BLOOD GROUPING REAGENTS

Anti-A (Murine Monoclonal)
Anti-B (Murine Monoclonal)
Anti-A,B (Murine Monoclonal)
Anti-D (Monoclonal Blend)
Anti-D (PK 1) (Monoclonal-IgM)
Anti-D (PK 2) (Monoclonal-IgM)
-E (Monoclonal), Anti-C (Monoclonal)
-e (Monoclonal), Anti-c (Monoclonal)
Anti-K (Monoclonal),
BECKMAN COULTER CONTROL
ormulated for Use in Automated Systems
ECKMAN COULTER® PK® SYSTEMS

U.S. License No: 1744

BECKMAN COULTER.

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INTENDED USE

The BECKMAN COULTER® PK® SYSTEM BLOOD GROUPING and PHENOTYPING REAGENTS are intended for the determination of blood ABO group and Rh type and Kell phenotypes in blood donors using the BECKMAN COULTER PK7200 and/or the BECKMAN COULTER PK7300 Automated Microplate System(s).

The Anti-A, Anti-B, and Anti-A,B reagents are used in the red blood cell determination of the ABO blood group. They are used to determine the absence or presence of erythrocytic antigens A and/or B on the surface of human red blood cells.

The Anti-D reagents: Anti-D, Anti-D (PK 1), Anti-D (PK 2), are used to determine the Rh type. They are used to detect the presence of the D (Rh) antigen on the surface of human red blood cells. The Anti-C, Anti-E, Anti-c, Anti-e, and Anti-K are used for Rh-Kell phenotyping of human red blood cells. These reagents detect the presence of antigens C, E, c, e, and K on the surface of red blood cells. The BECKMAN COULTER CONTROL is devoid of antibody activity and should be used in parallel testing with the BECKMAN COULTER PK SYSTEM BLOOD GROUPING and PHENOTYPING REAGENTS to differentiate between specific and non-specific agglutination.

SUMMARY OF TEST

ABO BLOOD GROUP SYSTEM

The determination of an ABO blood group is defined by demonstrating the presence or absence of antigens A and/or B on the surface of human red blood cells and by detecting the presence or absence of anti-A and/or anti-B antibodies in the plasma. It is therefore appropriate to identify the erythrocyte antigens using known anti-A and anti-B, then to confirm the results by verifying the presence of the corresponding antibodies in the plasma from the test blood using known red blood cells A1 and B (reverse group). Additional testing of the red blood cells with Anti-A,B reagent facilitates the recognition of certain weak subgroups and is sometimes used as further confirmation of the reactions obtained with Anti-A and Anti-B reagents.

THE PRINCIPLE ANTIGENS AND ANTIBODIES OF THE ABO SYSTEM

ABO Blood Group	Antigen present on the red blood cells	Antibodies regularly present in the serum/plasma
O	neither A or B	anti-A and anti-B
A	A	anti-B
B	B	anti-A
AB	A and B	none

Rh BLOOD GROUP SYSTEM

After the A and B antigens of the ABO blood group system, D is the most important blood group antigen in routine blood banking. Unlike antibodies of the ABO system, those of the Rh system do not occur naturally in the serum, but are most often the result of exposure to the antigen during pregnancy or through transfusion. The presence or absence of the D antigen is determined by testing the red blood cells with Anti-D. Agglutination indicates that the test cells are D positive. No agglutination indicates that the test cells are D negative. Approximately 85% of the white population and 94% of the black population are positive for the D antigen. The term "weak D" is used to describe forms of the D antigen that may not be agglutinated directly by Anti-D reagents. The red blood cells of donors are required to be tested for weak D before being classified as D negative [1,2].

After the D antigen, the other most important antigens in the Rh system are C, E, c and e. These antigens are not as immunogenic as D, but may cause rapid destruction of red blood cells in the presence of the corresponding antibody. Positive results indicate the presence of the antigen, while negative results indicate the absence of the antigen on the red blood cells. It is significant to identify the presence of these antigens when selecting blood for transfusion to patients with those antibodies.

Table 1 lists the five most common Rh antigens, the Wiener nomenclature and the approximate frequency of each antigen in the Caucasian population. Table 2 lists the most common patterns of reactions obtained and the most common genotypes.

