Blood Grouping Reagent
immuClone® Anti-D rapid IgM
immuClone® (1) Anti-C IgM, immuClone® (2) Anti-C IgM
immuClone® (1) Anti-c IgM, immuClone® (2) Anti-c IgM
immuClone® (1) Anti-E IgM, immuClone® (2) Anti-E IgM
immuClone® (1) Anti-e IgM, immuClone® (2) Anti-e IgM
immuClone® (1) Anti-K (Kell) IgM
For Tube, Slide, Microplate and Automated Microplate Tests

- IVD In Vitro Diagnostic Medical Device
- Consult Instructions for Use
- 2 C 8 C Temperature limitation
- Discard if markedly turbid

CAUTIONS: DO NOT PIPETTE BY MOUTH. ALL BLOOD PRODUCTS SHOULD BE TREATED AS POTENTIALLY INFECTIOUS. THIS PRODUCT HAS COMPONENTS (DROPPER BULBS) THAT CONTAIN DRY NATURAL RUBBER.

IMMUCOR Med. Diagnostik GmbH
Robert-Bosch-Strasse 32
63303 Dreieich, GERMANY

557-6

Blood Grouping Reagent	Blood Grouping Reagent
For Tube, Slide, Microplate and Automated Microplate Test	For Tube, Slide, Microplate and Automated Microplate Test
Human Monoclonal	Human Monoclonal
Clone	Clone
(Kell) Human Monoclonal	(Kell) Human Monoclonal

Intended Use:
immuClone® Anti D rapid IgM, immuClone® (1) Anti C IgM, immuClone® (1) Anti-c IgM, immuClone® (1) Anti E IgM, immuClone® (1) Anti-e IgM, immuClone® (2) Anti C IgM, immuClone® (2) Anti-c IgM, immuClone® (2) Anti E IgM, immuClone® (2) Anti-e IgM and immuClone® (1) Anti-K IgM are for typing the C, c, D, E and e and K antigens on human erythrocytes and are for use in slide, tube, and microplate tests.

Summary:
Individuals who lack particular Rh system antigens are easily stimulated by antigen-positive pregnancy or blood transfusion to produce the corresponding antibody. This may cause haemolytic disease of the newborn or severe haemolytic transfusion reactions.

The Rh blood group system contains more than forty antigens or antigen complexes expressed on human erythrocytes. The five basic Rh antigens and their specific antibodies are most important in pre-transfusion testing and prediction of haemolytic disease of the newborn.

The frequencies of Rh antigens vary in different populations. In the general Caucasian population antigen frequencies are approximately:

Antigen	Frequency
D (RH1)	85%
C (RH2)	70%
E (RH3)	30%
c (RH4)	80%
e (RH5)	98%

Weakened Expression of the Rh D antigen
The collective term "D^{u}" is widely used to describe red cells which have a weaker expression of the D antigen than normal. The term "D weak" denotes individuals with a reduced number of entire D antigen sites per red cell. The term "D partial" denotes individuals with missing D epitopes. D category VI is the D partial category which lacks most D epitopes. immuClone® Anti-D rapid will detect most examples of D weak and partial D red cells by direct agglutination, but will not detect D category VI (as recommended by patient testing guidelines). This reagent is recommended as particularly suitable for grouping patients.

Since the discovery of the K antigen (K1 or Kell) by Coombs in 1946 and its antithetical partner, k (K2 or Cellano) by Levine in 1949, the Kell system classification has been expanded to include 22 phenotypes. Anti-K (Anti-K1) and Anti-k (Anti-K2) can cause severe transfusion reactions and haemolytic disease of the newborn.

