Clearview® H. pylori
Serum or plasma
Serum oder Plasma
Serum eller plasma
Suero o plasma
Seerumi tai plasma
Sérum ou plasma
Ορός ή πλάσμα
Siero o plasma
Serum of plasma
Serum eller plasma
Soro ou plasma
Serum eller plasma

Venipuncture whole blood
Venepunktion Vollblut
Venepunkturfuldblod
Venipunción sangre total
Suonesta otettu kokoveri
Sang total par ponction veineuse
Αιμοληψία από φλέβα Ολικό αίμα
Venipuntura sangue intero
Venapunctie volbloed
Fullblod fra venepunktsjon
Punção venosa sangue total
Venprov helblod

Fingerstick whole blood
Fingerpunktion Vollblut
Fingerprikfuldblod
Pinchador sangre total
Sormenpäästä otettu kokoveri
Sang total par prélèvement au doigt
Τρύπημα δαχτύλου Ολικό αίμα
Puntura sul dito sangue intero
Vingerprik volbloed
Fullblod fra fingerstikk
Picada no dedo sangue total
Fingerblodprov helblod
H. pylori

10m/10’

+   -
Clearview H. pylori

A rapid test for the qualitative detection of antibodies to Helicobacter pylori (H. pylori) in whole blood, serum, or plasma. For professional in vitro diagnostic use only.

Intended Use
Clearview H. pylori (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibodies to H. pylori in whole blood, serum, or plasma to aid in the diagnosis of H. pylori infection.

Summary
H. pylori is a small, spiral-shaped bacterium that is able to survive in the surface of the stomach and duodenum. It is implicated in the etiology of a variety of gastrointestinal diseases, including duodenal and gastric ulcer, non-ulcer dyspepsia and active and chronic gastritis. Both invasive and non-invasive methods are used to diagnose H. pylori infection in patients with symptoms of gastrointestinal disease. Specimen-dependent and costly invasive diagnostic methods include gastric or duodenal biopsy followed by urease testing (presumptive), culture, and/or histologic staining. Non-invasive techniques include the urea breath test, which requires expensive laboratory equipment and moderate radiation exposure, and serological methods. Individuals infected with H. pylori develop antibodies which correlate strongly with histologically confirmed H. pylori infection.

Clearview H. pylori (Whole Blood/Serum/Plasma) is a simple test that utilizes a combination of H.pylori antigen coated particles and anti-human IgG to qualitatively and selectively detect H. pylori antibodies in whole blood, serum, or plasma.

Principle
Clearview H. pylori (Whole Blood/Serum/Plasma) is a qualitative membrane based immunoassay for the detection of H. pylori antibodies in whole blood, serum, or plasma. In this test procedure, anti-human IgG is immobilized in the test line region of the test. When the specimen is added to the specimen well of the device, it mobilizes the H. pylori antigen coated particles and the mixture migrates chromatographically along the length of the test. If the specimen contains H. pylori antibodies these will complex with the H. pylori antigen coated particles and the immobilized anti-human IgG. A colored line will appear in the test line region indicating a positive result. If the specimen does not contain H. pylori antibodies, a colored line will not appear in this region indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Reagents
The device contains H. pylori antigen coated particles and anti-human IgG coated on the membrane.

Precautions
• For professional in vitro diagnostic use only. Do not use after the expiration date.
• Do not eat, drink or smoke in the area where the specimens or kits are handled.
• Do not use test if pouch is damaged.
• Handle all specimens as if they contain infectious agents. Observe...
established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.

- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- The used device should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

**Storage and Stability**

清远辉 H. pylori (Whole Blood/Serum/Plasma) should be stored at 2-30°C. Do not use after the stated expiry date.

**Specimen Collection and Preparation**

- **Clearview H. pylori** (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum, or plasma.

- **Venipuncture Whole Blood specimens:**
  Collect anti-coagulated blood specimen (sodium or lithium heparin, potassium or sodium EDTA, sodium oxalate, sodium citrate) following standard laboratory procedures.

- **Fingerstick Whole Blood specimens:**
  - Wash the patient’s hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - The Fingerstick Whole Blood specimen can be applied to the test using either a capillary tube or by hanging drops.

- **Capillary tube**
  - Touch the end of the capillary tube to the blood until filled to approximately 50 μL. Avoid air bubbles.
  - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen well (S) of the test device.

- **Hanging drops**
  - Position the patient’s finger so that the drop of blood is just above the specimen well (S) of the test device.
  - Allow 2 hanging drops of fingerstick whole blood to fall into the specimen well (S) of the test device, or move the patient’s finger so that the hanging drop touches the specimen well (S). Avoid touching the finger directly to the specimen well (S).

- **Serum and Plasma Specimens**
  - Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.

**Specimen Storage**

- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
**Test Procedure**

Allow the device, specimen, buffer, and/or controls to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the device from the sealed pouch and use it as soon as possible.
2. Place the device on a clean and level surface.
   
   For **Serum or Plasma specimens**: Hold the dropper vertically and **transfer 4 drops of serum or plasma** (approximately 100 μL) to the specimen well (S) of the test device, then start the timer. See illustration.
   
