

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)	R1: 2 vials, 2x33 mL	TL-022HP01
200 Det/kit	R2: 1 vial, 1x7 mL	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 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 (2-8°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 TC220 (Tecom) analyzer manual and instructions for use provided with the kit.

Loading of reagents:

Load reagents according to the TC220 (Tecom) analyzer manual.

Calibration curve establishment:

A 6 point calibration curve can be established in TC220 (Tecom) 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:

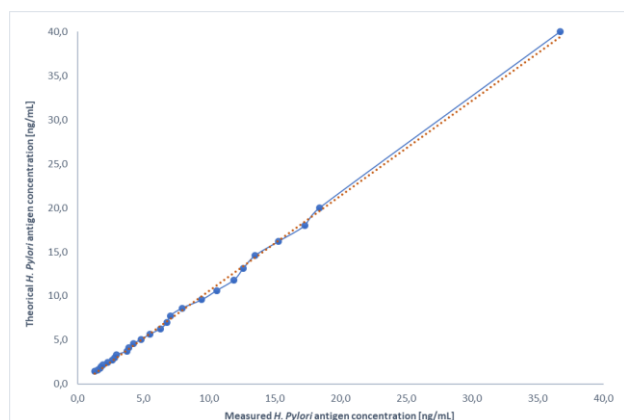
The results are evaluated automatically by the analyzer and presented in ng H. pylori antigen/mL.

Performance characteristics

The following results have been obtained during the validation of H.pylori Turbilatex on the TC220 (Tecom) analyzer.

Linearity:

H. pylori Turbilatex on TC220 (Tecom) 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 TC220 (Tecom) analyzer. Samples higher concentrated than 2000 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 TC220 (Tecom) 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	20	20	20
Mean (ng/mL)	2.6	10.3	36.7
SD (ng/mL)	0.2	0.4	0.6
CV (%)	8	4	2

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 Turbilatex vs CerTest H. pylori	86.5%	>98%

Shipping damage

Please notify your distributor, if 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
	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.

TC220 (Tecom) /Application parameters

ASSAY PARAMETERS	
Std. No	6
R1	250 µL
Sample	45 µL
R2	30 µL
Others	NA
Reaction mode	Two points
Primary wavelength	546 nm
Secondary wavelength	None
Direction	Increase
Self blank	10 seg after R2 addition
Final lecture	400 seg after R2 addition
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	0 s
Addition Sample	120 s
Incubation	
Addition R2	320 s
Blank Lecture	330 s
Incubation	
Final lecture	730 s

TC Series Automatic chemistry Analyzer

Simbolo Nombre Cod. de barras Param Basicos Param Calibracion

metodo 1ª Long.O. 2ª long.O. Decimal Und.

(Rtvo. 1+Rtvo. 2)+S

Rtvo. 1 Vol. (10-400ul) Incub. Rtvo. Rtvo. 1 Pos. Vol. Del envase ml 2ª posicion

Rtvo. 2 Vol. (0-400ul) Rtvo. 2 Pos. Vol. Del envase ml 2ª Posicion

S Vol. (1.0-50.0ul) Incub. Rtvo. Vel. de Mezcla Tiempos de reaccion Check Time(s)

Rango Linealidad — Correccion de resultados X + ratio de Dilucion (2-150)

Absorbance Range — Agotamiento de Sustrato Vol. Muestra (3-70)

m. de Linealidad Vol. Total (120-500)

Ratio de Dilucion

test blanco Reactivo Blanco de Rtvo. — Blanco Reactivo todos ciclos dil.

todo el Vol.n de dilucion

Punto detectado en la Pendiente =

Fabricante No. Lote Caducidad

Item: TP, ALB, TBA, GLU, CRE, UA, TC, TG, CK, LDH, AMY, Ca, Mg, Fe, NH3, MgO, CREO, P, PO, PTO, UREA, CLR, LACT, CALP2, FOB, **PYL**

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