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Key: Underline = Addition or significant change; ▲ = Deletion of text

BLOOD GROUPING REAGENT
immuClone® Anti-D rapid IgM
immuClone® (1) Anti-C IgM, immuClone® (2) Anti-C IgM
immuClone® (1) Anti-c IgM, immuClone® (2) Anti-c IgM
immuClone® (1) Anti-E IgM, immuClone® (2) Anti-E IgM
immuClone® (1) Anti-e IgM, immuClone® (2) Anti-e IgM
immuClone® (1) Anti-K (Kell) IgM
For Tube, Slide, Microplate and Automated Microplate Tests

IMMUCOR®

The frequencies of the K and k antigens vary in different populations:

	White	Black
K (KEL1)	9.0%	3.5%
k (KEL2)	99.8%	>99.9%

Principle:
Direct agglutination of red cells with a particular reagent indicates the presence of the corresponding antigen. No agglutination generally indicates its absence (see LIMITATIONS). The Rh (C,c,D,E,e) phenotype of a red cell specimen is determined from the pattern of reactivity obtained with the reagents tested.

Reagents:
immuClone® Anti-D rapid is derived from cell line RUM-1
immuClone® (1) Anti-C is derived from the cell line MS-24.
immuClone® (1) Anti-c is derived from the cell line MS-33.
immuClone® (1) Anti-E is derived from the cell lines MS-80 and MS-258.
immuClone® (1) Anti-e is derived from the cell lines MS-16, MS-21 and MS-63.
immuClone® (2) Anti-C is derived from the cell line MS-273.
immuClone® (2) Anti-c is derived from the cell line MS-35.
immuClone® (2) Anti-E is derived from the cell lines MS-12 and MS 260.
immuClone® (2) Anti-e is derived from the cell lines MS-62 and MS-69.
immuClone® (1) Anti-K is derived from the cell line MS-56

Antibodies are diluted in a buffered saline solution containing bovine albumin, ethylenediamine tetraacetate (EDTA), and macromolecular chemical potentiators. The Bovine Albumin Solution is sourced from donor animals of United States origin that have been inspected and certified by US Veterinary Service inspectors to be disease free. This ruminant-based product is deemed to have low-TSE (Transmissible Spongiform Encephalopathy) risk. Sodium azide (< 0.1% final concentration) has been added to each reagent as a preservative. In addition, immuClone® (1) Anti-e contains porcine material.

These reagents are to be used as supplied without further dilution or additions.

Precautions:
For professional in vitro diagnostic use only.

▲Sodium azide (< 0.1%) has been added as a preservative to these reagents. ▲

Sodium azide may react with lead and copper plumbing to form explosive compounds. If discarded into the sink, flush with a large volume of water to prevent azide build-up.

Store at 2-8°C when not in use. Do not freeze or expose to elevated temperatures.

Discard if markedly turbid Discard if markedly turbid

NOTE: immuClone® (1) Anti-e IgM and immuClone® (2) Anti-e IgM show a clear to slightly opaque appearance which is characteristic of the product formulation and not indicative of contamination.

Avoid contaminating this product during use. Contamination will adversely affect a product's performance during its shelf life. Marked turbidity may indicate reagent deterioration or contamination. Do not use if a precipitate, fibrin gel or particles are present. Do not use contaminated reagents. Do not use leaking vials. Do not use unlabeled vials.

Handle and dispose of reagent as if potentially infectious. The human donor or the cell line used to produce these reagents has been tested and found to be negative for Anti-HIV, Anti-HCV, HBsAg, EBV and Mouse Antibody Production (MAP) viruses. No known tests can guarantee that any product derived from human blood is free from infectious agents.

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Do not use beyond the expiry date. The format for the expiry date is CCYY-MM-DD, i.e. the date 28th May, 2008 would be expressed as 2008-05-28.

Specimen Collection:

Draw a blood specimen using an acceptable phlebotomy technique.

In manual tests, sample drawn into tubes containing EDTA, ACD, CPD, CPDA-1, CP2D or tubes without anticoagulant may be used.

Automated or semiautomated methods may require the use of samples drawn into an anticoagulant. For microplate testing with automated instrumentation, refer to instructions provided in the instrument operator manual.

Testing should be performed as soon as possible following collection to minimize the chance that falsely positive or falsely negative reactions will occur due to improper storage or contamination of the specimen. Failure to store the specimens at the correct temperature, for example, storage at higher temperature or repeated freezing and thawing may result in false positive or false negative results.