Table 1

Fisher-Race	Wiener	Caucasian %
D	Rh_0	85
C	rh'	70
E	rh''	30
c	hr'	80
e	hr''	98

Table 2

Anti					Probable Genotypes	
D	C	E	c	e	Wiener	Fisher-Race
+	+	0	+	+	R^1r	CDe/cde
+	+	0	0	+	R^1R^1	CDe/CDe
0	0	0	+	+	rr	cde/cde
+	+	+	+	+	R^1R^2	CDe/cDE
+	0	+	+	+	R^2r	cDE/cde
+	0	+	+	0	R^2R^2	cDE/cDE
+	0	0	+	+	R^0r	cDe/cde
0	+	0	+	+	$r'r$	Cde/cde
0	0	+	+	+	$r''r$	cdE/cde

KELL BLOOD GROUP SYSTEM

The most frequently encountered antibody in the Kell system is anti-K. The K(K1) antigen is strongly immunogenic, and anti-K is frequently found in the sera of transfused patients. A positive test indicates the presence of the K antigen, while a negative test indicates the absence of the K antigen on the red blood cells. Approximately 90% of donors are K negative. It is significant to identify the K antigen when selecting blood for transfusion to patients with anti-K.

III. PRINCIPLE OF PROCEDURE

The test is based on the principles of agglutination and pattern recognition. When red blood cells bearing antigens are pretreated with BECKMAN COULTER PK SYSTEM BROMELIN, agglutination will occur with the reagent containing the corresponding antibody. Agglutination with a particular antibody indicates the presence of the specific antigen. The absence of agglutination indicates the red blood cells are negative for the antigen. The PK7200 and PK7300 analyzers will read the settling patterns of the red blood cells in each well of the microplate and make a determination based on the threshold settings chosen for each reagent. For complete details on the setup and operation of the BECKMAN COULTER PK7200 please refer to the Operator's Manual, and for the PK7300 refer to the User's Guide

IV. REAGENTS

Blood Grouping Reagents, Anti-A, Anti-B, Anti-A,B, Anti-D, Anti-D (PK1), Anti-D (PK2), Anti-C, Anti-c, Anti-E, Anti-e, and Anti-K for the Beckman Coulter PK Systems are manufactured from antibodies derived from the supernatants of in vitro cultures of hybridomas of murine or human origin. These reagents contain sodium azide (<0.1%), sodium arsenite (0.02%) and bovine albumin. Any bovine albumin used in the manufacture of this product is sourced from donor animals that have been inspected and certified by Veterinary Service Inspectors to be disease free. BECKMAN COULTER CONTROL is based on the formulation of the BLOOD GROUPING and PHENOTYPING REAGENTS, but devoid of antibodies. The reagents are intended for in-vitro diagnostic use on the BECKMAN COULTER PK7200 and/or PK7300 Automated Microplate System only. The ready to use reagents are supplied in 30 ml: glass and/or 20ml: plastic vials. Do not use any reagent past the expiration date. PK SYSTEM BLOOD GROUPING REAGENTS and/or PHENOTYPING REAGENTS left at room temperature for 12 hours or more should be discarded. Once opened, the contents of either the PK7200 or PK7300 BLOOD GROUPING REAGENTS, PHENOTYPING REAGENTS and/or BECKMAN COULTER CONTROL should be used within 30 days or discarded.

Component	Clone	Type	Origin
Anti-A (Murine Monoclonal Blend)	2521B8 + 16243G2	IgM	Murine
Anti-A (Murine Monoclonal)	9113D10	IgM	Murine
Anti-B (Murine Monoclonal)	9621A8	IgM	Murine
Anti-B (Murine Monoclonal Blend)	16485G10 + 7821D9	IgM	Murine
Anti-A,B (Murine Monoclonal Blend)	2521B8 + 16243G2 + 16247E10 + 7821D9	IgM	Murine
Anti-D (Monoclonal Blend)	P3X61 + P3X21223B10 + P3X290 + P3X35	IgM IgG	Human
Anti-D (PK 1) (Monoclonal-IgM)	P3X61	IgM	Human
Anti-D (PK 2) (Monoclonal-IgM)	HM10	IgM	Human
BECKMAN COULTER CONTROL			
Anti-C (Monoclonal IgM)	P3X26513G8 + MS24	IgM	Human
Anti-E (Monoclonal IgM)	908	IgM	Human
Anti-c (Monoclonal IgM)	B51	IgM	Human
Anti-e (Monoclonal IgM)	P3GD512 + MS63	IgM	Human
Anti-K (Monoclonal IgM)	MS56	IgM	Human

The following antibodies are produced using intermediate products produced for Diagast in a shared manufacturing agreement with Millipore (UK) Ltd., 9 Fleming Road, Kirkton Campus, EH547BN, Livingston, UK; FFMU License Number 1761.

