

Application Note

H. pylori Turbilatex, Biolis i24/i50 (Tokio Boeki)
(AN-Hp-Biolis.EN rev. 2019.05.27)

For *in vitro* diagnostic device
ENGLISH



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	Cat. reference
Turbidimetric reagents (R1 & R2) 200 Det/kit	R1: 2 vials, 2x33 mL R2: 1 vial, 1x7 mL	TL-022HP01 TL-022HP02
Auxiliary Reagents	Quantity	Cat. reference
Calibration kit	Calibrator: 6 vials, 6x1mL.	TL-022HP70, TL-022HP71, TL-022HP72, TL-022HP73, TL-022HP74, TL-022HP75
Controls kit	Control C1, 2 vials, 2x1mL/vial. Control C2, 2 vials, 2x1 mL/vial.	TL-022HP08 TL-022HP09
Sample diluent kit	4 vials, 4x125 mL/vial	TL-022HP03E
Sample dilutions vials	1x2 mL/vial 1x2 mL/vial	MST-0014MP MST-0015P

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 Biolis i24 (Tokio Boeki) analyzer manual and instructions for use provided with the kit.

Loading of reagents:

Load reagents according to the Biolis i24 (Tokio Boeki) analyzer manual.

Calibration curve establishment:

A 6 point calibration curve can be established in Biolis i24 (Tokio Boeki) 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.

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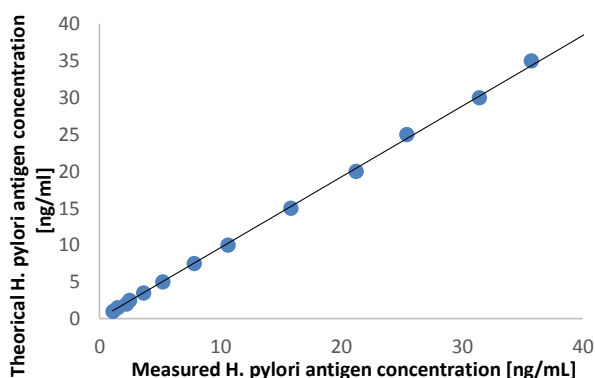


Performance characteristics

The following results have been obtained during the validation of H.pylori Turbilatex on the Biolis i24 (Tokio Boeki) analyzer.

Linearity:

H. pylori Turbilatex on Biolis i24 analyzer using calibrator kit is linear in the calibration range of 0-50 ng H.pylori antigen/mL.



Measuring range:

H.pylori Turbilatex assay measuring range is 1-40 ng H.pylori antigen/ml on the Biolis i24 (Tokio Boeki) 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 2000 ng H.pylori/mL. Samples with H. pylori antigen concentration of 100 ng H. pylori antigen/ml give a typical positive result >40 ng H.pylori antigen/mL.

Detection limit

Limit of detection (LOD): 0.5 ng H. pylori antigen/mL. The lower limit of detection of Calprotectin 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 Biolis i24 (Tokio Boeki) 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 Biolis i24 (Tokio Boeki) analyzer were compared with an immunochromatographic test (CerTest H. pylori, CerTest). The results were as follows:

	Sensitivity	Specificity
H. pylori Turbilatex vs CerTest H. pylori	88%	>98%

Shipping damage

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

Symbols key

	For <i>in vitro</i> diagnostic use only		Keep dry
	Consult instructions for use		Temperature limitation
	Catalogue number		Lot number
	Use by		Manufacturer
	Contains sufficient for <n> test		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.

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The parameters optimized for Biolis i24 might be applied for Biolis i50.

