











REF	90263005
Pack Size	5 ml

Anti-D (IgG)

 +2°C - +8°C Store at 2-8°C	 Manufacturer	 IVD In vitro Diagnostic Medical Device	 LOT Batch Number / Lot Number	 Expiry date	D-IgG SBIOCAT™ Anti-D (IgG)
 Consult Instructions for use	 Date of Manufacture	 REF Catalogue Number	 This side up	 Keep Away from Sunlight	

SUMMARY

Human red blood cells are classified as Rho (D) positive or Rho (D) negative depending upon the presence or absence of Rho (D) antigen on them. Most Rho (D) positive red cells show clear positive results with Anti-D reagent. For some D positive red cells, demonstration of Rho (D) antigen requires incubation with Anti-D reagent followed by antiglobulin phase. The red cells giving negative or weaker reactions in direct Anti-D test and positive by IAT after incubation are considered as weak D. In SBIOCAT™ System using direct Anti-D test, reactions greater than or equal to 3+ indicates the presence of D antigen, and reactions weaker than 3+ indicates weak D. Weak positive reactions may vary depending upon the monoclonal cell lines used. In SBIOCAT™ System weak D testing can be done by using monoclonal SBIOCAT™ Anti-D IgG reagent on SBIOCAT™ Coombs Anti-IgG card.

REAGENTS

SBIOCAT™ contains monoclonal Anti-D IgG (Clone-MS-26,LOR-15C9). The concentration of Anti-D IgG is standardized for application on SBIOCAT™ System.

STORAGE AND STABILITY

Store the reagent at 2-8°C. DO NOT FREEZE. The shelf life of the reagent is as per the expiry date mentioned on the reagent vial label. Once opened, the shelf life of reagent is as per the expiry date mentioned on the reagent vial label, provided it is not contaminated.

ADDITIONAL REAGENTS AND MATERIALS REQUIRED

SBIOCAT™ Diluent-2 LISS for preparation of red cell suspension. SBIOCAT™ Coombs Anti-IgG Card (Refer package insert before use). Gel card centrifuge (85g), Incubator (37°C), Work station, Micropipette capable of delivering 5-50µl of specimen and Bottle top dispenser.

PRINCIPLE

IgG antibodies are also known as incomplete antibodies. These antibodies can sensitize red cells when allowed to incubate at 37°C in presence of corresponding antigen. SBIOCAT™ Anti-D IgG contains monoclonal Anti-D IgG in a standardized concentration. Red blood cells when allowed to incubate with SBIOCAT™ Anti-D IgG, red blood cells will get

sensitized if Rho (D) antigen or weaker expression is present. This reaction can be detected when SBIOCAT™ card containing Coombs Anti-IgG is centrifuged under controlled conditions. Cells sensitized with Anti-D IgG will be trapped within the gel matrix in presence of Coombs Anti-IgG. The red blood cells, which do not react are not trapped in the gel column and get settled at the bottom of the microtube.

SAMPLE COLLECTION

No special preparation of patient is required prior to sample collection by approved techniques. For optimal results, freshly collected samples should be used. Anticoagulants like EDTA, CPD-A and Citrate can be used. Samples should be centrifuged at 1500g for 10 minutes to avoid fibrin residue which may interfere with results.

SAMPLE PREPARATION

Prepare 0.8% red blood cell suspension in SBIOCAT™ Diluent- 2 LISS as follows:

1. Bring the SBIOCAT™ Diluent-2 LISS to room temperature before use.
2. Dispense 1.0 ml of SBIOCAT™ Diluent -2 LISS into a clean test tube.
3. Add 10µl of packed red cells to SBIOCAT™ Diluent -2 LISS collected in test tube and mix gently.
4. Red blood cell suspension so obtained should be used for testing.

TEST PROCEDURE

1. Label the appropriate microtube of the SBIOCAT™ Coombs Anti-IgG card with patient's / donor's name or identification number. Remove the aluminium foil of required number of microtubes carefully by pulling it backwards.
2. Pipette 50µl of 0.8% patient's / donor's red blood cell suspension to the microtube, taking care to ensure that the micropipette tip does not touches the microtube.
3. Add 25µl of SBIOCAT™ Anti-D IgG to the above microtube.
4. Incubate the SBIOCAT™ card for 15 minutes at 37°C in an incubator.
5. After incubation, centrifuge the SBIOCAT™ card for 10 minutes in the gel card centrifuge.

- Retrieve the card from centrifuge, read and record the results.

INTERPRETATION OF RESULTS

Positive reaction: Agglutinated red blood cells forming a clear line at the top of the gel column or agglutinates dispersed in the gel column.

Negative reaction: Non-agglutinated red blood cells settle at the bottom of the microtube forming a compact button.

WEAK D CONFIRMATION BY IAT

Reaction for Rho (D)

Rho (D) positive	Weak D	Rho (D) Negative
++++	± to +++	-

Interpretation of Rho (D) and Weak D	Rho (D) positive	Weak D
Direct test using a SBIOCAT™ card with Anti-D	++++	+++ to neg.
Confirmatory test with SBIOCAT™ Coombs Anti-IgG card	++++	+++ to ±

The reaction strength may be recorded as follows:

Strength of reaction	Comments
4+	Agglutinated red blood cells form a line on the surface of the gel microtube.
3+	Most agglutinated red blood cells remain in the upper half of the gel microtube.
2+	Agglutinated red blood cells are observed throughout the length of the gel microtube. A small button of red blood cells may also be visible at the bottom of the gel microtube.
1+	Most agglutinated red blood cells remain in the lower half of the gel microtube. A button of cells may also be visible at the bottom of the gel microtube.
±	Most agglutinated red blood cells are in the lower third part of the gel microtube.
Negative	All the red blood cells pass through and form a compact button at the bottom of the gel microtube.
Mixed field agglutination	Agglutinated red blood cells form a line on the surface of the gel and non-agglutinated red blood cells form a compact button at the bottom of the gel microtube.
H	Hemolysis of red blood cells

04/01/VER/01

NOTE

- In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.
- The SBIOCAT™ Anti-D IgG contains sodium azide <0.1% as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantity of water.
- Use of red blood cells concentration/ volume and reagents other than those described may lead to erroneous results. Follow the instructions carefully.
- Do not use hemolysed, lipemic, icteric and hyperproteic samples.
- Extreme turbidity or discoloration may indicate microbial contamination or denaturation of protein due to thermal damage. Such reagents should be discarded.
- Contamination of reagents during usage may cause false positive or negative results.
- To avoid contamination always use fresh tips to pipette reagent from reagent vial.

REMARKS

Known positive and negative controls should be tested as per Good Laboratory Practices.

BIBLIOGRAPHY

- Human Blood Groups by Geoff Daniels, 2nd Edition, Blackwell Science, Oxford 2002.
- HMSO, Guidelines for the Blood Transfusion Services, 2nd Edition, 1993.
- H. Malyska & D. Weiland, The Gel Test. Laboratory Medicine Vol. 25, No.2, February 1994, pp. 81-85.
- M.C.Z. Novaretti et al. Comparison of Tube and Gel Techniques for Antibody Identification. Immunohematology 2000;16:138-141.
- D. Voak, New Developments in Blood Group Serology, Infusion Therapy Transfusion Medicine 1999;26:258-260.
- Blood Transfusion in Clinical Medicine, P.L. Mollison, 10th Edition.
- Data on file: Singapore Biosciences PTE Ltd.



Singapore 
Biosciences PTE Ltd.

11 Yishun Street 51, 304-23, The Criterion, Singapore 767971