

## CDIA™ Rapid Human Antibody Isotyping Kit

*Cat. No.: DTSJYJ001*

*Pkg. Size: 25T*

### Intended Use

The CDIA™ Rapid Human Antibody Isotyping Kit determines the immunoglobulin class, subclass, and light chain type in a rapid 5-minute dipstick assay.

### Principle of the Test

The CDIA™ Rapid Human Antibody Isotyping assay is a lateral flow screening test. In the assay, the properly diluted sample is allowed to run on a series of capillary beds. Following its application to the sample pad, the sample is pretreated and discharged onto the conjugate pad. BioAssay Works' proprietary Human Antibody Isotype Conjugate is released upon contact with the flowing sample and forms soluble complexes with the analytes. These complexes travel the length of the membrane and are captured in the test region by anti-isotype antibody immobilized on the nitrocellulose membrane. A red colored line formed in the test region indicates the presence and class, subclass, or light chain type of human antibodies in the test specimen. Absence of the colored line in the test region indicates a negative result. A red colored line in the control region (C) will always appear and indicates a properly functioning test.

### Reagents and Materials Provides

1. Human IgG<sub>1</sub>, IgG<sub>2</sub>, IgG<sub>3</sub>, and IgG<sub>4</sub> tests, 25 dipsticks
2. Human IgA, IgM, κ and λ tests, 25 dipsticks
3. Sample Diluent Buffer

### Materials Required but Not Provided

1. 10 x 75 mm Culture Tubes
2. Vortexer/Orbital Shaker
3. 1X PBS (Only required if additional sample dilution is necessary or samples are diluted to a volume greater than 200 µL)

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## Sample Preparation

No special preparation is required for cell culture/supernatant fluid extraction. No additives or preservatives are required for testing. Use only freshly extracted supernatant fluid.

## Assay Operation

1. Bring all components to room temperature. Label all required 10 x 75 mm culture tubes with the sample that will be tested and place them vertically in a tube rack.
2. Add 200  $\mu$ L of Sample Diluent Buffer (Part Number SDB- 004) to each of the culture tubes.
3. Add 2  $\mu$ L of freshly extracted supernatant fluid to the properly labeled culture tubes and vortex to mix. \*(See NOTE Below.)
4. Insert a single test strip into each culture tube required for testing. Do not swirl or mix once the test strip is added to the culture tube.
5. Within 2-5 minutes, a red indicator line should develop toward the top of the area specified by the printed letters, ...CCC... (Control Line), and potential red lines may develop toward the top of the areas specified by the class, subclass, and light chain type indications.
6. Allow 10-20 minutes for the solution front to travel the length of the lateral flow strip. Read results after 10 minutes but no later than 20 minutes.

\*NOTE: For supernatants that contain antibodies at less than 10  $\mu$ g/mL, dilute the supernatant fluid sample 1:10 (instead of 1:100) by adding 22  $\mu$ L of freshly extracted supernatant fluid in Step 3 above (instead of 2  $\mu$ L). If the Sample Diluent Buffer (Part Number SDB-004) is expended, 1X PBS may be used for sample dilution.

## Results

**Negative (-)** : A red line should develop towards the top or slightly above the multiple 'C's' printed on the laminate, ...CCC... This Control Line indicates that the test has run properly. If NO red line develops towards the top or slightly above the printing for the class, subclass, or light chain type, that class, subclass, or light chain type is NOT present in the supernatant fluid tested.

**Positive (+):** A red line should develop towards the top or slightly above the multiple 'C's' printed on the laminate, ...CCC... This Control Line indicates that the test has run properly. A red line that develops towards the top or slightly above the printing for the class, subclass, or light chain type indicates the presence of that class, subclass, or light chain type in the supernatant fluid tested.



Figure 1 - Completed HIS1R 'Red' Strips. Note that the red lines indicating a positive result are above the printing on the strip cover.

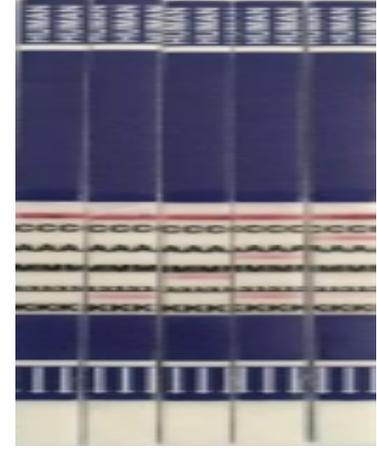


Figure 2 - Completed HIS2B 'Blue' Strips. Note that the red lines indicating a positive result are above the printing on the strip cover

**NOTE:** If after 20 minutes no red line develops towards the top or slightly above the Control Line area, the test results for that lateral flow test strip are considered indeterminate, and the sample should be re-tested with a new lateral flow strip. Do not interpret results after 20 minutes.

## Limitation of the Assay

1. Results of the assay should be used as an aid in determining the classes, subclasses, and light chain types present in the sample tested. The lateral flow assay is not intended for quantitative analysis.
2. Any test in which the Control Line fails to develop is considered indeterminate, and the sample must be re-run.
3. The test procedure and interpretation of the results must be followed closely to obtain reliable results.
4. The CDIA™ Rapid Human Antibody Isotyping Kit is intended for research use only and is not intended for human or animal diagnostic, therapeutic, or commercial use.
5. Each lateral flow test strip is single use only. DO NOT REUSE.

## Storage

**Storage Temperature:** The kit is to be stored at room temperature (4 to 30°C). Do not freeze the test kit.