Fortress Comp Test (BLOOD GROUPING GEL CARDS)	
BGGCFCT1-12	**BGGCFCT1-24**
12 FORTRESS GEL CARDS	**24 FORTRESS GEL CARDS**
STORE AT 2-8°C	
FOR IN-VITRO DIAGNOSTIC USE ONLY	

IVD

INTENDED USE

This test allows the detection of ABO, Rh incompatibility and unexpected blood group antibodies in patient's serum against antigens on donor cells or in donor's serum against antigens on patient's cells in gel technique.

INTRODUCTION

The compatibility test includes an ABO and Rh grouping performed on the donor and recipient samples, screening of the donor's and patient's sera for unexpected antibodies. The cross-match became part of a series of pre-transfusion test known as compatibility testing. The crossmatch procedure determines whether donor blood is compatible (or incompatible) with recipient blood. The major cross-match is used to detect unexpected blood group antibodies in patient's serum against antigens on donor cells. The minor cross-match is used to detect unexpected blood group antibodies in donor's serum against antigens on patient's cells

PRINCIPLE OF TEST

Fortress Comp Test allows the detection of ABO, Rh incompatibility and unexpected blood group antibodies in patient's serum against antigens on donor cells on a single gel card.
The test contains 8 microtubes gel matrix. First three microtubes contain monoclonal antibodies for ABO Rh, and the others AHG (2X) , Neutral gel (3x)
The red blood cells will agglutinate in the presence of antibody directed towards the antigen. Agglutinated cells forming a red button on the surface of the gel or agglutinates dispersed in the gel is a positive result and indicates the presence of the corresponding antibody.

KIT CONTENTS

12 or 24 Fortress Comp Test gel cards. 1 gel card contains 8x1 microtubes

A	B	D	Ctl	Enz Major	Enz Minor	AHG	AHG Ctl

Ready to use. Contains Sodium azide as preservative.
Each microtube of the card contains buffered gel medium with preservative and mixed different reagent.
- microtube A : monoclonal anti-A IgM (clone A-11H5)
- microtube B : monoclonal anti-B IgM (clone B-6F9)
- microtube D : mixture of IgG and IgM antibodies (clone BS 225, LDM3, ESD1)

This anti-D monoclonal reagent detects weak D and partial variants of the D antigen. But DVI variant of the D antigen will not be detected directly with this monoclonal reagent. This reagent will detect DVI by IAT method.
-microtube Enz Major: Neutral gel for Major Crossmatch
-microtube Enz Minor: Neutral gel for Minor Crossmatch
-microtube AHG: Polyspecific anti-human globulin. Mixture of polyclonal anti-IgG and monoclonal anti-C3d antibodies.
microtube AHG Ct: AHG control
-microtube Ctl: Neutral gel without antibodies (control microtube)

MATERIAL REQUIRED BUT NOT PROVIDED

- 10 µl, 50 µl and 1 ml automatic pipettes.
- Disposable pipette tips.
- Test tubes.
- Fortress LISS Diluent
- Centrifuge for Blood Grouping Gel System.
- Papain or Bromelin solution.
- Incubator

STORAGE CONDITIONS AND STABILITY

- Store the gel cards at 2-8 °C in upright position.
- Do not freeze.
- Avoid exposure of the cards to any heat source, direct air-conditioning sources or direct sunlight.
- Do not use reagents over the expiration date.

-All the components of the kit are stable until the expiration date on the label when stored 2-8 °C.
- Do not remove foil seal until ready to use. Once opened, the gel may begin to dry out which could affect test results.
- Use the card within 2 hours after removing the aluminum foil . Otherwise, don't use the card.
- Stability of the opened gel card is 2 hours.

PRECAUTIONS AND WARNINGS

- This reagent kit is for in vitro diagnosis only.
- This reagent kit is for professional use only.
- All human sourced material (monoclonal antibodies) are tested free from HBsAg, Anti-HCV and Anti-HIV. However, all materials of human origin should be considered as potentially infectious and it is recommended that all kit materials and test specimens to be handled using established good laboratory practice.
- All kit components and specimens should be regarded as potential hazards to health. It should be used and discarded according to your own laboratory's safety procedures.