   For **Venipuncture Whole Blood specimens**: Hold the dropper vertically and **transfer 2 drops of whole blood** (approximately 50 μL) to the specimen well (S) of the test device, then **add 1 drop of buffer** (approximately 40 μL) and start the timer. See illustration.
   
   For **Fingerstick Whole Blood specimens**:
   - To use a capillary tube: Avoiding air bubbles, fill the capillary tube and **transfer approximately 50 μL of fingerstick whole blood** to the specimen well (S) of the device, then **add 1 drop of buffer** (approximately 40 μL) and start the timer. See illustration.
   - To use hanging drops: **Allow 2 hanging drops of fingerstick whole blood** (approximately 50 μL) to fall into the center of the specimen well (S) on the device. Avoid touching the finger directly to the specimen well (S). Then **add 1 drop of buffer** (approximately 40 μL) and start the timer. See illustration.

3. Wait for the colored line(s) to appear. **Read results at 10 minutes**. Do not interpret the result after 20 minutes.

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**Kit Contents**

Each **Clearview H. pylori** kit contains sufficient materials for 20 tests:

- 20 Pouched devices: Each sealed foil pouch contains a *H. pylori* device, 1 disposable pipette and 1 desiccant packet
- 1 Positive control
- 1 Negative control
- 1 Specimen buffer
- 1 Package insert
- 1 Procedure card

**Materials Required But Not Provided**

- Specimen collection containers
- Centrifuge
- Lancets (for fingerstick whole blood only)
- Timer
- Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)
Interpretation of Results
(Refer to illustration)

**POSITIVE:** Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).

*NOTE:* The intensity of the color in the test line region (T) will vary depending on the concentration of *H. pylori* antibodies in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

**NEGATIVE:** One colored line appears in the control line region (C). No line appears in the test line region (T).

**INVALID:** Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new device. If the problem persists, discontinue using the kit immediately and contact your local distributor.

Quality Control

**Internal Quality Control**
An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal positive procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

**External Quality Control**
It is recommended that a positive and negative external control be run every 20 tests, and as deemed necessary by your internal laboratory procedures. External positive and negative controls are supplied in the kit. If controls do not perform as expected, assay results are invalid.

**Procedure for External Quality Control Testing**
Using the positive or negative external controls in place of a patient sample, add 2 drops of positive or negative control solution to the sample well (S) of a new test device, then add 1 drop of Buffer. Start the timer. Continue with Step 3 in the Test Procedure section.

Limitations

1. **Clearview H. pylori** (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. The test should be used for the detection of *H. pylori* antibodies in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in *H. pylori* antibody concentration can be determined by this qualitative test.

2. **Clearview H. pylori** (Whole Blood/Serum/Plasma) will only indicate the presence of *H. pylori* antibodies in the specimen and should not be used as the sole criteria for the diagnosis of *H. pylori* infection.

3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of *H. pylori* infection.

Expected Values

**Clearview H. pylori** (Whole Blood/Serum/Plasma) has been compared with Culture/Histology, demonstrating an overall accuracy of 90.7%.

Performance Characteristics

**Clinical Sensitivity, Specificity and Accuracy**
**Clearview H. pylori** (Whole Blood/Serum/Plasma) has been evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals who presented for endoscopic examination.
Biopsy (Culture) served as the reference method for the **Clearview H. pylori** (Whole Blood/Serum/Plasma). Histology and a Rapid Urease Test (RUT) were performed on all negative culture specimens. The specimen was considered positive if Culture was positive. The specimen was also considered positive if the Culture was negative, but both Histology and RUT were positive. The result shows that the sensitivity of the **Clearview H. pylori** (Whole Blood/Serum/Plasma) is 93.0% and the specificity is 89.2% relative to Biopsy/Histology/RUT.

**Clearview H. pylori vs. Biopsy/Histology/RUT**

<table>
<thead>
<tr>
<th>Method</th>
<th>Biopsy/Histology/RUT</th>
<th>Total Results</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clearview H. pylori</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>119</td>
<td>139</td>
</tr>
<tr>
<td>Negative</td>
<td>9</td>
<td>174</td>
</tr>
<tr>
<td>Total Results</td>
<td>128</td>
<td>185</td>
</tr>
</tbody>
</table>

Relative Sensitivity: 93.0% (87.1%-96.7%)*
Accuracy: 90.7% (87.0%-93.7%)*
Relative Specificity: 89.2% (83.8%-93.3%)*
*95% Confidence Intervals

**Precision**

**Intra-Assay**

Within-run precision has been determined by using 10 replicates of four specimens: a negative, a low positive, a medium positive and a high positive. The negative, low positive, medium positive and high positive values were correctly identified >99% of the time.

**Inter-Assay**

Between-run precision has been determined by 10 independent assays on the same four specimens: a negative, a low positive, a medium positive and a high positive. Three different lots of **Clearview H. pylori** (Whole Blood/Serum/Plasma) have been tested using negative, low positive, medium positive and high positive specimens. The specimens were correctly identified >99% of the time.

