

Email: ukneqas@immqas.org.uk

Web Address: <https://www.immqas.org.uk>

UK NEQAS for Antibodies to Nuclear and Related Antigens

Distribution :	186	October 2018	Participant :	94317
-----------------------	------------	---------------------	----------------------	--------------

649 out of 726 participants returned data for this distribution. 89% response rate.

Nil Responses

10066, 10272, 10668, 11052, 11690, 12192, 12204, 12207, 12212, 13923, 14182, 14558A, 14575, 14605, 14631, 14638, 14640, 14668, 14685, 14804, 14877, 14880, 14888, 14896, 14996, 90367A, 90413, 90559, 90604, 90856, 91453A, 91539, 91562, 91593, 91666, 91835, 91896, 91976, 92015, 92138, 92447, 92464, 92464A, 92601B, 92700, 92761, 92786, 92787, 93214, 93682, 93740, 94346, 94647, 94653A, 94679, 94734, 94931, 95042, 95169, 95180, 95406, 95551, NOKLUS, YVSOLAB, PHAD_T, ANAND, KRIT, ORG_G, ORG_A, VAR, DEKS, ORG, BIOG, INFO, CODEX, TVN, SEQC

Sample 186-1 was a serum from a patient with systemic sclerosis.

Sample 186-2 was a serum from a donor with SLE.

Sample	Analyte	Target Response	Your Response	Score
186-1	ANA (nuclear, cytoplasmic, mitotic)	Positive	Negative	1
	dsDNA	Negative	Negative	0
	Centromere	Positive	Negative	1
	ENA	Equivocal	Negative	0

Sample	Analyte	Target Response	Your Response	Score	OMIS
186-2	ANA (nuclear, cytoplasmic, mitotic)	Positive	Negative	1	2
	dsDNA	Positive	Negative	1	1
	Centromere	Negative	Negative	0	1
	ENA	Ro	Negative	1	1
Total MIS				5	

The current window of analysis comprises the previous six distributions.

Comments

Sample 186-1

Designated Response Optional Response
 ENA Equivocal Ro

The designated response for the ENA element of this sample has been marked as equivocal as consensus was not met :

The majority of participants correctly identified the presence of Centromere antibodies, however 316/445 (71%) of participants also reported the presence of Ro antibodies with 81 laboratories commenting on the presence of Ro52. The presence of Ro52 is not uncommon in association with Centromere antibodies; a weak Ro52 was probably present in this sample which is supported by very few (29) participants reporting a speckled nuclear immunofluorescence pattern (AC-2, AC-4, AC-5, AC-29) in comparison to 409 participants reporting a Centromere pattern (AC-3). The presence of Ro52 reflects a different clinical scenario than Ro60.

From the results submitted the blots appeared to be more likely to report a negative Ro result when compared to ELISA methods , this may reflect the different antigens and antigen combinations each assay contains.

Laboratories are encouraged to understand and validate the specificity and sensitivity of their assay for their cohort and clinical use.

Sample 186-2

Designated Response Optional Response
 Ro Sm/RNP

48 laboratories reported a cytoplasmic speckled pattern (AC-18, AC-19, AC-20) and 59 laboratories commented on the presence of Ribosomal P antibodies.

Director Prof W Egner / Mrs D Patel, Operations Manager Mr D Gill / Dr H Wilkinson
 Telephone 0114 271 5715, Fax 0114 226 6754

Sheffield Teaching Hospitals

NHS Foundation Trust

The Misclassification scoring (**Total MIS**) system for the **qualitative** element of the scheme gives an indication of the number of instances where a laboratory's response is at variance with that defined for each specimen in a window of **six** distributions.

A panel of reference laboratories (10656, 10660, 10674, 10739, 10776, 11801, 14604, 91325, 92923, 93635, 93779) were in agreement in providing the target responses.

Laboratories have been given misclassification marks for an incorrect response to each analyte.

An OMIS of 2 or more for any one analyte will be classed as poor performance.

The qualitative elements are assessed by misclassification over a 12 sample window. The categories of performance are:

	<u>Total MIS</u>
● Good	zero
● Adequate	1-2
● Poor	>2

For further performance criteria information please see our website at <http://www.immqas.org.uk>.

If laboratories require further assistance please contact the centre.

Summary Page for Sample 186-1

Distribution : 186

October 2018

Participant : 94317

	Sample 186-1		
	Returns	Positive	Negative
Analyte			
ANA (nuclear, cytoplasmic, mitotic)	569	558	11
dsDNA	591	10	581
Centromere	457	447	10

Extractable Nuclear Antigens	
Ro	308
Ro/La	1
Ro/Jo-1	5
Ro/RNP/Sm	1
Ro/Sm/Scl-70	1
Other	37
Screen Only Positive	65
Negative	92
Total Responses	510
Correct Response	100 %

HEp2 Cell Pattern Source	HEp2 Cell Pattern Category (ICAP)	Count
Nuclear	Homogeneous (AC-1)	4
Nuclear	Centromere (AC-3)	409
Nuclear	Discrete nuclear dots (AC-6, AC-7)	1
Nuclear	Nucleolar (AC-8, AC-9, AC-10)	1
Nuclear	Pleomorphic (AC-13, AC-14)	1
Nuclear	Speckled (AC-2, AC-4, AC-5, AC-29)	29
Nuclear	Dense fine speckled (AC-2)	1
Nuclear	Fine speckled (AC-4)	12
Nuclear	Large/coarse speckled (AC-5)	1
Nuclear	Few nuclear dots (AC-7)	1
Nuclear	CENP-F-like (AC-14)	1
Cytoplasmic	Reticular / AMA (AC-21)	1
Cytoplasmic	Rods and rings (AC-23)	1
Cytoplasmic	Fibrillar (AC-15, AC-16, AC-17)	3
Cytoplasmic	Speckled (AC-18, AC-19, AC-20)	74
Cytoplasmic	Linear/actin (AC-15)	1
Cytoplasmic	Filamentous/microtubules (AC-16)	1
Cytoplasmic	Discrete dots (AC-18)	1
Cytoplasmic	Dense fine speckled (AC-19)	29
Cytoplasmic	Fine speckled (AC-20)	15
Mitotic	Centrosome (AC-24)	3
Mitotic	Mitotic chromosomal envelope (AC-28)	2
Other		7
Negative	Negative (AC-0)	3