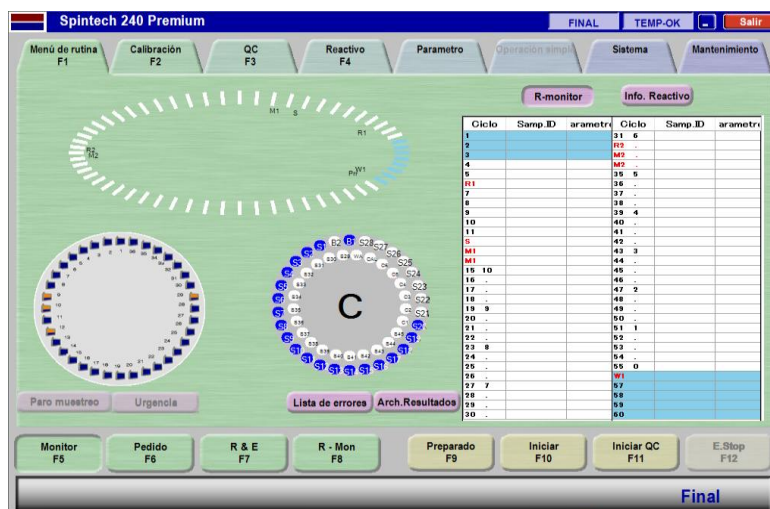
Biolis i24 (Tokio Boeki) /Application parameters

ASSAY PARAMETERS	
Std. No	6
R1	305 µL
Sample	15 µL
R2	25 µL
Others	NA
Reaction mode	Endpoint
Primary wavelength	450 nm
Secondary wavelength	800 nm
Direction	Increase
Reagent blank lecture	33-34 cycle
Final lecture	51-52 cycle
Reaction time	10 min
Linear range	0-40 ng/ml
CALIBRATION	
Calibration Method	Linear
Calibration set	6 calibrators
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	

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Spintech 240 Premium

S.STOP TEMP-OK

Menú de rutina F1 Calibración F2 QC F3 Reactivo F4 Parametro Operación simpli Sistema Mantenimiento

No. Parametr 21 Nombre para: HPyl 1 Nombrecomp: HPylori 1 Optica

Información Datos

Unidades: ng/ml

Decimales: 3

Analisis

Tipo: Punto Final: Abs principal fuera

Longitud de onda princ: 450nm

Longitud de onda Sub: 800nm

Metodo:

Correlación

Pendiente: 1 Intercepción: 0

Y = 1 * X + 0

Calibración

Tipo: Spline 1

Blanco	0	#1	2.5	#2	5
#3	10	#4	20	#5	40
#6					

Estabilidad Cal: 0

Tamaño Botella (ml)

24 Parametros

REACTIVO1: 60 REACTIVO2 R1: 40 REACTIVO2 R2: 20

36 Parametros

REACTIVO1: 40 REACTIVO2 R1: 25 REACTIVO2 R2: 13

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Monitor F5 Pedido F6 R & E F7 R - Mon F8 Preparado F9 Iniciar F10 Iniciar QC F11 E.Stop F12

Paro de muestreo

Spintech 240 Premium

S.STOP TEMP-OK

Menú de rutina F1 Calibración F2 QC F3 Reactivo F4 Parametro Operación simpli Sistema Mantenimiento

No. Parametr 21 Nombre para: HPyl 1 Nombrecomp: HPylori 1 Optica

Aspiración

Clase: Individual Doble

Clase	Vol.	Unidades
Muestra	15	ul
Reactivo 1	205	ul
Reactivo 2	25	ul

Valor Blanco: Blanco Agua Blanco Reactivo

Pantalla Reacción

Nivel 0 Puntos: 1

Extensión: 3

Datos a procesar

Leer

	Iniciar	Final
Principal	11	52
Sub	34	95

Abs. Limite: Bajo -3 Alto 3

Corrección en valor

Corrección en blanco: 1

Límite Punto Final: 3

Comprobar Linealidad (%): 90

Chequeo Prozona

	Iniciar	Final	Límite (X)
Primero			
Segundo			

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Monitor F5 Pedido F6 R & E F7 R - Mon F8 Preparado F9 Iniciar F10 Iniciar QC F11 E.Stop F12

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