Instructions for Use

Fecal Helicobacter pylori-Antigen ELISA

Enzyme immunoassay for the quantitative and qualitative determination of Helicobacter pylori antigen in feces.

REF **RE58891**

Σ **96**

2-8°C

EU: IVD CE

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INTENDED USE

This microplate-based ELISA (enzyme linked immunosorbent assay) kit is intended for the quantitative and qualitative detection of *Helicobacter pylori* antigen in feces. The assay is a useful tool in the detection of active *H. pylori* infection.

SUMMARY OF PHYSIOLOGY

H. pylori (previously known as *Campylobacter pyloridis*) is a type of bacterium that infects the stomach and is a common cause of peptic ulcers. *H. pylori* bacteria can be passed from person to person through direct contact with saliva, vomit or fecal matter. *H. pylori* can also be spread through contaminated food or water. The infection is normally acquired during childhood. *H. pylori* usually goes undiagnosed until symptoms of a peptic ulcer occur. *H. pylori* infection is quite common and is present in about half the people in the world.

ASSAY PRINCIPLE

This “sandwich” ELISA is designed, developed and produced for the quantitative measurement of *H. pylori* antigen in stool specimen. The assay utilizes the microplate-based enzyme immunoassay technique by coating highly purified anti-*H. Pylori* antibody onto the wall of microtiter wells. Assay calibrators and fecal specimen are added to microtiter wells of microplate that was coated with a highly purified monoclonal *H. pylori* antibody on its surface. During the assay, the *H. pylori* antigen will be bound to the antibody coated plate after an incubation period. The unbound material is washed away and another HRP-conjugated monoclonal antibody, which specifically recognizes the protein of *H. pylori* is added for further immunoreactions. After an incubation period, the immunocomplex of “*H. pylori* Antibody – *H. pylori* Antigen – HRP-conjugated Anti-*H. pylori* Tracer Antibody” is formed, if *H. pylori* antigen is present in the test sample. The unbound tracer antibody and other proteins in buffer matrix are removed in the subsequent washing step. HRP conjugated tracer antibody bound to the well is then incubated with a substrate solution in a timed reaction and then measured in a spectrophotometric microplate reader. The enzymatic activity of the tracer antibody bound to *H. pylori* proteins captured on the wall of each microtiter well is directly proportional to the amount of *H. pylori* antigen level in each test specimen.

REAGENTS: Preparation and Storage

This test kit must be stored at 2 – 8 °C upon receipt. For the expiration date of the kit refer to the label on the kit box. All components are stable until this expiration date.
Prior to use, allow all reagents to equalize to room temperature.
Reagents from different kit lot numbers should not be combined or interchanged.

1. Microtiter Plate **MTP**
One microplate with 12 x 8 strips (96 wells total) coated with highly purified H. pylori antibody. The plate is framed and sealed in a foil zipper bag with a desiccant. This reagent should be stored at 2 – 8 °C and is stable until the expiration date on the kit box.

2. Enzyme Conjugate **ENZCONJ**
One vial containing **12 mL** ready-to-use horseradish peroxidase (HRP)-conjugated monoclonal *H. pylori* antibody in a stabilized protein matrix. This reagent should be stored at 2 – 8 °C and is stable until the expiration date on the kit box.

3. TMB Substrate Solution **TMB SUBS**
One bottle containing **12 mL** of tetramethylbenzidine (TMB) with hydrogen peroxide. This reagent should be stored at 2 – 8 °C and is stable until the expiration date on the kit box.

4. TMB Stop Solution **TMB STOP**
One bottle containing **12 mL** of 0.5 M sulfuric acid. This reagent should be stored at 2 – 8 °C or room temperature and is stable until the expiration date on the kit box.

5. Calibrator Level 6 **CAL**
One vial containing **1.5 mL** of H.pylori Antigen Calibrator Level 6. This calibrator is in a liquid bovine serum albumin-based matrix with mercury and sodium azide preservative. **Refer to vials for exact concentration.** This reagent should be stored at 2 – 8°C and are stable until the expiration date on the kit box, -20 °C for long term storage.

6. Wash Buffer **WASHBUF** **CONC**
One bottle containing **30 mL** of 30-fold concentrate. Before use the contents must be diluted with 870 mL of distilled water and mixed well. Upon dilution this yields a working wash solution containing a surfactant in phosphate buffered saline with a non-azide and non-mercury based preservative. The diluted wash buffer should be stored at room temperature and is stable until the expiration date on the kit box.

