BLOOD GROUPING REAGENTS

Anti-A	**REF 17301**
Anti-A	**REF 27301**
Anti-B	**REF 17302**
Anti-B	**REF 27302**
Anti-A,B (Murine Monoclonal)	**REF 17303**
Anti-D	**REF 17304**
Anti-D (PK 1)	**REF 17305**
Anti-D (PK 2)	**REF 17306**
Anti-E	**REF 17307**
Anti-C	**REF 17309**
Anti-e	**REF B49558**
Anti-c	**REF 17314**
Anti-K (Human/Murine Monoclonal)	**REF 17315**

DIAGAST

Manufactured by:
DIAGAST
251, Avenue Eugène Avinée
Eurasanté Parc
59120 LOOS – FRANCE

BECKMAN COULTER

Distributed by:
BECKMAN COULTER, INC.
250 S. Kraemer Blvd.
BREA, CA 92821 USA

CONTROL

CONTROL **REF 17317**

Formulated for Use in Automated Systems
Beckman Coulter PK Systems

140EN03: May 2025

- For *in vitro* diagnostic use
- Meets FDA potency requirements
- Discard if turbid
- Preservative: <0.1% (w/v) sodium azide, (0.02%) sodium arsenite

I. INTENDED USE

The *PK SYSTEM BLOOD GROUPING REAGENTS* and *PK SYSTEM CONTROL* are intended for the determination of ABO blood group, Rh and Kell phenotypes in blood donors using the BECKMAN COULTER PK7400 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(D) type. They are used to detect the presence of the Rh(D) 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 Subgroups and 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 *CONTROL* is devoid of antibody activity and should be used in parallel testing with the *PK SYSTEM BLOOD GROUPING REAGENTS* to differentiate between specific and non-specific agglutination.

II. SUMMARY AND EXPLANATION

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 A_1 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 these antibodies.

Table 1 lists the five most common Rh antigens, the Weiner 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: Rh antigens frequency

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

Table 2: Rh Common patterns of reaction and probable genotype

Anti-D	Anti-C	Anti-E	Anti-c	Anti-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 Caucasian 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 *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 PK7400 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 PK7400 please refer to the Instructions for Use.

IV. REAGENTS

Blood Grouping Reagents, Anti-A, Anti-B, Anti-A,B, Anti-D, Anti-D (PK 1), Anti-D (PK 2), 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. The *PK SYSTEM CONTROL* is based on the formulation of the *BLOOD GROUPING REAGENTS*, but devoid of antibodies. The reagents are intended for *in vitro* diagnostic use on the BECKMAN COULTER PK7400 Automated Microplate System only. The ready to use reagents are supplied in 20mL plastic vials.

Cat No.	Designation	Packaging	Clone(s)	Type	Origin
17301	Anti-A	10 x 20 mL	2521B8 + 16243G2	IgM	Murine
27301	Anti-A	10 x 20 mL	9113D10	IgM	Murine
17302	Anti-B	10 x 20 mL	9621A8	IgM	Murine
27302	Anti-B	10 x 20 mL	164B5G10 + 7821D9	IgM	Murine
17303	Anti-A,B	10 x 20 mL	2521B8 + 16243G2 + 16247E10 + 7821D9	IgM	Murine
17304	Anti-D	10 x 20 mL	P3X61 + P3X21223B10 + P3X290 + P3X35	IgM IgG	Human/Murine
17305	Anti-D (PK 1)	10 x 20 mL	P3X61	IgM	Human/Murine
17306	Anti-D (PK 2)	10 x 20 mL	HM10	IgM	Human/Murine
17309	Anti-C	1 x 20 mL	P3X25513G8 + MS24	IgM	Human/Murine
17307	Anti-E	1 x 20 mL	906	IgM	Human/Murine
17314	Anti-c	1 x 20 mL	951	IgM	Human/Murine
B49558	Anti-e	1 x 20 mL	P3GD512 + MS16 +MS21 + MS63	IgM	Human/Murine
17315	Anti-K	1 x 20 mL	MS56	IgM	Human/Murine
17317	CONTROL	10 x 20 mL			