Specificity	Clone ID
Anti-e (RH5)	MS63
Anti-C (RH2)	MS24
Anti-K (KEL1)	MS56

WARNINGS AND PRECAUTIONS

1. Handle as if capable of transmitting disease. The absence of infectious agents cannot be established. *Do not pipette any reagents by mouth.*
2. Avoid cross-contamination of reagents or specimens.
3. The microplates must be clean and dry before use. Improper cleaning of the microplates can adversely affect a test result by causing a false-negative or false-positive reaction. The suggested cleaning procedures for the PK microplates can be found in the PK7200 Operator's Manual and the PK7300 User's Guide.
4. Visible signs of microbial growth in any reagent may indicate degradation and warrant discontinuance of use.
5. Sodium azide is present in these reagents as a preservative, at a concentration of less than 0.1 %. *Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. If discarded into sinks, flush with a large volume of water to prevent azide build-up.*
6. Sodium arsenite is present in these reagents as a preservative, at a concentration of 0.02 %. Sodium arsenite is a carcinogen and a teratogen. Avoid contact with skin and mucous membranes. Flush areas of exposure well with running water.
7. Handle all specimens and controls of human origin as if potentially infectious. Refer to the guidelines from the Center for Disease Control and Prevention on specimen handling.
8. Carryover between specimens is a potential source of interference.
9. Microbial contamination of the specimen may produce effects that cannot be predicted.
10. Positive and negative control material should be handled in the same manner as donor samples.
11. Incorrect sampling of the specimen, diluent or reagent could result in erroneous test results.
12. Failure to follow directions contained in the package insert may result in erroneous results.
13. The use of calibrated or verified equipment is required.
14. Phosphate Buffered Saline should *not* be used in the test system.
15. Effort should be made to prevent contamination and evaporation during use of the product. Do not transfer reagent back into the original container or between containers once dispensed or placed into use on the analyzer.
16. Reagents should not be used past the expiration date.
17. Agglutination may be weaker with older cells than with those from freshly drawn blood and may result in a higher no type determined (NTD) rate.
18. For *in vitro* diagnostic use.

VI. REAGENT PREPARATION

1. The reagents are intended for use as supplied. No prior preparation or dilution of the reagents is required or permitted.
2. All reagents should be brought to room temperature (+15° C - +30° C) before use on the analyzer.
3. Effort should be made to minimize contamination during use of the product.
4. The date on which any reagent container is opened should be recorded on the container.
5. Do not transfer reagents back into the original container or between containers once dispensed or put into use.

VII. STORAGE

1. Store reagents at 2° to 8°C when not in use. Do not freeze.
2. Do not use beyond the expiration date.

VIII. SPECIMEN COLLECTION AND PREPARATION

1. No special preparation of the donor is required prior to specimen collection. Blood samples must be collected in EDTA anticoagulant in either glass or plastic tubes. Clotted samples should not be used when red blood cell testing is being carried out.
2. Specimens from donors with protein abnormalities may give erroneous results on the PK7200 and/or PK7300. Lipemic, icteric or hemolyzed samples may produce erroneous results in plasma ABO testing (reverse ABO grouping). Anticoagulated samples containing clots may also give erroneous results in ABO cell testing.
3. If testing must be postponed for longer than 24 hours from collection, the specimen should be stored at 2° to 8° C. Samples must be returned to room temperature (15° C - 30° C) prior to analysis. Testing should be carried out within five (5) days of collection (see Warnings and Precautions #17). *For ABO testing, refer to the instructions for use for the specific Reagent Red Blood Cells used in order to determine sample age requirements for the reverse grouping.*
4. Bacterial contamination of the specimen may cause erroneous test results.
5. Proper centrifugation of the samples is necessary to achieve optimum performance of the PK7200 and/or PK7300. False-positive results may be observed in tests involving the plasma from the sample if particulate matter is not removed during centrifugation.

