Application Note

H. pylori Turbilatex, Biolis 24i/50i (Tokio Boeki)

(AN-Hp-Biolis.EN rev. 2020.02.28)

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. referece**
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 (2-8ºC) 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 Biolis 24i (Tokio Boeki) analyzer manual and instructions for use provided with the kit.

Loading of reagents:
Load reagents according to the Biolis 24i (Tokio Boeki) analyzer manual.

Calibration curve establishment:
A 6 point calibration curve can be established in Biolis 24i (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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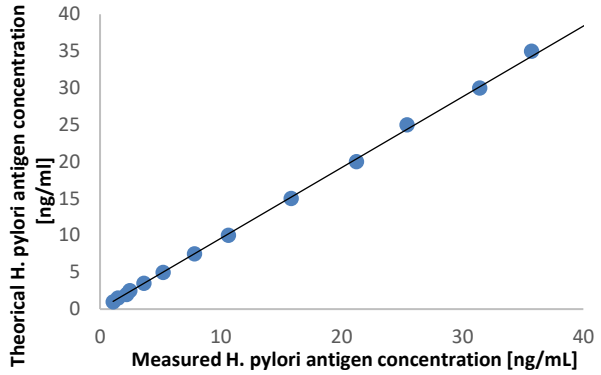
Performance characteristics

The following results have been obtained during the validation of H.pylori Turbilatex on the Biolis 24i (Tokio Boeki) analyzer.

Linearity:
H. pylori Turbilatex on Biolis 24i 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 1-40 ng H.pylori antigen/ml on the Biolis 24i (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): 0.8 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): 0.8 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 24i (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 24i (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*	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

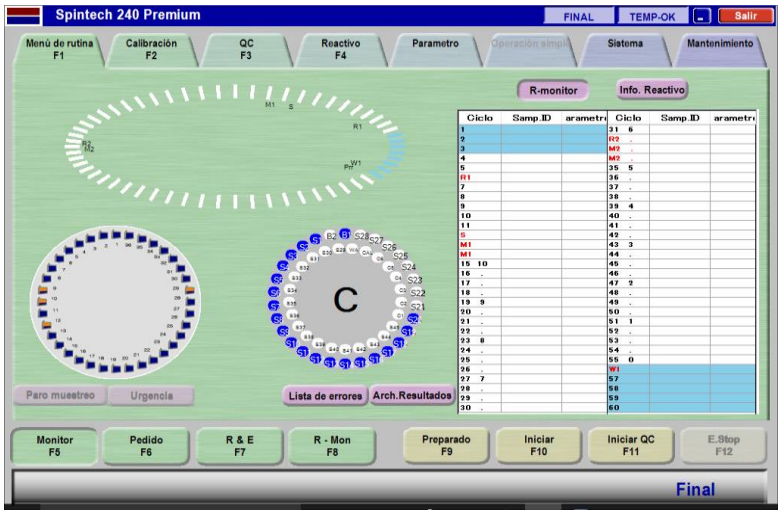
NOTES

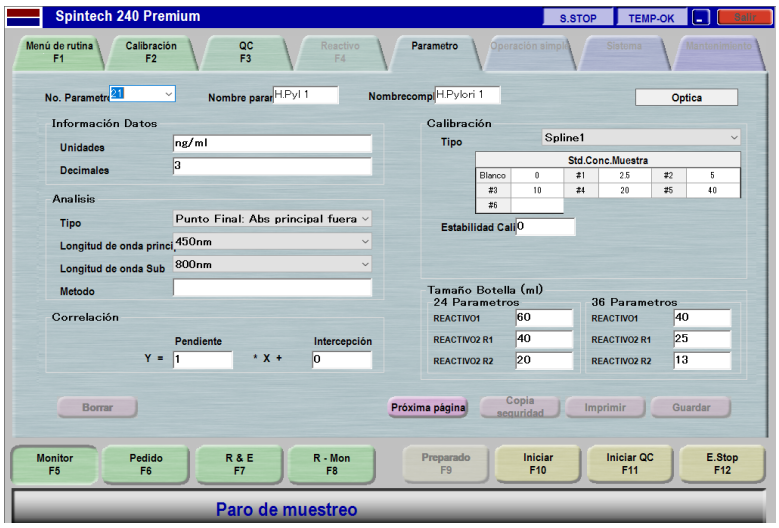
Please refer to the instruction for use for the detailed information about the test on the following:
Synthesis; Principle; Precautions; Reagents; Specimen collection and preparation; Interpretation of results and limitations.