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)	MS16 / MS21 / MS63
Anti-C (RH2)	MS24
Anti-K (KEL1)	MS56

V. WARNINGS AND PRECAUTIONS

1. *CAUTION: THESE BLOOD GROUPING REAGENTS ARE DERIVED FROM MONOCLONAL SOURCE MATERIAL WHICH CANNOT BE TESTED FOR INFECTIOUS AGENTS.* NO KNOWN TEST METHOD CAN OFFER COMPLETE ASSURANCE THAT PRODUCTS DERIVED FROM HUMAN SOURCES WILL NOT TRANSMIT INFECTIOUS AGENTS.
2. These reagents contain material of human or animal origin and may transmit infectious agents and should be handled with extreme caution. The absence of all viruses has not been determined in these reagents.
3. Handle as if capable of transmitting disease. *Do not pipette any reagents by mouth.*
4. Avoid cross-contamination of reagents or specimens.
5. 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 PK7400 Instructions for Use.

6. Visible signs of microbial growth in any reagent may indicate degradation and warrant discontinuance of use.
7. Do not use if contamination or particulate matter is observed in the vial.
8. Sodium azide is present in these reagents as a preservative, at a concentration of less than 0.1%. *Sodium azide may be toxic if ingested and 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. Handle and dispose of reagents as potentially infectious, in accordance with local, state, and national laws.*
9. 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.
10. 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.
11. Carryover between specimens is a potential source of interference.
12. Microbial contamination of the specimen may produce effects that cannot be predicted.
13. Positive and negative control material should be handled in the same manner as donor samples.
14. Incorrect sampling of the specimen, diluent or reagent could result in erroneous test results.
15. Failure to follow directions contained in the instructions for use may result in erroneous results.
16. The use of calibrated or verified equipment is required.
17. Phosphate Buffered Saline should *not* be used in the test system.
18. Effort should be made to prevent contamination and evaporation during use of the product.
19. Do not pool or transfer reagents in or between vials in any manner. Do not transfer reagent from a new vial to an open vial. Do not transfer reagent from an open vial to any other container.
20. Reagents should not be used past the expiration date.
21. Agglutination may be weaker with older specimen samples than with those from freshly drawn blood and may result in a higher no type determined (NTD) rate.
22. 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 to +30°C) before use on the analyzer.
3. The date on which any reagent container is opened should be recorded on the container.
4. Effort should be made to minimize contamination during use of the product.
5. Do not pool reagents in or between vials in any manner. Do not transfer reagent from a new vial to an opened vial. Do not transfer reagent from an open vial to any other container.

VII. STORAGE

1. Do not use reagents beyond the expiration date.
2. Store reagents at +2°C to +8°C when not in use. Do not freeze.
3. Discard reagents left on board on the BECKMAN COULTER PK Systems for 12 continuous hours or more with the exception of anti-e (REF B49558). Anti-e (REF B49558) should be discarded after 12 cumulative hours on board the PK7400 Automated Microplate System.
4. Discard reagents left at room temperature for 12 hours or more.
5. Once opened, the reagents should be used within 30 days or discarded.

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 PK7400. 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°C to +8°C. Samples must be returned to room temperature (+15°C to +30°C) prior to analysis. Testing should be carried out within five (5) days of collection (see Warnings and Precautions #21). *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 PK7400. 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 PK7400
- 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 the Instructions for Use for the PK7400.

IX. MATERIALS

MATERIALS PROVIDED

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

MATERIALS REQUIRED BUT NOT PROVIDED

- BECKMAN COULTER PK7400 Automated Microplate System(s)
- BECKMAN COULTER terraced microplates
- PK SYSTEM BROMELIN
- Centrifuge
- Control samples (positive and negative)
- 2% A_1 and B Reagent Red Blood Cells for reverse grouping

The PK7400 is programmable analyzer, the operation of which is controlled by user defined software settings. A list of recommended parameters and threshold settings for ABO/Rh(D) grouping and Rh Subgroups and Kell phenotyping on the PK7400 is shown below. Good laboratory practice dictates that each laboratory validates the operating parameters. For further information, please consult Chapter 3 of the PK7400 Instructions for Use.

