



**FIELD TRIAL CARRIED OUT AT  
DUKE UNIVERSITY MEDICAL CENTRE**

**MONOCLONAL BLOOD GROUPING ANTI-D REAGENTS**

**ANTI-D Alpha (LDM1) Product code Z031**

**ANTI-D Beta (LDM3) Product code Z036**

**ANTI-D Optimum (LDM1/ESD1M) Product code Z039**

**ANTI-D Blend (LDM3/ESD1) Product code Z041**

**Field Trial Summary Report**

**2.1 General**

The field trial was performed according to the plan, with no deviations reported.

**2.2 Test Methods**

The test methods that were used throughout were as detailed the product instructions for use.

**2.3 Test Samples**

The number samples tested was as detailed in the field trial guidelines agreed between Diagnostics Scotland and DUMC. A total of 405 samples were tested. Test samples used in the evaluation included Clinical and Neonatal samples, which had been collected for the purpose of routine blood grouping. No samples were collected specifically for the performance evaluation.

**2.4 Results**

When the test results were compared with the performance of the comparator reagent, Ortho/MTS Anti-D (403715), which was tested in parallel, only one typing discrepancy was identified. Sample 417 was taken from a patient with Hunters Syndrome who had received a bone marrow transplant and had been transfused with both RhD positive and RhD negative blood. Test results were negative on slides with the reference being weakly reactive and negative/weakly reactive in tube tests. Repeat testing was carried out in tubes by both immediate spin and 37°C incubation and mixed field reactions were observed with test and reference.

The reagents performed as specified in slide and tube tests (including IAT tests for negative results with the D Blend reagent) and no other unexpected reactions were observed.

**2.5 Conclusion**

It can be concluded from the results of the field trial that the Anti-D reagents, Product Code Z031, Z036, Z039 and Z041 performed as specified and are suitable for use as routine blood typing reagents when used according to the slide and tube methods detailed in the instructions for use.

## SUMMARY OF RESULTS

### MONOCLONAL BLOOD GROUPING ANTI-D REAGENTS

**ANTI-D Alpha (LDM1) Product code Z031**

**ANTI-D Beta (LDM3) Product code Z036**

**ANTI-D Optimum (LDM1/ESD1M) Product code Z039**

**ANTI-D Blend (LDM3/ESD1) Product code Z041**

Test Reagent Anti-D Alpha Lot No. Z0310630 Exp Date: 2006 APR 16

Test Reagent Anti-D Beta Lot No. Z036 Exp Date: 2005 AUG 03

Test Reagent Anti-D Optimum Lot No. Z0390090 Exp Date: 2005 NOV 24

Test Reagent Anti-D Blend Lot No. Z0410600 Exp Date: 2005 DEC 11

Reference Anti-D Lot No. 403715 Expiry Date: 2005 APR 26 (OCD/MTS)

A total of 405 samples were tested by slide and tube:

Reagent	Positive results		Negative results		Total
	Test	Ref	Test	Ref	
Slide Test	349	349	56	56*	405
Immediate spin Tube Test	206	206	36	36*	405
15' incubation 37°C Tube	143	143	20	20	
Indirect Antiglobulin Test			20	20	

\* sample 417 gave equivocal reactions.

Types of sample tested:

Sample Type	Number tested
EDTA	405
Clotted	0
CPD	0
Frozen	0
Panel cell	0

Disease State or variant	Number tested
Sickle cell	6
Pregnancy	41
Cord sample	9
Neonate	6
Geriatric >80 years	23
Weak or partial D	0
Disproteinaemia	0
Cold or warm auto agglutinin	2
Other	5 Lymphoma, 12 Leukaemia, 16 BMT, 7 Transfused, 1 Multiple Myeloma, 1 Macroglobulinaemia, 1 Hunters Syndrome

*Susan Galloway*

Susan Galloway CSci FIBMS

Quality Control Manager

Diagnostics Scotland

26<sup>th</sup> January 2005.