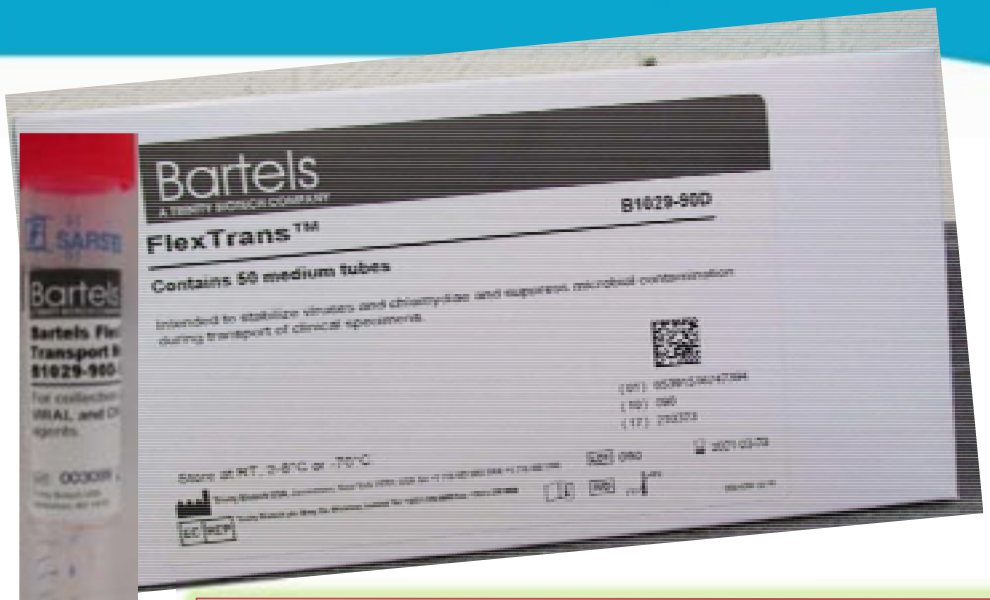
Bartels FlexTrans™ Medium

Catalog No. B1029-90D (50 vials)

The Bartels FlexTrans™ Transport Medium is intended to stabilize viruses and chlaymdiae, and suppress microbial contamination during transport of clinical specimens from the point of collection to the testing site.



- 3 ml of transport medium in a 15 ml conical centrifuge tube allowing specimen collection, transport and processing in the same container.
- The transport tube also contains glass beads to aid in the disruption of patient cells in the specimen, with subsequent release of viruses or chlamydia into the medium.
- Manufactured in USA
- USFDA Certified

****** See following Pages for more information and specifications ******

www.dvjmedical.com **email: dvjahn@mail.com**
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GSA Contracts: 65IIF:V797D-70060 **65IIA: 36F79718D0559** **CAGE Code: 7J4L1** **DUNS: 049949834**

510(k) Premarket Notification

New Search

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Device Classification Name	Culture Media, Non-Propagating Transport[22]
510(K) Number	K935987
Device Name	FLEXTRANS
Applicant	BAXTER DIAGNOSTICS, INC. 2005 NW SAMMAMISH RD. Issaquash, WA 98027
Applicant Contact	Nancy Mallinak
Correspondent	BAXTER DIAGNOSTICS, INC. 2005 NW SAMMAMISH RD. Issaquash, WA 98027
Correspondent Contact	Nancy Mallinak
Regulation Number	866.2390[23]
Classification Product Code	JSM[24]
Date Received	12/14/1993
Decision Date	08/15/1994
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Microbiology
510k Review Panel	Microbiology
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

FlexTrans™

Viral & Chlamydial Transport Medium

B1029-90C	25 Vials
B1029-90D	50 Vials

INTENDED USE

The **Bartels FlexTrans™ Transport Medium** is intended to stabilize viruses and chlaymdiae, and suppress microbial contamination during transport of clinical specimens from the point of collection to the testing site. For *in vitro* Diagnostic Use. Store at room temperature, 2-8ºC or -70ºC.

