

### **510(k) Summary**

This summary of 510(k) safety and effectiveness information is being submitted in accordance to requirements of SMDA 1990 and 21 CFR §807.92.

### **Submitter's Details**

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### **Device Information**

Device Name:	IH-Card Neutral
Common Name:	IH-Card Neutral
Classification Name:	Automated Blood Grouping and Antibody Test System
510(k) number:	BK140138
Device Class:	II
Product Code:	OQX
Regulation number:	21 CFR 864.9175

### **Identification of the Legally Marketed Device (Predicated Device)**

Trade Name:	ORTHO ProVue® Analyzer
Classification Name:	Automated Blood Grouping and Antibody Test System
510(k) number:	BK110029
Device Class:	II
Product Code:	KSZ
Regulation number:	21 CFR 864.9175
Clearance Letter:	July 14, 2011

### **Device Description**

The IH-Card Neutral is a plastic card with six microtubes containing gel in a buffered medium without antibodies.

### Intended use

The IH-Card Neutral is intended for the detection of antibodies to human red blood cell antigens in an automated test system using IH-1000.

### Comparison to Predicate Device

The following table identifies the predicate device that was used to show equivalence of the IH-Card Neutral with the already FDA approved MTS™ Buffered Gel Card.

<b>Parameter</b>	<b>Predicate Device Micro Typing Systems Inc. MTS™ Buffered Gel Card</b>	<b>Subject Device Bio-Rad IH-Card Neutral</b>
Indications for Use Statement	For the detection of antibodies to red blood cells.	For serum grouping to be used with IH-Cell A2 on the IH-1000 Analyzer.
Composition	MTS™ Buffered Gel Card consists of six microtubes with buffered gel suspension and preservative.	IH-Card Neutral consists of six microtubes with with buffered gel suspension and preservative.
Storage Conditions	2 to 25 °C	18 to 25 °C
Reagent Preparation	Ready to use	Ready to use
Preservative	0.1 % Sodium Azide	0.1 % Sodium Azide

### Non-clinical and clinical performance characteristics

Bio-Rad conducted internal performance tests and a clinical study at four US sites. The samples tested in the four clinical sites included more than 1,000 donor and patient samples from a diverse population covering broad geographical areas. All these tests have been compared with licensed reference A2 Reagent Red Blood Cells in the tube method. All tests have been conducted with acceptable results.

### Conclusion

Bio-Rad concludes, based on all information submitted and discussed in this submission and in this summary that IH-Card Neutral is safe, effective and substantially equivalent to the predicate device and has been demonstrated to meet all requirements for a product to be marketed in the U.S.A.