Samples that cannot be tested within 24 hours should be stored at 2-8° C. Do not use samples drawn into tubes with neutral gel separators. False positive results may occur with such samples. EDTA samples can be tested up to 10 days, clotted samples up to 21 days. Cells drawn into ACD, CPD, CPDA-1 or CP2D may be tested up to the expiration of the anticoagulant.

Procedure:

Materials Provided:

immuClone® Anti D rapid, immuClone®(1) Anti-C, immuClone®(1) Anti-c, immuClone®(1) Anti E, immuClone®(1) Anti-e, immuClone®(2) Anti-C, immuClone®(2) Anti-c, immuClone®(2) Anti-E, immuClone®(2) Anti-e and immuClone® (1) Anti-K antisera in vials ready for use (with dropper for manual use).

Additional Materials Required:

All manual methods:

1. Donor or patient red cells
2. Marking pens
3. Isotonic saline or phosphate-buffered (approximately 15mM) isotonic saline, pH 6.5-7.5

Tube method:

1. Transfer pipettes
2. 10x75mm or 12x75 mm test tubes and a test tube rack
3. Serological centrifuge*
4. Interval timer

Microplate methods (manual):

1. Transfer pipettes or pipetting system* (e.g., ABS Precis, Hamilton Microlab AT, Packard Multiprobe 104/204)
2. Microplates*
3. Centrifuge* (e.g., Sorval T6000, IEC Centra-8, Jouan C422, Hettich 30F, Heraeus Labofuge 400) with rotor and carriers capable of accommodating rigid 96-well plates
4. Mechanical microplate shaker* (e.g., Titramax 3101) (optional)
5. Microplate reader* (e.g., I-STAR) (optional)

Automated Microplate method:

For microplate testing with automated instrumentation, refer to instructions provided in the instrument operator manual.

Slide method:

1. Glass or plastic slides
2. Wax marker (optional)
3. Applicator sticks
4. Stopwatch or timer
5. Transfer pipettes

*It is the user's responsibility to validate an accessory device for its intended use.

Test Methods:

A. TUBE TEST:

1. Label 1 test tube for each blood grouping reagent to be tested.
2. Add 1 drop (approximately 50 µl) of each blood grouping reagent to the appropriately labeled tube.
3. Using a transfer pipette add 1 drop (approximately 50 µl) of a 2-5% suspension of red cells prepared in saline to each tube. (Cells may be washed prior to their resuspension in saline). Mix the contents of each tube thoroughly and centrifuge.*
4. Gently agitate each tube to resuspend the red cells buttons. Examine for agglutination.
5. Record results.

*Suggested centrifugation time: 15-30 seconds at 900-1000 x g or a time, appropriate for the centrifuge used, that produced the strongest reaction of antibody with antigen-positive cells, yet allows easy resuspension of antigen-negative red cells. The centrifugal force applied should be the minimum required to produce a clear supernatant and a clearly delineated red cell button that can be easily resuspended.

No single speed or time can be recommended for all types of available centrifuges or test applications. Centrifuges should be calibrated individually to determine the optimal time and speed required to achieve the desired results.

NOTE: Incubation for 5-60 minutes at 18-30°C may be necessary to enhance the reactivity of the blood grouping reagents with some of the rare phenotypes.

B. MICROPLATE TEST:

1. Label the microplates to be used in testing.
2. Add 1 drop (approximately 50 µl) of each reagent under test to labeled or identified wells.
3. Prepare a 2-4% approximate suspension of red cells in saline. (Cells may be washed prior to their resuspension in saline).
4. Using a transfer pipette add 1 drop (approximately 50 µl) of each red cell suspension to the appropriate wells.
5. Mix the contents of each well thoroughly by tapping the plate manually or by using a mechanical microplate shaker.*
6. Centrifuge the plate at 100-250 x g for 40-60 seconds, or for an appropriate time and speed to produce positive results with antigen-positive red cells and negative results with antigen–negative red cells.**
7. Agitate the plate to resuspend each cell button by manually tapping the plate or placing the plate on a plate agitator. Examine each well for agglutination. If desired, a mirror or reader may be used to examine the reaction in each well.
8. Record results.

