

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D2022140	(X3) Date Survey Completed 12/07/2023
Name of Provider or Supplier Nura Plc Plc	Street Address, City, State 7450 France Ave S, Suite 265, Edina, MN	
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	The Nura PLLC laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the validation survey performed on December 7, 2023. The following standard-level deficiency was cited: 493.1242 Specimen submission, handling, and referral
D5313	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b)</p> <p>The laboratory must document the date and time it receives a specimen.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to document the time toxicology specimens were received into the laboratory for all specimens tested in 2022 and 2023. Findings are as follows: 1. The laboratory performed high complexity Toxicology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 10:05 a.m. on 12/07/23. 2. Specimens were received from a clinic located across the street from the laboratory and from another clinic located approximately 20 miles away. 3. The time of specimen receipt into the laboratory was not documented on three of three requisition forms from 2022 and 2023 reviewed on date of survey. 4. Requirements for specimen receipt time documentation were not found in the Processing Steps for Urine Drug Testing procedure located in the Laboratory Manual. 5. The laboratory performed approximately 86,756 toxicology tests annually as indicated on the Clinical Laboratory Improvements (CLIA) Application for Certification Form CMS-116 provided by the laboratory on date of survey. 6. In an interview at 11:35 a.m. on 12/07/23, the General Supervisor confirmed the above finding.</p>