Reagent Red Blood Cells
IH-Panel 11 / IH-Panel 11 Papain / IH-Panel Plus 6
0.6 ± 0.1%

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
Rx only

Product-Identification:

IH-Panel 11	07100	IH-Panel 11 Papain	07300	IH-Panel Plus 6	07500
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	[VOL] 11 x 4 mL vials	[REF] 814070100
IH-Panel 11 Papain	[VOL] 11 x 4 mL vials	[REF] 814080100
IH-Panel Plus 6	[VOL] 6 x 4 mL vials	[REF] 814090100

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^a, Pr, Ch^a, Rg^a 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.

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.
Do not use damaged vials.
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 contains the following antigens: D, C, E, c, e, K, k, Fy^a, Fy^b, Lu^a, Lu^b, Jk^a, Jk^b, Js^b, M, N, S, s, Le^a, Le^b, P1, Xg^a, Co^a and if available: Js^a, Di^a, C^w and Kp^a.
IH-Panel 11 Papain contains the antigens: D, C, E, c, e, K, k, Lu^a, Lu^b, Jk^a, Jk^b, Le^a, Le^b, P1, Co^a, and if available: Js^a, Di^a, C^w and Kp^a.

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

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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.
- Consult **downloads.bio-rad.com** to download the valid version of this instruction for use.

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 or IH-500 User Manual U.S. for card and instrument specific specimen collection and preparation requirements, respectively.

TEST PROCEDURE FOR MANUAL AND 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-LISS Rack or IH-LISS Solution
- Dispenser pipette capable of delivering 1 mL
- Pipettes: 10 µL, 25 µL, 50 µL and 1 mL
- Disposable pipette tips
- Glass or plastic test tubes
- IH-Incubator L for manual working
- IH-Centrifuge L or IH-Reader 24 to centrifuge the IH-Cards at 85g with pre-set time for manual working
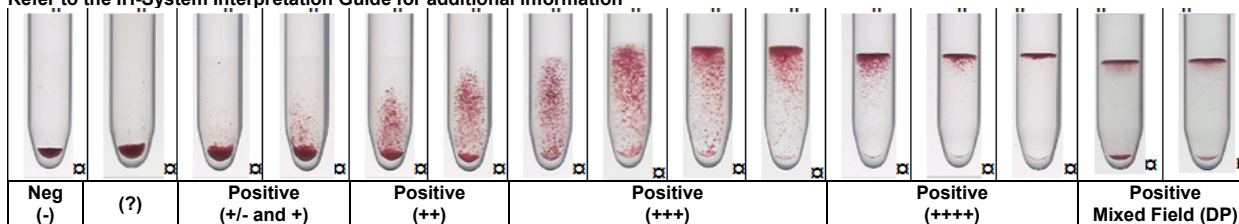- IH-1000 or IH-500 for fully automation

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

INTERPRETATION OF RESULTS
For visual interpretation
- **Positive result** - Agglutinates (on the surface of or dispersed through the gel) or hemolysis (in case of serum test with very few or no red blood cells in the gel column. Report as a positive test result if hemolysis is present in the microtube but not in the sample column. Red blood cells may remain suspended on the top of the gel or are dispersed throughout the gel in varying degrees. A few cells may form a button in the microtube bottom in some positive reactions.
- **Negative result** - A compact button of red blood cells at the microtube bottom is a negative test result.

Refer to the IH-System Interpretation Guide for additional information

| Neg (-) | (?) | Positive (+/- and +) | Positive (++) | Positive (+++) | Positive (++++) | Positive Mixed Field (DP) |

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 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.
+	For Blood Grouping 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.
++	For Blood Grouping 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.
+++	For Blood Grouping 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.
++++	For Blood Grouping 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.
Mixed Field (DP)	Blood Grouping 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 and Phenotyping including Anti-D Blend, Antibody Detection and Identification, Direct Antiglobulin Testing = Not interpretable For Crossmatching = Incompatible	Ambiguous result.

For automated reading
Below is a description of the various reaction grades and how the software uses that well reaction to determine the result interpretation. Please refer to the IH-Reader 24 User Manual or IH-1000, IH-500 and IH-Com User Manual U.S. for further information.

