Quality approved by SD BIOSENSOR / For *In vitro* diagnostics use only

REF C-ETBF-01

STANDARD E
TB-Feron Control

STANDARD™ E TB-Feron Control

PLEASE READ THE INSTRUCTION CAREFULLY BEFORE YOU PERFORM THE TEST

EN

STANDARD™

INTENDED USE
STANDARD E TB-Feron Control is intended for use as an external quality control material to monitor the performance of STANDARD™ E TB-Feron ELISA test kits. This product contains a set of 3 interferon –gamma (IFN-γ) controls which are provided at three levels (1, 2 and 3) within the linear range of the TB-Feron ELISA.

TEST PRINCIPLE
This product was designed for use with STANDARD E TB-Feron ELISA to monitor assay performance and maintain quality assurance. This product should be analyzed in the same manner as unknown specimens according to instructions of the STANDARD E TB-Feron ELISA kit being used.

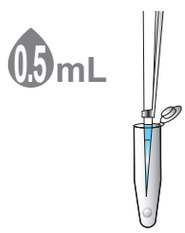
CONTENTS
STANDARD E TB-Feron ELISA includes 1 to 3 levels, 15 each.
① Control Level 1: 1 lyophilized tablet/tube
② Control Level 2: 1 lyophilized tablet/tube
③ Control Level 3: 1 lyophilized tablet/tube
④ Instructions for use

STORAGE AND STABILITY
Store the STANDARD E TB-Feron Control at 2-30˚C/36-86˚F. Kit materials are stable until expiration date printed on the outer box.

WARNINGS AND PRECAUTIONS
1. Check the expiration date on the test kit, and do not use expired product.
2. If there is evidence of microbial contamination in the reconstituted control, discard the control.
3. The control bottle itself is a dehumidifier. Cap the control bottle tightly to maintain the quality.

CONTROL TEST PROCEDURE
[PREPARATION]
1. Check the expiry date on the label of the STANDARD E TB-Feron Control bottle. Open each bottle of the controls (Control Level 1, 2, and 3) and take a tube out from each bottle. The set of 3 controls (Level 1, 2, and 3) should be used at the same time.

2. Reconstitute each of the vials with 0.5ml of room temperature (15-25˚C) distilled or deionized water, ensuring complete resuspension by pipetting.



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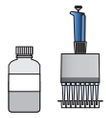
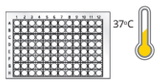
[TEST PROCEDURE]
1. Perform a Human IFN-γ ELISA test to test the 3 controls as though they are plasma samples, as directed in the STANDARD E TB-Feron ELISA package insert (with the Level 1 control replacing a 'Nil' plasma sample, the Level 2 control replacing the 'TB Antigen' plasma sample and the Level 3 control replacing the 'Mitogen' plasma sample).

Human IFN-γ ELISA
1. Sample preparation (1 to 3 levels of tubes).
2. IFN-γ ELISA Testing.





2. Discard reconstituted controls after use.

[INTERPRETATION OF RESULTS]
1. Calculate STANDARD E TB-Feron Control values using STANDARD E ANALYSIS SOFTWARE. When using this software, assign each STANDARD E TB-Feron Control level as a specimen/sample. Final values can be obtained from the software report.
2. Check the test result whether it is within the given range on the label of the control bottle.

CAUTION
- If the control result is fail or invalid, repeat the test using a new test kit and a new control. If the retest result is also fail or invalid, please contact the customer service center. The result value must be within the Acceptable range.

NOTE
- Each lot of STANDARD E TB-Feron Control is Quality Control tested using multiple ELISA kit lots to determine the assigned concentration range of IFN-γ. Both the mean concentration and acceptable ranges are printed on the label of each control bottle. The indicated mean and expected range of the mean are only intended as a guide for assessing the performance of the TB-Feron ELISA assay in individual laboratories. Determine the validity of a TB-Feron ELISA as described in the ELISA package insert.
- Variations from these typical results may be observed based on differences in laboratory technique, instrumentation, reagent lot, and other systemic and non-systemic errors. A laboratory may choose to establish its own expected range for each STANDARD E TB-Feron Control lot.

CE IVD

Manufactured by SD Biosensor, Inc.
Head office : C-4th&5th, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA
Manufacturing site : 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, REPUBLIC OF KOREA

EC REP **Authorized Representative**
MT Promedt Consulting GmbH
Altenhofstrasse 80 66386 St. Ingbert Germany
Phone : +49 6894 581020, Fax : +94 6894 581021

Any inquiries regarding instructions provided should be addressed to: sales@sdbiosensor.com
or you can also contact us through www.sdbiosensor.com

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REF Reference number | IVD *In vitro* Diagnostics | Consult Instructions for Use | Contains Sufficient for <n> Tests | To indicate the temperature limitations in which the transport package has to be kept and handled. | Do not re-use | Use by | LOT Batch code | Manufacturer | Date of manufacture | EC REP Authorised representative in the european community | CE Fulfill the requirements of Directive 98/79/EC on *in vitro* diagnostic medical devices

SD BIOSENSOR

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STANDARD E

TB-Feron ELISA

REF ETBF11G

STANDARD™ E TB-Feron ELISA

PLEASE READ THE INSTRUCTION CAREFULLY BEFORE PERFORMING THE TEST

STANDARD™

INTRODUCTION

Tuberculosis (TB) is an infectious disease, which is caused by infection with *M. tuberculosis complex organisms*. It spreads to new hosts through the air from patients who have respiratory tuberculosis disease. Individuals newly infected would get symptoms from tuberculosis within weeks to months.
STANDARD E TB-Feron ELISA is a blood assay that can help diagnose human tuberculosis and developed based on IGRA (Interferon Gamma Releasing Assay) method. An IGRA may be used in place of a TST in all situations in which CDC recommends tuberculin skin testing as an aid in diagnosing M. tuberculosis infection. An IGRA is preferred for testing persons who have received BCG vaccine or are unlikely to return for TST reading.

INTENDED USE

STANDARD E TB-Feron ELISA is an *in vitro* diagnostic test using TB-specific recombinant protein Antigens (ESAT-6, CFP-10 and TB 7.7) to stimulate cells in heparinized whole blood. Detection of interferon-gamma (IFN-γ) by enzyme-linked immunosorbent assay (ELISA) is used to identify *in vitro* responses to those Recombinant TB Antigens that are associated with *Mycobacterium tuberculosis* infection. The test is an sandwich test for *M. tuberculosis* infection (including disease) and is intended for use in conjunction with risk assessment, radiography, and other medical and diagnostic evaluations.

TEST PRINCIPLE

To measure the IFN-γ in samples, TB-Feron utilizes sandwich ELISA method using a specific to human IFN-γ antibody. It is designed especially for assessment of cell mediated immunity by measurement IFN-γ after cultivating heparin treated whole blood with stimulating antigen.
The IFN-γ is a cytokine which is used as specific marker in cell-mediated immune response. When exogenous or endogenous antigens are added to the blood, antigen specific effector/memory T lymphocyte is rapidly re-stimulated to produce interferon gamma (IFN-γ). The stimulation technology of effector T lymphocytes in whole blood with specific antigens and the accurate IFN-γ measurement in a plasma, which are the basis of the TB-Feron ELISA technology.
STANDARD E TB-Feron ELISA uses specialized blood collection tubes, which are antigen-sensitized. Incubation of the blood occurs in the tubes for 16 to 24 hours, after which, plasma is harvested and tested for the presence of IFN-γ produced in response to the peptide antigens.
The test is performed in two stages. First, whole blood is collected into each of the blood collection tubes, which include a Nil tube, TB Antigen tube, and Mitogen tube. The Nil tube adjusts for background IFN-gamma level of sample. The TB Antigen tube contains TB-specific recombinant protein antigens (ESAT-6, CFP-10, and TB7.7) to assess IFN-gamma responses in T cells from individuals infected with M.tuberculosis, but generally not from uninfected or BCG vaccinated people without disease or risk for latent TB infection. And the Mitogen tube can be used with the test as a positive control. This tube may also serve as a control for correct blood handling and incubation. These three tubes should be incubated at 37°C as soon as possible and within 16 hours of blood collection. Following 16 to 24 hours incubation period, the tubes are centrifuged, the plasma is collected and the amount of IFN-γ (IU/ml) measured by ELISA.
A test is considered positive for an IFN-γ response to the TB Antigen tube that is significantly above the Nil IFN-γ IU/ml value. A low response to Mitogen (<0.5 IU/ml) indicates an indeterminate result when a blood sample also has a negative response to the TB antigens. This pattern may occur with insufficient lymphocytes, reduced lymphocyte activity due to improper specimen handling, incorrect filling/mixing of the generate IFN-γ. The Nil sample adjusts for background, heterophile antibody effects, or non-specific IFN-γ in blood samples. The IFN-γ level of the Nil tubes is subtracted from the IFN-γ level for the TB Antigen tubes and Mitogen tubes (if used).

ACTIVE INGREDIENTS OF MATERIALS AND REAGENT PROVIDED

Component	Composition
Antibody coated microplate	96 wells coated with monoclonal anti-IFN-γ antibody
STANDARDs	Rec. Human Interferon-γ
	Preservative: Proclin 300
ELISA Diluent	Phosphate buffered saline
	Preservative: Proclin 300
Wash Buffer (20x concentrate)	PolySorbate 20
	physiological phosphate buffered saline solution conc.
	Preservative: Proclin 300
Enzyme conjugate	Mouse monoclonal anti-IFN-γ antibody : Peroxidase conjugate
	Preservative: Proclin 300
TMB substrate	Tetramethylbenzidine (TMB)
	Hydrogen peroxidase
Stop solution	1N sulfuric acid

MATERIALS PROVIDED

STANDARD E TB-Feron ELISA	2 plates/Kit	5 plates/Kit	10 plates/Kit
Antibody coated microplate	2 ea	5 ea	10 ea
STANDARDs	6 ea	15 ea	30 ea
ELISA Diluent	30mL/bottle X 1	60mL/bottle X 1	60mL/bottle X 2
Wash Buffer (20x concentrate)	100ml/bottle X 1	250ml/bottle X 1	250ml/bottle X 2
Enzyme conjugate	200µl/tube X 1	500µl/tube X 1	1mL/tube X 1
TMB substrate	30ml X 1	80ml X 1	80ml X 2
Stop solution	30ml X 1	80ml X 1	200ml X 1
Adhesive plate sealer	4 ea	10 ea	20 ea
Instructions for use	1 ea	1 ea	1 ea
STANDARD E TB-Feron Tubes (Sold separately)	**TB-Feron Tubes 100**	**TB-Feron Tubes 200**	**TB-Feron Tubes 300**
Mitogen tubes	100	N/A	100
TB Antigen tubes	N/A	100	100
Nil tubes	N/A	100	100

MATERIALS REQUIRED BUT NOT PROVIDED

1. Heparin blood collection tubes
2. Calibrated micropipets (10µl to 1000µl) with disposable tips
3. Incubator capable of maintaining temperature at 37±1°C/96.8~100.4°F
4. Distilled or deionized water
5. Absorbent paper or paper towel
6. Microplate washer (automated plate washer recommended)
7. ELISA plate reader with 450nm filter (A reference wavelength between 620nm and 650nm)
8. Timer
9. Waste discard container with suitable fresh disinfectant
10. Personal Protective Equipment(PPE)

PRECAUTIONS

1. For *in vitro* diagnostic use.
2. Icteric, lipaemic, heamolytic or contaminated sample must not be used.
3. Do not use expired date reagents.
4. Do not mix reagent of different lots.
5. Keep remaining wells after use in their sealed bag with desiccants.
6. Use thoroughly clean glassware. Free from contamination of metal ions or oxidation substances.
7. Wear personal protective equipment, such as (but not limited to) gloves and lab coats when handling kit reagents. Wash hands thoroughly afterwards.
8. Dispose of all specimens and materials used to perform the test as biohazardous waste.
9. As TMB is susceptible to contamination from metal ions, do not allow the working TMB come into contact with metal surfaces. Avoid prolonged exposure to direct light.
10. Sodium azide inhibits conjugate activity. Clean pipette tips must be used for the conjugate addition so that sodium azide is not carried over from other reagents.
11. Use separate disposable materials for each sample in order to avoid cross-contamination which can cause erroneous results.

STORAGE AND STABILITY

[STNADARD E TB-Feron Tubes 100, 200, 300]
1. Store TB-Feron Tubes 100, 200, 300 at 2~25°C.
2. This test kit is stable through the expiration date printed in the package and in the label of each tube.

[STANDARD E TB-Feron ELISA]
1. This test kit is stable through the expiration date printed in the package and in the label of each material/reagents as unopened state.
2. Store at 2-8°C/36-46°F.

SPECIMEN COLLECTION AND STORAGE

[Plasma]
1. Collect the venous whole blood and incubate collected blood in the STANDARD E TB-Feron Tubes. Then, Centrifuge blood for 15 minutes at RCF 2200 to 2300g to get supernatant plasma specimen.
2. If plasma in an anti-coagulant tube is stored at 2-8°C, the specimen can be used for testing within 1 week after collection. Using the specimen in the long-term keeping more than 1 week can cause non-specific reaction. For prolonged storage, it should be stored at below -20°C.

Caution
- Blood refrigeration and freezing are not allowed.
- Heparin tubes MUST BE ONLY USED when collecting whole blood. Other anticoagulant tubes (EDTA, sodium citrate, etc.) must not be used.

PREPARATION OF REAGENTS

1. Reconstituted STANDARDs: Add 0.5ml of the distilled or deionized water per one vial of STANDARDs before use. The fully dissolved STANDARD solution is 16 IU/ml. DO NOT re-use the STANDARDs.
2. Preparation of diluted wash buffer.
   The 20X concentrated wash buffer must be diluted 1 to 19 using distilled/deionized water before use. For example, mix 50ml of wash buffer(20x concentrate) with 950ml of distilled/deionized water.
3. Preparation of Working Detector solution
   1) Prepare Working Detector solution as necessary before use.
   2) Enzyme conjugate should be diluted 1:250 with ELISA Diluent to prepare Working Detector solution.
   [Example: If the required Working Detector solution is 10ml, add 40µl of Enzyme conjugate to the 10ml of ELISA Diluent and mix well.]

Reagent	Storage	Stability
Diluted Wash Buffer	Room Temp.(15~25°C)	1 week
Working Detector Solution	2~8°C	4 hours

TEST PROCEDURE

NOTE
- Ensure all reagents equilibrated room temperature (15-25°C/59-77°F) before testing.
- Do not open a container including STANDARDs tubes until it is equilibrated to room temperature(15~25°C/59~77°F).

Step 1 : Incubation of blood sample and collecting of plasma
1. STANDARD E TB-Feron ELISA should use the following tubes.
   1) Mitogen tubes (purple cap)
   2) TB Antigen tubes (red cap)
   3) Nil tubes (gray cap)
2. Take out the TB-Feron Tubes at room temperature (15-25°C/59-77°F) for 15~30 minutes before using, and inject the blood without cold air.
3. Collect blood from the patient and inject respectively 1ml into each TB-Feron Tube (Nil tube, TB Antigen tube, and Mitogen tube).
   1) Insert a needle into the tube for 2~3 seconds after the injection is completed in order to collect the correct volume.
   2) The black line on the side of the tube indicates 1.0ml.
   3) When using Butterfly needle, Purge tube must be used.
   4) If the tubes are not filled to the black line due to vacuum, open the cap and fill it up with additional blood up to the black line.
4. As soon as the tube is filled with blood, shake it 10 times gently or use a Roller-rocker to allow the entire surface of the tube to be immersed in blood so that it can mix well with the antigen on the tube wall.
   - DO NOT SHAKE THE TUBE EXCESSIVELY to prevent blood cells from breaking. Since it is an experiment that requires living lymphocytes, it should be mixed to the extent that cell damage does not occur. Also, Excessive shaking may cause gel disruption and could lead to accurate results.
5. Incubate the well-mixed blood tubes at 37°C for 16 to 24 hours. When incubating, the tubes should be inserted into a rack vertically.
   * When it is difficult to incubate right after blood collection, it should be stored at room temperature (15-25°C/59-77°F). The tubes must be incubated within 16 hours after collection.

NOTE
- If it is difficult to inject blood into each TB-Feron Tube, collect blood in the blood collection tube containing heparin. Collect a least 3.5ml of blood in a heparin tube and shake it gently up and down blood to dissolve the heparin. It prevents blood from clotting. After blood collection, it should be stored at room temperature (15-25°C/59-77°F). Within 16 hours after collection, dispense 1ml into each TB-Feron Tube with pipette, mix well and start incubating. When dispensing blood with pipette after opening the cap of the TB-Feron Tubes, sterile tips must be used so that blood could be dispensed in an aseptic.

6. After incubation of the tubes at 37°C, collect plasma by centrifuging tubes for 15 minutes at RCF 2200 to 2300g.
   - When collecting plasma, DO NOT pipetting or plasma mixing in the tube and spearing the gel with pipette tip.

Step 2 : Human IFN-γ ELISA
1. Preparation of STANDARD solution
   1) Label S1, S2, S3, S4 on 4 empty tubes.
   2) Add 300µl of ELISA Diluent to each tube.
   3) Add 100µl of Reconstituted STANDARDs to STANDARD tube1 (S1) and mix thoroughly. (S1 contains 4 IU/ml.)
   4) Transfer 100µl of the STANDARD tube1 (S1) solution to STANDARD tube 2 (S2). (S2 contains 1 IU/ml.)
   5) Transfer 100µl of the STANDARD tube2 (S2) solution to STANDARD tube 3 (S3). (S3 contains 0.25 IU/ml.)
   6) ELISA Diluent serves as a zero STANDARD (S4).
2. Working Detector solution & Sample incubation
   1) Dispense 50µL of prepared Working Detector solution into each of the wells.
   2) Dispense 50µL of The STANDARD 1 to 4 and samples into the plate wells respectively. (Refer to recommended plate layout below.)
   3) Lightly beat the frame and mix well. Cover the plate with the attached plate sealer and incubate at 37±1°C for 1 hour.

Table 2.1 Reference: Recommended plate layout (28 tests per plate)
When Nil, TB Antigen and Mitogen tubes are used
S1 (Standard 1), S2 (Standard 2), S3 (Standard 3), S4 (Standard 4)
1N (Sample. Nil plasma), 1T (Sample. TB Antigen plasma), 1M (Sample. Mitogen plasma)

	1	2	3	4	5	6	7	8	9	10	11	12
A	1N	1T	1M	S1	S1	S1	13N	13T	13M	21N	21T	21M
B	2N	2T	2M	S2	S2	S2	14N	14T	14M	22N	22T	22M
C	3N	3T	3M	S3	S3	S3	15N	15T	15M	23N	23T	23M
D	4N	4T	4M	S4	S4	S4	16N	16T	16M	24N	24T	24M
E	5N	5T	5M	9N	9T	9M	17N	17T	17M	25N	25T	25M
F	6N	6T	6M	10N	10T	10M	18N	18T	18M	26N	26T	26M
G	7N	7T	7M	11N	11T	11M	19N	19T	19M	27N	27T	27M
H	8N	8T	8M	12N	12T	12M	20N	20T	20M	28N	28T	28M

Table 2.2. Reference: Recommended plate layout (44 tests per plate)
When Only Nil and TB Antigen are used
S1 (Standard 1), S2 (Standard 2), S3 (Standard 3), S4 (Standard 4)
1N (Sample. Nil plasma), 1T (Sample. TB Antigen plasma)

	1	2	3	4	5	6	7	8	9	10	11	12
A	1N	5N	9N	13N	17N	S1	S1	25N	29N	33N	37N	41N
B	1T	5T	9T	13T	17T	S2	S2	25T	29T	33T	37T	41T
C	2N	6N	10N	14N	18N	S3	S3	26N	30N	34N	38N	42N
D	2T	6T	10T	14T	18T	S4	S4	26T	30T	34T	38T	42T
E	3N	7N	11N	15N	19N	21N	23N	27N	31N	35N	39N	43N
F	3T	7T	11T	15T	19T	21T	23T	27T	31T	35T	39T	43T
G	4N	8N	12N	16N	20N	22N	24N	28N	32N	36N	40N	44N
H	4T	8T	12T	16T	20T	22T	24T	28T	32T	36T	40T	44T

3. Washing Procedure
   1) Wash the wells five times with 350µl of diluted wash buffer and aspirate all liquid from the wells. Or, wash the wells using an automatic washer with 350µl of diluted wash buffer. An automated plate washer is recommended.
   2) Leave the wash buffer in each well for 4-5 seconds per washing cycle and then empty the wells.
   3) After washing (either by manual or automated washer), thoroughly dispose of all liquid from the microplate by tapping it on absorbent paper with the openings facing downwards to remove all residual wash buffer.

NOTE
- Residual liquid in the reagent wells after washing can interfere with the TMB substrate and lead to false low extinction values. Insufficient washing (e.g., less wash cycles, too small wash buffer volumes, or too short residence times) can lead to false high extinction values.

4. TMB Substrate incubation
   1) Add 100µl of TMB substrate into each of the wells.
   2) Incubate for 30 minutes at room temperature (15-25°C/59-77°F) in the dark.
5. Stopping the reaction
   1) Add 100µl of stop solution into each of the wells in the same order and at approximately same speed as the TMB substrate in step 6. Mix by gentle shaking.
6. Measurement
   1) Read the absorbance values of the wells at 450nm in a ELISA plate reader (with reference wavelength between 620nm and 650nm) right after from the end of assay, within 30 minutes

QUALITY CONTROL OF TEST

The accuracy of the test results depends on the generation of accurate standard curves. Therefore, results derived from the standards (S1, S2, S3, S4) must be examined before test sample results can be interpreted.

1. The mean O.D value for S1 must be more than 0.600.
2. The %CV of O.D value for S1 and S2 replicate OD values must be 15% or less.
3. The difference between each O.D values of S3 and S4 must be less than 0.040.
4. The mean O.D value for S4 must be 0.150 or less.
5. The correlation coefficient (r) of the standard curve obtained from each mean value should be 0.980 or more.

INTERPRETATION OF TEST RESULT

1. Check the results using the STANDARD E ANALYSIS SOFTWARE.
2. Results of the STANDARD E should be judged according to the following criteria.

NOTE

- Diagnosing or excluding tuberculosis disease, and assessing the probability of LTBI, requires a combination of epidemiological, historical, medical, and diagnostic findings that should be taken into account when interpreting STANDARD E TB-Feron ELISA results.

Table 1. When Nil, TB Antigen and Mitogen tubes are used

Nil [IU/mL]	TB Antigen - Nil [IU/mL]	Mitogen - Nil [IU/mL][1]	STANDARD E Result	Report/Interpretation
≤ 8.0	< 0.35	≥ 0.5	Negative	M. tuberculosis infection NOT likely
	≥ 0.35 and < 25% of Nil value	≥ 0.5	Negative	
	≥ 0.35 and ≥ 25% of Nil value	Any	Positive[2]	M. tuberculosis infection likely
	< 0.35	< 0.5	Indeterminate	Results are indeterminate for TB Antigen responsiveness
	≥ 0.35 and < 25% of Nil value	< 0.5	Indeterminate	
> 8.0	Any	Any	Indeterminate	

[1] Responses to the Mitogen positive control (and occasionally TB Antigen) can be commonly outside the range of the microplate reader. This does not affect the test results.

