

remel

A.C.T.[®] II

INTENDED USE

Remel A.C.T.[®] II (Aerobic/Anaerobic Culture Transport) is a sterile system recommended for use in qualitative procedures for the collection of clinical specimens and transport to the laboratory for microbiological culture of anaerobic, facultative, and aerobic organisms. A.C.T.[®] II is intended for use in clean environments (e.g., surgical suites, clean rooms) and consists of one tube of transport medium and a rayon-tipped swab; A.C.T.[®] II Dual is packaged with one tube and two swabs. The system is designed for use with fluid specimens or swabs when swab collection is appropriate.

SUMMARY AND EXPLANATION

In 1946, Stuart successfully transported specimens for recovery of *Neisseria gonorrhoeae* on charcoal-impregnated cotton swabs immersed in a non-nutrient semi-solid medium that was reduced and buffered.¹ In further studies, Stuart et al. determined that prevention of desiccation and oxidation was paramount to organism survival.^{2,3} These fundamentals of specimen transport were found to be applicable to a variety of fastidious and non-fastidious organisms, as reported by Cooper in 1957.⁴ In 1967, Amies modified the Stuart formulation by increasing the agar content, adding an inorganic phosphate buffer, and substituting sodium thioglycollate for thioglycollic acid.⁵ This modification extended the shelf life of the medium and prevented the overgrowth of coliforms. A.C.T.[®] II medium is based on the findings of Stuart and Amies. It is designed to protect aerobic, facultative, and anaerobic bacteria against the lethal effects of atmospheric oxygen, unfavorable pH conditions, toxic fatty acids, and desiccation during transport.

PRINCIPLE

A.C.T.[®] II is prepared in a reduced state and maintained in an oxygen-free environment. Resazurin is incorporated as an Eh indicator. A screw cap with a butyl rubber stopper facilitates injection of aspirated specimens using a needle and syringe. The nonnutritive medium maintains a favorable pH and provides a moist, inert, protective environment that preserves the specimen and minimizes overgrowth of competing microorganisms.

REAGENTS (CLASSICAL FORMULA)*

Sodium Chloride	3.0	g
Cysteine Hydrochloride.....	1.0	g
Dipotassium Phosphate.....	1.0	g
Sodium Thioglycollate.....	1.0	g
Calcium Chloride	0.1	g
Magnesium Chloride.....	50.0	mg
Resazurin.....	2.0	mg
Agar	10.0	g
Demineralized Water	1000.0	ml

pH 7.2 +/- 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 room temperature until used. Do not freeze or overheat. Do not incubate prior to use.

PRODUCT DETERIORATION

This product should not be used if (1) the outer package is damaged, (2) there is evidence of contamination, (3) more than 3 mm of the medium is oxidized (pink or lavender color), (4) the expiration date has passed, (5) the agar is broken, or (6) there are other signs of deterioration.

SPECIMEN COLLECTION, STORAGE, AND TRANSPORT

Specimens should be collected and handled following recommended guidelines.⁶⁻⁸ Specimens should be processed as soon as possible after they are received in the laboratory.

MATERIALS REQUIRED BUT NOT SUPPLIED

(1) Swabs, syringes, needles, (2) Sterile forceps, sterile Pasteur pipettes, (3) Supplemental media, (4) Inoculating loop, loop sterilization device, (5) Incubators, alternative environmental systems, (6) Quality control organisms, and (7) Materials required for organism identification

PROCEDURE

Swab Specimens:

1. Wear gloves to remove the outer packaging outside of the clean area (avoid touching the contents). Take the package containing the sterile tube and swab into the clean area.
2. After collecting the swab specimen, remove the A.C.T.[®] II cap and quickly insert the swab deep into the agar.
3. Break the swab shaft evenly with the lip of the tube.
4. Replace the cap and quickly tighten to minimize exposure to air.
5. Label with appropriate patient information.
6. Maintain A.C.T.[®] II at room temperature.
7. Send to the laboratory for processing with minimal delay.
8. Upon receipt in the laboratory, remove the cap and use sterile forceps to remove the swab.
9. Use the swab to inoculate culture media and prepare smears following established laboratory procedures.