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 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.
+	For Blood Grouping 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.
++	For Blood Grouping 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.
+++	For Blood Grouping 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.
++++	For Blood Grouping 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.
Mixed Field (DP)	Blood Grouping 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 and Phenotyping including Anti-D Blend, Antibody Detection and Identification, Direct Antiglobulin Testing = Not interpretable For Crossmatching = Incompatible	Ambiguous result.

* RBCs = Red Blood Cells

- 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.

STABILITY OF REACTIONS
For visual reading of reactions, best results are obtained within six (6) hours of centrifugation. Interpretation may be affected by drying of the gel, hemolysis of red blood cells and slanting of reaction patterns due to storage in a non-upright position. Processed cards that are stored in the refrigerator (2 to 8 °C) and properly sealed to protect from evaporation may be interpreted for up to one (1) day. Gel cards should not be interpreted after the first sign of drying, or if hemolysis is observed. The age and condition of red blood cells, as well as the temperature at which the card is stored, will affect how long cards can be stored. The presence of sodium azide in the gel may cause the red blood cells to become dark in color over time. This darkening does not interfere with the test result.

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 Cells hemolysis.
    - Contamination between microtubes through pipetting errors.
- False positive reactions might occur due to:
    - Cold antibodies
    - HTLA antibodies
    - Auto antibodies
    - Panagglutinins
    - Patient's medication (e.g. antibiotics, plasma expanders of high molecular weight)
- Grossly icteric blood samples, hemolytic or lipemic 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 or questionable results. Icteric blood samples may cause difficulty in interpretation and test results should be used with caution.
- Fibrin, clots, particulates or other artifacts may cause some red blood cells to be trapped at the top of the gel and may cause an anomalous result. They may appear as a pinkish layer. In a negative reaction the false appearance of a mixed field could lead to misinterpretation.
- If red blood cells (pellet at the bottom of the microtube) are too low in concentration they become difficult to visualize, and, in certain cases, a weak positive reaction can fail to be detected.
- In very rare cases HLA-antigens 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.
- Use of Reagent Red Blood Cells from different lots leads to undetermined results.
- 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 using IH-1000
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 U.S. and IH-Com User Manual U.S. for more information on verification of results.

Results from Clinical Trials

Test	Tested on	Negative Agreement N	Negative Agreement (one-sided Exact 95% LCL)	Positive Agreement N	Positive Agreement (one-sided Exact 95% LCL)
IH-Panel 11	IH-Card AHG Anti-IgG	150	88.00% (82.73%)	106	98.11% (94.18%)
IH-Panel 11	IH-Card AHG Anti-IgG,-C3d	167	90.42% (85.81%)	39	100% (92.61%)
IH-Panel 11 Papain	IH-Card AHG Anti-IgG	201	92.54% (88.74%)	154	90.91% (86.15%)
IH-Panel Plus 6	IH-Card AHG Anti-IgG	81	91.36% (84.38%)	61	100% (95.21%)
IH-Panel Plus 6	IH-Card AHG Anti-IgG,-C3d	80	92.50% (85.73%)	9	88.89% (57.09%)

Results from In-House Study with well-characterized and/or contrived samples

Test	Tested on	Negative Agreement N	Negative Agreement (one-sided Exact 95% LCL)	Positive Agreement N	Positive Agreement (one-sided Exact 95% LCL)
IH-Panel 11	IH-Card AHG Anti-IgG	212 [a]	97.17% (94.49%)	64 [a]	100% (95.43%)
IH-Panel 11	IH-Card AHG Anti-IgG	61 [b]	100% (95.21%)	Not Tested	NA
IH-Panel 11	IH-Card AHG Anti-IgG,-C3d	212 [a]	98.11% (95.73%)	64 [a]	100% (95.43%)
IH-Panel 11 Papain	IH-Card AHG Anti-IgG	284 [a]	96.48% (94.10%)	62 [a]	100% (95.28%)
IH-Panel Plus 6	IH-Card AHG Anti-IgG	213 [a]	99.06% (97.07%)	Not Tested	NA
IH-Panel Plus 6	IH-Card AHG Anti-IgG,-C3d	213 [a]	98.59% (96.40%)	64 [a]	100% (95.43%)

NA= not applicable
[a] In-house Study A
[b] In-house Study B

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 run, 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.