[2] When M.tuberculosis infection is not suspected, initial positive results can be confirmed by re-testing the original plasma samples. If the repeated test results of the replicates are positive, they should be considerd as positive.

Table 2. When Only Nil and TB Antigen are used

Nil [IU/mL]	TB Antigen - Nil [IU/mL]	STANDARD E Result	Report/Interpretation
≤ 8.0	< 0.35	Negative	M. tuberculosis infection NOT likely
	≥ 0.35 and < 25% of Nil value	Negative	
	≥ 0.35 and ≥ 25% of Nil value	Positive	M. tuberculosis infection likely
> 8.0	Any	Indeterminate	Results are indeterminate for TB Antigen responsiveness

3. If not using the STANDARD E ANALYSIS SOFTWARE, creation of the STANDARD curve
   1) Measure the mean OD values of the STANDARDs.
   2) Construct a log(e)-log(e) STANDARD curve by the log(e) plot of the mean OD (y-axis) against the log(e) value (x-axis) of the IFN-γ concentration of the STANDARDs, removing the zero STANDARD from these calculations. Calculate the most suitable STANDARD curve by regression analysis.
   3) Use the STANDARD curve and OD value of the sample to measure the IFN-γ concentration (IU/ml) for each of the test plasma samples.
   4) These calculations can be performed using software available with microplate readers, standard spreadsheet and statistical software (ex: Microsoft Excel). It is recommended that these packages be used to calculate the regression analysis, the coefficient of variation (%CV) for the standards and the correlation coefficient (r) of the STANDARD curve.

LIMITATION OF TEST

1. The test procedure, precautions and interpretation of results sections for this test kit must be followed closely when testing.
2. Testing could be performed on patients with clinical symptoms on when exposure is suspected.
3. Unreliable or indeterminate results may occur due to:
   1) Excessive levels of circulating IFN-γ or presence of heterophile antibodies.
   2) The TB-Feron tubes must be incubated within 16 hours after blood collecting.
4. Test results must be considered with other clinical data available to the physician.
5. For more accuracy of immune status, additional follow-up testing using other laboratory methods is recommended

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12. Diel, R. et al. (2006) Tuberculosis contact investigation with a new, specific blood test in a lowincidence population containing a high proportion of BCG-vaccinated persons. Respir. Res. 7, 77.
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15. Gerogianni, I. et al. (2008) Whole-blood interferon-gamma assay for the diagnosis of tuberculosis infection in an unselected Greek population. Respirology 13, 270.
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SYMBOLS ON THE PRODUCT LABELS

The following symbols may have been used in the labeling of this product.

MW Ab	Microplate coated with antibodies
STANDARDS	STANDARDs
ELISA DIL	ELISA Diluent
WASH BUF 20x	Wash buffer 20X
CONJ	Enzyme conjugate
SUBS TMB	Substrate hydrogen peroxidase and Tetramethylbenzidine (TMB)
SOLN STOP	Stop solution
	Xi = Irritant

Product Disclaimer
Whilst every precaution has been taken to ensure the diagnostic ability and accuracy of this product, the product is used outside of the control of the manufacturer and distributor and the result may accordingly be affected by environmental factors and/or user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result.

Warning
The manufacturers and distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect of consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

ABBREVIATED TEST PROCEDURE

To measure the IFN-γ in samples, TB-Feron utilizes sandwich ELISA method using a specific to human IFN-γ antibody. It is designed especially for assessment of cell mediated immunity by measurement IFN-γ after cultivating heparin treated whole blood with stimulating antigen.

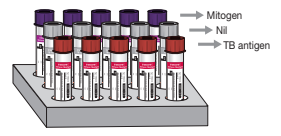
* Blood Stimulating Tube System
STANDARD E TB-Feron ELISA uses lithium heparin tubes as a blood anticoagulant or SD BIOSENSOR TB-Feron 3 kinds of Tubes (Mitogen, TB antigen, Nil) for accurate results. TB-Feron ELISA requires 3 ml whole blood - each 1 ml blood in each of the 3 tubes.

Nil tube (Gray cap)	TB antigen tube (Red cap)	Mitogen tube (Purple cap)
		
This is used to adjust for background noise INF-γ as negative control.	This is used to assess INF-γ response to specific TB antigens.	This can be useful as positive control to check patient's immune status.

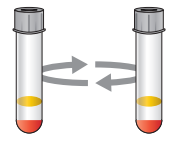
Blood incubation and Harvesting

1. Blood collection in 3 tubes. (Nil, TB Antigen, Mitogen).

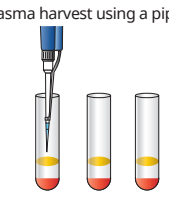
2. Incubate for 16-24hrs in 37°C incubator.



3. Centrifuge tubes about 15 min.

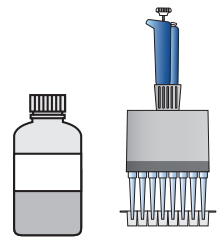


4. Plasma harvest using a pipet.

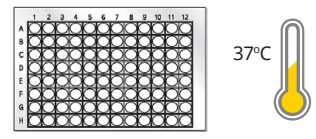


Human IFN-γ ELISA

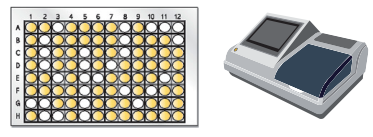
1. Sample preparation (Standard, Plasma of 3 tubes).



2. IFN-γ ELISA Testing.



3. Mearsure the optical density (OD).



4. Calculation and Test Interpretation.

CE

EC REP **Authorized Representative** MT Promedt Consulting GmbH
Altenhofstrasse 80 66386 St. Ingbert Germany. Phone: +49-6894-581020 I Fax: +49-6894-581021

Manufactured by SD Biosensor, Inc.
Head office
C-4th&5th, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, Republic of Korea
Manufacturing site
74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea

Any inquiries regarding the instruction provided should be addressed to: sales@sdbiosensor.com
or you can also contact us through www.sdbiosensor.com

L27TBF3ENR1
Issue date : 2019.07

REF Reference number | IVD *In vitro* Diagnostics | Consult Instructions for Use | Contains Sufficient for <n> Tests | Caution | NOTE | Do not re-use | Xi = Irritant | To indicate the temperature limitations in which the transport package has to be kept and handled. | Use by | LOT Batch code | CE Fulfill the requirements of Directive 98/79/EC on *in vitro* diagnostic medical devices | Manufacturer | Date of manufacture | EC REP Authorized Representative

Quality approved by SD BIOSENSOR / For *In vitro* use only

STANDARD E

TB-Feron Tubes

TB-Feron Tubes

PLEASE READ THE INSTRUCTION CAREFULLY BEFORE YOU PERFORM THE TEST

STANDARD™

NOTE

- Please read this information before using TB-Feron Tubes.
- For more information on performing, carefully read the package insert for STANDARD E TB-Feron ELISA.

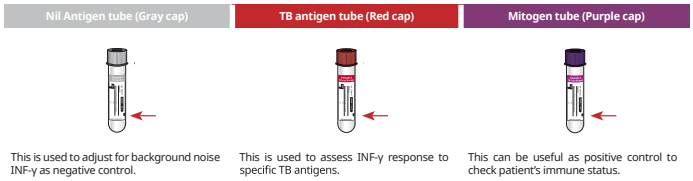
INTRODUCTION

[INTENDED USE]

TB-Feron Tubes is intended to collect blood specimen for use with STANDARD E TB-Feron ELISA.

[PRODUCT DESCRIPTION AND TEST PRINCIPLE]

STANDARD E TB-feron ELISA uses specialized blood collection tubes, which are antigen-sensitized. Incubation of the blood occurs in the tubes for 16 to 24 hours, after which, plasma is harvested and tested for the presence of IFN-γ produced in response to the peptide antigens. The test is performed in two stages. First, whole blood is collected into each of the blood collection tubes, which include a Nil tubes, TB Antigen tubes, and a Mitogen tubes. The Mitogen tubes can be used with the test as a positive control. This tubes may also serve as a control for correct blood handling and incubation. The tubes should be incubated at 37°C as soon as possible after injection, and within 16 hours of collection. Following 16 to 24 hours incubation period, the tubes are centrifuged, the plasma is collected and the amount of IFN-γ (IU/ml) measured by ELISA.



[MATERIALS PROVIDED]

Cat. No.	Product Name	Contents
07TBFA30	TB-Feron Tubes 300	100 x TB-Feron Nil Antigen tubes 100 x TB-Feron TB Antigen tubes 100 x TB-Feron Mitogen tubes
07TBFA20	TB-Feron Tubes 200	100 x TB-Feron Nil Antigen tubes 100 x TB-Feron TB Antigen tubes
07TBFA10	TB-Feron Tubes 100	100 x TB-Feron Mitogen tubes

PRECAUTION

1. TB-Feron Tubes is for use with the STANDARD E TB-Feron ELISA.
2. TB-Feron Tubes should be stored at 2℃ to 8℃ (36℉ to 46℉).
3. TB-Feron Tubes is stable through the expiration date printed in the package and in the label of each tube.
4. Do not use beyond the expiration date.
5. It is for single use only. Do not reuse.
6. Discard the used tubes according to your local guideline.

TEST PROCEDURE

1. STANDARD E TB-Feron ELISA should use the following tubes.
   - Mitogen tubes (purple cap)
   - TB Antigen tubes (red cap)
   - Nil Antigen tubes (gray cap)
2. Take out the TB-Feron Tubes at room temperature (15-25°C/59-77°F) for 15~30 minutes before using, and inject the blood without cold air.
3. Collect blood from the patient and inject respectively 1ml into each TB-Feron Tube (Nil Antigen tube, TB Antigen tube, and Mitogen tube).
   1) Insert a needle into the tube for 2~3 seconds after the injection is completed in order to collect the correct volume.
   2) The black line on the side of the tube indicates 1.0ml.
   3) When using Butterfly needle, Purge tube must be used.
   4) If the tubes are not filled to the black line due to vacuum, open the cap and fill it up with additional blood up to the black line.
4. As soon as the tube is filled with blood, shake it 10 times gently or use a Roller-rocker to allow the entire surface of the tube to be immersed in blood so that it can mix well with the antigen on the tube wall.
   - DO NOT SHAKE THE TUBE EXCESSIVELY to prevent blood cells from breaking. Since it is an experiment that requires living lymphocytes, it should be mixed to the extent that cell damage does not occur. Also, Excessive shaking may cause gel disruption and could lead to accurate results.
5. Incubate the well-mixed blood tubes at 37°C for 16 to 24 hours. When incubating, the tubes should be inserted into a rack vertically.
   * When it is difficult to incubate right after blood collection, it should be stored at room temperature (15-25°C/59-77°F). The tubes must be incubated within 16 hours after collection.

NOTE

- If it is difficult to inject blood into each TB-Feron Tube, collect blood in the blood collection tube containing heparin. Collect a least 3.5ml of blood in a heparin tube and shake it gently up and down blood to dissolve the heparin. It prevents blood from clotting. After blood collection, it should be stored at room temperature (15-25°C/59-77°F). Within 16 hours after collection, dispense 1ml into each TB-Feron Tube with pipette, mix well and start incubating. When dispensing blood with pipette after opening the cap of the TB-Feron Tubes, sterile tips must be used so that blood could be dispensed in an aseptic.

6. After incubation of the tubes at 37°C, collect plasma by centrifuging tubes for 15 minutes at RCF 2200 to 2300g.
   - When collecting plasma, DO NOT pipetting or plasma mixing in the tube and spearing the gel with pipette tip.

SYMBOL

Cat. No.	Catalogue Number		Consult Instructions for Use
LOT	Batch code	IVD	In vitro Diagnostics
	Manufacturer	EC REP	Authorized Representative in the European Community
CE	Fulfill the requirements of Directive 98/79/EC on in vitro diagnostic medical devices		Date of manufacture
Σ	Contains Sufficient for <n> Tests		Do not reuse
	Use by		To indicate the temperature limitations in which the transport package has to be kept and handled

CE IVD

Manufactured by SD Biosensor, Inc.
Head office : C-4th&5th, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA
Manufacturing site : 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, REPUBLIC OF KOREA

EC REP **Authorized Representative**
MT Promedt Consulting GmbH
Altenhofstrasse 80 D-66386 St. Ingbert Germany
Phone : +49 6894 581020, Fax : +49 6894 581021

Any inquiries regarding instructions provided should be addressed to: sales@sdbiosensor.com
or you can also contact us through www.sdbiosensor.com

L27TBFA1ENR2
Issue date: 2018.04

2021 SD BIOSENSOR

PRODUCT CATALOG

STANDARD F
Fluorescent immunoassay

STANDARD Q
RDT Series

STANDARD E
ELISA Series

STANDARD M
Molecular diagnostics

Chronic Care
BGMS / MultiCare / LipidoCare / G6PD

SD BIOSENSOR

SD BIOSENSOR

PRODUCT CATALOG

2021

Pursuing to be the global leading IVD company

At SD BIOSENSOR, we strive to make the world healthier through our innovative IVD products. Our goal is to be the global leading *In-vitro* diagnostics company. We pursue to grow harmoniously with our clients through infinite trust and responsibility.

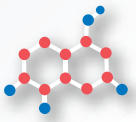

STANDARD F
Fluorescent immunoassay
STANDARD Q
Rapid diagnostics test
CHALLENGE
EFFICIENCY
RELATIONSHIP
STANDARD E
ELISA
Chronic Care
BGMS/LipidoCare/ MultiCare

Pursuing to be the global leading IVD company

At SD BIOSENSOR, we strive to make the world healthier through our innovative IVD products. Our goal is to be the global leading *In-vitro* diagnostics company. We pursue to grow harmoniously with our clients through infinite trust and responsibility.

STANDARD M

Molecular diagnostics



We are never complacent where we are.

From starting with BGMS products, we have expanded our business to STANDARD Q (RDTs), STANDARD F (FIA), STANDARD E (ELISA) and STANDARD M (POC MDx). SD BIOSENSOR's broad range portfolio of IVD products will bring success to your business.

SD BIOSENSOR's History of Innovation

Since 2010, SD BIOSENSOR has grown and evolved to make the world healthier through our innovative IVD products. Our goal is to be the global leading *In-vitro* diagnostics company. From starting with BGMS products, we have expanded our business to STANDARD Q (RDT), STANDARD F (FIA), STANDARD E (ELISA) and STANDARD M (POC MDx). We are never complacent where we are but strive to become the No. 1 global *in-vitro* diagnostic company through continuous technological innovations.

2010 - 2011

2010

- Established SD BIOSENSOR, Inc
- Obtained approval for Blood Glucose Self-Monitoring System "SD CodeFree" by U.S. FDA
- SD CHECK GOLD Health Canada and SFDA approved
- SD CodeFree Health Canada approved

2011

- Obtained CE Marking for and launched STANDARD LipidoCare
- Obtained CE Marking for and launched STANDARD Link 0.3

2012

- Established a branch office in India
- Obtained CE Marking for and launched STANDARD Mentor
- Won "The Customer Quality Satisfaction Awards" in 2012
- New construction of 2nd Production Factory in O-song Bio Techno Valley in Sejong-si, Korea
- Established a branch office in the U.S.
- Launched STANDARD A1cCare / GlucoNavii GDH / GlucoNavii NFC

2013

- Won "The Best Brand Award" chosen by consumers from Forbes Korea
- Obtained STANDARD GlucoNavii GDH / GlucoNavii NFC CE Marking
- Obtained STANDARD A1cCare CE Marking
- Met ISO15197 (2013) standards for SD CodeFree cleared
- Completed construction of 2nd Factory in O-song Bio Techno Valley in Sejong-si, Korea

2014

- Obtained approval for STANDARD Mentor by U.S. FDA
- Met ISO15197 (2013) standards for STANDARD Mentor
- Met ISO15197 (2013) standards for STANDARD GlucoNavii NFC/GDH

2015

- Obtained MFDS approval for and launched STANDARD Mentor BT
- Developed Ebola Zaire Ag rapid diagnosis kit
- Developed MERS-CoV Ag rapid diagnosis kit
- Established a branch office in China
- Newly built a local factory in India

2016

- Awarded "Promising Enterprise in Gyenggi-Do"
- Launched STANDARD MultiCare
- Launched STANDARD Q (Immunochromatographic assay)
- Launched STANDARD F (Fluorescent Immunoassay)
- Launched STANDARD E (ELISA)

2017

- Newly changed CI for our dynamic future with expanding IVD portfolio
- Listed on UNICEF Supply Chain Catalog for Q Line Ebola Zaire Ag Kit
- Long-term Contracts with UNICEF for Zika RDT kits
- Developed G6PD Test
- Developed TB-Feron ELISA

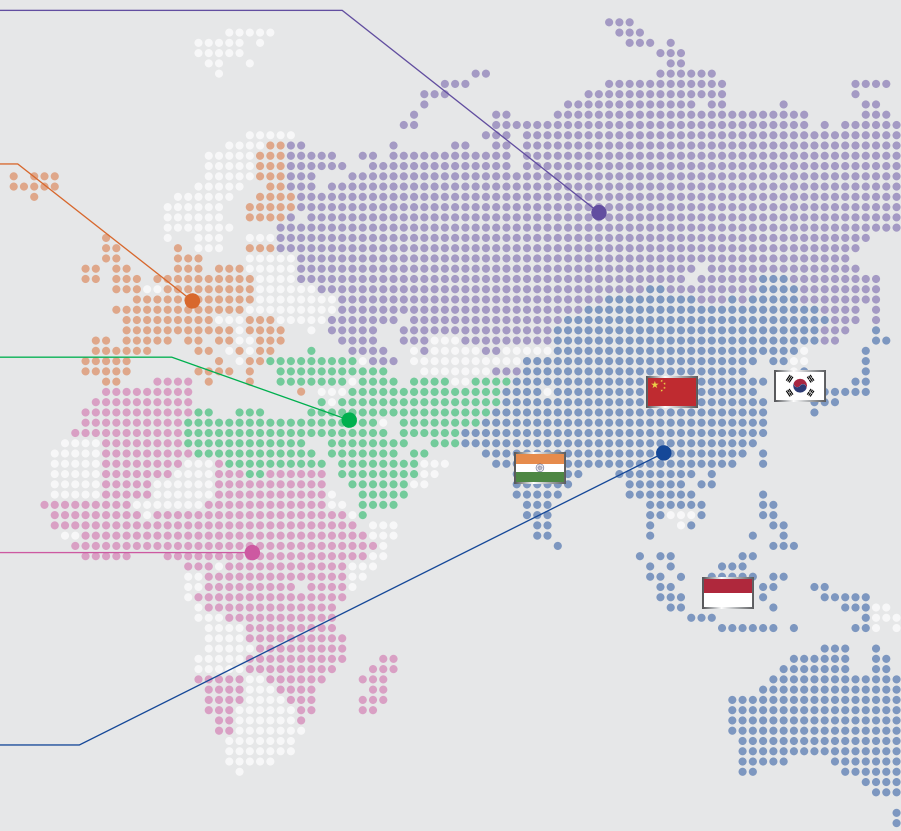
2019

- Listed on Global Fund/UNITAID Catalog with ERPD authorization
  - STANDARD G6PD
  - STANDARD Q HIV/Syphilis Combo
- Received CE mark for 'List A' product
  - STANDARD Q HCV Ab

SD BIOSENSOR

SD BIOSENSOR's Global Sales Networks

SD BIOSENSOR has grown and evolved in chronic care and *in-vitro* diagnostics(IVD) industries over the last few years. Our IVD portfolio has expended from immuno-based IVD to POC MDx(molecular diagnostics) through the continuous technological innovations. As our product line has expanded in accordance with the global needs for IVD, our customers have increased world-wide. We are based in South Korea and have 3 subsidiaries in India, Indonesia and China, and a branch in the U.S. We also have more than 130 distribution partners in more than 100 countries, and the number is still growing.



CIS

AZERBAIJAN
GEORGIA
KAZAKHSTAN
RUSSIA
TAJIKISTAN

Europe

AUSTRIA
BOSNIA
BULGARIA
CROATIA
CYPRUS
CZECH
DENMARK
FINLAND
FRANCE
GERMANY
GREECE
ICELAND
IRELAND
ITALY
KOSOVO
LATVIA
NETHERLANDS
POLAND
PORTUGAL
ROMANIA
SLOVAKIA
SLOVENIA
SPAIN
SWITZERLAND
UK

Middle East

AFGHANISTAN
EGYPT
IRAN
IRAQ
ISRAEL
JORDAN
LEBANON
LIBYA
QATAR
SAUDI ARABIA
TURKEY
UAE
YEMEN

Africa

ALGERIA
BENIN
BURKINA FASO
BURUNDI
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NEW ZEALAND
PAKISTAN
PHILIPPINES
SINGAPORE
SOUTH KOREA
SRI LANKA
TAIWAN
THAILAND
TIMOR
VIETNAM

SD BIOSENSOR, INC. (Headquarter)

Address C-4&5 Floor, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC of KOREA

Tel +82-31-300-0400

E-mail sales@sdbiosensor.com

Website www.sdbiosensor.com

SD BIOSENSOR (Factory)

Address 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, REPUBLIC of KOREA

E-mail sales@sdbiosensor.com

Website www.sdbiosensor.com

SD BIOSENSOR (Shanghai Co. Ltd)

Address Room 520, 5th Floor, Building 20, 3998 Hongxin Road, Minhang District Shanghai, China

Tel +86 186-0171-5789

E-mail slzhao@sdbiosensor.com

Website www.sdbiosensor.com

SD BIOSENSOR (HEALTHCARE PVT. Ltd.)

Address SCO-34, Sector-15, Part-II, Gurgaon, Haryana - 122001, India, INDIA

Tel +91-124-4540908/Toll Free No.

