Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0704110	08/26/2025
Name of Provider or Supplier	**Street Address, City, State**	
Nih Niddk Pecrb Decrs	1550 E Indian School Rd, Phoenix, AZ	

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 review of laboratory records and interview with staff, the laboratory failed to have a competency assessment policy and failed to perform competency assessments for clinical consultants. 1. Review of the form CMS-209 (Laboratory Personnel Report) signed by the Laboratory Director on August 20, 2025, the laboratory employed three Clinical Consultants. 2. Review of the laboratory's "Staff Competency" binder found no competency assessments for the three Clinical Consultants, nor a policy for competency assessment for Clinical Consultants. 3. During interview on August 26, 2025, at approximately 9:45 am, the Laboratory Director stated the three Clinical Consultants did not have competency assessments, nor did the laboratory have a policy for assessing the competency of Clinical Consultants.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure, direct observation, laboratory testing records, and interview with the laboratory director, the laboratory failed to follow their procedure and ensure the conditions of transport were within their temperature ranges for specimens (Glucose and Complete Blood Counts) received from outside laboratories for one of one months reviewed as evidenced by: 1. In review of the the laboratory's procedure titled Glucose Policy and Methodology stated. "the glucose concentration is general stable for as long as 8 hours at 25 degrees C and up to 72 hours at 4 degree C." 2. In review of the laboratory's procedure titled Symex XN-450 Automated Hematology Analyzer stated," If stored at 2-8 within 6 hours of collection. EDTA blood samples with normal results may be analyzed up to 48 hours..." 3. In direct observation at 1144 the laboratory did not take temperature once open the shipping container was opened or recorded temperature environment of the specimens that were being transported. The following patient was observed: a. ETCH0317 4. In review of the laboratory testing records from August 2025 to the date of the survey, the laboratory did not document the conditions of transport for glucose and Complete Blood Counts (CBCs). The laboratory provided no documentation to ensure specimen were within 2-8 degrees C and 4 degree C. 3. In interview with the laboratory director at 1204 she confirmed they did not record temperatures of the specimens when received from outside laboratories. She also stated that all specimens come in with ice packs and should be refrigerated.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with laboratory staff, the laboratory failed to perform maintenance on analyzers as required by the manufacturer for two of two analyzers. I. TOSOH AIA-900 No Serial Number Available 1. Review of the TOSOH AIA-900 immunoassay analyzer maintenance log found the log contained maintenance requirements for daily, weekly, monthly and quarterly tasks. Quarterly maintenance tasks were not documented by the laboratory for seven of seven months (January 2025-July 2025). 2. During interview on August 26, 2025, at approximately 1:30 pm, the Laboratory Director confirmed the laboratory failed to perform quarterly maintenance for the TOSOH AIA-900. II. TOSOH G8 Analyzer Serial Number 15631210 1. Review of the TOSOH G8 HPLC (High Performance Liquid Chromatography) analyzer maintenance log found the laboratory failed to replace the fluid supply line filters as required by the manufacturer for eight months (November 2024-June 2025). 2. Review of the TOSOH Bioscience operator manual on page 162 found the following: "5.9 Suction Filter Replacement - every 6 months ..." 3. During interview on August 26, 2025, at approximately 1:30 pm, the Laboratory Director confirmed the laboratory failed to replace the fluid supply line filters on the TOSOH G8 every six months.