   To prepare samples for analysis:
   - Examine for clots prior to centrifugation by inverting the sample.
   - Thoroughly mix and centrifuge samples within 10 hours of analysis on the PK7200 and/or PK7300
   - Centrifuge samples for a minimum of 10 minutes at 1000 x g.

   Note: *Centrifugation speed and time may need to be varied depending on sample age, time between centrifugation and analysis, and storage temperature. For further details refer to the Operator's Manual for the PK7200 and the User's Guide for the PK7300*

IX. DIRECTIONS FOR USE

MATERIALS PROVIDED

- BECKMAN COULTER PK SYSTEM BLOOD GROUPING REAGENTS; Anti-A, Anti-B, Anti-A,B, Anti-D, Anti-D (PK 1), Anti-D (PK 2)
- BECKMAN COULTER CONTROL
- BECKMAN COULTER PK SYSTEM PHENOTYPING REAGENTS; Anti-C, Anti-E, Anti-c, Anti-e, Anti-K

MATERIALS REQUIRED BUT NOT PROVIDED

- BECKMAN COULTER PK7200 and/or PK7300 Automated Microplate System
- BECKMAN COULTER terraced microplates
- Transfer pipettes or equivalent
- BECKMAN COULTER PK SYSTEM BROMELIN
- Centrifuge
- Control samples (positive and negative)
- 2 % A, and B Reagent Red Blood Cells for reverse grouping
- Mixing Comb (PK7200 only)

The PK7200 and PK7300 are programmable analyzers, the operation of which is controlled by user defined software settings. A list of recommended parameters and threshold settings for ABO/Rh grouping and Rh/K phenotyping on the PK7200 and PK7300 is shown below. Good laboratory practice dictates that each laboratory validates the operating parameters. For further information, please consult Section 8.18 of the PK7200 Operator's Manual and/or Section D of the PK7300 User's Guide.

PK7200 RECOMMENDED PARAMETERS

Parameter	Setting
Sample Volume	20 µL
Diluent Volume	1000 µL *(stroke pln G 1.0)*
Sample/Diluent Ratio	20/1000
Diluted Sample Volume	25 µL
Reagent Volume	25 µL
Channel Name	Variable
Decision Logic	+/-
Temperature Setting	26° C
Incubation Time	60 min
Well	16 µm

Dynamic Range	Setting		Threshold	Setting	
P	Low	45	SPC	Low	14
	High	87		High	14
C	Low	0	P/C	(+) Limit	22
	High	99		(-) Limit	20
LIA	Low	0	LIA	(+) Limit	300
	ABO High	920		(-) Limit	100
	Rh High	980			
			LIA Selection	5	
			BG/C	MIDDLE	

PK7200 OPERATING INSTRUCTIONS:

1. Using the reagent and diluent configuration displayed on the TEST REQUISITION screen, add the antisera in the appropriate channels of the reagent container using a transfer pipette. The BECKMAN COULTER PK SYSTEM BLOOD GROUPING, PHENOTYPING REAGENTS, and BECKMAN COULTER CONTROL are ready for use on the analyzer and should not be altered in any way prior to use.
2. Place the diluent line(s), for ABO/Rh and/or phenotyping, tubing into the diluent container(s) filled with BECKMAN COULTER PK SYSTEM BROMELIN.
3. Place the reagent container and mixing comb (mixing comb required for reagent red blood cells, not antisera) on the analyzer. Press the R MIX switch on the analyzer to start the motion of the mixing comb if there is any delay in initiating processing.
4. Remove the G stroke pins for the diluent lines if a black rack filled with saline tubes is not being processed at the beginning of the run.
5. Push the PREP switch on the analyzer.
6. When the PREP cycle is complete, place the G stroke pins in the locations indicated on the TEST REQUISITION screen being certain to use the G 1.0 stroke pin for the ABO/Rh and/or phenotyping diluent line.
7. Press the DIAG switch on the analyzer control panel to expel bubbles in the reagent, sample and diluted sample probes.
8. Proceed with sample analysis as described in Section 7 of the BECKMAN COULTER PK7200 Operator's Manual.

