AVANOS | CLOTEST* Rapid Urease Test

CLOTEST*: RAPID UREASE TEST FOR THE DIAGNOSIS OF H. PYLORI[1]

ACCURACY

- 98% sensitivity and 97% specificity[2]
- Diagnosis of 75% of H. Pylori infections with no false positives within 20 minutes[3]

CONVENIENCE

- Easy to read colour changes: from yellow to magenta
- Positive control test separately available: Jack Bean Urease Test

AFFORDABILITY

- Less expensive diagnosis than culture or histology

CLOTEST® will diagnose 75% of H. Pylori infections with no false positives within 20 minutes. Within one hour, 85% of positive patients will be detected, at 3 hours, 90% will be detected, and between 3 and 24 hours another 5% of patients will be detected by CLOTEST®.

CLOTEST*
Rapid Urease Test

Golden Rules

Refer to the CLOTEST* Instructions for Use in the box for complete instructions.

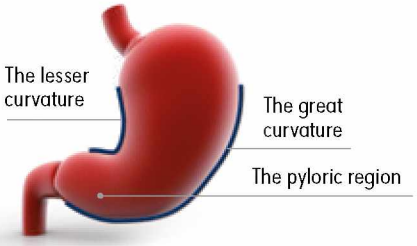
Storage: Standard refrigerator range: 2-8°C

Shelf Life: 18 months

Precautions: Do not use if the gel is not yellow,
seal is damaged,
gel is dehydrated and
expiration date has passed.

Preparation:

- Discontinue the use of antibiotics and bismuth preparations 3 weeks prior to the biopsy
- Put the slide 7-10 minutes at room temperature to obtain a faster result
- Make sure the biopsy sample is completely immersed in the gel
- Put the CLOTEST* slide on a warming plate (30-40°C) to speed the reaction time (<3h)



Optimal sampling:

- The pyloric region (at least 2 cm away from the pylorus)
- The great or lesser curvature
- Avoid sampling from eroded tissue

Positive control test: Jack Bean Urease Test

In case the slide is still yellow after 24 hours:

- Insert one CLOTEST* positive control sample in the gel
- Re-seal the lid over the slide and wait 10 minutes
- Look at the gel for a positive colour change (contact your sales representative in case of no colour change)

PRODUCT CODE	DESCRIPTION	PACKAGING
60480	CLOTEST* Rapid Urease Test	25 each
60407	Jack Bean Urease Control Tablets	50 each

References: 1. Rosaida M.S. et al. Evaluation of a new biopsy urease test for the diagnosis of Helicobacter Pylori infection. European Journal of Gastroenterology and Hepatology, 2004; 16: 195-199. 2. Dye KD, Marshall MJ, Frierson HF, Barrett LJ, Guerrant RL, McCallum RW. Is CLOtest alone adequate to diagnose Campylobacter pyloridis. Am J Gastroenterol 1988; 83: 1032 (abstract). 3. Marshall BJ, Warren JR, Francis GJ, Langton SR, Goodwin CS, Blincow E. Rapid Urease test in the management of Campylobacter pyloridis- associated gastritis. Am J Gastroenterol 1987; 82(3) 200-210.

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For more information, please send an email to customerservice.uk.ie@avanos.com or visit www.avanos.co.uk.

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TECHNICAL DATA SHEET

CLOtest*
Rapid Urease Test

CE IVD

Description
Item# 60480:
AVANOS CLOtest* Rapid Urease Test (RUT) accurately and conveniently detects the urease enzyme of Helicobacter pylori in gastric mucosal biopsies.
Its use is intended for the presumptive diagnosis of H. pylori infection.

Indication
The CLOtest* RUT detects 75% of H. pylori infections within 20 minutes with no false positives.
By one hour 85% of positive patients will be detected by CLOtest*
and at three hours 90% are detected.
Easy to read colour changes.
Single use product.

Counter indication
Do not reuse this device.
Consult the Instruction for Use.

Main materials
Urease indicator gel sealed inside a plastic slide.
The gel contains urea, USP (29 mg/mL) phenol red (a pH indicator), buffers and a bacteriostatic agent to prevent the growth of contaminating urease-positive organisms.
Not formulated with Natural rubber latex.
Not formulated with DEHP.

Packaging
Dispenser of 25 units CLOtest*in plastic slides.

Box size: 7,94 x 15,0 x 4,44 cm (LxWxD)
Box weight: 181 g (0,400 lbs)
Bar coding: GS1-128 symbology, linear on carton box.

Item #	Single Unit	Carton box
60480	none	350770927459

Manufacturing
Manufactured in USA.
The manufacturing site's quality is ISO13485 compliant.

Regulatory information
Product CE marked as per 98/79/EEC Directive relative to In Vitro Diagnostic Medical Device.
Class of the device: I-(IVD).

Storage
Store in a dry and cool place at 2°- 8°C (36°–48°F) temperature.
Do not use the product if the gel is not yellow, if the seal is damaged
and the gel appears dehydrated, or if the expiration date has passed.
Keep as much as practicably possible in its dispenser.

Shelf life
18 months, from date of manufacture.

Sterilisation
These products are non-sterile.

The dimensions and properties listed above can vary within pre-established specifications. This document was created using the most recent information. In the interest of continuous improvement, the characteristics of the product may change without prior notice.

AVANOS

5405 Windward Parkway
Alpharetta, GA 30004

T 1-844-425-9273
avanos.com

EC Declaration of Conformity

Name of Products:	Diagnostic Products
Product Codes:	60480 – CLOtest* 60407 – CLOtest* Reagent Urease Type III
GMDN Code:	52787 (Helicobacter pylori urease IVD, kit, chromogenic)
Legal Manufacturer (Place of Issue):	Avanos Medical, Inc 5405 Windward Parkway Alpharetta, Georgia (GA) 30004, USA
EU Authorized Representative:	Avanos Medical Belgium BVBA Leonardo Da Vincilaan 1 1930 Zaventem Belgium
Product Standards:	N/A
Start of CE:	07/10/2019
Conformity Assessment Route:	Annex III
Device Classification, Rules:	General IVD
CE certificate number:	N/A (Self-certification)
Notified Body:	N/A (Self-certification)
Quality System Certificate:	FM 702907

I, the undersigned, hereby declare that the above specified medical devices meet the applicable provisions of European In Vitro Diagnostic Medical Devices Directive 98/79/EC and are in accordance with Annex III of the EC Directive, supported by the Conformity Assessment Procedure, and adhering to the essential requirements in accordance with Annex I of the Directive 98/79/EEC

This declaration is based on the existing Technical Documentation as per Annex III CE marking carried out as per Annex X of the Directive 98/79/EC

All supporting documentation that contains proof of compliance to the aforementioned Directives is retained under the premises of Avanos Medical, Inc This declaration applies to all devices from the signature date forward

Authorized Signature:

Name Thomas Kozma
Title Director, Regulatory Affairs
Avanos Medical, Inc
Date 17 July 2019