E-mail india@sdbiosensor.com

Website www.sdbiosensor.co.in

PT. STANDARD BIOSENSOR INDONESIA

Address GD.GL'avenue office tower 21 floor, Unit C, Jalan Raya Pasar Minggu Kav.16. Jakarta Selatan - 12780

Tel +62-21-8066-7161

E-mail purbayu.mulyanto@sdbiosensor.co.id

Website www.sdbiosensor.co.id

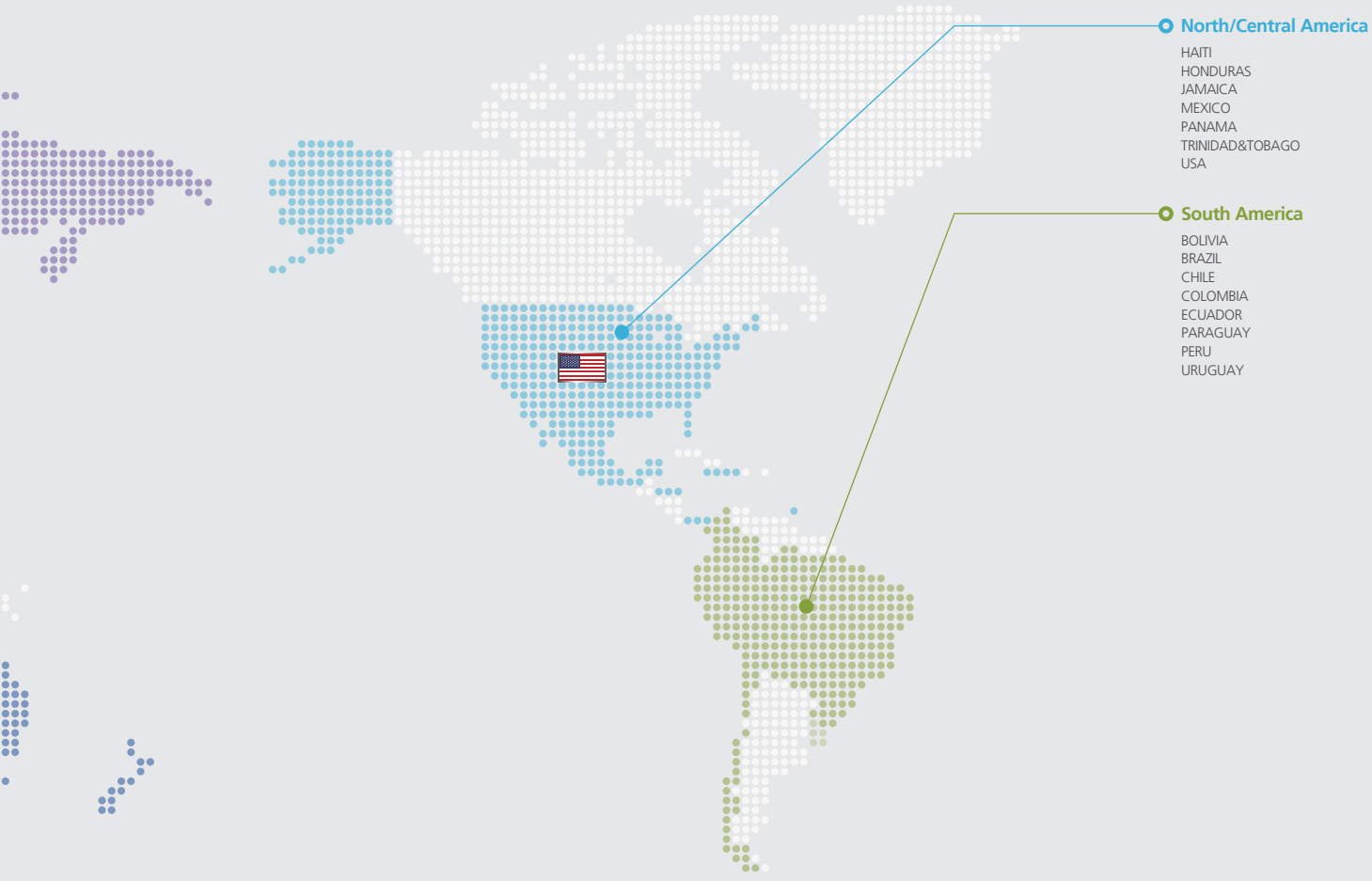


TABLE OF CONTENTS

01
STANDARD F
Fluorescent Immunoassay

02
STANDARD Q
Immunochromatographic Assay

03
STANDARD E
Enzyme-Linked Immunosorbent Assay


Test
Read Only
SD BIOSENSOR

STANDARD™

STANDARD F

STANDARD F will be
the **best diagnostic partner** of your laboratory.

STANDARD F

Fluorescent Immunoassay Analyzer

Experience highly accurate FIA test with STANDARD F analyzers

» STANDARD F analyzer is a next-generation fluorescent immunoassay system. It is a multi-parametric and random accessible immunoassay system providing accurate diagnostic results to your laboratory.

Assay Principle

Fluorescent Immunoassay (FIA)

Specific Antigen or Antibody

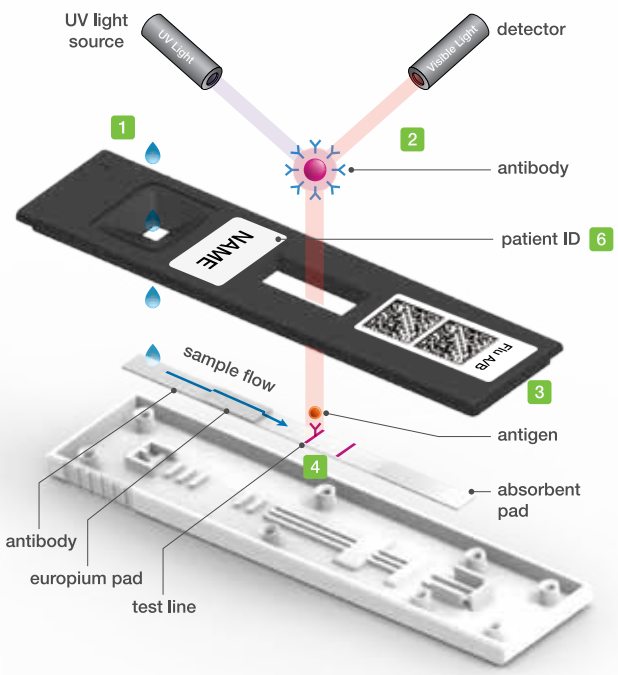
- High sensitivity and specificity
- Fast assay time
- Cost effective

Europium bead

- Strong signals
- Excellent stability
- Minimized interference

Parameter information

2D barcode contains all the information required for the test

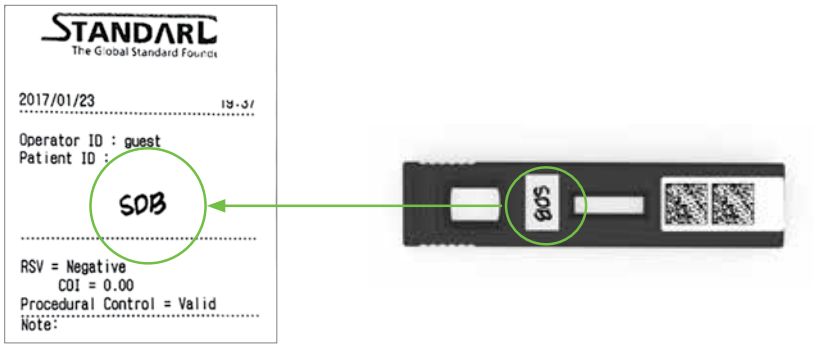


Random Access

All the parameters can be randomly accessible to the STANDARD F Analyzer without any pre-procedure. The analyzer recognizes each parameter once the test device is inserted, and displays graphical Test Procedure for the sample preparation.

Patient ID Printing System

A hand-written patient ID on the test device is printed with the test result for user's convenience



Connectivity

Bluetooth

- F100 communicate with mobile via the bluetooth

Direct cable

- STANDARD F Analyzers connect with computer via the direct cable

Data share

- Via the cloud server

LIS/HIS connectivity

- Connect to the majority of existing information systems.

STANDARD F 2400

» The best way to reduce turn-around time and improve service quality of your laboratory.

» Technical Specification

CE

Model	STANDARD™ F2400
Test method	Fluorescent immunoassay (FIA)
Analysis	Quantitative / Qualitative tests
Test capacity	70 tests per hour
Test mode	STANDARD TEST
Power	AC/DC Adapter
Display	10" Color touch screen
Printer	Built-in
Connectivity	HL7 v2.6(PCD-01) / POCT1-A
Auto-ID	2D Barcode
Accessories	Keyboard / Barcode scanner
Dimension	510 x 566 x 297 mm
Weight	20.0 kg

STANDARD F 200

» Convenient and powerful immunoassay analyzer.
» F200 is a user friendly designed FIA analyzer. Its compact design and convenience features will make your lab-work easier and smoother.

» Technical Specification

CE

Model	STANDARD™ F200
Test method	Fluorescent immunoassay (FIA)
Analysis	Quantitative / Qualitative tests
Test capacity	1 test
Test mode	STANDARD TEST, READ ONLY
Power	AC/DC Adapter
Display	7" Color touch screen
Printer	Built-in
Connectivity	HL7 v2.6(PCD-01) / POCT1-A
Auto-ID	2D Barcode
Accessories	Keyboard / Barcode scanner
Dimension	200 x 240 x 205 mm
Weight	2.5 kg

STANDARD F 100

» Fully portable POCT Analyzer
» F100 is a battery powered POCT analyzer. Its portable feature and accurate test result will improve the quality of the patient management.

» Technical Specification

CE

Model	STANDARD™ F100
Test method	Fluorescent immunoassay (FIA)
Analysis	Quantitative / Qualitative tests
Test capacity	1 test
Test mode	STANDARD TEST, READ ONLY
Power	Battery (AAx4) / AC/DC Adapter
Display	Graphic LCD
Printer	External
Connectivity	Bluetooth classic
Auto-ID	2D Barcode
Accessories	Thermal Printer
Dimension	105 x 135 x 100 mm
Weight	0.7 kg

STANDARD™ d-BLOCK Incubator

STANDARD d-BLOCK Incubator is an auxiliary device providing a constant temperature during the test. This product is designed for IVD products required thermal incubation.

» Technical Specification

CE

Model	STANDARD™ d-BLOCK Incubator
Dimension	220*184*73 mm
Initial time	15 minutes
Set temperature range	35~40°C (95~104°F)
Accuracy of temperature	+/- 1°C
Environment condition	Temperature: 10°C ~ 30°C (50°F to 86°F) Humidity: 20% ~ 80% Non condensing
Storage condition	Temperature: 0°C ~ 70°C (32°F to 125°F) Humidity: 10 ~ 90%
Equipment Control	4 buttons
Equipment Measurement unit	°C, °F
Equipment Display type	LCD (Customized)
Weight	1.9 Kg
Equipment Ratings	12 V(DC), 5A

STANDARD F Parameters

SARS-CoV-2 nAb FIA

» Background

STANDARD F SARS-CoV-2 nAb FIA is the fluorescent immunoassay for qualitative measurement of circulating neutralizing antibodies against SARS-CoV-2 in human serum and plasma.

» Product Specification

CE

Test type	Professional use only
Specimen type	Serum, Plasma(EDTA)
Specimen volume	100µl
Testing time	35 mins
Storage condition	2 – 30 °C / 36 - 86 °F

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
VNT	100% (36/36)	Serum 99.0% (1,089/1,100), Plasma 98.8% (494/500)

» Ordering Information

Product	Pack Size	CAT No.
F SARS-CoV-2 nAb FIA	10 Sets/Kit (20 Tests)	10COV80B

STANDARD F COVID-19 Ag FIA

» Background

STANDARD F COVID-19 Ag FIA is the fluorescent immunoassay for the qualitative detection of specific nucleoprotein antigens to SARS-CoV-2 present in human nasopharynx.

» Product Specification

KOREA MFDS Approved CE

Test type	Professional use only
Specimen type	Nasal swab, Nasopharyngeal swab / Transport media
Specimen volume	4 drops
Testing time	15 mins
Storage condition	2 – 30 °C / 36 - 86 °F

» Test Performance

Reference : Clinical evaluation

Reference	Sensitivity	Specificity
PCR	93.70% (106/111)	99.63% (538/543)

» Ordering Information

Product	Pack Size	CAT No.
F COVID-19 Ag FIA	25 Tests	10COV30D
F COVID-19 Ag FIA (Nasal)	25 Tests	10COV31D

COVID-19 IgM/IgG Combo FIA

» Background

STANDARD F COVID-19 IgM/IgG Combo FIA is the fluorescent immunoassay for the qualitative detection of specific antibodies to SARS-CoV-2 present in human serum, plasma and whole blood.

» Product Specification

CE

Test type	Professional use only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	20µl,10µl
Testing time	15 mins
Storage condition	2 – 30 °C / 36 - 86 °F

» Test Performance

Reference : Clinical evaluation

Reference	Sensitivity	Specificity
PCR	100% (119/119) (≥7 days after symptom onset)	95.33 (143/150)

» Ordering Information

Product	Pack Size	CAT No.
F COVID-19 IgM/IgG Combo FIA	40 Tests	10COV50G

STANDARD F COVID/Flu Ag Combo FIA

» Background

STANDARD F COVID/Flu Ag Combo FIA is a fluorescent immunoassay for the qualitative detection of specific antigens to SARS-CoV-2, Influenza A and Influenza B present in human nasal and nasopharyngeal swab specimen.

» Product Specification

CE

Test type	Professional use only
Specimen type	Nasal swab, Nasopharyngeal swab / Transport media
Specimen volume	4 drops
Testing time	15 mins
Storage condition	2 – 30 °C / 36 - 86 °F

» Ordering Information

Product	Pack Size	CAT No.
F COVID/Flu Ag Combo FIA (Nasal)	25 Tests	10COV70D
F COVID/Flu Ag Combo FIA	25 Tests	10COV71D

STANDARD F Influenza A/B FIA

» Background

STANDARD F Influenza A/B FIA (Analyzer+Test device) is a commercially available rapid diagnostics test system. It can perform the test accurately and rapidly within 1.5-10 minutes with the STANDARD F analyzer.

» Product Specification

CE

Test type	Professional use only
Specimen type	Nasal swab / Nasopharyngeal swab / Nasopharyngeal wash / Nasopharyngeal aspirate / Transport media
Specimen volume	4 drops
Testing time	10 mins (Early detection available)
Storage condition	2 – 30 °C / 36 - 86 °F

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
RT-PCR	A : 97.0% (93.0-99.0%) B : 94.3% (88.0-97.9%)	A : 97.6% (93.1-99.5%) B : 97.6% (93.1-99.5%)

» Ordering Information

Product	Pack Size	CAT No.
F Influenza A/B FIA	25 Tests	10INF20D
Influenza A/B Control	Pos x 10 / Neg x 10	10INFC10

STANDARD F RSV Ag FIA

» Background

STANDARD F RSV Ag FIA test system can aid in making treatment decision, such as medicine prescribing and further diagnosis, in clinical settings.

» Product Specification

CE

Test type	Professional use only
Specimen type	Nasopharyngeal swab / Nasopharyngeal aspirate / Nasopharyngeal wash / Transport media
Specimen volume	4 drops
Testing time	15 mins (Early detection available)
Storage condition	2 – 30 °C / 36 - 86 °F

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
RT-PCR	90.57% (48/53)	92.19% (118/128)

» Ordering Information

Product	Pack Size	CAT No.
F RSV Ag FIA	25 Tests	10RSV10D
RSV Ag Control	Pos x 10 / Neg x 10	10RSVC10

STANDARD F Strep A Ag FIA

» Background

STANDARD F Strep A Ag FIA test system (Analyzer + Test device) detects group A Streptococcal (Strep A) antigen through throat swabs of symptomatic patients or confirms Group A Streptococcal colonies that are recovered from culture.

» Product Specification

CE

Test type	Professional use only
Specimen type	Throat swab
Specimen volume	100µl
Testing time	5 mins (Early detection available)
Storage condition	2 – 30 ℃ / 36 - 86 ℉

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
Bacterial culture	93.3% (28/30)	95% (38/40)

» Ordering Information

Product	Pack Size	CAT No.
F Strep A Ag FIA	25 Tests	10STR10D
Strep A Ag Control	Pos x 10 / Neg x 10	10STRC10

STANDARD F *Legionella* Ag FIA

» Background

STANDARD F *Legionella* Ag FIA test system (Analyzer + Test device) detects *Legionella pneumophila* serogroup 1, 3, 5, 6 and 8 antigens via urine sample. Without any further sample processing, STANDARD F *Legionella* Ag FIA performs highly sensitively, and the test is not affected by Rheumatoid factor.

» Product Specification

CE

Test type	Professional use only
Specimen type	Urine
Specimen volume	100µl
Testing time	15 mins (Early detection available)
Storage condition	2 – 30 ℃ / 36 - 86 ℉

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
Fluorescent immunoassay	97.67% (42/43)	99.38% (160/161)

» Ordering Information

Product	Pack Size	CAT No.
F *Legionella* Ag FIA	25 Tests	10LEG10D
Legionella Ag Control	Pos x 10 / Neg x 10	10LEGC10

STANDARD F *S. pneumoniae* Ag FIA

» Background

STANDARD F *S. pneumoniae* Ag FIA test system (Analyzer + Test Device) finds *S. pneumoniae* antigen in urine if patients have pneumonia, and in cerebral spinal fluid sample if patients have meningitis.

» Product Specification

CE

Test type	Professional use only
Specimen type	Urine, CSF
Specimen volume	100µl
Testing time	10 mins (Early detection available)
Storage condition	2 – 30 °C / 36 - 86 °F

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
Blood culture	100% (52/52)	99.26% (135/136)

» Ordering Information

Product	Pack Size	CAT No.
F *S. pneumoniae* Ag FIA	25 Tests	10SPN10D
S. pneumoniae Ag Control	Pos x 10 / Neg x 10	10SPNC10

STANDARD F Adeno Respi Ag FIA

» Background

STANDARD F Adeno Respi Ag FIA (Analyzer+Test device) is a commercially available rapid diagnostics test system. It can perform the test accurately and rapidly within 15 minutes with the STANDARD F analyzer.

» Product Specification

CE

Test type	Professional use only
Specimen type	Nasal swab, Nasopharyngeal swab
Specimen volume	4drops
Testing time	15 mins (Early detection available)
Storage condition	2 – 30 °C / 36 - 86 °F

» Ordering Information

Product	Pack Size	CAT No.
F Adeno Respi Ag FIA	25 Tests	10ADE10D
Adeno Respi Ag Control	Positive control x 10 / Negative control x 10	10ADEC10

STANDARD F TB-Feron FIA (IFN-gamma)

» Background

STANDARD F TB-Feron FIA (IFN-gamma) aids to diagnosis of Tuberculosis infection. TB Antigens coated in TB-Feron Tube stimulate T cells in heparinized whole blood from patients with symptoms of Tuberculosis (TB), and T cells secrete interferon-γ (IFN-γ). The concentration of IFN-γ is measured by fluorescent immunoassay (FIA) to identify *in vitro* responses to those recombinant TB Antigens that are associated with *M.tuberculosis* infection.

» Product Specification

CE

Test type	Professional use only
Product Name	STANDARD™ F TB-Feron FIA (IFN-gamma)
Test Method	Fluorescent Immunoassay
Sample volume	100µl of plasma (collected from sensitized whole blood in TB-Feron Tubes)
Dynamic range	0.145 – 10 IU/ml
Testing time	15 mins
Storage Tempera-ture	2-30°C / 36-86°F

» Test Performance

Reference : Internal evaluation

		Product Q(4 tubes format)		Total
		Positive	Negative	
STANDARD F TB-Feron FIA (IFN-gamma)	Positive	26	0	26
	Negative	2	26	28
Total		28	26	54

- Positive agreement (%): **93 %**
- Negative agreement (%): **100 %**
- Total agreement (%): **96.3 %**

» Ordering Information

Cat. No.	Product Name	Pack size
10TBF10E	F TB-Feron FIA (IFN-gamma)	30T/Kit
07TBFA40	TB-Feron Tube SPP	30 tubes
10TBFC10	F TB-Feron Control	Lv1 x 10 / Lv2 x 10 / Lv3 x 10

STANDARD F Dengue NS1 Ag FIA

» Background

STANDARD F Dengue NS1 Ag FIA is a fluorescent immunoassay for the detection of Dengue virus NS1 antigen in human whole blood, serum, and plasma samples.

» Product Specification

CE

Test type	Professional use only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	100µl
Testing time	5 - 15 mins
Storage condition	2 – 30 °C / 36 - 86 °F

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
RT-PCR	100% (130/130)	100% (280/280)

» Ordering Information

Product	Pack Size	CAT No.
F Dengue NS1 Ag FIA	25 Tests	10DEN10D

STANDARD F Dengue IgM/IgG FIA

» Background

STANDARD F Dengue IgM/IgG FIA is a fluorescent immunoassay for the detection of Dengue virus–specific IgM and IgG antibodies in human whole blood, serum, and plasma samples.

» Product Specification

CE

Test type	Professional use only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	10µl
Testing time	15 mins
Storage condition	2 – 30 °C / 36 - 86 °F

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
ELISA	97.7% (42/43)	99.5% (183/184)

» Ordering Information

Product	Pack Size	CAT No.
F Dengue IgM/ IgG FIA	25 Tests	10DEN20D

STANDARD F Zika Ag FIA

» Background

STANDARD F Zika Ag FIA is a fluorescent immunoassay for the detection of Zika virus antigen in human whole blood, serum, and plasma samples.

» Product Specification

CE

Test type	Professional use only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	100µl
Testing time	5 - 15 mins
Storage condition	2 – 30°C / 36 - 86°F

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
RT-PCR	96.3% (52/54)	97.4% (150/154)

» Ordering Information

Product	Pack Size	CAT No.
F Zika Ag FIA	25 Tests	10ZK10D

STANDARD F Zika IgM FIA

» Background

STANDARD F Zika IgM FIA is a fluorescent immunoassay for the detection of Zika virus-specific IgM antibody in human whole blood, serum, and plasma samples.

» Product Specification

CE

Test type	Professional use only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	10µl
Testing time	15 mins
Storage condition	2 – 30°C / 36 - 86°F

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
ELISA	94.7% (36/38)	100% (74/74)

» Ordering Information

Product	Pack Size	CAT No.
F Zika IgM FIA	25 Tests	10ZK30D

STANDARD F Chikungunya IgM/IgG FIA

» Background

STANDARD F Chikungunya IgM/IgG FIA is a fluorescent immunoassay for the detection of Chikungunya virus-specific IgM and IgG antibodies in human whole blood, serum, and plasma samples.

» Product Specification

CE

Test type	Professional use only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	10µl
Testing time	15 mins
Storage condition	2 – 30 °C / 36 - 86 °F

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
ELISA	97.2% (35/36)	98.9% (178/180))

» Ordering Information

Product	Pack Size	CAT No.
F Chikungunya IgM/IgG FIA	25 Tests	10CHI10D

STANDARD F Tsutsugamushi IgM/IgG FIA

» Background

Scrub typhus is a disease caused by Orientia tsutsugamushi that is spread through chiggers (larval mites). STANDARD F Tsutsugamushi IgM/IgG FIA is a fluorescent immunoassay for the detection of *O. tsutsugamushi* bacteria specific IgM and IgG antibodies in human whole blood, serum, and plasma samples.

