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Certificate of Analysis

| Product Name | STANDARD™ F NT-proBNP FIA | | | |
|-----------------------|---|--|-------------|--------|
| Cat No. | 10NTP10B | Ref No. | F-NTP-01 | |
| LOT No. | 6414672AC | MFG Date | 2023.06.07. | |
| | | EXP Date | 2024.12.06. | |
| Testing categories | | Specification | | Result |
| Appearance Inspection | Uniform Gap between upper and lower device No scratch, stain and crack etc. No contamination There should be no colored lines. Check device type Check buffer amount | | | Pass |
| Barcode Check | The product name and 'apply sample' should be displayed on the screen. | | | Pass |
| Repeatability | • Whole blood, Serum CV ≤ 15% | | | Pass |
| Dynamic range | Testing temperature range: 15-32°C 59-90°F Testing Range: 50 ~ 25,000 pg/mL | | | Pass |
| Packaging Inspection | 20 Test Device, 20 Buffer, Disposable dropper 100µl(20ea), 1 IFU | | | Pass |
| | No leackage in sealing part of pouch | | | Pass |
| | No leackage in sealing part of buffer solution tube | | | Pass |
| | Manufacturing and expiration date between the pouch and package of test kit. | | | Pass |
| | LOT No. between the pouch an | LOT No. between the pouch and package of test kit. | | |

According to SD Biosensor's quality assurance system, the above QC tests have been completed and passed the specification. We hereby approve this product release.



Ko Jongkwan

Quality Management Representative QA Division

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