

Human IgG (Fc) Rapid Assay Kit

DESCRIPTION

Product Name

Human IgG (Fc) Rapid Assay Kit

Packaging specifications

Cat No.	Size
RA10082	10T
RA10082	50T

Intended Use

For detection of human IgG antibody (or recombinant protein products containing a human Fc fragment) concentration.

Test Principle

This reagent uses latex bead-labeled immunochromatography and the sandwich method principle to detect human IgG antibody (or recombinant protein products containing a human Fc fragment) in samples. During testing, the human Fc fragment in the sample binds to the labeled antibody to form a reaction complex, which migrates to the test line (T line) by capillary action and binds to the coated anti-human Fc secondary antibody, producing a red line. Latex bead-labeled chicken IgY migrates to the control line (C line) and binds to the coated substance, producing a red line. The higher the concentration of the human Fc fragment in the sample, the darker the red line at the test line; the concentration is directly proportional to the color intensity.

Kit Components

Detection Card, Running Buffer, Instruction Manual

Storage and Shelf Life

Unopened reagent should be stored sealed and dry at 2–30°C. Shelf life: 12 months. Expiration date is indicated on the label. It is recommended to use the reagent and running buffer immediately after opening.

Detection Method

- Read this instruction manual carefully before use.
- Before testing, allow refrigerated test samples to equilibrate to room temperature.
- Verify that the product information and lot number on the reagent card match the outer packaging.
- Tear open the aluminum foil pouch, remove the detection card, and place it on a level bench top.
- Using a pipette, transfer 80 μ L of running buffer into an empty centrifuge tube.
- Using a pipette, transfer 20 μ L of sample into the running buffer tube. Mix for 10 seconds using a vortex mixer.
- Using a pipette, take 70 μ L from the prepared sample/running buffer tube and add it to the sample well of the detection card.
- Read the results after 15 minutes.

Notes:

Pre-dilution of test sample:

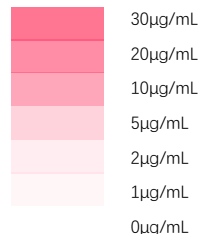
If the concentration of the target tagged protein is known, directly dilute the sample with the provided running buffer to 5 μ g/mL.

If the concentration is unknown, pre-dilute the test sample derived from a prokaryotic expression system by 25-fold, and pre-dilute the test sample derived from a eukaryotic expression system by 5-fold using the provided running buffer. Vortex to mix.

If the sample after pre-dilution produces a test line intensity outside the linear range of the reagent, further adjust the dilution factor until the test line intensity falls within the linear range.

Product Performance Characteristics

- Detection range: 1–30 μ g/mL. Color reference as follows:



- Repeatability: Using a colloidal gold immunochromatography analyzer to test the company's repeatability reference, the repeatability CV $\leq$ 15%.
- Accuracy: Using a colloidal gold immunochromatography analyzer to test the company's accuracy reference, the relative deviation is within $\pm$ 15%.
- Compatibility with common detergents and salts:

Name	Maximum Concentration	Name	Maximum Concentration
NaCl	0.5M	EDTA	5mM
Urea	0.4M	Glycerol	10%
TritonX-100	1%	KCl	0.5M
Tween-20	1%	CHAPS	1%
SDS	0.2%	RIPA	100%
NP-40	1%	Imidazole	0.5M

Precautions

- This reagent is intended only for the detection of human IgG antibody (or recombinant protein products containing a human Fc fragment). Do not use expired product.
- The reagent is for single use only.
- This reagent provides semi-quantitative detection and should not be used for precise quantification.
- Other factors may cause incorrect test results, including technical reasons, operational errors, and other sample factors.
- The test results from this reagent are for auxiliary purposes only and should be interpreted in conjunction with the actual situation. If the test results are abnormal, further investigation is required.
- Avoid vibration and keep the detection card stationary during the test.
- Do not mix components from different kit lots.
- If the control line does not appear, the test result is invalid, as shown in the figure below.

