



BRISK REAGENT SET

REF 20 RGT100

Σ 100



WARRANTY

The manufacturer makes no express warranty other than the diagnostic kit will measure the designated analyte when used in accordance with the manufacturer's printed instructions. The use of the diagnostic kit for any other purpose is outside the intended use of this product and is done at the user's own risk.

The manufacturer disclaims any and all implied warranties of merchantability, fitness for use or implied utility for any other purposes. Any and all damages for failure of the diagnostic kit to perform according to its instructions are limited to the replacement value of the kit. The sole liability of Bioclone Australia Pty Limited and its distributors is limited to either replacement of the product or refund of the purchase price. Bioclone Australia Pty Limited is not liable for property damage, personal injury or economic loss caused by the products.

Manufactured by Bioclone Australia Pty Limited
(a subsidiary of Hitachi Chemical Co., Ltd) ABN 14 002 036 071
71-73 Railway Parade Marrickville NSW AUSTRALIA 2204
Tel +61 (0) 2 9517 1966 Fax +61 (0) 2 9517 2990 Freecall 1800 251 138
Email sales@bioclone.com.au Web www.bioclone.com.au

EC REP Hitachi Chemical Diagnostics Inc.
Hitachi Europe Limited, Whitebrook Park, Lower Cookham Road
Maidenhead, Berkshire, SL6 8YA, UK. Phone: +44 1628 585 591

INTENDED USE

The BRISK Kit has been designed for *in vitro* diagnostic measurement of allergen specific IgE in serum or plasma.

PRINCIPLES

The BRISK Kit is a radioimmunosorbent assay system. Patient serum is incubated with cellulose discs to which specific allergens are covalently bound. any allergen specific IgE thus binds to the disc. After washing, the disc-allergen-IgE complex is incubated with the ¹²⁵I labelled anti-IgE. The disc-allergen complex is then washed again and the amount bound is counted in a gamma counter and the percentage of bound counts to counts added is calculated as radioactive uptake. The percent radioactive uptake in sample is directly proportional to the amount of allergen-specific IgE present in the sample. this result can be recorded as a particular score as compared to a reference sera.

REAGENTS PROVIDED, STABILITY AND STORAGE

Kit size - 100 tests. The kit and all its components, unopened or opened, should be stored at 2-8°C until the listed expiry dates.

BRISK: Tracer

1 vial REF # RAI1
11 mL containing ¹²⁵I labelled anti-IgE (5µCi) in BSA PBS buffer, non-immune animal serum and an orange dye.

Contains sodium azide, 0.1% w/v. Ready to use.

BRISK: Wash Concentrate

1 vial REF # IEW1
120 mL of a 12.5 x concentrated wash solution. Contains sodium azide, 1% w/v. To be diluted before use.

NB: Allergen discs are sold separately. A full range of discs relevant to Australia are available from Bioclone.

PRECAUTIONS AND WARNINGS TO USERS

Handling of specimens and kit components, their use, storage and disposal should be in accordance with any local or national laboratory safety procedures or regulations.

Specimens

It is recommended that all samples be handled as if capable of transmitting infectious disease.

Preservatives

The kit contains sodium azide as a preservative. As reagents contain a potentially toxic preservative, care should be taken in handling, to avoid ingestion or skin contact. Sodium azide may react with lead and copper plumbing to form potentially explosive azides.

Radioactive Material

The tracer contains radioactive material.

SPECIMEN COLLECTION AND HANDLING

No special patient preparation is required. Specimens can be either serum or plasma collected in a manner appropriate for laboratory testing. Serum is preferred, however the anticoagulant heparin or EDTA can be employed without sacrificing accuracy.

Avoid grossly haemolytic, lipaemic and turbid specimens. Specimens can be stored at 2-8°C for up to 48 hours. Specimens held for longer should be stored at or below -20°C. Specimens should not be frozen and thawed repeatedly. Thawed specimens should be checked for flocculent matter and mixed by inversion just prior to testing.

Turbid specimens or specimens containing particulate matter should be centrifuged prior to use.

