

INTRODUCTION

As part of the Binding Site's Optilite Seed Site Project Universitair Ziekenhuis, Brussels completed an evaluation of the Binding Site's latest special protein system, Optilite compared to the current system BN™II. The evaluation included comparison, precision, linearity, throughput and antigen excess testing.

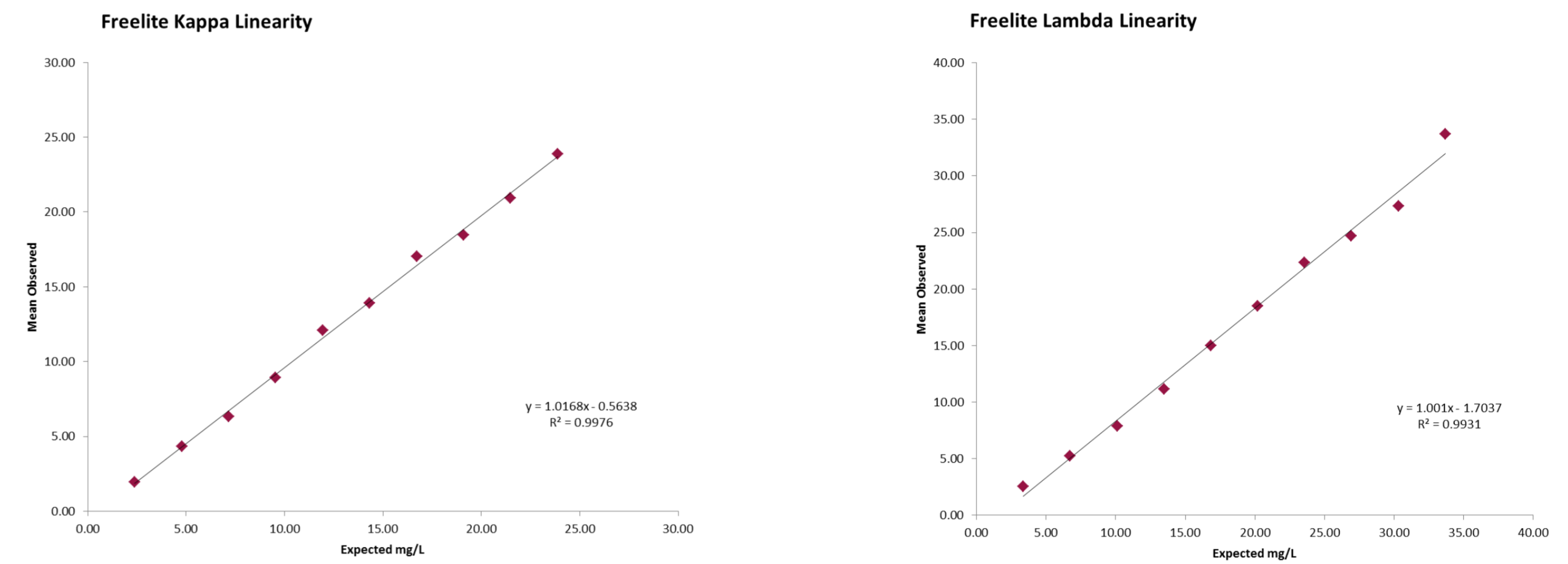
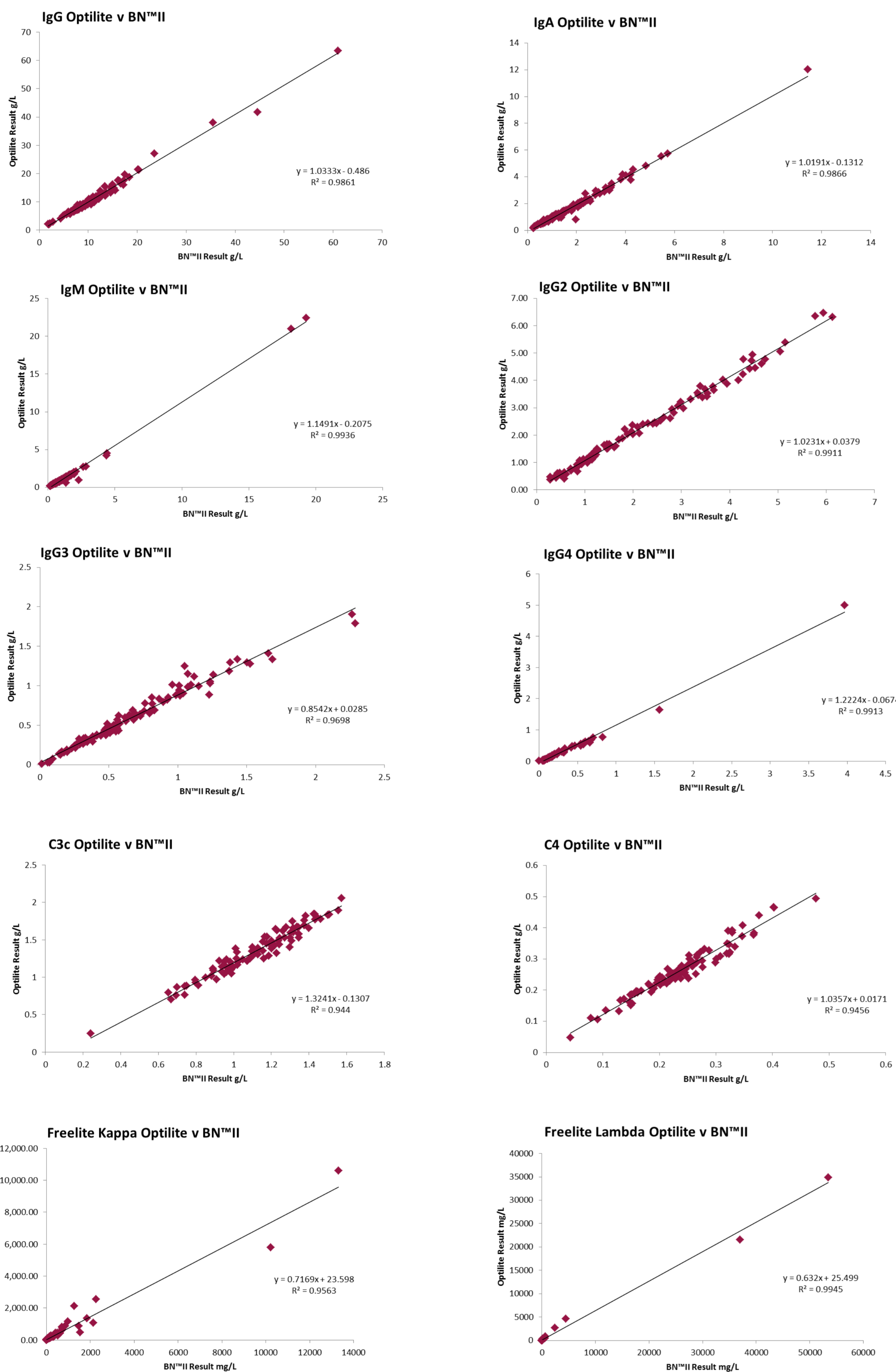
Reagent specificities assessed during the evaluation project included IgG, IgA, IgM, C3c, C4, Freelite®Kappa, Freelite Lambda, IgG2, IgG3 and IgG4. Binding Site reagents were used on the BN™II where the specificity is underlined.

