

# Reagent Red Blood Cells

## IH-Cell A1&B / IH-Cell A2

### 0.6 ±0.1%

English, B186520, Version 06, 2016.07

**For In Vitro Diagnostic Use**  
**Reagent Red Blood Cells for use with the IH-System**  
**No U.S. Standard of Potency**  
**U.S. LICENSE NUMBER: 1845**

Product-Identification:

<b>IH-Cell A1&amp;B</b>	<b>79000</b>
IH-Cell A1	79100
IH-Cell B	79200
IH-Cell A2	79010

IH-Cell A1&B:	<b>VOL</b> 2 x 10 mL vials.....	<b>REF</b> 814 010 100
IH-Cell A2:	<b>VOL</b> 1 x 10 mL vial.....	<b>REF</b> 814 020 100

#### INTENDED USE

IH-Cell A1&B and IH-Cell A2 are intended for the detection of antibodies to ABO blood group antigens on human red blood cells.

#### SUMMARY

Between 1900 and 1902, Landsteiner and associates discovered the ABO system of red blood cell antigens. The importance of this discovery is the recognition that antibodies are present when the corresponding antigens are lacking. The ABO system is the only blood group system in which the reciprocal antibodies are consistently and predictably present in most people. The IH-Cell A1&B and IH-Cell A2 are used to test for the presence or absence of the corresponding antibodies in plasma or serum grouping for the ABO system. Serum grouping should include at least A1 and B red blood cells.

#### PRINCIPLES OF THE TEST

Refer to the instructions for use for the specific IH-Card tested with the Reagent Red Blood Cells.

#### REAGENTS

**IVD**

#### OBSERVABLE INDICATIONS

Do not use if markedly hemolyzed or discolored

NOTE: INSPECT THE CONDITION OF THE REAGENT BEFORE USE (SEE PRECAUTIONS).

Each vial contains a 0.6 ± 0.1% suspension of pooled red cells prepared in a buffered (bovine albumin) preservative solution to retard hemolysis and/or loss of antigenicity during shelf life.

IH-Cell A1&B and IH-Cell A2 have the following antigen combinations:

- IH-Cell A1: A1 Rh negative (ccddee)
- IH-Cell B: B Rh negative (ccddee)
- IH-Cell A2: A2 Rh negative (ccddee)

The IH-Cell A1&B and IH-Cell A2 should be used directly from the vial without further modification. The contents of each vial should be resuspended by gentle mixing.

Preservative: 32 µg/mL Trimethoprim and 160 µg/mL Sulfamethoxazol

#### STORAGE REQUIREMENTS

- Store at 2 to 8 °C.
- Do not use reagents beyond their expiration date which is expressed as YYYY-MM-DD (year-month-day).
- Do not freeze or expose reagents to excessive heat.
- Store in an upright position.
- Do not store near any heat, air conditioning sources or ventilation outlets.

## PRECAUTIONS

- All IH-System reagents and test samples must be brought to room temperature (18 to 25 °C) prior to use.
- Use reagents as furnished.
- Once the IH-Card has been used for testing, it may contain infectious material and should therefore be handled and disposed of as biohazardous waste in accordance with local, state and national regulations.
- As with all Reagent Red Blood Cells, the reactivity of the cells may decrease during the dating period.
- Pooled red blood cells are not recommended for pretransfusion test, done in lieu of a major crossmatch, to detect unexpected antibodies in patient samples.
- Caution: The packaging of this product (dropper bulbs) contains natural rubber latex which may cause allergic reactions.
- Caution: ALL BLOOD PRODUCTS SHOULD BE TREATED AS POTENTIALLY INFECTIOUS. SOURCE MATERIAL FROM WHICH THIS PRODUCT WAS DERIVED WAS FOUND NEGATIVE WHEN TESTED WITH FDA LICENSED EIA/ELISA TESTS. NAT TESTING WAS NOT PERFORMED. NO KNOWN TEST METHOD CAN OFFER ASSURANCE THAT PRODUCTS DERIVED FROM HUMAN BLOOD WILL NOT TRANSMIT INFECTIOUS AGENTS.

## SPECIMEN COLLECTION AND PREPARATION

No special preparation of the patient or donor is required prior to specimen collection. Blood samples should be collected following general blood sampling guidelines. Do not use grossly hemolyzed, lipemic or icteric samples.