Aspirated Specimens (syringe):

1. Wear gloves to remove the outer packaging outside of the clean area (avoid touching the contents). Take the package containing the sterile tube and swab into the clean area.
2. Disinfect the rubber stopper with an appropriate disinfectant, such as alcohol.
3. After collecting the specimen, push the needle through the rubber stopper and slowly inject the specimen on top of agar.
4. Carefully remove the needle and syringe; dispose of it in an appropriate sharps biohazard container. Follow established procedures for safe and proper disposal of sharps and biohazards.⁸
5. Label with appropriate patient information.
6. Maintain A.C.T.[®] II at room temperature.
7. Send to the laboratory for processing with minimal delay.
8. Upon receipt in the laboratory, remove the cap and use a sterile Pasteur pipette to aspirate the specimen.
9. Use the fluid to inoculate culture media and prepare smears following established laboratory procedures.

INTERPRETATION OF THE TEST

This transport medium serves as a vehicle for maintaining organism viability while transporting the specimen to the laboratory.

QUALITY CONTROL

All lot numbers of A.C.T.® II have been tested using the following quality control organisms and have been found to be acceptable. Microscopic examination of each lot number of A.C.T.® II meets or exceeds the bio-burden standard recommended by Clinical and Laboratory Standards Institute.⁹ 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

Bacteroides fragilis
ATCC® 25285

INCUBATION

Aerobic, 72h @
Room Temperature

RESULTS

Good recovery
on subculture

Streptococcus pyogenes
ATCC® 19615

Aerobic, 72h @
Room Temperature

Good recovery
on subculture

LIMITATIONS

1. Optimal recovery of microorganisms is achieved by inoculation of culture media immediately after specimen collection. When specimen processing may be delayed, A.C.T.® II provides an alternative for specimen transport to the laboratory.
2. Condition, timing, and volume of specimen collected for culture are significant variables in obtaining reliable culture results. Follow recommended guidelines for specimen collection.^{6,7}
3. *Chlamydia*, *Mycoplasma*, and viruses require special transport systems. Consult appropriate references for transport of suspected potential pathogens.^{6,7}
4. Specimens for culture of anaerobes should be handled in a manner that minimizes exposure to oxygen during processing.

EXPECTED VALUES

Results obtained will largely depend on proper and adequate specimen collection, as well as timely transport and processing in the laboratory. Organisms in fluid specimens or the logarithmic phase of growth may continue to grow until endogenous nutrients are depleted.

Every effort is made to minimize or eliminate sources of bio-burden that may lead to the observation of nonviable organisms on microscopic examination.

PERFORMANCE CHARACTERISTICS

An evaluation of 9 potentially pathogenic organisms held for 72 hours in the A.C.T.® II transport system showed viability comparable to a similar commercially available transport system.

BIBLIOGRAPHY




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2. Moffett, M.B., J.L. Young, and R.D. Stuart. 1948. Br. Med. J. 2:421-424.
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4. Cooper, G.N. 1957. J. Clin. Pathol. 10:226-230.
5. Amies, C.R. 1967. Can. J. Public Health. 58:296-300.
6. Murray, P.R., E.J. Baron, J.H. Jorgensen, M.L. Landry, and M.A. Pfaller. 2007. Manual of Clinical Microbiology. 9th ed. ASM Press, Washington, D.C.
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8. Chosewood, L.C. and D.E. Wilson. 2007. Biosafety in Microbiological and Biomedical Laboratories. 5th ed. U.S. Dept. of H.H.S. CDC and National Institutes of Health, Washington, D.C.
9. Clinical and Laboratory Standards Institute (CLSI). 2003. Quality Control of Microbiological Transport Systems; Approved Standard. M40-A. CLSI, Wayne, PA.

PACKAGING

REF R12402, A.C.T.® II 10/Pk
Single rayon-tipped swab w/ plastic shaft, sterile packed in individual Tyvek® envelope with 16 X 125 mm tube.

REF R124022, A.C.T.® II Dual 10/Pk
Two rayon-tipped swabs w/ plastic shaft, sterile packed in individual Tyvek® envelope with 16 X 125 mm tube.

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)

A.C.T.® is a registered trademark of Remel Inc.

ATCC® is a registered trademark of American Type Culture Collection.

Tyvek® is a registered trademark of E. I. duPont de Nemours and Company.

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