MATERIALS AND EQUIPMENT REQUIRED BUT NOT PROVIDED

- * Allergen disc
- * Distilled or deionised water
- * Disposable plastic test tubes 12 x 75 mm
- * Precision pipettes
- * Repeating pipettes
- * Timer
- * Forceps
- * Vortex mixer
- * Parafilm
- * Aspirator with vacuum pump
- * Gamma counter

PROCEDURAL NOTES

Bring all reagents and specimens to room temperature (20-25°C) and mix by gentle inversion prior to use. Duplicates are recommended. Contamination of reagents will lead to poor performance. All assay steps should be performed without interruption.

Reagents are matched in each kit and therefore reagents from different lot numbers should not be mixed. The gamma counter and all pipettes used should be calibrated appropriately before use.

Washing

The efficiency of the wash step is vital for good precision.

Quality Control

Control specimens should be run in every assay to ensure correct procedure. Control values should lie within laboratory ranges before assay is approved.

ASSAY PROCEDURE

Preparation of Reagents Wash Solution

Dilute the wash concentrate 1 in 12.5 with deionised water. The wash solution can be stored at room temperature (20-25°C) for 6 months.

Protocol

1. Assemble and label test tubes in duplicate according to the number of tests required. Include Total Counts (TC), controls and specimens.
2. Take the discs (not supplied) from the cassette, using forceps, and place them in the test tubes.
3. Pipette 50µL of sample (control and specimen) in duplicate into the appropriate test tubes.
4. Cover the tubes with parafilm and incubate for 3 hours at room temperature (20-25°C).
5. Wash the tubes 3 times with washing solution as follows:
 - a) Add 2 mL of wash solution to each tube.
 - b) Aspirate the solution from the tubes and repeat a further 2 times.

Ensure all liquid is removed from the tubes after the last wash.

6. Pipette 100 µL of BRISK Tracer (yellow) into all tubes. Set TC tubes aside.
7. Cover the tubes with parafilm and incubate overnight (16-20 hours) at room temperature (20-25°C).
8. Repeat wash step except TC tubes.
9. Count all tubes for two minutes using a gamma counter. Record the cpm of each tube.
10. Calculate results.

CALCULATION OF RESULTS

1. Average counts per minute (cpm) for any duplicates.
2. Calculate % uptake of ¹²⁵I-anti-IgE onto the allergen discs:

$$\% \text{ Uptake} = \frac{\text{cpm Sample} \times 100}{\text{cpm Total Counts}}$$

Below is an example for use of %uptake in conjunction with reference standards to determine results using a scoring method.

Reference Serum	% Uptake (expected range)
Ref A	25 - 40%
Ref B	15 - 25%
Ref C	10 - 15%
Ref D	5 - 10%

Determination of BRISK SCORES

% Uptake of test samples BRISK SCORE

> Ref. A	4	Highest level of allergen-specific IgE
< Ref. A, > Ref B	3	
< Ref. B, > Ref C	2	
< Ref. C, > Ref D	1	
< Ref. D	0	Undetectable allergen-specific IgE

LIMITATIONS

Serum specimens showing gross haemolysis, gross lipaemia, or turbidity may give false results.

Specimens that contain appreciable background radioactivity should not be used. Any suspect specimens should be screened for radioactivity before performing the assay and should be held until the radioactivity has decayed, or a new specimen requested.

As in the case of any other diagnostic procedure, the values obtained by use of this kit must be used only as an adjunct to other information available to the physician (such as adequate case history).

When testing for food allergies, results may not be expected due to the food proteins being modified during cooking thus not being allergenically the same as the food tested.

Interference

No interference with analyte recovery was observed for concentrations of haemoglobin up to 250 mg/dL, bilirubin up to 10 mg/dL and triglycerides up to 970 mg/dL.

ORDERING INFORMATION

The *BRISK REAGENT SET* is manufactured by:

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NSW 2204, AUSTRALIA.

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TECHNICAL SERVICE

Full technical service is available by calling Bioclone on

+61 (0) 2 9517 1966 or Freecall 1800 251 138