

# HEMOCOMPATIBILITY DETERMINATION STUDY

for the InVision-Plus® Neutral Advantage Technology

**Table 1: Hemolytic Parameters**

| Hemolytic Index                             | Results              |
|---|----------------------|
| InVision-Plus® Neutral Advantage Technology | 0.00 % Non-Hemolytic |
| Negative Control                            | 0.40 %               |

| Hemolytic Index above the Negative Control | Hemolytic Grade    |
|--|--------------------|
| 0.0% - 2.0%                                | Non-Hemolytic      |
| 2.0% - 5.0%                                | Slightly Hemolytic |
| Above 5.0%                                 | Hemolytic          |

**Table 2: Hematological Parameters**

| Mean | InVision-Plus® Neutral Advantage Technology | Unexposed Negative Control | P-Value* |
|------|---|----------------------------|----------|
| WBC  | 4.20 K/microliter                           | 4.15 K/microliter          | 0.656    |
| RBC  | 4.20 M/microliter                           | 4.22 M/microliter          | 0.829    |
| HgB  | 12.60 g/dL                                  | 12.80 g/dL                 | 0.573    |
| Hct  | 36.40 %                                     | 36.50 %                    | 0.944    |
| MCV  | 86.80 fL                                    | 86.50 fL                   | 0.072    |
| MCH  | 30.10 pg                                    | 30.30 pg                   | 0.253    |
| MCHC | 34.70 g/dL                                  | 35.10 g/dL                 | 0.129    |
| RDW  | 13.70 %                                     | 13.70 %                    | 0.731    |
| PLT  | 45.00 K/microliter                          | 44.00 K/microliter         | 0.799    |
| MPV  | 9.97 fL                                     | 9.60 fL                    | 0.290    |

\* The ANOVA analysis was performed by comparing all three device replicates with all the unexposed negative control replicates. A p-value > 0.05 indicates similarity and a p-value <0.05 indicates a difference.

WBC (White Blood Cell Count)  
RBC (Red Blood Cell Count)  
HgB (Hemoglobin)  
Hct (Hematocrit)  
MCV (Mean Corpuscular Volume)

MCH (Mean Corpuscular Hemoglobin)  
MCHC (Mean Corpuscular Hemoglobin Concentration)  
RDW (Red Cell Distribution Width)  
PLT (Platelet Count)  
MPV (Mean Platelet Volume)



InVision-Plus® is a registered trademark of RyMed Technologies, LLC  
U.S. Patent Numbers: 6,113,068; 6,299,131; 6,994,315; 7,530,546 B2; 8,096,525 B2,  
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