» Product Specification

CE

Test type	Professional use only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	10µl
Testing time	15 mins
Storage condition	2 – 30 °C / 36 - 86 °F

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
ELISA	IgM 100% (35/35) IgG 100% (63/63)	100% (180/180)

» Ordering Information

Product	Pack Size	CAT No.
F Tsutsugamushi IgM/IgG FIA	25 Tests	10TSU10D

VECTOR BORNE DISEASE

STANDARD F Lyme IgM/IgG FIA

» Background

Lyme disease is caused by bacteria, Borrelia burgdorferi that are transmitted through black-legged or deer tick. STANDARD F Lyme IgM/IgG FIA is a fluorescent immunoassay for the detection of *B. burgdorferi* specific IgM and IgG antibodies in human whole blood, serum, and plasma samples.

» Product Specification

CE

Test type	Professional use only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	10µl
Testing time	15 mins
Storage condition	2 – 30°C / 36 - 86°F

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
ELISA	IgM 100% (29/29) IgG 100% (30/30)	100% (212/212)

» Ordering Information

Product	Pack Size	CAT No.
F Lyme IgM/IgG FIA	25 Tests	10LYM10D

GASTROINTESTINAL DISEASE

STANDARD F Norovirus Ag FIA

» Background

STANDARD F Norovirus Ag FIA is a fluorescent immunoassay for the detection of Norovirus antigen in human fecal sample. The test kit is for *in vitro* use only.

» Product Specification

CE

Test type	Professional use only
Specimen type	Feces
Specimen volume	40-70mg
Testing time	15 mins
Storage condition	2 – 30°C / 36 - 86°F

» Ordering Information

Product	Pack Size	CAT No.
F Norovirus Ag FIA	25 Tests	10NOR10D

STANDARD Q Rotavirus Ag

» Background

STANDARD Q Rotavirus Ag Test is a Colloidal gold-based immunochromatographic assay for the detection of Rotavirus in human fecal sample. The test result can be determined visually and using the STANDARD F analyzers.

» Product Specification

CE

Test type	Professional use only
Specimen type	Feces
Specimen volume	40-70mg
Testing time	15 mins
Storage condition	2 – 30 ℃ / 36 - 86 ℉

» Ordering Information

Product	Pack Size	CAT No.
Q Rotavirus Ag	25 Tests	09ROT10D

STANDARD F Rota/Adeno Ag FIA

» Background

STANDARD F Rota/Adeno Ag FIA is a fluorescent immunoassay for the qualitative detection of the presence of Rotavirus and/or Adenovirus antigens in fecal specimens. STANDARD F Rota/Adeno Ag FIA should be used with STANDARD F Analyzers manufactured by SD BIOSENSOR.

» Product Specification

CE

Test type	Professional use only
Specimen type	Feces
Specimen volume	50-75mg
Testing time	15 mins
Storage condition	2-8 ℃/ 36-46 F

» Ordering Information

Product	Pack Size	CAT No.
F Rota/Adeno Ag FIA	25 Tests	10ROT10D

STANDARD Q Rota/Adeno Ag

» Background

STANDARD Q Rota/Adeno Ag Test is a Colloidal gold-based immunochromatographic assay for simultaneous detection and differentiation of Rotavirus and Adenovirus in human fecal sample. The test result can be determined visually and using the STANDARD F analyzers.

» Product Specification

CE

Test type	Professional use only
Specimen type	Feces
Specimen volume	40-70mg
Testing time	20 mins
Storage condition	2 – 30 ℃ / 36 - 86 ℉

» Ordering Information

Product	Pack Size	CAT No.
Q Rota/Adeno Ag	25 Tests	09ROT20D

STANDARD F *H. pylori* Ag FIA

» Background

STANDARD F *H. pylori* Ag FIA is a fluorescent immunoassay for the detection of *H. pylori* antigen in human fecal samples.

» Product Specification

CE

Test type	Professional use only
Specimen type	Feces
Specimen volume	40-70mg
Testing time	10 mins
Storage condition	2 – 30 ℃ / 36 - 86 ℉

» Test Performance

Reference : Internal evaluation

	Sensitivity	Specificity
Internal Study	100% (5/5)	100% (150/150)

» Ordering Information

Product	Pack Size	CAT No.
F *H. pylori* Ag FIA	25 Tests	10HPY10D

STANDARD F *C. difficile* GDH FIA

» Background

STANDARD F *C. difficile* GDH FIA qualitatively analyzes *Clostridium difficile* Glutamate dehydrogenase (GDH) antigen in human feces.

» Product Specification

CE

Test type	Professional use only
Specimen type	Feces
Specimen volume	40-70mg
Testing time	15 mins
Storage condition	2 – 30 ℃ / 36 - 86 ℉

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
Culture GDH	95.24% (80/84)	100% (150/150)
EIA GDH (Well type)	100% (77/77)	100% (79/79)

» Ordering Information

Product	Pack Size	CAT No.
F *C. difficile* GDH FIA	25 Tests	10CDG10D

STANDARD F *C. difficile* Toxin A/B FIA

» Background

STANDARD F *C. difficile* Toxin A/B FIA qualitatively analyzes *C. difficile* Toxin A & B in human feces.

» Product Specification

CE

Test type	Professional use only
Specimen type	Feces
Specimen volume	40-70mg
Testing time	15 mins
Storage condition	2 – 30 ℃ / 36 - 86 ℉

» Ordering Information

Product	Pack Size	CAT No.
F *C. difficile* Toxin A/B FIA	25 Tests	10CDT10D

STANDARD F Anti-HBs FIA

» Background

STANDARD F Anti-HBs FIA is a fluorescent immunoassay for the qualitative detection of antibodies directed against Hepatitis B surface antigen (HBsAg) present in patients' whole blood, serum, and plasma.

» Product Specification

CE

Test type	Professional use only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	100 µl
Testing time	15 mins
Storage condition	2 – 30 ℃ / 36 - 86 ℉

» Ordering Information

Product	Pack Size	CAT No.
F Anti-HBs FIA	25 Tests	10AHB10D

STANDARD F HBsAg FIA

» Background

STANDARD F HBsAg FIA is a fl uorescent immunoassay for the qualitative detection of Hepatitis B surface antigen (HBsAg) present in whole blood, serum and plasma.

» Product Specification

CE

Test type	Professional use only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	100 µl
Testing time	20 mins
Storage condition	2 – 30 ℃ / 36 - 86 ℉

» Ordering Information

Product	Pack Size	CAT No.
F HBsAg FIA	25 Tests	10HBS10D

STANDARD F HCV Ab FIA

» Background

According to WHO, about 130-150 million people globally have chronic HCV infection, with more than 350,000 people dying from Hepatitis C-related liver diseases each year. STANDARD F HCV Ab FIA is a fluorescent immunoassay for the detection of Hepatitis C virus (HCV) antibodies in human whole blood, serum, and plasma samples.

» Product Specification

Test type	Professional use only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	10µl
Testing time	15 mins (5 mins early detection for strong positive sample)
Storage condition	2 – 30 °C / 36 - 86 °F

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
CLIA	99.77% (439/440)	100% (1,210/1,210)

» Ordering Information

Product	Pack Size	CAT No.
F HCV Ab FIA	25 Tests	10HCV10D

STANDARD F HAV IgM FIA

» Background

Hepatitis A infection is caused worldwide and typically transmitted by the fecal oral route either via direct contact with an infectious person or consumption of contaminated food or water. STANDARD F HAV IgM FIA is a fluorescent immunoassay for the detection of hepatitis A virus IgM antibody in human whole blood, serum, and plasma samples.

» Product Specification

CE

Test type	Professional use only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	10µl
Testing time	15 mins
Storage condition	2 – 30 °C / 36 - 86 °F

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
CLIA	100% (98/98)	98.4% (189/192)

» Ordering Information

Product	Pack Size	CAT No.
F HAV IgM FIA	25 Tests	10HAV10D

BLOOD BORNE DISEASE

STANDARD F HIV Ag/Ab FIA

» Background

Fourth-generation HIV test detects both HIV antibodies and p24 antigens, which provides a faster diagnosis of HIV than 2nd or 3rd generation tests. STANDARD F HIV Ag/Ab FIA is a fluorescent immunoassay for the simultaneous detection of p24 antigen and HIV antibodies in human whole blood, serum, and plasma samples.

» Product Specification

Test type	Professional use only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	100µl
Testing time	15 mins
Storage condition	2 – 30 °C / 36 - 86 °F

» Ordering Information

Product	Pack Size	CAT No.
F HIV Ag/Ab FIA	25 Tests	10HIV20D

STI

STANDARD F Syphilis Ab FIA

» Background

Syphilis is a sexually transmitted infection (STI) caused by *Treponema pallidum* (TP). It is transmissible by sexual contact with infectious lesions, from mother to fetus in utero and via blood product transfusion. STANDARD F Syphilis Ab FIA is a fluorescent immunoassay for the detection of TP antibodies in human whole blood, serum, and plasma samples.

» Product Specification

CE

Test type	Professional use only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	Whole blood: 20µl Serum/Plasma: 10µl
Testing time	15 mins (5 mins early detection for strong positive sample)
Storage condition	2 – 30°C / 36 - 86°F

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
CLIA	100% (56/56)	100% (531/531)

» Ordering Information

Product	Pack Size	CAT No.
F Syphilis Ab FIA	25 Tests	10SYP10D

STANDARD F HbA1c

» Background

STANDARD F HbA1c is a test for quantitative measurement of glycated hemoglobin (HbA1c) in human capillary or venous whole blood. This test is to monitor glycemic control in people with diabetes.

» Product Specification

Test type	Professional use only
Specimen type	Whole blood
Specimen volume	5µl
Measuring range	4 – 15 % [NGSP], 20 – 140 mm/mol [IFCC]
Reference range	≤ 5.6% (Normal) | 5.7 – 6.4% (Prediabetes) | ≥ 6.5% (Diabetes) 7% (ADA target for diabetes patients)
Testing time	3 mins
Storage condition	2 – 30 °C / 36 - 86 °F

» Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F HbA1c	
Correlation with HPLC	y=0.9765x + 0.1254, R^2=0.9973, n=80
CV%	< 3%
Differ(%)	within 6% (NGSP criteria)

» Ordering Information

Product	Pack Size	CAT No.
F HbA1c	20 Tests	10A1C10B
SDB HbA1c Control	Lv1 x 10 / Lv2 x 10	03ACS10

STANDARD F U-Albumin FIA

» Background

STANDARD F U-Albumin FIA is a test for the quantitative measurement of microalbumin in human urine. This test is to aid to the prediction of diabetic nephropathy and cardiovascular diseases (CVD).

» Product Specification

Test type	Professional use only
Specimen type	Random urine
Specimen volume	3µl
Measuring range	5 – 250 mg/L
Reference range	< 20 mg/L (Normal) | 20 - 200 mg/L (Microalbuminuria) | > 200 mg/L (Macroalbuminuria or proteinuria)
Testing time	5 mins
Storage condition	2 – 30 °C / 36 - 86 °F

» Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F U-Albumin FIA	
Correlation with Immunoturbidimetric assay	y=0.9969x + 0.0181, R^2=0.9983, n=210
CV%	< 7%
Differ(%)	within 10%

» Ordering Information

Product	Pack Size	CAT No.
F U-Albumin FIA	20 Tests	10UAL10B
F U-Albumin Control	Lv1 x 10 / Lv2 x 10	10UALC10

STANDARD F PCT FIA (Serum)

» Background

STANDARD F PCT FIA (Serum) is a fluorescent immunoassay for the quantitative measurement of procalcitonin level in human serum. PCT helps assess the severity and prognosis of bacterial infections, and support early diagnosis of sepsis.

» Product Specification

Test type	Professional use only
Specimen type	Serum
Specimen volume	50µl
Measuring range	0.1 – 50 ng/ml
Reference range	< 0.5 ng/mL (SEPSIS) | <0.25 ng/mL (LRTI)
Testing time	15 mins
Storage condition	2 – 30 °C / 36 - 86 °F

» Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F PCT (Serum)	
Correlation vs ECLIA Method	y=0.9942x + 0.0158, R=0.9933, n=210
CV%	QCL=5.8% / QCM=6.5% / QCH=5.8%
Differ(%)	within 12%

» Ordering Information

Product	Pack Size	CAT No.
F PCT FIA (Serum)	20 Tests	10PCT10B
F PCT Control	Lv1 x 10 / Lv2 x 10	10PCTC10

STANDARD F PCT FIA

» Background

STANDARD F PCT FIA is a fluorescent immunoassay for the quantitative measurement of procalcitonin level in human serum, plasma, and whole blood. Procalcitonin helps assess the severity and prognosis of bacterial infections, and support early diagnosis of sepsis.

» Product Specification

Test type	Professional use only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	100µl
Measuring range	0.05 – 50 ng/ml
Reference range	< 0.5 ng/mL (SEPSIS) | <0.25 ng/mL (LRTI)
Testing time	15 mins
Storage condition	2 – 30 °C / 36 - 86 °F

» Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F PCT	
Correlation vs ECLIA Method	y = 1.02147x +0.0743, R=0.9946, n=210
CV%	QCL=7.5% / QCM=9.2% / QCH=8.9%
Differ(%)	within 15%

» Ordering Information

Product	Pack Size	CAT No.
F PCT FIA	20 Tests	10PCT20B
F PCT-02 Control	Lv1 x 10 / Lv2 x 10	10PCTC20

INFLAMMATION

STANDARD F CRP

» Background

STANDARD F CRP is an immunoassay for the quantitative measurement of C-reactive protein level in human serum, plasma and whole blood. CRP helps access the severity and prognosis of inflammation and infection.

CE

» Product Specification

Test type	Professional use only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	5µl
Measuring range	1 – 150 mg/L (Whole blood) | 1 – 130 mg/L (Serum, Plasma)
Reference range	< 10.0 mg/L
Testing time	3 mins
Storage condition	2 – 30 °C / 36 - 86 °F

» Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F CRP	
Correlation vs ECLIA Method	y=0.9884x + 0.2003, R=0.9840, n=120
CV%	QCL=7.7% / QCM=8.1% / QCH=7.6%
Differ(%)	within 15%

» Ordering Information

Product	Pack Size	CAT No.
F CRP	20 Tests	10CRP10B
SDB CRP Control	Lv1 x 10 / Lv2 x 10	03CCS10

CARDIOVASCULAR DISEASE

STANDARD F CK-MB FIA

» Background

STANDARD F CK-MB FIA is a fluorescent immunoassay for the quantitative measurement of Creatine Kinase Isoenzyme-MB level in human serum and whole blood. This test is to screen and monitor the Acute Myocardial Infarction (AMI).

CE

» Product Specification

Test type	Professional use only
Specimen type	Whole blood(EDTA), Serum
Specimen volume	100µl
Measuring range	1 – 200 ng/mL
Reference range	< 5.0 ng/mL
Testing time	10 mins
Storage condition	2 – 30 °C / 36 - 86 °F

» Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F CK-MB FIA	
Correlation vs ECLIA Method	y=0.9937x – 0.047, R=0.9973, n=210
CV%	QCL=6.0% / QCM=6.3% / QCH=7.0%
Differ(%)	within 15%

» Ordering Information

Product	Pack Size	CAT No.
F CK-MB FIA	20 Tests	10CKM10B
F CK-MB Control	Lv1 x 10 / Lv2 x 10	10CKBC10

STANDARD F TnI FIA

» Background

STANDARD F TnI FIA is a fluorescent immunoassay for the quantitative measurement of Troponin I level in human serum and whole blood. This test is to screen and monitor the Acute Myocardial Infarction (AMI).

» Product Specification

Test type	Professional use only
Specimen type	Whole blood(EDTA), Serum
Specimen volume	100µl
Measuring range	0.05 – 20 ng/mL
Reference range	< 0.16 ng/mL
Testing time	10 mins
Storage condition	2 – 30 °C / 36 - 86 °F

» Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F TnI FIA	
Correlation vs ECLIA Method	y=0.9677x-0.0069, R=0.9918, n=120
CV%	QCL=8.8% / QCM=7.4% / QCH=7.1%
Differ(%)	Within 15% (Serum) / Within 20% (Whole blood)

» Ordering Information

Product	Pack Size	CAT No.
F TnI FIA	20 Tests	10TNI10B
F TnI Control	Lv1 x 10 / Lv2 x 10	10TNIC10

STANDARD F NT-proBNP FIA

» Background

STANDARD F NT-proBNP FIA is a fluorescent immunoassay for the quantitative measurement of N-terminal B-type Natriuretic Peptide (NT-proBNP) level in human serum and whole blood (EDTA). This test is to help diagnose congestive heart failure.

» Product Specification

Test type	Professional use only
Specimen type	Whole blood(EDTA), Serum
Specimen volume	100µl
Measuring range	50 – 25,000 pg/mL
Reference range	• Acute HF Rule-out : <300 pg/mL • Symptomatic chronic HF Rule-out : <125 pg/mL (<75 yrs) <450 pg/mL (≥75 yrs)
Testing time	15 mins
Storage condition	2 – 30 °C / 36 - 86 °F

» Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F NT-proBNP FIA	
Correlation vs ECLIA Method	y=0.9842x + 11.036, R^2= 0.9694 n=180
CV%	QCL=11.3% / QCM=11.2% / QCH=11.3%
Differ(%)	15%

» Ordering Information

Product	Pack Size	CAT No.
F NT-proBNP FIA	20 Tests	10NTP10B
F NT-proBNP Control	Lv1 x 10 / Lv2 x 10	10NTPC10

STANDARD F D-dimer FIA

» Background

STANDARD F D-dimer FIA is a fluorescent immunoassay for the quantitative measurement of D-dimer level in human plasma and whole blood. This test is performed to help rule out Deep Vein Thrombosis(DVT), Pulmonary embolism(PE), and stroke.

» Product Specification

CE

Test type	Professional use only
Specimen type	Whole blood(Sodium citrate), Plasma(Sodium citrate)
Specimen volume	10µl
Measuring range	25 - 5,000 ng/mL FEU
Reference range	≤ 500 ng/mL FEU
Testing time	7 mins
Storage condition	2 – 30 °C / 36 - 86 °F

» Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F D-dimer FIA	
Correlation vs ECLIA Method	y=1.0062x + 17.742, R=0.9920, n=120
CV%	QCL=6.8% / QCM=7.5% / QCH=8.8%
Differ(%)	within 15%

» Ordering Information

Product	Pack Size	CAT No.
F D-dimer FIA	20 Tests	10DDI10B
F D-dimer Control	Lv1 x 10 / Lv2 x 10	10DDIC10

STANDARD F hs-CRP

» Background

STANDARD F hs-CRP is an immunoassay for the quantitative measurement of C-reactive protein level in human serum, plasma, and whole blood. This test is performed to help predict a healthy person's risk of cardiovascular disease as part of a cardiovascular risk profile.

» Product Specification

CE

Test type	Professional use only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	5µl
Measuring range	0.1 – 15 mg/L
Reference range	< 1.0 (Normal) | 1.0 – 3.0 (Average risk) | > 3.0 (High risk)
Testing time	3 mins
Storage condition	2 – 30 °C / 36 - 86 °F

» Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F hs-CRP	
Correlation vs ECLIA Method	y=0.9994x-0.01, R=0.9989, n=120
CV%	QCL=7.6% / QCM=9.7% / QCH=9.8%
Differ(%)	within 15%

» Ordering Information

Product	Pack Size	CAT No.
F hs-CRP	20 Tests	10HSC10B
F hs-CRP Control	Lv1 x 10 / Lv2 x 10	10HSCC10

STANDARD F Vitamin D FIA

» Background

STANDARD F Vitamin D FIA is an in vitro diagnostic for the quantitative measurement of total 25-hydroxy Vitamin D (25-OH Vitamin D) in human serum and plasma.

» Product Specification

CE

Test type	Professional use only
Specimen type	Serum, Plasma
Specimen volume	35 µl
Testing time	45 mins
Storage condition	2 – 30°C / 36 - 86°F

» Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F Vitamin D FIA	
Correlation vs ECLIA Method	Y = 0.937x +1.347, R = 0.960, n=100
CV%	QCL =5.3% / QCH = 6.3%
Differ(%)	Within 15%

» Ordering Information

Product	Pack Size	CAT No.
F Vitamin D FIA	20 Tests	10VIT10B

STANDARD F β-hCG FIA

» Background

STANDARD F β-hCG FIA is a fluorescent immunoassay for the quantitative measurement of β-hCG level in human serum and whole blood. This test is performed to help diagnose pregnancy if a women is to undergo a medical treatment, be placed on certain drugs, or have other testing, such as x-rays, that might harm the developing baby.

» Product Specification

CE

Test type	Professional use only
Specimen type	Whole blood, Serum
Specimen volume	50µl
Measuring range	5 - 1,500 mIU/mL
Reference range	≥ 5.0 mIU/mL
Testing time	15 mins (Whole blood) | 10 mins (Serum)
Storage condition	2 – 30 °C / 36 - 86 °F

» Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F β-hCG FIA	
Correlation vs ECLIA Method	y=1.0161x-6.6452, R=0.9968, n=180
CV%	QCL=4.7% / QCM=4.7% / QCH=4.5%
Differ(%)	Within 15%

» Ordering Information

Product	Pack Size	CAT No.
F β-hCG FIA	20 Tests	10BHC10B
F β-hCG Control	Lv1 x 10 / Lv2 x 10	10BHCC10

STANDARD F LH FIA

» Background

STANDARD F LH FIA is a fluorescent immunoassay for the quantitative measurement of LH level in human serum, plasma and whole blood. This test is performed to help evaluate fertility issues, function of reproductive organs (ovaries or testicles), or to detect the ovulation.

» Product Specification

Test type	Professional use only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	20µl
Measuring range	1 – 100 mIU/mL
Reference range	14.0 – 95.6 mIU/mL (during ovulation phase)
Testing time	15 mins
Storage condition	2 – 30 °C / 36 - 86 °F

» Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F LH FIA	
Correlation vs ECLIA Method	y=0.9916x + 0.0866, R=0.9921, n=210
CV%	QCL=8.3% / QCM=8.0% / QCH=8.2%
Differ(%)	Within 15%

» Ordering Information

Product	Pack Size	CAT No.
F LH FIA	20 Tests	10LH10B
F LH Control	Lv1 x 10 / Lv2 x 10	10LHC10

STANDARD F TSH-II FIA

» Background

STANDARD F TSH-II FIA is a fluorescent immunoassay for the quantitative measurement of Thyroid Stimulating Hormone level in human serum and whole blood. This test is to help diagnose thyroid disorder; to monitor treatment of hypothyroidism and hyperthyroidism.

