Sigma-Swabs
Technical File

mwe
medical wire

mwe
medical wire

The new generation of preanalyticals

Σ-Transwab®

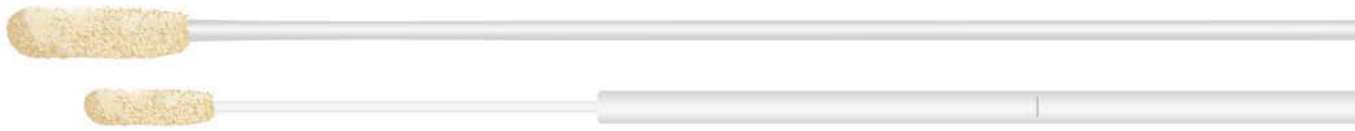
Σ-Virocult®

Σ-VCM®

Σ-Swab®

Multipurpose collection and transportation systems

CE 0800



Ordering information

Code	Vial	Fill	Swab Configuration*	Cap
Sigma Transwab				
MW167S	Small	1.0ml	2 Standard Sigma Swabs with break point	White
MW176S	Small	1.0ml	1 Standard Sigma Swab with break point	Purple
MW177S	Small	1.0ml	1 Mini tip Sigma Swab with break point	Orange
Sigma VCM				
MW910S	Small	1.0ml	1 Standard Sigma Swab with break point	Red
MW911S	Small	1.0ml	1 Mini tip Sigma Swab with break point	Red
MW912S	Small	1.0ml	1 Standard, 1 Mini tip Sigma Swab with break point	Red
MW915T	Small	1.0ml	Tube Only	Red
MW916T	Small	3.0ml	Tube Only	Red
MW918S	Large	3.0ml	1 Standard Sigma Swab with break point	Red
MW919S	Large	3.0ml	1 Mini tip Sigma Swab with break point	Red
MW920S	Large	3.0ml	1 Standard, 1 Mini tip Sigma Swab with break point	Red
MW921S	Large	3.0ml	2 Standard Sigma Swabs with break point	Red
MW924S	Large	1.5ml	2 Standard Sigma Swabs with break point, no glass beads	Red
MW925	Large	3.0ml	1 Standard Rayon Swab with break point	Red
MW926T	Large	3.0ml	Tube Only	Red
Sigma Virocult				
MW950S	Large	2.0ml	1 Standard Sigma Swab with break point	Green
MW950SENT	Large	2.0ml	1 Mini tip Sigma Swab with break point	Green
MW950S2	Large	2.0ml	2 Standard Sigma Swabs with break point	Green
MW950SE2	Large	2.0ml	1 Standard, 1 Mini tip Sigma Swab with break point	Green
MW950T	Large	2.0ml	Tube Only	Green
MW951S	Small	1.0ml	1 Standard Sigma Swab with break point	Green
MW951SENT	Small	1.0ml	1 Mini tip Sigma Swab with break point	Green
MW951T	Small	1.0ml	Tube Only	Green
Sigma Swab				
MW940			Sigma Swab and Peel Pouch	
MW941			Sigma Swab Individually Tubed and Labelled	
MW942			Duo Sigma Swab in Single Tube and Labelled	
MW943			Mini tip Sigma Swab and Peel Pouch	
MW944			2 Sigma Swabs and Peel Pouch	
MW945			1 Standard , 1 Mini Sigma Swab and Peel Pouch	

** The position of the breakpoint varies according to product. For variants with swab capture, the breakpoint is set to ensure that after breaking, the swab fits into the cap. For variants without swab capture, the breakpoint is set to allow the swab to sit within the vial without contact with the cap.*

References

1 Amies CR. Canadian Journal of Public Health 1967; 58: 296-300

2 Cassity, T.R., 1982, Comparison of Swabs for the Collection of Clinical Specimens for Anaerobic Cultures, Poster, Scioto Memorial Hospital, Portsmouth, Ohio

3 Graver, M.A., and J.J. Wade, 2003, Refrigeration Does Not Impair The Recovery Of *Neisseria Gonorrhoeae* From Charcoal Transport Medium. Poster, 43rd Annual Interscience Conference on Antimicrobial Agents and Chemotherapy, Chicago

4 Rishmawi, N. et al, 2007, Survival of Fastidious and Non- Fastidious Anaerobic Bacteria in Three Bacterial Transport Swab Systems. J.Clin. Micro. 45, 1278-83

