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Reagent Red Blood Cells
IH-Cell I-II-III / IH-Cell I-II / IH-Cell Pool
0.6 ±0.1%

English, B186522, Version 10, YYYY.MM

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:

IH-Cell I-II-III	**79020**	**IH-Cell I-II**	**79040**	**IH-Cell Pool**	**79050**
IH-Cell I	79120	IH-Cell I	79140		
IH-Cell II	79220	IH-Cell II	79240		
IH-Cell III	79320				

IH-Cell I-II-III:	VOL 3 x 10 mL vials.....	REF 814 030 100
IH-Cell I-II:	VOL 2 x 10 mL vials.....	REF 814 050 100
IH-Cell Pool:	VOL 1 x 10 mL vials.....	REF 814 060 100

INTENDED USE

IH-Cell I-II and IH-Cell I-II-III are intended for the detection of antibodies to human red blood cell antigens in patients and donors. IH-Cell Pool is intended for the detection of antibodies to human red blood cell antigens in donors.

SUMMARY

Unexpected red blood cell alloantibodies are found in 0.3% to 38% of the population[1], depending on the group studied and the detection method used. These antibodies may have clinical significance as they can cause red blood cell destruction as the result of transfusion reactions, hemolytic disease of the newborn or autoimmune hemolytic anemia. Antibody screening tests are employed to reveal the presence of these antibodies in patient and donor sera.

IH-Cell I-II-III, IH-Cell I-II and IH-Cell Pool are selected red blood cells used to test for the presence or absence of unexpected 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
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-Cell I-II-III and IH-Cell I-II are Reagent Red Blood Cells derived from three or two single group O blood donors, respectively, in separate vials for the detection of red blood cell antibodies.

IH-Cell I-II-III and IH-Cell I-II and IH-Cell Pool contain the following antigens: D, C, E, c, e, K, k, Fy^a, Fy^b, Jk^a, Jk^b, M, N, S, s, Le^a, Le^b, P1, Xg^a. All vials of IH-Cell I-II-III, IH-Cell I-II and IH-Cell Pool contain red blood cells which are negative for the following low-incidence blood antigens: Js^a, Kp^a, Wr^a, Di^a, Vw, V, Lu^a and C^w unless otherwise noted on the accompanying antigen profile.

The specifications for the IH-Cell I-II-III are: vial 1 R_1R_1 or $R_1{}^wR_1$, vial 2 R_2R_2 and vial 3 rr, a double dose expression of the following antigens: M, N, S, s, Fy^a, Fy^b, Le^a, Le^b, Jk^a and Jk^b and expression of Lu^b, Kp^b, Xg^a and Co^a.
The specifications for the IH-Cell I-II are: vial 1 R_1R_1 or $R_1{}^wR_1$ and vial 2 R_2R_2, a double dose expression of at least Jk^a; expression of Lu^b, Kp^b, Xg^a and Co^a antigens and negative for Wr^a.

IH-Cell Pool is a single vial containing Reagent Red Blood Cells derived from two single group O blood donors.

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

IH-Cell I-II-III, IH-Cell I-II and IH-Cell Pool 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.

The bovine albumin used for the production of this reagent is purchased from BSE-free sources.

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.
• Pooled red blood cells are not recommended for pretransfusion test, done in lieu of a major crossmatch, to detect unexpected antibodies in patient samples.

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, **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-Cell I-II-III
• IH-Cell I-II
• IH-Cell Pool

Materials recommended but not provided
• IH-Card AHG Anti-IgG, or
• IH-Card AHG Anti-IgG,-C3d
• IH-LISS Rack and 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 full automation

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

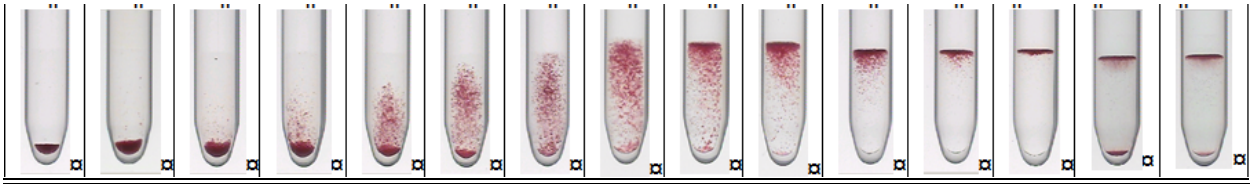
INTERPRETATION OF RESULTS

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)

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, 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.