Summary Page for Sample 186-2

Distribution : 186

October 2018

Participant : 94317

Analyte	Sample 186-2		
	Returns	Positive	Negative
ANA (nuclear, cytoplasmic, mitotic)	569	566	2
dsDNA	592	582	10
Centromere	437	4	433

Extractable Nuclear Antigens	
Ro	95
Ro/La	5
Ro/RNP	122
Ro/Sm	29
Ro/La/RNP	2
Ro/La/Sm	1
Ro/RNP/Sm	184
Ro/La/RNP/Sm	1
Ro/RNP/Sm/Scl-70	2
Ro/RNP/Sm/Jo-1	1
Ro/La/RNP/Sm/Scl-70	1
Screen Only Positive	67
Negative	7
Total Responses	517
Correct Response	96%

HEp2 Cell Pattern Source	HEp2 Cell Pattern Category (ICAP)	Count
Nuclear	Homogeneous (AC-1)	404
Nuclear	Nuclear envelope (AC-11, AC-12)	1
Nuclear	Speckled (AC-2, AC-4, AC-5, AC-29)	74
Nuclear	Dense fine speckled (AC-2)	3
Nuclear	Fine speckled (AC-4)	24
Nuclear	Large/coarse speckled (AC-5)	3
Cytoplasmic	Reticular / AMA (AC-21)	7
Cytoplasmic	Fibrillar (AC-15, AC-16, AC-17)	1
Cytoplasmic	Speckled (AC-18, AC-19, AC-20)	48
Cytoplasmic	Dense fine speckled (AC-19)	21
Cytoplasmic	Fine speckled (AC-20)	11
Mitotic	Mitotic chromosomal envelope (AC-28)	3
Other		5

ANA (nuclear, cytoplasmic, mitotic) Responses Sample 186-1

Distribution : 186	October 2018	Participant : 94317
---------------------------	---------------------	----------------------------

Your Results	
Positive : False	Unit : Titre
Negative : True	Method : Indirect Immunofluorescence
Quantitative :	Manufacturer : Binding Site
	Substrate : Hep2

INDIRECT IMMUNOFLUORESCENCE

SUBSTRATE	Returns	Positive	Negative	Mean	Observed Ranges	
Rat Tissue	3	3	0	680	80	1280
Euroimmun	3	3	0	680	80	1280
Hep2	408	399	9	1456	1	10240
A. Menarini - Zenit EIA	15	15	0	835	36	2560
AESKU	29	29	0	1291	80	5120
Alpha Dia	1	1	0	320	320	320
Binding Site	1	0	1	0		
BioDiagnostics	9	9	0	1792	640	5120
Bio-Rad/Kallestad/Sanofi	48	46	2	1210	80	5120
Biosystems	17	16	1	836	80	1600
Diamedix	1	1	0	640	640	640
Diasorin	4	3	1	160	160	160
Euroimmun	87	86	1	2032	1	10240
Generic Assays	1	1	0	2560	2560	2560
Immunoconcepts	17	17	0	1750	160	5120
In House	1	1	0	2560	2560	2560
Inova	154	152	2	1305	40	5120
MBL- BION	3	3	0	1280	1280	1280
Medica	2	1	1	0		
ORGenTec	1	1	0	640	640	640
Other ...	5	5	0	2040	160	5120
THERADIAG (BMD)	1	1	0	1280	1280	1280
Trinity Biotech (Immco)	9	9	0	232	1	640
ZEUS	2	2	0	1280	1280	1280
Hep2000	42	42	0	1142	160	5120
Immunoconcepts	42	42	0	1142	160	5120
Other ...	3	3	0	586	160	1280
Euroimmun	2	2	0	800	320	1280
Other ...	1	1	0	160	160	160

Please note: The statistical figures in the tables above are trimmed

ANA (nuclear, cytoplasmic, mitotic) Responses Sample 186-1

Distribution : 186	October 2018	Participant : 94317
-----------------------	--------------	------------------------

ENZYME IMMUNOASSAY

UNIT	Returns	Positive	Negative	Mean	Observed Ranges	
IU/ml	13	13	0	110	5	187
A. Menarini - Zenit EIA	1	1	0	135	135	135
Genesis	1	1	0	38	38	38
Hycor Biomedical	1	1	0	187	187	187
Inova	8	8	0	124	5	178
ORGenTec	1	1	0	6	6	6
Other ...	1	1	0	97	97	97
Units/ml	1	1	0	7	7	7
Dr Fooke	1	1	0	7	7	7
Ratio	73	72	1	8	1	25
Diasorin	1	1	0	8	8	8
Euroimmun	1	1	0	6	6	6
Inova	1	1	0	6	6	6
ORGenTec	3	3	0	7	3	13
Other ...	3	2	1	8	6	10
Phadia 100 EliA	2	2	0	22	19	24
Phadia 1000/2500 EliA (CTD)	4	4	0	7	6	7
Phadia 250 EliA	17	17	0	11	6	25
Phadia 250 EliA (CTD)	41	41	0	7	1	22
Other ...	2	2	0	39	20	58
Palex Diagnostica	2	2	0	39	20	58
Index	4	4	0	4	2	8
AESKU	4	4	0	4	2	8

Chemiluminescence

UNIT	Returns	Positive	Negative	Mean	Observed Ranges	
Units/ml	4	4	0	201	200	202
Inova QUANTA Flash	4	4	0	201	200	202
Index	2	2	0	9	7	12
A. Menarini - Zenit RA	2	2	0	9	7	12

Luminex Technology

UNIT	Returns	Positive	Negative	Mean	Observed Ranges	
Index	11	10	1	7	7	8
Luminex Tech. - Bio-Rad Bioplex 2200	11	10	1	7	7	8

Other ...

