

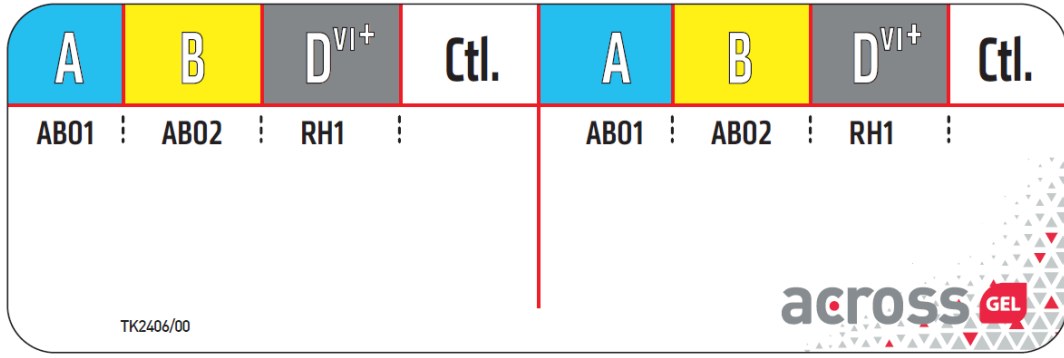
PROYECTO RÓTULOS Y MANUALES DE INSTRUCCIONES:

- 1) (N° de referencia: 810206) Across Gel Double ABO / DVI+



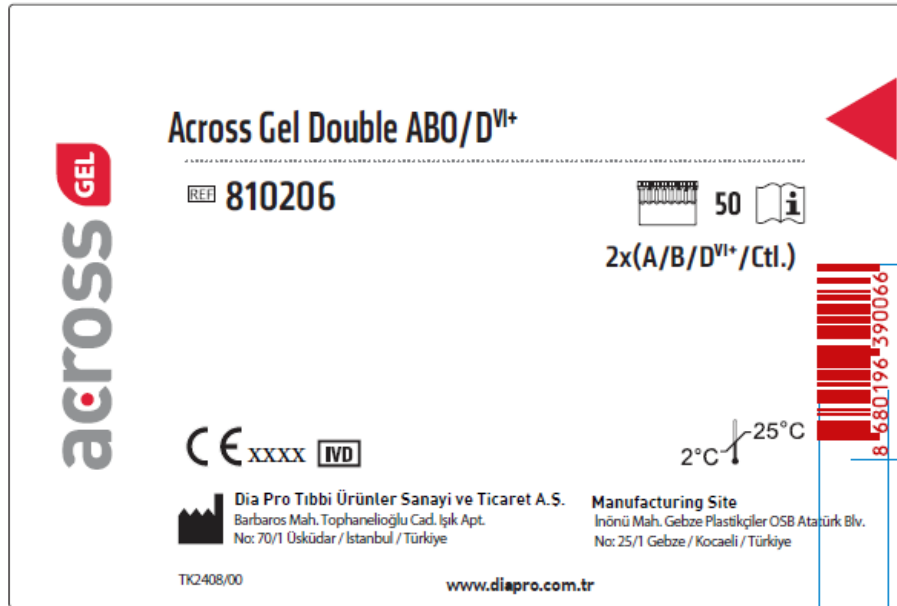

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810206 Kart Kutu Üst Etiketi Barkodlu 50'li
TK2408/00

BOY: 60,5mm



EN: 90mm

Handwritten signatures and stamps:

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2) (N° de referencia: 810207) Across Gel Double ABO / DVI-



TK2413/00

across 

**Across Gel Double
ABO / D^{VI}-**

2°C  25°C

LOT **0157020**

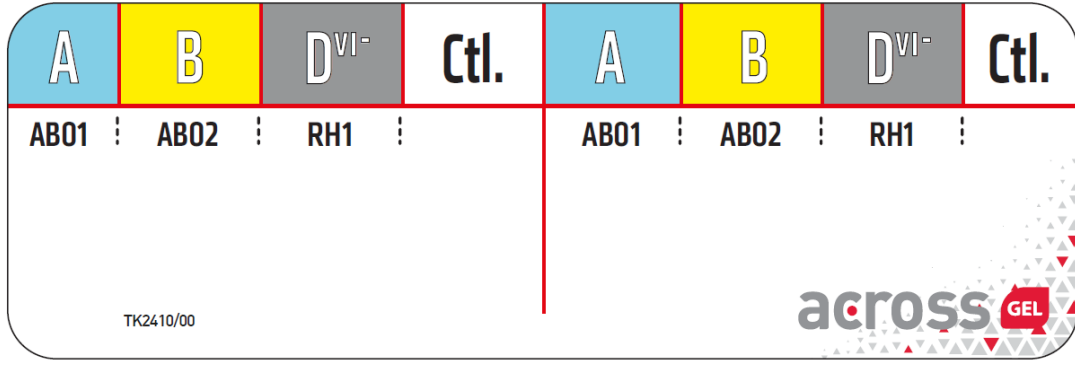
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REF **810207**

