SBio CARD ABD

Blood Grouping Card for ABO/Rho(D)
Forward Grouping with Autocontrol

REF	90340024
Pack	24 tests

2°C 30°C Store at 2-30°C	Do not use if package is damaged	IVD *In vitro* Diagnostic Medical Device	LOT Batch Number / Lot Number	Expiry date	Keep away from sunlight
Consult Instructions for use	Date of Manufacture	REF Catalogue Number	This side up	Reagent Description of the reagent	Do not reuse

SUMMARY

Human Blood group system comprises of 26 blood group systems. Out of these ABO and Rh are the blood group systems capable of causing severe hemolytic transfusion reactions. Inclusion of bed side ABO and Rh testing as pre transfusion testing will help in reducing the ABO & Rh incompatible transfusions. **SBio CARD ABD** can be used as bed side testing for patient and donor's blood unit prior to transfusion. **SBio CARD ABD** can also be used for donor's blood group screening in outdoor camps as well as in blood banks.

REAGENTS

1. **SBio CARD ABD** Blood Grouping Card for ABO/Rho(D) Forward Grouping with Autocontrol is based on the principle of lateral flow guided by capillary action. The appropriate reagents are pre-dried at the appropriate sample pad beneath the sample well namely Anti-A (IgM) antibodies in sample well A, Anti-B (IgM) antibodies in sample well B, Anti-D (IgM)(VI-) antibodies in sample well D. The autocontrol is a negative control that does not contain any antibodies in sample well (Ctrl) and serves to validate the test results.
2. Reagent Buffer (Proprietary Buffer) contains Sodium azide (< 0.1%) as a preservative.

STORAGE AND STABILITY

1. Store the **SBio CARD ABD** at 2-30°C .
2. The shelf life of the **SBio CARD ABD** is as per the expiry date mentioned on the label.
3. Avoid exposure of **SBio CARD ABD** to direct sunlight or any direct heat source.

ADDITIONAL REAGENTS AND MATERIAL REQUIRED

1. Sterile Blood Lancet (when finger prick blood is to be used).
2. 5 µl micropipette (**SBio CARD Micropipette** Cat. No. 90350005).
3. Micropipette tips (**SBio CARD MICROPIPETTE tips** Cat. No. 90360100).

PRINCIPLE

When 5 µl of the whole blood sample to be tested is placed on to the sample well pad and the test is run using the reagent buffer, the agglutinated red cells adhere onto the sample well pad and are visible as a red patch (positive test result) indicating that the test result is positive for that specific blood group antigen. Unagglutinated red cells are washed away by the reagent buffer revealing a white colour sample pad (negative test result) indicating that the red cells are negative for the corresponding antigen. The autocontrol must be negative at all times to validate the test results. For each red cell so tested on the card the blood group of the sample can be determined.

SAMPLE COLLECTION

1. Finger prick blood or venous whole blood can be used for testing.
2. Finger prick blood should be tested immediately without letting the blood to clot.
3. No special preparation of the patient is required prior to sample collection by approved techniques.
4. Do not use hemolysed samples for testing.
5. Anticoagulated venous blood using various anticoagulants should be tested.
6. For optimal results, freshly collected sample should be used.

TEST PROCEDURE

1. Bring the pouch and reagent buffer bottle to room temperature.
2. Tear open the pouch just prior to testing and remove the **SBio CARD ABD** test device.
3. Label the **SBio CARD ABD** test device with the patient's ID and date.
4. For finger prick samples, sample collection loop provided in the kit should be used and for samples collected in anticoagulant use of 5µl micropipette is recommended.
5. Using a micropipette/sample collection loop add 5 µl of the patient's whole blood sample to each of the sample wells indicated as 'S'. When using a micropipette, ensure that only the blood drop is in contact with the pre-dried reagent on the sample pad and absorbed by it as shown in figure 1. In case the micropipette tip touches the sample pad, discard the tip and use fresh tip for dispensing the sample into the next sample well. When sample collection loop is used, the loop should be held in vertical position for collecting sample from finger prick as shown in figure 2.

   Once a sample collection loop is used to dispense the sample on a sample pad, the same loop should not be used to dispense sample on any other sample pad. It should be discarded and new sample collection loop should be used.