» Product Specification

Test type	Professional use only
Specimen type	Whole blood, Serum
Specimen volume	35µl
Measuring range	0.1 – 100 mIU/L
Reference range	0.45 – 4.5 mIU/L
Testing time	15 mins
Storage condition	2 – 30 °C / 36 - 86 °F

» Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F TSH-II FIA	
Correlation vs ECLIA Method	y=0.9874 + 0.1170, R=0.9971 n=180
CV%	QCL=11.6% / QCM=12.0% / QCH=11.0%
Differ(%)	within 15%

» Ordering Information

Product	Pack Size	CAT No.
F TSH-II FIA	20 Tests	10TSH20B
F TSH Control	Lv1 x 10 / Lv2 x 10	10TSHC10

STANDARD F TSH FIA

» Background

STANDARD F TSH FIA is a fluorescent immunoassay for the quantitative measurement of Thyroid Stimulating Hormone level in human serum. This test is to help diagnose thyroid disorder; to monitor treatment of hypothyroidism and hyperthyroidism.

» Product Specification

CE

Test type	Professional use only
Specimen type	Serum
Specimen volume	100µl
Measuring range	0.1 – 100 mIU/L
Reference range	0.45 – 4.5 mIU/L
Testing time	15 mins
Storage condition	2 – 30 °C / 36 - 86 °F

» Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F TSH FIA	
Correlation vs ECLIA Method	y=1.1097x – 0.5, R=0.9943, n=110
CV%	QCL=7.4% / QCM=6.5% / QCH=4.9%
Differ(%)	within 15%

» Ordering Information

Product	Pack Size	CAT No.
F TSH FIA	20 Tests	10TSH10B
F TSH Control	Lv1 x 10 / Lv2 x 10	10TSHC10

STANDARD F fT4

» Background

STANDARD F fT4 is an immunoassay for the quantitative measurement of free thyroxin(fT4) level in human serum. This test is to help diagnose thyroid disorder; to monitor treatment of hypothyroidism and hyperthyroidism.

» Product Specification

CE

Test type	Professional use only
Specimen type	Serum
Specimen volume	50µl
Measuring range	1 – 100 pmol/L
Reference range	12 – 22 pmol/L (0.93 – 1.7 ng/dL)
Testing time	15 mins
Storage condition	2 – 30 °C / 36 - 86 °F

» Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F fT4	
Correlation vs ECLIA Method	y=1.002x – 0.1452, R= 0.9943 n=120
CV%	QCL=7.5% / QCM=8.0% / QCH=8.0%
Differ(%)	Within 15%

» Ordering Information

Product	Pack Size	CAT No.
F fT4	20 Tests	10FT410B
F fT4 Control	Lv1 x 10 / Lv2 x 10	10FT4C10

STANDARD F T4

» Background

STANDARD F T4 is an immunoassay for the quantitative measurement of thyroxin(T4) level in human serum. This test is to help diagnose thyroid disorder; to monitor treatment of hypothyroidism and hyperthyroidism.

CE

» Product Specification

Test type	Professional use only
Specimen type	Serum
Specimen volume	50µl
Measuring range	20 – 300 nmol/L
Reference range	66 – 181 nmol/L (0.93 – 1.7 ng/dL)
Testing time	15 mins
Storage condition	2 – 30 ℃ / 36 - 86 ℉

» Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F T4	
Correlation vs ECLIA Method	y=1.0113x – 0.6502, R= 0.9943 n=120
CV%	QCL=7.7% / QCM=7.7% / QCH=8.0%
Differ(%)	Within 15%

» Ordering Information

Product	Pack Size	CAT No.
F T4	20 Tests	10T410B
F T4 Control	Lv1 x 10 / Lv2 x 10	10T4C10

STANDARD F PSA FIA

» Background

STANDARD F PSA FIA is a fluorescent immunoassay for the quantitative measurement of Prostate Specific Antigen level in human serum, plasma and whole blood. This test is performed to help screen men for prostate cancer, and to help determine the necessity for a biopsy of the prostate.

CE

» Product Specification

Test type	Professional use only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	100µl (Serum, Plasma) / 20µl (Whole blood)
Measuring range	0.1 – 100 ng/ml (Serum/Plasma) | 2 – 100 ng/ml (Whole blood)
Reference range	≤ 4.0 ng/ml
Testing time	10 mins
Storage condition	2 – 30 °C / 36 - 86 °F

» Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F PSA FIA	
Correlation vs ECLIA Method	y=0.9589x – 0.2336, R=0.9948, n=180
CV%	QCL=9.0% / QCM=8.0% / QCH=7.2%
Differ(%)	within 15%

» Ordering Information

Product	Pack Size	CAT No.
F PSA FIA	20 Tests	10PSA10B
F PSA Control	Lv1 x 10 / Lv2 x 10	10PSAC10

STANDARD F iFOB FIA

» Background

STANDARD F iFOB FIA is a fluorescent immunoassay for the quantitative measurement of hemoglobin in fecal sample. This test is offered as a screening test for the early detection of bowel cancer in patients without symptoms.

CE

» Product Specification

Test type	Professional use only
Specimen type	Feces
Specimen volume	3 drops
Measuring range	25 – 1,000 ng/mL (5 – 200 µg Hb/g feces)
Reference range	< 100 ng/mL (20 µg Hb/g feces)
Testing time	5 mins
Storage condition	2 – 30 °C / 36 - 86 °F

» Ordering Information

Product	Pack Size	CAT No.
F iFOB FIA	50 Tests	10IFO10C
F iFOB Control	Lv1 x 10 / Lv2 x 10	10IFOC10

STANDARD Q POCT Parameters

STANDARD Q COVID-19 Ag

Test type	Professional Use Only
Specimen type	Nasopharyngeal swab, VTM
Specimen volume	3 drops
Testing time	15-30 mins
Storage condition	2-30°C / 36-86°F

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
RT-PCR	95.92% -100% (CT≤25)	98.94%

» Ordering Information

Product	Pack Size	CAT No.
Q COVID-19 Ag Test	25 Tests	09COV30D
Q COVID-19 Ag Control Swab	Pos x 10, Neg x 10	10COVC11

STANDARD Q COVID-19 Ag (Nasal)

Test type	Professional Use Only
Specimen type	Nasal swab
Specimen volume	4 drops
Testing time	15-30 mins
Storage condition	2-30°C / 36-86°F

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
RT-PCR	97.12% (101/104)	100% (399/399)

» Ordering Information

Product	Pack Size	CAT No.
Q COVID-19 Ag Test (Nasal)	25 Tests	09COV33D
Q COVID-19 Ag Control Swab	Pos x 10, Neg x 10	10COVC11

STANDARD Q COVID-19 IgM/IgG Plus

Test type	Professional Use Only
Specimen type	Whole blood, Serum, Plasma, Capillary whole blood
Specimen volume	Whole blood : 20ul, Serum/Plasma : 10ul
Testing time	10 - 15 mins
Storage condition	2-30°C / 36-86°F

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity (≥ 7 days)	Specificity
RT-PCR	96.82% (152/157)	98.65%

» Ordering Information

Product	Pack Size	CAT No.
Q COVID-19 IgM/IgG Combo Test	25 Tests	09COV70DM
COVID-19 IgM/IgG Control	Pos x 10, Neg x 10	09COV50G

STANDARD Q COVID-19 Ag Saliva

CE

Test type	Professional Use Only
Specimen type	Saliva with mucus
Specimen volume	4 drops
Testing time	30 mins
Storage condition	2-30°C / 36-86°F

» Ordering Information

Product	Pack Size	CAT No.
Q COVID-19 Ag Saliva Test	25 Tests	09COV90D
COVID-19 Ag Control Swab	Pos x 10, Neg x 10	10COVC11

STANDARD Q COVID/Flu Ag Combo

CE

Test type	Professional Use Only
Specimen type	Nasopharyngeal swab
Specimen volume	4 drops
Testing time	15-30 mins
Storage condition	2-30°C /36-86°F

» Ordering Information

Product	Pack Size	CAT No.
Q COVID/Flu Ag Combo Test	25 Tests	09COV100D
COVID-19 Ag Control Swab	Pos x 10, Neg x 10	10COVC11
Influenza A/B Control	Pos x 10, Neg x 10	10INFC10

STANDARD Q COVID-19 Ag Home Test

Test type	Self-diagnostic test
Specimen type	Nasal swab
Specimen volume	4 drops
Testing time	15-30 mins
Storage condition	2-30°C /36-86°F

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
RT-PCR	82.5 (33/40)	100% (109/109)

» Ordering Information

Product	Pack Size	CAT No.
Q COVID-19 Ag Home Test	1 Test	09COV130
Q COVID-19 Ag Home Test	2 Test	09COV130H
Q COVID-19 Ag Home Test	5 Test	09COV130J
Q COVID-19 Ag Home Test	25 Test	09COV130D
COVID-19 Ag Control Swab	Pos x 10, Neg x 10	10COVC11

STANDARD i-Q COVID-19 Ag Home Test

Test type	Self-diagnostic test
Specimen type	Nasal swab
Testing time	15-30 mins
Storage condition	2-30°C / 36-86°F

» Ordering Information

Product	Pack Size	CAT No.
i-Q COVID-19 Ag Home Test	1 test	09COV121
i-Q COVID-19 Ag Home Test	2 test	09COV120H
COVID-19 Ag Control Swab	Pos x 10, Neg x 10	10COVC11

STANDARD Q Influenza A/B

CE

Test type	Professional Use Only
Intended use	Detection of influenza A/B antigens
Specimen type	Nasopharyngeal swab / Nasopharyngeal wash/aspirate
Testing time	8-12 mins (Do not read after 30 mins)
Storage condition	2 – 40°C / 36 - 104°F

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
PCR	A: 97.44% (95% CI: 86.52-99.94%) B: 90.63% (95% CI: 74.98-98.02%)	A: 100% (95% CI: 99.12-100.00%) B: 98.82% (95% CI: 97.26-99.61%)

» Ordering Information

Product	Pack Size	CAT No.
Q Influenza A/B Test	25 Tests	09INF40D
Influenza A/B Control	Pos x 10 / Neg x 10	10INFC10

STANDARD Q RSV Ag

CE

Test type	Professional Use Only
Intended use	Detection of Respiratory Syncytial Virus (RSV) antigens
Specimen type	Nasopharyngeal swab / Nasopharyngeal wash/aspirate
Testing time	15 mins (Do not read after 30 mins)
Storage condition	2 – 40°C / 36 - 104°F

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
PCR	92.45% (49/53)	98.44% (126/128)

» Ordering Information

Product	Pack Size	CAT No.
Q RSV Ag	25 Tests	09RSV40D
RSV Ag Control	Pos x 10 / Neg x 10	10RSVC10

STANDARD Q Strep A Ag

Test type	Professional Use Only
Intended use	Detection of Group A streptococcal antigens
Specimen type	Throat swab
Testing time	5 mins (Do not read after 15 mins)
Storage condition	2 – 40°C / 36 - 104°F

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
FIA	98.2% (56/57)	99.26% (135/136)

» Ordering Information

Product	Pack Size	CAT No.
Q Strep A Ag	25 Tests	09STR40D
Strep A Ag Control	Pos x 10 / Neg x 10	10STRC10

STANDARD Q *Legionella* Ag

Test type	Professional Use Only
Intended use	Detection of *Legionella pneumophila* serogroup 1, 3, 5,6 and 8 antigens
Specimen type	Urine
Specimen volume	100µl
Testing time	15 mins (Do not read after 30 mins)
Storage condition	2 – 40°C / 36 - 104°F

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
DFA (Direct fluorescent-antibody testing)	97.6% (41/42)	100% (165/165)

» Ordering Information

Product	Pack Size	CAT No.
Q *Legionella* Ag	25 Tests	09LEG30D
Legionella Ag Control	Pos x 10 / Neg x 10	10LEGC10

STANDARD Q *S.pneumoniae* Ag

Test type	Professional Use Only
Specimen type	Urine
Specimen volume	100µl
Testing time	15 mins (Do not read after 30 mins)
Storage condition	2 – 40°C / 36 - 104°F

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
PCR	11/11 (100%)	98% (98/100)

» Ordering Information

Product	Pack Size	CAT No.
Q *S.pneumoniae* Ag	25 Tests	09SPN30D
S.pneumoniae Ag Control	Pos x 10 / Neg x 10	10SPNC10

STANDARD Q Adeno Respi Ag

CE

Test type	Professional Use Only
Intended use	Detection of adenovirus antigens in respiratory specimens
Specimen type	Nasal swab, Nasopharyngeal swab
Specimen volume	4 drops
Testing time	15 mins (Do not read after 20 mins)
Storage condition	2 – 30°C / 36 - 86°F

» Ordering Information

Product	Pack Size	CAT No.
Q Adeno Respi Ag	25 Tests	09ADE10D
Adeno Respi Ag Control	Pos x 10 / Neg x 10	10ADEC10

STANDARD Q MERS-CoV Ag

CE

Test type	Professional Use Only
Intended use	Detection of MERS-CoV antigens
Specimen type	Nasopharyngeal swab / Nasopharyngeal aspirate / lower respiratory tract aspirate
Testing time	15 mins (Do not read after 30 mins)
Storage condition	2 – 40°C / 36 - 104°F

» Ordering Information

Product	Pack Size	CAT No.
Q MERS-CoV Ag	25 Tests	05MC10

STANDARD Q TB MPT64 Ag

CE

Test type	Professional Use Only
Intended use	Detection of Mycobacterium tuberculosis MPT64 antigen
Specimen type	Liquid culture, Solid culture
Testing time	10 mins (Do not read after 15 mins)
Storage condition	2 – 40°C / 36 - 104°F

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
PCR confirmed	100%	100%

» Ordering Information

Product	Pack Size	CAT No.
Q TB MPT64 Ag	25 Tests	09MPT10D

STANDARD Q Ebola *Zaire* Ag

CE

Test type	Professional Use Only
Intended use	Detection of *Zaire ebolavirus* antigens
Specimen type	Whole blood, Serum, Plasma
Testing time	20 mins (Do not read after 30 mins)
Storage condition	2 – 40°C / 36 - 104°F

» Ordering Information

Product	Pack Size	CAT No.
Q Ebola *Zaire* Ag	25 Tests	05EZ10

STANDARD Q Dengue Duo

CE

Test type	Professional Use Only
Intended use	Detection of Dengue NS1 antigen & IgM/IgG antibodies
Specimen type	Whole blood, Serum, Plasma
Specimen volume	NS1: 100µl, IgM/IgG: 10µl
Testing time	15-20 mins
Storage condition	2 – 40°C / 36 - 104°F

» Test Performance

Reference : Internal evaluation

	Reference	Sensitivity	Specificity
NS1	RT-PCR	92.9% (184/198)	98.7% (222/225)
IgM	ELISA	97.5% (77/79)	96.6% (346/358)
IgG	ELISA	97.2% (140/144)	96.2% (282/293)

» Ordering Information

Product	Pack Size	CAT No.
Q Dengue Duo Test	10 Tests	09DEN30A

STANDARD Q Dengue NS1 Ag

CE

Test type	Professional Use Only
Intended use	Detection of Dengue NS1 antigen
Specimen type	Whole blood, Serum, Plasma
Specimen volume	100µl
Testing time	15-20 mins
Storage condition	2 – 40°C / 36 - 104°F

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
RT-PCR	92.9% (184/198)	98.7% (222/225)

» Ordering Information

Product	Pack Size	CAT No.
Q Dengue NS1 Ag Test	25 Tests	09DEN10D

STANDARD Q Dengue IgM/IgG

CE

Test type	Professional Use Only
Intended use	Detection of Dengue IgM and IgG antibodies
Specimen type	Whole blood, Serum, Plasma
Specimen volume	10µl
Testing time	15-20 mins
Storage condition	2 – 40°C / 36 - 104°F

» Test Performance

Reference : Internal evaluation

	Reference	Sensitivity	Specificity
IgM	ELISA	97.5% (77/79)	96.6% (346/358)
IgG	ELISA	97.2% (140/144)	96.2% (282/293)

» Ordering Information

Product	Pack Size	CAT No.
Q Dengue IgM/IgG Test	25 Tests	09DEN20D

STANDARD Q Zika IgM

Test type	Professional Use Only
Intended use	Detection of Zika IgM antibody
Specimen type	Whole blood, Serum, Plasma
Specimen volume	10µl
Testing time	15-20 mins
Storage condition	2 – 40°C / 36 - 104°F

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
MAC- ELISA / PCR	98.0% (49/50)	100% (70/70)

» Ordering Information

Product	Pack Size	CAT No.
Q Zika IgM Test	25 Tests	09ZK40D

STANDARD Q Chikungunya IgM/IgG

Test type	Professional Use Only
Intended use	Detection of Chikungunya IgM and IgG antibodies
Specimen type	Whole blood, Serum, Plasma
Specimen volume	10µl
Testing time	15-20 mins
Storage condition	2 – 40°C / 36 - 104°F

» Test Performance

Reference : Internal evaluation

	Reference	Sensitivity	Specificity
IgM	ELISA	100% (21/21)	97.7% (253/259)
IgG	ELISA	100% (21/21)	99.6% (258/259)

» Ordering Information

Product	Pack Size	CAT No.
Q Chikungunya IgM/IgG Test	25 Tests	09CHI20D

STANDARD Q Yellow Fever IgM

Test type	Professional Use Only
Intended use	Detection of Yellow Fever IgM antibody
Specimen type	Whole blood, Serum, Plasma
Specimen volume	10µl
Testing time	15-20 mins
Storage condition	2 – 40°C / 36 - 104°F

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
ELISA	100% (8/8)	98.3% (173/177)

» Ordering Information

Product	Pack Size	CAT No.
Q Yellow Fever IgM Test	25 Tests	09YEL20D

STANDARD Q Arbovirus Multi Tests

STANDARD Q Arbo Panel I (Z/D/C/Y)

Test type	Professional Use Only
Intended use	Detection of Dengue NS1 antigen and IgM specific to Zika, Dengue, Chikungunya, or Yellow fever
Specimen type	Whole blood, Serum, Plasma
Specimen volume	NS1: 100µl, IgM : 10µl
Testing time	15-20 mins
Storage condition	2 – 40°C / 36 - 104°F

STANDARD Q ZIKV/DENV/CHIKV Fast Quad

Test type	Professional Use Only
Intended use	Detection of Dengue NS1 antigen and IgM specific to Zika, Dengue, or Chikungunya
Specimen type	Whole blood, Serum, Plasma
Specimen volume	NS1: 100µl, IgM : 10µl
Testing time	15-20 mins
Storage condition	2 – 40°C / 36 - 104°F

STANDARD Q Dengue/Chikungunya Trio

Test type	Professional Use Only
Intended use	Detection of Dengue NS1 antigen and IgM/IgG specific to Dengue or Chikungunya
Specimen type	Whole blood, Serum, Plasma
Specimen volume	NS1: 100µl, IgM/IgG : 10µl
Testing time	15-20 mins
Storage condition	2 – 40°C / 36 - 104°F

STANDARD Q Zika/Dengue Fast Trio

Test type	Professional Use Only
Intended use	Detection of Dengue NS1 antigen and IgM specific to Zika or Dengue
Specimen type	Whole blood, Serum, Plasma
Specimen volume	NS1: 100µl, IgM : 10µl
Testing time	15-20 mins
Storage condition	2 – 40°C / 36 - 104°F

» Ordering Information

Product	Pack Size	CAT No.
Q Arbo Panel I (Z/D/C/Y) Test	10 Tests	09ZK110U
Q ZIKV/DENV/CHIKV Fast Quad Test	10 Tests	09ZK100A
Q Dengue/Chikungunya Trio Test	10 Tests	09DEN40A
Q Zika/Dengue Fast Trio Test	10 Tests	09ZK61A

STANDARD Q Malaria P.f Ag

WHO PQ approved CE

Test type	Professional Use Only
Intended use	Detection of Malaria *Plasmodium falciparum* specific Histidine Rich Protein 2 (HRP-2)
Specimen type	Whole blood
Specimen volume	5µl
Testing time	15-30 mins
Storage condition	2 – 40°C / 36 - 104°F

» Test Performance

Reference : Internal evaluation

	Reference	Sensitivity	Specificity
Venous whole blood	Microscopy	99.59% (487/489)	100% (1104/1104)
Capillary whole blood	Microscopy	99.38% (322/324)	100% (256/256)

» Ordering Information

Product	Pack Size	CAT No.
Q Malaria P.f Ag Test	25 Tests	09MAL10D

STANDARD Q Malaria P.f/P.v Ag

WHO PQ approved CE

Test type	Professional Use Only
Intended use	Detection of Malaria *P. falciparum* specific HRP-2 and *Plasmodium vivax* specific Plasmodium lactate dehydrogenase (pLDH)
Specimen type	Whole blood
Specimen volume	5µl
Testing time	15-30 mins
Storage condition	2 – 40°C / 36 - 104°F

» Test Performance

Reference : Internal evaluation

	Reference		Sensitivity	Specificity
Venous whole blood	Microscopy	P.f	99.59% (487/489)	100% (1006/1006)
		P.v	100% (123/123)	
Capillary whole blood	Microscopy	P.f	99.38% (322/324)	100% (256/256)
		P.v	100% (25/25)	

» Ordering Information

Product	Pack Size	CAT No.
Q Malaria P.f/P.v Ag Test	25 Tests	09MAL20D

STANDARD Q Malaria P.f/Pan Ag

WHO PQ approved CE

Test type	Professional Use Only
Intended use	Detection of Malaria *P. falciparum* specific HRP-2 and Plasmodium species (*P. falciparum, vivax, ovale* and *malariae*) specific pLDH
Specimen type	Whole blood
Specimen volume	5µl
Testing time	15-30 mins
Storage condition	2 – 40°C / 36 - 104°F

» Test Performance

Reference : Internal evaluation

	Reference		Sensitivity	Specificity
Venous whole blood	Microscopy	P.f	99.58% (476/478)	100% (1000/1000)
		P.v, P.m. and P.o. confirmed specimen on Pan	100% (129/129)	
Capillary whole blood	Microscopy	P.f	99.68% (312/313)	100% (11/11)
		P.v, P.m. and P.o. confirmed specimen on Pan	100% (31/31)	

» Ordering Information

Product	Pack Size	CAT No.
Q Malaria P.f/ Pan Ag Test	25 Tests	09MAL30D

STANDARD Q Malaria/CRP Duo

CE

Test type	Professional Use Only
Intended use	Detection of Malaria *P. falciparum* specific HRP-2 and *Plasmodium* species (*P. falciparum, vivax, ovale* and *malariae*) specific pLDH & C-Reactive Protein (CRP)
Specimen type	Whole blood
Specimen volume	Mal: 5µl / CRP: 10µl
Testing time	Mal: 15-30 mins / CRP: 15-20 mins
Storage condition	2 – 40°C / 36 - 104°F

» Test Performance

Reference : Internal evaluation

	Reference	Sensitivity	Specificity
P.f	Microscopy	99.58% (476/478)	100% (1000/1000)
P.v, P.m. and P.o. confirmed specimen on Pan	Microscopy	100% (129/129)	
CRP	Immunoturbidimetric	87.5% (21/24)	100% (50/50)