7. Assay Buffer **ASSAYBUF** **CONC**
One bottle containing **30 mL** of **4-fold** concentrated buffer matrix with protein stabilizers and preservative. This reagent should be stored at 2 – 8 °C and is stable until the expiration date on the kit box. Before use the concentrated buffer must be diluted with **90 mL** of demineralized water and mixed well. Upon dilution, this yields as **1x Assay Buffer**, which serves as a Calibrator Level1, and as a **patient sample diluent** containing a surfactant in phosphate-buffered saline with a non-azide preservative. The diluted reagent is stored at 2 – 8 °C and is stable until the expiration date on the kit box.

SAFETY PRECAUTIONS

The reagents must be used in a laboratory and are for professional use only. Materials sourced for reagents containing bovine serum albumin were derived in the contiguous 48 United States and obtained only from healthy donor animals maintained under veterinary supervision and found free of contagious diseases. Wear gloves while performing this assay and handle these reagents as if they are potentially infectious. Avoid contact with reagents containing TMB, hydrogen peroxide, or sulfuric acid. TMB may cause irritation to skin and mucous membranes and cause an allergic skin reaction. TMB is a suspected carcinogen. Sulfuric acid may cause severe irritation on contact with skin. Do not get in eyes, on skin, or on clothing. Do not ingest or inhale fumes. On contact, flush with copious amounts of water for at least 15 minutes. Use Good Laboratory Practices.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Precision single channel pipettes capable of delivering 10 µL, 50 µL, 100 µL, and 1000 µL, etc.
2. Repeating dispenser suitable for delivering 100 µL.
3. Disposable pipette tips suitable for above volume dispensing.
4. Disposable 12 x 75 mm or 13 x 100 glass or plastic tubes.
5. Disposable plastic 1000 mL bottle with cap.
6. Aluminum foil.
7. Deionized or distilled water.
8. Plastic microtiter well cover or polyethylene film.
9. ELISA multichannel wash bottle or automatic (semi-automatic) washing system.
10. Spectrophotometric microplate reader capable of reading absorbance at 450/620 nm.

SPECIMEN COLLECTION & STORAGE

Fresh fecal sample should be collected into a stool sample collection container. It is required to collect a minimum of 1-2 mL liquid stool sample or 1-2 g solid sample. The collected fecal sample must be transported to the lab in a frozen condition (-20 °C). If the stool sample is collected and tested the same day, it is allowed to be stored at 2-8 °C.

ASSAY PROCEDURE

1. Reagent Preparation

1. Prior to use allow all reagents to come to room temperature. Reagents from different kit lot numbers should not be combined or interchanged.
2. Concentrated **ASSAYBUF** must be diluted to working solution prior use.
   Please see REAGENTS section for details.
3. Concentrated **WASHBUF** must be diluted to working solution prior use.
   Please see REAGENTS section for details.
4. Prepare **1:3** serially diluted calibrators using Calibrator Level 6 **CAL** and 1x Assay Buffer as the dilution buffer. Store at 2 – 8 ºC , -20°C for long term storage. Avoid more than 3x freeze thaw cycle.

Calibrator	Calibrator Volume	Volume of 1x Assay Buffer
CAL 6	Calibrator Level 6	-
CAL 5	0.5 mL of CAL 6	1 mL
CAL 4	0.5 mL of CAL 5	1 mL
CAL 3	0.5 mL of CAL 4	1 mL
CAL 2	0.5 mL of CAL 3	1 mL
CAL 1	1x Assay Buffer	-

2. Patient Sample Preparation

2.1 For manual weighing procedure only:

1. Label a test tube (12x75 mm) or a 4 ml plastic vial.
2. With solid stool sample, take or weigh an equivalent amount (about **40mg,** size as a grain of rice) with a spatula or a disposable inoculation loop. Suspend the solid stool sample with **1 mL 1x Assay Buffer** and mix well on a vortex mixer (**Sample dilution is 1:24**).
3. Centrifuge the diluted fecal sample at 3000 rpm (800- 1500 g) for 5-10 minutes. The supernatant can be directly used in the assay. As an alternative to centrifuging, let the diluted samples sit and sediment for 30 minutes and take the clear supernatant for testing.

Note: If the test procedure is performed on an automated ELISA system, the supernatant must be particle-free by centrifuging the sample**.**

4. This sample can be stored at 2-8 °C up to three days and below -20 °C for longer storage. Avoid more than 3x freeze and thaw cycle.

