A commercial method suitable for measuring oestradiol in the concentration range 5 - 2000 pmol/L.

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Introduction

Measurement of serum oestradiol has attracted increased attention due to the possible link between low oestradiol concentrations in serum and risk of osteoporosis in the elderly.
Most oestradiol assays performed by modern automated immuno assay analysers are not designed to measure concentrations below 150 pmol/L[1,2].
Therefore, we have
1) examined the distribution of clinical oestadiol results produced by our automated routine method, Bayer Centaur Oestradiol-6.
2) compared the results obtained with the automated method with those obtained by a more sensitive method capable of measuring oestradiol concentrations down to 5 pmol/L, according to the manufacturer, Orion Diagnostica, Finland.
3) evaluated the performance of the sensitive manual radio immuno assay.
4) determined the reference intervals for men and post-menopausal women using the sensitive method.

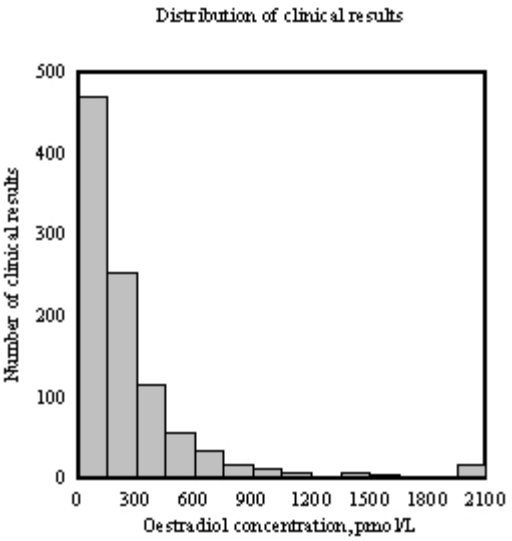
Methods

	Orion Sensitive Oestradiol RIA	Bayer Centaur Oestradiol-6
Dynamic range, pmol/L	5 - 2000	37 - 3700
No. of calibrators	6	master curve + 2
Sample volume, L	2 x 200	50
Analytical principle	competitive antibody binding	competitive antibody binding
Tracer	^{125}I-oestradiol	acridinium labelled oestradiol derivative
Degree of automation	manual method, once a day	fully automated, random access
Time to first result	4 hrs	20 min.

Results

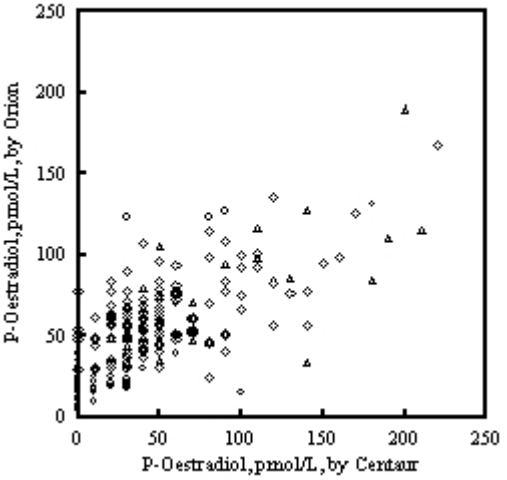
Distribution of clinical results obtained by the automated method.

From October 3rd. 2001 to March 22nd. 2002 our laboratory produced 990 oestradiol results by our routine Centaur Oestradiol-6 method. The distribution of these results are shown in the graph. 470 results (48 %) were below 150 pmol/L and 723 results (74 %) were below 300 pmol/L. Fourteen results were above 2000 pmol/L. ">" is missing in the graph.



Comparison of the Orion sensitive Oestradiol with Bayer Centaur Oestradiol-6 method.

203 sera with oestradiol concentrations below 250 pmol/L using the Centaur Oestradiol-6 were reanalysed using the Orion method. The correlation coefficient (r) was 0.69.



: Clinical samples; : Male blood donors;
: Post menopausal female blood donors

Day-to-day variations were estimated by analysing Bio-Rad Lyphocheck Immunoassay Plus Controls, Level 1, Level 2 and Level 3 in each run:

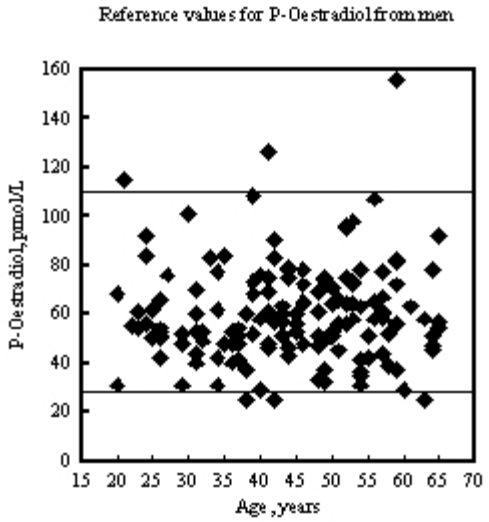
	Level 1, lot 40101		Level 2, lot 40102		Level 3, lot 40103	
Method	Centaur	Orion	Centaur	Orion	Centaur	Orion
n	294	19	297	17	293	19
Mean, pmol/L	280	115	620	291	920	599
SD, pmol/L	50	6,7	48	15,7	63	44,9
CV, %	17,8	5,9	7,7	5,4	6,8	7,5

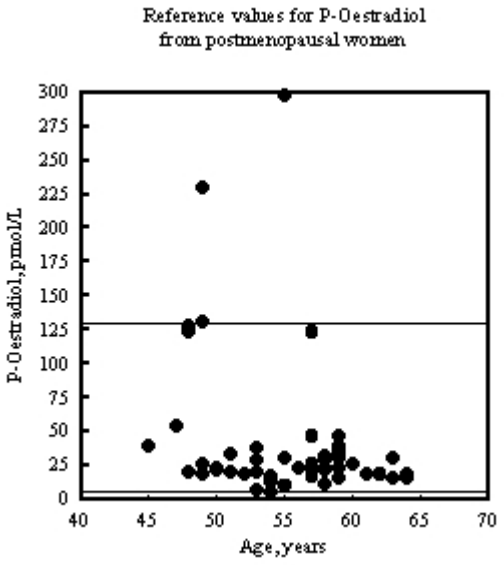
Although the Orion method is a manual method, it is more reproducible than the automated Centaur method at low concentrations of oestradiol.

Reference intervals.

The reference interval for men was determined by analysing blood from 147 male blood donors, aged 20-65 y employing non-parametric statistics.

The reference interval for postmenopausal women was determined by analysing blood from 51 female blood donors, more than 45 y old, not taking hormone replacement therapy and having a FSH above 20 U/L. These reference limits were determined by best clinical judgement.





	Our reference intervals by Orion's method, pmol/L	Orion's reference intervals, pmol/L	Bayer's reference intervals, pmol/L
Girls, 3 - 5 yrs,	-	< 36	-
Men	28 - 110	34 - 226	< 191
Post-menopausal women	6 - 130	11 - 50	< 136
Women, follicular phase	-	105 - 217	40 - 606
Women, mid cycle	-	416 - 1400	536 - 1930
Women, luteal phase	-	165 - 788	121 - 719

Comparison with UK NEQAS ALTM

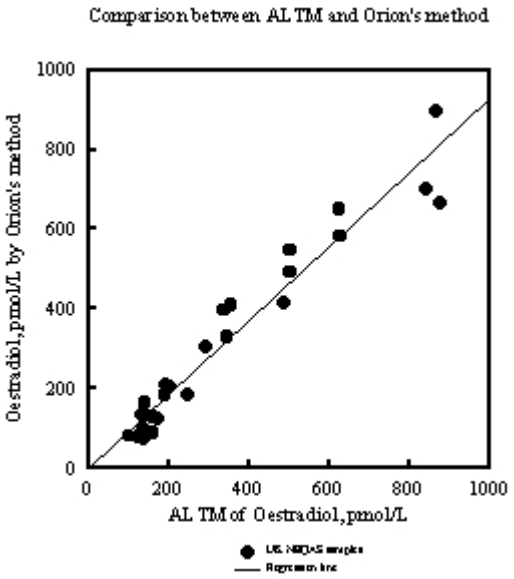
Twenty eight samples from the UK NEQAS Oestradiol scheme were analysed by the Orion method, and the results were evaluated by using linear regression.

The results were:

Intercept: -2,9 pmol/L

Slope: 0,93

Correlation coefficient (r): 0,97.



Conclusion

A mayor part (74 %) of our clinical results for oestradiol are below 300 pmol/L.

These samples might benefit by being analysed by a more sensitive and accurate method.

The Orion sensitive radio immuno method is suitable for measuring oestradiol in men and in post-menopausal women.

References

1) M. J. Wheeler: Automated immunoassay analysers. Ann Clin Biochem; 38: 217 - 229 (2001).

2) Jonathan Middle: UK NEQAS for Steroid Hormones, Annual Review November 2001 for Oestradiol, 33 - 38 (2001).

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