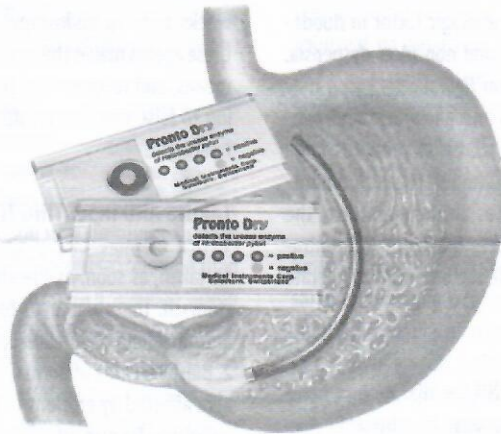


# Pronto Dry



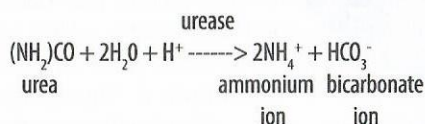
**The *Helicobacter pylori* test  
that makes life easier -  
The Nr. 1 dry RUT Worldwide**

**Der einfach anzuwendende  
*Helicobacter pylori* Test -  
Weltweit die Nr. 1 unter den  
trocken RUT's**

**Rapidité, précision, utilisation  
aisée réunies dans un test  
à l'uréase pour les infections  
à *Helicobacter pylori***

**INTENDED USE:** Pronto Dry is intended for use for the detection of urease enzyme in gastric mucosal biopsy specimens for the presumptive determination of *Helicobacter pylori* in symptomatic patients.

**SUMMARY / BIOLOGICAL PRINCIPLE:** *Helicobacter pylori* has been shown to cause active chronic gastritis and has been implicated as a primary etiologic factor in duodenal ulcer disease, gastric ulcer and non-ulcer dyspepsia. By causing chronic inflammation *Helicobacter pylori* may weaken the mucosal defenses and allow acid and pepsin to disrupt the epithelium. *H. pylori* produces large amounts of urease enzyme. Although urease primarily allows *H. pylori* to utilize urea as a nitrogen source, the breakdown of urea also produces high local concentrations of ammonia, which enable the organism to tolerate low pH (see reaction below).



Although *H. pylori* can be detected with histology or culture of gastric tissue, simple tests for the presence of urease enable more rapid and convenient diagnosis. Tests for gastric urease are specific for *H. pylori* because mammalian cells do not produce urease and very few microorganisms survive in the stomach, except for *H. pylori*.

**REAGENTS / STORAGE: Note: for in vitro diagnostic use only.** Pronto Dry consists of a dry filter paper containing urea, phenol red (a pH indicator), buffers and a bacteriostatic agent, in a sealed plastic slide. If the urease enzyme of *H. pylori* is present in an inserted tissue sample, the resulting decomposition of urea causes the pH to rise and the color of the dot turns from yellow to a bright magenta. Before use, each Pronto Dry slide should be inspected to make sure the dot is yellow. If the dot is red or magenta, the slide should not be used. The tests should be stored between 4° and 42° degrees C. Pronto Dry has a shelf life of 24 months.

**SPECIMEN COLLECTION AND HANDLING: WARNING: POTENTIALLY BIOHAZARDOUS MATERIAL.** Treat all biopsy specimens as if capable of transmitting disease.

Caution should be used in handling and disposing of these specimens. Your laboratory procedures should also be followed, as well, as any other local or state health recommendations.

**PREPARATION OF THE PATIENT:** Patients should not have taken antibiotics or bismuth salts for at least three weeks prior to endoscopy. Suppression of *H. pylori* by these agents makes the organism difficult to detect by any means, and re-growth of *H. pylori* may be patchy, leading to false negative results in the first few weeks after treatment.

**TAKING AND INSERTING THE BIOPSIES:**

1. One or more biopsy specimens for Pronto Dry may be taken, as soon, as the endoscopist has examined the stomach. The usual areas to biopsy are the antrum, along the greater curve, and the fundus.
2. Biopsy an area of normal-looking tissue, rather than an area affected by erosions or ulceration. This is because *H. pylori* may be present in smaller numbers, if the epithelium is eroded, or the mucous layer is denuded. The standard biopsy forceps will provide a specimen of sufficient size (2 - 3 mm diameter).
3. If the biopsy specimens appear to be very small, it may be worthwhile taking a third biopsy and inserting all specimens into Pronto Dry. Be careful not to contaminate the specimens with blood from the other biopsy sites.

