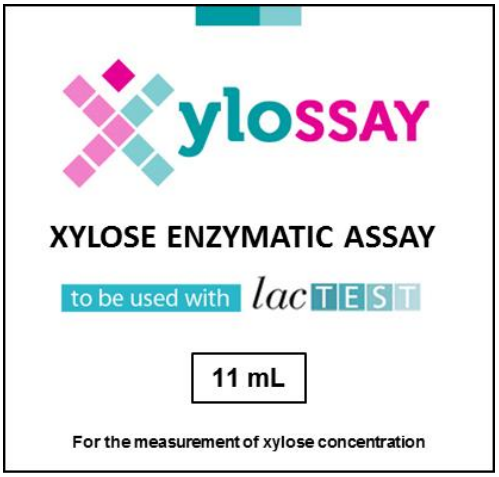
REF: 760XYLK-11ML



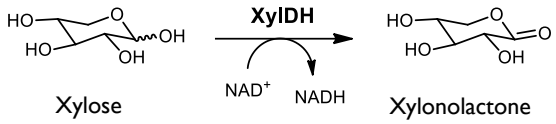
IVD CE

DESCRIPTION:

Xylossay® is a reliable and automatable method for the quantification of xylose present in urine. **Xylossay®** is the recommended method for xylose detection after the administration of **LacTEST 0.45 g.**

METHOD RATIONALE:

The enzyme xylose dehydrogenase (XylDH)[1] catalyzes the specific oxidation of xylose to yield xylonolactone[2]. As XylDH is a NAD^+ dependent enzyme, this reaction requires a concomitant reduction of this cofactor to NADH:



Production of NADH can be spectrophotometrically detected and quantified by the increase of the absorbance at 340 nm during the reaction. This way, absorbance increments will be directly proportional to the amount of xylose present in the sample.

COMPONENTS OF THE KIT:

Xylossay® is supplied in a format suitable for performing approximately 50 xylose determinations. The number of determinations can vary depending on the automated analyzer used (consult the website: **www.venterpharma.com/xylossay/).** Each kit contains a vial of each one of the following components:

VIAL	CONTENT AND FORMAT	AMOUNT
Brown	Phosphate buffer, 50 mM, pH 8.0 (Solution)	11 mL
Orange	β-Nicotinamide Adenine Dinucleotide (NAD^+) (Lyophilized)	33.17 mg ± 12%
Purple	D-Xylose Dehydrogenase (Lyophilized)	0.3 mg ± 10%
Pink	Calibrator: D-(+)-Xylose (Solution)	2 mL; 3.75 mg/dL ± 5%.

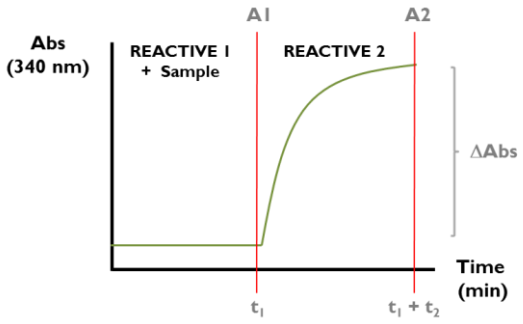
1. Sánchez-Moreno, I. *et al. J. Biotechnol.* (2016) 234:50-57.
2. Stephens, C. *et al. J. Bacteriol.* (2007) 189:2181-2185.

PREPARATION OF REAGENTS AND PROTOCOLS:

The preparation of the reagents as well as the assay protocol of **Xylossay®** application depend on the automated analyzer used, having specific modifications in function of its operational characteristics. To obtain the specific protocol for your automated analyzer, please download or consult the document on the website **www.venterpharma.com/xylossay/.**

ASSAY AND ANALYTICAL PERFORMANCE:

Absorbance values (340 nm) per assay:



A1 = Initial absorbance of the mixture **REACTIVE 1** + Sample (t_1 min).

A2 = Final absorbance after adding **REACTIVE 2** (t_1 + t_2 min).

Differences between the two absorbance values will be proportional to xylose concentration, which can be calculated using the standard xylose solution provided with the kit (Xylose standard solution, pink vial):

ΔAbsorbance (340 nm) = ΔAbs = A2 - A1

Sample concentration = [*Sample*] (*mg/dL*)

Xylose concentration (Calibrator) = *3.75 mg/dL*

$$[Sample] = \frac{\Delta Abs\ (Sample)}{\Delta Abs\ (Calibrator)}\ x\ 3.75\ mg/dL$$

The total amount of xylose in the Sample (mg) can be calculated using the total volume of urine collected during the test.

$$Xylose\ (mg) = [Sample]\ x\ Volume\ of\ Sample\ (dL)$$

The analytical parameters established for **Xylossay®** can slightly vary in function of the characteristics of the equipment used (see website **www.venterpharma.com/xylossay/**).

CONSERVATION AND STABILITY:

Xylossay® must be stored at temperatures between 4° and 8°C until use, being stable under these conditions for at least 18 months. After being prepared, REACTIVES 1 and 2 are stable for at least 39 days when maintained at temperatures between 4 and 10°C (stability in automated equipments). Both REACTIVE 1 and REACTIVE 2 can be frozen at -20°C without any activity loss. Both reagents can be frozen and thawed at least 6 times without altering their function.

REFERENCE VALUES:

Normal values in adults:

Test	Xylose in urine (mg)
LacTEST 0.45 g	≥ 19.18

Values below 19.18 mg indicate hypolactasia.

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