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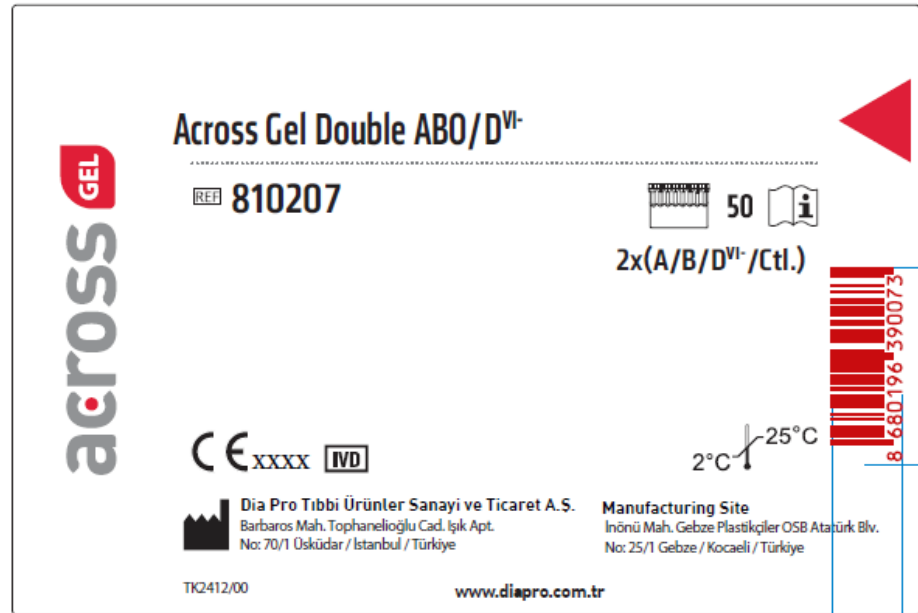

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810207 Kart Kutu Üst Etiketi Barkodlu 50'li TK2412/00

BOY: 60,5mm



EN: 90mm

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INTRODUCTION

The ABO system was the first human blood group system discovered by Landsteiner⁽¹⁾, and is still the most important system in transfusion practice.

The determination of Rh (D) is defined by the presence or absence of the D (RH1) antigen in the red blood cells. Anti-A, Anti-B and Anti-D reagents are used in ABO and Rh blood group typing.

INDICATION

The ABO system is defined by the presence or absence of the A and/or B antigens on the surface of red blood cells (forward grouping). Across Gel Double ABO / D^{VI} card is used for determination of A (ABO1), B (ABO2) and D (RH1) antigens.

PRINCIPLE

The principle of this test depends on using gel centrifugation technique to detect agglutination reactions which occur when antigens in red blood cells are bound (coated) with corresponding antibodies, present in the reagent, serum and plasma samples. Across Gel card contains polymerized dextran microspheres (gel) which function as a filter within the buffer solution in all microtubes on the card. Dextran and specific antibody containing reagent(s) or buffer solution are mixed. During the centrifugation of the cards, red blood cells agglutinates collected on the gel surface and throughout the length of the column according to their sizes. Non-agglutinated red blood cells go to the bottom of the microtube.

CONTENT

Microtubes of Across Gel Double ABO / D^{VI} card are identified by the front labels of the card:

- **A (ABO1) Microtube:** Monoclonal Anti-A (mixture of IgM antibodies of murine origin, BIRMA-1, ES-15 clone)
- **B (ABO2) Microtube:** Monoclonal Anti-B (mixture of IgM antibodies of murine origin, LB-2, 9621A8 clone)
- **D^{VI} (RH1) Microtube:** Monoclonal Anti-D (mixture of IgM and IgG antibodies, RUM-1, P3x61, ESD1M clone and MS-26)
- **Ctl. Microtube:** Neutral gel (buffered solution without antibodies)
- All microtubes contain Sodium Azide (NaN₃) as a preservative.
- Reagents are ready for use. Use microtubes immediately when foils are opened.

STORAGE CONDITIONS

Store cards upright at 2-25°C. Do not place cards in front of and/or next to any source of heat (places under direct sunlight, radiators, air conditioners, big devices which radiate heat when operating) or air ducts. Do not freeze cards. When the box is kept in intact package, it is stable until the expiry date specified on the outer label.

MATERIAL REQUIRED FOR TEST BUT NOT PROVIDED IN THE KIT

- Across Auto System semi-automatic or automatic instruments
- Across System Card Centrifuge
- Across System Card Reader
- Across System Dispenser
- Across System Pipette
- Across System Workstation
- Across LISS
- Disposable pipette tips
- Tube for preparation of suspension

COLLECTION AND PREPARATION OF SAMPLES

Samples

Blood samples with anticoagulant (containing plasma) can be used.
Do not use haemolysed, cloudy, contaminated blood samples or with clot presence.

