

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2124280	(X3) Date Survey Completed 11/20/2024
Name of Provider or Supplier Clinical Discovery Institute Llc	Street Address, City, State 7901 Riviera Blvd Suite 100, Miramar, 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 from 11/05/2024 to 11/20/2024. CLINICAL DISCOVERY INSTITUTE clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to retain Quality Control (QC) record for one out of five testing days reviewed. Findings included: 1- Review of five patient reports and QC records for a Complete Blood Cell count (CBC): Patient (P)#1 (12/01/2022), P#2 (03/01/2024), P#3 (10/16/2023), P#4 (02/28/2024) and P#5 (09/09/2024), revealed that for P#1 the laboratory could not provide the QC records for that testing date. During an interview on 11/05/2024 at 12:35 PM, the Director of Research and Quality Systems (DRQS) explained that the laboratory could not locate the record for that day and the analyzer used for that test was not in use anymore (ACT5 Diff), the laboratory is currently using a different analyzer, the Sysmex XN 40. The surveyor agreed to give time to the laboratory to locate the record, during a call with the DRQS on 11/20/2024 at 1:30 PM she confirmed that the laboratory could not locate the record of reference.</p>