

EliA PR3^S

Launch Presentation

EliA PR3^S - Launch Presentation

- Why EliA PR3^S ?
- Product Details – Technical Performance
- Clinical Performance

Why EliA PR3^S

- S stands for “sensitive”.
- The old EliA PR3 assay used native human purified PR3 which was directly coated to the polystyrene EliA Well.
- The new EliA PR3^S assay uses the same native human purified PR3, but an indirect coating to the polystyrene EliA Well using a spacer between the polystyrene EliA Well and the antigen, which presents the antigen better.
- This technology is also called “anchor”.
- There are several reasons for this update:
 - Customer feedback revealed that our old EliA PR3 test shows a lack of sensitivity.
 - Competitor kits with higher sensitivity are already on the market.
 - A recently introduced international standard for PR3 antibodies allows results in IU/ml, but makes re-calibration or new development necessary.

EliA PR3^S

Product Details – Technical Performance

EliA PR3^S - Product Details

Product name	Package size	Article number	
■ EliA PR3 ^S Well	48	14-5536-01	new

EliA PR3^S is calibrated against the CDC PR3-ANCA Human Reference Serum #16. Results are given in International Units (IU/ml).

Therefore EliA PR3^S has a different normal range than other EliA tests
negative < 2.0 IU/ml; equivocal 2.0 – 3.0 IU/ml, positive > 3.0 IU/ml

EliA PR3^S - Controls

■ EliA ANCA/GBM Positive Control 100	83-1039-01
■ EliA ANCA/GBM Positive Control 250	83-1034-01
■ EliA IgG/IgM/IgA Negative Control 100	83-1042-01
■ EliA IgG/IgM/IgA Negative Control 250	83-1037-01

Please note:

- Controls are the current products and can also be used together with the new EliA PR3^S test.
- Ranges for EliA PR3^S test used together with Control lots already on the market will be communicated separately at launch.
- Control certificates of future Control lots will contain ranges for both the new EliA PR3^S test and the old EliA PR3 test as long as the old test is on the market.

EliA PR3^S – Precision

ImmunoCAP 100

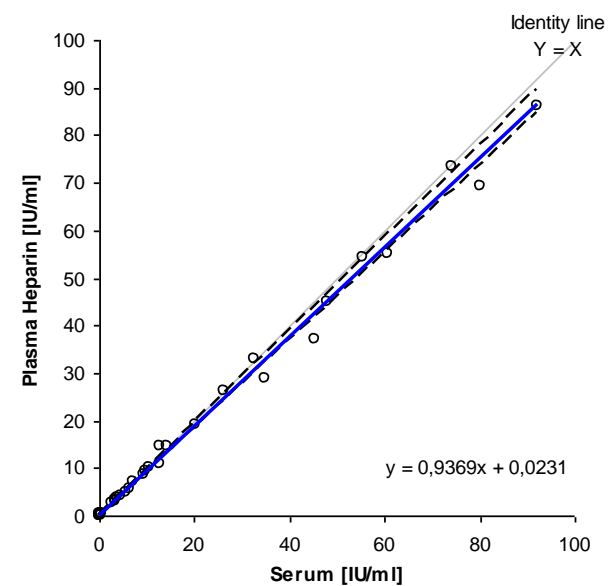
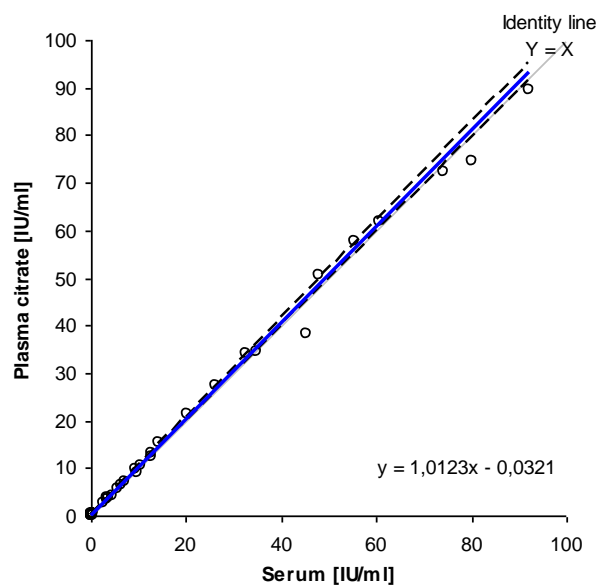
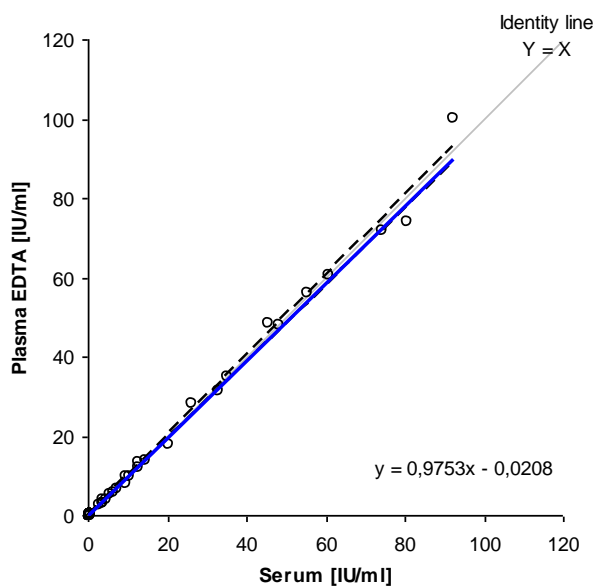
Test	Sample	Unit	Mean Value	Coefficients of variation (%)	
				Intra-Run	Inter-Run
EliA PR3 ^S	1	IU/ml	1.6	10.5	4.2
	2	IU/ml	6.1	6.4	7.0
	3	IU/ml	18.4	3.9	0.0