2.2 Using EDI Fecal Sample Collection Kit, (REF RE58898)

1. Label a Fecal Sample Collection tube
2. Continue assay by following the instruction according the Sample Collection Kit insert.
3. Centrifuge the diluted fecal sample at 3000rpm (800 - 1500 g) for 5-10 minutes. As an alternative to centrifuging, let the diluted samples sit and sediment for 30 minutes and take the clear supernatant for testing.

Note: If the test procedure is performed on an automated ELISA system, the supernatant must be particle-free by centrifuging the sample**.**

4. This sample can be stored at 2-8 °C up to three (3) days and below -20 °C for longer storage. Avoid more than 3x freeze and thaw cycle.

3. Assay Procedure

1. Place a sufficient number of anti-H. Pylori monoclonal antibody coated microwell strips in a frame.
2. Test Configuration

ROW	STRIP 1	STRIP 2	STRIP 3
A	CAL 1	CAL 5	SAMPLE 3
B	CAL 1	CAL 5	SAMPLE 3
C	CAL 2	CAL 6	SAMPLE 4
D	CAL 2	CAL 6	SAMPLE 4
E	CAL 3	SAMPLE 1	SAMPLE 5
F	CAL 3	SAMPLE 1	SAMPLE 5
G	CAL 4	SAMPLE 2	SAMPLE 6
H	CAL 4	SAMPLE 2	SAMPLE 6

Alternative Procedure (Qualitative Measurement):

If a qualitative measurement is desired,

use the Calibrator Level 6 as the positive control CAL = POS CTL

and diluted Assay Buffer as the negative control ASSAYBUF = NEG CTL .

ROW	STRIP 1	STRIP 2	STRIP 3
A	NEG CTL	SAMPLE 3	SAMPLE 7
B	NEG CTL	SAMPLE 3	SAMPLE 7
C	POS CTL	SAMPLE 4	SAMPLE 8
D	POS CTL	SAMPLE 4	SAMPLE 8
E	SAMPLE 1	SAMPLE 5	SAMPLE 9
F	SAMPLE 1	SAMPLE 5	SAMPLE 9
G	SAMPLE 2	SAMPLE 6	SAMPLE 10
H	SAMPLE 2	SAMPLE 6	SAMPLE 10

3. Add **100 µL** of **calibrators and diluted patient stool samples** into each designated microwell. Cover the plate with a plate sealer and also with aluminum foil to avoid exposure to light. Mix by gently tapping the plate.
4. Incubate plate at room temperature for **1 hour**
5. Remove plate sealer. Aspirate the contents of each well. Wash each well **5 times** by dispensing **350 µL to 400 µL** of **diluted Wash Buffer** into each well, then completely aspirating the contents. Alternatively, an automated microplate washer can be used.
6. Add **100 µL** ready-to-use **Enzyme Conjugate** to each of the wells.
7. Cover the plate with one plate sealer and also with aluminum foil to avoid exposure to light. Mix by gently tapping the plate.
8. Incubate plate at room temperature for **30 minutes**.
9. Remove plate sealer. Aspirate the contents of each well. Wash each well **5 times** by dispensing **350 µL to 400 µL** of **diluted Wash Buffer** into each well and then completely aspirating the contents. Alternatively, an automated microplate washer can be used.
10. Add **100 µL** of **TMB Substrate** into each of the wells.
11. Cover the plate with a new plate sealer and also with aluminum foil to avoid exposure to light.
12. Incubate plate at room temperature for **20 minutes**
13. Remove the aluminum foil and the plate sealer. Add **100 µL** of **TMB Stop Solution** into each of the wells. Mix gently.
14. Read the absorbance at 450 nm with reference filter at 620 nm or 650 nm.

PROCEDURAL NOTES

1. It is recommended that all calibrators and unknown samples be assayed in duplicate. The average absorbance reading of each duplicate should be used for data reduction and the calculation of results.
2. Keep light-sensitive reagents in the original amber bottles.
3. Store any unused antibody coated strips in the foil zipper bag with desiccant to protect from moisture.
4. Careful technique and use of properly calibrated pipetting devices are necessary to ensure reproducibility of the test.
5. Incubation times or temperatures other than those stated in this insert may affect the results.
6. All reagents should be mixed gently and thoroughly prior use. Avoid foaming.