Performance characteristics using IH-500
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 using IH-500 v.2.1.14. 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 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 using the IH-500

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 samples. Note: See the IH-500 User Manual U.S. and IH-COM User Manual U.S. for more information on verification of results.

Results from Clinical Trials with IH-500 v.2.1.14

Test	Tested on	Sample type	Negative Agreement N	Negative Agreement (one-sided Exact 95% LCL)	Positive Agreement N	Positive Agreement (one-sided Exact 95% LCL)
IH-Panel 11	IH-Card AHGAnti-IgG	Known Antibody Positive Samples	NA	NA	153	100% (98.06%)
IH-Panel 11	IH-Card AHGAnti-IgG,C3d	Known Antibody Positive Samples	NA	NA	153	99.35% (96.94%)
IH-Panel 11 Papain	IH-Card AHGAnti-IgG	Known Antibody Positive Samples	NA	NA	148	100% (98.00%)
IH-Panel Plus 6	IH-Card AHGAnti-IgG	Known Antibody Positive Samples	NA	NA	79	100% (96.28%)
IH-Panel Plus 6	IH-Card AHGAnti-IgG,C3d	Known Antibody Positive Samples	NA	NA	80	100% (96.32%)

NA= not applicable

Results from In-House Study with well-characterized samples with IH-500 v.2.1.14

Test	Tested on	Sample type	Negative Agreement N	Negative Agreement (one-sided Exact 95% LCL)	Positive Agreement N	Positive Agreement (one-sided Exact 95% LCL)
IH-Panel 11	IH-Card AHGAnti-IgG	Known Antibody Positive Samples	60	100% (95.13%)	60	100% (95.13%)
IH-Panel 11	IH-Card AHGAnti-IgG,C3d	Known Antibody Positive Samples	Not tested	NA	60	100% (95.13%)
IH-Panel 11 Papain	IH-Card AHGAnti-IgG	Known Antibody Positive Samples	60	91.67% (83.27%)	NT	NT
IH-Panel Plus 6	IH-Card AHGAnti-IgG	Known Antibody Positive Samples	Not tested	NA	Not tested	NA
IH-Panel Plus 6	IH-Card AHGAnti-IgG,C3d	Known Antibody Positive Samples	Not tested	NA	Not tested	NA

NA= not applicable

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 three external sites 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. Reproducibility for the IH-Panels intended for use for antibody identification using the IH-500 was demonstrated within run, between runs and between sites.

Internal comparison studies have been performed with IH-500 v.2.1.14 and IH-500 v.3.0. The study included testing of known samples. The 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.

Results from In-House Study comparing IH-500 v.2.1.14 with IH-500 v.3.0

Test	Tested on	Sample type	Negative Agreement N	Negative Agreement (one-sided Exact 95% LCL)	Positive Agreement N	Positive Agreement (one-sided Exact 95% LCL)
IH-Panel 11	IH-Card AHG Anti-IgG	Known Antibody Positive Samples	NA	NA	95	100% (96.9%)
IH-Panel 11 Papain	IH-Card AHG Anti-IgG	Known Antibody Positive Samples	NA	NA	95	100% (96.9%)

NA = Not Applicable

Performance characteristics for manual testing

A multi-center clinical trial, which included testing at five 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 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 manually using the IH-Centrifuge L and IH-Incubator L.

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 samples.

Results from Clinical Trials

Test	Tested on	Negative Agreement N	Negative Agreement (one-sided Exact 95% LCL)	Positive Agreement N	Positive Agreement (one-sided Exact 95% LCL)
IH-Panel 11	IH-Card AHGAnti-IgG	505	97.62% (96.18%)	173	93.64% (89.69%)
IH-Panel 11	IH-Card AHGAnti-IgG,-C3d	503	98.41% (97.15%)	174	93.10% (89.07%)
IH-Panel 11 Papain	IH-Card AHGAnti-IgG	224	99.11% (97.22%)	99	74.75% (66.55%)
IH-Panel Plus 6	IH-Card AHGAnti-IgG	131	98.47% (95.27%)	86	100% (96.58%)
IH-Panel Plus 6	IH-Card AHGAnti-IgG,-C3d	130	99.23% (96.40%)	84	100% (96.50%)