ImmunoCAP 250

Test	Sample	Unit	Mean Value	Coefficients of variation (%)	
				Intra-Run	Inter-Run
EliA PR3 ^S	1	IU/ml	1.3	8.5	0.0
	2	IU/ml	6.6	9.8	0.0
	3	IU/ml	18.1	4.1	2.3

Excellent comparability on both instruments, excellent precision

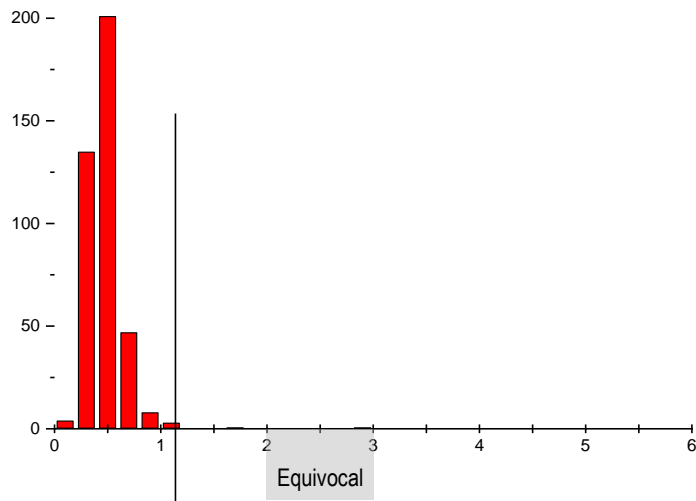
EliA PR3^S – Serum/Plasma Correlation



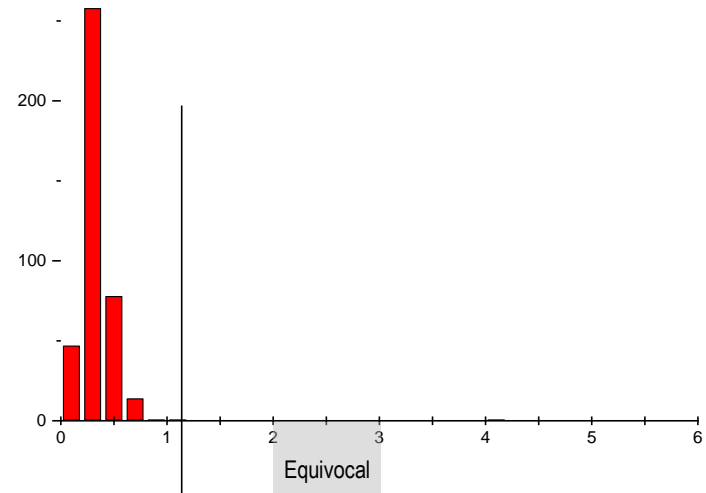
Both serum and all types of plasma can be used