Please refer to the instructions for use for the IH-Card used for testing and the **IH-1000 User Manual NA** for card and instrument specific specimen collection and preparation requirements, respectively.

## TEST PROCEDURE FOR AUTOMATED SYSTEMS

### Materials provided

- IH-Cell A1&B
- IH-Cell A2

### Materials recommended but not provided

- IH-Card ABO/Rh(DVI+) + Rev A1, B, or
- IH-Card ABO/Rh(DVI-) + Rev A1, B, or
- IH-Card Neutral (for A2 cells only)

- IH-1000

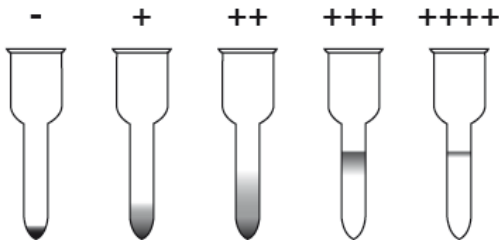
### Method

Please refer to the instructions for use for the specific IH-Card.

## INTERPRETATION OF RESULTS

### For automated systems

Below is a description of the various reaction grades and how the software uses that well reaction to determine the result interpretation.



Well Reaction Grade	Result Interpretation	Reaction Description
-	Negative	A compact, pellet of RBCs* with a smooth surface at the bottom of the well with no visible agglutination.
+/-	Blood Grouping, Antisera, and Phenotyping including Anti-D Blend, = Not interpretable For Reverse (serum) ABO Testing = Positive Direct Antiglobulin Test, Antibody Detection, Autocontrol = Positive Antibody Identification= no overall result interpretation, only well result shown as +/- For Crossmatching = Incompatible	A pellet of RBCs at the bottom of the well with a very few agglutinated RBCs visible above the pellet or an irregular pellet.
1+	For Blood Grouping, Antisera and Phenotyping including Anti-D Blend = Not interpretable For Reverse (serum) ABO Testing =	A pellet of RBCs at the bottom of the well with agglutinated RBCs visible in the lower half of the gel column.

	Positive For Antibody Detection and DAT = Positive For Antibody Identification= no overall result interpretation, only well result shown as positive For Crossmatching = Incompatible	
2+	For Blood Grouping, Antisera and Phenotyping including Anti-D Blend = Positive For Reverse (serum) ABO Testing = Positive For Antibody Detection and DAT = Positive For Antibody Identification= no overall result interpretation, only well result shown as positive For Crossmatching = Incompatible	Agglutinated RBCs distributed throughout the entire length of the gel column, with no line of RBCs on the top of the well.
3+	For Blood Grouping, Antisera and Phenotyping including Anti-D Blend = Positive For Reverse (serum) ABO Testing = Positive For Antibody Detection and DAT = Positive For Antibody Identification= no overall result interpretation, only well result shown as positive For Crossmatching = Incompatible	Most agglutinated RBCs concentrated at the top of the gel or upper half of the gel column.
4+	For Blood Grouping, Antisera and Phenotyping including Anti-D Blend = Positive For Reverse (serum) ABO Testing = Positive For Antibody Detection and DAT = Positive For Antibody Identification= no overall result interpretation, only well result shown as positive For Crossmatching = Incompatible	Agglutinated RBCs concentrated as a line on the top of the gel column with a few agglutinated RBCs just underneath the gel surface.
<b>Mixed Field (DP)</b>	Blood Grouping, Antisera, and Phenotyping including Anti-D Blend, = Not interpretable For Reverse (serum) ABO Testing = Positive Direct Antiglobulin Test, Antibody Detection, Autocontrol = Positive Antibody Identification= no overall result interpretation, only well result shown as DP For Crossmatching = Incompatible	Agglutinated RBCs as a line at the top of the gel or dispersed in upper part of the gel and non-agglutinated RBCs forming a pellet at the bottom of the well. The instrument interpretation software displays "DP" (double population) for a mixed field result.
?	For Blood Grouping including Reverse ABO Testing, Antisera, and Phenotyping including Anti-D Blend, Antibody Detection and Identification, Direct Antiglobulin Testing = Not interpretable For Crossmatching = Incompatible	Ambiguous result.