Determination of the antigens of ABO/Rh System:

- Fresh blood samples collected in tubes containing anticoagulants like EDTA or citrate can be used.
- Blood samples stored at 2-8°C up to 48 hours after extraction can be used.
- Blood samples stored at 2-8°C, collected from bags containing ACD, CPD, CPDA and SAG-Mannitol which are not beyond the expiry date specified on the label must be used.

Sample Preparation

a) Preparing erythrocyte (red blood cell) suspension (To detect ABO/Rh system antigens)

Prepare 5% erythrocyte suspension (Add 25 µl erythrocyte to 0.5 ml Across LISS).

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QUALITY CONTROL

It is recommended to include known positive and negative controls in each series of tests. If an unexpected control value is obtained, a complete verification of the instrument, reagents and material used must be made.

TEST PROCEDURE

Across Gel Double ABO / D^{VI} card is used with manual system and Across Auto System semi-automatic or automatic instruments.

Allow the samples and reagents to reach room temperature (18-25 °C). Check card condition before use (Do not use the card if you detect bubbles in microtube, lack of supernatant, reduction in gel amount, crack in gel or change in color of the microtube). Across Gel Double ABO / D^{VI} test method is the same principle for manual system and Across Auto System semi-automatic or automatic instruments see the instrument manual.

MANUAL METHOD

ABO / D^{VI} Antigen Determination (A-B-D^{VI}-Ctl)

1. Each card is individually identified by a barcode. Unless a barcode reader is used identify them manually.
2. Carefully peel off the aluminium foil that covers the microtubes and keep the card upright to avoid reagent cross contamination.
3. Ensure the resuspension of the red blood cells before use.
4. Pipette 10 µl 5% red blood cell suspension into the corresponding microtubes (Avoid contact of pipette tip with the walls or content of microtubes).
5. Centrifuge card or cards for 9 mins at 990 rpm.
6. Read the results.

RESULTS

Results Reading

Positive	4+	Agglutinated cells in the upper part of the column.
	3+	Medium-sized visible agglutinations in the upper half of the column.
	2+	Small or medium-sized visible agglutinations throughout the column.
	1+	Some small-sized visible agglutinations in the column.
	+/-	Scarce small-sized visible agglutinations in the lower half of the column.
Negative	-	Band of red blood cells at the bottom of the column and no visible agglutinations in the rest of the column.
DP		Double Population (double band of red blood cells, at the bottom and in the upper part of the column)

It is recommended that the results are read immediately after centrifuging the cards. Do not leave processed cards in horizontal position.

Where necessary, you may store cards and make readings up until 24 hours if cards are kept in vertical position, refrigerated at 2-8°C and sealed with parafilm or similar material to avoid evaporation of the supernatant.

Interpretation of the results

ABO System

Forward ABO Group			
A Microtube	B Microtube	Ctl. Microtube	ABO Group
0	0	0	0
+	0	0	A
0	+	0	B
+	+	0	AB

Rh System (D antigen)

Rh (D) Group		
D ^{VI} Microtube	Ctl. Microtube	Interpretation
+	0	D positive
0	0	D negative

+ = positive
0 = negative

Notes:

- Results are not alone eligible for diagnostic use. They should be evaluated with clinical findings of the patient and other data.
- The Ctl abbreviation is Control.
- Ctl microtube must be negative. If it is positive, the test is invalid. Wash red blood cells with physiological saline solution, and repeat the process after preparing a new suspension with washed red blood cells. If the repeated control is negative, test results are eligible for evaluation. If it is positive, the test is invalid and must be repeated with a new sample.
- In ABO/Rh system: In case of weak positive reactions less than +3, the presence of weak antigens should be investigated.
- D^{VI} microtube may not react with all D variants so negative reactions with the D^{VI} microtube must be verified using other reagents and techniques which may detect different variants of the D antigen.

PERFORMANCE CHARACTERISTICS

Specificity and sensitivity of antibodies present in Across Gel Double ABO/D^{VI} card have been analyzed with representative number of positive and negative samples.

Antibody	Number of Sample	Sensitivity(I)	Specificity(II)
anti-A	1061	100%	100%
anti-B	1061	100%	100%
anti-D ^{VI}	1061	98.5%	100%

(I) Sensitivity: [(number of true positive results) / (number of true positive results + number of false negative results)] x 100

(II) Specificity: [(number of true negative results) / (number of true negative results + number of false positive results)] x 100

