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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>24D2053440                  | <b>(X3) Date Survey Completed</b><br><br>07/12/2023 |
| <b>Name of Provider or Supplier</b><br><br>Minnesota Urology   | <b>Street Address, City, State</b><br><br>6001 96th Lane North Suite 250, Brooklyn Park, MN |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |   |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>  |
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| <b>D5417</b>              | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br/>CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by:<br/>                     . Based on observation and interview with laboratory personnel, the laboratory failed to ensure blood collection tubes were not used after the expiration date had been exceeded. Findings are as follows: 1. The laboratory performed Prostate Specific Antigen (PSA) under the subspecialty of Routine Chemistry as confirmed by North Region Clinic Manager (NRCM) during a tour of the laboratory at 10:00 a.m. on 07/12/23. 2. BD Lithium Heparin blood collection tubes with lot number 2048418 and expiration date 06/30/23 were observed as present and available for use during the tour of the laboratory. No other blood collection tubes were observed in the laboratory. 3. The laboratory performed PSA testing on seven patient specimens using expired blood collection tubes as indicated on the patient testing log located in the laboratory. See below. Date Number of patients tested 07/05/23 1 07/06/23 2 07/10/23 2 07/11/23 2 4. In an interview at 10:05 a.m. on 07/12/23, the NRCM confirmed the above finding. .</p> |