

## ● PSA – Calibration and Molarity Study

Workshops in Portugal

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## PSA – Calibration and Molarity Study

- The Prostate Cancer Risk Management Programme requires all laboratories performing PSA tests under the Programme to use assays that are calibrated in terms of the WHO International Standards and which are equimolar in dose response

## PSA – Calibration and Molarity Study

- There needs to be an annual assessment of the PSA assays available to laboratories to determine those which satisfy the requirements of the Programme

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## PSA – Calibration and Molarity Study

- Two WHO International Standards for PSA are defined: 96/670 for total PSA (90:10) and 96/668 for Free PSA, both with a normal content of 1 ug/ampoule

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## PSA – Calibration and Molarity Study

- The annual distribution consists of three samples at one of three levels of total PSA

2 ng/mL

3 ng/mL

4 ng/mL

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## PSA – Calibration and Molarity Study

- The three samples for 2006 are at the 3 ng/mL concentration
- At each level the samples with consist of blends of 96/670 and 96/668 in the ratio of:

100% 96/670

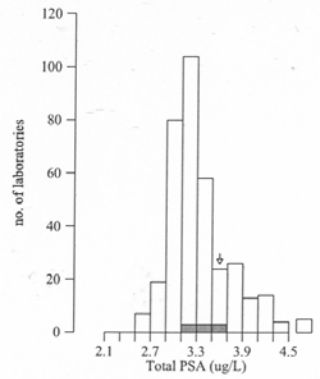
75% 96/670 + 25% 96/668

50% 96/670 + 50% 96/668

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Specimen : 0690

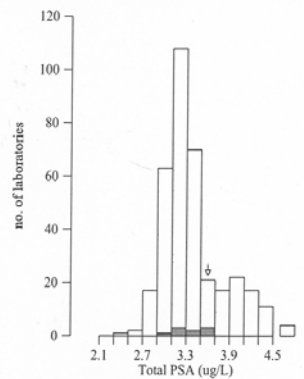
	n	Mean	SD	CV(%)
All methods	354	3.3	0.3	9.6
Abbott Architect	59	3.3	0.2	4.6
Abbott AxSYM	19	3.1	0.2	5.8
Bayer ADVIA Centaur	68	3.1	0.1	4.5
Beckman Access Hybritech	25	3.7	0.2	6.5
Dade Behring Opus	4	3.4	0.1	1.7
DPC Immulite 2000	49	4.0	0.3	6.9
DPC Immulite 2000 3rd Generation	9	3.4	0.2	5.8
DPC Immulite 3rd Generation	5	3.6	0.1	3.3
Roche E-170	79	3.2	0.1	2.9
Roche ELECSYS	15	3.1	0.3	9.1
TOSOH Eurogenetics	4	3.6	0.2	4.5



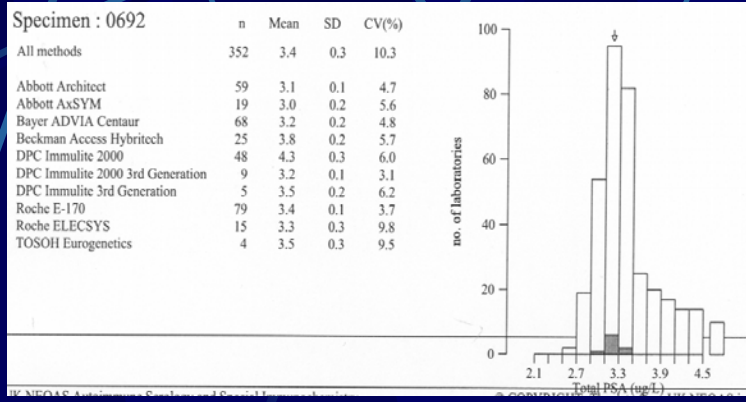
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Specimen : 0691