WARNINGS AND PRECAUTIONS

- It is used by the professional health team (health technician, biologist, health technician, etc.) working in health institutions such as hospital, blood centers where blood transfusion treatment is applied.
- Using a solution other than Across LISS in preparing red blood cell suspensions may change the reaction.
- Preparing the red blood cell suspension in a concentration other than the specified concentration may result in a false negative or a false positive test result.
- Adding a volume other than that stated in the method may change the reaction.
- Do not use a card with past expiry date.
- If dispersed droplets are observed on the microtube due to inappropriate handling or storage, it is recommended that cards are centrifuged before use. If droplets do not precipitate, do not use the card.
- Abnormal concentrations of serum proteins, presence of macromolecular solutions in serum or plasma, or presence of Wharton jelly in umbilical cord blood samples may result in non-specific agglutination of red blood cells. In such cases, it is recommended that red blood cells are washed before the test⁽²⁾.
- Double population may be seen in patients who have undergone blood transfusion or bone marrow transplantation⁽²⁾.
- Red blood cells from individuals with A or B variants may present a weak expression of the antigens, and may not be detected.
- As red blood cells may be completely coated with antibodies in patients with high gold antibody effect, spontaneous agglutination may occur⁽²⁾.
- All blood products and samples should be handled carefully as if they have potential for transmitting of disease.
- The product is recommended to be disposed of into a special container used for biological waste after use.
- If you encounter any adverse event or need further information regarding the use of this product, consult the authorized distributor in your country.
- Report any serious adverse events that occur with the device to the manufacturer (diapro@diapro.com.tr / +90(262)751-53-34) and the competent.

REFERENCES

1. Mollison PL, Engelfriet CP, Contreras M. Blood Transfusion in Clinical Medicine, 10th edition, Blackwell Scientific Publications, Oxford, 1993.
2. Technical Manual, 15th edition, American Association of Blood Banks, Bethesda, 2005

PACKAGING

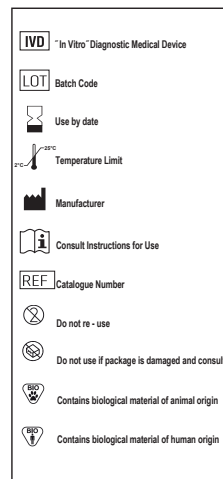
Across Gel Double ABO / D^{VI}

(2x A / B / D^{VI} / Ctl)

Ref No: 810206 ----50 Cards

Document No:TK3414

This document is available in several languages. Translations have been made from the IFU in Turkish. In case of doubt or



CE XXXX

INTRODUCCION

El sistema de ABO, es el primer sistema de grupo sanguíneo encontrado por parte de Landsteiner (1) y actualmente es un sistema más importante en las aplicaciones de transfusión. La detección del Rh (D) se basa en la detección de la presencia o ausencia del antígeno D (RH1) en los glóbulos rojos. Los reactivos Anti-A, Anti-B y Anti-D se utilizan para la tipificación de los grupos sanguíneos ABO y Rh.

OBJETO DE USO

El sistema ABO se define por la presencia o ausencia de antígenos A y/o B en la superficie eritrocitaria (agrupación directa hacia delante). La tarjeta Across Gel Double ABO / D^{VI} se utiliza para la detección de los antígenos A (AB01), B (AB02) y D (RH1).

PRINCIPIO

El principio de esta prueba se basa en la detección por centrifugación en gel de reacciones de aglutinación resultantes de la unión de antígenos de los hematíes con los correspondientes anticuerpos presentes en muestras de reactivo, suero o plasma. Todos los microtubos de la tarjeta Across Gel contienen microesferas de dextrano polimerizado (gel) que actúan como filtros en solución tampón. Los dextranos se mezclan con reactivo(s) o solución tampón que contienen anticuerpos específicos.

Durante la centrifugación de las tarjetas, dependiendo de su tamaño, se recogen aglutinaciones de hematíes en la superficie del gel y a lo largo de la columna. Los hematíes no aglutinados se depositan en el fondo del microtubo.

CONTENIDO

Los microtubos de la tarjeta Across Gel Double ABO / D^{VI} se identifican mediante etiquetas en la parte frontal de la tarjeta:

- **A (AB01) Microtubo:** Anticuerpo monoclonal Anti-A (mezcla de anticuerpos IgM de origen murino, BIRMA-1, clon ES-15)
- **B (AB02) Microtubo:** Anticuerpo monoclonal Anti-B (mezcla de anticuerpos IgM de origen murino, LB-2, clon 9621A8)
- **D^{VI}(RH1) Microtubo:** Monoclonal Anti-D (mezcla de anticuerpos IgM e IgG humanos, clon RUM-1, P3x81 clona.)
- **Ctl. Microtubo:** Gel Neutro (Solución tampón sin anticuerpos)
- Todos los microtubos contienen Azida Sódica (NaN3) como conservante.
- Los reactivos están listos para su uso. Una vez que abras las láminas de los microtubos, úsalos sin esperas.

CONDICIONES DE CONSERVACION

Guarde las tarjetas en posición vertical a 2-25°C. No coloque las tarjetas delante y/o junto a fuentes de calor (luz solar directa, radiadores de calefacción, aparatos de aire acondicionado, grandes electrodomésticos que emitan calor durante su funcionamiento, etc.) o fuentes de aire. No congele las tarjetas. Si la caja se conserva sin abrir, es estable hasta la fecha de caducidad indicada en la etiqueta exterior.