5 Inverarity, D. , M. Diggle, G. Edwards, & T. Mitchell, 2006, An Evaluation of Media Suitable for the Transportation by Air of Streptococcus pneumoniae. Federation of Infection Societies Conference, Cardiff

6 Birrell, K., 2007, Comparative Study of Copan Venturi Transystem & Medical Wire & Equipment Transwab Microbiological Swabs using the Roll-Plate Method, Poster P1153, ECCMID 2007, Munich

7 Birrell, K., 2007, Investigation Of The Ability Of Transport Swabs To Release Collected Micro-Organisms - Using The Roll Plate Method, Poster C-369 / 076, 107th General Meeting of American Society for Microbiology, Toronto

8 Lindsay, G., 2008, Evaluation of the survival and recovery of *Neisseria gonorrhoeae* from four commercial swab transport systems media and a flock type swab ,Personal communication

9 Porterfield J.N., Hume R.D. Evaluation of Virocult collection and transport device. American Society of Microbiology AGM 1979

10 Johnson F.B., Leavitt R.W., Richards D.F., Evaluation of Virocult transport tube for isolation of Herpes simplex virus from clinical specimens. J.Clin Microbiol 1984: 20: 120-122

11 Johnson F. B., 1990, Transport of Viral Specimens, p. 120 – 131. Clinical Microbiology Reviews, 3, 120-131

12 Arvin A.M., Prober, C.G. Herpes Simplex Viruses in Manual of Clinical Microbiology, 7th Edition, 1999, American Society of Microbiology

13 Chapin, K.C., & F.W. Westenfeld, 2003, Reagents, Stains, Media, and Cell Lines: Virology, p.1250 in Murray P.R., E.J. Baron, J.H. Jorgensen, M.A. Pfaller, & R.H. Yolken, 2003, Manual of Clinical Microbiology, 8th Edition, ASM Press, Washington D.C.

14 Rudsdale, A., 2009, Evaluation Of A Virology Specimen Transport Device With Six Viruses Using CLSI Standard M40-A, Poster C-053 ASM 109th General Meeting, Philadelphia

15 Rudsdale, A., and D.J Shedden, 2009, Investigation Of The Suitability Of The Virocult® Swab Transport Device For Influenza A Specimens Which Are To Be Analyzed By Cell Culture Or Molecular Techniques, Poster M42 ,25th Annual Clinical Virology Symposium, Daytona Beach

16 Lina, B. et al, 1996, Surveillance of Community-Acquired Viral Infections Due to Respiratory Viruses in Rhone-Alpes (France) during Winter 1994 to 1995, J. Clin. Microbiol., 34: 3007-3011

17 Lina, B., 2005, Test Evaluation Report Medix Biochemica Infl uenza A & B

(Ref 2832ETMB) Actim Influenza A & B (Ref 32832ETAC), World Health Organization Collaborating Centre for Virus Reference and Research

18 Magnard, C., et al, 1999, Comparison of Two Nested PCR, Cell Culture, and Antigen Detection for the Diagnosis of Upper Respiratory Tract Infections due to Influenza Viruses, J. Medical Virol., 59: 215-220

19 Rezza, G., et al, 2006, Respiratory Viruses and Influenza-Like Illness: A Survey in the Area of Rome, Winter 2004-2005, Eurosurveillance 11 (10), 01 October 2006

20 Schweiger, B., et al, 2000, Application of a Fluorogenic PCR Assay for Typing and Subtyping of Influenza Viruses in Respiratory Samples, J. Clin. Microbiol. 38: 1552-1558

21 Esposito, S.,et al, 2008, Impact of Human Bocavirus on Children and Their Families, J. Clin. Microbiol. 46: 1337-1342

22 Schmutzard, J., et al, 2004, Detection of Herpes Simplex Virus Type 1, Herpes Simplex Virus Type 2, and Varicella-Zoster Virus in Skin Lesions. Comparison of Real Time PCR, Nested PCR, and Virus Isolation, J. Clin. Virol., 29:120-126

23 Valette, M., & B. Lina, 2009, Milieu de Transport et Persistance du Virus Grippal. (Personal communication)

24 Mack, K. et al, 2008, Clinical Performance of Foam vs Flocked Swabs collected from the anterior nares in a rapid antigen test for influenza A & B, Poster M8 at Pan American Society for Clinical Virology 24th Clinical Virology Symposium

25 Beall, A.R., 2003, Evaluation of Six Swab Transport Systems: Recovery of clinically relevant anaerobes. Poster C-051 at American Society for Microbiology 103rd General Meeting, Washington D.C.

