Drug Discovery Research Clinical Screening

DELFIA® fertility system Complete diagnosis for reproductive dysfunction





From the puberty to post-menopause

measurement hormones

In all types of infertility and gynaecology investigations, the unique Wallac DELFIA® system gives an unbeatable combination of advantages. Advantages which are appreciated by clinicians, by patients and by the laboratory staff of many of the world's foremost laboratories. Such laboratories have found that the DELFIA system, with its effective laboratory routines, provides the most direct path from the patient sample to the quality controlled result in the patient report.

The DELFIA system includes fully integrated measuring instruments, assay kits and computer software. You can choose between either fully automatic or modular versions; both are based on the same robust chemistry and allow extremely sensitive measurement. In terms of user convenience, DELFIA stands for minimal dilution of samples, short assay times and pleasing user interfaces.

Non-radioactive, and truly walk-away, the DELFIA system covers all reproductive hormones of major importance to clinical laboratories.

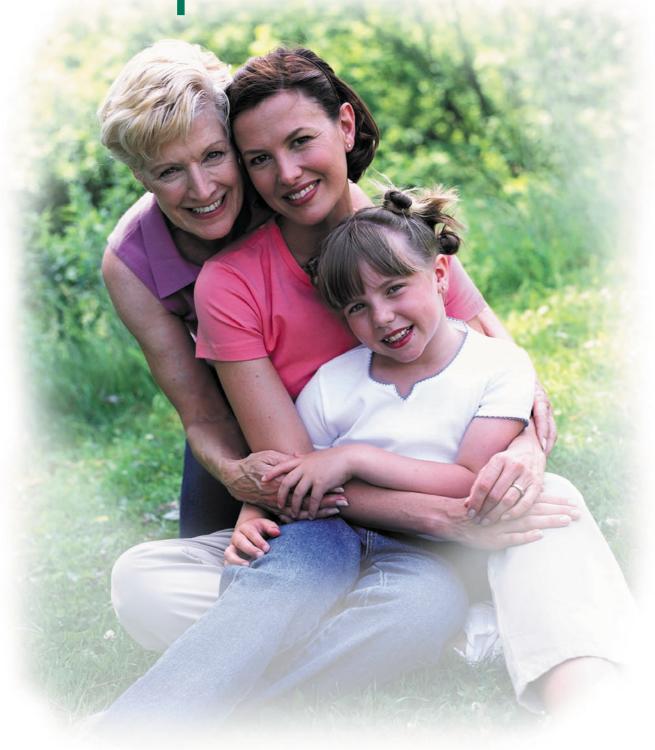
From PerkinElmer Life Sciences

PerkinElmer Life Sciences offers a unique combination of skills in label-assay measurement. The company's Wallac DELFIA system, based on time-resolved fluorometry has gained a substantial share of the market for endocrinology testing.

Our services and products represent the highest standards of quality. We have long worked according to GMP guidelines and were amongst the first companies in the field to embrace the ISO 9000 standard. Our operations, covering all of our products, instruments, kits, reagents and software, are certified to meet the most stringent of the ISO 9000 series standards, ISO 9001: 2000.

e the DELFIA® system stands for quality in the

of reproductive

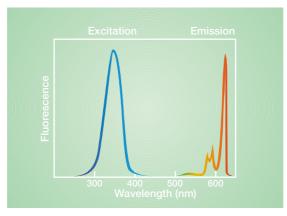


Today's exciting alternative for your laboratory

The Wallac DELFIA system is based on unique time-resolved fluorometry (TRF) measuring technology employing europium chelate labels. Conjugation of these involves mild labelling procedures, the basis for highly specific immunoassays with the best correlation to biological activity. Other important quality indicators are the extreme sensitivity and wide dynamic range that characterize DELFIA assays.

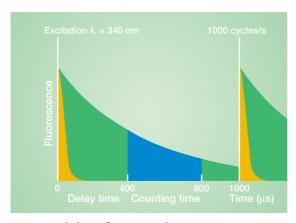
Why is time-resolved fluorometry far more sensitive?