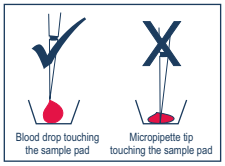

Fig. 1

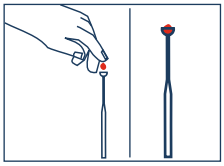

Fig. 2

6. After waiting for two minutes allowing the sample to react with the reagent on sample pad, add two drops of the reagent buffer to each of the reagent well indicated as 'R'.
7. After addition of reagent buffer wait for 3 minutes to interpret the test results. The autocontrol should show a colourless patch before the results can be interpreted correctly. If the autocontrol pad has a colour (invalid result) then the test results should not be interpreted.

INTERPRETATION OF TEST RESULTS

Reaction in the Sample pad

A	B	D	Ctrl	Results
●	○	●	○	A Rh+ve
●	○	○	○	A Rh-ve
○	●	●	○	B Rh+ve
○	●	○	○	B Rh-ve

A	B	D	Ctrl	Results
●	●	●	○	AB Rh+ve
●	●	○	○	AB Rh-ve
○	○	●	○	O Rh+ve
○	○	○	○	O Rh-ve

The test results may be noted for future reference. Using a marking pen the test results may also be noted on the card. The test results are stable for a period of 1 week provided the storage is done in a sealed cover without contamination in a cool dry place. Do not expose to direct heat and sunlight.

NOTES

1. In vitro diagnostic reagent for laboratory and professional use. Not for medicinal use.
2. **SBio CARD ABD** contains <0.1% sodium azide as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantity of water.
3. Contamination of reagents or blood samples may cause false positive or negative results.
4. To avoid contamination use separate micropipette tips to dispense in all the circular sample wells, taking care to ensure that micropipette tip does not touch the side walls of the sample wells.
5. **SBio CARD ABD** can be used as bed side testing of patient and donor's blood unit prior to transfusion, donor's blood group screening in outdoor camps and in blood banks.
6. Fresh samples will give more accurate results as compared to aged or old cells.
7. Red cell aggregation or rouleaux formation may interfere with test results and give false positive results. Rouleaux formation can occur in samples collected in heparin and in patients treated with plasma expanders, oncological patients and patients with coagulation dysfunction.
8. Clotted samples or fibrin if present in sample may lead to erroneous results.
9. Due to use of monoclonal antibodies, red cells with weaker A subgroup (like A_3 and A_2) may also be detected. Red cells showing weaker reaction with Anti-A and/or Anti-B probably indicate subgroups of A and / or B and results should be correlated with laboratory testing.
10. Use of red blood cell concentration / volumes and reagents other than those described may lead to erroneous results.
11. The **SBio CARD ABD** device is colour coded sequentially as coloured squares at the top of the device and should be checked before testing. The sequence of colour code should be blue, yellow, grey and red for A, B, D and Control respectively.

LIMITATIONS OF THE TEST

1. **SBio CARD ABD** is not a substitute for complete blood grouping or compatibility test (cross match) by tube technique, solid phase or Gel technique.
2. Weak D/ Partial D type human red cells and red cells with weaker antigenic expression like weaker subgroup of A or B may give a weaker or negative reaction. Results of weak D confirmation by Coombs test should be taken into account.
3. Anti-D does not detect DVI variant.
4. Cold auto antibodies if present in sample may cause a false positive reaction.
5. Blood samples with hematocrit (PCV) less than 15% may give false negative or weak reactions.

REMARKS

1. Known positive and negative control should be tested as per Good Laboratory Practices for each lot of **SBio CARD ABD.**
2. The monoclonal Anti D used does not detect D VI variant.

PERFORMANCE CHARACTERISTICS

The performance of **SBio CARD ABD** was evaluated on over 3269 samples (from donors, clinical and neonates) drawn in the recommended anticoagulants.
The evaluation demonstrated 100% specificity of each reagents versus the expected results with common known phenotypes A_1,A_2,A_1B,A_2B,B and O. The sensitivity of Anti-A reagent is 99.91%, Anti-B reagent is 100% and Anti-D IgM reagent is 98.09% The sample with weak expression of A antigen and Weak D samples showed negative results.

WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

1. Mollison, P.L. Blood Transfusion in Clinical medicine: - 10th Edition. Oxford: Blackwell Scientific Publications, 1997.
2. Human Blood Groups by Geoff Daniels, Blackwell Science Ltd, 1995.

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