UNIT	Returns	Positive	Negative	Mean	Observed Ranges	
IU/ml	1	1	0	38	38	38
Other ...	1	1	0	38	38	38
Ratio	2	2	0	7	6	7
Other ...	2	2	0	7	6	7

Please note: The statistical figures in the tables above are trimmed

ANA (nuclear, cytoplasmic, mitotic) Responses Sample 186-2

Distribution : 186	October 2018	Participant : 94317
---------------------------	---------------------	----------------------------

Your Results	
Positive : False	Unit : Titre
Negative : True	Method : Indirect Immunofluorescence
Quantitative :	Manufacturer : Binding Site
	Substrate : Hep2

INDIRECT IMMUNOFLUORESCENCE

SUBSTRATE	Returns	Positive	Negative	Mean	Observed Ranges	
Rat Tissue	3	3	0	1280	1280	1280
Euroimmun	3	3	0	1280	1280	1280
Hep2	407	405	1	1881	1	12800
A. Menarini - Zenit EIA	15	15	0	1089	47	2560
AESKU	29	29	0	1748	80	5120
Alpha Dia	1	1	0	160	160	160
Binding Site	1	0	1	0		
BioDiagnostics	9	9	0	1280	640	2560
Bio-Rad/Kallestad/Sanofi	48	48	0	1635	80	10000
Biosystems	17	17	0	1173	320	2560
Diamedix	1	1	0	640	640	640
Diasorin	4	4	0	640	640	640
Euroimmun	86	86	0	2517	1	12800
Generic Assays	1	1	0	5120	5120	5120
Immunoconcepts	17	17	0	2325	160	10240
In House	1	1	0	1280	1280	1280
Inova	154	154	0	1708	40	5120
MBL- BION	3	3	0	5120	5120	5120
Medica	2	2	0	1280	1280	1280
ORGenTec	1	1	0	1280	1280	1280
Other ...	5	5	0	2048	640	5120
THERADIAG (BMD)	1	1	0	0		
Trinity Biotech (Immco)	9	9	0	544	1	1280
ZEUS	2	1	0	0		
Hep2000	43	43	0	1578	160	10240
Euroimmun	1	1	0	1000	1000	1000
Immunoconcepts	42	42	0	1596	160	10240
Other ...	3	3	0	746	320	1280
Euroimmun	2	2	0	800	320	1280
Other ...	1	1	0	640	640	640

Please note: The statistical figures in the tables above are trimmed

ANA (nuclear, cytoplasmic, mitotic) Responses Sample 186-2

Distribution : 186	October 2018	Participant : 94317
-----------------------	--------------	------------------------

ENZYME IMMUNOASSAY

UNIT	Returns	Positive	Negative	Mean	Observed Ranges	
IU/ml	13	13	0	131	6	400
A. Menarini - Zenit EIA	1	1	0	51	51	51
Genesis	1	1	0	400	400	400
Hycor Biomedical	1	1	0	79	79	79
Inova	8	8	0	122	10	182
ORGenTec	1	1	0	6	6	6
Other ...	1	1	0	174	174	174
Units/ml	1	1	0	7	7	7
Dr Fooke	1	1	0	7	7	7
Ratio	73	72	1	59	2	941
Diasorin	1	1	0	12	12	12
Euroimmun	1	1	0	8	8	8
Inova	1	1	0	6	6	6
ORGenTec	3	3	0	7	3	14
Other ...	3	2	1	9	7	12
Phadia 100 EliA	2	2	0	32	32	32
Phadia 1000/2500 EliA (CTD)	4	4	0	13	2	32
Phadia 250 EliA	17	17	0	48	32	80
Phadia 250 EliA (CTD)	41	41	0	110	6	941
Other ...	2	2	0	182	24	340
Palex Diagnostica	2	2	0	182	24	340
Index	4	4	0	6	3	12
AESKU	4	4	0	6	3	12

Chemiluminescence

UNIT	Returns	Positive	Negative	Mean	Observed Ranges	
Units/ml	4	4	0	201	200	202
Inova QUANTA Flash	4	4	0	201	200	202
Index	2	2	0	28	26	31
A. Menarini - Zenit RA	2	2	0	28	26	31

Luminex Technology

UNIT	Returns	Positive	Negative	Mean	Observed Ranges	
Index	11	11	0	8	8	9
Luminex Tech. - Bio-Rad Bioplex 2200	11	11	0	8	8	9

Other ...

UNIT	Returns	Positive	Negative	Mean	Observed Ranges	
IU/ml	1	1	0	24	24	24
Other ...	1	1	0	24	24	24
Ratio	2	2	0	420	420	420
Other ...	2	2	0	420	420	420

Please note: The statistical figures in the tables above are trimmed

dsDNA Responses Sample 186-1

Distribution : 186	October 2018	Participant : 94317
---------------------------	---------------------	----------------------------

Your Results	
Positive : False	Unit : IU/ml
Negative : True	Method : Enzyme Immunoassay/ELISA
Quantitative : 0.7	Manufacturer : Phadia 1000/2500 EliA
	Substrate : Not Applicable

INDIRECT IMMUNOFLUORESCENCE

SUBSTRATE	Returns	Positive	Negative	Mean	Observed Ranges	
Hep2	1	0	1	0		
Inova	1	0	1	0		
Crithidia Lucillae	152	3	149	10	0	50
A. Menarini - Zenit EIA	7	0	7	15	10	20
AESKU	7	0	7	0		
Alpha Dia	1	0	1	0		
BioDiagnostics	3	0	3	10	10	10
Bio-Rad/Kallestad/Sanofi	20	0	20	10	10	11
Biosystems	10	0	10	10	10	10
Euroimmun	33	2	31	15	0	50
Immunoconcepts	18	0	18	12	10	20
In House	1	0	1	0		
Inova	45	1	44	9	0	20
ORGenTec	1	0	1	0		
Other ...	1	0	1	0	0	0
Palex Diagnostica	2	0	2	10	10	10
Trinity Biotech (Immco)	3	0	3	5	1	10

