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Calprotectin
Fast Test Kit
(Immunofluorescence Assay)

Instructions for Use

REF IF1139 for Getein1100
IF5139 for Getein1160
IF3139 for Getein1180

INTENDED USE

Calprotectin Fast Test Kit (Immunofluorescence Assay) is used for the in vitro quantitative determination of calprotectin in human fecal sample. The test is used as an aid in the adjunctive diagnosis of inflammatory bowel diseases. For professional and laboratory use.

SUMMARY

Fecal calprotectin is a protein mainly secreted by neutrophils and monocytes. When an inflammatory response occurs in the intestines, the permeability of the intestinal mucosa increases, neutrophils tend to infiltrate into the intestines, and release calprotectin, which mixes with the feces. It can serve as a biomarker for inflammatory bowel diseases (including Crohn's disease and ulcerative colitis), capable of distinguishing patients with inflammatory bowel disease from those without, helping to avoid unnecessary colonoscopy examinations. In addition, changes in fecal calprotectin concentration can reflect the activity of the disease, which is helpful in assessing the severity of the disease and the effectiveness of treatment.

PRINCIPLE

Calprotectin Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay in a sandwich design. After the sample has been applied to the test strip, the fluorescence latex-labelled calprotectin monoclonal antibody binds with the calprotectin in sample and forms a marked antigen-antibody complex. This complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by another calprotectin monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of calprotectin in sample. Fluorescent signals intensity can be analyzed by applicable device thus the calprotectin in sample be detected quantitatively.

APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1160 Immunofluorescence Quantitative Analyzer
Getein 1180 Immunofluorescence Quantitative Analyzer

CONTENTS

Materials provided	Getein 1100/ Getein 1160/ Getein 1180	
	10 T/kit	25 T/kit
Calprotectin test card	10 pcs	25 pcs
Sample diluent	10*2 mL/tube	25*2 mL/tube
User manual	1 pc	1 pc
SD card	1 pc	1 pc

* Calprotectin test card
A test card consists of:
Fluorescence latex-labelled calprotectin monoclonal antibody, calprotectin monoclonal antibody and goat anti-mouse IgG antibody.
Sample diluent
Sample diluent consists of:
Sample diluent mainly contains phosphate buffer (20 mmol/L), NaN3 (＜0.1%).

Note:
1. 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".
2. Do not mix or interchange different batches of kits.

STORAGE AND STABILITY

Realtime stability:
Store the kit at 4~30℃ with a valid period of 24 months. The test kits are stable until the expiry date printed on the labels.
In-use stability:
Use the test card within 1 hour once the foil pouch is opened.

PRECAUTIONS

1. For professional and laboratory use only, not for near-patient testing or self-testing.
2. Do not use the test card if the foil pouch or the cartridge is damaged.
3. Do not open pouches until performing the test.
4. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
5. Carefully read and follow instructions for use to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

Sample Collection and Processing:
1. Fecal specimen can be used for this test .
2. Fecal specimen should be stored in a clean container.
3. Unscrew the Sample diluent tube, remove the sampler, insert the sampler into the fecal specimen three times, each time taking a different part of the fecal specimen, then put the sampler back into the tube, screw it tight, and shake it well. (In order to sample evenly in the spiral groove of the stick and ensure an appropriate sample to buffer ratio, avoid obtaining feces lumps as much as possible.) Please refer to the sampling schematic diagram for specific operations.

Sample Storage:
Store the samples in the sample diluent, which can be stored for up to 1 day at room temperature and up to 5 days under conditions of 2-8℃.

Sampling Schematic Diagram

CALIBRATION

Calibration: The regression equation fitting the concentration value of the working calibrator with the reaction signal value is written into the SD card in advance. Before detection, the SD card is written into the instrument, which can automatically read the calibration curve information in the SD card. During detection, the content of analyte can be calculated by substituting the obtained signal value into the regression equation. Calibration Frequency: A new calibration is required when using a new reagent lot or a new instrument.