MATERIALES NECESARIOS PARA EL ESTUDIO DE LA PRUEBA PERO NO INCLUIDOS EN EL KIT

- Across Auto System Dispositivos semiautomáticos o totalmente automáticos
- Across system tarjeta de Centrifugadora
- Across system Lector de tarjetas
- Across system Dispensador
- Across system Pipeta
- Across system estación de trabajo
- Across LISS
- Puntas de pipeta desechables

RECOGIDA Y PREPARACIÓN DE MUESTRAS

Ejemplos

Pueden utilizarse muestras de sangre anticoagulada (que contenga plasma). No utilice muestras de sangre hemolizada, turbia, contaminada o coagulada.

Detección de antígenos del sistema ABO/Rh :

- Pueden utilizarse muestras de sangre fresca recogidas en tubos que contengan anticoagulante EDTA o citrato.
- Se pueden utilizar muestras de sangre tomadas hasta 48 horas antes almacenadas a 2-8°C
- Trabajar con muestras de sangre extraídas de bolsas que contengan ACD, CPD, CPDA y SAG-Mannitol almacenadas a 2-8°C y con la fecha de caducidad indicada en la etiqueta.

Preparación de muestras

a) Preparación de suspensión de eritrocitos (glóbulos rojos) (para la detección de antígenos del sistema ABO/Rh)
Preparar una suspensión de hematíes al 5% (añadir 25 µl de eritrocitos a 0,5 ml de Across LISS).

CONTROL DE CALIDAD

Se recomienda realizar controles positivos y negativos conocidos para cada serie de pruebas. Cuando se obtenga un valor de control inesperado, deberán comprobarse los instrumentos, reactivos y materiales utilizados.

PROCEDIMIENTO DE ENSAYOS

La tarjeta Across Gel Double ABO / D^{VI} puede ejecutarse con equipos manuales o con instrumentos semiautomáticos o totalmente automatizados Across Auto System. Deje que la muestra y los reactivos alcancen la temperatura ambiente (18-25°C). Compruebe el estado de las tarjetas antes de utilizarlas (no utilice la tarjeta si aparecen burbujas en el microtubo, falta sobrenadante, se reduce la cantidad de gel, el gel está agrietado o cambia el color del microtubo). Los principios de funcionamiento de la tarjeta Across Gel Double ABO / D^{VI} con equipos manuales y dispositivos semiautomáticos y totalmente automáticos Across Auto System son equivalentes. Para los dispositivos semiautomáticos y totalmente automáticos Across Auto System, consulte las instrucciones de funcionamiento.

METODO MANUAL

- ABO / D^{VI}: Determinación de Antígeno (A-B-D^{VI}-Ctl)**
1. Cada tarjeta se identifica individualmente mediante un código de barras. Identifique las tarjetas manualmente a menos que se utilice un lector de códigos de barras.
 2. Retire con cuidado el papel de aluminio que cubre los microtubos y mantenga la tarjeta en posición vertical para evitar la contaminación cruzada de reactivos.
 3. Asegúrese de que los hematíes están resuspendidos antes de su uso.
 4. Pipetear 10 µl de suspensión de hematíes al 5% en los microtubos indicados (tener cuidado de no tocar con la punta de la pipeta las paredes o el contenido de los microtubos).
 5. Centrifugar la tarjeta a 990 rpm durante 9 min.
 6. Evaluar los resultados.

RESULTADOS

Lectura de Resultados

Positivo	4+	Si las células aglutinadas se encuentran en la parte superior de la columna.
	3+	Agglutination de tamaño medio en la mitad superior de la columna.
	2+	Si se observan aglutinaciones pequeñas o medianas en toda la columna.
	1+	Si hay una pequeña cantidad de aglutinación de pequeño tamaño en la columna.
Negativo	+/-	Si aparecen trazas de aglutinación de pequeño tamaño en la mitad inferior de la columna.
	-	Si la banda de hematíes se encuentra en la base de la columna y no se aprecia aglutinación a lo largo de ella.
DP		Doble población (doble banda de glóbulos rojos en la base y en la parte superior de la columna)

Se recomienda leer inmediatamente las tarjetas centrifugadas. No deje las tarjetas estudiadas en posición horizontal. En caso necesario, las tarjetas pueden guardarse y leerse hasta 24 horas en posición vertical, a 2-8°C y cubiertas con parafilm, etc. para evitar la evaporación del sobrenadante.

