General Information

Intended use:

H. pylori Turbilatex is a latex turbidimetric **assay only for the quantitative detection of *Helicobacter pylori antigen* in human stool samples** (not to be used for body fluid as blood, serum, plasma, urine, cerebrospinal fluid, oral fluid, synovial fluid or empyema fluid). This assay is simple and widely applicable.

For professional *in vitro* diagnostic use only.

H. pylori Turbilatex can be performed on every open chemistry analyser. Please follow the subsequent instructions in order to assure performance characteristics as describes in the instructions for use. This instruction has been validated by CerTest BIOTEC S.L. Laboratories.

Additionally, please read the "Instructions for use" for instructions on operating and programming user defined test.

Reagents:

Materials provided by CerTest BIOTEC S.L.:

Reagents	Quantity	Code
Turbidimetric reagents (R1 & R2) 200 Det/kit	R1: 2 vials, 2x33 mL R2: 1 vial, 1x7 mL	TL-022HP01 TL-022HP02
Auxiliary Reagents		
Calibration kit	Calibrator: 6 vials, 6x1 mL.	TL-022HP70, TL-022HP71 TL-022HP72 TL-022HP73 TL-022HP74 TL-022HP75
Controls kit	Control C1, 2 vials, 2x1 mL/vial. Control C2, 2 vials, 2x 1 mL/vial.	TL-022HP08 TL-022HP09
Sample diluent kit	4 vials, 4x125 mL/vial	TL-022HP03E
Sample dilutions vials	1x2 mL/vial 1x2.4 mL/vial	MST-0014MP MST-0020P

Preparation of reagents:

R1 and R2 are ready to use.

Calibrators are ready to use

Controls are ready to use.

Storage and stability

Kit components must be stored at temperature indicated on the label. Do not freeze.

Reagents are stable up to the expiration date printed on the label, always considering that reagent containers must be properly closed to avoid any contamination, must be kept away from the sunlight and conserved at temperature indicated on the label of each reagent.

Specimen:

Collect enough quantity of human stool samples. These samples should be collected in clean and dry containers (no preservatives or transport media). The samples can be stored in the refrigerator (2-8ºC) for 7 days prior to testing. Homogenise stool samples as thoroughly as possible prior to preparation.

The sample dilution vial with diluted sample can be stored for 7 days in the refrigerator (2-8ºC) prior to testing.

Use H.pylori Turbilatex stool collection tubes for sample collections described the instructions for use.

Assay procedure

Application parameter set up:

Specific analyzers settings for H. pylori Turbilatex must be programmed onto the analyzer, see below. For instructions, consult the AU480/AU680 (Beckman Coulter) analyzer manual and instructions for use provided with the kit.

Loading of reagents:

Load reagents according to the AU480/AU680 (Beckman Coulter) analyzer manual.

Calibration curve establishment:

A 6 point calibration curve can be established in AU480/AU680 (Beckman Coulter) analyzer. For instructions consult analyzer manual.

Calibration stability:

Calibrate the system at least once a month is extremely recommended. Recalibrate the system when reagent lot is change or when the controls are out of the assigned range given in the control labels and CoA.

QC controls:

H. pylori Turbilatex controls C1 and C2 must be assayed each day before running patient faecal sample extract to validate the calibration curve. The controls have assigned value ranges indicated on the label and certificate of analysis supplied. The control measurements must be within the indicated value range to obtain valid results for patient faecal extract. If the control values are out of range, follow next procedures: 1) Repeat QC control measurement, 2) Repeat calibration measurement.

Results:

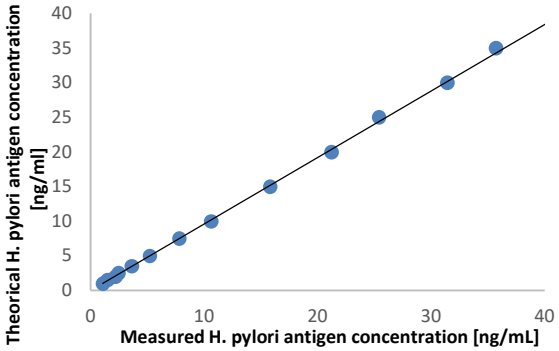
The results are evaluated automatically by the analyzer and presented in ng H.pylori antigen/mL.

