



*UK NEQAS-Monoclonal
Protein Identification-EQA*

Review

13-14th November 2006

Portugal

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Participation

▶ Number of participants:

approx. 307 participants (98 non-UK)

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Scoring- qualitative

- ▶ Cumulative performance scores are based on:
 - MIS scoring for monoclonal Identification element of the scheme
- ▶ The MI scoring is cumulated over a six distribution (twelve month) time window.

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Criteria of Performance

- ▶ Laboratory performance is classified as:

	OMIS
Good	0
Adequate	1-3
Poor	>3

An MIS of 3 or more for any one interpretative component is also considered as poor performance.

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OMIS SCORES

Lab No.	0561	0562	0611	0612	0621	0622	0631	0632	0641	0642	0651	0652	OMIS
5030	0	0	NR	NR	0	0	0	0	0	1	NR	NR	1
5036	0	0	0	0	0	0	0	0	NR	NR	0	#	0
5041	0	0	0	0	0	0	0	0	0	0	0	#	0
5082	0	0	0	0	0	0	0	0	0	0	0	#	0
5083	0	0	0	0	0	0	0	0	0	0	0	#	0
5088	0	0	0	0	NR	NR	0	0	0	0	1	#	1
10484	NR	NR	0	0	0	0	0	0	0	0	1	#	1
10728	0	0	0	0	0	0	0	0	0	0	0	#	0
10771	-	-	-	-	-	-	N	NT	N	NT	N	NT	-
11361	-	-	0	2	0	0	0	2	0	NT	0	#	4
11892	0	NT	0	NT	0	NT	0	NT	0	NT	1	NT	1
11929	-	-	-	-	0	0	0	0	0	0	NR	NR	0
13286	0	0	0	0	0	0	0	0	0	0	0	#	0
13413	0	0	0	0	0	0	0	0	0	0	0	#	0
90172	0	0	0	0	0	0	0	0	0	0	0	#	0
90198	NR	NR	NR	NR	NR	NR	NR	NR	0	0	NR	NR	0
90218	0	0	0	0	0	0	0	0	0	0	1	#	1
90243	-	-	-	-	-	-	-	-	0	0	0	#	0
90259	0	0	0	0	0	0	0	0	0	0	NR	NR	0
90492	-	-	-	-	-	-	-	-	0	0	0	#	0
90572	-	-	0	0	0	0	NR	NR	0	0	1	#	1
90599	-	-	-	-	0	0	0	0	0	0	0	#	0
90658	0	0	0	0	0	0	0	0	0	0	0	#	0
90706	-	-	-	-	NR	NR	NR	NR	NR	NR	NR	NR	-
90717 A	0	0	0	0	0	0	0	0	0	0	1	#	1
91040	0	0	0	0	0	0	0	0	0	0	0	#	0
91075 A	0	0	0	0	0	0	0	0	0	2	N	#	2
94033	0	0	0	0	0	0	0	0	0	0	0	#	0

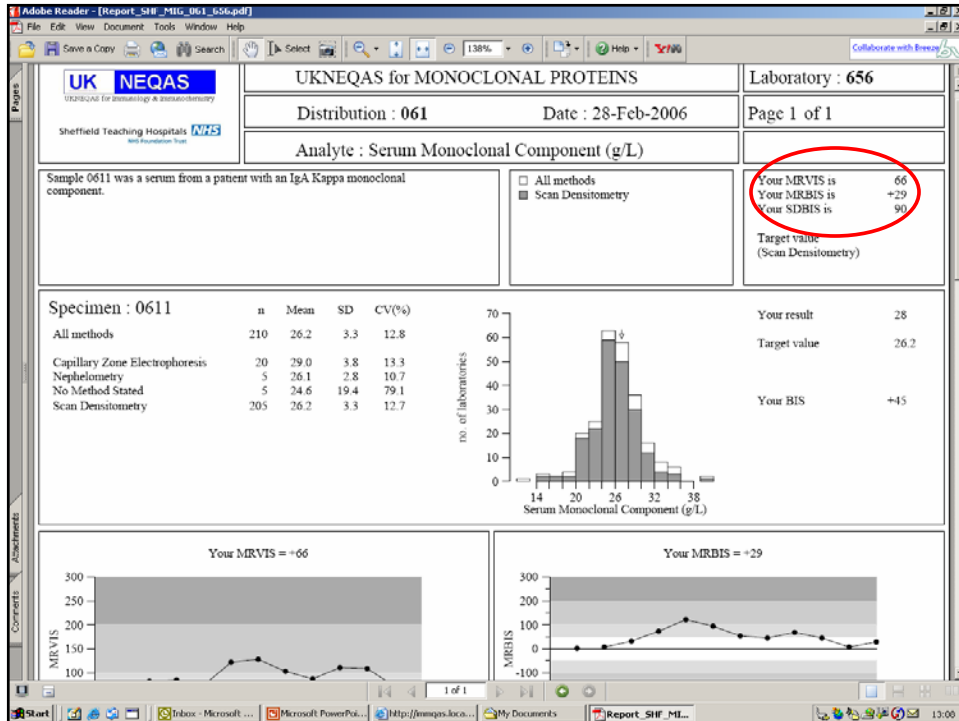
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Scoring- quantitative