Mixed Field (DP)	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

• 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.

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

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 re-suspension of the red blood cells.
- Sample or Reagent Red Blood Cells hemolysis.
- Contamination between microtubes through pipetting errors.

• Grossly icteric, hemolytic or lipemic 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 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 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.
• Use of the IH-Cell Pool should be limited to donor blood testing or processing.
• Complement-dependent antibodies may not be detected if a plasma specimen is used.
• Low frequency antigens may not always be present on IH-Cell I-II-III, IH-Cell I-II, and IH-Cell Pool. Therefore, negative reactions with the screening Reagent Red Blood Cells do not always indicate the absence of unexpected antibodies.
• 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 the IH-1000 ◄

A multi-center clinical trial, which included testing at four 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 detection. 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 detection 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.

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-Cell Pool	IH-Card AHG Anti-IgG	2,942	99.12% (98.78%)	86	89.53% (82.45%)	Not Tested	NA	64	100% (95.43%)
	IH-Card AHG Anti-IgG,-C3d	563	98.76% (97.68%)	72	93.06% (85.95%)	Not Tested	NA	64	100% (95.43%)
IH-Cell I-II	IH-Card AHG Anti-IgG	1,188	97.05% (96.11%)	12	100% (77.91%)	Not Tested	NA	64	100% (95.43%)
	IH-Card AHG Anti-IgG,-C3d	1,996	99.05% (98.61%)	6	100% (60.70%)	Not Tested	NA	64	100% (95.43%)
IH-Cell I-II-III	IH-Card AHG Anti-IgG	469	97.23% (95.63%)	68	98.53% (93.21%)	Not Tested	NA	64	100% (95.43%)
	IH-Card AHG Anti-IgG,-C3d	1,262	97.39% (96.52%)	75	97.33% (91.84%)	Not Tested	NA	63	100% (95.36%)

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-Cells intended for use for antibody detection 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-Cells intended for use for antibody detection.

Performance characteristics using the 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 detection when tested using **IH**-500. 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.

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

Test	Tested on	Sample type	Results from Clinical Trials			
			Negative Agreement		Positive Agreement	
			N	Point Estimate (one-sided Exact 95% LCL)	N	Point Estimate (one-sided Exact 95% LCL)
IH-Cell Pool	IH-Card AHG Anti-IgG	Random samples	248	100% (98.80%)	2	50% (2.53%)
		Known Ab pos	4[1]	75.00% (24.86%)	66	100% (95.56%)
		All samples	252	99.60% (98.13%)	68	98.53% (93.21%)
	IH-Card AHG Anti-IgG,C3d	Random samples	250	99.60% (98.12%)	NA	NA
		Known Ab pos	4[2]	100% (47.29%)	66	100% (95.56%)
		All samples	254	99.61% (98.15%)	66	100% (95.56%)
IH-Cell I-II	IH-Card AHG Anti-IgG	Random samples	335	99.10% (97.70%)	15	53.33% (30.00%)
		Known Ab pos	NA	NA	100	100% (97.05%)
		All samples	335	99.10% (97.70%)	115	93.91% (88.87%)