X. DIRECTIONS FOR USE

PK7400 RECOMMENDED PARAMETERS

Parameter	Setting
Sample Volume	15 µL
Sample/Diluent Ratio	1.5%
Diluted Sample Volume	25 µL
Reagent Volume	25 µL
Channel Name	Variable
Decision Logic	+/-
Temperature Setting	30°C
Incubation Time	60 min
Well	16 µm
Dynamic Range SPC	Low 0, High 60
Dynamic Range P	Low 45, High 87
Dynamic Range C	Low 0, High 99
Dynamic Range LIA ABO	Low 0, High 920
Dynamic Range LIA Rh	Low 0, High 980
Threshold SPC	Low 14, High 14
Threshold P/C	(+) Limit 45, (-) Limit 20
Threshold LIA	(+) Limit 450, (-) Limit 100
LIA Selection	5
BG/C	MIDDLE

PK7400 OPERATING INSTRUCTIONS

Proceed with sample analysis as outlined in *Basic Operations,* Chapter 2 of the BECKMAN COULTER PK7400 Instructions for Use.

XI. 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 positive (+) 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 PK7400 Instructions for Use for additional information concerning the use of control samples.

XII. INTERPRETATION

The PK7400 will read the settling patterns of the red blood cells in each well based on the threshold settings chosen for each reagent. Refer to Appendix A of the BECKMAN COULTER PK7400 Instructions for Use for complete details of the manner in which the analyzer interprets reactions. The PK7400 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 Chapter 2 of the BECKMAN COULTER PK7400 Instructions for Use for information concerning microplate review. The sequence of reactions for ABO/Rh(D) and Rh Subgroups and Kell are compared to user-defined logic for ABO blood group and Rh and Kell phenotype determination.

XIII. 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 A_x). Red blood cells of the A_x, and sometimes the A_xB 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 A_x (*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_1 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_1 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 forward and reverse group 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 PK7400 or by another method.

Blood Group	Anti-A	Anti-B	Anti-A,B	A1 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 PK7400 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 *PK SYSTEM 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 *PK SYSTEM 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) or Anti-D (PK 2), *and* Anti-D are listed in the table below.

Rh	Anti-D	Anti-D (PK 1) -or- Anti-D (PK 2)	Control ‡
NEG	-	-	-
POS	+	+	-
POS	+	-	-
POS	+	?	-
POS	?	+	-
POS	-	+	-
???	?	-	-
???	?	?	-
???	-	?	-
???	+	+	+

??? = No Type Determined
Any other results or combination of results give a ??? test interpretation

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

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

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

Rh Subgroups and-Kell	Frequency % in Whites	Frequency % in 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

XIV. LIMITATIONS OF THE PROCEDURE

1. Depending on the strength of the antigen expression, some examples of the A_x and A_xB 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 A_x 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 *PK SYSTEM BLOOD GROUPING REAGENTS*.
3. *PK SYSTEM BROMELIN* must be used as the diluent for red blood cell testing.
4. The *PK SYSTEM CONTROL* must be used as a negative control for Rh, Rh-K typing.
5. Anti-C (clone P3X25513G8) is sensitive to the presence of Tween. This may induce false negative reactions.
6. Frozen-thawed red blood cells may not give dependable results.
7. 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.

8. Agglutination is weaker with older cells than with those from freshly drawn blood and may result in higher NTD rates.

XV. PERFORMANCE CHARACTERISTICS

Specific Performance Characteristics

The *PK SYSTEM BLOOD GROUPING REAGENTS* 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 *PK SYSTEM CONTROL*, which contains no antibody reactivity specific for a blood group antigen.

