



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

**MONOCLONAL BLOOD GROUPING REAGENT
ANTI-A,B (LA2, LB3, ES15) PRODUCT CODE Z023
LOT No. Z0230010 EXPIRY DATE: 2006 JAN 05**

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 500 samples required testing. 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 reagents, Ortho/MTS Anti-A (403715) and Anti-B (403715), which were tested in parallel, No typing discrepancies were identified. Sample 541 was recorded of having a positive reaction with test Anti-A,B this was negative on repeat testing by tube and slide. The reagent performed as specified in slide and tube tests and no unexpected reactions were observed.

2.5 Conclusion

It can be concluded from the results of the field trial that the Anti-A,B reagent, Product Code Z023, performs as specified and is suitable for use as a routine blood typing reagent when used according to the slide and tube methods detailed in the instructions for use.

SUMMARY OF RESULTS

MONOCLONAL BLOOD GROUPING REAGENT ANTI-A,B (LA2,LB3,ES15) PRODUCT CODE

Test Reagent Anti-A,B Lot No. Z0230010 Exp Date: 2006 JAN 05

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

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

Reference Anti-AB Lot No. 080703804 Expiry Date: 2005 MAY 12 (OCD/MTS)

A total of 505 samples were tested by slide and tube:

Reagent	Positive results	Negative results
Test Z0230010	285	219
Reference Anti-A 403715	189	216
Reference Anti-AB 080703804	50	50
Reference Anti-B 403715	346	59
Total 505		

Types of sample tested:

Sample Type	Number tested
EDTA	505
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

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