Performance characteristics

The following results have been obtained during the validation of H.pylori Turbilatex on the AU480/AU680 (Beckman Coulter) analyzer.

Linearity:

H. pylori Turbilatex on AU480/AU680 (Beckman Coulter) analyzer using calibrator kit is linear in the calibration range of 0-40 ng H.pylori antigen/mL.



Measuring range:

H.pylori Turbilatex assay measuring range is 0.8-40 ng H.pylori antigen/ml on the AU480/AU680 (Beckman Coulter) analyser. Samples higher concentrated than 40 ng H.pylori antigen/mL of stool must be diluted for proper quantification by the user, using additional sample buffer.

Prozone effect

Using the reported parameters, no prozone effect (hook effect) was observed up to 0.2 mg *H. pylori* antigen/mL of stool. Samples with H. pylori antigen concentration of 0.2 mg H. pylori antigen/mL give a typical positive result >40 ng H.pylori antigen/mL.

Detection limit

Limit of detection (LOD): 0.8 ng H. pylori antigen/ml. The lower limit of detection of H. pylori Turbilatex was determined on 20 samples and 2 sample replicates as the mean value + 2xSD.

Limit of quantification (LOQ): 1 ng H. pylori antigen/mL. The lower limit of quantification is defined as the lowest actual amount of analysis that can be reliably detected; imprecision is < 20% as CV% on the AU480/AU680 (Beckman Coulter) analyzer.

Precision

H. pylori Turbilatex was tested with three different controls levels.

	Low (1 ng/mL)	Medium (10 ng/mL)	High (40 ng/mL)
N	20	20	20
Mean (ng/mL)	1.08	10.23	39.76
SD (ng/mL)	0.12	0.79	2.01
CV (%)	11	8	5

Method comparison

Results obtained with H. pylori Turbilatex on the AU480/AU680 (Beckman Coulter) analyzer were compared with an immunochromatographic test (CerTest *H. pylori*, CerTest). The results were as follows:

	Sensitivity	Specificity
H. pylori Turbilatexvs CerTest H. pylori	**86.5%**	**>98%**

Shipping damage

Please notify your distributor, it this product was received damaged.

Symbols key

IVD	For *in vitro* diagnostic use only		Keep dry
	Consult instructions for use		Temperature limitation
REF	Catalogue number	LOT	Lot number
	Use by		Manufacturer
Σ n	Contains sufficient for <n> test	DIL	Sample diluent
	Keep out of the sunlight		

Manufacturer

CERTEST BIOTEC S.L.

Pol. Industrial Río Gállego II,Calle J, Nº 1, 50840,
San Mateo de Gállego, Zaragoza (SPAIN)
www.certest.es

NOTES

Please refer to the instruction for use for the detailed information about the test on the following:
Synthesis; Principle; Precautions; Reagents; Specimen collection and preparation; Interpretation of results and limitations.

AU480/AU680 (Beckman Coulter)/Application parameters

ASSAY PARAMETERS	
Std. No	6
R1	150 µL
Sample	7.5 µL
R2	12.5 µL
Others	NA
Reaction mode	Endpoint
Primary wavelength	450 nm
Secondary wavelength	800 nm
Direction	Increase
Reagent blank lecture	11 cycle
Final lecture	27 cycle
Reaction time	10 min
Linear range	0-40 ng/ml
CALIBRATION	
Calibration Method	Linear
Calibration set	5 calibrators + Blank
Blank	Calibrator 1 (0 ng/ml)
Calibrator 1	Calibrator 2 (2.5 ng/ml)
Calibrator 2	Calibrator 3 (5 ng/ml)
Calibrator 3	Calibrator 4 (10 ng/ml)
Calibrator 4	Calibrator 5 (20 ng/ml)
Calibrator 5	Calibrator 6 (40 ng/ml)
STEPS	
Addition R1	
Addition Sample	
Incubation	
Addition R2	
Blank Lecture	Cycle 11
Incubation	
Final lecture	Cycle 27