26 Stuczen M, and V. Edwards-Jones, 2009, Comparison of Medical Wire's new Sigma-Swab With HealthLink Amies Transport System (Copan) for maintenance of microorganisms viability, NVvM Spring Meeting, Papendal, Netherlands

27 Stuczen M, and V. Edwards-Jones ,Maintaining Viability of Aerobic and Anaerobic Bacteria from Wounds Using the New Sigma-Swab Transport System Poster C-052 ASM 109th General Meeting, Philadelphia

28 Edwards-Jones V, and M. Stuczen, 2009, Efficacy of a New Sigma-Swab Transport System (Medical Wire) in Maintaining Viability of Wound Pathogens, Poster P37, European Wound Management Association 19th Conference, Helsinki

29 CLSI. 'Quality Control of Microbiological Transport Systems'; Approved Standard M40-A. CLSI (formerly NCCLS) document M40-A. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2003.

30 CLSI, 2006, Viral Culture; Approved Guideline. CLSI Document M41A. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2003.

31 European Medical Devices Directive 93/42/EEC

32 European In Vitro Diagnostic Devices Directive 98/79/EC

mwe medical wire

Corsham, Wiltshire, SN13 9RT, U.K.
Telephone: 01225 810361 Fax: 01225 810153
E-mail: info@mwe.co.uk www.mwe.co.uk

Σ-Swab®

mwe
medical wire

Recovery trial with Sigma Swab

1. *Suspensions of various test organisms were prepared to an opacity equivalent to 0.5 McFarland.*
2. *For each organism 4 Sigma Swabs (MW941) were inoculated with 100µl suspension.*
3. *After 10 seconds one swab for each organism was plated onto the appropriate medium to give the zero time count.*
4. *The remaining swabs were stored at room temperature for 6, 24 or 48 hours before being plated out on the appropriate medium.*
5. *All plates were incubated overnight at 37^{O}C.*
6. *The results were recorded as follows.*

Organism	Zero hr control	6hrs (RT)	24hrs (RT)	48hrs(RT)
Staphylococcus aureus	4+ (dense growth)	3++(1000+)	3++	3+
Candida albicans	3+ (500+)	3+	3+	3+
Escherichia coli	4+	4+	3++	3+
Proteus mirabilis	4+	4+	4+	3++
Pseudomonas aeruginosa	4+	3++	3++	3++
Streptococcus agalactae	4+	4+	3++	3+
Streptococcus pyogenes	4+	3++	3+	1+
Neisseria gonorrhoea	4+	3+	0	
Haemophilus influenzae	4+	3++	1+	

Organism Growth Key

5+ = Confluent Growth
4+ = Dense growth
3+ = Individual Colonies but TNTC
2+ = 10-50 colonies
1+ = <10 colonies

October 2008
In House Study

The efficacy of Medical Wire Sigma-Swab transport system in maintaining viability of *Staphylococcus aureus* and *Escherichia coli*.

Monika Stuczen

Introduction

One of the crucial steps for effective laboratory diagnosis of infection is adequate collection and transport of specimens. Three quantifiable parameters influence mainly the performance of specimen transport: time, temperature and quality of transport medium. It is important to evaluate these parameters together to determine optimal transport conditions of clinical samples. In this study, we fallowed the procedure M40-A to evaluate specimen transport system Sigma-swab (Medical Wire) for survival of *Staphylococcus aureus* (NCTC 6571) and *Escherichia coli* (ATCC 8739). Additionally, we compared the standard M40-A method with a modified method for recovery of organisms in the presence of nutrients which allow them to overgrow. Bacterial inoculum prepared in nutrient broth was compared with saline based inoculum. During wound surface swabbing it is likely, that some nutrients (body liquids, skin cells), as well as bacteria can be transferred to the transport device. Those nutrients can cause overgrowth of organisms during the transport.

Aims

To test the efficacy of the new Sigma-swab transport system in maintaining viability of *S. aureus* and *E. coli* in the presence and absence of nutrients. Those organisms are significant pathogens, commonly encountered in clinical samples especially chronic wounds.

