

● **Nuclear Antibodies**

Workshops in Portugal 2006

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**Antibodies to Nuclear and
Related Antigens - 2006**

● UK Participants 170

● Non-UK Participants 507

Web entry system: 40%

Response rate: approx 80%

Antibodies to Nuclear and Related Antigens - 2006

Analyte	0611	0612	0621	0622	0631	0632	0641	0642
ANA	Positive 99%	Positive 95%	Negative 97%	Negative 84%	Positive 99%	Positive 98%	Positive 99%	Positive 98%
dsDNA	Positive 92%	Negative 77%	Negative 99%	Negative 99%	Positive 80%	Negative 85%	Equivocal	Negative 91%
ENA	Ro/La 95%	Sm/RNP 62%	Negative 99%	Negative 98%	Ro/La 94%	Ro 95%	Ro/La 97%	RNP 92%
ANA Staining	Speckled 79%	Speckled 88%	ANA Negative	ANA Negative	Speckled 83%		Speckled 71%	Speckled 97%

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Nuclear Antibodies - 2006

Extractable Nuclear Antigens	Sample 0612
RNP	43
Sm	61
Scl-70	1
Ro/La	4
Ro/Sm	2
RNP/Sm	201
Ro/La/RNP	3
Ro/La/Sm	2
Ro/RNP/Sm	4
Ro/La/RNP/Sm	1
Screen Only Positive	27
Negative	20
Total Responses	369
Correct Response	62%

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Antinuclear Antibody - 2006

Manufacturer	0611	0612	0621	0622
All Manufacturers	1125	273	62	97
Alpha Dia	2331	253	40	60
Binding Site	1038	254	86	90
BioDiagnostics	936	235	80	80
Bio-Rad/Kallestad/Sanofi	871	232	62	66
Biosystems	847	257	35	61
Diasorin	891	208	56	74
Euroimmun	1061	240	34	105
Immco	1234	994		60
Immunoconcepts	742	207	52	53
Inova	1664	317	95	160

IIF Titre - Minimum 10 users

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Antinuclear Antibody - 2006

Manufacturer	0631	0632	0641	0642
All Manufacturers	1222	861	2084	535
Alpha Dia	1724	1422	3880	640
Binding Site	1266	1133	1920	481
BioDiagnostics	741	804	1520	365
Bio-Rad/Kallestad/Sanofi	981	559	1269	480
Biosystems	840	819	896	539
Diasorin	977	600	2432	533
Euroimmun	1153	781	1940	481
Immco	1740	920	2400	320
Immunoconcepts	1091	708	1295	587
Inova	1698	1085	2833	749

IIF Titre - Minimum 10 users

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dsDNA Antibody - 2006

Manufacturer	0611	0612	0621	0622
All Manufacturers	145	17	12	13
Binding Site	306	23	30	30
BioDiagnostics	160		10	
Bio-Rad/Kallestad/Sanofi	100	10	10	10
Biosystems	104	25	10	10
Euroimmun	124	9	10	7
Immunoconcepts	210	20	10	10
Inova	118	18	14	20

IIF Crithidia - Minimum 10 users

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dsDNA Antibody - 2006

Manufacturer	0631	0632	0641	0642
All Manufacturers	66	22	60	22
Binding Site	33	23	18	7
BioDiagnostics	70	10	80	20
Bio-Rad/Kallestad/Sanofi	68	10	31	23
Biosystems	78	13	25	17
Euroimmun	57	6	35	7
Immunoconcepts	75	10	64	28
Inova	66	39	110	24

IIF Crithidia - Minimum 10 users

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dsDNA Antibody - 2006

Manufacturer	0611	0612	0621	0622
All Manufacturers	101	27	6	12
Axis Shield/Diastat	60	17	4	5
Binding Site	131	31	9	12
BioDiagnostics	151	27	21	27
Bio-Rad/Kallestad/Sanofi	123	35	3	10
Biosystems	62	62	41	58
Euroimmun	182	35	5	13
Grifols AESKU	30	12	3	5
Hycor Biomedical	108	29	5	10
Inova	309	108	26	67
ORG Tec	57	20	5	7
Phadia Elia	65	15	1	2
Phadia Varelisa	63	19	4	7
Trinity Biotech	129	13	5	7

IU/ml – Minimum 10 users

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dsDNA Antibody - 2006

Manufacturer	0631	0632	0641	0642
All Manufacturers	59	38	86	10
Axis Shield/Diastat	29	11	39	4
Binding Site	69	30	111	13
BioDiagnostics	75	20	36	9
Bio-Rad/Kallestad/Sanofi	59	15	84	4
Biosystems			61	19
Euroimmun	44	227	196	10
Grifols AESKU	17	15	24	6
Hycor Biomedical	53	36	47	7
Inova	286	292	694	55
ORG Tec	31	11	32	7
Phadia Elia	33	4	8	1
Phadia Varelisa	39	19	61	12
Trinity Biotech	75	68	13	7

IU/ml – Minimum 10 users

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The Challenge in Autoimmunity

- Analysis of data by method and source/manufacture indicates there is often good agreement in qualitative data or interpretation of the quantitative data

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The Challenge in Autoimmunity

- Numerical agreement is poor even where reference preparation exist
- Poor assay precision and variability in the application of reference intervals complicates the situation
- Dynamic ranges of kits available also vary significantly

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The Challenge in Autoimmunity

- The introduction of international standards alone will not resolve existing anomalies
- There appear to be subtle differences in the specificity of commercial assays

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The Challenge in Autoimmunity

- The future use of recombinant materials will have to be seriously considered as the ethical difficulties in obtaining donor sera increase

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Information about the programmes
can be found on website
www.immqas.org.uk

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