EliA PR3^S – Blood Donors and Normal Range

ImmunoCAP 100



ImmunoCAP 250



Most blood donors far below cut-off.
Only one sample gives an equivocal/positive result and is most likely not healthy.

EliA PR3^S - Clinical Performance

Performance using clinically defined samples

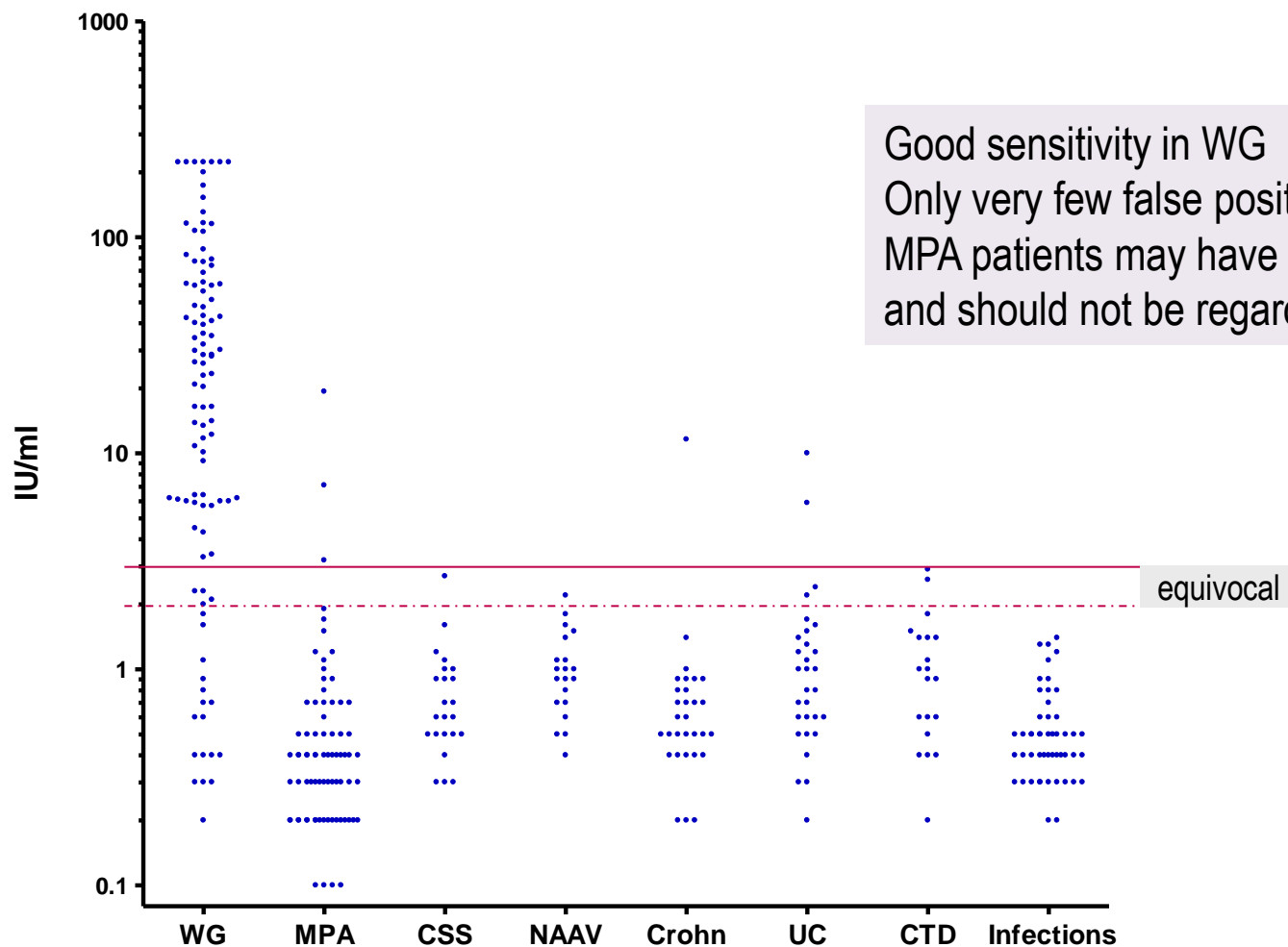
EliA PR3^S - Clinical Performance

Samples used for performance validation	n
■ Wegener's granulomatosis (WG)	100
■ Disease controls:	
Microscopic polyangiitis (MPA)	77
Churg-Strauss syndrome (CSS)	23
Non-ANCA associated vasculitis (NAAV)	20
Ulcerative colitis	30
Crohn's disease	30
Mixed connective tissue disease (MCTD)	5
Systemic lupus erythematoses (SLE)	7
Sjögren syndrome (SS)	8
Infections	50
<hr/>	
■ Total	350

EliA PR3^S - Clinical Performance

- EliA PR3^S finds most of the Wegener's granulomatosis patients → high sensitivity!