INTERPRETATION OF RESULTS

Quantitative Measurement:

1. Calculate the average absorbance for each pair of duplicate test results.
2. Subtract the average absorbance of the calibrator 1 (0 ng/mL) from the average absorbance of all other readings to obtain corrected absorbance.
3. The calibrator curve is generated by the corrected absorbance of all calibrator levels on the ordinate against the calibrator concentration on the abscissa using point-to-point or log-log paper. Appropriate computer assisted data reduction programs may also be used for the calculation of results.

The H. Pylori concentrations for the unknown samples are read directly from the calibration curve using their respective corrected absorbance.

Qualitative Measurement Visual:

1. Positive or reactive: Any sample well that is obviously more yellow than the negative control well.
2. Negative or non-reactive: Any sample well that is not obviously more yellow than the negative control well.

Note: The negative control, as well as some patient samples, may show some slight yellow color. A sample well must be obviously darker or more yellow than the negative control well, when it is interpreted as a positive result.

Qualitative Measurement ELISA Reader:

1. Calculate the average absorbance for each pair of duplicate test results.
2. Calculate the cut-off

   The positive cut-off and the negative cut-off are established by using following formula.
   Positive Cut-Off = 1.1 x (mean extinction of negative control + 0.10)
   Negative Cut-Off = 0.9 x (mean extinction of negative control + 0.10)
3. Interpret test result
   - Positive: patient sample extinction is greater than the Positive Cut-Off
   - Negative: patient sample extinction is less than the Negative Cut-Off
   - Equivocal: patient sample extinction is between the Positive Cut-Off and the Negative Cut-Off.
4. Assay quality control
   - Positive control must show an average OD reading greater than 0.8.
   - Negative control should show an average OD reading less than 0.09.

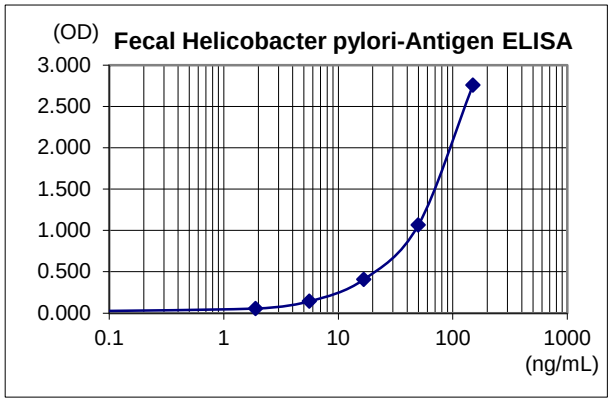
EXAMPLE DATA AND CALIBRATOR CURVE

Quantitative Measurement:

A typical absorbance data and the resulting calibrator curve from Fecal Helicobacter pylori-Antigen ELISA are represented.

This curve should not be used in lieu of calibrator curve run with each assay.

Well I.D.	OD 450/650 nm Absorbance		
	Readings	Average	Corrected
0 ng/mL	0.011 0.012	0.011	0.000
1.9 ng/mL	0.056 0.053	0.055	0.044
5.6 ng/mL	0.140 0.144	0.142	0.131
16.7 ng/mL	0.407 0.404	0.405	0.394
50 ng/mL	1.116 1.014	1.065	1.054
150 ng/mL	2.752 2.763	2.757	2.746



Qualitative Measurement:

	OD 450 nm	Average OD 450 nm
Negative Control	0.049 0.050	0.050
Positive Control	1.332 1.376	1.354

Positive Cut-Off = 1.1 x (0.050 + 0.10) = 0.165

Negative Cut-Off = 0.9 x (0.050 + 0.10) = 0.135

EXPECTED VALUES

Quantitative Measurement:

Stool from 25 normal adults were measured with Fecal Helicobacter pylori-Antigen ELISA. We found that normal people show undetectable H. pylori antigen in the extracted stool samples according to the sample collection, extraction and assay procedures described in this insert. The suggested positive cut-off for fecal H. pylori antigen is 3 ng/mL.

Qualitative Measurement:

Stool samples from 29 negative specimens and 17 positive specimens were tested with this ELISA.

Samples / ELISA	True Positive	True Negative	Total
Positive	17	0	17
Negative	0	29	29
Total	17	29	46

Sensitivity: 100% (17/17)
Specificity: 100% (29/29)
Accuracy: 100% (46/46)

LIMITATION OF THE PROCEDURE

(1) The results obtained with this Fecal Helicobacter pylori-Antigen ELISA serve only as a useful aid to diagnosis and should not be interpreted as diagnostic in themselves without taking other clinival findings such as somach endoscope and biopsy, etc.