Signal resolution by wavelength



Europium chelates have far wider Stokes shift than commonly used conventional fluorophores. This means that the wavelength of the emitted light is as much as 200-300 nm longer than that of the excitation light used.

Signal resolution by time



Europium chelates' fluorescence lasts 200,000 times longer than fluorescence from a conventional fluorophore. Time-resolved measurement starts only after non-specific background has died away.

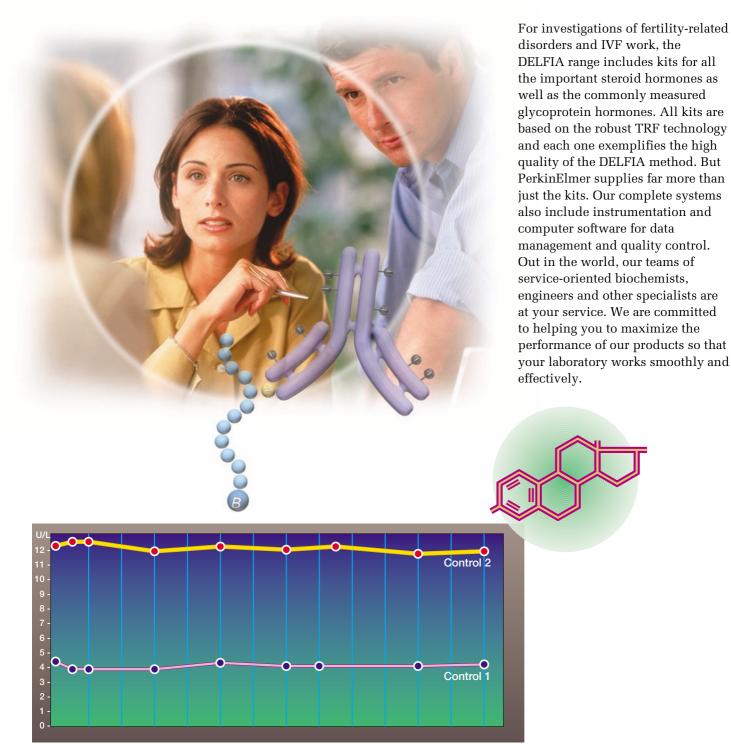
High sensitivity for critical infertility measurements

In many fertility-related conditions assay sensitivity is essential. The DELFIA system meets the most stringent sensitivity needs. At the same time, the method provides an extremely wide dynamic range. This means that you seldom need to dilute samples, and a time-consuming assay step and a source of error are both eliminated.

	Sensitivity	Range
hCG	0.5 U/L	0.5 - 10,000 U/L
hLH Spec	0.05 U/L	0.05 - 250 U/L
hFSH	0.05 U/L	0.05 - 256 U/L
Prolactin	0.04 ng/mL	0.04 - 250 ng/mL
Estradiol	0.05 nmol/L	0.05 - 15 nmol/L
Progesterone	0.8 nmol/L	0.8 - 120 nmol/L
Testosterone	0.3 nmol/L	0.3 - 65 nmol/L
SHBG	0.5 nmol/L	0.5 - 200 nmol/L

Sensitivity and wide dynamic range are characteristics shared by DELFIA® kits for all of the most important infertility analytes.

A complete system for all the glycoprotein and steroid hormones of importance in fertility investigations



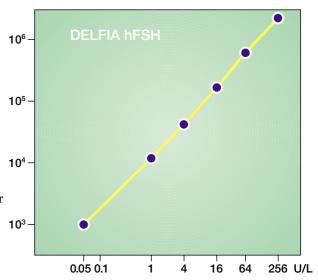
DELFIA® reagents are characterized by long shelf lives and exellent reproducibility.