PRINCIPLE

Cell culture isolation is an important tool in the diagnosis of viral and chlamydial infections. A specimen is collected from the site of suspected infection and immediately placed into specialized transport medium formulated to maintain viability of any viral or chlamydial organisms present in the specimen and suppress overgrowth of other microbial agents. Additionally, FlexTrans™ is non-inhibitory to cell culture, making it usable not only for transport but for cell culture inoculation. FlexTrans™ may also be used in rapid detection systems such as enzyme-linked immunosorbent assay (ELISA) and direct fluorescent testing. The specimen is transported on wet ice to the testing facility, where it is maintained at 2-8ºC until it can be processed.

PRODUCT DESCRIPTION

FlexTrans™ - 2 ml of transport medium in a 15 ml conical centrifuge tube, allowing specimen collection, transport and processing in the same container. Medium contains Minimal Essential Medium supplemented with L-glutamine and Hanks Salts, bovine serum albumin, sucrose, amphotericin B, gentamicin and streptomycin buffered with HEPES Buffer to a pH range of 7.0-7.4. Phenol red is added as a pH indicator. The transport tube also contains glass beads to aid in the disruption of patient cells in the specimen, with subsequent release of viruses or chlamydiae into the medium. FlexTrans™ is available in a variety of packaging formats. Please contact a Customer Service Representative in the U.S. at 1-800-325-3424, or outside the U.S. at (353) 1 276 9800 for additional information.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use.
2. FlexTrans™ should not be used beyond its expiration date.
3. All specimens and materials used to process them should be considered potentially infectious and handled in a manner which prevents infection of laboratory personnel. Decontamination is most effectively accomplished with a 0.5% sodium hypochlorite solution (1:10 dilution of household bleach).

STABILITY AND STORAGE

Prior to use, store at room temperature, 2-8ºC or -70ºC. The expiration dating on the vial applies to each storage temperature. The antifungal agent present in the FlexTrans™ kit may be light sensitive. It is recommended that the tubes are stored in the box or in the dark.

SPECIMEN COLLECTION

Proper specimen collection and handling are among the most important factors in successful detection of viruses and chlamydiae. Use sterile cotton or DACRON® swabs with plastic or wire shafts which are non-inhibitory to viruses and chlamydiae. Do **not** use calcium alginate swabs.

AUTOPSY OR BIOPSY SPECIMEN

1. Collect fresh tissue from appropriate site using a separate sterile instrument to cut and remove each sample. Each specimen need not be more than 1-2 cm in diameter.
2. Place each sample into an individual leakproof container and cover with sufficient transport medium to prevent drying of specimen.
3. Tissue specimens should not be formalinized or fixed.

CEREBROSPINAL FLUID (CSF)

1. Collect cerebrospinal fluid (CSF) in the usual manner.
2. Transfer up to 2 ml, equal to the amount of transport medium, into the vial.
3. If less than 1 ml of CSF is available, consult your laboratory for transport recommendations.

CERVIX FOR CHLAMYDIA CULTURE

1. Wipe the cervix prior to collection to remove WBC and mucus debris. Insert a sterile, large-tipped swab into the endocervix, rotate and remove. Discard this swab.
2. Insert a second, sterile swab into the cervical os to collect cells from the transitional zone. Rotate the swab vigorously in firm contact with cervical surface to facilitate the collection of columnar epithelial cells.
3. Withdraw swab without contacting vaginal surfaces.
4. Place swab into transport medium.

CERVIX FOR HERPES SIMPLEX CULTURE

1. Remove exocervical mucus with swab, and discard swab.
2. Insert fresh swab at least 1 cm into cervical canal, and rotate swab for 10 seconds.
3. Place swab into transport medium.
4. For detection of HSV shedding, collection of a vulvar sample may increase recovery.

CUTANEOUS/VESICULAR LESION

1. Gently cleanse vesicle using a swab moistened with sterile saline.
2. Aspirate fluid with a tuberculin syringe or collect lanced vesicle onto a swab.
3. If vesicle is absent, vigorously swab base of lesion.
4. Transfer fluid or swab into transport medium.

EYE

1. Gently swab the lower conjunctiva with a sterile, fine-tipped swab, collecting patient mucous membrane cells.
2. Place swab into transport medium.

NASOPHARYNX

1. Gently insert a sterile nasopharyngeal swab into one or both anterior nares to the posterior pharynx, rotate to collect mucous membrane cells and withdraw.
2. Place swab into transport medium.

RECTAL SWAB

1. Insert a sterile swab 1 cm past the anal sphincter, rotate in firm contact with the mucosal surface and withdraw.
2. Place swab into transport medium.

