

1. Product & Company Identification

DATE :	Besançon, March 13th 2007	REFERENCE :	2040
IN VITRO MEDICAL DEVICE :	MYCOVIEW ®	PRESENTATION :	20 Tests per Kit
INTENDED USE :	Please refer to IFU		
MANUFACTURER :	ZEAKON Diagnostics SARL 11, Rue A. de Vigny 25000 Besançon	REGULATORY :	<i>in vitro diagnostic devices</i> in conformity with the directive EC98/79
COUNTRY :	FRANCE	USE :	IN VITRO USE ONLY
Telephone Number	+33 9 54 74 40 10	Fax Number :	+33 381 53 47 92

2. Composition, informations on ingredients

REAGENTS	PROPERTIES	COMPONENTS
Transport Medium (T Broth)	n=20 vials with white cap: Each vial contains a volume of 2 ml of sterile limpid /pale yellow liquid Medium.	Liquid transport medium for mycoplasma sample transportation which contains the next antibiotic agents in small quantities for optimal preservation of specimen and minimize the growth of other microbiologic flora. Antibiotic agents -Ampicillin < 0.025g/L -Colimycin < 0.25 g/L -Cotrimoxazole < 0.15g/L
Culture Medium (C Medium)	n=20 vials with green cap: Each vial contains the freeze-dried medium made by sterile formulation in an orange-yellowish coloration. Note: For the test it has to be regenerated with the above transport medium which has been inoculated by the sample (see package insert).	Freeze-dried medium for the urogenital mycoplasmas culture which contains the next antibiotic agents in small quantities for optimal preservation of specimen and minimize the growth of other microbiologic flora. Formulation : yeast extract, horse serum, cysteine-HCl, urea, arginine and pH indicator phenol red; added antibiotic agents: -Ampicillin < 0.35% (w/w) -Colimycin < 0.05% (w/w) -Cotrimoxazole < 0.30% (w/w)
Mycoview Tray	n=10 pouches: Each containing 2 polystyrene tray devices sufficient for 2 tests. One tray device has 12 wells for the identification, enumeration and resistance test up to 9 different antibiotic agents in agreed concentrations for urogenital mycoplasmas testing ; each tray device has an adhesive film printed for the easy recognition of a specific test well. Two tray devices are hermetically closed in an aluminium pouch with a desiccant for preservation.	Plastic test device with 12 wells ; 11 wells with dried constituents for a test well.

Preparation names	Ingredients	CAS N°	Symbol	Toxicity	Used concentration
T Broth (2 mL)					
	NaCl	7647-14-5	Xi	20	<0.5g/L
	HCl N	7647-01-0	C	10	<0.1g/L
	Ampicillin				<0.025g/L
	Colimycin				<0.025g/L
	Cotrimoxazole				<0.15g/L
C Medium for 2mL T Broth					
	L-Cystein HCL	7048-04-6	Xi	20	<0.2g/L
	Colored indicator		Xi	20	<0.5g/L
	HCl N	7647-01-0	C	10	<0.1g/L
	Yeast extract				
	Urea	57-13-6			
	Arginine	74-79-3			
	Ampicillin	69-53-4			<0.35% (w/w)
	Colimycin				<0.35% (w/w)
	Cotrimoxazole				<0.35% (w/w)
Paraffin oil					
		8012-95-1			
Swabs –CE marked					
(Hardwood Products Company LP - USA)					

Preparation names / MycoView Tray	Ingredients	CAS N°	Danger Symbol	Toxicity	Active concentration µg/L	R Phrases	S Phrases
Well N°1	None						
Well N°2 / Uu≥10 ⁴	Antibiotic agent		Xi	20			
Well N°3 / M.h≥10 ⁴	Antibiotic agent		None				
Well N°4 / L	Lincomycin	859-18-7	Xi	20	8	36/37/38	26
Well N°5 / E	Erythromycin	114-07-8	None		4		
Well N°6 / ROX	Roxithromycin	80214-83-1	Xn	25	4	22	22/46/64
Well N°7 / AZM	Azithromycin	83905-01-5	None		4		
Well N°8 / JM	Josamycin	16846-24-5	None		4		
Well N°9 / MNO	Minocycline	10118-90-8	None		8		
Well N°10 / DO	Doxycycline	24390-14-5	None		8		
Well N°11 / OFX	NaCl	7647-14-5	Xi	20		34/37	22/26/45
	HCl N	7647-01-0	C	10			
	Ofloxacin	82419-36-1	None		4		
Well N°12 / NOR	NaCl	7647-14-5	Xi	20		34/37	22/26/45
	HCl N	7647-01-0	C	10			
	Norfloxacin	70458-96-7	None		2		

3. Hazards identification

A. Original state

The contents of T Broth and C Medium vials are classified as NOT DANGEROUS.