PK7300 RECOMMENDED PARAMETERS

Parameter	Setting
Sample Volume	20 µL
Sample/Diluent Ratio	1:7 % - 2:8 %
Diluted Sample Volume	25 µL
Reagent Volume	25 µL
Channel Name	Variable
Decision Logic	+/-
Temperature Setting	28° C
Incubation Time	60 min
Well	16 µm

Dynamic Range	Setting		Threshold	Setting	
SPC	Low	8	SPC	Low	14
	High	99		High	14
P	Low	45	P/C	(+) Limit	22
	High	87			
C	Low	0		(-) Limit	20
	High	99			
LIA	Low	0	LIA	(+) Limit	300
	ABO High	920		(-) Limit	100
	Rh High	980			
			LIA Selection	5	
			BG/C	MIDDLE	

PK7300 OPERATING INSTRUCTIONS

1. Using the PANEL configuration screen from the START CONDITION menu, place the reagent containers in the appropriate slots in the reagent tray. *The BECKMAN COULTER PK SYSTEM BLOOD GROUPING, PHENOTYPING REAGENTS, and BECKMAN COULTER CONTROL are packaged in ready to use containers that are placed directly into the reagent tray and should not be altered in any way prior to use.*
2. Place the diluent line for ABO/Rh and/or phenotyping tubing into the diluent container(s) filled with BECKMAN COULTER PK SYSTEM BROMELIN.
   From the SYSTEM STATUS menu, press the PREPARATION key, then check Diluent Priming and press the YES key.
4. After priming is complete, press the REAGENT/DILUENT STATUS key, then press the DILUENT CHECK START which will enable the use of the hand held scanner. Scan each diluent position ID label, then the diluent ID label. Press the DILUENT CHECK END key when scanning is completed.
5. Press the EDIT key and enter the volume for each diluent.
6. Press the REAGENT CHECK START key.
7. If no errors are detected in the diluent or reagent areas, the START key may be pressed to begin analysis.
8. Proceed with sample analysis as outlined in the Operating Procedures found in Section C of the BECKMAN COULTER PK7300 User's Guide.

X. QUALITY CONTROL

A series of quality control samples should be run at the beginning and end of each test run. A "test run" is defined as an uninterrupted analysis of test samples not to exceed 500 samples on a single analyzer. Interruptions in processing could include but are not limited to:

- changes in reagent lot number
- delays caused by electronic or mechanical malfunction
- addition of reagent or diluent

For the results of a sample test run to be considered valid, a positive and negative control at the beginning and end of each run should provide the expected results. Quality control samples should be tested in the same manner as all other samples. The control samples should be selected to verify positive and negative reactions with every reagent. The positive controls should produce (+) reactions and the negative controls should produce negative (-) reactions with the appropriate reagent. If the expected results are not obtained with an individual control sample, the suspect quality control sample should be inspected for both adequate quantity and compliance with the sample requirements. Failure of controls to perform as expected may indicate contamination or deterioration of one or more of the reagents comprising the system. When the expected results with control materials are not obtained repeatedly, contact BECKMAN COULTER Technical Support at 800-447-5852. Please refer to the PK7200 Operator's Manual and the PK7300 User's Guide for additional information concerning the use of control samples.

XI. INTERPRETATION

The PK7200 and the PK7300 will read the settling patterns of the red blood cells in each well based on the threshold settings chosen for each reagent. Refer to Section 12 in the BECKMAN COULTER PK7200 SOP and Section G in the BECKMAN COULTER PK7300 User's Guide for complete details of the manner in which the analyzer interprets reactions. Within 30 minutes after analyzer interpretations on the PK7200, results should be verified by visual review of the reaction patterns in the microplate wells against the analyzer printout. The PK7300 stores an actual image of the microplate and visual review may be performed at the operator's convenience. All plates should be visually reviewed. If any abnormalities are noted on the plate, the corresponding channel results and associated photometric data should be verified on the printout and appropriate notations made. Reactions associated with atypical or aberrant settling patterns and/or photometric data deserve further investigation and possible retesting. Visually, a positive test is a homogeneous layer of cells. Visually a negative test would result in a compact dense button surrounded by a clear zone. Samples identified during plate and printout review with suppressed image analysis measurements and abnormal cell settling patterns in the microplate well may be indicative of a weakly positive sample. Additional testing must be performed on any sample for which visual and analyzer interpretations do not agree unless difficulties with reagent and sample dispensing or sample/plate condition can be confirmed and documented. Refer to Section 11.13 of the BECKMAN COULTER PK7200 SOP and Section C of the BECKMAN COULTER PK7300 User's Guide for information concerning microplate review. The sequence of reactions for ABO/Rh and Rh and Kell are compared to user-defined logic for ABO blood group and Rh and Kell phenotype determination.