TEST PROCEDURE

1. Before use, you must carefully read the instructions for use and operate in strict accordance with the instructions, otherwise reliable results cannot be guaranteed.
2. Test kit and sample should be brought to room temperature before testing.
3. Confirm SD card lot No. in accordance with test kit lot No. Perform calibration using the SD card when necessary.
4. Please select the "Stool" type on the analyzer,(refer to the instructions of analyzer for details)

For Getein 1100:
(1) Remove the test card from the sealed pouch before use. Horizontally place the test card.
(2) Take out the treated sample mixture, clockwise turn off the cap lid, invert the mixture, discard the first 3 drops, and drip vertically 3 drops (about 100 μL) of the mixture without bubbles to the sample well on the test card.
(3) Reaction time: **15 minutes**. Insert the test card into Getein 1100 and press "ENT" button (click on “Start” icon for Android Getein 1100) after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein 1160/Getein 1180:
(1) Remove the test card from the sealed pouch before use. Horizontally place the test card.
(2) Take out the treated sample mixture, clockwise turn off the cap lid, invert the mixture, discard the first 3 drops, and drip vertically 3 drops (about 100 μL) of the mixture without bubbles to the sample well on the test card.
(3) 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 printed automatically.

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

RESULTS

Getein 1100/Getein 1160/Getein 1180 can scan the test card automatically and display the result on the screen. For additional information, please refer to the instructions for use of Getein 1100/ Getein 1160/ Getein 1180.

LIMITATIONS

1. The test is for *in vitro* diagnostic use only.

2. This test may produce false positive results due to cross-reactions or non-specific attachment of sample components to antibodies.
3. This test may yield false negative results if the antigen is masked by some unknown components, preventing the antibodies from detecting or capturing it. Additionally, the instability of the antigen or its degradation due to changes in time and temperature may also prevent antibodies from recognizing the antigen, leading to false negative results.
4. The test results of this kit are only for clinical reference and cannot be used as the basis for confirming or excluding cases alone. In order to achieve the purpose of diagnosis, this test result should be used in combination with clinical examination, medical history and other examination results.

EXPECTED VALUE

The expected value for calprotectin was determined by testing samples from 200 apparently healthy individuals. The 95th percentile of the concentration for calprotectin is 50μg/g.
Reference range of calprotectin:

Group	n	95% Reference range（μg/g）
Healthy human	200	＜50.0

Expected values may vary with age, sex, sample type, diet and geographical location. Each laboratory should verify the transferability of the expected values to its own population, and if necessary, determine its own expected values according to good laboratory practice.

PERFORMANCE CHARACTERISTICS

1. Measuring Range 10.0-600.0 μg/g
2. Limit of Detection ≤10.0μg/g
3. Within-Run Precision ≤10%
4. Between-Run Precision ≤15%

REFERENCES

1. Kallel L, Ayadi I, Matri S,et al. Fecal calprotectin is a predictive marker of relapse in Crohn's disease involving the colon: a prospective study[J]. Eur J Gastroenterol Hepatol, 2010, 22(3):340-345.
2. Meucci G, Renata D'Incà, Maieron R,et al. Diagnostic value of faecal calprotectin in unselected outpatients referred for colonoscopy: A multicenter prospective study[J]. Digestive and Liver Disease, 2010, 42(3):191-195.
3. Sharbatdaran M, Holaku A, Kashifard M,et al. Fecal calprotectin Level in patients with IBD and noninflammatory disease of colon: a study in Babol, Northern, Iran[J]. Caspian Journal of Internal Medicine, 2018, 9(1):60-64.
4. Sipponen, Taina. Diagnostics and prognostics of inflammatory bowel disease with fecal neutrophil-derived biomarkers calprotectin and lactoferrin. [J]. Dig Dis, 2013, 31(3-4):336-344.
5. Taina, Sipponen, Kaija-Leena, et al. Fecal calprotectin in diagnosis and clinical assessment of inflammatory bowel disease. [J]. Scandinavian journal of gastroenterology, 2015.
6. Montalto M, Gallo A, Santoro L, et al. Role of fecal calprotectin in gastrointestinal disorders[J]. European review for medical and pharmacological sciences, 2013, 17(12): 1569-1582.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on Calprotectin Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more details 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*	LOT	Batch code
	Temperature limit	IVD	*In vitro* diagnostic medical device
	Contains sufficient for <n> tests	EC REP	Authorized representative in the European Community/European Union
CE	CE mark		Do not use if package is damaged and consult *instructions for use*
REF	Catalogue number		

Thank you for using Calprotectin Fast Test Kit (Immunofluorescence Assay). Please read these instructions for use carefully before operating to ensure proper use. Please report any product problems or adverse events to the below manufacture or authorized representative in the European Community in time.

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Getein Biotech, Inc.
Add.: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68568508
Fax: +86-25-68568500
E-mail: tech@getein.com.cn
overseas@getein.com.cn
Website: www.getein.com

EC REP CMC Medical Devices & Drugs S.L.
Add.: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain
Tel: +34951214054