Measurements with the DELFIA® system show good correlation with biological activity

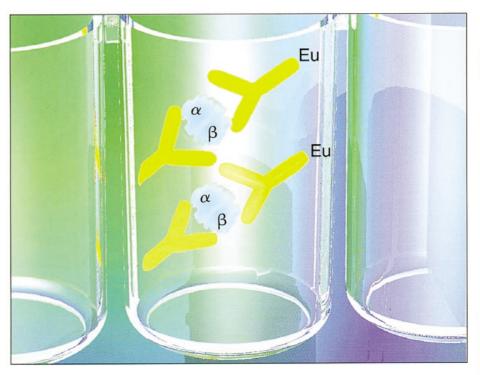
Many reproductive hormone immunoassays may be highly specific but still fall short in covering the biologically active gonadotrophin forms. The new generation immunoassays such as DELFIA hLH Spec and DELFIA hFSH have been shown to provide the best index of hormone activity.

There are two main reasons for this. One is the sensitivity resulting from the use of europium chelates and time-resolved fluorometry. The detection limit for the DELFIA LH Spec kit is shown by the manufacturer to be 0.05 U/L. The corresponding figure for DELFIA hFSH is also 0.05 U/L. Recent independent studies have set detection limits even lower.

The other reason for the good correlation between DELFIA assays and biological activity is the type of monoclonal antibodies used. Careful selection of the right antibodies has made it possible to produce kits with high specificity, detecting the biologically active forms of the hormones being measured.



DELFIA® hFSH allows direct measurement of samples with hormone concentrations from 0.05 to 256 U/L.



DELFIA® assays for glycoprotein hormones are based on a non-competitive sandwich-type design which imparts high sensitivity.

The sensitivity you need for investigation of reproductive dysfunction

For delayed or precocious puberty

High sensitivity in gonadotrophin testing is a number one requirement when investigating onset of puberty. The sensitivities achievable using the DELFIA hLH Spec kit make it highly suitable for distinguishing between constitutional factors and gonadotrophin deficiency in delayed puberty. Also important in this situation is DELFIA Estradiol. These highly sensitive kits allow earlier and better diagnoses. In the case of precocious puberty, DELFIA hLH Spec provides the best tool for reliable monitoring of treatment.



For IVF and menstrual disorders

Whether your need is for pinpointing ovulation time, for determining the causes of male or female infertility, or for investigating menstrual disorders, DELFIA products deliver your answer. For in-vitro fertilization DELFIA kits for Estradiol, Progesterone, hLH and hCG are considered the best tools available. DELFIA Estradiol with its special fast protocol allows results while your patient waits. For menstrual disorders, DELFIA Prolactin is also an extremely valuable tool.

For hyperandrogenism

Wallac offers DELFIA kits for both testosterone and sex hormone binding globulin (SHBG). Together these provide a reliable index of a patient's androgen status. The DELFIA kit for SHBG is unique in being supported by the availability of control samples.

For diagnosis of menopause

For the elderly woman, proper diagnostics of menopausal status by determination of FSH is crucial not only for preventive treatment of osteoporosis but also for hormone replacement therapies in general. The sensitive DELFIA kit for estradiol is an excellent tool in helping to improve the quality of your patient's life.

For trophoblastic disease

Complementing the extensive range of kits for tumour markers, our DELFIA hCG kit is useful both in the early detection of placental tumour, and in monitoring of treatment.

Another example where the unique properties of DELFIA assays lead to real clinical benefits is in the measurement of prolactin in prolactinomas. The unusually wide dynamic range for the DELFIA Prolactin kit makes it possible to measure the high prolactin concentrations produced by this tumour directly.

The complete DELFIA® system

DELFIA assays are performed by the fully automatic 1235 AutoDELFIA® system or by a modular system including the VICTOR $_{\text{\tiny TM}}^2D$ fluorometer.

DELFIA kits are available for the most commonly measured endocrinology analytes. Within the field of reproductive dysfunction, kits are currently available for the following analytes

- hLH Spec
- hFSH
- hCG
- Prolactin
- Progesterone
- Estradiol
- Testosterone
- SHBG

Data management, comprehensive quality control and computer / network connections are performed by MultiCalc® software.

All products may not be available in certain countries. For information on availability please contact your local representative.





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