Comentario de los resultados

Sistema de ABO

Grupo de Forward ABO			
A Microtubo	B Microtubo	Ctl. Microtubo	Grupo de ABO
0	0	0	0
+	0	0	A
0	+	0	B
+	+	0	AB

Sistema de Rh (Antígeno D)

Grupo de Rh (D)		Comentario
D ^{VI} Microtubo	Ctl. Microtubo	
+	0	D positivo
0	0	D negativo

+ = positivo

0 = negativo

Notas:

- Los resultados no son diagnósticos en sí mismos. Deben evaluarse junto con los conocimientos clínicos del paciente y otros datos.
- La abreviatura Ctl significa Control.
- El microtubo Ctl debe ser negativo. Si es positivo, la prueba no es válida. Si es positivo, lave los hematíes con solución salina fisiológica, prepare una nueva suspensión con hematíes lavados y repita el procedimiento.
- Si el control repetido es negativo, pueden evaluarse los resultados de la prueba. Si es positivo, la prueba no es válida y debe repetirse con una nueva muestra.
- En sistema ABO/Rh: En reacciones positivas más débiles que +3, debe investigarse la presencia de antígeno débil.
- El microtubo D^{VI} puede no reaccionar con todas las variantes D, por lo que las reacciones negativas con el microtubo D^{VI} deben confirmarse utilizando otros reactivos y técnicas que puedan detectar diferentes variantes del antígeno D.

CARACTERISTICAS DE PERFORMANCE

La especificidad y la sensibilidad de los anticuerpos presentes en la tarjeta Across Gel Double ABO/D^{VI} se estudiaron en un número representativo de muestras positivas y negativas.

Anticore	Num. Ejemplo	Sensibilidad (I)	Especificidad(II)
anti-A	1061	%100	%100
anti-B	1061	%100	%100
anti-D ^{VI}	1061	%98,5	%100

(I)Sensibilidad : [(número de resultados positivos verdaderos) / (número de resultados positivos verdaderos + número de resultados negativos falsos)] x 100

(II)Especificidad: [(número de resultados negativos verdaderos)/(número de resultados negativos verdaderos + número de resultados positivos falsos)] x 100

ATENCIONES Y PREVENCIONES

- Lo utiliza el equipo sanitario profesional (técnicos sanitarios, biólogos, técnicos sanitarios, etc.) que trabaja en instituciones sanitarias como hospitales, centros hematológicos donde se aplica la terapia de transfusión sanguínea.
- El uso de soluciones distintas de Across LISS durante la preparación de suspensiones de hematíes puede alterar la reacción.
- La preparación de la suspensión de hematíes a una concentración distinta de la especificada puede dar lugar a un resultado falso negativo o falso positivo.
- La adición de volúmenes distintos a los especificados en el método puede alterar la reacción.
- No utilizar tarjetas caducadas.
- Se recomienda centrifugar las tarjetas antes de usarlas si se observan gotitas dispersas en el microtubo debido a un transporte o almacenamiento inadecuados. No utilizar la tarjeta si las gotitas no descienden.
- Las concentraciones anormales de proteínas séricas, la presencia de soluciones macromoleculares en suero o plasma, o la presencia de gel de Wharton en muestras de sangre de cordón umbilical pueden provocar una aglutinación inespecífica de los hematíes. En tales casos, se recomienda lavar los hematíes antes de realizar la prueba(2).
- La doble población puede observarse en pacientes que han sufrido transfusiones de sangre o trasplantes de médula ósea(2).
- Es posible que no se detecten los antígenos de los hematíes de individuos con variantes A o B con una expresión débil del antígeno.
- Puede observarse aglutinación espontánea en pacientes con anticuerpos fríos de alta potencia, ya que los hematíes pueden estar completamente cubiertos de anticuerpos(2).
- Manipule todos los productos sanguíneos y las muestras con cuidado, como si tuvieran el potencial de transmitir enfermedades.
- Tras su uso, se recomienda desechar el producto en el contenedor especial para residuos biológicos.
- Si se encuentra con algún incidente adverso o necesita más información sobre el uso de este producto, consulte al distribuidor

RECURSOS

1. Mollison PL, Engelfriet CP, Contreras M. Blood Transfusion in Clinical Medicine, 10. Baski, Blackwell Scientific Publications, Oxford, 1993.
2. Technical Manual, 15. Baski, American Association of Blood Banks, Bethesda, 2005.

FORMA DE EMBALAJE

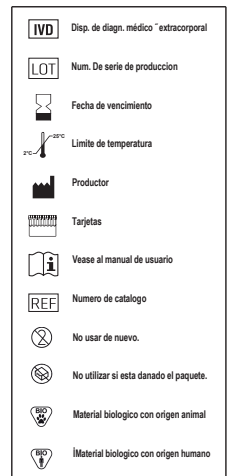
Across Gel Double ABO / D^{VI}

(2x A / B / D^{VI} / Ctl)

Ref No: 810207 ---- 50 Tarjeta

Documento no: TK3415

Este documento está disponible en varios idiomas. Las traducciones están hechas de IFU turco. En caso de duda o discrepancia, se deberán tener en cuenta las declaraciones del documento principal turco.



INTRODUCTION

The ABO system was the first human blood group system discovered by Landsteiner⁽¹⁾, and is still the most important system in transfusion practice.