RESPIRATORY ASPIRATE

(The quantity and quality of respiratory specimens to be tested can be improved by aspiration).

1. Collect aspirates from nose, nasopharynx and/or oropharynx.
2. Aspirates may be collected using a plastic disposable premature infant feeding tube attached to a 10 ml syringe. Alternately, a suction catheter with a mucous trap may be utilized.
3. Transfer up to 3 ml of aspirate into transport medium.

STOOL

1. Collect specimen in a clean, dry container.
2. Transfer sufficient faeces into transport medium to make a 20-40% suspension.

THROAT

1. Swab the posterior pharynx and tonsillar crypts vigorously with a largetipped, sterile swab.
2. Place swab into transport medium.

URETHRA (PATIENT SHOULD NOT HAVE URINATED WITHIN ONE HOUR OF COLLECTION).

1. Insert a sterile, fine-tipped swab 2-4 cm into the male urethra, or 1 cm into the female urethra and hold in place for 5 seconds.
2. Rotate the swab several times to obtain columnar epithelial cells and withdraw.
3. Place swab into transport medium.

URINE

1. Collect a fresh, clean-catch specimen in a sterile container.
2. Transfer 2 ml into transport medium.

TRANSPORT AND STORAGE

After collection, store specimen tubes at 2-8ºC. All collected specimens should be transported on wet ice to the laboratory immediately after collection. Failure to transport and store specimens at 2-8ºC may lead to loss of viral or chlamydial infectivity. If the specimen cannot be processed within 2 days, freeze it at –70ºC; however, freezing should be avoided if at all possible. Specific requirements for shipping specimens should follow recommendations found in Titles 42 and 49 of the Code of Federal Regulations for Interstate Transport of Etiologic Agents.

PROCESSING

FOR CHLAMYDIA CULTURE

1. Rotate the swab in the transport medium, then press against the inside of the tube to allow excess fluid to drain back into the transport medium. Discard the swab into an appropriate disinfectant, such as 0.5% sodium hypochlorite solution (1:10 dilution of household bleach).
2. Disrupt cellular material in the transport medium by vortexing with sterile glass beads for 30-60 seconds, or sonicating at 10 kc/sec for the same length of time. This will enhance the release of cell-associated chlamydiae into the medium.
3. To remove bacterial, fungal and cellular debris, centrifuge the transport medium at 900xg for 5 minutes. Supernatant is then used as the cell culture inoculum. Futher clarification of heavily contaminated specimens may be accomplished by passing the specimen through a low retention 0.45 micron filter. The filtrate is then used as the inoculum.

FOR VIRAL EXAMINATION

If the transport tube contains a swab, it should be handled with sterile forceps. The swab should be rotated in the transport medium, then pressed against the inside of the tube to allow excess fluid to drain back into the transport medium. If specimens are to be used for both direct detection and culture isolation/confirmation, half of the cells should be removed by centrifugation at 300 to 500xg and used for the direct specimen for cell culture isolation. Discard the swab into an appropriate disinfectant, such as 0.5% sodium hypochlorite solution (1:10 dilution of household bleach).

DIRECT DETECTION

1. Add 2 ml of phosphate buffered saline (PBS) to the specimen. Resuspend cells and add an additional 6 ml of PBS.
2. Centrifuge specimen at 300 to 500xg for 10 minutes to pellet patient cells.
3. If the specimen contains mucous, it will be observed as a hazy layer immediately above the cell pellet. Using a sterile Pasteur pipette, remove all of the supernatant, including any mucous layer, and discard into sodium hypochlorite solution.
4. Add 2 ml of PBS to the specimen to re-suspend cell pellet. Add an additional 6 ml of PBS.
5. Centrifuge specimen at 300 to 500xg for 10 minutes.
6. Remove supernatant, including any mucous and discard into sodium hypochlorite solution.
7. Repeat steps 4-6 until cells are free of mucous.

8. Add 2-8 drops of PBS to make a slightly cloudy cell suspension.
9. Using a Pasteur pipette, spot cells onto acetone-cleaned glass slides.
10. Air-dry slides completely.
11. Fix slides in acetone and allow to air-dry.
12. After fixation, slides may be held for several days at 2-8ºC before staining.