XII. INTERPRETATION OF RESULTS

ABO GROUPING

A person's ABO blood group is determined by testing their red blood cells with Anti-A and Anti-B. Agglutination of the test cells indicates the presence of the relevant antigen, while no agglutination indicates its absence. A positive reaction in the test with Anti-A,B indicates the presence of the A and/or B antigens, or may suggest that the blood is of a subgroup (such as Ax). Red blood cells of the Ax, and sometimes the AxB phenotypes may or may not react with Anti-A, depending on the strength to which the antigen is expressed on the particular cells. Most examples of Ax (i.e., all besides those having the weakest expression of the antigen) can be expected to react with Anti-A,B in the PK Systems.

Confirmation of the red blood cell testing results, is provided by testing the serum or plasma of the blood under investigation with group A, and group B red blood cells, and by comparing the resulting reaction patterns with those observed in red blood cell testing. Agglutination of group A, red blood cells indicates the presence in the serum or plasma of anti-A; agglutination of group B red blood cells indicates the presence of anti-B.

The most common reaction combinations are listed in the table below. A sample with test results that do not match any of the reaction combinations below receives a ???, test interpretation and is considered a No Type Determined (NTD). NTD samples require additional testing which can either be performed on the PK7200 PK7300 or by another method.

Blood Group	Forward Group			Reverse Group	
	Anti-A	Anti-B	Anti-A,B	A Cells	B Cells
A	+	-	+	-	+
B	-	+	+	+	-
AB	+	+	+	-	-
O	-	-	-	+	+

Rh GROUPING

The determination of D antigen status is accomplished by testing the donor's red blood cells only. *If it is intended that Rh negative donors be labeled from testing on the PK7200 and/or PK7300 then a combination of two Anti-D reagents must be used, one of which must be Anti-D.* Anti-D (PK 1) and/or Anti-D (PK 2) must be used as the second source of Anti-D reagent. Anti-D is capable of giving a positive reaction with most weak D cells and

partial D Category VI cells. If this combination is not used, then the Rh negative status must be confirmed by testing the donor's red blood cells with a method and Anti-D reagent recommended for the detection of weak D cells and partial D Category VI cells.

A positive test with either Anti-D, Anti-D (PK 1), or Anti-D (PK 2) indicates that the red blood cells being tested are D positive (+).

A negative test with Anti-D (PK 1) and/or Anti-D (PK 2) and a positive test with Anti-D is indicative of a weak D or partial D Category VI sample.

A negative test with Anti-D and Anti-D (PK 1) and/or Anti-D (PK 2) usually indicates that the red blood cells being tested are D negative (-).

However, recognition of all the rare, weak or variant antigen motifs cannot be guaranteed with any of the Anti-D reagents.

The BECKMAN COULTER CONTROL is a negative control for Anti-D, Anti-D (PK 1), Anti-D (PK 2), Anti-E, Anti-C, Anti-e, Anti-c, Anti-K and must be negative. If the BECKMAN COULTER CONTROL is positive on any sample, all Rh typing and Rh and Kell phenotyping results on that sample are considered invalid (see example in table below).

Normal reaction combinations for Rh grouping using Anti-D (PK 1) and/or Anti-D(PK 2), and Anti-D are listed in the table below.

