

General Information

Intended use:

H. pylori Turbilatex is a latex turbidimetric assay **for the quantitative detection of *Helicobacter pylori* antigen in human stool samples**. 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: 5 vials, 5x14 mL R2: 1 vial, 1x6 mL	TL-022HP01C TL-022HP02C
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.	TL-022HP08
	Control C2, 2 vials, 2x 1 mL/vial.	TL-022HP09
Sample dilutions vials	1x2 mL/vial	MST-0014MP
	1x2,4 mL/vial	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 (2-8°C) 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 (2-8°C) 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 ChemWell®-T (Awareness Technology Inc.) analyzer manual and instructions for use provided with the kit.

Loading of reagents:

Load reagents according to the ChemWell®-T (Awareness Technology) analyzer manual.

Calibration curve establishment:

A 6 point calibration curve can be established in ChemWell®-T (Awareness Technology Inc.) 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 fecal 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 fecal extract. If the control values are out of range, follow next procedures: 1) Repeat QC control measurement, 2) Repeat calibration measurement.

Results:

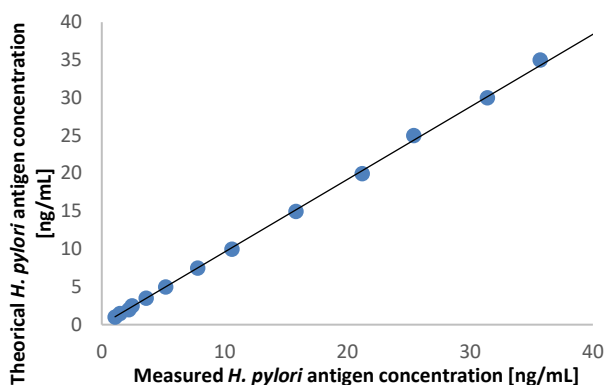
The results are evaluated automatically by the analyzer and presented in ng *H. pylori* antigen/mL.

Performance characteristics

The following results have been obtained during the validation of H. pylori Turbilatex on the ChemWell®-T (Awareness Technology Inc.) analyzer.

Linearity:

H. pylori Turbilatex on ChemWell®-T (Awareness Technology Inc.) 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 2.5-40 ng H. pylori antigen/mL on the ChemWell®-T (Awareness Technology Inc.) analyzer. 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): 1 ng H. pylori antigen/mL (*). The lower limit of detection of H. pylori Turbilatex was determined on 10 samples and 2 sample replicates as the mean value + 2·SD.

Limit of quantification (LOQ): 2.5 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 ChemWell®-T (Awareness Technology Inc.) analyzer.

(* Data obtained by the analyser Biolis 24i (Tokyo Boeki)

Precision

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

	Low (2.5 ng/mL)	Medium (10 ng/mL)	High (40 ng/mL)
N	10	10	10
Mean (ng/mL)	2.67	9.75	40.05
SD (ng/mL)	0.19	0.55	2.38
CV (%)	7.1	5.6	5.9

Method comparison

Results obtained with H. pylori Turbilatex on the analyser Biolis 24i (Tokyo Boeki) 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

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

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

Symbols key

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.

ChemWell®-T (Awareness) /Application parameters

ASSAY PARAMETERS	
Std. No	6
R1	350 µL
Sample	45 µL
R2	30 µL
Others	NA
Reaction mode	Endpoint
Primary wavelength	450 nm
Secondary wavelength	None
Direction	Increase
Reagent blank lecture	10 seconds after R2 addition
Final lecture	300 seconds after blank lecture
Reaction time	10 min
Linear range	0-40 ng/ml
CALIBRATION	
Calibration Method	Polinomial 4 th order
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	5 min
Addition R2	
Blank Lecture	
Incubation	5 min
Final lecture	



H. Pylori Turbilatex - Assay definition

Assay Name: H. Pylori Turbilatex
Assay Type: Chemistry
Assay Mode: Polynomial 4th order
Version: 1
Temperature: 37 °C
Last Modified On: 19/06/2016 12:22:38
Last Modified By: Security disabled
Normal: 0.0 - 2.0
Linear: 0.0 - 200.0
Units: ng/mL
of decimals: 1
Assay Description:

Controls:

H. Pylori Level 1, Warn-Continue if out of range, Valid Interval: 7 days 0 hours
H. Pylori Level 2, Warn-Continue if out of range, Valid Interval: 7 days 0 hours

Standards:

H. Pylori Cal 0, Concentration = 0.0, Minimum number to use: 1
H. Pylori Cal 1, Concentration = 2.5, Minimum number to use: 1
H. pylori Cal 2, Concentration = 5.0, Minimum number to use: 1
H. Pylori Cal 3, Concentration = 10.0, Minimum number to use: 1
H.Pylori Cal 4, Concentration = 20.0, Minimum number to use: 1
H. Pylori Cal 5, Concentration = 40.0, Minimum number to use: 1
Curve valid Interval: 7 days 0 hours
Axis Mode: Y = Abs, X = Conc

ASSAY STEPS

Add Reagent [R1 H.Pylori], Volume [350.0 µL], One By One

Aspiration Speed=8, Air Gap=1µL, Dispense Speed=8, Dispense Height=Low

Add Sample, Volume [45.0 µL]

Aspiration Speed=8, Air Gap=1µL, Dispense Speed=8, Dispense Height=Low, Mix 3 sec, Mix Height=0

Clean Probe with [Cleaning Solution], Volume [100 µL]

Aspiration Speed=8, Air Gap=1µL, Mix (default time), Mix Height=0

Incubate 00:05:00 [0h 5min 0sec]

Add Reagent [R2 H.Pylori], Volume [30.0 µL], One By One

Aspiration Speed=8, Air Gap=1µL, Dispense Speed=8, Dispense Height=Low, Mix 3 sec, Mix Height=0

Incubate 00:00:05 [0h 0min 5sec]

Read with Primary Filter[450], Differential Filter[None]

Incubate 00:05:00 [0h 5min 0sec]

Read with Primary Filter[450], Differential Filter[None]