The determination of Rh (D) is defined by the presence or absence of the D (RH1) antigen in the red blood cells. Anti-A, Anti-B and Anti-D reagents are used in ABO and Rh blood group typing.

INDICATION

The ABO system is defined by the presence or absence of the A and/or B antigens on the surface of red blood cells (forward grouping) Across Gel Double ABO / D^{Vi} is card used for determination of A (ABO1), B (ABO2) and D (RH1) antigens.

PRINCIPLE

The principle of this test depends on using gel centrifugation technique to detect agglutination reactions which occur when antigens in red blood cells are bound (coated) with corresponding antibodies, present in the reagent, serum and plasma samples. Across Gel card contains polymerized dextran microspheres (gel) which function as a filter within the buffer solution in all microtubes on the card. Dextran and specific antibody containing reagent(s) or buffer solution are mixed. During the centrifugation of the cards, red blood cells agglutinates collected on the gel surface and throughout the length of the column according to their sizes. Non-agglutinated red blood cells go to the bottom of the microtube.

CONTENT

Microtubes of Across Gel Double ABO / D^{Vi} card are identified by the front labels of the card:

- **A(ABO1) Microtube:** Monoclonal Anti-A (Mixture of IgM antibodies of murine origin, BIRMA-1, ES-15 clone)
- **B(ABO2) Microtube:** Monoclonal Anti-B (Mixture of IgM antibodies of murine origin, LB-2, 9621A8 clone)
- **D^{Vi}(RH1) Microtube:** Monoclonal Anti-D (Mixture of IgM antibodies of human origin, RUM-1, P3x61)
- **Ctl. Microtube:** Neutral gel (buffered solution without antibodies)
- All microtubes contain Sodium Azide (NaN₃) as a preservative.
- Reagents are ready for use. Use microtubes immediately when foils are opened.

STORAGE CONDITIONS

Store cards upright at 2-25°C. Do not place cards in front of and/or next to any source of heat (places under direct sunlight, radiators, air conditioners, big devices which radiate heat when operating) or air ducts. Do not freeze cards. When the box is kept in intact package, it is stable until the expiry date specified on the outer label.

MATERIAL REQUIRED FOR TEST BUT NOT PROVIDED IN THE KIT

- Across Auto System semi-automatic or automatic instruments.
- Across System Card Centrifuge
- Across System Card Reader
- Across System Dispenser
- Across System Pipette
- Across System Workstation
- Across LISS
- Disposable pipette tips
- Tube for preparation of suspension

COLLECTION AND PREPARATION OF SAMPLES

Samples

Blood samples with anticoagulant (containing plasma) can be used.

Do not use haemolysed, cloudy, contaminated blood samples or with clot presence.

Determination of the antigens of ABO/Rh System:

- Fresh blood samples collected in tubes containing anticoagulants like EDTA or citrate can be used.
- Blood samples stored at 2-8°C up to 48 hours after extraction can be used.
- Blood samples stored at 2-8°C, collected from bags containing ACD, CPD, CPDA and SAG-Mannitol which are not beyond the expiry date specified on the label must be used.

Sample Preparation

a) Preparing erythrocyte (red blood cell) suspension (To detect ABO/Rh system antigens)

Prepare 5% erythrocyte suspension (Add 25 µl erythrocyte to 0.5 ml Across LISS).

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QUALITY CONTROL

It is recommended to include known positive and negative controls in each series of tests. If an unexpected control value is obtained, a complete verification of the instrument, reagents and material used must be made.

TEST PROCEDURE

Across Gel Double ABO / D^{Vi} is used with manual system and Across Auto System semi-automatic or automatic instruments. Allow the samples and reagents to reach room temperature (18- 25°C). Check card condition before use (Do not use the card if you detect bubbles in microtube, lack of supernatant, reduction in gel amount, crack in gel or change in color of the microtube). Across Gel Double ABO / D^{Vi} test method is the same principle for manual system and Across Auto System semi-automatic or automatic instruments see the instrument manual.

MANUAL METHOD

ABO / D^{Vi} Antigen Determination (A-B-D^{Vi}-Ctl)

1. Each card is individually identified by a barcode. Unless a barcode reader is used identify them manually.
2. Carefully peel off the aluminium foil that covers the microtubes and keep the card upright to avoid reagent cross contamination.
3. Ensure the resuspension of the red blood cells before use.
4. Pipette 10 µl 5% red blood cell suspension into the corresponding microtubes (Avoid contact of pipette tip with the walls or content of microtubes).
5. Centrifuge card or cards for 9 mins at 990 rpm.
6. Read the results.

RESULTS

Results Reading

Positive	4+	Agglutinated cells in the upper part of the column.
	3+	Medium-sized visible agglutinations in the upper half of the column.
	2+	Small or medium-sized visible agglutinations throughout the column.
	1+	Some small-sized visible agglutinations in the column.
	+/-	Scarce small-sized visible agglutinations in the lower half of the column.
Negative	-	Band of red blood cells at the bottom of the column and no visible agglutinations in the rest of the column.
DP		Double Population (double band of red blood cells, at the bottom and in the upper part of the column)

It is recommended that the results are read immediately after centrifuging the cards. Do not leave processed cards in horizontal position.

