

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 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 (2-8°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 Cobas C311 (ROCHE) analyzer manual and instructions for use provided with the kit.

Loading of reagents:

Load reagents according to the Cobas C311 (ROCHE) analyzer manual.

Calibration curve establishment:

A 6 point calibration curve can be established in Cobas C311 (ROCHE) 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:

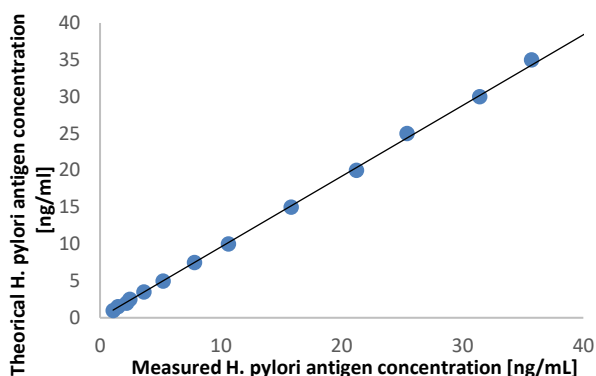
The results are evaluated automatically by the analyzer and presented in ng H.pylori antigen/mL.

Performance characteristics

The following results have been obtained during the validation of H.pylori Turbilatex on the Cobas C311 (ROCHE) analyzer.

Linearity:

H. pylori Turbilatex on Cobas C311 (ROCHE) 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 Cobas C311 (ROCHE) 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 Cobas C311 (ROCHE) analyzer.

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

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 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

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.

Cobas C311 (ROCHE)/Application parameters

| ASSAY PARAMETERS | |
|-------------------------|--------------------------|
| Std. No | 6 |
| R1 | 180 µL |
| Sample | 10 µL |
| R2 | 15 µL |
| Others | NA |
| Reaction mode | Endpoint |
| Primary wavelength | 480 nm |
| Secondary wavelength | None |
| Direction | Increase |
| Reagent blank lecture | 12 cycle |
| Final lecture | 40 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 12 |
| Incubation | |
| Final lecture | Cycle 40 |