SAMPLE COLLECTION

Fresh red blood cells are preferred for testing . Use the red blood cells collected with anticoagulants for determination of the antigens of the ABO/Rh system . If necessary, samples stored at 2-8 °C can be used up to 48 hours .
Red blood cells collected in ACD, CPD, SAGM and PAGGSM can also be used until the expiry date indicated on the label of the bag at 2-8 °C.
Plasma and serum must be cleared . Fibrin residues may interfere with the reaction pattern.

PREPARATION OF BLOOD SAMPLE

0.8 % red blood cell suspension :

Do not use haemolysed, cloudy or contaminated samples or those containing clots

1- Bring Fortress LISS Diluent to reach room temperature before use
2- Dispense 1 mL of Fortress LISS Diluent into a clean tube.
3- Add 20 µL of whole blood or 10 µL of packed cells to the diluent and mix gently.

Plasma or Serum :

If necessary, samples stored at 2-8 °C can be used up to 48 hours after their extraction; or frozen samples (from -20 °C to -70 °C) up to the time of performing the test.

TEST PROCEDURE

Allow the test card and cell reagent to reach room temperature before use.

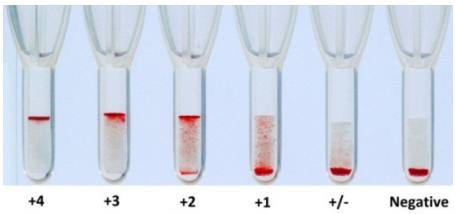
A. Confirmation of the ABO/Rh (patient only) and Crossmatch

1- Label the appropriate gel card with patient's name or identification number. Remove the aluminium foil carefully.
2- Pipette 50 µl of the patient's red cell suspension to microtubes 1,2,3,4,6, and 8 (A,B,D, Ctl,Enz Min, AHGctl,).
3-Pipette 50 µl of the donor's red cell suspension to microtubes and 5 and 7 (Enz Major,AHG) (Crossmatch test).
4- Add 25 µl of the patient's plasma or serum to microtubes 5 and 7 (Enz Major,AHG).
5- Add 25 µl of the donor's plasma or serum to microtube 6 (Enz minor) .
6- Add 25 µl of papain or bromelin solution to microtube 5 and 6 (Enz Major,Enz Minor).
7- Incubate the gel card for 15 minutes at 37°C in the incubator.
8- Centrifuge the gel cards for 10 minutes in the gel card centrifuge.
9- Read the results.

B. ABO/Rh isogroups compatibility (donor and patient) test and Crossmatch

1- Label the appropriate gel card with patient's name or identification number. Remove the aluminium foil carefully.
2-Pipette 50 µl of the patient's red cell suspension to microtubes 1,2,3,4,6 and 8 (A,B,D, Ctl ,Enz Min,AHG ct,).
3-Pipette 50 µl of the donor's red cell suspension to microtubes 1,2,3, 5 and 7 (A,B,D, Enz Maj,AHG).
4- Add 25 µl of the patient's plasma or serum to microtubes 5 and 7 (Enz Major,AHG).
5- Add 25 µl of the donor's plasma or serum to microtube 6 (Enz minor) .
6- Add 25 µl of papain or bromelin solution to microtube 5 and 6 (Enz Major,Enz Minor).
7-Incubate the gel card for 15 minutes at 37°C in the incubator.
8-Centrifuge the gel cards for 10 minutes in the gel card centrifuge.
9- Read the results.

Negative	*Band of red blood cells at the bottom of the column and no visible agglutinations in the rest of the column.*
+/-	*Scarce small-sized agglutinations in the lower half of the column*
+1	*Some small-sized agglutinations in the column*
+2	*Small or medium-sized agglutinations throughout the column*
+3	*Most agglutinated red blood cells remain in the upper half of the gel column*
+4	*Agglutinated red blood cells form a band at the top of the gel column*



Stability of the results:
it is recommended an immediate reading of the results after centrifuging the cards. Do not leave processed cards in horizontal position.If necessary, a delayed reading can be made up until 24 hours after processing the cards if kept in vertical position, refrigerated (2-8°C) and sealed with parafilm or similar material to avoid evaporation of the supernatant.

