Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D1071563	06/11/2025
Name of Provider or Supplier	**Street Address, City, State**	
National Institute On Aging Irp/Lci	3001 S Hanover St 5th Floor, Baltimore, MD	

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 record review and interview with laboratory staff, the laboratory failed to have a policy to assess competency for technical consultant and clinical consultant for 2 of 2 years reviewed. Findings included: 1. Review of the form CMS 209 (Laboratory Personnel Report) signed by the laboratory director on June 9, 2025, found the laboratory had one Technical Consultant and three Clinical Consultants. 2. Review of the Standard Operating Procedures manual found no policy or procedure for assessing the competency of the Technical Consultant or the Clinical Consultants. 3. Review of laboratory staff competency assessment documentation found no assessments for the one Technical Consultant and three Clinical consultants for 2023 and 2024. 4. During interview on June 11, 2025, at 10:25 am, Testing Personnel 1 (TP 1) stated the laboratory has never performed competency assessments for the Technical Consultant or the Clinical Consultants.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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, review of manufacturer's instructions, lack of humidity records, and interview with staff, the laboratory failed to ensure the humidity range was within manufacturer's specifications for the operation of 3 of 3 chemistry analyzers. Findings included: 1. During a tour of the laboratory on June 11, 2025, at approximately 12 pm, two YSI 2900 chemistry analyzers (serial numbers 18B100529 and 18B100530) and one Horiba Pentra C400 analyzer (serial number 701C4-0472) were observed. 2. The operator's manual for the YSI 2900 analyzer stated the following: "1.4 2900 Series General Specifications ... Working Environment:... Relative Humidity 10% - 75%, (non-condensing)" 3. The operator's manual for the Horiba Pentra C400 analyzer stated the following: "2. 2 Humidity and Temperature Conditions ... Humidity Conditions: Relative humidity of 20% - 85% maximum, without condensation." 4. The surveyor requested and did not receive records documenting humidity levels in the laboratory. 5. During interview on June 11, 2025, at approximately 12:10 pm, Testing Personnel 1 (TP 1) stated humidity levels were not monitored or documented in the laboratory.