



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

**MONOCLONAL BLOOD GROUPING REAGENT
ANTI-Le^a (LEA2) PRODUCT CODE Z212
LOT No. V038613 EXPIRY DATE: 2006 SEP 10**

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^a 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^a (LAB123A), which was tested in parallel, One test (957) was repeated as the reference failed to react originally the results were comparable on repeat.

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^a reagent, Product Code Z212, 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^a PRODUCT CODE Z212

Test Reagent Anti-Le^a Lot No. V038613 Expiry Date: 2006 SEP 10 (DS).
Reference Anti-Le^a Lot No. LAB123A Expiry Date: 2006 FEB 06 (OCD).

A total of 100 samples were tested:

| Reagent | Positive results | Negative results |
|-------------------|------------------|------------------|
| Test V038613 | 18 | 82 |
| Reference LAB123A | 18* | 82 |

* Negative first test, positive on repeat.

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 |

100% correlation was confirmed between Anti-Le^a Lot No. V038613 and comparator reagent, Anti-Le^a Lot No. LAB123A.

Susan Galloway
10 Dec 04

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



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^a (LEA2) PRODUCT CODE Z212

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^a blood typing reagent, product code Z212, 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^a (LEA2) PRODUCT CODE Z212

Test Reagent Anti-Le^a Lot No. Z2120160 (DS)

Test Reagent Anti-Le^a Lot No. V038125(DS)

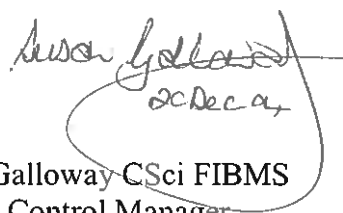
Reference Anti-Le^a Lot No. LK162A (OCD)

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

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

100% correlation was confirmed between Anti-Lea Z2120160/V038125 and the reference Anti-Lea LAB122AX.

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



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20 Dec 07

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