- Cumulative performance scores are also based on:
 - VIS scoring for quantitative element of the scheme-monoclonal component



Criteria of Performance

- Laboratory performance is classified as:

	MRVIS
Ideal	<50
Good	50-100
Adequate	101-200
Poor	>200 or SDBIS >200

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Review of sample distribution

- ▶ Over the last 12 months (distributions 055-065)
- ▶ Serum: IgA Lambda x1
IgA Kappa x2
IgM Lambda x1
IgG Kappa x2
IgD Lambda x1
- ▶ Urine: KFLC x2
Negative x4

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Problems Encountered

- ▶ Over the last 12 months generally few problems with regards to monoclonal identification however recently 2 issues have arisen:
 - IgD detection
 - Freelite assay

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IgD data

- ▶ IgD monoclonal sample has been distributed on the following occasions:

–995

–023

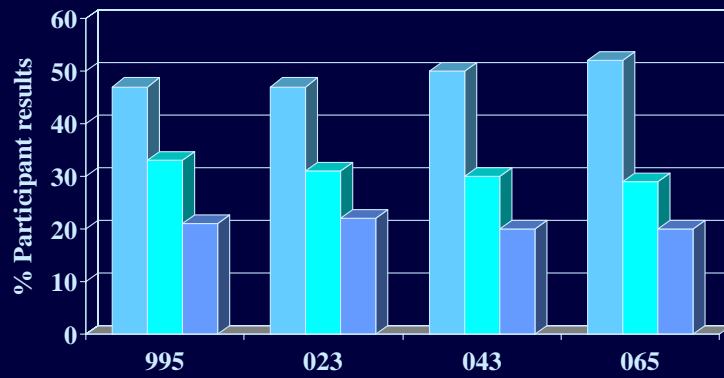
–043

–065

- ▶ A significant number of laboratories seem to have difficulty identifying IgD monoclonals!

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IgD Monoclonal Identification



Distribution

	995	023	043	065
Reported IgD Monoclonal	47	47	50	52
Missed IgD Monoclonal	21	22	20	20
Referred IgD Monoclonal	33	31	30	29



Freelite data

- ▶ The Binding Site have released a product to enable detection of free light chains in serum- *Freelite assay*
- ▶ Currently approximately 54 users report results to the scheme
- ▶ Quantitation of serum free light chain has produced significantly anomalous results within the manufacturer groups.

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Dist. 063 IgG Kappa

Manuf.	n	Kappa (mg/L) ALTM	CV %	Lambda (mg/L) ALTM	CV %	K:L Ratio range
Beckman	7	4965	27	14.2	48	49- 569
Dade Behring	22	4465	23	8.76	27	237- 547
Roche	7	4001	64	76.6	154	164- 499
Not Stated	13	5276	63	59.9	150	43- 531



Raw data for dist 063-Beckman

Kappa (mg/L)	Lambda (mg/L)
>1620*	26.3
>162*	8.1
4650	<18.0*
4600	<8.0*
7050	14.1
5450	12.0
34600*	9.6
5820	700*
4376	20.6
>1620*	8.9

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Raw data for dist 063-Behring

Kappa (mg/L)	Lambda (mg/L)
4590	10.7
3650	9.2
4440	6.2
2750	11.6
5560	5.6
4570	<7.6*
3510	6.7
3690	10.8
5200	13.3
3460	10.8
6910	7.0
5160	6.3
2740	23.6*
5665	6.3
9450*	6.5

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Raw data for dist 063-Roche

Kappa (mg/L)	Lambda (mg/L)
3686	9.8
3967	9.2
4495	9.0
3913	9.2
3226	8.8
10.4	290
8710	200

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Dist. 064 IgA Kappa

Manuf.	n	Kappa (mg/L) ALTM	CV %	Lambda (mg/L) ALTM	CV %	Ratio range
Beckman	8	9428	66	5124	68	1.2-74.4
Dade Behring	24	78.8	32	15.4	77	1.4-29.6
Roche	8	332.4	30	10.3	71	10-55.7
Not Stated	10	6066	175	858	207	1.8-67.2

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Raw data for dist 064-Beckman

Kappa (mg/L)	Lambda (mg/L)
>3780*	2541
>162*	>270*
>8100*	11700
6160	4000
8208	6866
16760	6320
16550	<8.0*
>3240*	3360
690	9.3
8200	6200

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Raw data for dist 064-Behring

Kappa (mg/L)	Lambda (mg/L)
103	29.6
97.8	8.8
78.6	15.4
91.1	30.7
144	16.2
42.6	16.4
69.4	17.5
96.8	20.9
77.7	8.7
47.5	18.4
93.9	3.0
57.0	10.8
63.9	15.4
60.6	1.3
10200*	12.4

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Raw data for dist 064-Roche

Kappa (mg/L)	Lambda (mg/L)
531	7.2
288	8.6
307	27.0
281	9.9
385	7.8
212	6.8
379	1.4

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Why ?

- ▶ Currently we are unable to explain the differences in observed results between the different manufacturer groups
- ▶ We are in contact with The Binding Site to try to resolve the issues
- ▶ Undertaken a small independent study recently

WAIT FOR THE RESULTS!

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