(2) Single H. pylori negative results in untreated patients do not rule out H. pylori infection.

(3) For unknown samples value read directly from the assay that is greater than the highest calibrator, it is recommended to measure a further diluted sample for more accurate measurement.

(4) Bacterial or fungal contamination of stool specimens or reagents, or cross-contamination between reagents may cause erroneous results.

QUALITY CONTROL

To assure the validity of the results each assay should include adequate controls with known H. pylori antigen levels. We recommend that all assays include the laboratory's own controls.

PERFORMANCE CHARACTERISTICS

Sensitivity

The sensitivity of the Fecal H. pylori Ag ELISA as determined by the 95% confidence limit on 16 duplicate determination of zero standard is approximately 0.165 ng/mL.

Precision

The intra-assay precision was validated by measuring two samples in a single assay with 12 replicate determinations.

Mean H. pylori Value (ng/mL)	CV (%)
13.1	5.4
1.8	2.8

The inter-assay precision was validated by measuring two samples in duplicate in 12 individual assays.

Mean H. pylori Value (ng/mL)	CV (%)
13.9	5.9
1.8	5.2

Specificity

The assay does not cross react to following organisms:
Cryptosoridium parvum, Giardia lamblia, rotavirus and adenovirus.

Linearity

Two stool samples were collected, diluted with 1x Assay Buffer and tested. The results of H. pylori percent recovery value in ng/mL are as follows:

DILUTION	OBSERVED VALUE (ng/mL)	RECOVERY %
Neat A	77.4	-
1:2	38.1	98.4
1:4	17.5	90.4
Neat B	24.8	-
1:2	12.2	98.6
1:4	6.3	102.7

Spike Recovery

Two spiked stool samples and three assay calibrators (1.9, 16.7 and 50 ng/mL) were combined at equal volumes and tested. The results are as follows:

DILUTION	OBSERVED VALUE (ng/mL)	RECOVERY %
Neat A	0.3	-
CAL 2 (1.9 ng/mL)	1.1	97.2
CAL 4 (16.7 ng/mL)	7.1	84.2
CAL 5 (50 ng/mL)	20.9	83.2
Neat B	0.3	-
CAL 2 (1.9 ng/mL)	1.0	93.8
CAL 4 (16.7 ng/mL)	7.0	82.0
CAL 5 (50 ng/mL)	21.0	83.1

REFERENCES

1: Ungar BL, Yolken RH, Nash TE, Quinn TC. Enzyme-linked immunosorbent assay for the detection of H. Pylori in fecal specimens. J Infect Dis. 1984 Jan;149(1):90-7.

2: Rosenblatt JE, Sloan LM, Schneider SK. Evaluation of an enzyme-linked immunosorbent assay for the detection of H. Pylori in stool specimens. Diagn Microbiol Infect Dis. 1993 May-Jun;16(4):337-41.

3: Stibbs HH, Samadpour M, Manning JF. Enzyme immunoassay for detection of H. Pylori cyst antigens in formalin-fixed and unfixed human stool. J Clin Microbiol. 1988 Sep;26(9):1665-9.

4: Stibbs HH. Monoclonal antibody-based enzyme immunoassay for H. Pylori antigen in human stool. J Clin Microbiol. 1989 Nov;27(11):2582-8.

5: Janoff EN, Smith PD, Blaser MJ. Acute antibody responses to H. Pylori are depressed in patients with AIDS. J Infect Dis. 1988 Apr;157(4):798-804.

SHORT ASSAY PROCEDURE OF FECAL H.PYLORI ANTIGEN ELISA

(1) Add **100 µL** of calibrators, controls and **100 µL** of patient samples into the designated microwell.

(2) Mix, cover and incubate the plate at room temperature **NO SHAKING for 1 hour**

(3) Wash each well 5 times.

(4) Add **100 µL** of Tracer Antibody into the designated microwell.

(5) Mix, cover and incubate the plate at room temperature **NO SHAKING for 30 minutes.**

(6) Wash each well 5 times.

(7) Add **100 µL** ELISA HRP Substrate into each well.

(8) Cover and incubate plate at room temperature for **20 minutes**.

(9) Add **100 µL** of ELISA Stop Solution into each of the wells.

(10) Read the absorbance at OD **450/620nm**.