Since the preparations in the bottom of the wells of the MycoView tray are coated in a thin film, the risks are non-existent. However, in case of product deterioration, do not breathe the potentially produced dust and avoid its direct contact.

Antibiotic agents in accepted quantities, for *in vitro diagnostic* use do not represent an active risk for the qualified user, during its exposure.

B. Specific use

Modification of the concentrations (by dilution or addition) in the mixture T Broth + C Medium or in the reconstituted wells does not modify the hazards.

Note : Samples and seeded reagents are potentially infectious. Due to the presence of eventual growth of microorganisms in the culture medium, additional precautions associated with the use of cultures should be taken such as :

- Protocols for the safe conduct of the work should be agreed and strictly adhered to.
- Local rules should be drawn up to ensure that working practices take into account the measures necessary to control exposure that may arise from the specific work activity. Laboratory rules, disinfection, waste disposal and emergency procedures must be specified.
- Each procedure should be conducted in a designated area of the laboratory with sufficient space for working safely.
- Work should be conducted at a work station which is clearly identified.
- There should be sufficient room to work safely. There should be enough benchspace to ensure the working practices are not compromised due to lack of space.
- A microbiological safety cabinet or other form of primary containment should be used when infected material may be dispersed, by for example, tissue homogenisation, vigorous mixing etc
- Where required, a microbiological safety cabinet should be available for use in the laboratory and any procedures that may give rise to potentially infectious aerosols must be conducted in the cabinet.
- The designated working area should be kept clear of any unnecessary equipment.
- Access of unauthorised persons to the working area should be prevented to ensure that the person carrying out the work is free from the risk of disturbance or accidental physical contact with others.
- Access to the laboratory must be restricted to authorised persons who have received training for work in that laboratory.
- Gloves and other personal protective items appropriate to the task (e.g. eye protection) should be worn throughout the work.
- Gloves should be worn at all times when handling samples in the laboratory.
- If during use gloves become punctured or grossly contaminated they should be removed and disposed of, hands should be washed and clean gloves put on.
- On completion of handling samples gloves should always be removed and discarded, and hands should be washed.
- Single use (disposable) gloves should not be re-used.
- Eye protection (goggles or safety glasses) and a plastic overall should be worn if splashing is likely to occur.
- Lesions on exposed skin should be covered with waterproof dressings.
- Since infections can occur via lesions in the skin all workers in the laboratory should cover cuts and abrasions with a waterproof dressing.
- In addition, good basic hygiene practices, including regular handwashing, must be practised at all times.
- The use of glassware and sharps should be avoided.
- The use of glassware and sharps should be banned. If this is not feasible then handling procedures should be designed to minimise the likelihood of puncture wounds. Wherever possible glass items should be replaced with plastic alternatives. Glass pipettes must not be used.
- If it is necessary to use sharps, then used sharps should be placed directly into a sharps bin. Equipment should not be put down and transferred later as this increases the risk. Unless safe means have been introduced needles should never be resheathed. All sharps and hypodermic needles must be disposed of directly to a sharps container which conforms to the British Standard 7320: 1990. Sharps bins should not be overfilled, used sharps protruding from bins are very dangerous for those who have to handle them. Sharps and sharps bins must never be placed in plastic bags.
- The term sharp should be taken to refer to any item that is sharp and not be restricted to needles and scalpels. Commonly used items that could easily cause damage to the skin include all glass items (including microscope slides and cover slips), ampoules, pointed nose forceps, dissection instruments, scissors, wire loops that are not closed circles and gauze grids used in electron microscopy work. This list is not exhaustive and all items should be assessed for sharp edges.
- The bench surface and any equipment used should be decontaminated immediately on completion of a session of work.
- Contamination of benches and equipment should be avoided and at the end of each working session (or day) these should be routinely cleaned and disinfected.

- Equipment must be fully decontaminated prior to maintenance work. A signed statement should be issued to this effect before maintenance work is allowed.
- A satisfactory disinfection policy must be in operation.
- Disinfectants should be used in accordance with the GLP disinfection policy.
- All contaminated waste must be disposed of safely. Local rules must specifically state laboratory procedures and arrangements for disposal of contaminated materials.

For environment : Various substances, included in the preparation of in vitro diagnostic kits, are not well-known in terms of ecotoxicity and should be used with precautions. The preparation contains antimicrobial agents that should not be discarded in the environment to prevent a development of microorganism resistance. After use, the preparations must be handled as infectious.