Please note: The statistical figures in the tables above are trimmed

dsDNA Responses Sample 186-1

Distribution : 186

October 2018

Participant : 94317

ENZYME IMMUNOASSAY

UNIT	Returns	Positive	Negative	Mean	Observed Ranges	
IU/ml	314	3	311	5	0	320
AESKU	6	2	4	53	1	300
Axis Shield/Diastat	4	0	4	3	3	4
Bio-Rad/Kallestad/Sanofi	4	0	4	5	0	10
Diasorin	2	0	2	7	7	7
Diesse	2	0	2	10	10	11
Euro Diagnostica	8	0	8	2	0	4
Euroimmun	13	0	13	5	0	10
Generic Assays	1	0	1	4	4	4
Genesis	1	0	1	0	0	0
Hycor Biomedical	1	0	1	2	2	2
Inova	9	0	9	8	6	11
Inova QUANTA Lite	2	0	2	45	33	58
Luminex Tech. - THERADIAG (BMD)	1	0	1	3	3	3
ORGenTec	24	0	24	6	0	14
ORGenTec Alegria	12	0	12	4	0	16
Other ...	3	0	3	1	0	3
Phadia 100 EliA	8	0	8	0	0	0
Phadia 1000/2500 EliA	11	0	11	0	0	0
Phadia 250 EliA	200	1	199	3	0	320
Phadia Varelisa	2	0	2	0	0	0
Units/ml	1	0	1	0	0	0
Dr Fooke	1	0	1	0	0	0

Please note: The statistical figures in the tables above are trimmed

dsDNA Responses Sample 186-1

Distribution : 186

October 2018

Participant : 94317

Chemiluminescence

	UNIT	Returns	Positive	Negative	Mean	Observed Ranges
IU/ml		64	0	64	2	0 10
A. Menarini - Zenit RA		27	0	27	0	0 6
Inova QUANTA Flash		37	0	37	5	2 10

Immunoblotting

	UNIT	Returns	Positive	Negative	Mean	Observed Ranges
Other ...		2	0	2		
Other ...		2	0	2		
N/A		4	1	3	3	0 6
AESKU		1	1	0	0	0 0
D-tek		3	0	3	5	4 6

Luminex Technology

	UNIT	Returns	Positive	Negative	Mean	Observed Ranges
IU/ml		37	0	37	3	1 25
Luminex Tech. - Bio-Rad Bioplex 2200		34	0	34	1	1 1
Luminex Tech. - THERADIAG (BMD)		2	0	2	2	1 3
ZEUS		1	0	1	25	25 25

Other ...

	UNIT	Returns	Positive	Negative	Mean	Observed Ranges
IU/ml		2	1	1	3	0 7
Other ...		2	1	1	3	0 7
Other ...		5	0	5	0	0 0
Other ...		5	0	5	0	0 0

Radioimmunoassay(RIA)

	UNIT	Returns	Positive	Negative	Mean	Observed Ranges
IU/ml		9	2	7	3	0 14
IBL INTERNATIONAL		4	0	4	0	0 2
Immulite-SMS Diag. Ltd		1	0	1	0	0 0
Trinity Biotech		4	2	2	8	4 14

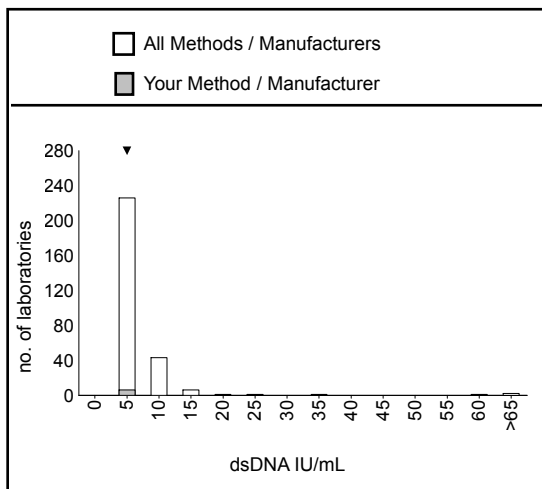
Please note: The statistical figures in the tables above are trimmed

dsDNA Responses Sample 186-1

Distribution : 186

October 2018

Participant : 94317



Your Method: Enzyme Immunoassay/ELISA

Your Manufacturer: Phadia 1000/2500 EiiA

Your Result: 0.7

Your Unit: IU/ml

dsDNA Responses Sample 186-2

Distribution : 186

October 2018

Participant : 94317

Your Results	
Positive : False	Unit : IU/ml
Negative : True	Method : Enzyme Immunoassay/ELISA
Quantitative : 1	Manufacturer : Phadia 1000/2500 EliA
	Substrate : Not Applicable

INDIRECT IMMUNOFLUORESCENCE

SUBSTRATE	Returns	Positive	Negative	Mean	Observed Ranges	
Hep2	1	1	0	0		
Inova	1	1	0	0		
Crithidia Lucillae	151	147	4	1722	1	40960
A. Menarini - Zenit EIA	7	6	1	693	160	1280
AESKU	7	7	0	40	40	40
Alpha Dia	1	1	0	1280	1280	1280
BioDiagnostics	3	3	0	680	80	1280
Bio-Rad/Kallestad/Sanofi	20	19	1	549	10	2560
Biosystems	10	10	0	136	10	320
Euroimmun	33	32	1	1246	10	5120
Immunoconcepts	17	17	0	4904	80	40960
In House	1	1	0	640	640	640
Inova	45	45	0	2137	5	40960
ORGenTec	1	1	0	0		
Other ...	1	1	0	0		
Palex Diagnostica	2	2	0	480	320	640
Trinity Biotech (Immco)	3	2	1	5	1	10

Please note: The statistical figures in the tables above are trimmed

dsDNA Responses Sample 186-2

Distribution : 186

October 2018

Participant : 94317

ENZYME IMMUNOASSAY

	UNIT	Returns	Positive	Negative	Mean	Observed Ranges	
IU/ml		312	306	6	579	0	5614
AESKU		6	5	1	448	6	1172
Axis Shield/Diastat		4	4	0	2038	2038	2038
Bio-Rad/Kallestad/Sanofi		4	4	0	150	150	150
Diasorin		2	2	0	1755	1755	1755
Diesse		2	2	0	150	150	150
Euro Diagnostica		8	8	0	1843	300	3386
Euroimmun		13	13	0	1177	280	2302
Generic Assays		1	1	0	301	301	301
Genesis		1	1	0	3785	3785	3785
Hycor Biomedical		1	1	0	1000	1000	1000
Inova		9	9	0	2181	535	5614
Inova QUANTA Lite		2	2	0	1265	1078	1453
Luminex Tech. - THERADIAG (BMD)		1	1	0			
ORGenTec		24	24	0	1068	50	4695
ORGenTec Alegria		12	12	0	220	120	425
Other ...		3	3	0	470	470	470
Phadia 100 EliA		8	8	0	934	471	3550
Phadia 1000/2500 EliA		11	10	1	328	1	454
Phadia 250 EliA		198	194	4	420	0	1270
Phadia Varelista		2	2	0	394	312	476
Units/ml		2	2	0	1756	9	3502
Dr Fooke		1	1	0	9	9	9
Inova		1	1	0	3502	3502	3502

