remel

SELECTIVE RAPID UREA

INTENDED USE
Remel Selective Rapid Urea is a medium recommended for use to detect preformed urease enzyme activity in gastric mucosal biopsy specimens, indicating the presence of *Helicobacter pylori.*

SUMMARY AND EXPLANATION
In 1983, Warren reported unidentified curved bacilli in gastric biopsy specimens from cases of active chronic gastritis.[1] Subsequent investigators confirmed the finding of what is now known to be a distinct species named *H. pylori*.[2] In 1987, Marshall et al. described a method for detecting the organism in biopsy specimens by demonstration of preformed urease activity in a rapid test.[3,4] Hazell et al. reported 100% specificity with a rapid urease test performed on biopsy specimens, with 75% of the positives reacting in less than one hour.[5] Coudron and Kirby compared Selective Rapid Urea, a modification of Stuart's formula, and CLOtest® with staining and culture.[6,7] They found Selective Rapid Urea to be the most sensitive and specific, with most of the positive biopsies reacting in one hour. Because urease is not produced by mammalian cells, any enzyme activity detected in the gastric mucosa is of bacterial origin. Since *H. pylori* is the only organism known to survive in the stomach in significant numbers, the specimen is not likely to be contaminated with other bacteria.[8] In contrast with standard culture methods, a rapid presumptive test allows identification and treatment of patients suffering chronic gastritis and peptic ulcer.

PRINCIPLE
Preformed urease splits urea into two molecules of ammonia resulting in a pH shift to alkaline. Selective Rapid Urea is a lightly buffered medium containing phenol red as an indicator which yields a pink color in an alkaline environment. Selective agents in the medium reduce the possibility of false-positive reactions.

REAGENTS (CLASSICAL FORMULA)*

Urea	20.0 g
Yeast Extract	0.1 g
Monopotassium Phosphate	0.09 g
Phenol Red	0.01 g
Disodium Phosphate	95.0 mg
Selective Agents	28.0 mg
Agar	5.0 g
Demineralized Water	1000.0 ml

pH 6.8 ± 0.1 @ 25°C

*Adjusted as required to meet performance standards.

PRECAUTIONS
This product is for *In Vitro* diagnostic use and should be used by properly trained individuals. Precautions should be taken against the dangers of microbiological hazards by properly sterilizing specimens, containers, and media after use. Directions should be read and followed carefully.

STORAGE
This product is ready for use and no further preparation is necessary. Store product in its original container at 2-8°C until used. Allow product to equilibrate to room temperature before use. Do not incubate prior to use.

PRODUCT DETERIORATION
This product should not be used if (1) the product is contaminated, (2) the color has changed from the original straw, (3) the expiration date has passed, or (4) there are other signs of deterioration.

SPECIMEN COLLECTION, STORAGE, TRANSPORT
Refer to standard medical texts for surgical procedures detailing the collection of biopsy specimens.[9] Transport specimens to the laboratory in a suitable medium, without delay. For short-term transport (< 4 h) sterile saline (0.85%) is sufficient; otherwise, a semisolid transport medium maintained at 4°C is preferable. If culture is not possible within 24 h, biopsy specimens should be frozen at ≤ -70°C without any medium and transported on dry ice. Consult appropriate references for further instructions.[10,11]

MATERIALS REQUIRED BUT NOT SUPPLIED
(1) Loop sterilization device, (2) Inoculating loop, swabs, collection containers, (3) Incubators, alternative environmental systems, (4) Supplemental media, (5) Quality control organisms, (6) Applicator sticks.

PROCEDURE
1. Insert the biopsy specimen into the agar. A sterile applicator stick or cotton swab may be used to push the specimen into the agar.
2. Incubate the tube aerobically at 35-37°C.
3. Observe for an intense pink-red color around the biopsy specimen, frequently within 30 minutes. This reaction may also be observed at room temperature incubation.
4. Continue incubation of negative tests for a maximum of 24 hours. The development of an intense pink-red color is indicative of urease enzyme activity.

INTERPRETATION
Positive Test - An intense pink-red color in the medium around the biopsy specimen

Negative Test - No color change in the medium around the biopsy specimen

QUALITY CONTROL
All lot numbers of Selective Rapid Urea have been tested using the following quality control organisms and found to be acceptable. Testing of control organisms should be performed in accordance with established laboratory quality control procedures. If aberrant quality control results are noted, patient results should not be reported.

CONTROL	INCUBATION	RESULTS
Helicobacter pylori ATCC® 43504	Aerobic, 30 min. @ RT	Positive
Proteus mirabilis ATCC® 12453	Aerobic, 1h @ 33-37°C	Negative
Candida albicans ATCC® 10231	Aerobic, 24h @ 33-37°C	Negative
Escherichia coli ATCC® 25922	Aerobic, 24h @ 33-37°C	Negative
Staphylococcus aureus ATCC® 25923	Aerobic, 24h @ 33-37°C	Negative

LIMITATIONS

1. An improperly transported specimen may result in an inaccurate test.[10,11]
2. A false-positive reaction may result if the medium becomes contaminated with a urease-producing organism.
3. A false-negative reaction could result from a biopsy containing an insufficient number of organisms. **Note:** A negative rapid urease test does not rule out the possibility of *H. pylori* colonization.
4. Urea test media rely on demonstration of alkalinity and are not specific for detection of urease activity. Peptones in the medium may be hydrolyzed releasing alkaline by-products that may increase the pH causing a pink color in the medium which should not be confused with the intense pink-red color of a positive result.[12]

PERFORMANCE CHARACTERISTICS

Evaluation #1: In a comparison study, biopsy specimens were cultured for *H. pylori* using standard culture techniques, Selective Rapid Urea, and Christensen's urea agar.[7] The following results were obtained:

	Remel Selective Rapid Urea		
Culture	Positive	Negative	Total
Positive	52	11	63
Negative	0	36	36
Total	52	47	99

Specificity = 100% Sensitivity = 83%

	Christensen's Urea Agar		
Culture	Positive	Negative	Total
Positive	34	29	63
Negative	5	31	36
Total	39	60	99

Specificity = 86% Sensitivity = 54%

Evaluation #2: In a second study, biopsy specimens were tested for *H. pylori* with Selective Rapid Urea, standard culture techniques, and histological stain (hematoxylin-eosin).[13] The following results were obtained:

	Remel Selective Rapid Urea		
Culture	Positive	Negative	Total
Positive	4	0	4
Negative	*2	31	33
Total	6	31	37

*(Organism seen on histological stain)
Specificity = 94% *(100%) Sensitivity = 100%

	Remel Selective Rapid Urea		
Histology	Positive	Negative	Total
Positive	4	0	4
Negative	*2	21	23
Total	6	21	27

*(Organism recovered by culture)
Specificity = 91% *(100%) Sensitivity = 100%

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PACKAGING

REF R20389, Selective Rapid Urea (0.5 ml/Vial)..... 24/Pk

Symbol Legend

REF	Catalog Number
IVD	In Vitro Diagnostic Medical Device
LAB	For Laboratory Use
	Consult Instructions for Use (IFU)
	Temperature Limitation (Storage Temp.)
LOT	Batch Code (Lot Number)
	Use By (Expiration Date)

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