4. First aid measures

As a general rule, in any doubts, accident, feeling of sickness, or if symptoms appear or persist, always seek medical advice and show this document.

A. Non-seeded reagent

Remove the person from the contaminated area.
Never feed an unconscious person.

In case of accident by inhalation :

Move to fresh air.
Make blow the nose.
In case of breathing difficulties, seek medical attention.

In case of contact with skin :

Immediately wash off with soap and plenty of water.

In case of contact with eyes :

In any case of contact with eyes, check if the victim wears lenses and if so, remove them.
Immediately rinse opened eyes with plenty of water for at least 15 minutes. Seek medical advice and show this document.

If swallowed :

Rinse mouth and drink plenty of water (only if person is conscious).
Do not induce vomiting, unless in case of medical advice.
Call a Poison Control Center and seek medical advice.

Symptoms :

Irritation of the eyes, the respiratory system and the skin.

First-aid worker equipment : lab coat, glasses, gloves.

Aggravating circumstances : Not known at the present time.

B. Seeded reagent

Previous first aid measures, as well as additional precautions associated with the use of microbial cultures should be taken into account.

Reagents concerned : T Broth, C Medium & wells of MycoView tray

Contamination can occur via aerosol, projection or spillage

In case of contact with skin :

Also use a disinfectant

In case of inhalation, ingestion or contact with eyes :

After, seek medical advice

5. Fire-fighting measures

Suitable extinguishing means : Spray water, powder or dry ice

Risks associated to the product :

if kits are stored in large quantity : burning of plastics trays and caps can produce toxic fumes.

6. Accident release measures

Personal protection : Gloves, mask, lab coat.

Limit the spreading by using absorbent material.

If the reagents are seeded :

Prohibit admittance in the contaminated area. Decontaminate the area with a disinfectant. Use of absorbent material

Waste disposal : Specific container

7. Handling and storage

Handling : Usual precautions to prevent vial breakages or tray pouch deterioration.

Storage : In their original packaging, at 2-8°C* in a specific and safe storage room. Do not freeze.

* Paraffin oil and swabs should be stored at 18-25°C in a specific and safe storage room.

Specific use : By authorized personnel, according to Instructions For Use and Good Laboratory Practices.

8. Exposure controls/personal protection

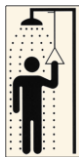
In general, additional personal protection is not required, normal laboratory precautions are sufficient.

Exposure limit value : NA

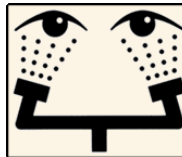
Exposure Control : Not required

Facility protective equipment :

Shower :



Eyewash fountain :



Personal protective equipment :

Lab coat



glasses



gloves



Hygienic measures : Take off immediately all contaminated clothing. Avoid contact with skin. Wash hands after use.

Do not eat or drink when using the reagents.

Flammability : No risk of flammability of any component of the kit.

9. Physical and chemical properties

ITEM	Physical and Chemical Data (Typical Values)			
	Appearance	Boiling Point	pH	Solubility in Water
Transport Medium (T Broth)	Clear, mobile liquid, Limpid/pale yellow color	<100°C	pH 6.0 ± 0.2	Completely miscible
Culture Medium (C Medium)	Freeze-Dried medium (solid) orange-yellow color	<100°C*	-	Completely miscible *Once regenerated
MycoView Tray	Polystyrene test device with 12 wells each	-	-	-
Paraffin Oil	Clear, mobile liquid, Mineral oil	360°C	-	Insolub
Swab - CE marked (Hardwood Products Company LP - USA)	Plastic holder and white Dacron head swab	-	-	-

10. Toxicological information

None, the ingredients used in the composition of the kit have been tested and found not to be toxic at their final concentrations when taken separately or associated. Nevertheless, the kit and reagents should be used with proper precautions.

11. Disposal information

Proceed in accordance with IFU.

Any waste material from the clinical laboratory should be handled according to the legislation of the country of use.

12. Transport information

Contact the supplier for all information regarding the proper transportation method for this material.

13. Regulatory information

Label requirements : according to 98/79EC Directive

MycoView is a EC registered IVD kit and can be sold in the French market and in the other Member states of the European Community. MycoView kit can be exported without restrictions to non-EC Member States.

14. Other information

This kit is for professional use only. Reagents must be handled according to Instructions For Use and to Good Laboratory Practices.

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

The manufacturer and the distributors will not assume any kind of responsibility in the case of inappropriate use.

· **Department issuing data specification sheet:** Quality Assurance Department

· **Contact:** ZEAKON Diagnostics SARL, 11 Rue Alfred de Vigny, 25000 Besançon, France. Tel. (+33) 9 54 74 40 10.