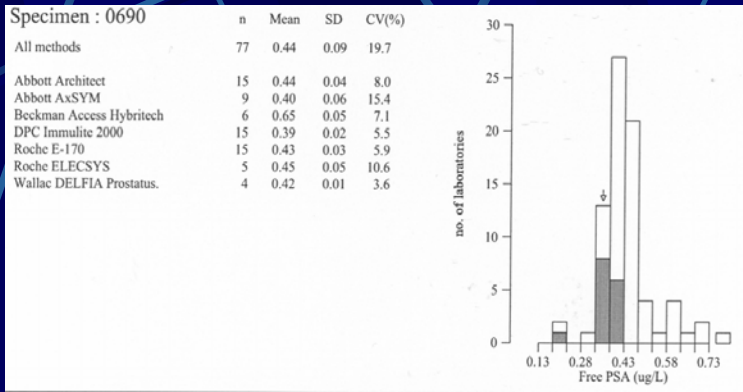
	n	Mean	SD	CV(%)
All methods	353	3.3	0.3	9.8
Abbott Architect	59	3.2	0.1	4.2
Abbott AxSYM	19	3.1	0.1	4.9
Bayer ADVIA Centaur	68	3.1	0.2	5.0
Beckman Access Hybritech	25	3.8	0.2	4.3
Dade Behring Opus	4	3.4	0.1	4.2
DPC Immulite 2000	49	4.2	0.2	5.3
DPC Immulite 2000 3rd Generation	9	3.4	0.2	6.1
DPC Immulite 3rd Generation	5	3.6	0.2	5.5
Roche E-170	78	3.3	0.1	3.0
Roche ELECSYS	15	3.2	0.3	9.5
TOSOH Eurogenetics	4	3.5	0.2	4.9



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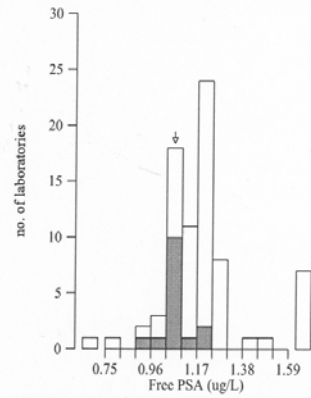
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Specimen : 0691

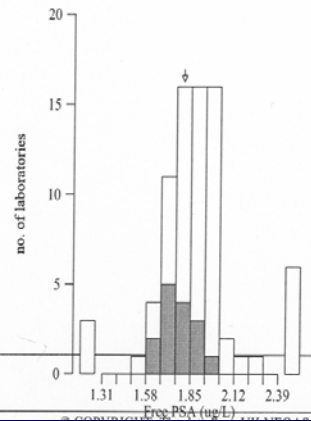
	n	Mean	SD	CV(%)
All methods	77	1.18	0.14	11.7
Abbott Architect	15	1.24	0.04	3.3
Abbott AxSYM	9	1.09	0.15	13.6
Beckman Access Hybritech	6	1.65	0.06	3.6
DPC Immulite 2000	15	1.10	0.05	4.8
Roche E-170	15	1.18	0.06	5.0
Roche ELECSYS	5	1.18	0.05	4.4
Wallac DELFIA Prostatus.	4	1.10	0.03	2.4



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Specimen : 0692

	n	Mean	SD	CV(%)
All methods	77	1.86	0.16	8.5
Abbott Architect	15	1.96	0.06	2.9
Abbott AxSYM	9	1.82	0.14	7.7
Beckman Access Hybritech	6	2.55	0.11	4.4
DPC Immulite 2000	15	1.79	0.10	5.4
Roche E-170	15	1.87	0.08	4.4
Roche ELECSYS	5	1.84	0.11	5.7
Wallac DELFIA Prostatus.	4	1.74	0.05	2.8



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# PSA – Calibration and Molarity Study

- Comparison of 6 Automated Assays for Total and Free Prostate-Specific Antigen with Special Reference to Their Reactivity toward the WHO 96/670 Reference Preparation
- Clinical Chemistry 52:8 1568 – 1574 (2006)

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# PSA – Calibration and Molarity Study

## Beckman Access

Clinical Chemistry Study      Approx  $\frac{12}{10}$  = 20% positive bias

UK NEQAS Study                       $\frac{3.7}{3.0}$  = 23% positive bias

Kort et al have presented plots rather than 'actual' values

Clinical Chemistry 52:8 1568 – 1574 (2006)

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## PSA – Calibration and Molarity Study

	Free PSA	Total PSA 3.0 µg/L	Ratio	Kort et al Ratio 2.5 µg/L
Beckman Access	0.65	3.7	0.176	0.16
Abbott AxSYM	0.40	3.1	0.13	0.11
Bayer Centaur	NR	3.1		0.12
Abbott Architect	0.44	3.3	0.13	0.13
Roche E-170	0.43	3.2	0.13	0.10
Immulin 2000	0.39	4.0	0.098	0.10

Clinical Chemistry 52:8 1568 – 1574 (2006)

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## PSA – Calibration and Molarity Study

- Differences among PSA assays appear to have decreased since introduction of the WHO 96/670 reference preparation but further efforts are needed to harmonise fPSA assays!

Clinical Chemistry 52:8 1568 – 1574 (2006)

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Information about the programmes  
can be found on website  
[www.immqas.org.uk](http://www.immqas.org.uk)

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