Rh	Anti-D (PK 1)	Anti-D (PK 2)	Anti-D	Beckman Coulter Control
NEG	-	-	-	-
POS	+	+	+	-
POS	+	+	+	-
POS	+	?	+	-
POS	-	+	+	-
POS	-	-	+	-
POS	-	?	+	-
POS	?	+	+	-
POS	?	-	+	-
POS	?	?	+	-
POS	+	+	?	-
POS	+	-	?	-
POS	+	+	?	-
POS	+	?	?	-
POS	?	+	?	-
POS	?	+	-	-
POS	+	+	-	-
POS	+	-	-	-
POS	+	?	-	-
POS	+	+	-	-
???	+	+	+	+

XII. LIMITATIONS OF THE PROCEDURE

1. Depending on the strength of the antigen expression, some examples of the Ax and AxB phenotypes may not react with the Anti-A reagent. Most samples with these phenotypes can be expected to react with the Anti-A,B reagent on the analyzer(s). However, some Ax samples, with extremely weak expression of the A antigen, may not react with the Anti-A,B reagent.
2. Recognition of all of the rare, weak or variant antigen motifs cannot be guaranteed for any of the BECKMAN COULTER PK SYSTEM BLOOD GROUPING REAGENTS or PHENOTYPING REAGENTS.
3. Performance of the PHENOTYPING REAGENTS was evaluated during field trials by testing randomly chosen samples from normal blood donors. Samples were not chosen with regard to weakened or special antigen characteristics. 434 randomly chosen samples were tested on the PK7200, and a separate set of 470 samples on the PK7300.
4. BECKMAN COULTER PK SYSTEM BROMELIN must be used as the diluent for red blood cell testing.
5. BECKMAN COULTER CONTROL must be used as a negative control for Rh, Rh-K typing.
6. Anti-C (clone P3X255136B) is sensitive to the presence of Tween. This may induce false negative reactions.
7. Frozen-thawed red blood cells may not give dependable results.
8. Contamination of blood specimens, reagent and/or supplementary materials may result in erroneous test results. Heavily lipemic, icteric or hemolyzed samples, as well as those containing clots, may yield erroneous results.
9. Agglutination is weaker with older cells than with those from freshly drawn blood and may result in higher NTD rates.

XIV. EXPECTED VALUES

The tables below list the frequencies of the ABO blood groups, D antigen, and the Rh-Kell antigens in the main population groups of the United States.

ABO Blood Group	Frequency %	
	Whites	Blacks
A	40	27
B	11	20
AB	4	4
O	45	49

Rh	Frequency %	
	Whites	Blacks
D +	85	94
D -	15	6

Rh-Kell	Frequency %	
	Whites	Blacks
E+	30	21
E-	70	79
C+	70	33
C -	30	67
e +	98	99
e -	2	1
c +	80	97
c -	20	3
K+	9	2
K-	91	98

XV. SPECIFIC PERFORMANCE CHARACTERISTICS

BECKMAN COULTER PK BLOOD GROUPING REAGENTS Anti-A, Anti-B, Anti-A,B, Anti-D, Anti-D (PK 1), Anti-D (PK 2) and BECKMAN COULTER PHENOTYPING REAGENTS Anti-E, Anti-C, Anti-e, Anti-c, Anti-K meet FDA potency requirements for Blood Grouping Reagents to be used on automated blood grouping equipment. There is no U.S. standard of potency for the BECKMAN COULTER CONTROL, which contains no antibody reactivity specific for a blood group antigen. Every lot of each product is tested on the PK7200 and PK7300 analyzers with a battery of cells positive and negative for the relevant antigen(s) to assure reliable reactivity and specificity in use in accordance with FDA requirements. Details of specificity testing as carried out prior to lot release, or as performed subsequent to release will be furnished on request, by contacting Beckman Coulter Technical Support at 800-447-5852.

For questions or complaints concerning the use of this product(s), please contact Beckman Coulter Technical Support at 800-447-5852.

BIBLIOGRAPHY

1. Standards for Blood Banks and Transfusion Services. 24th ed. 2006; American Association of Blood Banks: 5.8.2; and, 21 CFR 606.121(c)(12).
2. Technical Manual. 15th ed. 2005; American Association of Blood Banks: 322-323.

GLOSSARY OF SYMBOLS

Symbol	Definition	Symbol	Definition
LOT	Batch code		Use by YYYY-MM-DD or YYYY-MM
REF	Catalog number		Upper limit of temperature
	Consult instructions for use	IVD	*In vitro* diagnostic medical device

Manufactured by:
DIAGAST, 251, Av. Avinée, 59120 LOOS - FRANCE

Manufactured for:
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