CELL CULTURE INOCULATION

1. Disrupt cellular material in the transport medium or supernatant by vortexing with sterile glass beads for 30-60 seconds, sonicating at 10 kc/second for the same length of time, or by other methods determined by the laboratory to be effective in disrupting cellular material. This will enhance the release of cell associated virus into the medium.
2. To remove bacterial, fungal and cellular debris, centrifuge the transport medium at 2000xg for 10 minutes. Supernatant is then used as the cell culture inoculum.

FOR ELISA TESTING

Follow ELISA kit manufacturer's instructions for specimen processing.

QUALITY ASSURANCE

FlexTrans™ is tested for microbiological contamination, toxicity to host cell culture, and the ability to maintain viability of desired agents. Quality assurance information is available upon request. Individuals may evaluate the ability of FlexTrans™ to support viral and/or chlamydial agents by inoculating FlexTrans™ with an individual agents of choice. After 72 hours at 2-8ºC, using appropriate isolation procedures for the selected agent, positive growth should be obtained. Verify isolation by methodology appropriate to the selected agent.

LIMITATIONS

1. **Do not** use FlexTrans™ if leakage, evaporation, pH change or signs of contamination are apparent.
2. Improper storage of FlexTrans™ may lead to decreased antibacterial and antimycotic activity.
3. Freezing of specimens should be avoided; freezing may decrease recovery of viruses.
4. When performing a direct immunofluorescent test, **do not** freeze or vortex FlexTrans™ prior to slide preparation, as this can result in cellular disruption.

EXPECTED VALUES

From December 1992 through November 1993, 4,455 clinical cultures were processed using FlexTrans™ Virus was isolated in 7.0% (325) of these cultures, and chlamydiae was isolated in 3.5% (34). The viruses are listed below.

Virus	Number of Isolates
HSV 1	114
HSV 2	57
CMV	38
Adenovirus	23
Enterovirus	76
Influenza A	13
Influenza B	3
RSV	1

Specimens were transported under a variety of conditions: cool packs, refrigerated, frozen (dry ice) and ambient temperature. The patient population and demographics were diverse: newborn to elderly of both sexes were evaluated. Specimens were not selected for a particular disease, but were those submitted to the laboratory for routine screening. This lack of selection may account for the isolation rates observed.

PERFORMANCE CHARACTERISTICS

Sterility and toxicity of FlexTrans™ were determined by inoculation of the indicated cell lines. Transports were held at both ambient temperature and 2-8ºC for 5 days prior to inoculation of cells. Cell cultures were held at 34-37ºC in a CO2 environment for 8 days.

Cell Line	# wells examined	# shell vials examined	Sterility	Toxicity
McCoy	24	10	All	None
MRC-5	24	10	All	None
HF	24	10	All	None
Vero	24	10	All	None

FlexTrans™ inhibits the following organisms for at least 10 days after a log phase inoculation*: E. coli, Ps. aeruginosa, Legionella pneumophilia, Enterococcus faecalis, Staphylococcus aureus, Mycoplasma hominis, Ureaplasma ureolyticus, Klebsiella oxytoca, Micrococcus luteus*. In comparative studies with other commercially available transports, FlexTrans™ was found to be equivalent for the recovery of viral agents and suitable for the satisfactory survival and transport of chlamydia FlexTrans™ and other commercially available transports were each inoculated with 10 TCID50 of an HSV-2 stock virus strain. After 48 hours of refrigeration at 2-8ºC, 0.2 ml of each transport was inoculated into duplicate MRC-5 shell vials. After 48 hours incubation at 35ºC, the shell vials were stained with HSV-2 typing reagent. Equal growth was seen in all transports. Negative control vials were negative for growth and toxicity. Following refrigeration at 2-8ºC, one MRC-5 shell vial was inoculated every other day for 14 days with 0.2 ml from each transport. Shell vials were then incubated for 48 hours and then stained. FlexTrans™ showed growth in all transports, indicating that FlexTrans™ can maintain the viability of viruses when stored at 2-8ºC for 14 days. Five clinical specimens containing either *CMV strain AD 169 or CMV strain Towne* were inoculated into FlexTrans™ previously stored at either room temperature or 2-8ºC and another commerically available transport, and stored for 24 hours at 2-8ºC. Transports were then subcultured into cell culture vials and incubated at 34-37ºC for 48 hours. Cell culture vials were then fixed and stained with *Bartels CMV Immediate Early Antigen Direct Fluorescent Antibody*. All vials inoculated with CMV showed growth with negative control vials from both storage conditions showing no growth. In addition, the effectiveness of FlexTrans™ for the transport of respiratory viruses was determined by comparing FlexTrans™ with another commecially available transport media. Eight of each transport were inoculated with 0.2 ml stock influenza A culture material (105/ 0.2 ml). Four (each) of the two transports were either refrigerated or maintained at room temperature. At 24, 48, 72 and 96 hours, 0.2 ml of each transport was inoculated onto A-549 shell vials and incubated for 48 hours. Detection of infection was determined following staining with the Bartels Influenza A Indirect Fluorescent Antibody. A 2+ or greater immunofluorescence was considered positive. Positive growth was seen in all FlexTrans™ transports, whereas the other commercially available transport showed negative growth in all vials held at room temperature and inoculated at 96 hours.