» Ordering Information

Product	Pack Size	CAT No.
Q Malaria/CRP Duo Test	25 Tests	09MAL50D

STANDARD Q Leptospira IgM/IgG

CE

Test type	Professional Use Only
Intended use	Detection of *Leptospira interrogans* IgM and IgG antibodies
Specimen type	Whole blood, Serum, Plasma
Specimen volume	10µl
Testing time	15-20 mins
Storage condition	2 – 40°C / 36 - 104°F

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
ELISA	96.6% (29/30)	98.6% (143/145)

» Ordering Information

Product	Pack Size	CAT No.
Q Leptospira IgM/IgG Test	25 Tests	09LEP10D

STANDARD Q Tsutsugamushi IgM/IgG

CE

Test type	Professional Use Only
Intended use	Detection of *Orientia tsutsugamushi* IgM and IgG antibodies
Specimen type	Whole blood, Serum, Plasma
Specimen volume	10µl
Testing time	15-20 mins
Storage condition	2 – 40°C / 36 - 104°F

» Ordering Information

Product	Pack Size	CAT No.
Q Tsutsugamushi IgM/IgG Test	25 Tests	09TSU10D

STANDARD Q HIV/Syphilis Combo

WHO PQ approved

Test type	Professional Use Only
Intended use	Detection of specific antibodies to all isotypes of HIV-1/2 and *Treponema pallidum*
Specimen type	Whole blood, Serum, Plasma
Specimen volume	Whole blood: 20µl, Serum/Plasma: 10µl
Testing time	15 mins (Do not read after 20 mins)
Storage condition	2 – 40°C / 36 - 104°F

» Test Performance in accordance with CTS

Detection of HIV Ab			
Sensitivity [95% CI]		**Specificity** [95% CI]	
Total	**100.0%** [99.4-100.0%](637/637)	Total	**99.9%** [99.6-100.0%](1,898/1,900)
HIV-1 positive	100.0% (497/497)	EDTA plasma	100.0% (1,000/1,000)
HIV-1 positive(non-B subtypes*)	100.0% (40/40)	Whole blood	99.8% (499/500)
HIV-2 positive	100.0% (100/100)	Hospitalized patients	99.5% (199/200)
		Pregnant women	100.0% (200/200)

* non-B subtypes: A, A1, CRF01_AE, CRF02_AG, CRF06_cpx, CRF36_cpx, D, F1, F2, G, H, J, K, Group O

Detection of *Treponema pallidum* Ab			
Sensitivity [95% CI]		**Specificity** [95% CI]	
Total	**98.8%** [97.1-99.5%](395/400)	Total	**100.0%** [99.8-100.0%](1,900/1,900)
Tp & HIV positive	98.4% (246/250)	EDTA plasma	100.0% (1,000/1,000)
Tp positive	99.3% (149/150)	Whole blood	100.0% (500/500)
		Hospitalized patients	100.0% (200/200)
		Pregnant women	100.0% (200/200)

» Ordering Information

Product	Pack Size	CAT No.
Q HIV/Syphilis Combo Test	25 Tests	09HIV20D

STANDARD Q Syphilis Ab

CE

Test type	Professional Use Only
Intended use	Detection of specific antibodies to *Treponema pallidum*
Specimen type	Whole blood, Serum, Plasma
Specimen volume	Whole blood: 20µl, Serum/Plasma: 10µl
Testing time	5-20 mins
Storage condition	2 – 40°C / 36 - 104°F

» Test Performance

Reference	Sensitivity	Specificity
RPR, ELISA, TPHA	100%(700/700)	100% (1,200/1,200)

Reference : Ghana - NPHRL(National Public Health and Reference Laboratory)
India - RPL (Rao's Pathlab)

» Ordering Information

Product	Pack Size	CAT No.
Q Syphilis Ab Test	25 Tests	09SYP10D
Q Syphilis Ab Test	100 Tests	09SYP10FM
Syphilis Ab Control	Pos x 10 / Neg x 10	10SYPC10

BLOOD BORNE DISEASE

STANDARD Q HIV 1/2 Ab 3-Line

WHO PQ approved

Test type	Professional Use Only
Intended use	Detection of specific antibodies to all isotypes of HIV-1/2
Specimen type	Whole blood, Serum, Plasma
Specimen volume	Whole blood: 20µl, Serum/Plasma: 10µl
Testing time	10-20 mins
Storage condition	2 – 40°C / 36 - 104°F

» Test Performance in accordance with CTS

STANDARD Q HIV 1/2 Ab 3-Line Test			
Sensitivity [95% CI]		**Specificity** [95% CI]	
Total	**99.8%** [98.9-100.0%](500/501)	Total	**100.0%** [99.8-100.0%] (1,900/1,900)
HIV-1 positive	99.7% (360*/361)	EDTA plasma	100.0% (1,000/1,000)
HIV-1 positive (non-B subtypes**)	100.0% (40/40)	Whole blood	100.0% (500/500)
		Hospitalized patients	100.0% (200/200)
HIV-2 positive	100.0% (100/100)	Pregnant women	100.0% (200/200)

* The missed sample was collected from a patient receiving HAART very soon after seroconversion phase.
** non-B subtypes: A, A1, CRF01_AE, CRF02_AG, CRF06_cpx, CRF36_cpx, D, F1, F2, G, H, J, K, Group O

» Ordering Information

Product	Contents	Pack Size	CAT No.
Q HIV 1/2 Ab 3-Line Test	Device/Assay diluent/Capillary Tube/Lancet/Alcohol swab	25 Tests	09HIV30D
	Device/Assay diluent	25 Tests	09HIV30DM
	Multi-Device/Assay diluent	100 Tests	09HIV30F

HEPATITIS

STANDARD Q HAV IgM

CE

Test type	Professional Use Only
Intended use	Detection of Hepatitis A virus IgM antibody
Specimen type	Whole blood, Serum, Plasma
Specimen volume	10µl
Testing time	15-20 mins
Storage condition	2 – 40°C / 36 - 104°F

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
CLIA	100% (26/26)	98.04% (450/459)

» Ordering Information

Product	Pack Size	CAT No.
Q HAV IgM Test	25 Tests	09HAV10D

STANDARD Q HCV Ab

WHO PQ approved

Test type	Professional Use Only
Intended use	Detection of Hepatitis C virus antibody
Specimen type	Serum, Plasma
Specimen volume	10µl
Testing time	5-20 mins
Storage condition	2 – 40°C / 36 - 104°F

» Test Performance in accordance with CTS

Detection of HCV Ab			
Sensitivity [95% CI]		**Specificity** [95% CI]	
Total	**100.0%** [99.1-100.0%](413/413)	Total	**97.67%** (1465/1500)
HCV positive	100.0% (311/311)	EDTA Plasma	97.2% (972/1000)
HCV positive(genotypes*)	100.0% (102/102)	Whole blood	98.6% (493/500)

* HCV genotypes: 1, 1a, 1b, 2a, 2c, 2b, 3, 3a, 3b, 3k, 4a, 4c, 4d, 4e, 4h, 5, 5a, 6, 6a

» Ordering Information

Product	Contents	Pack Size	CAT No.	
Q HCV Ab Test	Device/Assay diluent/Capillary Tube	25 Tests	09HCV10D	
	Device/Assay diluent	25 Tests	09HCV20D	CE 0123
	Multi-Device/Assay diluent	100 Tests	09HCV20F	

STANDARD Q HBsAg

Test type	Professional Use Only
Intended use	Detection of Hepatitis B virus surface antigen (HBsAg)
Specimen type	Whole blood, Serum, Plasma
Specimen volume	100µl
Testing time	20-30 mins
Storage condition	2 – 40°C / 36 - 104°F

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
CLIA	100% (43/43)	100% (162/162)

» Ordering Information

Product	Pack Size	CAT No.
Q HBsAg Test	25 Tests	09HBS10D

STANDARD Q Anti-HBs

Test type	Professional Use Only
Intended use	Detection of antibody against HBV surface antigen
Specimen type	Whole blood, Serum, Plasma
Specimen volume	100µl
Testing time	15-30 mins
Storage condition	2 – 40°C / 36 - 104°F

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
CLIA	98.5% (197/200)	98.0% (294/300)

» Ordering Information

Product	Pack Size	CAT No.
Q Anti-HBs Test	25 Tests	09AHB10D
Q Anti-HBs Test	100 Tests	09AHB10F

STANDARD Q *H. pylori* Ab

Test type	Professional Use Only
Intended use	Detection of *Helicobacter pylori* antibody
Specimen type	Whole blood, Serum, Plasma
Specimen volume	Whole blood: 20µl, Serum/Plasma: 10µl
Testing time	10-20 mins
Storage condition	2 – 40°C / 36 - 104°F

» Ordering Information

Product	Pack Size	CAT No.
Q *H. pylori* Ab Test	25 Tests	09HPY10D

STANDARD Q *H. pylori* Ag

Test type	Professional Use Only
Intended use	Detection of *Helicobacter pylori* antigen
Specimen type	Feces
Specimen volume	40-70 mg
Testing time	10-15 mins
Storage condition	2 – 30°C / 36 - 86°F

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
ELISA	98.5% (64/65)	100% (35/35)

» Ordering Information

Product	Pack Size	CAT No.
Q *H. pylori* Ag Test	25 Tests	09HPY20D

STANDARD Q Norovirus Ag

Test type	Professional Use Only
Intended use	Detection of Norovirus antigen
Specimen type	Feces
Specimen volume	40 - 70mg
Testing time	15 mins
Storage condition	2 – 30°C / 36 - 86°F

» Ordering Information

Product	Pack Size	CAT No.
Q Norovirus Ag Test	25 Tests	09NOR20D

PARASITIC DISEASE

STANDARD Q Filariasis Ag

CE

Test type	Professional Use Only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	75µl
Testing time	10-20 mins
Storage condition	2-40°C / 36-104°F

» Ordering Information

Product	Pack Size	CAT No.
Q Filariasis Ag Test	25 Tests	09FIL10D

CARDIOVASCULAR DISEASE

STANDARD Q TnI

CE

Test type	Professional Use Only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	100µl
Testing time	15-20 mins
Storage condition	2-40°C / 36-104°F

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
ECLIA Analyzer	98.4% (62/63)	99.37% (160/161)

» Ordering Information

Product	Pack Size	CAT No.
Q TnI Test	25 Tests	09TNI10D

STANDARD E
Parameters

STANDARD E Dengue NS1 Ag ELISA

CE

Test type	Professional use only
Intended use	Detection of Dengue NS1 antigens
Specimen type	Serum / Plasma
Storage condition	2 – 8°C / 36 - 46°F
Shelf life	15 months

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
RT-PCR	93.5% (58/62)	94.3% (66/70)

» Ordering Information

Product	Pack Size	CAT No.
E Dengue NS1 Ag ELISA	96 wells/Kit	07DEN10

STANDARD E Dengue IgM ELISA

CE

Test type	Professional use only
Intended use	Detection of specific IgM to Dengue virus
Specimen type	Serum / Plasma
Storage condition	2 – 8°C / 36 - 46°F
Shelf life	15 months

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
ELISA	98.2% (54/55)	95.4% (62/65)

» Ordering Information

Product	Pack Size	CAT No.
E Dengue IgM ELISA	96 wells/Kit	07DEN30

STANDARD E Dengue IgG ELISA

CE

Test type	Professional use only
Intended use	Detection of specific IgG to Dengue virus
Specimen type	Serum / Plasma
Storage condition	2 – 8°C / 36 - 46°F
Shelf life	15 months

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
ELISA	97.2% (140/144)	96.2% (282/293)

» Ordering Information

Product	Pack Size	CAT No.
E Dengue IgG ELISA	96 wells/Kit	07DEN20

STANDARD E Zika IgM ELISA

Test type	Professional use only
Intended use	Detection of specific IgM to Zika virus
Specimen type	Serum / Plasma
Storage condition	2 – 8°C / 36 - 46°F
Shelf life	15 months

» Test Performance

Reference	Specificity
RT-PCR	100% (60/60)

» Ordering Information

Product	Pack Size	CAT No.
E Zika IgM ELISA	96 wells/Kit	07ZK30

STANDARD E Chikungunya IgM ELISA

Test type	Professional use only
Intended use	Detection of specific IgM to Chikungunya virus
Specimen type	Serum / Plasma
Storage condition	2 – 8°C / 36 - 46°F
Shelf life	15 months

» Ordering Information

Product	Pack Size	CAT No.
E Chikungunya IgM ELISA	96 wells/Kit	07CHI20

STANDARD E Chikungunya IgG ELISA

Test type	Professional use only
Intended use	Detection of specific IgG to Chikungunya virus
Specimen type	Serum / Plasma
Storage condition	2 – 8°C / 36 - 46°F
Shelf life	15 months

» Ordering Information

Product	Pack Size	CAT No.
E Chikungunya IgG ELISA	96 wells/Kit	07CHI10

VECTOR BORNE DISEASE

STANDARD E Malaria Ag ELISA

Test type	Professional use only
Intended use	Detection of *Plasmodium falciparum, P.vivax, P.ovale, P.malariae* and *P.knowlesi* species
Specimen type	Whole blood
Storage condition	2 – 8°C / 36 - 46°F
Shelf life	15 months

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
Microscopy	96.36% (53/55)	97.0% (97/100)

» Ordering Information

Product	Pack Size	CAT No.
E Malaria Ag ELISA	96 wells/Kit	07MAL10
	480 wells/Kit	07MAL10A

RESPIRATORY DISEASE

STANDARD E TB-Feron ELISA

Test type	Professional use only
Intended use	Detection of specific to human IFN-γ antibody
Specimen type	Plasma (collected from sensitized whole blood in TB-Feron Tubes)
Storage condition	2 – 8°C / 36 - 46°F
Shelf life	15 months
Positive agreement rate with Q ELISA	98.4%
Negative agreement rate with Q ELISA	95.9%

» Ordering Information

Product	Specimen	Pack Size	CAT No.
E TB-Feron ELISA (2 plates)	Plasma	192 wells/Kit	07TBF10C
E TB-Feron Tubes 100	WB	Mitogen tube x 100	07TBFA10
E TB-Feron Tubes 200	WB	TB Antigen tube x 100	07TBFA20
	WB	Nil tube x 100	
E TB-Feron Control		Lv1 x 15 / Lv2 x 15 / Lv3 x 15	07TBFC10

STANDARD M
Assay Menu

STANDARD M10

Versatile Point-of-Care MDx Platform

COMING SOON 2021

The STANDARD M10 is a novel Point-of-Care molecular diagnostic (MDx) system that enables simple, fast and accurate diagnosis of infectious disease, drug resistance, and genetic testing. Its' scalable modular configuration is suitable for any healthcare settings from near-patient to a large laboratory. STANDARD M10 all-in-one cartridge enables 'Sample-in Result-out' process with minimum hands-on time which minimizes human error and contamination.

» Clinical IVD Test Menu

Category	Product		Pack size	Cat. no.
Respiratory disease	STANDARD™ M10 SARS-CoV-2	Detection of SARS-CoV-2 causing COVID-19 in 45-60 minutes	10 tests	11COV10A
	STANDARD™ M10 SARS-CoV-2 20'	Rapid detection of SARS-CoV-2 causing COVID-19 in 20-30 minutes	10 tests	11COV20A
	STANDARD™ M10 Flu/SARS-CoV-2 20"	Rapid detection of SARS-CoV-2, Flu A&B in 20-30 minutes	10 tests	11COV30A
Tropical disease	STANDARD™ M10 Arbovirus 6 (ZIKV/DENV/CHIKV)	Detection and differenciation of Zika virus, Chikugunya virus, and Dengue virus 1~4 in 30 minutes	10 tests	11ARB10A
	STANDARD™ M10 ZIKV	Rapid detection of Zika virus in 30 minutes	10 tests	11ZIK10A
Tuberculosis	STANDARD™ M10 MDR-TB	Detection of mycobacterium tuberculosis(TB), rifampicin resistance mutation and isoniazid resistance mutation in 60 minutes	10 tests	11MTB10A
Virology	STANDARD™ M10 HIV-1 VL	Viral load testing of HIV-1 in serum or plasma using qPCR	10 tests	11HIV10A
	STANDARD™ M10 HBV VL	Viral load testing of HBV in serum or plasma using qPCR	10 tests	11HBV10A
	STANDARD™ M10 HCV VL	Viral load testing of HCV in serum or plasma using qPCR	10 tests	11HCV10A

STANDARD M nCoV Real-Time Detection kit

» Intended use

STANDARD M nCoV Real-Time Detection kit is used for identification and detection of SARS-CoV-2 ORF1ab (RdRp) gene and E gene in human nasopharyngeal swab, oropharyngeal swab, and sputum specimens using reverse transcription (RT) real-time PCR.

CE

KOREA MFDS EUA FDA

Test type	Professional Use Only
Specimen type	Nasopharyngeal swab, Oropharyngeal swab, Sputum
Storage condition	-25~-15 ℃

» Test Performance

Reference : Internal evaluation

Reference	Clinical Sensitivity	Clinical Specificity	Limit of Detection (LoD)
RT-PCR	100% (120/120, 95% CI: 96.97% -100%)	100% (157/157, 95% CI: 97.68% -100%)	- ORF1ab (RdRp) gene- 0.5 copies/µl - E gene- 0.5 copies/µl

» Ordering Information

Product	Pack Size	CAT No.
M nCoV Real-Time Detection kit	96 tests	11NCO10

STANDARD M Flu/SARS-CoV-2 Real-Time Detection Kit

» Intended use

STANDARD M Flu/SARS-CoV-2 Real-Time Detection Kit is a real-time reverse transcription PCR assay for the qualitative detection of Influenza A, Influenza B and SARS-CoV-2 nucleic acids in human nasopharyngeal swab, oropharyngeal swab, and sputum specimens.

CE

Test type	Professional Use Only
Specimen type	Nasopharyngeal swab, Oropharyngeal swab, Sputum
Storage condition	-25~-15 ℃

» Ordering Information

Product	Pack Size	CAT No.
M Flu/SARS-CoV-2 Real-Time Detection Kit	96 tests	11NCO10

STANDARD M SPIN-X Viral RNA Extraction Kit

» Intended use

CE

STANDARD M SPIN-X Viral RNA Extraction Kit is an in vitro diagnostic kit designed for the extraction of viral RNA from various human samples.

Test type	Professional Use Only
Specimen type	Plasma, Serum, Nasopharyngeal swab, Oropharyngeal swab, Sputum
Storage condition	15~35 ℃

» Ordering Information

Product	Pack Size	CAT No.
M SPIN-X Viral RNA Extraction Kit	100 tests	11SPN10

STANDARD M SPIN-X Viral DNA/RNA Extraction Kit

» Intended use

CE

STANDARD M SPIN-X Viral DNA/RNA Extraction Kit is intended for the extraction, enrichment and purification of nucleic acids (DNA/RNA) from serum, plasma, whole blood, nasal swab, pharyngeal swab, nasopharyngeal swab and urogenital swab specimens.

Test type	Professional Use Only
Specimen type	Plasma, Serum, Nasopharyngeal swab, Oropharyngeal swab, Sputum
Storage condition	8~25 ℃

» Ordering Information

Product	Pack Size	CAT No.
M SPIN-X Viral DNA/RNA Extraction Kit	96 tests	11SPN20


Chronic Care
Systems

BGMS

Simple & Accurate
Blood Glucose Monitoring System

Blood Glucose (GDH-FAD) Monitoring System

STANDARD GlucoNavii® PRO

» Advantage of STANDARD GlucoNavii ® PRO

Management for Target glucose level
- High & Low Limit set-up

Glucose Status with color LED and signal
- Intuitive status alert

Strip Ejection Function
- Reduce the risk of cross-infection

Various Sample type
- Capillary, Venous, Arterial, Neonatal(Professional Use Only)

Bluetooth Low Energy (Optional model)

CE 0123

Blood Glucose (GDH-FAD) Monitoring System

STANDARD GlucoNavii® GDH

» Advantage of STANDARD GlucoNavii ® GDH

Clinically Proven Accuracy
- Compliance with EN ISO15197:2015 standard

GDH-FAD
- Minimizing risk of interference

Broad HCT Range
- 0-70%

Various Sample type
- Capillary, Venous, Arterial, Neonatal(Professional Use Only)

Pre & Post Meal Mark
- Easy analyze glucose results before or after meal

NFC Function (Optional)

CE 0123

» Ordering Information

Category	Product	Pack size	Cat. no.
STANDARD GlucoNavii GDH	STANDARD GlucoNavii GDH Blood Glucose Monitoring System (Test strips x 10)	1Unit	01GC30
	STANDARD GlucoNavii GDH Blood Glucose Monitoring System	1Unit	01GC32
	STANDARD GlucoNavii GDH Blood Glucose Test Strip	25T x 2	01GS30

The smallest blood volume

STANDARD Mentor

» Advantage of STANDARD Mentor

Clinically Proven Accuracy
- Compliance with EN ISO15197:2015 standard

0.3µl Smallest Blood Volume
- Less blood, less pain

Pre & Post Meal Mark
- Easy analyze glucose results before or after meal

No Coding
- Easy and accurate

NFC Function (Optional)

FDA

CE 0123

» Ordering Information

Category	Product	Pack size	Cat. no.
STANDARD Mentor	STANDARD Mentor Blood Glucose Monitoring System (Test strips x 10)	1Unit	01GC210
	STANDARD Mentor Blood Glucose Monitoring System	1Unit	01GC212
	STANDARD Mentor Blood Glucose Test Strip	25T x 2	01GS21

Convenient to use

SD CHECK GOLD 2

» Advantage of SD CHECK GOLD 2

No Coding
- Improved previous model

Wide Gold Electrode
- Conductive and stable for electrode reaction

Glucose Specific Detection
- Minimizing risk of interference

Adhere to Basic Function for blood glucose test

» Ordering Information

Category	Product	Pack size	Cat. no.
SD CHECK GOLD 2	SD CHECK GOLD 2 Blood Glucose Monitoring System	1Unit	01GC22
	SD CHECK GOLD 2 Blood Glucose Test Strip	50T x 1	01GS20C

BGMS Products

Simply accurate

STANDARD CodeFree® Plus

» Advantage of STANDARD CodeFree Plus

CodeFree Test Strip
- Compatible with CodeFree test strip

Color Customization
- OEM service is available

Data Transfer
- NFC or Bluetooth (optionally available)

No Coding
- Easy and accurate

Hypo Warning
- Helpful to warm hypoglycemia symptom

CE 0123

» Ordering Information

Category	Product	Pack size	Cat. no.
STANDARD CodeFree Plus	STANDARD CodeFree Plus Blood Glucose Monitoring System (Test strips x 10)	1Unit	01GC50
	STANDARD CodeFree Plus Blood Glucose Test Strip	25T x 2	01GS50

The best seller

SD CodeFree

» Advantage of SD CodeFree

Clinically Proven Accuracy
- Compliance with EN ISO15197:2015 standard

No Coding
- Easy and accurate

Wide Gold Electrode
- Conductive and stable for electrode reaction

Pre & Post Meal Mark
- Easy analyze glucose results before or after meal

Hypo Warning
- Helpful to warm hypoglycemia

Post-Meal Alarm
- Helpful reminder to test 2 hours after meal

FDA

CE 0123

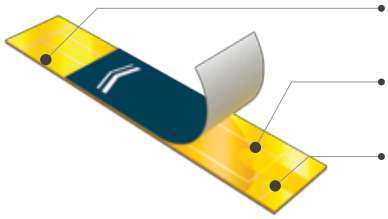
» Ordering Information

Category	Product	Pack size	Cat. no.
SD CodeFree	SD CodeFree Blood Glucose Monitoring System (Test strips x 10)	1Unit	01GC110
	SD CodeFree Blood Glucose Monitoring System	1Unit	01GC112
	SD CodeFree Blood Glucose Test Strip	25T x 2	01GS11

BGMS Strip Advantages

» 99.9% gold electrode

Gold is the best stable material for electrical resistance, so it helps to get the best accuracy rather than other material like carbon.