Where necessary, you may store cards and make readings up until 24 hours if cards are kept in vertical position, refrigerated at 2-8 °C and sealed with parafilm or similar material to avoid evaporation of the supernatant.

Interpretation of the results

ABO System

Forward ABO Group			
A Microtube	B Microtube	Ctl. Microtube	ABO Group
0	0	0	0
+	0	0	A
0	+	0	B
+	+	0	AB

Rh System (D antigen)

Rh (D) Group		
D ^{Vi} Microtube	Ctl. Microtube	Interpretation
+	0	D positive
0	0	D negative

+ = positive

0 = negative

Notes:

- Results are not alone eligible for diagnostic use. They should be evaluated with clinical findings of the patient and other data.
- The Ctl abbreviation is Control.
- Ctl microtube must be negative. If it is positive, the test is invalid. Wash red blood cells with physiological saline solution, and repeat the process after preparing a new suspension with washed red blood cells. If the repeated control is negative, test results are eligible for evaluation. If it is positive, the test is invalid and must be repeated with a new sample.
- In ABO/Rh system: In case of weak positive reactions less than +3, the presence of weak antigens should be investigated.
- Preparing the red blood cell suspension in a concentration other than the specified concentration may result in a false negative test result or a false positive test result.
- D^{Vi} microtube may not react with all D variants so negative reactions with the D^{Vi} microtube must be verified using other reagents and techniques which may detect different variants of the D antigen.

Dia Pro Tıbbi Ürünler Sanayi ve Ticaret A.Ş.

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PERFORMANCE CHARACTERISTICS

Specificity and sensitivity of antibodies present in Across Gel Double ABO / D^{Vi} card have been analyzed with representative number of positive and negative samples.

Antibody	Number of Sample	Sensitivity(I)	Specificity(II)
anti-A	1061	100%	100%
anti-B	1061	100%	100%
anti-D ^{Vi}	1061	98,5%	100%

(I) Sensitivity: [(number of true positive results) / (number of true positive results + number of false negative results)] x 100

(II) Specificity: [(number of true negative results) / (number of true negative results + number of false positive results)] x 100

WARNINGS AND PRECAUTIONS

- It is used by the professional health team (health technician, biologist, health technician, etc.) working in health institutions such as hospital, blood centers where blood transfusion treatment is applied.
- Using a solution other than Across LISS in preparing red blood cell suspensions may change the reaction.
- Preparing the red blood cell suspension in a concentration other than the specified concentration may result in a false negative or a false positive test result.
- Adding a volume other than that stated in the method may change the reaction
- Do not use a card with past expiry date.
- If dispersed droplets are observed on the microtube due to inappropriate handling or storage, it is recommended that cards are centrifuged before use. If droplets do not precipitate, do not use the card.
- Abnormal concentrations of serum proteins, presence of macromolecular solutions in serum or plasma, or presence of Wharton jelly in umbilical cord blood samples may result in non-specific agglutination of red blood cells. In such cases, it is recommended that red blood cells are washed before the test⁽²⁾.
- Double population may be seen in patients who have undergone blood transfusion or bone marrow transplantation⁽²⁾.
- Red blood cells from individuals with A or B variants may present a weak expression of the antigens, and may not be detected.
- As red blood cells may be completely coated with antibodies in patients with high cold antibody effect, spontaneous agglutination may occur⁽²⁾.
- All blood products and samples should be handled carefully as if they have potential for transmitting of disease.
- The product is recommended to be disposed of into a special container used for biological waste after use.
- If you encounter any adverse event or need further information regarding the use of this product, consult the authorized

REFERENCES

1. Mollison PL, Engelfriet CP, Contreras M. Blood Transfusion in Clinical Medicine, 10th edition, Blackwell Scientific Publications, Oxford, 1993.
2. Technical Manual, 15th edition, American Association of Blood Banks, Bethesda, 2005

PACKAGING

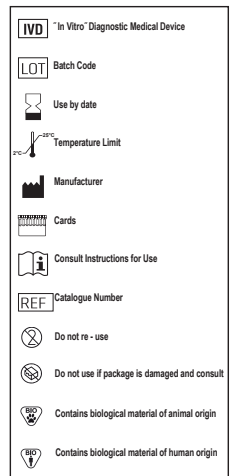
Across Gel Double ABO / D^{Vi}

(2x A / B / D^{Vi} / Ctl)

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CE XXXX



República Argentina - Poder Ejecutivo Nacional
AÑO DE LA RECONSTRUCCIÓN DE LA NACIÓN ARGENTINA

Hoja Adicional de Firmas
Anexo

Número:

Referencia: ROTULOS E INSTRUCCIONES DE USO NG MED S.R.L.

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