| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 24D2259069 | 02/15/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Bloomington Labs Llc | 8040 Old Cedar Ave S, Bloomington, 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 Bloomington Labs LLC 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 initial survey performed on February 15, 2024. The following standard-level deficiency was cited: 493.1241 Test request . |
| **D5301** | TEST REQUEST<br>CFR(s): 493.1241(a)<br><br>The laboratory must have a written or electronic request for patient testing from an authorized person.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, document review, and interview with laboratory personnel, the laboratory failed to utilize written test request forms for all Toxicology testing completed from date of implementation in February 2024. Findings are as follows: 1. The laboratory performed Toxicology drugs of abuse testing as indicated by Testing Personnel 1 during a tour of the laboratory at 10:05 a.m. on 02/15/24. 2. A Thermo Fischer Scientific Indiko Plus clinical chemistry analyzer was observed as present and in use during the tour. The laboratory began testing using this analyzer on 02/08/24. 3. The Specimen Collection and Handling procedure, found in the laboratory's electronic procedures, indicated a requisition form accompanied each specimen to the laboratory and was used for specimen identity verification and test order entry into Beacon, the laboratory information system. 4. Requisition forms were not found for three of three patient test results reviewed on date of survey. The laboratory was unable to provide the requisition forms upon request. 5. In an interview at 12:30 p.m. on 02/15/24, the Laboratory Consultant (LC) confirmed the above finding and indicated requisition forms were not in use. The LC indicated patient names were emailed on a UA List to the collection personnel when testing was requested by a physician. |