- EliA PR3^S shows very few false positive results → high specificity!

EliA PR3^S - Clinical Performance



Good sensitivity in WG
Only very few false positives.
MPA patients may have PR3 antibodies
and should not be regarded as real controls

equivocal

EliA PR3^S - Clinical Performance Compared to Competition

- The same panel of 350 clinically defined sera as mentioned before was used.
- We compared to IFA and to the (to our knowledge) most sensitive tests in the market including the new generation “anchor” or “spacer” assays (Data can be presented by request)

EliA PR3^S - Clinical Performance Compared to Competition

1. Compared to Indirect Immunofluorescence (IFA)
2. Clinical performance in combination with IFA
3. Compared to ELISA competition

EliA PR3^S - Clinical Performance Compared to Competition

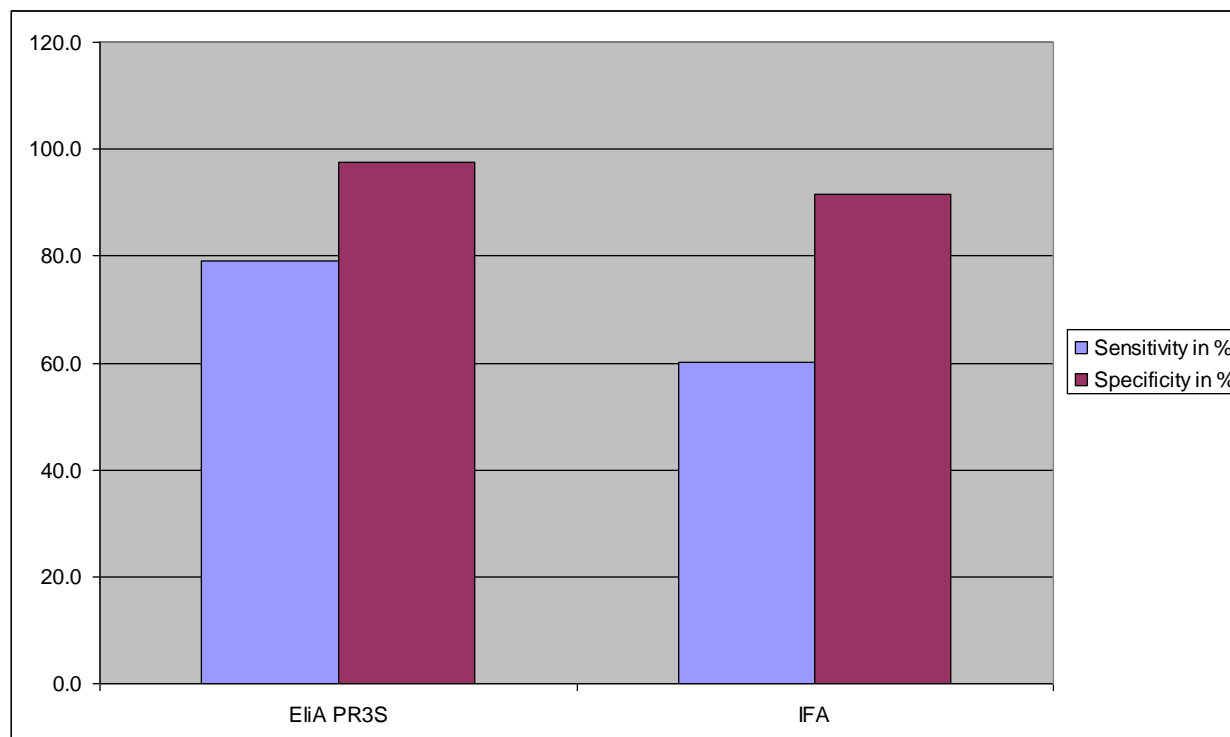
1. Compared to Indirect Immunofluorescence (IFA)