Please note: The statistical figures in the tables above are trimmed

dsDNA Responses Sample 186-2

Distribution : 186

October 2018

Participant : 94317

Chemiluminescence

	UNIT	Returns	Positive	Negative	Mean	Observed Ranges	
IU/ml		65	65	0	1429	600	4538
A. Menarini - Zenit RA		27	27	0	1279	600	4538
Inova QUANTA Flash		38	38	0	1533	600	2640

Immunoblotting

	UNIT	Returns	Positive	Negative	Mean	Observed Ranges	
Other ...		2	2	0			
Other ...		2	2	0			
N/A		4	4	0	36	0	69
AESKU		1	1	0	0	0	0
D-tek		3	3	0	55	41	69

Luminex Technology

	UNIT	Returns	Positive	Negative	Mean	Observed Ranges	
IU/ml		37	37	0	359	207	1493
Luminex Tech. - Bio-Rad Bioplex 2200		34	34	0	266	207	348
Luminex Tech. - THERADIAG (BMD)		2	2	0	1294	1095	1493
ZEUS		1	1	0	808	808	808

Other ...

	UNIT	Returns	Positive	Negative	Mean	Observed Ranges	
IU/ml		2	2	0	220	200	240
Other ...		2	2	0	220	200	240
Other ...		5	5	0	127	4	389
Other ...		5	5	0	127	4	389

Radioimmunoassay(RIA)

	UNIT	Returns	Positive	Negative	Mean	Observed Ranges	
IU/ml		11	11	0	684	98	2044
IBL INTERNATIONAL		4	4	0	796	98	2044
Immolute-SMS Diag. Ltd		1	1	0	101	101	101
Trinity Biotech		5	5	0	747	151	1344
Trinity Biotech (Immco)		1	1	0	801	801	801

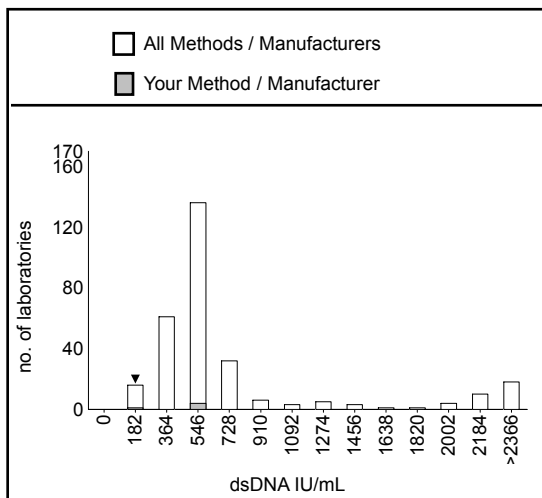
Please note: The statistical figures in the tables above are trimmed

dsDNA Responses Sample 186-2

Distribution : 186

October 2018

Participant : 94317



Your Method: Enzyme Immunoassay/ELISA

Your Manufacturer: Phadia 1000/2500 EiiA

Your Result: 1

Your Unit: IU/ml

Centromere Responses Sample 186-1

Distribution : **186**

October 2018

Participant : **94317**

Your Results	
Positive : False	Unit : IU/ml
Negative : True	Method : Enzyme Immunoassay/ELISA
Quantitative : 0.4	Manufacturer : Phadia 250 EliA
	Substrate : Not Applicable

INDIRECT IMMUNOFLUORESCENCE

SUBSTRATE	Returns	Positive	Negative	Mean	Observed Ranges	
Rat Tissue	1	1	0	0		
Euroimmun	1	1	0	0		
Hep2	154	149	5	1333	0	6400
A. Menarini - Zenit EIA	7	7	0	480	160	640
AESKU	4	4	0	186	80	320
Alpha Dia	1	1	0	320	320	320
BioDiagnostics	3	3	0	0		
Bio-Rad/Kallestad/Sanofi	21	20	1	1144	160	2560
Biosystems	7	5	2	720	0	1280
Diamedix	1	1	0	640	640	640
Euroimmun	32	31	1	1502	10	6400
Immunoconcepts	7	7	0	2666	1280	5120
Inova	63	63	0	1342	80	5120
Luminex Tech. - THERADIAG (BMD)	1	1	0	1280	1280	1280
MBL- BION	1	1	0	0		
Medica	1	0	1	0		
Other ...	1	1	0	5120	5120	5120
Trinity Biotech (Immco)	4	4	0	160	160	160
Hep2000	11	11	0	1351	320	5120
Immunoconcepts	11	11	0	1351	320	5120
Other ...	1	1	0	320	320	320
Euroimmun	1	1	0	320	320	320

Please note: The statistical figures in the tables above are trimmed

Centromere Responses Sample 186-1

Distribution : 186

October 2018

Participant : 94317

ENZYME IMMUNOASSAY

	UNIT	Returns	Positive	Negative	Mean	Observed Ranges	
IU/ml		131	127	4	273	0	638
A. Menarini - Zenit EIA		1	1	0	308	308	308
AESKU		3	3	0	146	2	420
Axis Shield/Diastat		1	1	0			
Euroimmun		2	2	0			
Inova		5	5	0	114	95	135
ORGenTec		7	7	0	252	110	300
Other ...		2	2	0	420	420	420
Phadia 100 EliA		5	5	0	467	240	600
Phadia 250 EliA		105	101	4	283	0	638
Units/ml		40	40	0	309	11	555
Dr Fooke		1	1	0	11	11	11
Phadia 100 EliA		1	1	0	240	240	240
Phadia 1000/2500 EliA		9	9	0	240	240	240
Phadia 250 EliA		29	29	0	366	240	555
Ratio		2	2	0	151	3	300
ORGenTec		1	1	0	300	300	300
Other ...		1	1	0	3	3	3