Symbols / Symbole / Symbôles / Símbolos / Símbolos / Σύμβολα

REF	Cat.-No.: / Kat.-Nr.: / No.- Cat.: / Cat.-No.: / N.º Cat.: / N.–Cat.: / Αριθμός-Κατ.:
LOT	Lot-No.: / Chargen-Bez.: / No. Lot: / Lot-No.: / Lote N.º: / Lotto n.: / Αριθμός -Παραγωγή:
	Use by: / Verwendbar bis: / Utiliser à: / Usado por: / Usar até: / Da utilizzare entro: / Χρησιμοποιείται από:
	No. of Tests: / Kitgröße: / Nb. de Tests: / No. de Determ.: / N.º de Testes: / Quantità dei tests: / Αριθμός εξετάσεων:
CONC	Concentrate / Konzentrat / Concentré / Concentrar / Concentrado / Concentrato / Συμπύκνωμα
LYO	Lyophilized / Lyophilisat / Lyophilisé / Liofilizado / Liofilizado / Liofilizzato / Λυοφιλιασμένο
IVD	In Vitro Diagnostic Medical Device. / In-vitro-Diagnostikum. / Appareil Médical pour Diagnostics In Vitro. / Dispositivo Médico para Diagnóstico In Vitro. / Equipamento Médico de Diagnóstico In Vitro. / Dispositivo Medico Diagnostico In vitro. / Ιατρική συσκευή για In-Vitro Διάγνωση.
	Evaluation kit. / Nur für Leistungsbewertungszwecke. / Kit pour évaluation. / Juego de Reactivos para Evaluació. / Kit de avaliação. / Kit di evaluazione. / Κιτ Αξιολόγησης.
	Read instructions before use. / Arbeitsanleitung lesen. / Lire la fiche technique avant emploi. / Lea las instrucciones antes de usar. / Ler as instruções antes de usar. / Leggere le istruzioni prima dell'uso. / Διαβάστε τις οδηγίες πριν την χρήση.
	Keep away from heat or direct sun light. / Vor Hitze und direkter Sonneneinstrahlung schützen. / Garder à l'abri de la chaleur et de toute exposition lumineuse. / Manténgase alejado del calor o la luz solar directa. / Manter longe do calor ou luz solar directa. / Non esporre ai raggi solari. / Να φυλάσσεται μακριά από θερμότητα και άμεση επαφή με το φως του ηλίου.
	Store at: / Lagern bei: / Stocker à: / Almacene a: / Armazenar a: / Conservare a: / Αποθήκευση στους:
	Manufacturer: / Hersteller: / Fabricant: / Productor: / Fabricante: / Fabbricante: / Παραγωγός:
	Caution! / Vorsicht! / Attention! / ¡Precaución! / Cuidado! / Attenzione! / Προσοχή!

Symbols of the kit components see MATERIALS SUPPLIED.
Die Symbole der Komponenten sind im Kapitel KOMPONENTEN DES KITS beschrieben.
Voir MATERIEL FOURNI pour les symbôles des composants du kit.
Símbolos de los componentes del juego de reactivos, vea MATERIALES SUMINISTRADOS.
Para símbolos dos componentes do kit ver MATERIAIS FORNECIDOS.
Per i simboli dei componenti del kit si veda COMPONENTI DEL KIT.
Για τα σύμβολα των συστατικών του κιτ συμβουλευτείτε το ΠΑΡΕΧΟΜΕΝΑ ΥΛΙΚΑ.

COMPLAINTS: Complaints may be submitted initially written or vocal. Subsequently they need to be filed including the test performance and results in writing in case of analytical reasons.

WARRANTY: The product is warranted to be free from material defects within the specific shelf life and to comply with product specifications delivered with the product. The product must be used according to the Intended use, all instructions given in the instructions for use and within the product specific shelf life. Any modification of the test procedure or exchange or mixing of components of different lots could negatively affect the results. These cases invalidate any claim for replacement.

LIMITATION OF LIABILITY: IN ALL CIRCUMSTANCES THE EXTENT OF MANUFACTURER'S LIABILITY IS LIMITED TO THE PURCHASE PRICE OF THE KIT(S) IN QUESTION. IN NO EVENT SHALL MANUFACTURER BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING DAMAGES FOR LOST PROFITS, LOST SALES, INJURY TO PERSON OR PROPERTY OR ANY OTHER INCIDENTAL OR CONSEQUENTIAL LOSS.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