- The same panel of 350 clinically defined sera as mentioned before was used.
- Both sensitivity and specificity of EliA PR3^S are much better than of IFA.
- This is in contrast to the general opinion, that IFA is the most sensitive test for ANCA.
- The excellent performance of EliA PR3^S is a strong argument for using this test alone or at least in combination with IFA in the first step.

EliA PR3^S - Clinical Performance Compared to Competition

1. Compared to Indirect Immunofluorescence (IFA)

	EliA PR3 ^S	IFA
Sensitivity in %	79.0	60.0
Specificity in %	97.6	91.6



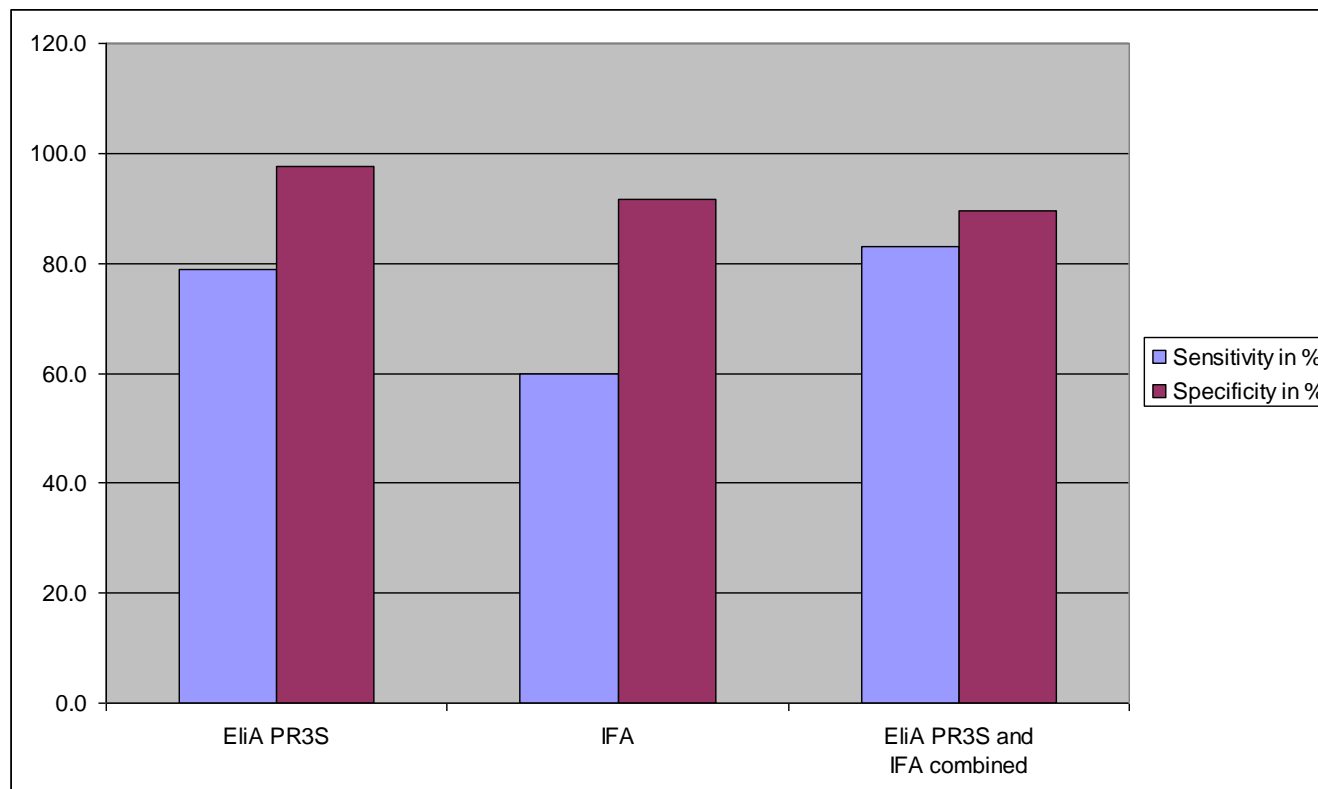
EliA PR3^S - Clinical Performance Compared to Competition