Wide Gold Electrode
Makes best accurate results

Laser patterning
Ensures an excellent precision

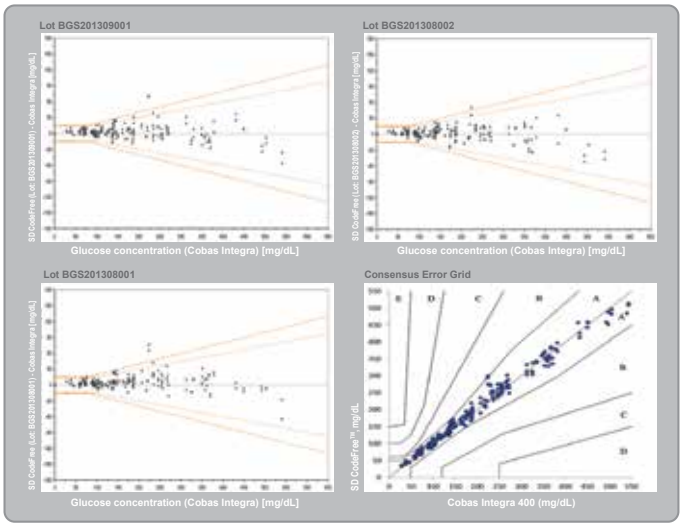
Fast Draw Technology
Makes test fast and easy

» Performance

GOD Strip

SD Codefree™ blood glucose system complies with the system accuracy requirements of ISO 15197:2013 standard. 581 of 600 (96.8%) results meet the requirements.

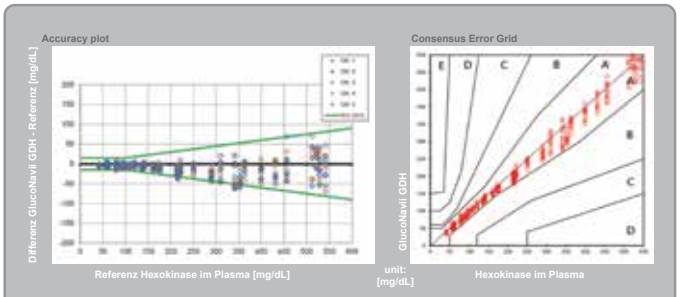
Investigative Site	Institut für Diabetes (IDT), Germany
Test system	SD Codefree™
Reference system	Cobas Integra 400 Plus
Samples	whole blood (capillary)



GDH Strip

STANDARD™ GlucoNavil® GDH blood glucose system complies with the system accuracy requirements of ISO 15197:2013 standard. 514 of 525 (97.9%) results meet the requirements.

Investigative Site	IMCARMED Gmbh, Germany
Test system	STANDARD™ GlucoNavil® GDH
Reference system	Hexokinase method
Samples	whole blood (capillary)



Lot no.	Linear regression equaion	Correlation coefficient
S0713010	Y = 0.9550 X – 4.96 mg/dL Y = 0.9550 X – 0.275 mmol/L	0.9944
S0713011	Y = 0.9879 X – 5.57 mg/dL Y = 0.9879 X – 0.309 mmol/L	0.9972
S0713012	Y = 1.0274 X – 10.46 mg/dL Y = 1.0274 X – 0.580 mmol/L	0.9956

The Brilliant All in One Analyzer

MultiCare

CE

» Product Specification

Method	Quantitative Immunochromatography
Dimension	163 mm x 96 mm x 52 mm
Weight	500g
Display	LCD
Data transfer	Mini USB cable, Bluetooth(optional)
Storage Capacity	999 Patient Data
Operating Temperature	15-32 ℃ / 59-90 °F
Humidity	30-80 %
Test kit storage temperature	2-30 ℃ / 36-86 °F
Optional Accessories	Thermal printer, Barcode Scanner

» HbA1c

- Sample: Whole blood
- Volume: 5µl
- Range: 4.0-15.0 %
- Time: 3 mins.

» CRP

- Sample: Whole blood, Serum, Plasma
- Volume: 5µl
- Range:
  - Whole blood: 3-150 mg/L
  - Serum, Plasma: 3-120 mg/L
- Time: 3 mins.

» U-Albumin

- Sample: Urine
- Volume: 3µl
- Range: 5-300 mg/L
- Time: 3 mins.

» Lipid Profile

- Sample: Whole blood, Serum, Plasma
- Volume: 35µl
- Range:
  - TC : 100 - 450 mg/dL
  - TG : 45 - 650 mg/dL
  - HDL : 25 - 95 mg/dL
- Time: 3 mins.

» Ordering Information

Category	Product	Pack size	Cat. no.
Analyzer	MultiCare Analyzer	1Unit	03MA10
	MultiCare Analyzer (Bluetooth)	1Unit	03MA20
Test device	MultiCare HbA1c Test Kit	20T	03MS10
	MultiCare U-Albumin Test Kit	20T	03MS20
	MultiCare CRP Test Kit	20T	03MS30
	MultiCare Lipid Profile Test kit	20T	03MS40

Small in size, Big in performance

STANDARD LipidoCare

CE 0123

» Product Specification

Method	Lipid: Photometric / Glucose: Electrochemical
Specimen type	Finger Stick, Venous-WB/Serum/Plasma (EDTA or heparin)
Sample volume	Single: 10µl / Lipid Profile: 35µl
Measuring range	TC: 100 - 450 mg/dL , HDL: 25 - 95 mg/dL, TG: 45 - 650 mg/dL Calculated LDL, LDL/HDL, TC/HDL, non-HDL, Glucose: 20 - 600 mg/dL
Measuring time	5 sec. (Glucose), 3 mins (Cholesterol)
Data transfer	Mini USB cable, Bluetooth(optional)
Test kit storage temperature	2 - 32°C (36 -90°F)
Shelf life	18 months

» Ordering Information

Category	Product	Pack size	Cat. no.
Analyzer	STANDARD LipidoCare Analyzer	1Unit	02LA10G
	STANDARD LipidoCare Analyzer (Bluetooth)	1Unit	02LA20G
Test device	STANDARD LipidoCare Lipid Test Strip - Lipid Profile	25T	02LS10A
	STANDARD LipidoCare Lipid Test Strip - TC	25T	02LS20
Control Solution	SDB Lipid Control Solution	Level 1x1/ Level 2x1	02LCS10

Quantitative G6PD enzyme activity analyzer

STANDARD G6PD

CE

» Product Specification

Method	Colorimetric
Specimen type	Whole blood
Sample volume	10µl
Measuring range	Total hemoglobin: 4-25 g/dL G6PD: 0-20 U/g Hb
Measuring time	2 mins
Test kit storage temperature	2-30°C / 36 - 86°F
Shelf life	12 months

» Ordering Information

Category	Product	Pack size	Cat. no.
Analyzer	STANDARD G6PD Analyzer	1Unit	02GA10
Test device	STANDARD G6PD Test	25T	02G6S10
Control	STANDARD G6PD Control	Level 1x10/ Level 2x10	02G6C10

2021 SD BIOSENSOR Ordering Information

STANDARD F

» Analyzer

Product	Pack size	Dimension (W/L/H)	Weight	Cat. no.
F2400	Unit	510 x 566 x 297mm	20.0Kg	10FA24
F200	Unit	200 x 240 x 205mm	2.5Kg	10FA20
F100	Unit	105 x 135 x 100mm	0.7Kg	10FA10

» Parameters

Category	Product	Specimen	Specimen volume	Testing time	Pack size	Cat. no.
Qualitative assays						
Respiratory Disease	COVID-19 Ag FIA NEW	NP**swab	4 drops	15 mins	25T	10COV30D
		Nasal swab			25T	10COV31D
	COVID-19 IgM/IgG Combo FIA NEW	WB/S/P*	10-20 µl	15 mins	25T	10COV50G
	SARS-CoV-2 nAb FIA NEW	S/P*	100 µl	15 mins	20T	10COV80B
	COVID/Flu Ag Combo FIA NEW	Nasal swab	4drops	15 mins	25T	10COV100D
	Influenza A/B FIA	NP** swab /wash /aspirate	-	1.5-10 mins	25T	10INF20D
	RSV Ag FIA	NP** swab /wash /aspirate	-	5-15 mins	25T	10RSV10D
	Strep A Ag FIA	Throat swab	-	5 mins	25T	10STR10D
	Legionella Ag FIA	Urine	100 µl	5-15 mins	25T	10LEG10D
	S. pneumoniae Ag FIA	Urine, CSF	100 µl	5-10 mins	25T	10SPN10D
	Adeno Respi Ag FIA	NP**swab, Nasal swab	-	15 mins	25T	10ADE10D
	TB-Feron FIA (IFN-gamma)	Plasma	100 µl	15 mins	30T	10TBF10E
Vector Borne Disease	Dengue NS1 Ag FIA	WB/S/P*	100 µl	5-15 mins	25T	10DEN10D
	Dengue IgM/IgG FIA	WB/S/P*	10 µl	15 mins	25T	10DEN20D
	Zika Ag FIA	WB/S/P*	100 µl	5-15 mins	25T	10ZK10D
	Zika IgM FIA	WB/S/P*	10 µl	15 mins	25T	10ZK30D
	Chikungunya IgM/IgG FIA	WB/S/P*	10 µl	15 mins	25T	10CHI10D
	Tsutsugamushi IgM/IgG FIA	WB/S/P*	10 µl	15 mins	25T	10TSU10D
	Lyme IgM/IgG FIA	WB/S/P*	10 µl	15 mins	25T	10LYM10D
Gastrointestinal Disease	Norovirus Ag FIA	Feces	40-70 mg	15 mins	25T	10NOR10D
	Rotavirus Ag	Feces	40-70 mg	15 mins	25T	09ROT10D
	Rota/Adeno Ag FIA NEW	Feces	50-75 mg	20 mins	25T	10ROT10D
	Rota/Adeno Ag	Feces	40-70 mg	20 mins	25T	09ROT20D
	H. pylori Ag FIA	Feces	40-70 mg	10 mins	25T	10HPY10D
	C. difficile GDH FIA	Feces	40-70 mg	15 mins	25T	10CDG10D
	C. difficile Toxin A/B FIA	Feces	40-70 mg	15 mins	25T	10CDT10D
Hepatitis	Anti-HBs FIA NEW	WB/S/P*	100 µl	15 mins	25T	10AHB10D
	HBsAg FIA NEW	WB/S/P*	100 µl	20 mins	25T	10HBS10D
	HCV Ab FIA	WB/S/P*	10 µl	15 mins	25T	10HCV10D
	HAV IgM FIA	WB/S/P*	10 µl	15 mins	25T	10HAV10D
Blood Borne Disease	HIV Ag/Ab FIA	WB/S/P*	100 µl	15 mins	25T	10HIV20D
STI	Syphilis Ab FIA	WB/S/P*	WB: 20 µl, S/P: 10 µl	15 mins	25T	10SYP10D
Quantitative assays						
Chronic Disease	HbA1c	Whole blood	5 µl	3 mins	20T	10A1C10B
	U-Albumin FIA	Urine	3 µl	5 mins	20T	10UAL10B
Inflammation	PCT FIA (Serum)	Serum	50 µl	15 mins	20T	10PCT10B
	PCT FIA	WB/S/P*	100 µl	15 mins	20T	10PCT20B
	CRP	WB/S/P*	5 µl	3 mins	20T	10CRP10B
Cardiovascular Disease	CK-MB FIA	WB/S*	100 µl	10 mins	20T	10CKM10B
	TnI FIA	WB/S*	100 µl	10 mins	20T	10TNI10B
	NT-proBNP FIA	WB/S*	100 µl	15 mins	20T	10NTP10B
	D-dimer FIA	WB/P*	10 µl	7 mins	20T	10DDI10B
	hs-CRP	WB/S/P*	5 µl	3 mins	20T	10HSC10B
Hormone	Vitamin D FIA NEW	S/P*	35 µl	45 mins	20T	10VIT10B
	β-hCG FIA	WB/S*	50 µl	15 mins	20T	10BHC10B
	LH FIA	WB/S/P*	20 µl	15 mins	20T	10LH10B
	TSH-II FIA	WB/S*	35 µl	15 mins	20T	10TSH20B
	TSH FIA	Serum	100 µl	15 mins	20T	10TSH10B
	fT4	Serum	50 µl	15 mins	20T	10FT410B
	T4	Serum	50 µl	15 mins	20T	10T410B
Tumor Marker	PSA FIA	WB/S/P*	WB: 20 µl, S/P: 100 µl	10 mins	20T	10PSA10B
	iFOB FIA	Feces	3 drops	5 mins	50T	10IFO10C

*WB : Whole Blood / S : Serum / P : Plasma, **NP : Nasopharyngeal

STANDARD Q

» Parameters

Category	Product	Specimen	Specimen volume	Testing time	Pack size	Cat. no.
Respiratory Disease	COVID-19 Ag NEW	NP**swab	3 drops	15-30 mins	25T	09COV30D
	COVID-19 Ag (Nasal) NEW	Nasal swab	4 drops	15-30 mins	25T	09COV31D
	COVID-19 IgM/IgG Plus NEW	WB/S/P*	10~20 µl	10-15 mins	25T	09COV70DM
	COVID-19 Ag Saliva NEW	Saliva with mucus	-	30 mins	25T	09COV90D
	COVID/Flu Ag Combo NEW	NP** swab /Nasal swab	4 drops	15-30 mins	25T	09COV100D
	COVID-19 Ag Home Test NEW	Nasal swab	4 drops	15-30 mins	1T	09COV120
	COVID-19 Ag Home Test NEW	Nasal swab	4 drops	15-30 mins	2T	09COV130H
	COVID-19 Ag Home Test NEW	Nasal swab	4 drops	15-30 mins	5T	09COV130J
	COVID-19 Ag Home Test NEW	Nasal swab	4 drops	15-30 mins	25T	09COV130D
	i-Q COVID-19 Ag Home Test NEW	Nasal swab	4 drops	15-30 mins	1T	09COV121
	i-Q COVID-19 Ag Home Test NEW	Nasal swab	4 drops	15-30 mins	2T	09COV120H
	Influenza A/B	NP** swab /wash /aspirate	-	8-30 mins	25T	09INF40D
	RSV Ag	NP** swab /wash /aspirate	-	15-30 mins	25T	09RSV40D
	Strep A Ag	Throat swab	-	5-15 mins	25T	09STR40D
	Legionella Ag	Urine	100 µl	15-30 mins	25T	09LEG30D
	S. pneumoniae Ag	Urine	100 µl	15-30 mins	25T	09SPN30D
	Adeno Respi Ag	NP**swab, Nasal swab	4 drops	15-20 mins	25T	09ADE10D
	MERS-CoV Ag (strip)	NP** swab /wash /aspirate	-	15-30 mins	25T	05MC10
	TB MPT64 Ag	Liquid culture, Solid culture	-	10-15 mins	25T	09MPT10D
	Ebola *Zaire* Ag	WB/S/P*	100 µl	20-30 mins	25T	05EZ10
Vector Borne Disease	Dengue Duo	WB/S/P*	NS1: 100 µl, IgM/IgG: 10 µl	15-20 mins	10T	09DEN30A
	Dengue NS1 Ag	WB/S/P*	100 µl	15-20 mins	25T	09DEN10D
	Dengue IgM/IgG	WB/S/P*	10 µl	15-20 mins	25T	09DEN20D
	Zika IgM	WB/S/P*	10 µl	15-20 mins	25T	09ZK40D
	Chikungunya IgM/IgG	WB/S/P*	10 µl	15-20 mins	25T	09CHI20D
	Yellow Fever IgM	WB/S/P*	10 µl	15-20 mins	25T	09YEL20D
	Arbo Panel I (Z/D/C/Y)	WB/S/P*	NS1: 100 µl, IgM: 10 µl	15-20 mins	10T	09ZK110U
	ZIKV/DENV/CHIKV Fast Quad	WB/S/P*	NS1: 100 µl, IgM: 10 µl	15-20 mins	10T	09ZK100A
	Dengue/Chikungunya Trio	WB/S/P*	NS1: 100 µl, IgM/IgG: 10 µl	15-20 mins	10T	09DEN40A
	Zika/Dengue Fast Trio	WB/S/P*	NS1: 100 µl, IgM: 10 µl	15-20 mins	10T	09ZK61A
	Malaria P.f Ag	WB	5 µl	15-30 mins	25T	09MAL10D
	Malaria P.f/P.v Ag	WB	5 µl	15-30 mins	25T	09MAL20D
	Malaria P.f/Pan Ag	WB	5 µl	15-30 mins	25T	09MAL30D
	Malaria/CRP Duo	WB	Mal: 5 µl / CRP: 10 µl	Mal: 15-30 mins / CRP: 15-20 mins	25T	09MAL50D
	Leptospira IgM/IgG	WB/S/P*	10 µl	15-20 mins	25T	09LEP10D
	Tsutsugamushi IgM/IgG	WB/S/P*	10 µl	15-20 mins	25T	09TSU10D
Blood Borne Disease	HIV/Syphilis Combo	WB/S/P*	WB: 20 µl, S/P: 10 µl	15-20 mins	25T	09HIV20D
	Syphilis Ab	WB/S/P*	WB: 20 µl, S/P: 10 µl	5-20 mins	25T	09SYP10D
	Syphilis Ab (multi)	WB/S/P*	WB: 20 µl, S/P: 10 µl	5-20 mins	100T	09SYP10FM
	HIV 1/2 Ab 3-Line	WB/S/P*	WB: 20 µl, S/P: 10 µl	10-20 mins	25T	09HIV30D
	HIV 1/2 Ab 3-Line (multi)	WB/S/P*	WB: 20 µl, S/P: 10 µl	10-20 mins	100T	09HIV30F
Hepatitis	HAV IgM	WB/S/P*	10 µl	15-20 mins	25T	09HAV10D
	HCV Ab	WB/S/P*	WB: 20 µl, S/P: 10 µl	5-20 mins	25T	09HCV10D
	HCV Ab	S/P*	10 µl	5-20 mins	25T	09HCV20D
	HCV Ab (multi)	WB/S/P*	WB: 20 µl, S/P: 10 µl	5-20 mins	100T	09HCV20F
	HBsAg	WB/S/P*	100 µl	20-30 mins	25T	09HBS10D
	Anti-HBs	WB/S/P*	100 µl	15-30 mins	25T	09AHB10D
	Anti-HBs	WB/S/P*	100 µl	15-30 mins	100T	09AHB10F
Gastrointestinal Disease	*H. pylori* Ab	WB/S/P*	WB: 20 µl, S/P: 10 µl	10-20 mins	25T	09HPY10D
	H. pylori Ag	Feces	40-70 mg	10-15 mins	25T	09HPY20D
	Norovirus Ag	Feces	40-70 mg	15 mins	25T	09NOR20D
	Rotavirus Ag (QF)	Feces	40-70 mg	15-20 mins	25T	09ROT10D
	Rota/Adeno Ag (QF)	Feces	40-70 mg	20-25 mins	25T	09ROT20D
Parasitic Disease	Filariasis Ag NEW	WB/S/P*	75 µl	10-20 mins	25T	09FIL10D
Cardiovascular Disease	TnI NEW	WB/S/P*	100 µl	15-20 mins	25T	09TNI10D

*WB : Whole Blood / S : Serum / P : Plasma, **NP : Nasopharyngeal

» STANDARD Q & F Control Solution

Category	Product	Pack size	Shelf life	Storage	Cat. No.
STANDARD Q & F	COVID-19 Ag Control NEW	Pos x10 / Neg x10	18M	2 – 30℃ / 36 – 86 °F	10COVC10
	COVID-19 IgM/IgG Control NEW	M Pos x10 / G Pos x10 / Neg x10	18M	2 – 30℃ / 36 – 86 °F	10COVC20
	H. pylori Ag Control NEW	Pos x10 / Neg x10	36M	2 – 30℃ / 36 – 86 °F	10HPYC10
	C. difficile Control NEW	Pos x10 / Neg x10	36M	2 – 30℃ / 36 – 86 °F	10CDGC10
	C. difficile Toxin A/B Control NEW	Pos x10 / Neg x10	36M	2 – 30℃ / 36 – 86 °F	10CDTC10
	HBsAg Control NEW	Pos x10 / Neg x10	24M	2 – 30℃ / 36 – 86 °F	10HBSC10
	Influenza A/B Control	Pos x10 / Neg x10	18M	2 – 30℃ / 36 – 86 °F	10INFC10
	RSV Ag Control	Pos x10 / Neg x10	18M	2 – 30℃ / 36 – 86 °F	10RSVC10
	Strep A Ag Control	Pos x10 / Neg x10	18M	2 – 30℃ / 36 – 86 °F	10STRC10
	Legionella Ag Control	Pos x10 / Neg x10	18M	2 – 30℃ / 36 – 86 °F	10LEGC10
	S.pneumoniae Ag Control	Pos x10 / Neg x10	18M	2 – 30℃ / 36 – 86 °F	10SPNC10
	Adeno Respi Ag Control	Pos x10 / Neg x10	18M	2 – 30℃ / 36 – 86 °F	10ADEC10
	Syphilis Ab Control	Pos x10 / Neg x10	18M	2 – 30℃ / 36 – 86 °F	10SYPC10
STANDARD F	Vitamin D Control NEW	Lv1 x10 / Lv2 x10	36M	2 – 30℃ / 36 – 86 °F	10VITC10
	PCT Control	Lv1 x10 / Lv2 x10	18M	2 – 30℃ / 36 – 86 °F	10PCTC10
	PCT-02 Control	Lv1 x10 / Lv2 x10	18M	2 – 30℃ / 36 – 86 °F	10PCTC20
	CRP Control	Lv1 x10 / Lv2 x10	18M	2 – 30℃ / 36 – 86 °F	03CCS10
	HbA1c Control	Lv1 x10 / Lv2 x10	18M	2 – 30℃ / 36 – 86 °F	03ACS10
	U-Albumin Control	Lv1 x10 / Lv2 x10	18M	2 – 30℃ / 36 – 86 °F	10UALC10
	CK-MB Control	Lv1 x10 / Lv2 x10	18M	2 – 30℃ / 36 – 86 °F	10CKBC10
	TnI Control	Lv1 x10 / Lv2 x10	18M	2 – 30℃ / 36 – 86 °F	10TNIC10
	NT-proBNP Control	Lv1 x10 / Lv2 x10	18M	2 – 30℃ / 36 – 86 °F	10NTPC10
	D-dimer Control	Lv1 x10 / Lv2 x10	18M	2 – 30℃ / 36 – 86 °F	10DDIC10
	hs-CRP Control	Lv1 x10 / Lv2 x10	18M	2 – 30℃ / 36 – 86 °F	10HSCC10
	β-hCG Control	Lv1 x10 / Lv2 x10	18M	2 – 30℃ / 36 – 86 °F	10BHCC10
	LH Control	Lv1 x10 / Lv2 x10	18M	2 – 30℃ / 36 – 86 °F	10LHC10
	TSH Control	Lv1 x10 / Lv2 x10	18M	2 – 30℃ / 36 – 86 °F	10TSHC10
	fT4 Control	Lv1 x10 / Lv2 x10	18M	2 – 30℃ / 36 – 86 °F	10FT4C10
	T4 Control	Lv1 x10 / Lv2 x10	18M	2 – 30℃ / 36 – 86 °F	10T4C10
	PSA Control	Lv1 x10 / Lv2 x10	18M	2 – 30℃ / 36 – 86 °F	10PSAC10
	iFOB Control	Lv1 x10 / Lv2 x10	18M	2 – 30℃ / 36 – 86 °F	10IFOC10
	F TB-Feron Control	Lv1 x10 / Lv2 x10 / Lv3 x 10	18M	2 – 30℃ / 36 – 86 °F	10TBFC10

