

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2326295	(X3) Date Survey Completed 03/06/2026
Name of Provider or Supplier University Of Miami Hospital & Clinics	Street Address, City, State 2111 Sole Mia Way Ste 7030, North 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	An announced CLIA initial survey was conducted at UNIVERSITY OF MIAMI HOSPITAL & CLINICS -SOLE MIA from February 5, 2026 to March 6, 2026. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiency cited as follows:
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. This STANDARD is not met as evidenced by: Based on records review and staff interview, the laboratory failed to have documentation of the acceptability of the Quality Control (QC) slide for Hematoxylin & Eosin (H&E) stain on February 2026. Findings included: 1-Review of policy "AP 02-Intraoperative Consultations (Frozen Section) Procedure approved by the laboratory Director on 10/09/2025, revealed that in section "QUALITY CONTROL", stated " If the frozen section was performed at the UMHC then, confirmation of optimal H&E stain by the attending pathologist will be via electronic image transmission. In these cases, the log will state "H&E stain was reviewed via electronic image transmission by attending pathologist's initials" under comments the case number will be written, and the attending pathologists name as well." 2-The laboratory used the "H & E Stain Quality Log" to record the acceptability of the daily H&E stain. Review of the QC log for February 2026 testing dates 02/03/2026 and 02 /04/2026, revealed that the laboratory documented the Nuclear Quality Stain and Cytoplasmatic Quality, the name of the Pathologist, the case number and the Initials of the Histotechnologist. The laboratory failed to document that the pathologist did

the review via electronic image and failed to have documentation of the acceptance by the pathologist. 3-Review of "INTRA-OPERATIVE CONSULTATION FORM" and final report for case #1 (date 02/03/2026) and case #2 (02/04/2026), revealed that no reference to the acceptability to the Quality control of the stain by the pathologist was not documented. 4-During an interview on 02/05/2026 at 12:00 PM the Director of Laboratory Services for Anatomic Pathology confirmed that the laboratory failed to document the acceptability of the Daily QC slide for H& E Stain by the pathologist for the days of reference in item 2.