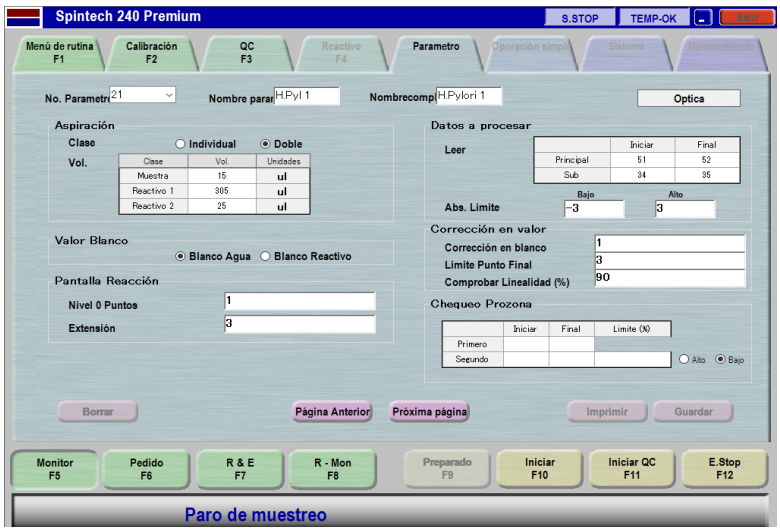
The parameters optimized for Biolis 24i might be applied for Biolis 50i.

Biolis 24i (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	


Spintech 240 Premium
FINAL
TEMP-OK
Salir
Menú de rutina F1
Calibración F2
QC F3
Reactivo F4
Parametro
Operación simple
Sistema
Mantenimiento
R-monitor
Info. Reactivo
Ciclo
Samp.ID
Paro muestreo
Urgencia
Lista de errores
Arch.Resultados
Monitor F5
Pedido F6
R & E F7
R - Mon F8
Preparado F9
Iniciar F10
Iniciar QC F11
E.Stop F12
Final


Spintech 240 Premium
S.STOP
TEMP-OK
Salir
Parametro
No. Parametr
Nombre para
H.Pyl 1
Nombrecomp
H.Pylori 1
Optica
Información Datos
Unidades
ng/ml
Decimales
3
Analisis
Tipo
Punto Final: Abs principal fuera
Longitud de onda princi
450nm
Longitud de onda Sub
800nm
Metodo
Correlación
Pendiente
Intercepción
Y =
1
* X +
0
Calibración
Tipo
Spline1
Std.Conc.Muestra
Blanco
#1
#2
#3
#4
#5
#6
Estabilidad Cali
0
Tamaño Botella (ml)
24 Parametros
REACTIVO1
60
REACTIVO2 R1
40
REACTIVO2 R2
20
36 Parametros
REACTIVO1
40
REACTIVO2 R1
25
REACTIVO2 R2
13
Borrar
Próxima página
Copia seguridad
Imprimir
Guardar
Paro de muestreo


Spintech 240 Premium
S.STOP
TEMP-OK
Salir
Parametro
No. Parametr
Nombre para
H.Pyl 1
Nombrecomp
H.Pylori 1
Optica
Aspiración
Clase
Individual
Doble
Vol.
Clase
Vol.
Unidades
Muestra
15
ul
Reactivo 1
305
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
51
52
Sub
34
35
Abs. Limite
Bajo
-3
Alto
3
Corrección en valor
Corrección en blanco
1
Limite Punto Final
3
Comprobar Linealidad (%)
90
Chequeo Prozona
Iniciar
Final
Limite (N)
Primero
Segundo
Alto
Bajo
Borrar
Página Anterior
Próxima página
Imprimir
Guardar
Paro de muestreo