 of 424 days the

temperatures were recorded. Observation on 09/11/2024 at 11:30 AM, showed the temperature range was -15 to -25 degrees C in Freezer #36 for All Type NGS Library Prep Kit. Review of the temperature logs for Freezer #36 showed that the freezer was warmer than -15 degrees C for 17 of 424 days and colder than 25 degrees C for 32 of 424 days the temperatures were recorded. Review of the temperature logs for the freezers showed listed the temperature range as -5 to -35 degrees C and there was no documentation of corrective action taken for temperatures On 09/11/2024 at 11:20 AM General Supervisor A acknowledged there was no corrective action documented when temperatures where out of range for reagents stored in them.