

# Reagent Red Blood Cells

## IH-Panel 11 / IH-Panel 11 Papain / IH-Panel Plus 6

### 0.6 ± 0.1%

English, B186525, Version 07, 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-Panel 11 07100</b>		<b>IH-Panel 11 Papain 07300</b>		<b>IH-Panel Plus 6 07500</b>	
IH-Panel 1	07110	IH- Panel 1 P	07310	IH-Panel 13	07510
IH- Panel 2	07120	IH- Panel 2 P	07320	IH-Panel 14	07520
IH- Panel 3	07130	IH-Panel 3 P	07330	IH-Panel 15	07530
IH- Panel 4	07140	IH-Panel 4 P	07340	IH-Panel 16	07540
IH-Panel 5	07150	IH-Panel 5 P	07350	IH-Panel 17	07550
IH-Panel 6	07160	IH-Panel 6 P	07360	IH-Panel 18	07560
IH-Panel 7	07170	IH-Panel 7 P	07370		
IH-Panel 8	07180	IH-Panel 8 P	07380		
IH-Panel 9	07190	IH-Panel 9 P	07390		
IH-Panel 10	07200	IH-Panel 10 P	07400		
IH-Panel 11	07210	IH-Panel 11 P	07410		

IH-Panel 11  
IH-Panel 11 Papain  
IH-Panel Plus 6

**VOL** 11 x 4 mL vials  
**VOL** 11 x 4 mL vials  
**VOL** 6 x 4 mL vials

**REF** 814 070 100  
**REF** 814 080 100  
**REF** 814 090 100

#### INTENDED USE

IH-Panel 11, IH-Panel 11 Papain and IH-Panel Plus 6 are intended for the identification of antibodies to human red blood cell antigens. IH-Panel 11 Papain is intended for use as a supplemental test for complex antibody identification.

#### SUMMARY

Antibody identification is used to determine the specificity of antibodies against red blood cell antigens. These antibodies may have clinical significance as they can cause red blood cell destruction as result of transfusion reactions, hemolytic disease of the fetus and newborn or autoimmune hemolytic anemia.

With samples that contain multiple antibody specificities or exhibit weak reactivity, it may be necessary to use additional test methods to identify the antibody specificity(ies). The use of enzyme-treated red blood cells is one of the primary means by which antibody differentiation and recognition can be accomplished. Identification of antibodies using supplementary IH-Panel 11 Papain should be considered an adjunct test and not be used as the primary test.

Proteolytic enzymes modify red blood cell antigens in ways that enhance the reactivity of some antigen/antibody reactions and destroy or weaken others. The reactions of Rh, Lewis, Kidd and P system blood group antibodies are usually enhanced along with most cold agglutinins. Enzyme treatment destroys or weakens antigens in the MNS and Duffy systems as well as Xg<sup>a</sup>, Pr, Ch<sup>a</sup>, Rg<sup>a</sup> and JMH, thus reducing or eliminating the reactivity of the corresponding antibody.

IH-Panel 11, IH-Panel 11 Papain and IH-Panel Plus 6 are selected red blood cells used to test for the presence or absence of unexpected red blood cell antibodies when mixed with patient or donor sera or plasma under certain test conditions.

#### PRINCIPLES OF THE TEST

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

#### REAGENTS



#### OBSERVABLE INDICATIONS

Do not use if markedly hemolyzed or discolored

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

All Reagent Red Blood Cells are of human origin, suspended in a buffered (bovine albumin) preservative suspension medium at 0.6±0.1%.

IH-Panel 11 are Reagent Red Blood Cells with polyvalent antigens of eleven single blood donors in separate vials for the identification of red blood cell antibodies.

IH-Panel 11 Papain are papain treated Reagent Red Blood Cells with polyvalent antigens of eleven single blood donors, in separate vials for the identification of Reagent Red Blood Cells antibodies.

IH-Panel Plus 6 are Reagent Red Blood Cells with polyvalent antigens of six single blood donors in separate vials for the identification of red blood cell antibodies used in addition to the IH-Panel 11.

IH-Panel 11 contain the following antigens: D, C, E, c, e, K, k, Fy<sup>a</sup>, Fy<sup>b</sup>, Lu<sup>a</sup>, Lu<sup>b</sup>, Jk<sup>a</sup>, Jk<sup>b</sup>, Js<sup>b</sup>, M, N, S, s, Le<sup>a</sup>, Le<sup>b</sup>, P1, Xg<sup>a</sup>, Co<sup>a</sup> and if available: Js<sup>a</sup>, Di<sup>a</sup>, C<sup>w</sup> and Kp<sup>a</sup>.

IH-Panel 11 Papain contains the antigens: D, C, E, c, e, K, k, Lu<sup>a</sup>, Lu<sup>b</sup>, Jk<sup>a</sup>, Jk<sup>b</sup>, Le<sup>a</sup>, Le<sup>b</sup>, P1, Co<sup>a</sup>, and if available: Js<sup>a</sup>, Di<sup>a</sup>, C<sup>w</sup> and Kp<sup>a</sup>.

IH-Panel Plus 6 contains additional cells for complex antibody identifications.

For the exact antigen content of each production lot, please refer to the enclosed antigen profile for the specific lot. The complete antigen profile will vary with each individual lot.

IH-Panel 11, IH-Panel 11 Papain and IH-Panel Plus 6 can 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 reagent beyond the expiry on the label 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-reagent 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.
- 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.
- As with all Reagent Red Blood Cells, the reactivity of the cells may decrease during the dating period.

