F-QP-0026-0016-0055



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Rev.00 (2023.10.16.)

Certificate of Analysis

| Product Name | STANDARD™ F Strep A Ag FIA | | | |
|--------------------------|--|----------|-------------|------|
| Cat No. | 10STR10D | Ref No. | FSRA01G | |
| Main Lot | 6034C41AC | MFG Date | 2023.12.04. | |
| | | EXP Date | 2025.06.03. | |
| Testing categories | Specification | | Result | |
| Appearance Inspection | Uniform Gap between upper and lower device No scratch, stain and crack etc. No contamination There should be colored lines. Check device type Check buffer amount | | | Pass |
| Barcode Check | The product name and 'apply sample' should be displayed on the screen. | | | Pass |
| Sensitivity | In-house reference panels for the sensitivity test 1) All panels must be interpreted as positive. | | | Pass |
| Specificity | In-house reference panels for the specificity test 1) All panels must be interpreted as negative. | | | Pass |
| Packaging Inspection | Test Device (25ea) / Sterile swab (25ea) / Extraction buffer 1 (25ea) / Extraction buffer 2 (1ea) / Disposable dropper(100ul) (25ea) / Positive control swab(1ea) / Negative control swab (1ea) / IFU (1ea) | | 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 and package of test kit. | | Pass | |

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.

SD Biosensor, Inc.

Ko Jongkwan

Quality Management Representative **QA Division**

Jongkwan Ko

Quality Management Representative QA Division

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