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| <b>Statement of Deficiencies</b>                                                                                           | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>22D2322768            | <b>(X3) Date Survey Completed</b><br><br>01/22/2026 |
| <b>Name of Provider or Supplier</b><br><br>Thrive Medical Partners Plc                                                     | <b>Street Address, City, State</b><br><br>800 W Cummings Park, Suite 2500, Woburn, MA |                                                     |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |                                                                                       |                                                     |

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| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>D0000</b>              | An on-site validation survey was conducted on January 22, 2026 with the following standard level deficiencies cited.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>D5413</b>              | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br/>CFR(s): 493.1252(b)</p> <p>(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of manufacturer's instructions, laboratory environmental records, and confirmed in interview, the laboratory failed to ensure manufacturer's room temperature specifications for the NanoEntek Frend Testosterone and Prostate Specific Antigen (PSA) test cartridges for three of three months. Findings: 1. Review of the manufacturer's instructions revealed the following: a. NanoEntek Frend Testosterone (NESPI-FRTEAP-002EN) instructions stated " ... (1) Prepare the Frend Testosterone cartridges, pretreatment tube, and specimen at room temperature (18-25 C) ..." b. NanoEntek Frend PSA (NESPI-FRPS-002EN) instructions stated " ... Warnings and Precautions ...Allow cartridges to come to room temperature for 15-30 minutes prior to use ..." The manufacturer's instructions defined room temperature in this statement: "Prior to assay, slowly bring frozen samples to room temperature (18-25 C) and mix gently but thoroughly before testing ..." 2. Review of the laboratory's environmental records for October, November, and December 2025 revealed the laboratory's acceptable room temperature was 59 - 80F (15 - 27C). The laboratory's</p> |

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|              | <p>lower temperature limit (15C) exceeded the manufacturer's specification of 18C by three degrees. The laboratory's upper room temperature limit (25C) exceeded the manufacturer's specification of 25C by two degrees. 3. In a phone interview on 01/22/2025 at 11:10 am, the Technical Consultant confirmed the findings.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>D5421</b> | <p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b><br/>CFR(s): 493.1253(b)(1)</p> <p>(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on observation, review of manufacturer's instructions, laboratory patient reports, verification studies for the NanoEntek Frend analyzer, and confirmed in staff interview, the laboratory failed to have documentation of verifying patient reference intervals (normal values) as part of their verification studies for two of two analytes. Findings: 1. During a tour of the laboratory area on January 22, 2026, at 10:35 am, a NanoEntek Frend analyzer (Serial Number 240902-019) was observed to be in use by the laboratory for testosterone and prostate specific antigen (PSA) testing. 2. Review of the manufacturer's instructions for the Frend Testosterone and PSA tests revealed the following: a. Testosterone " ...Reference Interval ...Age range 21-49 ...Males 170.1-1263.6 ng/dL ...Age range 50-90 ... Males 152.4-1095.2 ng/dL ...: b. PSA " ... Reference Ranges ...Men &gt;= 50 yrs ...0-4.0 ng/mL ..." 3. Review of the laboratory's patient report forms revealed the laboratory's reference ranges: a. Testosterone Patient age 21-49; Males 170.1-1263.6 ng/dL Patient age 50-90; Males 152.4-1095.2 ng/dL b. PSA Males 50-71 years: 0-4.0 ng/mL 4. Review of the laboratory record titled "Frend Installation Verification" performed on 04/08/2025 revealed no documentation that the laboratory verified that the manufacturer's reference intervals corresponded to the normal values of their patient population. 5. In a phone interview on 01/22/2025 at 11: 10 am, the Technical Consultant confirmed that the laboratory failed to verify their normal values. Word Key: ng/dL=nanogram per deciliter ng/mL=nanogram per milliliter</p> |