Please note: The statistical figures in the tables above are trimmed

Centromere Responses Sample 186-1

Distribution : 186

October 2018

Participant : 94317

Chemiluminescence

	UNIT	Returns	Positive	Negative	Mean	Observed Ranges	
IU/ml		22	22	0	550	80	849
A. Menarini - Zenit RA		8	8	0	418	80	640
Inova QUANTA Flash		14	14	0	668	121	849

Immunoblotting

	UNIT	Returns	Positive	Negative	Mean	Observed Ranges	
N/A		43	43	0	67	0	161
AESKU		4	4	0	0	0	0
Alpha Dia		1	1	0	74	74	74
D-tek		7	7	0	98	94	100
Euroimmun		26	26	0	48	10	161
Generic Assays		1	1	0			
Other ...		4	4	0	91	90	92

Line Immunoassay/LIA

	UNIT	Returns	Positive	Negative	Mean	Observed Ranges	
N/A		5	5	0	80	80	80
Innogenetics		3	3	0	80	80	80
Other ...		2	2	0			

Luminex Technology

	UNIT	Returns	Positive	Negative	Mean	Observed Ranges	
IU/ml		6	6	0	206	100	371
Luminex Tech. - Bio-Rad Bioplex 2200		1	1	0			
Luminex Tech. - THERADIAG (BMD)		4	4	0	165	100	204
ZEUS		1	1	0	371	371	371
Index		36	35	1	8	8	8
Luminex Tech. - Bio-Rad Bioplex 2200		36	35	1	8	8	8

Other ...

	UNIT	Returns	Positive	Negative	Mean	Observed Ranges	
Other ...		5	5	0	146	3	311
Other ...		5	5	0	146	3	311

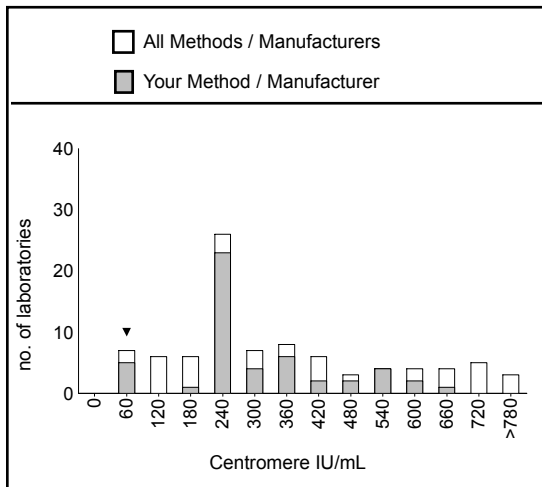
Please note: The statistical figures in the tables above are trimmed

Centromere Responses Sample 186-1

Distribution : 186

October 2018

Participant : 94317



Your Method: Enzyme Immunoassay/ELISA

Your Manufacturer: Phadia 250 ELIA

Your Result: 0.4

Your Unit: IU/ml

Centromere Responses Sample 186-2

Distribution : 186

October 2018

Participant : 94317

Your Results	
Positive : False	Unit : IU/ml
Negative : True	Method : Enzyme Immunoassay/ELISA
Quantitative : 0.5	Manufacturer : Phadia 250 EIIA
	Substrate : Not Applicable

INDIRECT IMMUNOFLUORESCENCE

SUBSTRATE	Returns	Positive	Negative	Mean	Observed Ranges	
Rat Tissue	1	0	1	0		
Euroimmun	1	0	1	0		
Hep2	142	1	141	82	0	160
A. Menarini - Zenit EIA	4	0	4	160	160	160
AESKU	4	0	4	80	80	80
BioDiagnostics	3	0	3	0		
Bio-Rad/Kallestad/Sanofi	21	0	21	85	40	160
Biosystems	6	0	6	40	0	80
Diamedix	1	0	1	0		
Euroimmun	29	1	28	42	0	160
Immunoconcepts	5	0	5	53	0	80
Inova	59	0	59	90	40	160
Luminex Tech. - THERADIAG (BMD)	1	0	1	0		
MBL- BION	1	0	1	80	80	80
Medica	2	0	2	0		
ORGenTec	1	0	1	0		
Other ...	1	0	1	80	80	80
Trinity Biotech (Immco)	4	0	4	160	160	160
Hep2000	11	0	11	80	80	80
Immunoconcepts	11	0	11	80	80	80
Other ...	1	0	1	320	320	320
Euroimmun	1	0	1	320	320	320

Please note: The statistical figures in the tables above are trimmed

Centromere Responses Sample 186-2

Distribution : 186

October 2018

Participant : 94317

ENZYME IMMUNOASSAY

UNIT	Returns	Positive	Negative	Mean	Observed Ranges	
IU/ml	125	2	123	2	0	34
A. Menarini - Zenit EIA	1	0	1	2	2	2
AESKU	3	0	3	2	0	5
Axis Shield/Diastat	1	0	1	1	1	1
Euroimmun	2	0	2	2	2	2
Inova	5	1	4	19	4	34
ORGenTec	6	0	6	1	0	3
Other ...	2	0	2	2	0	5
Phadia 100 EliA	5	0	5	1	1	2
Phadia 250 EliA	100	1	99	1	0	3
Units/ml	42	0	42	1	0	3
Dr Fooke	1	0	1	0	0	0
ORGenTec	1	0	1	1	1	1
Phadia 100 EliA	1	0	1	1	1	1
Phadia 1000/2500 EliA	8	0	8	1	1	2
Phadia 250 EliA	31	0	31	1	0	3
Ratio	2	0	2	0	0	1
ORGenTec	1	0	1	1	1	1
Other ...	1	0	1	0	0	0

Please note: The statistical figures in the tables above are trimmed

Centromere Responses Sample 186-2

Distribution : 186

October 2018

Participant : 94317

Chemiluminescence

	UNIT	Returns	Positive	Negative	Mean	Observed Ranges	
IU/ml		22	1	21	5	0	31
A. Menarini - Zenit RA		8	0	8	1	0	4
Inova QUANTA Flash		14	1	13	9	2	31

Immunoblotting

	UNIT	Returns	Positive	Negative	Mean	Observed Ranges	
Not Stated		1	0	1			
Euroimmun		1	0	1			
N/A		38	0	38	1	0	4
AESKU		3	0	3	0	0	0
Alpha Dia		1	0	1			
D-tek		7	0	7	3	3	4
Euroimmun		23	0	23	0	0	0
Generic Assays			0	0			
Other ...		4	0	4	0	0	0

Line Immunoassay/LIA

	UNIT	Returns	Positive	Negative	Mean	Observed Ranges	
N/A		5	0	5	40	0	80
Euroimmun		1	0	1	0	0	0
Innogenetics		2	0	2	80	80	80
Other ...		2	0	2			

Luminex Technology

	UNIT	Returns	Positive	Negative	Mean	Observed Ranges	
IU/ml		6	0	6	16	11	20
Luminex Tech. - Bio-Rad Bioplex 2200		1	0	1			
Luminex Tech. - THERADIAG (BMD)		4	0	4	15	11	20
ZEUS		1	0	1	20	20	20
Index		36	0	36	0	0	0
Luminex Tech. - Bio-Rad Bioplex 2200		36	0	36	0	0	0

Other ...