Test	Tested on	Sample type	Results from Clinical Trials			
			Negative Agreement		Positive Agreement	
			N	Point Estimate (one-sided Exact 95% LCL)	N	Point Estimate (one-sided Exact 95% LCL)
	IH-Card AHG Anti-IgG,C3d	Random samples	340	99.41% (98.16%)	10	80.00% (49.31%)
		Known Ab pos	NA	NA	100	99.00% (95.34%)
		All samples	340	99.41% (98.16%)	110	97.27% (93.10%)
IH-Cell I-II-III	IH-Card AHG Anti-IgG	Random samples	263	97.34% (95.06%)	87	91.95% (85.42%)
		Known Ab pos	NA	NA	100	100% (97.05%)
		All samples	263	97.34% (95.06%)	187	96.26% (93.08%)
	IH-Card AHG Anti-IgG,C3d	Random samples	273	98.90% (97.18%)	77	96.10% (90.24%)
		Known Ab pos	1	0% (NA)	99	98.99% (95.30%)
		All samples	274	98.54% (96.69%)	176	97.73% (94.87%)

1) Three (3) samples enrolled in the study as known antibody positive were negative by both the investigational and reference method during study testing. Historical results were used to determine the antibody status in the inventory samples and were not repeated prior to enrollment in the study. It was unknown if the titer of the antibody had dropped and if the antibody was still detectable after thawing and enrollment in this study.
2) Four (4) samples enrolled in the study as known antibody positive were negative by both the investigational and reference method during study testing. Historical results were used to determine the antibody status in the inventory samples and were not repeated prior to enrollment in the study.
It was unknown if the titer of the antibody had dropped and if the antibody was still detectable after thawing and enrollment in this study.

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-Cells intended for use for antibody detection was demonstrated using the **IH**-500 within run, between runs and between sites.

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 detection when tested manually using **IH**-Centrifuge L and **IH**-Incubator L. 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.

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.

Test	Tested on	Results from Clinical Trials			
		Negative Agreement		Positive Agreement	
		N	Point Estimate (one-sided Exact 95% LCL)	N	Point Estimate (one-sided Exact 95% LCL)
IH-Cell Pool	IH-Card AHG Anti-IgG	516	96.71% (95.10%)	124	99.19% (96.23%)
	IH-Card AHG Anti-IgG,-C3d	512	96.68% (95.06%)	128	100% (97.69%)
IH-Cell I-II	IH-Card AHG Anti-IgG	306	98.04% (96.17%)	110	98.18% (94.39%)
	IH-Card AHG Anti-IgG,-C3d	306	98.37% (96.60%)	110	98.18% (94.39%)
IH-Cell I-II-III	IH-Card AHG Anti-IgG	473	99.15% (98.08%)	139	99.28% (96.63%)
	IH-Card AHG Anti-IgG,-C3d	472	99.58% (98.67%)	140	100% (97.88%)

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-Cells intended for use for antibody detection was demonstrated using the **IH**-Centrifuge L and **IH**-Incubator L within run, between runs and between sites.

Performance characteristics using the 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 detection when tested manually using **IH**-Reader 24. 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.

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 and IH-Cell Pool for antibody detection when tested on 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.

Test	Tested on	Results from Clinical Trials				Results from In-House Study with well-characterized 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-Cell Pool	IH-Card AHG Anti-IgG	516	96.51% (94.87%)	124	98.39% (95.01%)	Not Tested	NA	Not Tested	NA
	IH-Card AHG Anti-IgG,-C3d	512	94.34% (92.36%)	128	96.88% (92.99%)	60	100% (95.13%)	60	100% (95.13%)
IH-Cell I-II	IH-Card AHG Anti-IgG	299	97.99% (96.08%)	59	100% (95.05%)	Not Tested	NA	Not Tested	NA
	IH-Card AHG Anti-IgG,-C3d	199	97.99% (95.46%)	70	100% (95.81%)	Not Tested	NA	Not Tested	NA
IH-Cell I-II-III	IH-Card AHG Anti-IgG	473	97.89% (96.44%)	139	100% (97.87%)	Not Tested	NA	Not Tested	NA
	IH-Card AHG Anti-IgG,-C3d	472	98.94% (97.79%)	140	100% (97.88%)	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-Cells intended for use for antibody detection was demonstrated using the **IH**-Reader 24 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
!	Caution, consult accompanying documents	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

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