



ST2 Fast Test Kit (Immunofluorescence Assay)

IF1078 for Getein 1100
IF2078 for Getein 1600
IF3078 for Getein 1180
IF4078 for Getein 1200
IF5078 for Getein 1160



Instructions for Use

INTENDED USE

ST2 Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of Growth Stimulation expressed gene2 (ST2) in serum, plasma or whole blood samples. The test is used as an aid in the diagnosis of acute myocardial infarction, chronic or acute heart failure. For professional and laboratory use only.

SUMMARY

Growth Stimulation expressed gene2 (ST2) is a novel cardiac marker as a member of the IL-1 receptor family which is mainly derived from cardiomyocytes and vascular endothelial cells. ST2 involves in myocardial fibrosis and remodeling and has the great advantage of not being affected by factors such as age, kidney function, etc. ST2 exists in the human body in two forms, one is bound ST2 (ST2L) and the other is soluble ST2 (sST2), which competitively binds to interleukin 33 and participates in multiple inflammatory and immune responses. ST2 is involved in fibrosis and myocardial remodeling after myocardial ischemia and can be used as one of the markers for predicting heart failure symptoms. Clinically, ST2 is mainly used for the early prediction of acute myocardial infarction and chronic heart failure.

PRINCIPLE

ST2 Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay in a sandwich design. After the sample has been applied to the test card, the fluorescence labelled ST2 monoclonal antibody I bind with ST2 in sample and forms a marked antigen-antibody complex. The complex moves to the detection area by capillary action, then it is captured by ST2 monoclonal antibody II coated on the detection area, forming a double-anti-

body complex. The complex generates a fluorescent signal and the intensity increases in proportion to the amount of ST2 in sample. Fluorescent signals intensity can be analyzed by applicable device thus the ST2 in sample be detected quantitatively.

APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1160 Immunofluorescence Quantitative Analyzer
Getein 1180 Immunofluorescence Quantitative Analyzer
Getein 1200 Immunofluorescence Quantitative Analyzer
Getein 1600 Immunofluorescence Quantitative Analyzer

CONTENTS

Materials provided	Getein 1100/ Getein 1160/ Getein 1180		Getein 1200/ Getein 1600	
	10 T/kit	25 T/kit	2*24 T/kit	2*48 T/kit
ST2 test card*	10 pcs	25 pcs	24 test cards in 1 cartridge, and 2 cartridges in 1 box	48 test cards in 1 cartridge, and 2 cartridges in 1 box
Disposable pipet	10 pcs	25 pcs	/	/
Sample diluent**	10 tube	25 tube	1 box	1 box
Instructions for use	1 pc	1 pc	1 pc	1 pc
SD card	1 pc	1 pc	1 pc in each cartridge	1 pc in each cartridge

*ST2 test card

A test card consists of: Fluorescence labelled ST2 monoclonal antibody I, ST2 monoclonal antibody II and polyclonal IgG antibody.

** Sample diluent

(1) Sample diluent for Getein 1100/Getein 1160/Getein 1180 is 1.0 mL contained in each tube consists of:

-Sample diluent mainly contains phosphate buffer, NaN₃.

(2) Sample diluent for Getein 1200/Getein 1600 is an independent packing box consists of:

-Sample diluent mainly contains phosphate buffer, NaN₃ (25 mL/bottle for Getein 1200, 40 mL/bottle for Getein 1600);

-Box with pipette tips (96 tips/box);

-Mixing plate (1 piece/box).

Note:

- The standard curve data can be written to RFID card in the kit. According to the function of RFID card, we define it as "Standard Curve Data Card", short for "SD Card".
- Do not mix or interchange different batches of kits.

STORAGE AND STABILITY

Realtime stability:

Store the kit at 4~30°C with a valid period of 24 months. The test kits are stable until the expiry date printed on the labels.