**Cross-Reactivity**

Sera containing known amounts of antibodies to *H. pylori* have been tested with *C. jejuni*, *C. fetus*, *C. coli*, *P. aeruginosa*, and *E. coli*. No interference was observed. Sera positive for Hepatitis A, B, C, E, HIV and Syphilis were also tested. No cross reactivity was observed, indicating that **Clearview H. pylori** (Whole Blood/Serum/Plasma) has a high degree of specificity for human antibodies to *H. pylori*.

**Interference Studies**

**Clearview H. pylori** (Whole Blood/Serum/Plasma) has been tested for possible interference from visibly hemolyzed and lipemic specimens, as well as serum specimens containing high bilirubin levels. In addition, no interference was observed in specimens containing up to 1,000 mg/dL hemoglobin; up to 1,000 mg/dL bilirubin; and up to 2,000 mg/dL human serum albumin.

**Advice Line**

For further information, please contact your distributor, or call Inverness Medical Technical Specialists on:

UK: 08705 134952
International: +44 (0) 1234 835959.

[www.clearview.com](http://www.clearview.com)
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Kuikkidä/avakulkus/Reciclable/Recyclage/Resirkuleringsring/Ponto verde/Återvinning

Consult instructions for use/Siehe Gebrauchs-anweisung/Se
bruger-vejledningen/Consultar el prospecto/Ks./kayttöohljeit/Lire
les instructions d'utilisation/Symboolesteite te oädhie
χρήσεις/Consultare le istruzioni per l'uso/Raadpleeg voor
gebruik/Sie bruks-anvisningar/Consult as instruções de
utilização/Läs instruktionerna för användning

Contains sufficient for 20 tests/Inhalt ausreichend für 20 Tests/
Indeholder materiale til 20 test./Contiene lo necesario para
20 ensayos/Sisältää tarvittavat välineet 20 määrään testejä/
Quantité suffisante pour 20 tests/Innehåller nog til 20 tester/Contém o suficiente para
20 testes/Innehålet räcker till 20 test

For in vitro diagnostic use only/Nur zur In-vitro-Diagnostik/Kun til
in vitro diagnostisk anvendelse/Sólo para uso en el diagnóstico
in vitro/In vitro testaan In vitro diagnostiseen käyttöön/Pour usage
diagnostic in vitro uniquement/Môno para in vitro diagnostiki
χρήση/Unicamente per uso diagnostico in vitro/Alleen voor in vitro
diagnostisch gebruik/Bare for in-vitro diagnostisk bruk/Appenas para
utilização no diagnóstico in vitro/Endast för in-vitro diagnostiskt bruk

Store at 2-30ºC/Lagerung bei 2° bis 30°C/Opbevaring ved 2-30°C/
Almacenar a 2-30ºC/Saílyttetavaa 2-30°C/Conservar entre 2 et 30 °C/
Φυλάσσεται στους 2-30°C/Conservare a 2 - 30 °C/Opbevare bij 2-30°C/
Oppbevares ved 2-30°C/Conserver a 2ºC-30ºC/Förvaras vid 2-30 °C

Do not reuse/Nur für den einmaligen Gebrauch/Kun til
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Μια χρήση/Non riutilizzare/Niet opnieuw gebruiken/Bare for
engangsbruk/Neu reutilizar

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de catálogo/Luettelonumero/Numéro de catalogue/Αριθμός
catalóguou/Numero di catalogo/Catalognummer/Número de catálogo/Katalognummer

Use By/Expiry Date/Haltbarkeits-/Ablaufdatum/Anvendes
for/Udløbsdato/Utilizar antes de/Fecha de caducidad/Kayts.
ennen/Vam. kaytt sleeves/Utiliser avant/Date di scadenza/Te
gebrauk voor/Uiterste houdbaarheidsdatum/Brukes innen/
uitlapsedato/Usar até/Prazo de Validez/Utgångsdatum

Lot number/Chargennummer/Produktsnr./Lotnummer/Numéro de lot/Αριθμός
partidias/Numero di lotto/Lothenummer/lot nummer/Número de
lote/Parti nr.

Attention, see instructions for use/Siehe Gebrauchsanweisung/Bemærk!
Se vejledningen/Atención, lea las instrucciones de uso/Huomio, katso
kayttöohljeit/Attention, voir les instructions d'utilisation/Προσοχή, ανατρέξτε
στις οδηγίες χρήσης/Attenzione: consultare le istruzioni per l'uso/Let op:
raadpleeg voor gebruik/Se bruksanvisning/Atención:
consultar as instruções de utilização/Obs! Se instruktioner för användning

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Biological risks/Biologische Risiken/Biologiske risici/Riesgos
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κίνδυνοι/Risch biologici/Biologische risico’s/Biologisk risiko/Riscos
biológicos/Biologiska risker
References/Literatur/Henvisninger/Referencias/Viiteluettelo/Références/
Παραπομπές/Bibliografia/Referenties/Referanser/Referências/Referenser


