

DIAGNOSTICS

BOOTS-CELLTECH LAUNCHES FERTILITY TEST

LONDON—Before AIDS, the prospects for condom manufacturers were unexciting enough that diversification made sense. That is one reason why London International, which markets leading U.K. brands of condoms, has been funding Boots-Celltech Diagnostics (Slough, U.K.) to develop a new monoclonal-antibody based ovulation predictor. It will be some time before the test, which measures the ratio of two hormones in urine, is available for home use, but it has just been launched in Britain for investigation of infertility.

Based on an invention by Boots-Celltech's director of research, Terry Baker, while he was still an academic, the test is an enzyme-linked immunoassay for the simultaneous detection of an estradiol metabolite, estrone-3 β -D-glucuronide, and a progesterone metabolite, pregnanediol-3 α -glucuronide. The ratio of the former to the latter peaks at about mid-cycle, the time of ovulation.

Baker's invention, and the key to the test, is the "mixed steroid antigen"—the two metabolites chemically coupled through their glucuronides via a six-carbon bridge—synthesized at Boots-Celltech. In the test, this compound is allowed to compete with the two metabolites in a urine sample in two simultaneous immunoassays carried out in a well of a microtiter plate. A monoclonal antibody to the progesterone metabolite coats the wall of the well; an antibody to the estradiol metabolite is in solution. When these reactions are completed, an enzyme-linked monoclonal antibody to the estradiol metabolite is used to assay the mixed steroid antigen attached to the wall of the well. The greater the ratio of the estradiol to the progesterone metabolite, the stronger the signal—a blue color.

In the investigation of infertility, the test will be used to screen for abnormal ovarian function, detected by a lack of blue color in mid-cycle urine samples. At present, the test is only suitable for laboratory use, and will cost around \$1.50 a well. But Boots-Celltech is confident that it can be adapted to dip-stick form for use at home. And since the ratio of metabolites begins to be detectable some days before ovulation, home users should be able to predict when conception is likely. The company believes that the ratio of hormone metabolites is a much better predictor of ovulation than is the concentration of urinary luteinizing hormone.

Boots-Celltech holds U.S. and Eu-

ropean patents on the test and has filed elsewhere. Royalties of a few percent on sales to clinics will be paid to the Middlesex Hospital (London), where Baker and his colleagues devised the test's prototype, to the World Health Organization, which was funding them at the time, and to London International, which has financed development. London International also has the marketing skills for home sales, and is expected to

share the proceeds of the home-use version of the test.

While originally hopeful that the mixed antigen principle would have other applications, Baker admits that none has emerged. The ovarian function test, itself, is likely to be the most profitable yet for Boots-Celltech. The company's chief executive, C. T. Hallam, "conservatively" estimates annual worldwide sales of \$15 million for the clinic test. —Peter Newmark

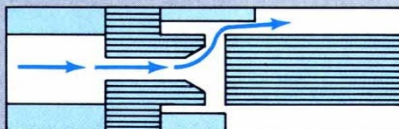
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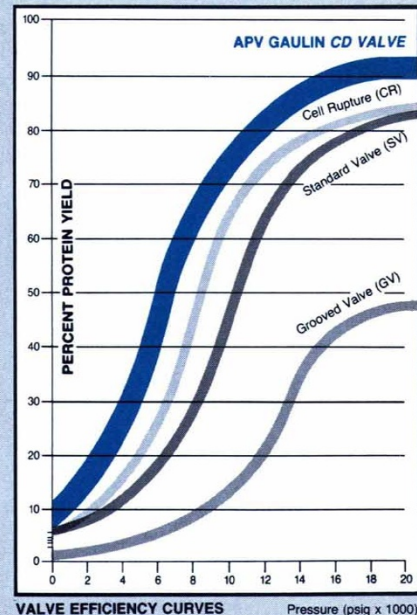
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