Methods

1. An organism suspension from freshly grown isolate of each strain was prepared in sterile saline and diluted 1:10. For growth control, serial 10-fold dilutions were prepared from suspension and plated on triplicate plates of nutrient agar. The plates were then incubated at 37°C for 24h, and a colony count was obtained to confirm inoculum concentration.
2. Swabs in triplicate were placed for 10 sec. into nutrient broth (10ml) with appropriate bacteria inoculum. Also, triplicates were placed into an organisms suspension in saline (1:10) to absorb inoculum.
3. Swabs were incubated at room temperature and at 4ºC for Time-zero, 24h and 48h.
4. After the appropriate incubation period, each swab was removed and placed into 1 ml of sterile saline and mixed for 1 minute.
5. Serial dilution in sterile saline were prepared and inoculated onto the nutrient agar using spiral plater (Don Whitley Scientific, BS5687) to perform quantitative count.
6. All plates were incubated at 37 ºC in aerobic conditions for 24 hours.
7. After incubation quantitative count was performed using Acolyte counter (Don Whitley Scientific).

Results

Table 1.Recovery of *Staphylococcus aureus* from Sigma-Swab incubated at 4°C and room temperature .

Staphylococcus aureus						
	SALINE **No. (%) of CFU recovered at**			**BROTH** **No. (%) of CFU recovered at**		
	Time-zero	**24h**	**48h**	**Time-zero**	**24h**	**48h**
Room temp.	3.61×10^5	1.47×10^5 (41)	9.06×10^5 (250)	1.62×10^6	6.51×10^6 (401)	3.25×10^7 (2006)
4ºC	3.61×10^5	3.18×10^5 (88)	2.24×10^5 (62)	1.62×10^6	1.87×10^6 (115)	3.89×10^6 (240)

Table 2.Recovery of *Escherichia coli* from Sigma-Swab incubated at 4°C and room temperature .

Escherichia coli						
	SALINE **No. (%) of CFU recovered at**			**BROTH** **No. (%) of CFU recovered at**		
	Time-zero	**24h**	**48h**	**Time-zero**	**24h**	**48h**
Room temp.	8.10×10^5	4.99×10^6 (616)	5.31×10^5 (655)	3.50×10^6	6.45×10^6 (184)	3.38×10^7 (965)
4ºC	8.10×10^5	1.27×10^5 (156)	2.22×10^6 (274)	3.50×10^6	6.61×10^6 (188)	1.74×10^7 (497)

Conclusion

Overgrowth of microorganisms, particularly gram-negative bacilli, in swab systems transported or held at 20ºC to 25 ºC continues to be a significant problem.

For specimens of *Staphylococcus aureus* held at room temperature and processed using standard M40-A procedure, there was 0.5log increase in the number of viable cells after 48h of incubation. Respectively, there was only 0.7log increase in count of *Escherichia coli* after 48h.

The presence of nutrients (nutrient broth) did not have much impact on the recovery of organisms from Sigma-swabs held at room temperature. There was only 1.15log increase in *Staphylococcus aureus* count and 1log increase in the number of viable cells of *Escherichia coli.*

The benefits of refrigeration have been noted in numerous publications, however maintaining specimens at 4ºC prior to processing is not routinely practiced. Loss of viability during the transport have a negative effect on culture results.

Sigma-swab could maintain the viability of *Staphylococcus aureus* and *Escherichia coli* for 48 hours for specimens held at 4 ºC even in the presence of nutrients (nutrient broth). For specimens held at room temperature the number of viable organisms began to increase at 24hours (approx. 0.5log) and 48h (1log).

References

1.Quality Control of Microbiological Transport Systems: Approved Standard. NCCLS document M40-A. 2003.

2. Sarina M, Lawrence D.M. Comparative Evaluation of Two New Amies Swab Transport Systems BD CultureSwab MaxV(+) (Copan) and the Fisherfinest (Starplex) Swab. ASM 105th General Convention, Atlanta 2005.

PRESENTED AT NVMM & NVVM SPRING MEETING 2009
PAPENDAL, NETHERLANDS

Comparison of Medical Wire's new Sigma-Swab With HealthLink Amies Transport System (Copan) for maintenance of microorganisms viability.

Stuczen M, Edwards-Jones V, Manchester Metropolitan University, Manchester, United Kingdom