	UNIT	Returns	Positive	Negative	Mean	Observed Ranges	
Other ...		5	0	5	0	0	1
Other ...		5	0	5	0	0	1

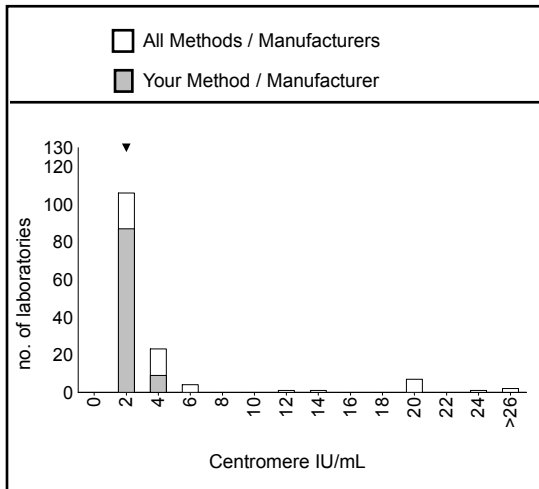
Please note: The statistical figures in the tables above are trimmed

Centromere Responses Sample 186-2

Distribution : 186

October 2018

Participant : 94317



Your Method: Enzyme Immunoassay/ELISA

Your Manufacturer: Phadia 250 EliA

Your Result: 0.5

Your Unit: IU/ml

ENA Responses Sample 186-1

Distribution : 186	October 2018	Participant : 94317
---------------------------	---------------------	----------------------------

Your Results

SSA: False	Sm: False	Other: False
SSA Method: Enzyme Immunoassay/ELISA	SM Method: Enzyme Immunoassay/ELISA	Other Method:
SSA Manufacturer: Phadia 1000/2500 EliA	SM Manufacturer: Phadia 1000/2500 EliA	Other Manufacturer:
SSB: False	Sci-70: False	Negative: True
SSB Method: Enzyme Immunoassay/ELISA	Sci-70 Method: Enzyme Immunoassay/ELISA	Negative Method: Enzyme Immunoassay/ELISA
SSB Manufacturer: Phadia 1000/2500 EliA	Sci-70 Manufacturer: Phadia 1000/2500 EliA	Negative Manufacturer: Phadia 1000/2500 EliA
RNP: False	Jo1: False	Screen Only: False
RNP Method: Enzyme Immunoassay/ELISA	Jo1 Method: Enzyme Immunoassay/ELISA	Screen Positive: False
RNP Manufacturer: Phadia 1000/2500 EliA	Jo1 Manufacturer: Phadia 1000/2500 EliA	Manufacturer:

Method	Ro (SSA)	La (SSB)	Sm	RNP	Sci-70	Jo-1	Other	Positive (Screen Only)	Negative
Chemiluminescence	36	1	0	0	0	0	6	0	9
A. Menarini - Zenit RA	21	1	0	0	0	0	1	0	0
Inova QUANTA Flash	15	0	0	0	0	0	5	0	9
DD	0	0	0	0	0	0	0	0	1
In House	0	0	0	0	0	0	0	0	1
ENA Screening Tests								57	6
A. Menarini - Zenit RA								4	1
AESKU								1	0
Bio-Rad/Kallestad/Sanofi								1	0
Diasorin								2	0
Euroimmun								1	3
Hycor Biomedical								0	1
Inova								1	0
Inova QUANTA Flash								6	0
Luminex Tech. - Bio-Rad Bioplex 2200								3	0
ORGenTec								2	0
ORGenTec Alegria								2	0
Phadia 100 EliA (CTD)								1	0
Phadia 1000/2500 EliA								4	0
Phadia 250 EliA								22	1
Phadia 250 EliA (CTD)								7	0
Enzyme Immunoassay/ELISA	199	0	1	1	0	1	6	0	25
AESKU	4	0	0	0	0	0	0	0	0
Bio-Rad/Kallestad/Sanofi	0	0	0	0	0	0	0	0	1
Dr Fooke	1	0	0	0	0	0	0	0	0
Euroimmun	1	0	0	0	0	0	0	0	5
Hycor Biomedical	0	0	0	0	0	0	0	0	2
Immunoconcepts	2	0	0	0	0	0	0	0	0
Inova	12	0	0	0	0	0	1	0	0
ORGenTec	19	0	0	0	0	0	0	0	0
ORGenTec Alegria	8	0	0	0	0	0	0	0	1
Other ...	4	0	0	0	0	1	0	0	2
Phadia 100 EliA	5	0	0	0	0	0	0	0	0
Phadia 1000/2500 EliA	6	0	0	0	0	0	0	0	1
Phadia 250 EliA	137	0	1	1	0	0	5	0	13

Please note: The statistical figures in the tables above are trimmed

ENA Responses Sample 186-1

Distribution : 186	October 2018	Participant : 94317
----------------------------------	---------------------	-----------------------------------