NOTE: Incubation for 5-60 minutes at 18-30°C may be necessary to enhance the reactivity of rare phenotypes.

*Suggested times for mechanical shaker: 1) Mixing: 10-30 seconds on a medium agitation setting. 2) Resuspension: 10-30 seconds on a medium setting or a time and speed appropriate for the shaker used, that allows complete resuspension of the entire cell button without destroying positive reactions.

**Suggested centrifugation time: 40-60 seconds at 100-250 x g or a time, appropriate for the centrifuge used, that produces the strongest reaction of antibody with antigen-positive cells, yet allows easy resuspension of antigen-negative red cells. The centrifugal force applied should be the minimum required to produce a clear supernatant and a clearly delineated red cell button that can be easily resuspended.

No single speed or time can be recommended for all types of available centrifuges or test applications. Centrifuges should be calibrated individually to determine the optimal time and speed required to achieve the desired results.

For microplate testing with automated instrumentation, refer to instructions provided in the instrument operator manual.

C. Automated Microplate method:

For microplate testing with automated instrumentation, refer to instructions provided in the instrument operator manual.

D. SLIDE TEST:

1. Label slide to be used in testing
2. Place one drop (approximately 50 µl) of each blood grouping reagent to be tested on separate clean glass or plastic slide. Do not place the slides on a heated illuminated surface.
3. Add one drop (approximately 50 µl) of whole blood (or 35-45% suspension of red cells in saline or group-compatible plasma or serum) from the sample to each reagent on glass or plastic slide using a transfer pipette or applicator stick.
4. Mix the blood and reagent. On glass slides, use a separate clean applicator stick to mix each reagent/cell mixture over and oval area approximately 20 x 40 mm. On plastic slides follow the manufacture's insert.
5. Observe for macroscopic agglutination. On glass slides this is achieved by slow rotation over a period up to a maximum of 2 minutes. On plastic slides follow the manufacture's insert. Do not place slides on a heated illuminated surface.
6. Record results.

Stability of the Reaction:

Following centrifugation, all tube tests should be read immediately and results interpreted without delay. Delays may result in dissociation of antigen-antibody complexes leading to falsely negative or, at most, weakly positive reactions. Slide tests should be completed within the time period specified to avoid the possibility that a negative result may be incorrectly interpreted as positive due to drying of the reagents. Microplate tests should be interpreted immediately following resuspension to avoid erroneous test results due to settling of red cells or dissociation of red cell agglutinates.

Quality Control:

To confirm the correct reactivity of immuClone® Anti-C, Anti-c, Anti-D rapid, Anti-E, Anti-e and Anti-K it is recommended that these reagents be tested each day of use with antigen positive and antigen negative cells, such as Immucor corQC Extend. For QC frequency minimum requirements refer to national guidelines. These reagents can be considered to be satisfactory if the antigen-positive cells are agglutinated and antigen negative cells are not agglutinated.

For microplate testing with automated instrumentation, refer to instructions provided in the instrument operator manual.

Interpretation of Results:

Positive Test (antigen detected): agglutination of red cells.

Negative Test (antigen not detected): no agglutination of red cells.

Limitations:

Falsely positive or falsely negative test results can occur from bacterial or chemical contamination of test materials, inadequate incubation time or temperature, improper centrifugation, improper storage of materials, or omission of test reagents. Many monoclonal human IgM anti-Rh antibodies have been shown to possess anti-I/i cold agglutinin activity, particularly with cord cells or enzyme tested cells. This may become apparent if tests are incubated below the recommended temperature.

Red cells that have a positive direct antiglobulin test (DAT) may produce false positive results. The use of immuClone® Rh-Hr Control reagent is recommended for detection of such potentially false positive results.

With reference to the microplate method, new, unused plastic microplates are capable of passively adsorbing cells and serum proteins to their surfaces. This nonspecific adsorption can lead to erroneous test results[5]. Each batch of microplates should be evaluated in the user's system prior to acceptance for routine use. Where necessary, microplates can be treated prior to use to block nonspecific adsorption. Bovine albumin (1-2%) or 1% gelatin can be used as a blocking agent. Incubate the solution in the wells for 10 minutes at 18-30°C. Plates should then be thoroughly rinsed (approximately 10 times) in distilled or deionized water. Decant the water from the wells as thoroughly as possible following each rinse. Allow plates to dry before their use in testing.