## 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-Panel 11
- IH-Panel 11 Papain
- IH-Panel Plus 6

### Materials recommended but not provided

- IH-Card AHG Anti-IgG, or
- IH-Card AHG Anti-IgG, -C3d (not for use with IH-Panel 11 Papain)

- IH-1000

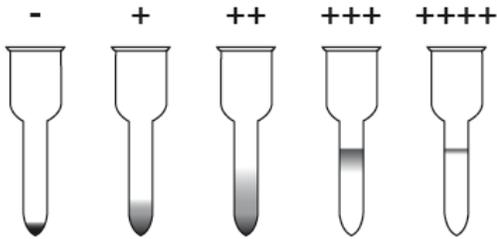
### Method

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 = Positive For Antibody Detection and DAT = Positive For Antibody Identification= no overall result interpretation, only well result shown as positive For Crossmatching = Incompatible	A pellet of RBCs at the bottom of the well with agglutinated RBCs visible in the lower half of the gel column.
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

- Weak reactions can appear and should be considered as positive results.
- For interpretation, please refer to the instructions for use for the appropriate IH-Card.
- When recording the reactions, ensure that the lot number of the Antigen Profile corresponds with the lot number of the Reagent Red Blood Cells used for testing.
- Identification of the antibody present in the serum or plasma may be made by matching the reactions obtained with the Antigen Profile furnished with the reagent. If the antibody specificity is not evident, testing with additional cells may be required.

## QUALITY CONTROL

An autocontrol may be useful in distinguishing autoantibodies. Reagent Red Blood Cells used for antibody identification may be periodically assessed for deterioration using antibodies against antigens known to deteriorate with storage.

## 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.
- Fibrins, 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.
- In very rare cases HLA-antigens within the product may lead to false positive reactions.
- The reactivity of the product may decrease during the dating period and therefore should not be used after expiration date. The rate of decrease in reactivity is partially dependent on individual donor characteristics that are neither controlled nor predicted by the manufacturer.
- Negative reactions will be obtained if the sample contains antibodies present in concentrations too low to be detected by the test method employed.
- No test method is capable of detecting all red blood cell antibodies.
- Papain-treated cells are more prone to lysis than untreated red blood cells when tested against hemolytic antibodies such as anti-Lea, anti-Leb, anti-Jka, anti-Vel and anti-PP1Pk.
- Enzyme treatment destroys or alters antigens in the MNS and Duffy systems as well as Xga, Pr, Cha, Rga and JMH, thus reducing or eliminating the reactivity of the corresponding antibody. Some antibodies may become hemolytic in the presence of enzyme-treated reagent cells and fresh serum.
- Complement-dependent antibodies may not be detected if a plasma specimen is used.
- Low frequency antigens may not always be present on IH-Panels.
- Because some antibodies show a dosage effect, the antigen density on the Reagent Red Blood Cells needs to be considered when evaluating the test results (homozygous or heterozygous hereditary disposition). A heterozygous expression of the antigen may result in non-detection of weak antibodies depending on the used test method.

## 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 Reagent is tested against antigen positive and negative samples to ensure suitable reactivity and specificity.

### Performance characteristics on the IH-1000 Analyzer

A multi-center clinical trial, which included testing at three different US clinical sites and an internal site, was conducted to evaluate the performance of IH-Card AHG Anti-IgG, -C3d, IH-Card AHG Anti-IgG and appropriate Reagent Red Blood Cells for antibody identification. The clinical trial included testing of patient and donor samples. The positive and negative percent agreements were calculated in comparison to the FDA licensed reference reagents. Additional internal studies have been performed with well-characterized and/or contrived samples to evaluate the performance of IH-Card AHG Anti-IgG, -C3d, IH-Card AHG Anti-IgG and appropriate Reagent Red Blood Cells for antibody identification when tested on the IH-1000.

The clinical trial results of positive percent agreement and negative percent agreement, as well as the one-sided Exact 95% Lower Confidence Limit (LCL), are listed in the data table below. Also included are the percent agreements and LCL for the additional testing with well-characterized and/or contrived samples. Note: See the IH-1000 User Manual NA and IH-COM User Manual NA for more information on verification of results.

Test	Tested on	Results from Clinical Trials				Results from In-House Study with well-characterized and/or contrived samples			
		Negative Agreement		Positive Agreement		Negative Agreement		Positive Agreement	
		N	Point Estimate (one-sided Exact 95% LCL)	N	Point Estimate (one-sided Exact 95% LCL)	N	Point Estimate (one-sided Exact 95% LCL)	N	Point Estimate (one-sided Exact 95% LCL)
IH-Panel 11	IH-Card AHG Anti-IgG	150	88.00% (82.73%)	106	98.11% (94.18%)	212	98.11% (95.73%)	64	100% (95.43%)
	IH-Card AHG Anti-IgG, -C3d	167	91.02% (86.51%)	39	100% (92.61%)	212	98.11% (95.73%)	64	100% (95.43%)
IH-Panel 11 Papain	IH-Card AHG Anti-	201	92.54% (88.74%)	154	90.91% (86.15%)	284	96.48% (94.10%)	62	100% (95.28%)

	IgG								
IH-Panel Plus 6	IH-Card AHG Anti-IgG	81	91.36% (84.38%)	61	100% (95.21%)	213	99.06% (97.07%)	Not Tested	NA
	IH-Card AHG Anti-IgG, -C3d	80	92.50% (85.73%)	9	88.89% (57.09%)	213	98.59% (96.40%)	64	100% (95.43%)

NA= not applicable

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-Panels intended for use for antibody identification 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-Panels intended for use for antibody identification.

**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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Bio-Rad Medical Diagnostics GmbH  
Industriestraße 1  
D-63303 Dreieich