Transport	24 Hours	48 Hours	72 Hours	96 Hours
FlexTrans™ RT	4/4	4/4	4/4	4/4
FlexTrans™ 2-8°C	4/4	4/4	4/4	4/4

FlexTrans™ is also effective for the transport of chlamydiae. *Chlamydia trachomatis* was inoculated into both FlexTrans™ and another commercially available transport and left at ambient temperature for three days. Each day, 0.2 ml was removed from each transport and inoculated into shell vials containing McCoy cells. All shell vials were treated similarly according to standard shell vial isolation procedures. After 48 hour incubation, the cells were fixed and stained with the Bartels Chlamydia Culture Confirmation Reagent. Equivalent growth was seen in shell vials inoculated on day one and day three.

FlexTrans™ can also be used for the transport of virus and chlamydiae for direct fluorescent antibody (DFA) and enzyme immunoassay (EIA) testing. When performing DFA or EIA, follow package insert instructions, paying particular attention to instructions for sample preparation, such as sample dilution prior to beginning testing. When performing a DFA test, **do not** vortex FlexTrans™ prior to slide preparation. Clinical specimens containing RSV, influenza A or chlamydiae, and stock cultures of *Chlamydia pneumoniae* and *Chlamydia psittaci* were inoculated into FlexTrans™ and stored at 2-8ºC or room temperature for 24 hours.

Transports were then tested in the appropriate Bartels ELISA, i.e., the Bartels RSV ELISA, the Bartels influenza A ELISA or the Bartels Chlamydiae ELISA. Transports were also inoculated into cell culture and confirmed via fluorescent antibody testing. All transports that tested positive in ELISA also tested positive in fluorescent antibody testing.

Clinical Samples	Replicates	ELISA Result	Culture Result
RSV-10 samples	90	All positive	All positive
Chlamydiae-10 samples	90	All positive	6/10 positive*
Influenza A-6 samples**	54	45 positive	All positive

*Four out of ten clinicals showed elementary bodies when stained with DFA, with no inclusions.
**Influenza A samples were tested 7 days after inoculation with FlexTrans™ Titer levels in some clinical samples were below the detection limit of the Bartels Influenza A ELISA.

Stock Cultures	Replicates	ELISA Result	Culture Result
Chlamydia pneumoniae	15	All positive	All positive
Chlamydia psittaci	15	All positive	All positive
Chlamydia trachomatis	15	All positive	All positive
Chlamydia trachomatis, LGV strain	15	All positive	All positive

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TECHNICAL INFORMATION

For further information or assistance, contact Technical Services.

ORDERING INFORMATION		
KIT		Bartels FlexTrans™ Medium
Catalog No.	Item	Quantity
B1029-90C	Bartels FlexTrans™ Medium	25 Vials
B1029-90D	Bartels FlexTrans™ Medium	50 vials


Manufactured

Authorized Representative


Consult accompanying documents

Product Number

Lot


Use by


Caution, consult accompanying documents


Store at 2-8ºC


Store at 2-30ºC

High Pos or Positive Control

Low Pos or Cut-Off Control

Negative Control

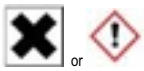
Calibrator

Coefficient Factor

Range

Standard

For *In Vitro* Diagnostic use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Hazard

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