



## **C-14 HELICOBACTERIA PYLORI TEST WITH 300 SL TDCR LSC**

<sup>14</sup>C-labeled urea in breath samples can be measured using Hidex 300 SL to identify the presence of the *H. pylori* bacterium.

### ***Introduction and assay principle***

The patient swallows a capsule containing a small amount of <sup>14</sup>C-labeled urea. If the <sup>14</sup>C-urea comes into contact with *H. pylori* in the stomach, it is hydrolyzed into <sup>14</sup>C-carbon dioxide and ammonia. The carbon dioxide enters the bloodstream and is exhaled by the patient. Ten minutes after ingesting the capsule, a breath sample is collected in a mylar balloon. The contents of the balloon are transferred into a breath collection fluid, then liquid scintillation cocktail is added to complete the solution. The breath sample can be analyzed using Hidex 300 SL with capacity of max. 40 samples/run. The measurement of each sample takes 3 minutes. If the breath sample contains <sup>14</sup>C, the patient has *H. pylori* (*High DPM*). If *H. pylori* is not present, the <sup>14</sup>C-Urea is hydrolyzed and is excreted in the urine (*Low DPM*). The raw data can be viewed during counting. The final data is analyzed automatically after completing the run to obtain quench corrected DPM values and results classified as positive/ negative/ indeterminate. The instrument control and data reduction is performed using 21 CFR Part11 compliant MS Windows based MikroWin 2000 software.

### ***Materials and Method***

<i>Sample</i>	Typically 2.5 mL CO <sub>2</sub> collection fluid added with 5 – 10 mL scintillation cocktail in 20 mL plastic vial.
<i>Protocol</i>	According to “Breath test.par” available at Hidex 300 SL parameter library. BACKGROUND Standard into A1. C14 Standard (e.g. 20,000 DPM) into A2 All Patient samples are inserted into remaining positions. Isotope: C-14, ROI: 1, Channel limits: 5 – 650 Type: beta, Tray size: 8 X 5, Activity type: standard Counting time: 180 sec



**Results and Discussion**

Figure shows an example of patient assay results on matrix format: Counting efficiency, Background, CPM-Background, DPM & classification as Positive (POS) / Negative (neg) / Indeterminate (???)

Measurement file : Breath test 20090911#3.dat		Valid Assay					Measurement date : 11.9.2009		
Template file : Breath Test.par							Measurement time : 14:11:28		
		----- %Eff Bkg / CPM-Bkg / DPM / Screening -----							
	1	2	3	4	5	6	7	8	
A	%Eff = 0	69.2 13488 C-14 Std 19500	Background= 4 6 neg	21.0 1035 1496 POS	2 3 neg	3478 5028 POS	94 136 ???	1 1 neg	
B	4 6 neg	12 17 neg	2 3 neg	109 158 ???	2 3 neg	0 0 neg	10 14 neg	6 9 neg	
C	3 4 neg	104 150 ???	2 3 neg	36 52 ???	2 3 neg	1 1 neg	11 16 neg	4606 6659 POS	
D	150 217 POS	27 39 neg	19 27 neg	2 3 neg	1 1 neg	22 32 neg	35 51 ???	0 0 neg	
E	5 7 neg	8 12 neg	0 0 neg	14 20 neg	58 84 ???	16 23 neg	29 42 neg	10 14 neg	

*Test criteria* <50 DPM is a NEG

>200 DPM is a POS and

50-200 DPM is an indeterminate.

An indeterminate results in a retest of that Patient sample. This may be due to incorrect fasting prior to the test etc by the Patient (Drinking Coffee, eating Breakfast, etc.). The Breath Test is Quasi Quantative. That being that depending on the degree of infection Patient results can be in the low '00's to mid '000's DPM for Positives.

**Advantages of Hidex 300 SL**

- External radioactive standard is not needed because results are automatically quench corrected using standard sample (constant quench) or TDCR method (variable quench).
- Reduced counting time down to 3 min/sample instead of around 5 min/sample in conventional counters with 2 PMTs.
- 21 CFR Part11 compliant MikroWin software with predefined test protocols, easy-to-use MS Windows based user interface and automatic data reduction and reporting.



## Application note

HIDEX 300 SL™

DOC 413-002

Version 1.1

### Ordering information:

Code No	Description
425-201	Hidex 300 SL automatic TDCR LSC
463-130	20 mL Vials
461-008	5 L Aqualight cocktail

C-14 urea capsules, balloons and trapping solution are available from reagent manufacturers locally.

### Product Information

Finland and International Hidex Oy, Tel. +358 2 2750557, fax +358 2 2410075, [info@hidex.com](mailto:info@hidex.com),  
[www.hidex.com](http://www.hidex.com)