



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

**MONOCLONAL BLOOD GROUPING REAGENT  
ANTI-k (LK1) PRODUCT CODE Z137  
LOT No. Z1370100 EXPIRY DATE: 2005 OCT 28**

**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-k 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-k (LK162A), which was tested in parallel, no typing discrepancies were identified.

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-k reagent, Product Code Z137, 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-k (LK1) PRODUCT CODE Z137

Test Reagent Anti-k Lot No. Z1370100 Expiry Date: 2005 OCT 28 (DS).  
Reference Anti-k Lot No. LK162A Expiry Date: 2006 JAN 26 (OCD).

A total of 100 samples were tested:

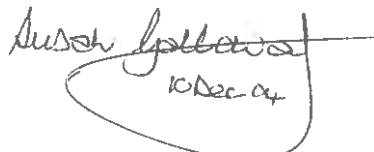
| Reagent          | Positive results | Negative results |
|------------------|------------------|------------------|
| Test Z1370100    | 90               | 10               |
| Reference LK162A | 90               | 10               |

Types of sample tested:

| Sample Type | Number tested |
|-------------|---------------|
| EDTA        | 88            |
| Clotted     | 0             |
| CPD         | 1             |
| Frozen      | 0             |
| Panel cell  | 11            |

| Disease State or variant     | Number tested |
|------------------------------|---------------|
| Sickle cell                  | 2             |
| Pregnancy                    | 8             |
| Cord sample                  | 2             |
| Neonate                      | 2             |
| Geriatric >80 years          | 5             |
| Weak or partial D            | 0             |
| Disproteinaemia              | 0             |
| Cold or warm auto agglutinin | 0             |
| Other                        | 1 (BM)        |

100% correlation was confirmed between Anti-k Lot No. Z1370100 and comparator reagent, Anti-k Lot No. LK162A.



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Diagnostics Scotland  
10<sup>th</sup> 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-k (LK1) PRODUCT CODE Z137**

#### **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-k blood typing reagent, product code Z137, 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-k (LK1) PRODUCT CODE Z137

Test Reagent Anti-k Lot No. Z1370100 Expiry Date 2005 OCT 28(DS)

Test Reagent Anti-k Lot No. Z1370090 Expiry Date 2005 SEP 25(DS)

Reference Anti-k Lot No. LK162A Expiry Date 2006 Jan 26 (OCD)

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

| Condition                  | Total samples | Positive | Negative |
|----------------------------|---------------|----------|----------|
| Multiple Myeloma           | 10            | 10       | 0        |
| Macroglobulinaemia         | 10            | 10       | 0        |
| Pregnancy                  | 10            | 10       | 0        |
| AIHA                       | 4             | 4        | 0        |
| Lymphoma                   | 10            | 10       | 0        |
| Leukaemia                  | 10            | 10       | 0        |
| Polyagglutinable red cells | 4             | 4        | 0        |
| DAT Positive               | 7             | 7        | 0        |
| Lipaemic                   | 10            | 10       | 0        |
| Haemolysed                 | 10            | 10       | 0        |

100% correlation was confirmed between Anti-k Z1370090/Z1370100 and the reference Anti-k LK162A.

It is noted that all tests produced positive results but given the proportion of the population which are positive for this antigen this result is not unexpected. Controls tested simultaneously gave expected results with k negative cells.

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 05

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