Method	Ro (SSA)	La (SSB)	Sm	RNP	Sci-70	Jo-1	Other	Positive (Screen Only)	Negative
Immunoblotting	38	0	1	0	1	1	31	0	38
AESKU	3	0	0	0	0	0	2	0	0
Alpha Dia	2	0	0	0	0	0	3	0	9
D-tek	4	0	0	0	0	0	1	0	3
Euroimmun	22	0	0	0	0	0	22	0	25
Innogenetics	0	0	0	0	0	0	1	0	0
Inno-LIA	3	0	1	0	1	1	0	0	0
MIKROGEN DIAGNOSTIK	3	0	0	0	0	0	1	0	0
ORGenTec	1	0	0	0	0	0	0	0	0
Other ...	0	0	0	0	0	0	1	0	1
Line Immunoassay/LIA	7	0	0	0	0	3	3	0	0
Human-Imtec	3	0	0	0	0	0	2	0	0
Innogenetics	4	0	0	0	0	3	1	0	0
Luminex Technology	31	0	0	0	0	0	7	0	11
Luminex Tech. - Bio-Rad Bioplex 2200	31	0	0	0	0	0	3	0	7
Luminex Tech. - THERADIAG (BMD)	0	0	0	0	0	0	4	0	2
ZEUS	0	0	0	0	0	0	0	0	2
Other ...	1	0	0	0	0	0	1	0	2
In House	0	0	0	0	0	0	0	0	1
Other ...	1	0	0	0	0	0	1	0	1

Please note: The statistical figures in the tables above are trimmed

ENA Responses Sample 186-2

Distribution : 186

October 2018

Participant : 94317

Your Results

SSA: False	Sm: False	Other: False
SSA Method: Enzyme Immunoassay/ELISA	SM Method: Enzyme Immunoassay/ELISA	Other Method:
SSA Manufacturer: Phadia 1000/2500 EliA	SM Manufacturer: Phadia 1000/2500 EliA	Other Manufacturer:
SSB: False	Sci-70: False	Negative: True
SSB Method: Enzyme Immunoassay/ELISA	Sci-70 Method: Enzyme Immunoassay/ELISA	Negative Method: Enzyme Immunoassay/ELISA
SSB Manufacturer: Phadia 1000/2500 EliA	Sci-70 Manufacturer: Phadia 1000/2500 EliA	Negative Manufacturer: Phadia 1000/2500 EliA
RNP: False	Jo1: False	Screen Only: False
RNP Method: Enzyme Immunoassay/ELISA	Jo1 Method: Enzyme Immunoassay/ELISA	Screen Positive: False
RNP Manufacturer: Phadia 1000/2500 EliA	Jo1 Manufacturer: Phadia 1000/2500 EliA	Manufacturer:

Method	Ro (SSA)	La (SSB)	Sm	RNP	Sci-70	Jo-1	Other	Positive (Screen Only)	Negative
Chemiluminescence	49	1	24	38	1	0	5	0	0
A. Menarini - Zenit RA	21	1	0	13	0	0	0	0	0
Inova QUANTA Flash	28	0	24	25	1	0	5	0	0
CIE	1	0	0	0	0	0	0	0	0
In House	1	0	0	0	0	0	0	0	0
DD	1	1	0	0	0	0	0	0	0
In House	1	1	0	0	0	0	0	0	0
ENA Screening Tests								59	2
A. Menarini - Zenit RA								4	0
AESKU								1	0
Bio-Rad/Kallestad/Sanofi								1	0
Diasorin								2	0
Hycor Biomedical								1	0
Inova								2	0
Inova QUANTA Flash								5	1
Luminex Tech. - Bio-Rad Bioplex 2200								3	0
Not Stated								1	0
ORGenTec								2	0
ORGenTec Alegria								2	0
Phadia 100 EliA (CTD)								1	0
Phadia 1000/2500 EliA								4	0
Phadia 250 EliA								24	1
Phadia 250 EliA (CTD)								6	0
Enzyme Immunoassay/ELISA	229	4	173	183	1	1	7	0	3
AESKU	4	0	1	1	0	0	0	0	0
Bio-Rad/Kallestad/Sanofi	1	0	1	1	0	0	0	0	0
Dr Fooke	1	0	0	1	0	0	0	0	0
Euroimmun	9	0	1	8	0	0	1	0	0
Hycor Biomedical	2	1	0	2	0	0	0	0	0
Immunoconcepts	2	0	1	2	0	0	0	0	0
Inova	11	0	11	12	0	0	1	0	0
ORGenTec	20	0	1	8	0	0	0	0	0
ORGenTec Alegria	9	0	0	5	0	0	0	0	0
Other ...	6	2	4	3	1	0	0	0	0
Phadia 100 EliA	5	0	5	5	0	0	0	0	0
Phadia 1000/2500 EliA	6	0	6	5	0	0	0	0	1
Phadia 250 EliA	153	1	142	130	0	1	5	0	2

Please note: The statistical figures in the tables above are trimmed

ENA Responses Sample 186-2

Distribution : 186	October 2018	Participant : 94317
----------------------------------	---------------------	-----------------------------------

Method	Ro (SSA)	La (SSB)	Sm	RNP	Sci-70	Jo-1	Other	Positive (Screen Only)	Negative
Immunoblotting	101	4	8	51	0	0	33	0	1
AESKU	4	0	0	0	0	0	2	0	0
Alpha Dia	15	1	4	12	0	0	2	0	0
D-tek	8	0	1	6	0	0	3	0	0
Euroimmun	65	2	0	31	0	0	23	0	1
Innogenetics	0	0	0	0	0	0	1	0	0
Inno-LIA	3	0	2	0	0	0	1	0	0
MIKROGEN DIAGNOSTIK	3	1	0	0	0	0	1	0	0
ORGenTec	1	0	0	0	0	0	0	0	0
Other ...	2	0	1	2	0	0	0	0	0
Line Immunoassay/LIA	8	0	6	2	0	0	6	0	0
Human-Imtec	3	0	1	1	0	0	2	0	0
Innogenetics	4	0	4	0	0	0	3	0	0
Other ...	1	0	1	1	0	0	1	0	0
Luminex Technology	48	0	4	33	1	0	11	0	0
Luminex Tech. - Bio-Rad Bioplex 2200	40	0	2	27	1	0	7	0	0
Luminex Tech. - THERADIAG (BMD)	6	0	0	4	0	0	4	0	0
ZEUS	2	0	2	2	0	0	0	0	0
Other ...	2	0	1	2	0	0	0	0	1
In House	0	0	0	0	0	0	0	0	1
Other ...	2	0	1	2	0	0	0	0	0

Please note: The statistical figures in the tables above are trimmed