

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0306899	(X3) Date Survey Completed 08/05/2024
Name of Provider or Supplier Urology Associates, Pc - Franklin	Street Address, City, State 4601 Carothers Parkway, Suite 475, Franklin, TN	
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
D5301	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: Based on a review of patient records and staff interviews, the laboratory failed to have written or electronic test requests from an authorized person for three of six patient test requisitions reviewed in 2023 and 2024. The findings include: 1. A random review of six patient laboratory orders revealed the following: - Patient 1980560 had the test "Semen Analysis - Post Vas" ordered on 01/03/2024 by the testing person (TP) -5 "on behalf of FRNR Franklin Nurse." - Patient 1977550 had the test "Semen Analysis - Post Vas" ordered on 12/11/2023 by TP-4 "on behalf of FRNR Franklin Nurse." - Patient 767410 had the test "Semen Analysis - Post Vas" ordered on 10/13 /2023 by TP-4 "on behalf of FRNR Franklin Nurse." - The physician signature lines on the laboratory orders for 1980560, 1977550, and 767410 were blank. 2. An interview with the technical consultant (TC) on 08/05/2024 at 11:30 a.m. revealed that "FRNR Franklin Nurse" was a generic profile in their electronic medical record system and not a specified provider. The TC confirmed that the laboratory did not document the authorized provider who ordered qualitative semen analysis testing for patients 1980560, 1977550, and 767410.</p>
D5787	<p>TEST RECORDS CFR(s): 493.1283(a)</p> <p>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4)</p>

The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:

Based on a review of patient test records, lack of documentation, and staff interviews, the laboratory failed to document the identity of the person performing qualitative semen analysis testing for three out of three patient test results reviewed in 2023 and 2024. The findings include: 1. A random review of patient records revealed the laboratory performed "Semen Analysis - Post Vas" testing on 01/03/2024 (ID: 1980560), 12/11/2023 (ID: 1977550), and 10/13/2023 (ID: 767410). 2. The laboratory could not provide documentation indicating the person who performed qualitative semen analysis testing on patients 1980560, 1977550, and 767410. 3. An interview with the technical consultant on 08/05/2024 at 11:30 a.m. confirmed the laboratory does not document the identity of the testing person performing qualitative semen analysis testing.