| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 99D2023356 | 01/15/2026 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Ichordx, Inc | 1300 Baxter Street, Suite 255, Charlotte, NC | |

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 |
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| **D0000** | Off-site revisit survey, May 19, 2026, found the deficiencies cited during the January 15, 2026 on-site survey are corrected and the laboratory is in compliance with 42 CFR Part 493 Requirements for Laboratories. |
| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and procedures, the absence of competency records for 2025, and interview with the Laboratory Director (LD) on 01/15/2026, the LD failed to perform the required annual competency assessments for the General Supervisors (GS #1 and GS #2) and Technical Supervisor (TS #2) for 2025. Findings: Review of laboratory policy, "Personnel Policy - Laboratory" section 6.13.5 page 6, revealed "...ongoing competency assessments...semi-annually in the first year after training...annually therafter." Review of laboratory procedure, "Training & Competency Assessment Procedure" section 3 page 2, revealed "Evaluating competency...semi-annually for the first year after completion of initial training and annually therafter..." Review of laboratory competency records revealed the absence of 2025 annual competency assessments for the following laboratory positions: GS #1 - 2025 GS #2 - 2025 TS #2 - 2025 During interview at approximately 3:46 p.m. the LD confirmed the absence of 2025 competencies for GS #1, GS #2, and TS #2. |
| **D6107** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(15)<br><br>(e)(15) Specify, in writing, the responsibilities and duties of each consultant and each |

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| | supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of personnel records for 2024, 2025, and 2026, and interview with the Laboratory Director (LD) 01/15/2026, the LD failed to specify in writing the duties and responsibilities for the Clinical Consultant (CC) involved with the daily operation of the laboratory and testing process. Findings: Review of personnel records for 2024, 2025, and 2026 revealed the absence of a job description for the CC position. During interview at approximately 2:02 p.m. the LD confirmed no position description available for the CC. |