remel

Spectra[™] UTI

INTENDED USE

Remel SpectraTM UTI is a solid chromogenic medium recommended for use in qualitative procedures for the primary isolation, differentiation, and presumptive identification of organisms that cause urinary tract infections (UTIs).

SUMMARY AND EXPLANATION

The diagnosis of urinary tract infections contributes significantly to the daily workload in clinical microbiology laboratories. Increasing resistance to conventional broad-spectrum antimicrobic agents demands rapid identification of pathogens.¹ In recent years, chromogenic media have been developed that allow for presumptive identification of frequently isolated urinary tract pathogens on primary plates.^{2,3} Both gram-negative and gram-positive bacteria can be differentiated based on contrasted colony colors produced by reactions of genus- or species-specific enzymes with proprietary chromogenic substrates.^{4,5}

Spectra[™] UTI is a white opaque medium containing two specific chromogenic substrates, which are cleaved by enzymes produced by *Enterococcus* spp., *Escherichia coli*, and members of the *Klebsiella*-*Enterobacter-Serratia* (KES) group. In addition, it contains phenylalanine and tryptophan, which provide an indication of tryptophan deaminase activity present among members of the *Proteus*-*Morganella-Providencia* (PMP) group. *Staphylococcus* spp. produce white colonies and *S. saprophyticus* produces a white colony with a pink halo. *Pseudomonas* spp. produce nonpigmented, translucent colonies. The base used is CLED (cysteine-, lactose-, and electrolyte-deficient) agar, which prevents the swarming of *Proteus* spp.

PRINCIPLE

One chromogen, X-Gluc, is targeted towards β -glucosidase and allows for the specific detection of enterococci through the formation of teal or blue-green colonies. The other chromogen, Red-Gal, is cleaved by the enzyme β -galactosidase, which is produced by *E. coli*, resulting in pink-red colonies. Cleavage of both chromogens occurs in the presence of coliforms (KES group), resulting in blue colonies. Any uncertainty in identification of *E. coli* may be resolved by performing an indole test using DMACA reagent to test pink-red colonies. Tryptophan, acts as an indicator of tryptophan and *Providencia* spp. appearing beige to brown and surrounded by a brownish halo.

REAGENTS (CLASSICAL FORMULA)*

Chromogenic Mix	26.3	g
Peptone	15.0	ğ
Agar	15.0	ă
Demineralized Water	1000.0	ml

pH 7.4 ± 0.2 @ 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 $2-8^{\circ}$ C in the dark 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) there is evidence of dehydration, (2) the product is contaminated, (3) the color has changed, (4) the expiration date has passed, or (5) there are other signs of deterioration.

SPECIMEN COLLECTION, STORAGE, AND TRANSPORT

Specimens should be collected and handled following recommended guidelines.^{6,7}

MATERIALS REQUIRED BUT NOT SUPPLIED

Loop sterilization device, (2) Inoculating loop, swabs, collection containers, (3) Incubators, alternative environmental systems, (4) Supplemental media and reagents, (5) Calibrated inoculating loops, 1 or 10 µl, (6) Quality control organisms, (7) Gram stain reagents, (8) Bactidrop[™] Spot Indole (ρ-Dimethylamino-cinnamaldehyde: DMACA) (REF R21550).

PROCEDURE

- . Inoculate and streak the specimen as soon as possible after it is received in the laboratory. **Note:** Inoculate a blood agar plate with each specimen along with the Spectra[™] UTI plate to recover organisms that may not grow on Spectra[™] UTI.
 - a. Immerse a calibrated loop (1 or 10 µl) into the urine specimen, holding it vertically.
 - b. Dispense the contents of the loop onto each plate making a single streak down the center of the plate.
 - c. Using the same loop, make perpendicular streaks over the entire surface of the plate, obtaining isolated colonies.
- Incubate plates in ambient air, protected from light, for not less than 20-24 hours at 35-37°C.
- 3. Observe colony characteristics, morphology, and color reactions.

INTERPRETATION

After incubation, use the following table to interpret the results of the color reactions and as a guideline for additional confirmatory tests. A Gram stain may be performed to confirm results.⁸

Organism	Colony color	Confirmatory Test(s)
Enterococci	Teal or blue-green	
Escherichia coli	Pink	Spot Indole
KES ^a group	Medium- to dark-blue	Spot Indole, Motility, ODC, DNase
PMP ^b group	Tan-brown w/brownish halo	Spot Indole, H ₂ S, ODC, Urea Hydrolysis
Pseudomonas	Nonpigmented, translucent	Oxidase, Fluorescence
Staphylococci	Opaque, white to cream	Catalase, Coagulase
Staphylococcus saprophyticus	White w/ pink halo	Catalase, Coagulase, Novobiocin Disk = 5µg
Streptococcus agalactiae*	Nonpigmented, white	Catalase, Hippurate Hydrolysis, CAMP Test

a = Klebsiella, Enterobacter, Serratia spp., b = Proteus, Morganella, Providencia spp.