Under-centrifugation or over-centrifugation may result in the occurrence of numerous false-negative or false positives.

Do not use these monoclonal reagents in indirect antiglobulin tests using antihuman globulin reagents.

Autoagglutinins reactive at room temperature are a potential source of error in phenotyping tests. The presence of these antibodies cannot be predicted. They can produce nonspecific agglutination when unwashed, plasma-suspended or serum – suspended cells are used. For this reason, the use of immuClone® Rh-Hr Control reagent is recommended for detection of such false positive results.

immuClone® Anti-D rapid IgM reagent will detect many examples of D weak and partial D red cells by direct agglutination, but will not detect D category VI (as required by guidelines for patient testing). Users wishing to detect D category VI should use immuClone® Anti-D Duo IgM/IgG or Novaclone® Anti D IgM/IgG blood grouping reagent in an antiglobulin test. Do not use immuClone® Anti-D rapid IgM monoclonal reagent in indirect antiglobulin tests using antihuman globulin reagents.

The slide technique is not recommended for the detection of weak D or variant cells.

Variants of the C-, c-, E- or e-antigen exhibiting a weakened antigen expression might not be detected by one of the two corresponding antigen-specific immuClone reagents. It is well recognized by the industry that different monoclonal antibodies may show varied reactivities with cells presenting altered antigen expression.

Samples displaying discrepant results are recommended to be investigated for further clarification, e.g. on molecular biological level.

Rare antigen variants have been discovered such as a mutated allel described as *KEL 2* which can cause a weakened Kell antigen expression. Those rare antigen variants can have variable reactivity with some monoclonal Anti-K reagents. Reactivity with these cells cannot be guaranteed.

Deviation from the Recommended Directions for Use may result in less than optimal product performance. Slide test procedures may not be sufficiently sensitive for reliable detection of weakened antigen expression. User-defined modifications to test procedures may require validation.

Key: Underline = Addition or significant change; ▲ = Deletion of text

Specific Performance Characteristics:

The results obtained show that immuClone® Anti D rapid, immuClone® (1) Anti-C, immuClone® (1) Anti-c, immuClone® (1) Anti E, immuClone® (1) Anti-e, immuClone® (2) Anti-C, immuClone® (2) Anti-c, immuClone® (2) Anti-E, immuClone® (2) Anti-e and immuClone® (1) Anti-K are safe and effective products for the determination of the presence of C, c, D, E, e and K antigens.

Technique	immuClone® Anti D rapid			
	n	Sensitivity	n	Specificity
Tube	968	99.9%	237	100%
Slide	493	99.8%	126	100%
Microplate (manual)	902	99.8%	226	100%
Microplate (automated)*	948	100%	309	100%

Technique	immuClone®(1) Anti-C			
	n	Sensitivity	n	Specificity
Tube	528	100%	343	100%
Slide	73	100%	39	100%
Microplate (manual)	70	100%	42	100%
Microplate (automated)*	108	100%	78	100%

Technique	immuClone®(1) Anti-c			
	n	Sensitivity	n	Specificity
Tube	178	100%	34	100%
Slide	92	100%	20	100%
Microplate (manual)	178	100%	34	100%
Microplate (automated)*	150	100%	36	100%

Technique	immuClone®(1) Anti E			
	n	Sensitivity	n	Specificity
Tube	54	100%	158	100%
Slide	31	100%	81	100%
Microplate (manual)	54	100%	158	100%
Microplate (automated)*	48	100%	138	100%

Technique	immuClone®(1) Anti-e			
	n	Sensitivity	n	Specificity
Tube	227	100%	5	100%
Slide	109	100%	3	100%
Microplate (manual)	227	100%	5	100%
Microplate (automated)*	183	100%	3	100%