STANDARD E

» Parameters

Category	Product	Specimen	Pack size	Cat. no.
Respiratory Disease	COVID-19 Total Ab ELISA NEW	S/P*	96 wells	07COV10
	SARS-CoV-2 nAb ELISA NEW	S/P*	96 wells	07COV30
	TB-Feron ELISA	P*	192wells	07TBF10C
	TB-Feron Tubes 100	WB*	100T (Mitogen Tube)	07TBFA10
	TB-Feron Tubes 200	WB*	100T (TB Antigen Tube)	07TBFA20
		WB*	100T (Nil Tube)	
	TB-Feron SPP	WB*	10T (Mitogen Tube)	07TBFA40
		WB*	10T (TB Antigen Tube)	
		WB*	10T (Nil Tube)	
Vector Borne Disease	Dengue NS1 Ag ELISA	S/P*	96T	07DEN10
	Dengue IgM ELISA	S/P*	96T	07DEN30
	Dengue IgG ELISA	S/P*	96T	07DEN20
	Zika IgM ELISA	S/P*	96T	07ZK30
	Chikungunya IgM ELISA	S/P*	96T	07CHI20
	Chikungunya IgG ELISA	S/P*	96T	07CHI10
	Malaria Ag ELISA	WB*	96T	07MAL10
		WB*	480T	07MAL10A

*WB : Whole Blood / S : Serum / P : Plasma, **NP : Nasopharyngeal

» STANDARD E Control Solution

Product	Pack size	Shelf life	Storage	Cat. No.
E TB-Feron Control	Lv1 x15 / Lv2 x15 / Lv3 x 15	18M	2 – 30℃ / 36 – 86 °F	07TBFC10

STANDARD M

» Analyzer

Product	Contents	Dimension (W/L/H)	Weight	Cat. no.
M10	1 M10 Console + 1 M10 Module NEW			11M1010
M10 Console	1 M10 Console NEW	18x23x41cm	4kg	11M1011
M10 Module	1 M10 Module NEW	14x33x32cm	7.5kg	11M1012

» Assay Menu

Category	Product	Specimen	Specimen volume	Testing time	Pack size	Cat. no.
Respiratory Disease	SARS-CoV-2 NEW	NP** swab /Nasal swab /Throat swab	600 µl	40-60 min	10T	11COV10A
	SARS-CoV-2 20′ NEW	NP** swab /Nasal swab /Throat swab	600 µl	20-30 min	10T	11COV20A
	Flu/SARS-CoV-2 20′ NEW	NP** swab /Nasal swab /Throat swab	600 µl	20-30 min	10T	11COV30A

*WB : Whole Blood / S : Serum / P : Plasma, **NP : Nasopharyngeal

» qPCR Reagent

Category	Product	Specimen	Specimen volume	Testing time	Pack size	Cat. no.
Respiratory Disease	nCoV Real-Time Detection kit NEW (Real-Time RT-PCR reagent)"	NP** swab /Oro* swab /Sputum	10 µl (Extracted RNA)	90 min	96T	11NCO10
	Flu/SARS-CoV-2 Real-Time Detection Kit NEW (Real-Time RT-PCR reagent)"	NP** swab /Oro* swab /Sputum	10 µl (Extracted RNA)	90 min	96T	11NCO20

*Oro : Oropharyngeal, **NP : Nasopharyngeal

» NA Extraction Kit

Category	Product	Pack size	Cat. no.
NA Extraction Kit	SPIN-X Viral RNA Extraction Kit	96T	11NCO10
	SPIN-X Viral DNA/RNA Extraction Kit	96T	11NCO20

INCUBATOR

» Analyzer

Category	Product	Pack size	Cat. no.
Analyzer	d-BLOCK Incubator NEW	1 Unit	12INC10

Chronic Care Systems

» BGMS (Blood Glucose Monitoring System)

Category	Product	Pack size	Cat. no.
GlucoNavii® PRO	GlucoNavii® PRO Blood Glucose Monitoring System (Test Strips x 10)	1 Unit	01GC60
	GlucoNavii® PRO Blood Glucose Test Strip	25T X 2	01GS60
GlucoNavii® PRO BT	GlucoNavii® PRO BT Blood Glucose Monitoring System (Test Strips x 10)	1 Unit	01GC610
STANDARD GlucoNavii GDH	STANDARD GlucoNavii GDH Blood Glucose Monitoring System (Test strips x 10)	1 Unit	01GC30
	STANDARD GlucoNavii GDH Blood Glucose Monitoring System	1 Unit	01GC32
	STANDARD GlucoNavii GDH Blood Glucose Test Strip	25T x 2	01GS30
STANDARD Mentor	STANDARD Mentor Blood Glucose Monitoring System (Test strips x 10)	1 Unit	01GC210
	STANDARD Mentor Blood Glucose Monitoring System	1 Unit	01GC212
	STANDARD Mentor Blood Glucose Test Strip	25T x 2	01GS21
STANDARD CodeFree Plus	STANDARD CodeFree Plus Blood Glucose Monitoring System (Test strips x 10)	1 Unit	01GC50
	STANDARD CodeFree Plus Blood Glucose Test Strip	25T x 2	01GS50
SD CodeFree	SD CodeFree Blood Glucose Monitoring System (Test strips x 10)	1 Unit	01GC110
	SD CodeFree Blood Glucose Monitoring System	1 Unit	01GC112
	SD CodeFree Blood Glucose Test Strip	25T x 2	01GS11
SD CHECK GOLD 2	SD CHECK GOLD 2 Blood Glucose Monitoring System	1 Unit	01GC22
	SD CHECK GOLD 2 Blood Glucose Test Strip	50T x 1	01GS20C
Control Solution	STANDARD Glucose Control Solution	Lv M x 1 / Lv H x 1	01GCS10
	STANDARD GlucoNavii Control Solution	Lv 2 x 1 / Lv 3 x 1	01GCS20

» STANDARD LipidoCare

Category	Product	Pack size	Cat. no.
Analyzer	STANDARD LipidoCare Analyzer	1 Unit	02LA10G
	STANDARD LipidoCare Analyzer (Bluetooth)	1 Unit	02LA20G
Test device	STANDARD LipidoCare Lipid Test Strip - Lipid Profile	25T	02LS10A
	STANDARD LipidoCare Lipid Test Strip - TC	25T	02LS20
Control Solution	SDB Lipid Control Solution	Lv 1 x 1 / Lv 2 x 1	02LCS10

» MultiCare

Category	Product	Pack size	Cat. no.
Analyzer	MultiCare Analyzer	1 Unit	03MA10
	MultiCare Analyzer (Bluetooth)	1 Unit	03MA20
Test device	MultiCare HbA1c Test Kit	20T	03MS10
	MultiCare U-Albumin Test Kit	20T	03MS20
	MultiCare CRP Test Kit	20T	03MS30
	MultiCare Lipid Profile Test kit	20T	03MS40
Control Solution	SDB HbA1c Control Solution	Lv 1 x 10 / Lv 2 x 10	03ACS10
	SDB U-Albumin Control Solution	Lv 1 x 10 / Lv 2 x 10	03UCS10
	SDB CRP Control Solution	Lv 1 x 10 / Lv 2 x 10	03CCS10
	SDB Lipid Control Solution	Lv 1 x 1 / Lv 2 x 1	02LCS10

» STANDARD G6PD

Category	Product	Pack size	Cat. no.
Analyzer	STANDARD G6PD Analyzer	1 Unit	02GA10
Test device	STANDARD G6PD Test	25T	02G6S10
Control	STANDARD G6PD Control	Lv 1 x 10 / Lv 2 x 10	02G6C10

SD BIOSENSOR

www.sdbiosensor.com

SD BIOSENSOR

Head office : C-4th&5th, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA
Manufacturing site : 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, REPUBLIC OF KOREA
TEL) +82-31-300-0400 FAX) +82-31-300-0499 E-MAIL) sales@sdbiosensor.com WEBSITE) www.sdbiosensor.com

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THE GLOBAL FUND

Ms Songjoo Lee
Regulatory Affairs Team
SD Biosensor, Inc
C-4th&5th Floor, Digital Empire Building,
16, Deogyeong-daero 1556beon-gil, Yeongtong-gu
Suwon-si, Gyeonggi-do, 16690
Republic of Korea

Geneva, 11th October 2021

Reference / Subject: ERPD-Round 16-2020-SUB-SDBiosensor_StandardETB / updated result of the quality risk assessment review by the ERPD

Dear Ms Lee,

We would like to inform you that below referenced product questionnaire submitted in response to the 7th April 2020 Expression of Interest for risk assessment to the Expert Review Panel Diagnostics (ERPD) Round 16 and the submitted additional data has been reviewed.

Product Code	Product Name	GF Reference
10TBF10C	STANDARD™ E TB-Feron ELISA	ERPD-Round 16-2020-SUB-SDBiosensor_StandardETB

The conclusion of the quality risk assessment review is that the product has been categorized by ERPD as **CATEGORY-2**, meaning that procurement with Global Fund and/or UNITAID resources of this product **will be permitted for a time limited period of 12 months**, **after which it is expected to have fully met the WHO prequalification requirements, WHO Global TB program endorsement through Policy recommendation or stringent regulatory approval (whatever applicable) in compliance with the Global Fund QA Policy for Diagnostics.** The referenced product **will be included in the procurement list dedicated to this type of products**, published by the Global Fund on their webpages.

For the time limited period **until 8th October 2022**, the product may only be procured **after ad hoc review of procurement requests from the Principal Recipients with Global**

Fund or UNITAID funds and the issue of a **No-objection letter** by the Global Fund secretariat within this period.

The manufacturer is also requested to inform Global Fund QA Manager immediately regarding major customer complaints and/or any product failures/adverse events.

We would like to remind you that the Global Fund requires the manufacturer to submit this specific product for WHO Prequalification review to reach prequalification, WHO Global TB program endorsement through Policy recommendation or stringent regulatory approval (whatever applicable) before the end of the ERPD authorized period, if not already done.

At least three months before the end of the time limited period, The Global Fund will reassess the status of the product and may envisage with you to submit a request for extension for the referenced products in case the products have not reached prequalification in the meantime.

At this occasion, the manufacturer will be expected to provide the additional data regarding the current deficiencies as outlined in the attached report that we would like you to address as well as the PMS data as suggested in the conclusions of this report.

Last but not least we would like you to send us one commercial sample of your product procured with Global Fund resources before any commercial delivery, if not already done with your submission.

Should you have any questions, please, do not hesitate to contact us.

Sincerely

(electronically signed)

Dr René Becker-Burgos (PhD)
Specialist, Diagnostic Products Quality Assurance
The Global Fund, Supply Operations

Encl. ERPD Product report

Cc: Alain Prat, Team Leader, Quality Assurance, Supply Operations, The Global Fund

Azizkhon Jafarov, Manager, Global Sourcing Health Technologies, Supply Operations,The Global Fund

Jackson Hungu, Programme Manager, Operations, Unitaid

ERPD ROUND 16_ EXTENSION REQUEST REPORT

REVIEW BASED ON INFORMATION SUBMITTED BY THE MANUFACTURER

Type of product	TB Diagnostic test
ERPD number	
Product name (code)	STANDARD E TB-Feron ELISA (07TBF10C) TB-Feron Tubes (07TBFA10, 07TBFA20, 07TBFA30) TB-Feron SPP (07TBFA40)
Proprietary Product Name (if relevant)	As above
WHO reference number (or ref number assigned by SRA to which the dossier is submitted and accepted, if applicable)	Not applicable
Name and complete address of the applicant	SD Biosensor, Inc. C-4th&5th, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, Republic of Korea
Authorized Contact	Ms Songjoo Lee Songfoo.lee@sdbiosensor.com
Date of extension request assessment	04 October 2021
Date of the submission (covering letter)	08 July 2021

CONCLUSIONS

The following deficiencies were observed:

1. QMS

The QMS is certified against the international standard EN ISO 13485:2016 and the scope sufficiently covers in vitro diagnostic ELISA kits and is therefore considered appropriate for the product. However, there was no audit report provided supporting the certificate submitted by TÜV SÜD.

The manufacturer is requested to submit the audit report(s) supporting the quality management system certificate issued by TÜV SÜD.

Additional information provided: An audit report was provided that supports the re-certification by TÜV SÜD Product Services indicating that SD Biosensor is operating with an ISO 13485:2016 compliant quality management system.

Extension request assessment:

A valid certificate for the QMS Standard ISO 9001:2015 for the supplier Junsei Chemical Co. was provided, the certification was issue by the Japan Chemical Quality Assurance LTD. This is acceptable.

2. RISK MANAGEMENT

Risk management plan, policy and scope covering the full product life cycle of STANDARD E TB-Feron ELISA, TB-Feron Tubes 100, 200, 300 and TB-Feron SPP were described and responsibilities are clearly defined. The manufacturer should provide an explanation for the reduction is the severity score of identified risks following implementation of risk mitgation measures. Furthermore, from the documentation submitted it does not appear that sterile products and design changes by external supliers are risks that have been considered.

To allow a full understanding of the risk assessment process the risk management procedure C-SDBC-1000 should be submitted for review.

Additional information provided: A Risk management procedure (C-SDBC-1000) and revised Risk Management report were submitted and are acceptable.

Extension request assessment:

No additional information submitted.

3. ANALYTICAL STUDIES

Analytical studies demonstrating precision (repeatability and reproducibility), analytical sensitivity (limit of detection), cytokine interferences and effect of different endogenous substances were submitted. The study design was appropriate and the results reported are acceptable. However, investigation of cross-reactivity with other mycobacteria and potential interference by heterophile antibodies does not appear to have been studied for the STANDARD E TB-FERON ELISA. It is recommended that the potential for a hook-effect should also be investigated.

Additional information provided: The manufacturer has indicated that additional specimens will be acquired to further investigate potential cross-reactivity. No additional data was submitted.

Extension request assessment:

Two additional interfering substances were assessed, namely: human anti-mouse antibody and rheumatoid factor, thus partially addressing the reviewer request. However, the manufacturer has not yet reported on the potential cross-reactivity with other mycobacteria, nor the potential for a hook-effect. The manufacturer has stated that the non-tuberculous mycobacterial cells (*M. kansasii, M. szulgai, M. marinum)* were purchased in July 2021. The report is pending.

4. CLINICAL STUDIES

Study plans for two clinical studies were submitted. However, there was no evidence provided to establish the clinical sensitivity and specificity of the IVD. The manufacturer is encourage to provide clinical study data for the Standard E-TB Feron ELISA.

Additional information provided: An interim study report from Korean National Tuberculosis Association was provided. This was an equivalency study, comparing the QFT plus test with the STANDARD E TB-Feron ELISA and the results reported demonstrate good correlation between the two assays. However, it is noted that the correlation was lower when blood was stored in heparin tubes for 12 hours compared to 6 hours. Furthermore, from the results reported 25% of positive patients were missed (19/77).

While a study report for one clinical study has been submitted, the study design (equivalency/agreement study) is not robust enough to fully assess the diagnostic ability of this test. Further independent clinical studies of the STANDARD E TB-FERON ELISA would be highly desirable.

Extension request assessment:

The manufacturer provided the final report of the study conducted at the Korean National Tuberculosis Association which confirms the interim results already reviewed in the previous submission, showing a good overall concordance (93.8%) between STANDARD E TB-FERON ELISA and QFT Plus. Among the 77 study participants with a history of TB or who tested positive for LTBI, the STANDARD E TB-FERON ELISA identified 58/77 compared to 51/77 by QFT Plus, supporting the equivalence of the two assays in this subset of study participants. The manufacturer has adequately addressed the additional concerns raised about specimen storage.

An additonal clinical research report has been submitted. An equivalence study aimed at comparing the performance of STANDARD E TB-FERON ELISA and QFT Plus on a total of 257 study participants was conducted at the Saint Mary's Hospital in Seoul between August 2019 and November 2020. Study participants included 199 health care workers (HCW) and 58 individuals with active TB or LTBI. The overall agreement between the two assays was 93%, which is consistent with previous results. A total of 69/257 participants were positive on STANDARD E TB-FERON ELISA as compared to 51/257 by QFT Plus. A total of 17/18 discordant cases including 10 HCW and 7 individuals with active TB (ATB) were re-tested by STANDARD E TB-FERON ELISA, 6/10 HCW reverted to negative while 7/7 ATB cases remained positive. These results further support equivalency between the two IGRA assays.

In addition to the study by Kweon OJ. *et al*. (PMID: 31533984) already mentioned, three additional independent recent studies on STANDARD E TB-FERON are to date available in Pubmed: Yoo IY. *et al.* (PMID: 34574000), Benachinmardi K. *et al.* (PMID: 34558465), and Jung J. *et al.* (PMID: 33805448). All studies show a substantial agreement between STANDARD E TB-FERON and QFT Plus among the different settings/study groups, including children (Benachinmardi K. *et al*.), indicating STANDARD E TB-FERON as a valid alternative to QFT Plus. The manufacturer should consider including these studies in the IFU Bibliogaphy section.

5. STABILITY STUDIES

The three types of stability studies were provided, accelerated stability, real-time stability and in-use stability. There was no study investigating the effect of shipping on stability of the IVD submitted. The accelerated stability study predicts 24 months stability under recommended storage conditions for the reagent kit and 15-months stability for the tubes. The real-time stability study is on-going with the aim of establishing an 18 month shelf-life for the ELISA kit, data was provided up to the 15-month time point that met the manufacturers acceptance criteria. An updated real-time study report should be provided when the study is completed.

The in-use stability study provided appears to be appropriate and support the claims made by the manufacturer in the IFU. However, a statement in the report that conflicts with the results should be clarified.

Additional information provided: Details of the shipping stability study that incorporates a real-time stability study following the shipping stress have been provided. However, clarification of the results reported in the in-use stability study was not addressed.

Extension request assessment:

In the in-use stability study the test result and conclusion sections are now aligned and report that the kit is stable for 2 weeks after opening if stored back at 5±3°C (but 1 week is reported in the IFU).

Some aspects of the in-use stability study remain unclear, the following points should be addressed:

- Please explain the following sentence in the conclusion section and indicate where the claim (i.e., 1 month stability) was made: "*But it could be various on different environment of laboratory or test interval, etc. Therefore, we have claimed that the STANDARD E TB-Feron ELISA can be stored at 5±3°C and reused until 1 month after opening date.*"
- Raw data reported in section 6 were collected at a timeframe completely different from that of the in-use stability study (0 to 18 months vs 1 to 8 weeks).

6. LABELING, including IFU

To improve clarity for the user some revision of the IFU is recommended. Information provided in the IFUs for the TB-Feron tubes and the test regents should be consolidated to ensure a full set of instructions is available with the STANDARD E TB-Feron ELISA Kit. In-use stability of the reagents should be included in the IFU.

Additional information provided: The manufacturer has submitted a revised IFU that effectively addresses many of the issues identified. However, it is noted that some further changes to language / grammar used would improve clarity of the instructions for the user.

Extension request assessment:

IFU: The revised version of the IFU incorporates all previously recommended changes. Overall, the language / grammar is acceptable but few minor edits would still be required: i) in the Introduction: replace the sentence "can help diagnose human tuberculosis and development based on…" with "can help diagnose Mycobacterium tuberculosis infection based on…" ; ii) in Specimen collection and storage replace the term "inject" in step 3 with "add"; iii) in Specimen collection and storage, point 6: remove from the text "When removing plasma".
It is suggested that the Bibliography section is updated to include available published studies (refer to section 4, above).

Labelling: The manufacturer has provided an example of the sticker applied on the tertiary packaging which contains all the required information. However, no details on the shipping carton were provided.

7. CUSTOMER SUPPORT

The manufacturer has mechanisms in place to obtain information about the performance of the IVD from the users. A global customer support network is in place, it is not clear how complaints received by distributors are transmitted to SD Biosensor for evaluation.

Additional information provided: Detail of the distribution agreement issued by SD Biosensor, Inc. was submitted, which allows understanding of how and which details are received from distributors in the event of complaints received.

Extension request assessment:

The manufacturer provided a letter containing PMS data for the product covering the dates 2020.07.01 – 2021.06-31 (Issue number BA200-20210706-QA2, July 6 2021). In summary, 10,336 kits were produced (11 lots), there was 1 customer claim received and no product recalls/adverse events or Field Safety Correction Notices. The manufacturer has stated that all customer claims have been processed according to the relevent procedures. This is acceptable.

Risk category 2

The product may be procured with Global Fund and/or UNITAID funds for a period of 12 months as the evidence currently submitted is sufficient to assure the quality of the product. Near the end of this 12 month period this recommendation will be re-evaluated.

The applicant is encouraged to collect any missing documentation as indicated in the report to be submitted for consideration of an extension at the end of the 12 month procurement period currently granted.

In particular, the possibility of cross-reactivity with other mycobacteria and the potential for a hook-effect with the STANDARD-E TB-Feron ELISA should be investigated. As evidence of SD Biosensor Inc.'s on-going QMS compliance details of any surveillance or recertification audits to the relevant international standards that take place during the next 12 months should also be submitted.

In addition, the applicant is expected to provide the Global Fund quality manager with post-market surveillance data near the end of the 12 months.