

AUTOZYME™ nDNA

Anti-nDNA antibodies

- **Ready to use, colour coded reagents**
- **New break-a-well format**
- **Room temperature incubations - total assay time only 90 minutes**
- **Dual protocol - quantitative and qualitative procedures**
- **Quantitative results calibrated to the IRP Wo/80**

● **Indication**

AUTOZYME™ nDNA anti-nDNA antibodies is a sandwich immunoassay for the quantitative or qualitative detection of anti-native deoxyribonucleic acid antibodies (nDNA) in human serum.

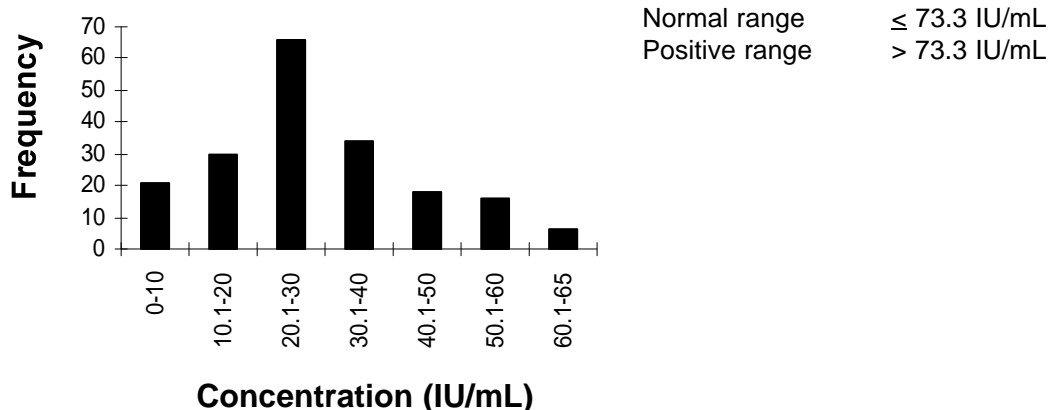
● **Summary and explanation of test**

AUTOZYME™ nDNA is an enzyme immunoassay (EIA) for the detection of autoantibodies against native deoxyribonucleic acid (nDNA). The assay is designed to be performed either quantitatively or qualitatively and used as an aid in the diagnosis and management of systemic lupus erythematosus (SLE). The presence of anti-nDNA autoantibodies is one of the four highly specific serological markers included in the 1982 American College of Rheumatology (ACR) revised criteria for the classification of SLE. The serum level of anti-nDNA antibodies in patients with SLE correlates significantly with the level of disease activity, particularly when there is renal involvement. Therefore, the test for anti-nDNA antibodies is useful for monitoring disease activity and the progress of therapy in patients with SLE.

The AUTOZYME™ nDNA kit provides rapid, objective results with guaranteed specificity for anti-nDNA antibodies. The antigen coated wells are specifically S₁nuclease treated to ensure that no interference occurs from single stranded DNA (ssDNA) antibodies. In addition, results are reported in IU/ml, units traceable to the World Health Organisation standard Wo/80.

The AUTOZYME™ nDNA kit has been designed to be performed by both manual and automated methodologies.

● **Reference ranges**



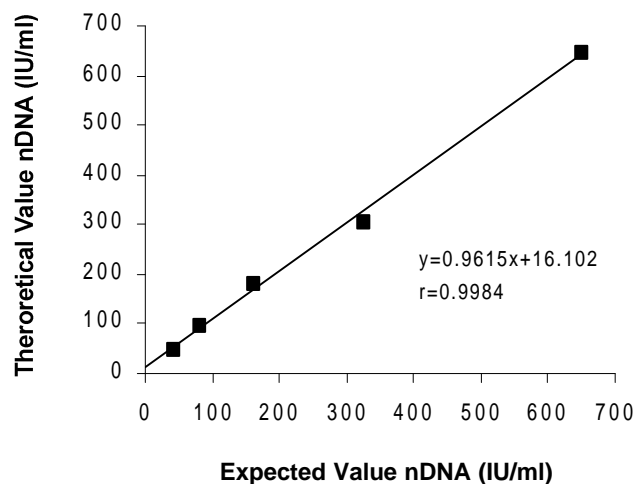
AUTOZYME™ nDNA Anti-nDNA antibodies

Catalogue No. Z4196

Precision

Intra-assay precision (n=20)		Inter-assay precision (n=6)	
Mean (IU/mL)	CV (%)	Mean (IU/mL)	CV (%)
52.1	16.5	56.1	10.8
160.0	14.5	201.6	9.3
132.8	16.1	170.6	17.4

Linearity



Interfering analytes/cross reactivity

No significant interference outside of the usual precision of the assay was detected with the following potential interferents:

Bilirubin	500 mg/L
Haemoglobin	5 g/L
Ascorbic acid	2 g/L
Lipids	10 %

Test Procedure