\* RBCs = Red Blood Cells

## QUALITY CONTROL

On each day of use, the IH-Cells should be tested with antibody positive and negative samples. Each IH-Cell is satisfactory for use if positive and negative samples react as expected.

## LIMITATIONS

Erroneous and abnormal results may be caused by:

- Bacterial or chemical contamination of the serum, plasma, red blood cells or equipment.
- Patient medication or disease yielding a cross-reaction.
- A red blood cell concentration or suspension medium different from that recommended.
- Incomplete resuspension of the red blood cells.
- Sample or Reagent Red Blood Cell hemolysis.
- Contamination between microtubes through pipetting errors.
- Grossly icteric blood samples, blood samples with abnormally high concentrations of protein or blood samples from patients who have received plasma expanders of high molecular weight may give false positive results.
- Fibrin, clots, particulates or other artifacts may cause some red blood cells to be trapped at the top of the gel that may cause an anomalous result.
- Weak reactions may be obtained in ABO serum/plasma blood grouping and is a valid result.
- Decreased ABO antibody reactivity may be seen with low titer isoagglutinin antibodies may be caused by disease states, the elderly or infants resulting in false negative reactions.
- Weak isoagglutinins may not be detectable by IH-Cell A2.
- Testing cord blood samples for ABO antibodies may give incorrect results.
- Pooled cells are not recommended for pretransfusion test, done in lieu of a major crossmatch, to detect unexpected antibodies in patients' samples.

- The reactivity of the product may decrease during the dating period and should not be used after the expiration date. The rate of decrease in reactivity is partially dependent on individual donor characteristics that are neither controlled nor predicted by the manufacturer
- The A2 Reagent Red Blood Cells may not be agglutinated by low-titered anti-A found in the sera of infants and elderly individuals who are group O and group B.

### SPECIFIC PERFORMANCE CHARACTERISTICS

The final release testing is performed according to the product specific Standard Operating Procedures. As part of the lot release process, each lot of Bio-Rad Blood Grouping Reagents is tested against antigen positive and negative samples to ensure suitable reactivity and specificity.

#### Performance characteristics on the IH-1000 Analyzer

Testing to determine the performance characteristics of the Bio-Rad IH-Cell A1&B and IH-Cell A2 was performed at four different US clinical sites and included patient, and donor samples. The positive and negative percent agreements were calculated for the Bio-Rad IH-Reagent Red Blood Cells in comparison to the FDA licensed reference reagents.

Results of the positive percent agreement and negative percent agreement, with the one-sided Exact 95% Lower Confidence Limit (LCL) are listed in the data table below. Note: See the IH-1000 User Manual NA and IH-COM User Manual NA for more information on verification of results.

Test	Results from Clinical Trials			
	Negative Agreement		Positive Agreement	
	N	Point Estimate (one-sided Exact 95% LCL)	N	Point Estimate (one-sided Exact 95% LCL)
A1	2,525	99.80% (99.58%)	3,805	99.89% (99.76%)
B	1,007	99.21% (98.57%)	5,312	99.85% (99.73%)
A2	443	97.52% (95.92%)	607	98.85% (97.84%)










Agreement between the methods does not imply which method obtained the correct result. The above results do not reflect any discrepancy resolution between the methods.

Reproducibility was evaluated at two external sites and one internal site by testing a reproducibility panel according to the following scheme: one lot of reagent x 3 sites x 1 operator x 5 non-consecutive days x 2 runs x 2 replicates over a period of 20 days using the IH-1000 Analyzer. Reproducibility was demonstrated for the IH-Cell A1&B and IH-Cell A2 within runs, between runs and between sites.

A precision study was conducted internally using three reagent lots x 5 non-consecutive days x 2 runs x 2 replicates over a period of 20 days using the IH-1000 Analyzer. Precision was demonstrated with all three lots of IH-Cell A1&B and IH-Cell A2

For technical support or further product information, contact Bio-Rad Laboratories, Inc at 800-224-6723.

### GLOSSARY OF SYMBOLS

Symbol	Definition	Symbol	Definition
	Batch code		<i>In vitro</i> diagnostic medical device
	Caution, consult accompanying documents		Consult instructions for use
	Manufacturer		use by (YYYY-MM-DD)
	Contains sufficient quantity for <n> test.		Catalog number
	Temperature limitation	VOL	Volume

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