Interpretation of the results:

A.Confirmation of the ABO/Rh groups

Anti A	Anti B	Anti AB	Ctl	ABO Group
Negative	Negative	Negative	Negative	**0**
+1 to +4	Negative	+1 to +4	Negative	**A**
Negative	+1 to +4	+1 to +4	Negative	**B**
+1 to +4	+1 to +4	+1 to +4	Negative	**AB**

The microtube Ctl must be negative. If it is positive, invalidate the test.The reactions between +/- and +3 may indicate A or B subgroups and further investigations should be performed

Rh System

D	
+1 to +4	**RhD Positive**
Negative	**RhD Negative**

The reactions weaker than +2 should be subject to further investigations to distinguish between weak and partial D types as appropriate for the category of sample being tested.

B. ABO/Rh Compatibility tests

ABO/D compatibility: If there is a single band, either in the upper zone or at the bottom of the column, indicates that the recipient's and donor's groups are the same and compatible.
ABO/D incompatibility: If there is double cell population
phenomenon (two different cell populations), indicates that the recipient's and donor's groups are different and incompatible.

If incompatibility is observed, ABO/D blood groups of both recipient and donors need to be retested.

Crossmatch; Screening of unexpected antibodies
- A positive reaction (+/- to +4) in one or both microtubes 5 and 7 (Enz, AHG) and a negative reaction in microtubes and 8 (AHG Ct) indicates the presence of antibodies in patient's serum against on donor cells.
- A positive reaction in microtube 6 (Enz Minor) indicates the presence of antibodies in donor's serum against on patient cells.
- A negative reaction in the microtubes 5,6 and 7 (Enz, AHG) and a negative reaction in microtube 8 AHG Ct indicates the absence of antibodies (Compatibility).
- The patient's sample should be submitted to further testing if a positive reaction in one or both microtubes 5 and 7 and a positive autocontrol is observed (AHG Ct).
- A positive reaction in microtube 8 may indicate a positive direct antiglobulin test (DAT) of the patient's cells. The patient's sample should be submitted to further testing.

LIMITATIONS
- Do not remove foil seal until ready to use. Once opened ,the gel may begin to dry out which could affect test results
- The Aluminum foil on the matrix gel card should be removed carefully and gently.
- Do not use matrix gel cards, which show signs of drying.
- The gel cards which show air bubbles in the gel or drops in the upper part of the microtubes and/or the seal, must be centrifuged before use
- Do not touch the pipet tip inside the gel card. Carryover problem may occur.
- Do not use hemolysed, cloudy or contaminated samples or with clot presence.
- Use of suspension solutions other than Fortress LISS Diluent may modify the reactions.
- Red blood cells from individuals with A or B variants may present a weak expression of the antigens.
- Abnormal concentrations of serum proteins, the presence of macromolecular solutions in the serum may cause the non-specific agglutination of the red blood cells. It is recommended to wash the red blood cells before performing the test.
- Transfused patients or those subjected to bone marrow transplant may present images of double population.
- Patients with high-potency cold antibodies may coat the red blood cells completely so spontaneous agglutination may occur.

PERFORMANCE CHARACTERISTICS
Diagnostic sensitivity and specificity of

ABO/Rh system :

The diagnostic sensitivity and specificity of the antibodies present in Fortress Comp Test for the determination of the antigens of the ABO and Rh systems have been studied in a representative number of positive and negative samples. In the study using 3092 blood samples the sensitivity and specificity of ODAK Blood Grouping Gel System was as follows.

	Number of samples	Sensitivity	Specificity
Anti-A	3092	% 100	% 100
Anti-B	3092	% 100	% 100
Anti-D	3092	% 100	% 100

ABO/Rh compatibility
The diagnostic sensitivity and specificity of the antibodies present in Fortress Comp Test, for the determination of compatibility of ABO and Rh systems, have been studied in 240 donor-recipient (experimental donor-recipient).

	Sensitivity	Specificity
Anti-A	% 100	% 100
Anti-B	% 100	% 100
Anti-D	% 100	% 100

Crossmatch tests :
There is no described procedure or technique capable of detecting all the possible unexpected antibodies present in a sample. We conducted our own performance study.
Coombs and enzymatic technique have been studied in 240 donor-recipients (experimental donor-recipient) and obtained same results with other established products of equivalent intended use.

Precision:
Inter-assay and intra-assay reproducibility tests; no false positive or false negative results were obtained. Variability between agglutination views in positive samples were 1 agglutination rating or less in all assays.

BIBLIOGRAPHY
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Label Symbols

LOT Batch code

Expiry date

Storage temperature

Consult instructions for use

IVD In vitro diagnostic medical device

REF Product code

Manufacturer

Harmful