

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2244185	(X3) Date Survey Completed 03/04/2024
Name of Provider or Supplier Clear Labs Llc	Street Address, City, State 6318 N Cicero Ave, Chicago, IL	
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
D8100	<p>INSPECTION REQUIREMENTS CFR(s): 493.1771</p> <p>Each laboratory issued a CLIA certificate must meet the requirements in 493.1773 and the specific requirements for its certificate type, as specified in 493.1775 through 493.1780. All CLIA-exempt laboratories must comply with the inspection requirements in 493.1773 and 493.1780, when applicable.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor's direct observation and interview with the laboratory owner (LO); the laboratory failed to comply with the inspection requirements in 493.1773. (Refer to D8101).</p>
D8101	<p>BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(a)</p> <p>A laboratory issued a certificate must permit CMS or a CMS agent to conduct an inspection to assess the laboratory's compliance with the requirements of this part. A CLIA-exempt laboratory and a laboratory that requests, or is issued a certificate of accreditation, must permit CMS or a CMS agent to conduct validation and complaint inspections.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's direct observation and interview with the laboratory owner (LO); the laboratory failed to permit the scheduled Centers for Medicare & Medicaid Services (CMS) initial certification survey of the laboratory on 03/04/2024 at 9:00 a. m. Findings include: 1. Direct observation on 03/04/2024 at 9:35 a.m., revealed the LO taking photographs of the outside of CLIA # 14D2244185 - CLEAR LABS LLC, 6318 N Cicero Ave, Chicago, IL 60646. 2. Surveyor's interview with the LO on 03/04</p>

/2024, at 9:35 a.m., confirmed the CMS survey would be completed as scheduled. 3. Direct observation on 03/04/2024, at 9:43 a.m., revealed the LO returned to his vehicle and left the laboratory.