2. Clinical Performance in Combination With IFA

- The combination of EliA PR3^S with IFA increases sensitivity only slightly compared to EliA PR3^S alone.
- The combination of EliA PR3^S with IFA increases sensitivity dramatically compared to IFA alone.
- The combination of EliA PR3^S with IFA decreases specificity enormously compared to EliA PR3^S alone.
- However, because high specificity is extremely important in ANCA testing, EliA PR3^S alone is the best option for reliable detection of PR3 antibodies.

EliA PR3^S – Clinical Performance in Combination With IFA

	EliA PR3 ^S	IFA	EliA PR3 ^S and IFA combined
Sensitivity in %	79.0	60.0	83.0
Specificity in %	97.6	91.6	89.6

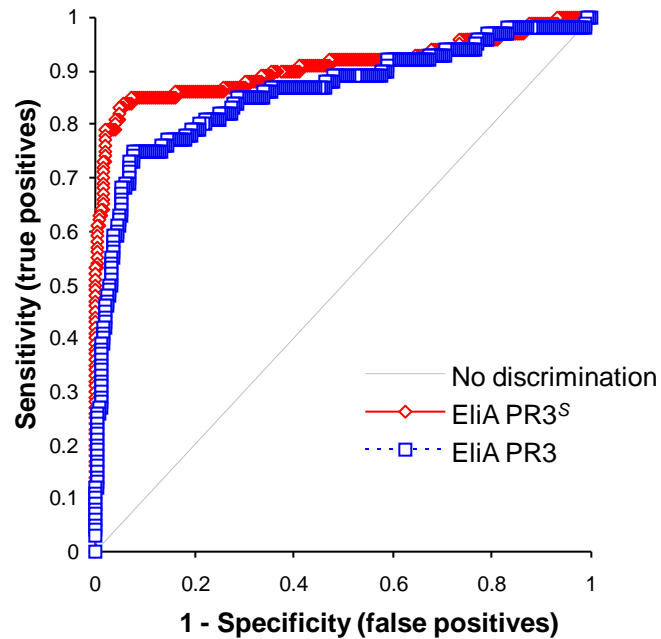


EliA PR3^S - Clinical Performance Compared to Competition

3. Compared to ELISA Competition

- The same panel of 350 clinically defined sera as mentioned before was used.
- EliA PR3^S is much more sensitive than the old EliA PR3 test.
- EliA PR3^S is even a bit more specific than the old EliA PR3 test.

EliA PR3^S – ROC Analysis compared to EliA PR3 (old)



- ROC Analysis EliA PR3^S performs much better than the old EliA PR3 test.

EliA PR3^S - Clinical Performance Summary

- EliA PR3^S shows dramatically increased sensitivity compared to the old EliA PR3 test.
- EliA PR3^S shows a slightly increased specificity compared to the old EliA PR3 test.
- EliA PR3^S shows the second highest specificity of all PR3 assays tested.

EliA PR3^S

**Find most of the Wegener's
patients and avoid wrong treatment**