Results from In-House Study with well-characterized samples

Test	Tested on	Negative Agreement N	Negative Agreement (one-sided Exact 95% LCL)	Positive Agreement N	Positive Agreement (one-sided Exact 95% LCL)
IH-Panel 11	IH-Card AHGAnti-IgG	Not tested	NA	61	100% (95.21%)
IH-Panel 11	IH-Card AHGAnti-IgG,-C3d	Not tested	NA	61	100% (95.21%)
IH-Panel 11 Papain	IH-Card AHGAnti-IgG	Not tested	NA	61	100% (95.21%)
IH-Panel Plus 6	IH-Card AHG Anti-IgG	Not tested	NA	Not tested	NA
IH-Panel Plus 6	IH-Card AHG Anti-IgG,-C3d	Not tested	NA	Not tested	NA

NA= not applicable

Reproducibility was evaluated at three external sites by testing a reproducibility panel according to the following scheme: one lot of reagent x 3 sites x 2 operators x 5 non-consecutive days x 2 runs x 2 replicates over a period of 20 days. Reproducibility for the IH-Panels intended for use for antibody identification using the IH-Centrifuge L and IH-Incubator L was demonstrated within run, between runs and between sites.

Performance characteristics using IH-Reader 24

A multi-center clinical trial, which included testing at five 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 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 manually using the IH-Reader 24.

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 samples. Note: See the IH-Reader 24 User Manual and IH-COM User Manual U.S. for more information on verification of results.

Results from Clinical Trials

Test	Tested on	Negative Agreement N	Negative Agreement (one-sided Exact 95% LCL)	Positive Agreement N	Positive Agreement (one-sided Exact 95% LCL)
IH-Panel 11	IH-Card AHGAnti-IgG	489	96.32% (94.59%)	109	88.07% (81.71%)
IH-Panel 11	IH-Card AHGAnti-IgG,-C3d	395	97.47% (95.74%)	99	91.92% (85.89%)
IH-Panel 11 Papain	IH-Card AHGAnti-IgG	247	95.95% (93.23%)	74	87.84% (79.74%)
IH-Panel Plus 6	IH-Card AHGAnti-IgG	133	97.74% (94.27%)	88	100% (96.65%)
IH-Panel Plus 6	IH-Card AHGAnti-IgG,-C3d	132	98.48% (95.31%)	89	100% (96.69%)

Results from In-House Study with well-characterized samples

Test	Tested on	Negative Agreement N	Negative Agreement (one-sided Exact 95% LCL)	Positive Agreement N	Positive Agreement (one-sided Exact 95% LCL)
IH-Panel 11	IH-Card AHGAnti-IgG	94	98.94% (94.48%)*	60	100% (95.13%)
IH-Panel 11	IH-Card AHGAnti-IgG,-C3d	Not tested	NA	60	100% (95.13%)
IH-Panel 11 Papain	IH-Card AHGAnti-IgG	94	98.94% (94.48%)*	60	100% (95.13%)
IH-Panel Plus 6	IH-Card AHGAnti-IgG	Not tested	NA	Not tested	NA
IH-Panel Plus 6	IH-Card AHGAnti-IgG,-C3d	Not tested	NA	Not tested	NA

NA= not applicable

*Sixty (60) well-characterized samples were tested in an initial stage and 34 samples in a second stage, due to one observed discrepant result in the initial stage.

Reproducibility was evaluated at three external sites by testing a reproducibility panel according to the following scheme: one lot of reagent x 3 sites x 2 operators x 5 non-consecutive days x 2 runs x 2 replicates over a period of 20 days. Reproducibility for the IH-Panels intended for use for antibody identification using the IH-Reader 24 was demonstrated within run, between runs and between sites.

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

GLOSSARY OF SYMBOLS

Symbol	Definition	Symbol	Definition

[LOT]	Batch Code	[IVD]	*In vitro* diagnostic medical device
!	Consult the instructions for use for important cautionary information such as warnings and precautions	I	Consult instructions for use
M	Manufacturer	e	Use by YYYY-MM-DD
s	Contains sufficient quantity for <n> tests	[REF]	Catalog number
t	Temperature limitation	[VOL]	Volume

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Key: **Underline** = Addition of changes ◄ = Deletion of text