OraChrom, Inc.

The Vanguard of Liquid Chromatography.

10-B Henshaw Street Woburn, MA 01801 USA

Phone (781) 932 0151 Fax (781) 932 0787 *E-mail:* info@orachrom.com www.orachrom.com

APPLICATION NOTE

Fast Detection of XELODA (Capecitabine) in Urine Sample with STYROS™ 2R/XH.

XELODA or Capecitabine is a drug with antineoplastic activity. It is bioactivated after ingestion from the gastrointestinal tract to 5-fluorouracil in the following metabolic pathway:

5-Fluorouracil is further metabolized at the cell level, to 5-fluoro-2'-deoxyuridine monophosphate and

5-fluorouridine triphosphate.

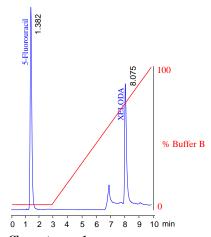
The oncologist is presently guided by the side effects of the drug and their severity, in prescribing the optimum dosage.

An alternative would have been the monitoring of the excess drug in the patient's urine or blood sample after ingestion of the prescribed drug dose.

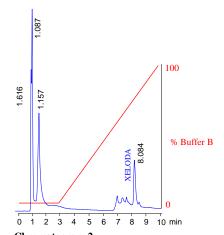
The following chromatograms show fast separations of the non metabolized excess Capecitabine in the patient's urine specimen as well as a standard separation of a mixture of XELODA (Capecitabine) and 5-Fluorouracil.

The absence of 5-Fluorouracil at 1.38 min., as well as the presence of the non metabolized excess drug at 8.08 min provide useful information to the treating physician.

Such test can be run in a short period of time under basic chromatographic conditions.



Chromatogram 1 STYROS™ 2R/XH 4.6 X 150 mm Mixture of XELODA and 5-Fluorouracil



Chromatogram 2
STYROS™ 2R/XH 4.6 X 150 mm
Urine sample during treatment

Table 1. Operating parameters for the chromatograms.

HPLC System.	HP 1100
Column	STYROS™ 2R/XH 4.6 X 150 mm
Mobile Phase	A: 0.1% TFA in H2O
	B: 0.1% TFA in ACN:H2O (95:5)
Flow rate	1 ml/min (360 cm/hr)
Gradient	3% B for 3 min., to 100% B in 12 min.
Temperature	37°C
Detection	214 nm
Injection volume	25 μl
Sample:	As indicated.