



FIELD TRIAL OF DIAGNOSTICS SCOTLAND MONOCLONAL BLOOD GROUPING REAGENTS

TESTING OF DISEASE STATE SAMPLES, INTERFERING SUBSTANCES AND WEAKENED ANTIGEN EXPRESSION

MONOCLONAL BLOOD GROUPING REAGENT
ANTI-Le^b(LEB2) PRODUCT CODE Z217

Field Trial Summary Report

1.1 General

The field trial was performed according to plan and no deviations were reported. Where possible ten samples were tested in each category although this was not possible to achieve for all due to lack of patients with the respective conditions.

1.2 Test Methods

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

1.3 Test Samples

Test samples used in the evaluation included clinical samples which had been collected for the purpose of routine blood typing. Due to the rarity of some of the specified conditions some frozen red cells were included from patients historically documented as conforming to the disease/interfering substance category.

1.4 Results

When the test results were compared with the comparator reagent, which was tested in parallel, no typing discrepancies were identified. The reagent performed as specified and no unexpected reactions were obtained.

1.5 Conclusion

Results from the field trial demonstrate that Monoclonal Anti-Le^b blood typing reagent, product code Z217, performs as specified and is suitable as a routine blood typing reagent when used according to the methods detailed in the instructions for use.

SUMMARY OF RESULTS

MONOCLONAL BLOOD GROUPING REAGENT
ANTI-Le^b (LEB2) PRODUCT CODE Z212
Test Reagent Anti-Le^b Lot No. Z2170210 (DS)
Reference Anti-Le^b Lot No. LBB223AX (OCD)

The following samples were tested against both lots of test reagent and the reference reagent:

Condition	Total samples	Positive	Negative
Multiple Myeloma	10	7	3
Macroglobulinaemia	10	4	6
Pregnancy	10	4	6
AIHA	4	1	3
Lymphoma	10	6	4
Leukaemia	10	9	0
Polyagglutinable red cells	4	2	2
DAT Positive	7	5	2
Lipaemic	10	8	2
Haemolysed	10	6	4

100% correlation was confirmed between Anti-Le^b Z2170210 and the reference Anti-Lea LBB223AX.

Further disease state and interfering substances are included in the samples tested at Duke Medical Centre, USA no discrepancies were noted.



Susan Galloway CSci FIBMS
Quality Control Manager
Diagnostics Scotland



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

**MONOCLONAL BLOOD GROUPING REAGENT
ANTI-Le^b (LEb2) PRODUCT CODE Z217
LOT No. Z2170210 EXPIRY DATE: 2006 AUG 20**

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. For Anti-Le^b 100 samples require to be 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 Clinical Diagnostics Anti-Le^b (LBB224A), which was tested in parallel, One test (961) was repeated as the test failed to react originally the results were comparable on repeat. One sample (942) gave a discrepant result although the result obtained with the Diagnostic Scotland antisera was confirmed with Immucor Anti-Le^b lot No 3K6776. See Quality Control Review attached.

The reagent performed as specified and no unexpected reactions were observed.

2.5 Conclusion

It can be concluded from the results of the field trial that the Anti-Le^b reagent, Product Code Z217, performs as specified and is suitable for use as a routine blood typing reagent when used according to the methods detailed in the instructions for use.

SUMMARY OF RESULTS

MONOCLONAL BLOOD GROUPING REAGENT ANTI-Le^b (LEB2) PRODUCT CODE Z217

Test Reagent Anti-Le^b Lot No. Z2170210 Expiry Date: 2006 FEB 01 (DS).
Reference Anti-Le^b Lot No. LBB224A Expiry Date: 2006 AUG 20 (OCD).

A total of 100 samples were tested:

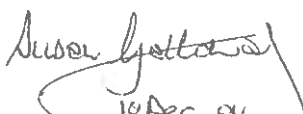
Reagent	Positive results	Negative results
Test Z2170210	68	32
Reference LBB224A	67*	33

Types of sample tested:

Sample Type	Number tested
EDTA	100
Clotted	0
CPD	0
Frozen	0
Panel cell	0

Disease State or variant	Number tested
Sickle cell	2
Pregnancy	5
Cord sample	0
Neonate	2
Geriatric >80 years	5
Weak or partial D	0
Disproteinaemia	1
Cold or warm auto agglutinin	0
Other	0

*99% correlation was confirmed between Anti-Le^b Lot No. Z2170210 and comparator reagent, Anti-Le^b Lot No. LBB224A. One sample (942) gave a discrepant result although the result obtained with the Diagnostic Scotland antisera was confirmed with Immucor Anti-Le^b lot No 3K6776. See Quality Control Review attached.


10 Dec 04
Susan Galloway CSci FIBMS
Quality Control Manager
Diagnostics Scotland
10th December 2004.