

LIMITATION OF THE ASSAY:

- 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.
- Any test in which the Control Line fails to develop is considered indeterminate, and the sample must be re-run.
- The test procedure and interpretation of the results must be followed closely to obtain reliable results.
- The Iso-Gold Rapid Human Antibody Isotyping Kit is intended for research use only and is not intended for human or animal diagnostic, therapeutic, or commercial use.
- Each lateral flow test strip is single use only. DO NOT REUSE. (2)

ASSAY ILLUSTRATIONS:

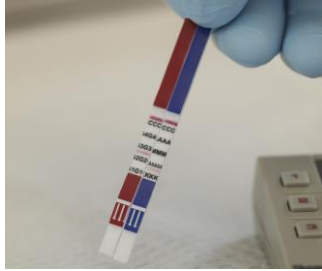


Figure 1 - Examples of Completed Test Strips

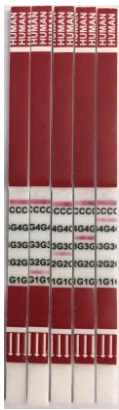


Figure 2 - Completed HIS1R 'Red' Strips. Note that the red lines indicating a positive result are **above** the printing on the strip cover.

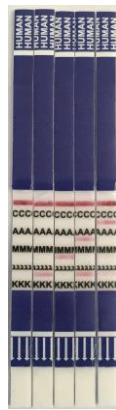


Figure 3 - Completed HIS2B 'Blue' Strips. Note that the red lines indicating a positive result are **above** the printing on the strip cover.

WARRANTY:

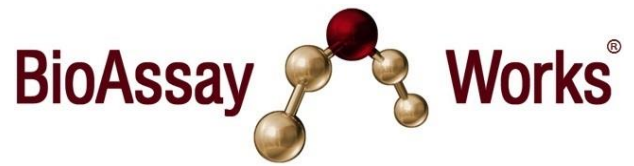
These products are warranted to perform as described in their labeling and in BioAssay Works, LLC's literature when used in accordance with their instructions. There are no warranties, which extend beyond this expressed warranty, and BioAssay Works, LLC disclaims any implied warranty of merchantability or warranty of fitness for a particular purpose. BioAssay Works, LLC's sole obligation and purchaser's exclusive remedy for breach of this warranty shall be, at the option of BioAssay Works, LLC, to repair or replace the products. In no event shall BioAssay Works, LLC be liable for any proximate, incidental, or consequential damages in connection with the products.

REF HISOT-010



Manufacturer:

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bioassayworks.com



Iso-Gold™ Rapid Human Antibody Isotyping Kit

Catalog Number: REF HISOT-010

Rapid Lateral Flow Assay for the Detection of Human Antibody Classes, Subclasses, and Light Chain Types

For Research Use Only

INTENDED USE:

The Iso-Gold Rapid Human Antibody Isotyping Kit is designed for the detection of human IgA and IgM classes, IgG1, IgG2, IgG3, and IgG4 subclasses, and specific detection of human kappa and lambda light chains using rapid lateral flow assay strips.

PRINCIPLE OF THE TEST:

The Iso-Gold 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.

MATERIALS PROVIDED:

Each kit contains material sufficient for 10 sample determinations.



HIS1R-010 .. Human Isotyping Strip 1: White Desiccated Tube with Ten (10) IgG1, IgG2, IgG3, and IgG4 Test Strips (lateral flow strips with sample pad, blocked pretreatment pad, conjugate pad, nitrocellulose membrane, wick, and red laminate cover)



HIS2B-010 .. Human Isotyping Strip 2: White Desiccated Tube with Ten (10) IgA, IgM, κ, and λ Test Strips (lateral flow strips with sample pad, blocked pretreatment pad, conjugate pad, nitrocellulose membrane, wick, and blue laminate cover)

SDB-004..... Sample Diluent Buffer: Opaque Bottle with 4 mL of Sample Diluent Buffer (tris buffered saline, protein stabilizer, detergent, and preservative)

MATERIALS REQUIRED BUT NOT PROVIDED:

10 x 75 mm Culture Tubes
Vortexer/Orbital Shaker

PRECAUTIONS AND WARNINGS:

- Read all instructions before use. 
- Each test strip is designed for a single use. 
- Treat all specimens and any material coming into contact with them as potentially infectious. Wear disposable gloves when handling specimens and kit components.
- As with any possible infectious material, proper laboratory procedures must be followed and precautions must be taken.
- Dispose in accordance with all local, regional, and national laws and regulations.
- Do not mix components of one kit lot with components from other lots.
- Do not use kit components beyond their expiration dates.
- Do not use reagents that show signs of contamination.
- Good Laboratory Practices should be employed to avoid cross contamination of specimens and reagents.

STORAGE AND STABILITY:

- When all materials provided with the kit are contained in the kit box, store the kit at 2-8°C.



- If kit components are stored separately:

- HIS1R-010... May be stored at 2-25°C



- HIS2B-010... May be stored at 2-25°C



- SDB-004 MUST be stored refrigerated, 2-8°C



- Do not freeze or expose to elevated temperatures.
- Keep all test strips sealed in the desiccated tube when not in use.
- Allow the tubes containing the test strips and the bottle containing the sample diluent buffer to warm to room temperature before opening.
- When stored as detailed above, the Iso-Gold Rapid Human Antibody Isotyping Kit and individual components are stable up to the expiration dates printed on the labels.
- Discard any remaining components after their expiration dating.

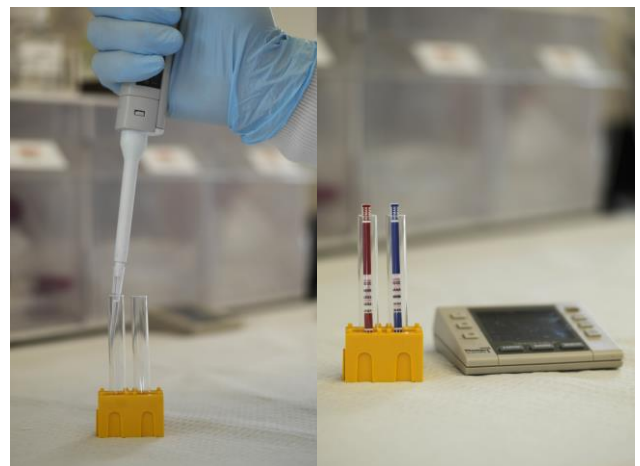
SPECIMEN COLLECTION AND HANDLING:

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 PROCEDURE:

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 µL of Sample Diluent Buffer (Part Number SDB-004) to each of the culture tubes.
3. Add 2 µL 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 µg/mL, dilute the supernatant fluid sample 1:10 (instead of 1:100) by adding 22 µL of freshly extracted supernatant fluid in Step 3 above (instead of 2 µL).



READING AND INTERPRETATION OF RESULTS:

The red lines indicating a positive result will develop towards the top or slightly above the areas specified by the printing on the lateral flow strip laminate covering.

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.

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.

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.

REFER TO PAGE 4 FOR COMPLETED ASSAY ILLUSTRATIONS