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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 41D0083685 | (X3) Date Survey Completed 04/08/2024 |
| Name of Provider or Supplier Brown Urology, Inc | Street Address, City, State 2 Dudley St, Providence, RI | |
| 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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| D6128 | <p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview the technical supervisor (TS) failed to evaluate the competency of all high complexity testing personnel (TP) annually in the specialties of Hematology and Diagnostic Immunology. Findings include: 1. Record review on 4/8/2024 of the laboratory's 2022 and 2023 TP competency records revealed: a. The laboratory did not have annual documented competency assessment using all the required six elements for Anti Sperm Antibody (ASA) test and Semen Analysis (SA) for TP1. b. TP1 performed PT testing only in 2022 and 2023 and was not evaluated for the other five required elements. 2. Staff interview on 4/8/2024 at 10:30 AM with the TS confirmed TP1 was not evaluated in five of six required competency assessment elements in 2022 and 2023 for ASA and SA. 3. The laboratory performs 1,250 tests annually in the specialty of Hematology and 18 tests annually in the specialty of Diagnostic Immunology.</p> |