COMPARISON

Regression analysis was performed to assess the correlation between the Optilite and BN™II. An average of 120 samples were used for each comparison.

FREELITE LINEARITY

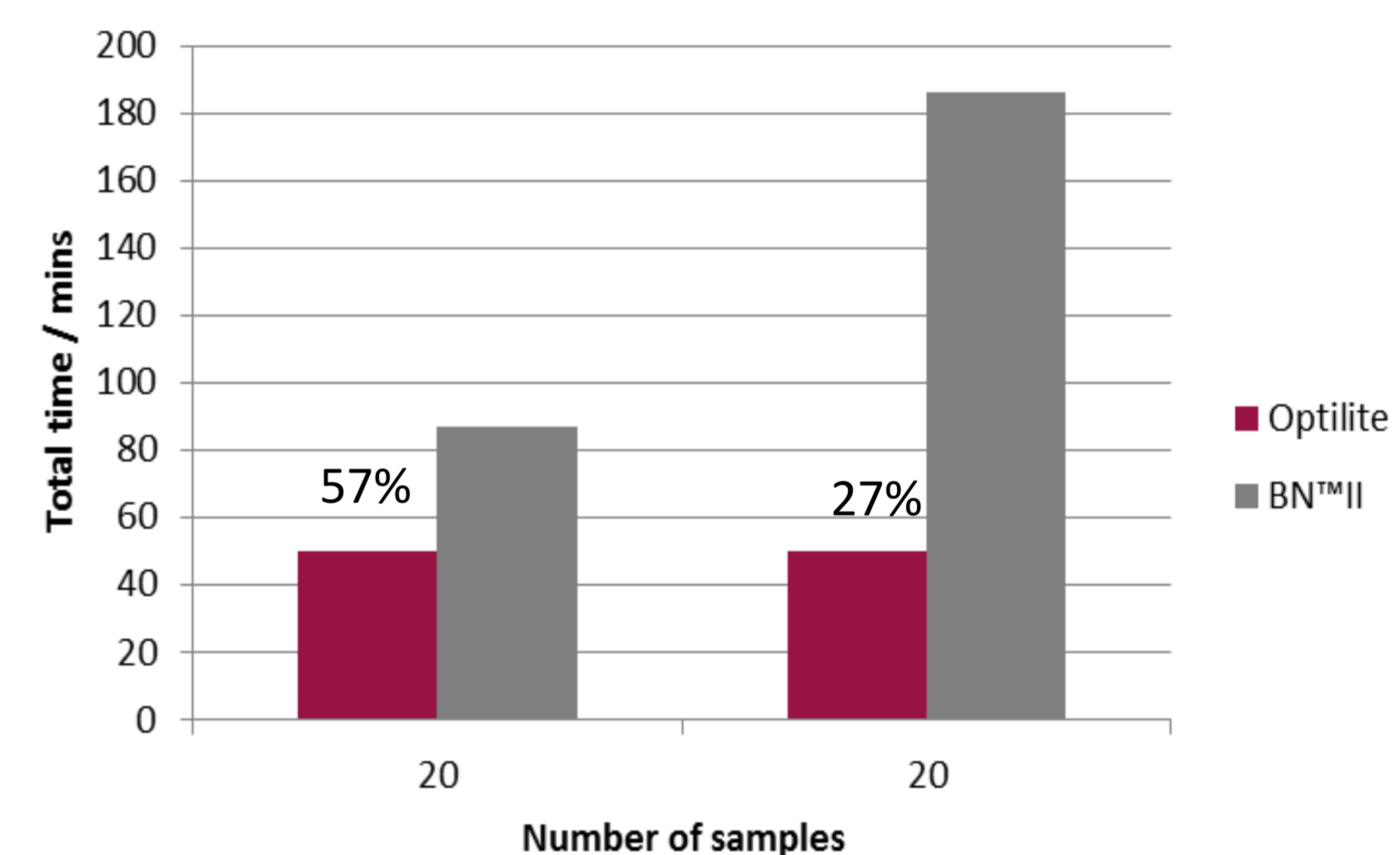
Linearity was assessed across the calibration curve at the lowest sample dilution using a polyclonal fluid supplied by Binding Site.



FREELITE THROUGHPUT

Total time taken for 20 Freelite Kappa and Lambda samples on the Optilite and BN™II.

- The data on the right hand side includes an additional manually ordered high re-dilution for all samples to check for antigen excess on the BN™II
- The percentages shown on the graph indicate the time taken by the Optilite as a percentage of the time taken by the BN™II



FREELITE ANTIGEN EXCESS

Freelite Kappa BN™II					Freelite Kappa Optilite			
100	2000	8000	40000	160000	10	100	1000	10000
97.3	>3550	3190			74.5	1276	3243	
29.6	305				98.5	450.14		
143	577				127.6	653.22		
127	>3550	>14200	10500		49.6	508.4	10811.3	
91.3	>3550	5690			69.9	890.3	4560	
114	1250				109.2	1276	1627.3	
109	>3550	>14200	14000		64.9	753.3	12760	11103.2
136			>71000	63600	25.7	29.7	5621.7	37663.4

Freelite Lambda BN™II					Freelite Lambda Optilite		
100	2000	8000	40000	160000	8	80	800
58.8	2370				24.6	1445.6	2877
>151		>12100	24800		39.9	751.1	14456

PRECISION

- Intra-assay CVs were calculated using 10 kit QC results obtained within a single run.
- Inter-assay CVs were calculated using approximately 50 results per specificity run over a 31 day period.

Assay	Intra-assay			Inter-assay		
	QC1	QC2	QC3	QC1	QC2	QC3
IgG	0.95%	1.70%		6.87%	13.65%	
IgA	6.44%	5.46%		5.84%	4.90%	
IgM	0.59%	0.80%		4.47%	3.50%	
IgG2	0.99%	0.79%		3.71%	3.96%	
IgG3	2.10%	2.35%	2.40%	6.37%	4.30%	3.60%
IgG4	1.24%	0.96%	7.31%	5.91%	6.96%	7.31%
C3c	0.58%	0.57%		6.17%	6.11%	
C4	0.59%	0.95%		5.13%	6.83%	
Freelite Kappa	1.42%	2.11%		7.88%	4.71%	
Freelite Lambda	2.67%	1.75%		7.69%	8.34%	

CONCLUSION

The Optilite demonstrated good comparison to the BN™II as well as good precision for IgG, IgG subclasses, IgA, IgM, C3, C4 and FLC kappa and lambda. Freelite linearity was perfect. Sample throughput is much better for the Optilite compared to the BN™II when running Freelite. Antigen excess was successfully detected in 7/8 samples with proven antigen excess for kappa FLC on the BNII system. One sample with lambda antigen excess on the BNII was missed by the Optilite. The Optilite evaluation was such a positive experience, that we purchased it!