KEY: ODC = ornithine decarboxylase, DNase = doxyribonuclease produced by Serratia spp.,⁹ H_2S = hydrogen sulfide, CAMP = test for detection of synergistic protein produced by S. agalactiae⁷

* *S. agalactiae* has been infrequently associated with urinary tract infections. It produces a small, white colony on Spectra[™] UTI, similar in appearance to *S. aureus*. A Gram stain and catalase test may be used to differentiate *S. agalactiae* and *Staphylococcus* spp. Consult appropriate references for additional differential tests.^{6,7,9}

QUALITY CONTROL

All lot numbers of Spectra[™] UTI 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 Enterobacter aerogenes ATCC [®] 13048	INCUBATION Ambient, 18-24 h @ 33-37°C	RESULTS Blue colonies
<i>Enterococcus faecalis</i> ATCC [®] 29212	Ambient, 18-24 h @ 33-37°C	Teal or Blue-Green colonies
Escherichia coli ATCC [®] 25922	Ambient, 18-24 h @ 33-37°C	Pink colonies
Proteus mirabilis ATCC [®] 12453	Ambient, 18-24 h @ 33-37°C	Brown colonies w/ brownish halo
Stapylococcus aureus ATCC [®] 25923	Ambient, 18-24 h @ 33-37°C	White, nonpigmented colonies

LIMITATIONS

- 1. Organisms with atypical enzyme patterns may give anomalous reactions.
- 2. An indole test can be performed using DMACA to distinguish between *E. coli* and *Citrobacter freundii* or *Enterobacter cloacae*, and also between *Proteus mirabilis* and other species. Do not use Kovac's indole reagent, as the color of the *E. coli* colonies may interfere with the red color of a positive Kovac's reaction. Do not apply indole reagent directly to the plate; perform test on suitable filter paper. Further biochemical tests should be performed when necessary.⁸
- 3. Members of the KES group, which produce colonies that are blue in color, require additional tests for identification. Consult appropriate references for additional differential tests.^{6,7,9}
- 4. Listeria monocytogenes is a gram-positive bacillus rarely associated with urinary tract infections (e.g., following spontaneous abortion, stillbirth, premature delivery). L. monocytogenes produces teal or blue-green colonies on Spectra™ UTI similar to enterococci; however, unlike enterococci, it is PYR negative. Other tests may be necessary to differentiate Listeria from enterococci including, a Gram stain and catalase test. Consult appropriate references for additional differential tests.^{67,9}

EXPECTED VALUES

Organism	Expected Result	
Escherichia coli	Medium to large pink colony	
Citrobacter, Enterobacter, Klebsiella, Serratia	Medium- to dark-blue or colony	
Enterococcus spp.	Small teal or blue-green colony	
Proteus mirabilis, Proteus vulgaris, Morganella morganii	Small, non-spreading, tan-brown colony w/ brownish halo	
Pseudomonas spp.	Medium nonpigmented, translucent colony w/ an irregular edge	
Staphylococcus aureus	Nonpigmented, white colony	
Stapylococcus saprophyticus	White colony w/ pink halo	
Streptococcus agalactiae	Small, nonpigmented to white colony	

PERFORMANCE CHARACTERISTICS

In a clinical study which included testing of 392 bacterial isolates from urinary tract infections, SpectraTM UTI performed as indicated in the following table.¹⁰

Organism	Total Isol.	UTI @ 24h	UTI @ 48h	UTI % @ 24 h	UTI % @ 48 h
C. freundii	4	4	4	100	100
E. aerogenes	2	2	2	100	100
E. cloacae	4	4	4	100	100
E. coli	192	186	189	96.9	98.4
K. oxytoca	13	13	13	100	100
K. pneumoniae	30	30	30	100	100
M. morganii	2	2	2	100	100
P. mirabilis	14	13	13	92.9	92.9
P. vulgaris	1	1	1	100	100
S. marcesens	1	1	1	100	100
P. aeruginosa	15	14	15	93.3	100
Enterococci	81	77	78	95.1	96.3
Staphylococci, coagulase-neg.	14	14	14	100	100
S. aureus	2	2	2	100	100
S. saprophyticus	1	1	1	100	100
Group B Streptococcus	16	8	8	50	50
Overall Total	392	372	377	94.9	96.2

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PACKAGING

REF	R01818, Spectra	[™] UTI	monoplate	10/Pk
REF	R01819, Spectra	[™] UTI	monoplate	100/Pk
REF	R02192, Spectra	[™] UTI	// Blood Agar biplate.	10/Pk

Symbol Legend

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

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