

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2036991	(X3) Date Survey Completed 10/14/2025
Name of Provider or Supplier University Of Miami Hospital And Clinics -	Street Address, City, State 8100 Sw 10th Street Crossroad Business Park Big 3, Plantation, 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 recertification survey was conducted at UNIVERSITY OF MIAMI HOSPITAL AND CLINICS - PLANTATION from September 15, 2025 to October 14, 2025. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
D6047	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(i)</p> <p>(b)(8)(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the Technical Consultant (TC) or a designee failed to do direct observation of patient testing during competency evaluation for testing personnel (TP), for three out four TP in 2025. Findings included: 1- Review of FORM CMS 209 signed by the Laboratory Director on 09/15 /2025, revealed the following: Laboratory Director (LD) was also Clinical Consultant. The laboratory had two Technical Consultant (TC#1, TC#2) for Chemistry specialty, and two Technical Supervisor (TS#1, TS#2); TS#2 was also the General Supervisor (GS) for the Hematology specialty. The laboratory had four testing persons (TP#1, TP#2, TP#3 and TP#4). 2-Review of personnel records initial competency for TP#1 for the Stago (9) coagulation and the Sysmex XN-1000, both analyzers in the Hematology specialty, revealed that the competency for patient testing was observed by TP#2 and on 01/06/2025 for Stago (9) and on 01/10/2025 for Sysmex XN-1000. TP#2 had no delegation letter to do competency. 3- Review of personnel records annual competency for TP#3, revealed that the direct observation of patient testing with the Integra 400 in Chemistry specialty and with the for Sysmex XN-1000 in Hematology specialty, was observed by TP#2 on 04/15/2025. TP#2 had no delegation letter to do competency. 4-Review of personnel records six-month competency for</p>

TP#4 for the Integra 400 in Chemistry specialty, revealed that the competency for patient testing was observed by TP#2 on 06/05/2025. TP#2 had no delegation letter to do competency. 5-During an interview on 09/15/2025 at 11:53 AM, the GS and TP#2 confirmed that TC did not perform the patient testing observation during competency for TP#1 on 01/10/2025 and 01/06/2025, TP#3 on 04/15/2025 and TP#4 on 06/05/2025.

D6050

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(iv)

(b)(8)(iv) Direct observation of performance of instrument maintenance and function checks;

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the Technical Consultant (TC) or a designee failed to do direct observation of performance of instrument and function check during competency evaluation for testing personnel (TP) for three out four TP in 2025. Findings included: 1- Review of FORM CMS 209 signed by the Laboratory Director on 09/15/2025, revealed the following: Laboratory Director (LD) was also Clinical Consultant. The laboratory had two Technical Consultant (TC#1, TC#2) for Chemistry specialty, and two Technical Supervisor (TS#1, TS#2) for Hematology specialty; TS#2 was also the General Supervisor (GS) for the Hematology specialty. The laboratory had four testing persons (TP#1, TP#2, TP#3 and TP#4). 2- Review of personnel records initial competency for TP#1 revealed that the direct observation of performance of instrument and function check for the Stago (9) coagulation and the Sysmex XN-1000 in the Hematology specialty, were observed by TP#2 and on 01/06/2025 for Stago (9) and on 01/10/2025 for Sysmex XN-1000. TP#2 had no delegation letter to do competency. 3-Review of personnel records annual competency for TP#3, revealed that the direct observation of performance of instrument and function check for the Integra 400 in Chemistry specialty, was observed by TP#2 on 04/15/2025. TP#2 had no delegation letter to do competency. 4- Review of personnel records six-month competency for TP#4, revealed that the direct observation of performance of instrument and function check for Integra 400 for Chemistry specialty was observed by TP#2 on 06/05/2025. TP#2 had no delegation letter to do competency. 5- During an interview on 09/15/2025 at 11:53 AM, the GS and TP#2 confirmed that TC failed to do direct observation of performance of instrument and function check during competency for TP#1 on 01/10/2025 and 01/06/2025, TP#3 on 04/15/2025 and TP4 on 06/05/2025.

D6121

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(8)(i)

The procedures for evaluation of the competency of the staff must include, but are not limited to-- (b)(8)(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the Technical Supervisor (TS) or a designee failed to do direct observation of patient testing during competency evaluation for three testing personnel (TP) out of four in 2025. Findings included: 1-- Review of FORM CMS 209 signed by the Laboratory Director on 09/15/2025,

revealed the following: Laboratory Director (LD) was also Clinical Consultant. The laboratory had two Technical Consultant (TC#1, TC#2) for Chemistry specialty, and two Technical Supervisor (TS#1, TS#2) for Hematology specialty; TS#2 was also the General Supervisor (GS) for the Hematology specialty. The laboratory had four testing persons (TP#1, TP#2, TP#3 and TP#4). 2-Review of personnel records initial competency for TP#1 revealed that the direct observation of patient testing with the Sysmex XN-1000 in the Hematology specialty, was observed by TP#2 on 01/10/2025. TP#2 had no delegation letter to do competency. 3- Review of personnel records annual competency for TP#3, revealed that the direct observation of patient testing with the Sysmex XN-1000 in Hematology specialty, was observed by TP#2 on 04/15/2025. TP#2 had no delegation letter to do competency. 4- Review of personnel records six-month competency for TP#4 revealed that the direct observation of patient testing with the Sysmex XN-1000 in Hematology specialty, was observed by TP#2 on 06/05/2025. TP#2 had no delegation letter to do competency. 5- During an interview on 09/15/2025 at 11:53 AM, the TS/GS admitted did not perform the patient testing observation during competency for TP#1 on 01/10/2025, TP#3 on 04/15/2025 and TP#4 on 06/05/2025.

D6124

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(8)(iv)

(b)(8)(iv) Direct observation of performance of instrument maintenance and function checks;

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the Technical Supervisor (TS) or a designee failed to do direct observation of performance of instrument and function check during competency evaluation for three out of four testing personnel (TP) in 2025. Findings included: 1- - Review of FORM CMS 209 signed by the Laboratory Director on 09/15/2025, revealed the following: Laboratory Director (LD) was also Clinical Consultant. The laboratory had two Technical Consultant (TC#1, TC#2) for Chemistry specialty, and two Technical Supervisor (TS#1, TS#2) for Hematology specialty; TS#2 was also the General Supervisor (GS) for the Hematology specialty. The laboratory had four testing persons (TP#1, TP#2, TP#3 and TP#4). 2-Review of personnel records initial competency for TP#1 revealed that the direct observation of performance of instrument and function check with the Sysmex XN-1000 in the Hematology specialty, was observed by TP#2 on 01/10/2025. TP#2 had no delegation letter to do competency. 3- Review of personnel records annual competency for TP#3, revealed that the direct observation of performance of instrument and function check with the Sysmex XN-1000 in Hematology specialty, was observed by TP#2 on 04/15/2025. TP#2 had no delegation letter to do competency. 4- Review of personnel records six-month competency for TP#4 revealed that the direct observation of performance of instrument and function check with the Sysmex XN-1000 in Hematology specialty, was observed by TP#2 on 06/05/2025. TP#2 had no delegation letter to do competency. 5- During an interview on 09/15/2025 at 11:53 AM, the TS /GS admitted did not perform direct observation of performance of instrument and function check during competency for TP#1 on 01/10/2025, TP#3 on 04/15/2025 and TP#4 on 06/05/2025.