**PRONTO DRY PROCEDURE:**

1. Peel back the label of the Pronto Dry thus exposing the dot. The plastic disk, stuck on the back of the label, should not fall off or be lost. It is necessary for pressing the biopsies into the Pronto Dry test dot.
2. With a sterile 19G needle, remove the specimen from the biopsy forceps and place them into the Pronto Dry. Make certain, that the tissue is positioned to have maximum contact with the dot.
3. Re-seal the Pronto Dry. Press the label over the dot with your finger to squeeze the tissue juice out of the specimens. On the label, record the name of the patient, the date and the time the specimen were inserted.
4. Accurate resealing is important to prevent the biopsy specimens from drying up.

**RESULTS - Reading the Pronto Dry:**

1. Note: Only if the external ring area is deepening in color and expanding in size, can the Pronto Dry be called positive. The internal dot always stays yellow, even with a positive test result. The color change is only in the external ring. Due to the increased color difference, the color change reaction is easily and clearly identifiable. True positives will have a color change that remains constant after 60 minutes.
2. The final reading of Pronto Dry is at 1 hour. Usually the first attempt to read the Pronto Dry is made, after the endoscopy report has been completed. This allows the endoscopist to objectively report the endoscopic findings before being aware of the presence of *H. pylori*.
3. If urease is present in the tissue, an expanding magenta color external ring will be noted around the biopsy specimens, or the Pronto Dry will gradually change to a deep orange, then magenta color. A pink-magenta ring at 1 hour is a positive result.
4. A negative result is when the external ring is still yellow 1 hour after insertion of the specimens. Subsequent color changes may occur, although in most cases a stable magenta or yellow color will be present.

**MATERIALS PROVIDED:** Pronto Dry is packaged in boxes of 10, 50 or 500 test slides with an instruction sheet.

**EXPECTED VALUES:** In a majority of cases, positive results will already be seen at 5 minutes and 30 minutes. All positive results are shown at 1 hour. The rare false-positive result will only appear after a longer period of time.

**PERFORMANCE CHARACTERISTICS:** Pronto Dry will diagnose 98% of *H. pylori* infections by 1 hour. Sensitivity and specificity data at 1 hour are:

	Pronto Dry	Culture
Sensitivity	98%	75%
Specificity	97%	100%

**DEGREE OF INFECTION / COLOR SCALE ON PRONTO DRY:**

Approximate Number of <i>H. pylori</i>	Reaction Time	Color
10 <sup>4</sup>	5 minutes	no color change
10 <sup>5</sup>	5 minutes	light pink
10 <sup>6</sup>	5 minutes	dark pink
10 <sup>7</sup>	5 minutes	amaranth
10 <sup>8</sup>	5 minutes	magenta
10 <sup>4</sup>	30 minutes	light pink
10 <sup>5</sup>	30 minutes	amaranth
10 <sup>6</sup>	30 minutes	magenta
10 <sup>7</sup>	30 minutes	magenta
10 <sup>8</sup>	30 minutes	magenta
10 <sup>4</sup>	60 minutes	dark pink
10 <sup>5</sup>	60 minutes	magenta
10 <sup>6</sup>	60 minutes	magenta
10 <sup>7</sup>	60 minutes	magenta
10 <sup>8</sup>	60 minutes	magenta

**LIMITATIONS:** False negative Pronto Dry results may occur, when very low numbers of *H. pylori* are present, or the bacterium has a patchy distribution. For example, in 1-5% of patients the bacterium is present in the fundus of the stomach, but not in the antrum, or vice versa. In patients with widespread intestinal metaplasia, an area of intestinal epithelium may be biopsied. As *H. pylori* does not colonize intestinal mucosa, a false negative Pronto Dry can result. To reduce the occurrence of false negatives, two Pronto Dries should be performed, one with a sample from the antrum and one from the fundus. All tests for *H. pylori*, including Pronto Dry, will be less sensitive, if the patient has taken antibiotics, bismuth, or proton pump inhibitors. Re-growth of *H. pylori* may be patchy after suppression with antibiotic. Again, an extra biopsy may be taken for Pronto Dry, to avoid a false negative reading. If there are factors, which might adversely affect the performance of Pronto Dry, the physician is advised to consider other diagnostic measures, such as culture with Gram stain and/ or histology, in order to confirm or disprove a diagnosis of *H. pylori* infection.