In-use stability:

-For the test card of Getein 1100/Getein 1160/Getein 1180: Use the test card within 1 hour once the foil pouch is opened.

-For test card of Getein 1200/Getein 1600: If the cartridge is opened, it could be stable within 24 hours once exposure to air. The valid period after opening is 7 days, it is recommended to put the cartridge back to the foil bag and reseal along the entire edge of zip-seal if not used up.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not use the kit beyond the expiration date.
- Do not use the test card if the foil pouch or the cartridge is damaged.
- Do not open pouches or the cartridge until ready to perform the test.
- Do not reuse the test card or pipet.
- Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.

SPECIMEN COLLECTION AND PREPARATION

- Serum, plasma and whole blood can be used as samples in the assay.
- Heparin, sodium citrate and EDTA can be used as the anticoagulants for plasma and whole blood. Do not use hemolytic specimens.
- This assay is designed and validated for use with human blood, other specimens or body fluids may not get accurate results.
- It is recommended to test the sample within 4 hours after collection. Serum and plasma are stable for 5 days when

stored at 2~8°C and 6 months when stored at -20°C. Whole blood is stable for 3 days when stored at 2~8°C.

- Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.

TEST PROCEDURE

- User must carefully read and operate in strict accordance with the instructions for use before testing, otherwise reliable results cannot be guaranteed.

- Test kit and sample should be brought to room temperature before testing.

For Getein 1100:

- Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
- Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
- Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
- Use disposable pipet or pipette, deliver 100 µL of sample into one tube of sample diluent, mix thoroughly. Then drop 100 µL of sample mixture into the sample well on the test card.
- Reaction time: **15 minutes**. Insert the test card into Getein 1100 and click on "Start" icon after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein 1160/Getein 1180:

- Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
- Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
- Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
- Use disposable pipet or pipette, deliver 100 µL of sample into one tube of sample diluent, mix thoroughly. Then drop 100 µL of sample mixture into the sample well on the test card.
- Insert the test card into Getein 1160/Getein 1180 immediately after sample loading. The analyzer will count down the

reaction time (15 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and displayed automatically.

For Getein 1200/Getein 1600:

- Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card which can calibrate automatically.
- Put the sample diluent at the correct position in Getein 1200/Getein 1600.
- Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein 1200/Getein 1600 will do the testing and print the result automatically.

Notes:

- It is required to perform "SD card" calibration when using a new batch of kits.
- It is suggested to calibrate once for one batch of kits for Getein 1100/Getein 1160/Getein 1180.
- Make sure the insertion of test card and the sample are correct and complete.

LIMITATIONS

- As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
- Some substances in blood as listed below may interfere with the test and cause erroneous results. The maximum allowance concentration of each is as follows:

Interferent	Concentration (Max)
Triglyceride	18 g/L
Bilirubin	0.1 g/L

EXPECTED VALUE

The expected normal value is determined by testing samples from 208 apparently healthy individuals and the upper 95th percentile value is 35.0 ng/mL.

The reference ranges for plasma and whole blood samples are the same as those for serum samples. It is recommended that each laboratory determine the applicability of the reference ranges through experimentation and establish their own

laboratory-specific reference ranges if necessary.

PERFORMANCE CHARACTERISTICS

Measuring Range	3.0~200.0 ng/mL
Limit of Detection (LoD)	3.0 ng/mL
Within-Run Precision	≤10%
Between-Run Precision	≤15%

REFERENCES

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DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on ST2 Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more detail in the European Standard EN ISO 15223-1:2021.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult instructions for use or consult electronic instructions for use		Batch code
	Temperature limit		In vitro diagnostic medical device
	Contains sufficient for <n> tests		Authorized representative in the European Community/European Union
	CE mark		Do not use if package is damaged and consult instructions for use
	Catalogue number		Caution

Thank you for using ST2 Fast Test Kit (Immunofluorescence Assay). Please read this instruction for use carefully before operating to ensure proper use.

Version: WIF85-S-03



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