Every lot of each product is tested on the PK7400 analyzer 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.

Comparison Study

Performance of the *BLOOD GROUPING REAGENTS* was evaluated during multi-site field trials on PK7400 analyzers by testing randomly chosen samples from normal blood donors in a comparison with FDA-licensed reagents. Samples were not chosen with regard to weakened or special antigen characteristics.

- More than 3400 samples were tested with ABO/Rh(D) reagents and 1696 samples were tested with Rh(C,c,E,e) and Kell reagents on the PK7400 analyzers.

  The estimated percent agreements on PK7400 testing and their lower limits of 95% one-sided confidence interval for all sites combined are indicated on the table below.

Overall Statistical Analysis results of the comparison study- PK7400

Reagent	NN	NPA ROA (LCB)	NP	PPA ROA (LCB)
17301 Anti-A	2135	100% (99.86%)	1329	100% (99.77%)
27301 Anti-A	2041	100% (99.85%)	1380	100% (99.78%)
17302 Anti-B	3008	100% (99.90%)	456	100% (99.35%)
27302 Anti-B	2915	100% (99.90%)	506	100% (99.41%)
17303 Anti-A,B	3462	100% (99.91%)	3423	100% (99.91%)
17304 Anti-D	1039	100% (99.71%)	5846	100% (99.95%)
17305 Anti-D (PK 1)	533	100% (99.44%)	2931	100% (99.90%)
17306 Anti-D (PK 2)	506	100% (99.41%)	2915	100% (99.87%)
17309 Anti-C	602	100% (99.50%)	1094	100% (99.73%)
17314 Anti-c	321	100% (99.07%)	1375	100% (99.78%)
17307 Anti-E	1220	100% (99.75%)	476	100% (99.37%)
B49558 Anti-e	51	100% (94.30%) (*)	1645	100% (99.82%)
17315 Anti-K	1561	100% (99.81%)	135	98.52% (95.41%) (**)

NN: Number of Negative Samples
NP: Number of Positive Samples
LCB: Lower 95% Confidence Bound
NPA: Negative Percent Agreement
PPA: Positive Percent Agreement
ROA: Overall Rate Of Agreement

* Anti-e: Lower value for NPA lower confidence bound was obtained due to the low frequency of Rh-e negative samples in the study population.

** Anti-K: Lower value for PPA lower confidence bound was obtained due to a combination two discordant results attributed to false positive with the reference method and the lower than expected frequency of Kell positive samples in the study population. The two discrepant samples tested negative on repeat testing with both the reference and PK7400 methods. Investigation ruled out reagent as a cause of the discrepancy.

Agreement between methods does not indicate which method gave the correct result(s).

Precision Study

Precision studies were performed on the PK7400 using Anti-A, Anti-B, Anti-A,B, Anti-D, Anti-D (PK 1), Anti-D (PK 2) and Anti-e (B49558) reagents and the same red blood cell sample panel, using multiple operators, days and runs to confirm repeatability and reproducibility of test results in the same run, day and with the same operator

and between runs, days and operators. There were no discordant results; all expected positive and all expected negative test outcomes generated unequivocal reactions.

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

XVI. BIBLIOGRAPHY

1. Standards for Blood Banks and Transfusion Services. 34th ed. Bethesda, MD: American Association of Blood Banks, 2024
2. Technical Manual. 21st ed. Bethesda, MD: American Association of Blood Banks, 2013.

XVII. GLOSSARY OF SYMBOLS

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

XVIII. DATE OF ISSUE

May 2025

Manufactured by:
DIAGAST 251, Avenue Eugène Avinée – Eurasanté Parc
59120 LOOS – FRANCE
U.S. License No.:1744

Distributed by:
BECKMAN COULTER, INC.
250 S. Kraemer Blvd., Brea, CA 92821 - USA

Technical Service
Telephone: 800-447-5852
www.beckmancoulter.com/en/support/contact-us