











REF	90223024
Pack Size	24 Cards

Direct Antiglobulin Test Card

 +4°C to +25°C Store at 4-25°C	 Manufacturer	 IVD In vitro Diagnostic Medical Device	 LOT Batch Number / Lot Number	 Expiry date	DAT SBIOCAT™ Direct Antiglobulin Test Card
 Consult Instructions for use	 Date of Manufacture	 REF Catalogue Number	 This side up	 Keep Away from Sunlight	

SUMMARY

A Direct Antiglobulin Test (DAT) is generally used to determine if the red cells have been coated *in vivo* with immunoglobulin (IgG), Components of complement (C₃d) or both. Most DATs are initially performed with a polyspecific Anti-Human Globulin (AHG) reagent capable of detecting both IgG and C₃d. If positive with polyspecific AHG, tests with monospecific anti-IgG and anti-complement reagents are recommended. These tests are useful in autoimmune hemolytic anemia, drug induced hemolytic anemia, hemolytic transfusion reactions and HDFN. SBIOCAT™ Direct Antiglobulin Test Card gives DAT results with differentiation for IgG and or C₃d activity.

REAGENTS

SBIOCAT™ Direct Antiglobulin Test Card contains six microtubes, pre-filled with a gel in a suitable buffer containing goat polyclonal Anti-Human IgG and monoclonal Anti-C₃d (Clone 12011D10) and neutral gel in appropriate microtubes.

STORAGE AND STABILITY

Store SBIOCAT™ gel cards in an upright position at 4-25°C. Do not freeze. Avoid exposure of SBIOCAT™ gel cards to direct sunlight or any heat source. The shelf life of SBIOCAT™ gel cards is as per the expiry date mentioned on the label. Do not use beyond expiry date. Once the aluminium foil is removed from the microtube, it should be used immediately.

ADDITIONAL REAGENTS AND MATERIALS REQUIRED

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

PRINCIPLE

As the SBIOCAT™ gel card containing red blood cells is centrifuged under specific conditions, red blood cells possessing the corresponding antigen will agglutinate in presence of the specific antibody and will be trapped in the gel column. The red blood cells which do not react, are not trapped in the gel column and get settled at the bottom of the microtube. The reactions are then read and graded according to their reactivity pattern.

SAMPLE COLLECTION

No special preparation of the patient is required prior to sample collection by approved techniques. For optimal results, freshly collected sample 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 testing.
2. Dispense 1.0 ml of SBIOCAT™ Diluent-2 LISS into a clean test tube.
3. Add 10µl of packed red cells and mix gently.
4. Red blood cell suspension so obtained should be used for testing.

TEST PROCEDURE

1. Label the first three microtubes of "SBIOCAT™ Direct Antiglobulin Test Card" with patient's name or identification number. Remove the aluminium foil carefully by pulling it backwards.
2. Pipette 50 µl of 0.8% patient's red blood cell suspension to the labeled microtubes, taking care to ensure that micropipette tip does not touches the microtube.
3. Centrifuge the cards for 10 minutes in the gel card centrifuge.
4. Retrieve the card from centrifuge, read and record the results.

INTERPRETATION OF RESULTS

The control microtube (Ctrl) must be negative to validate the results. If it is not negative then repeat the test after washing the patient's/ donor's red blood cells with warm saline.

Positive reaction: Agglutinated red blood cells forming a clear line on the surface of 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.

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 at the top 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

NOTE

- In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.
- The SBIOCAT™ gel cards contains sodium azide < 0.1% as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantity of water.
- All SBIOCAT™ gel cards should be centrifuged for one complete cycle (10 minutes) in gel card centrifuge before use.
- Visually inspect the SBIOCAT™ gel cards before use.
- SBIOCAT™ gel cards having bubble(s) entrapped within the gel can be centrifuged for two complete cycles in gel card centrifuge to remove the bubble, if bubbles are not removed the card should not be used.
- SBIOCAT™ gel cards that exhibit any signs of drying (i.e. absence or reduced level of reagent buffer above the gel column), decreased volume of gel, cracked gel should not be used.
- SBIOCAT™ gel cards with damaged aluminium foil seal should not be used.
- Freezing of SBIOCAT™ gel cards or evaporation of gel or reagent buffer due to exposure to heat may lead to erroneous results.
- Fibrin or particulate matter if present in the sample may

lead to erroneous results.

- Fibrin if present in the sample may trap red blood cells on the surface of the gel column presenting a pink line. To avoid, samples should be well centrifuged at 1500g for 10 minutes before taking serum or plasma and RBCs should be washed if not collected properly in an anticoagulant
- Use of red blood cells concentration/ volume and reagents other than those described may lead to erroneous results. Follow the instructions carefully.
- Aged or stored red blood cells may exhibit weaker reactivity than freshly collected cells.
- Old cell panels may give an unclear background with SBIOCAT™ gel cards.
- 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 SBIOCAT™ gel cards should be discarded.
- Contamination of reagents during usage may cause false positive or negative results.
- Red cell aggregation in the red cell suspension may interfere the passage.
- Aluminium foil seal of SBIOCAT™ gel cards should be removed gently and carefully by pulling the foil seal backwards to avoid contamination of reagents from one microtube to another.
- To avoid contamination always use fresh tips before dispensing into each microtube.
- Some pathological conditions are reported as causing non-specific reactions in AHG procedures.

REMARKS

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

PERFORMANCE

- 150 known samples were tested with SBIOCAT™ DAT card. The results showed 100% sensitivity and specificity.
- SBIOCAT™ Red Cell Preserving Solution (Cat. No.90262020) can be used as red blood cell preservative solution for preservation of known cells.

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- Data on file: Singapore Biosciences PTE Ltd.



Singapore
Biosciences PTE Ltd.

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