Technique	immuClone®(2) Anti-C			
	n	Sensitivity	n	Specificity
Tube	265	100%	175	100%
Slide	419	100%	201	100%
Microplate (manual)	330	100%	169	100%
Microplate (automated)*	108	100%	78	100%

Technique	immuClone®(2) Anti-c			
	n	Sensitivity	n	Specificity
Tube	366	100%	74	100%
Slide	469	100%	151	100%
Microplate (manual)	414	100%	86	100%
Microplate (automated)*	150	100%	36	100%

Technique	immuClone®(2) Anti-E			
	n	Sensitivity	n	Specificity
Tube	182	100%	380	100%
Slide	332	100%	787	100%
Microplate (manual)	132	100%	368	100%
Microplate (automated)*	48	100%	138	100%

Technique	immuClone®(2) Anti-e			
	n	Sensitivity	n	Specificity
Tube	488	100%	8	100%
Slide	1101	100%	18	100%
Microplate (manual)	447	100%	33	100%
Microplate (automated)*	183	100%	3	100%

Technique	immuClone® (1) Anti-K			
	n	Sensitivity	n	Specificity
Tube	9	100%	189	100%
Slide	10	100%	158	100%
Microplate (manual)	6	100%	162	100%
Microplate (automated)*	66	100%	120	100%

Microplate (automated)*: RN-010.09

The reagents were tested in parallel to a state-of-the-art reagent and 100% means 100% correlation to the product of comparison.
Definition from Common Technical Specification (CTS)
Diagnostic Sensitivity: The probability that the device gives a positive result in the presence of the target marker.
Diagnostic Specificity: The probability that the device gives a negative result in the absence of the target marker.

Prior to release, each lot of immuClone® Anti D rapid, immuClone®(1) Anti-C, immuClone®(1) Anti-c, immuClone®(1) Anti E, immuClone®(1) Anti-e, immuClone®(2) Anti-C, immuClone®(2) Anti-c, immuClone®(2) Anti-E, immuClone®(2) Anti-e and immuClone® (1) Anti-K antisera are tested by insert methods against a panel of appropriate antigen-positive and antigen-negative red cells to ensure appropriate reactivity and specificity. The performance of these products is dependent on adhering to the recommended methods found in this insert. Additional information regarding specificity testing performed at the time of the manufacture or as performed subsequent to product release may be furnished upon request by consulting Immucor's Technical Services

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5. Crawford MN, Gottman FE, Gottman CA, Microplate system for routine use in blood bank laboratories. Transfusion 1970;10:258.

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REF	Description
0007117; 0007127	immuClone® Anti-D rapid IgM
0066008; 0066085	immuClone® Anti-D rapid Galileo IgM
0007206; 0007204; 0007216; 0007214	immuClone® (1) Anti-C IgM
0066011	immuClone® (1) Anti-C Galileo IgM
0007306; 0007304; 0007316; 0007314	immuClone® (1) Anti-c IgM
0066013	immuClone® (1) Anti-c Galileo IgM
0007406; 0007404; 0007416; 0007414	immuClone® (1) Anti-E IgM
0066015	immuClone® (1) Anti-E Galileo IgM
0007506; 0007504; 0007516; 0007514	immuClone® (1) Anti-e IgM
0066017	immuClone® (1) Anti-e Galileo IgM
0007207; 0007205; 0007217; 0007215	immuClone® (2) Anti-C IgM
0066012	immuClone® (2) Anti-C Galileo IgM
0007307; 0007305; 0007317; 0007315	immuClone® (2) Anti-c IgM
0066014	immuClone® (2) Anti-c Galileo IgM
0007407; 0007405; 0007417; 0007415	immuClone® (2) Anti-E IgM
0066016	immuClone® (2) Anti-E Galileo IgM
0007507; 0007505; 0007517; 0007515	immuClone® (2) Anti-e IgM
0066018	immuClone® (2) Anti-e Galileo IgM
0008016; 0008026	immuClone® (1) Anti-K (Kell) IgM
0066020	immuClone® (1) Anti-K (Kell) Galileo IgM

CE 0088

Insert code 557-6
Rev. 12/16

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