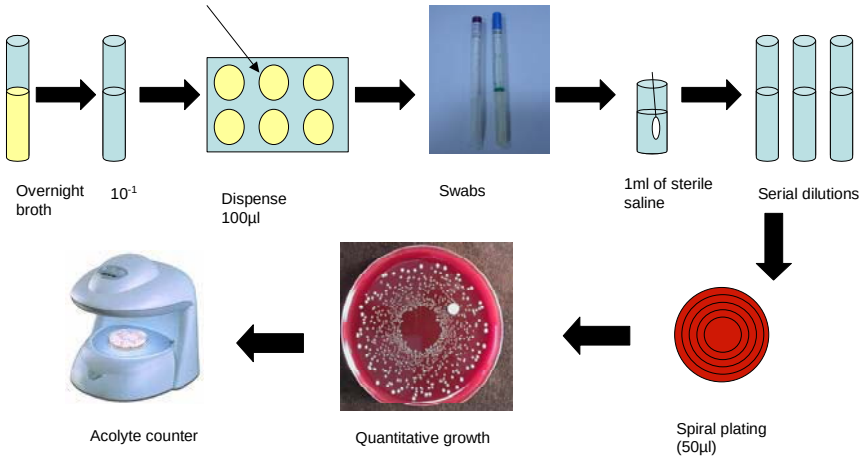
Introduction

Swab transport systems are used for a variety of specimen types and they must maintain organism viability during transport prior to plating. Also, the ideal swab system must absorb organisms from the infection site and allow release of organisms from the swab to the appropriate media. These are the most important aspects to be considered when choosing the appropriate collection device. Liquid and gel-based swab systems have been used for many years, but have limitations such that the specimen is diluted by immersion within the liquid or gel.

The objective of this study was to evaluate Medical Wire's Sigma-Swab and Copan's HealthLink Transporter (HLT) swab for their ability to release and maintain viability of *Escherichia coli* and *Staphylococcus aureus* and their mixtures. The Sigma-Swab is a new, medium free transport system and the absence of transport medium means there is no dilution of the specimen. In this study, the standard M40-A method (CSLI) was compared with a modified method, that incorporated the effect of nutrients absorbed onto the swab, on the recovery of organisms. During wound surface swabbing it is likely, that nutrients (body liquids, skin cells) as well as bacteria can be transferred to the transport device which can cause overgrowth during transport and these effects were tested for in the modified method.

Methods

- The suspension from a freshly grown isolate of each strain (*Staphylococcus aureus* - NCTC 6571 and *Escherichia coli* – ATCC 8739) was prepared in sterile saline diluted 1:10. Serial 10-fold dilutions were prepared from the suspension and plated onto nutrient agar as a control of quantitation. The plates were then incubated at 37°C for 24h, and a colony count was obtained to confirm inoculum concentration.
- Swabs were placed for 10 sec. into the saline suspension allowing the fluid to absorb. This was repeated using nutrient broth instead of saline in the modified method.
- Swabs were then inserted back into the transport device.
- Swabs were incubated at room temperature and at 4°C for 0, 24h and 48h.
- After the appropriate incubation period (to obtain baseline count – time zero - after 15 min. of incubation) each swab was removed and placed into 1 ml of sterile saline and mixed for 1 min.
- Serial dilutions prepared in sterile saline were inoculated onto the nutrient agar using spiral plater (Don Whitley Scientific, BS5687).
- All plates were incubated at 37°C for 24h in aerobic conditions.
- After incubation, a quantitative count was performed using Acolyte counter (Don Whitley Scientific).
- All experiments were carried out in triplicate



Results

Table 1. Recovery of S.aureus and E.coli from Sigma-Swab and Amies swab incubated at 4°C and RT and processed by standard CSLI procedure.

Organism	Swab System	No of CFU recovered at time period. (% in parenthesis)		
		0h	24h	48h
Staphylococcus aureus 4ºC	Sigma-Swab	8.62×10^5	7.75×10^5 (90)	7.61×10^5 (88)
	Amies swab	4.65×10^5	4.01×10^5 (86)	4.74×10^5 (102)
Escherichia coli 4ºC	Sigma-Swab	1.14×10^6	1.10×10^6 (96)	2.59×10^6 (227)
	Amies swab	9.44×10^5	9.53×10^5 (101)	2.42×10^6 (256)
Staphylococcus aureus RT	Sigma-Swab	8.62×10^5	2.38×10^6 (276)	3.58×10^6 (415)
	Amies swab	4.65×10^5	1.59×10^6 (342)	2.44×10^6 (524)
Escherichia coli RT	Sigma-Swab	1.14×10^6	4.67×10^6 (409)	4.57×10^6 (401)
	Amies swab	9.44×10^5	5.28×10^6 (559)	9.75×10^6 (1032)

Table 2. Recovery of S.aureus and E.coli from Sigma-Swab and Amies swab incubated at 4°C and RT and processed by modified method.

Organism	Swab System	No of CFU recovered at time period. (% in parenthesis)		
		0h	24h	48h
Staphylococcus aureus 4ºC	Sigma-Swab	3.76×10^6	8.48×10^6 (225)	1.16×10^7 (308)
	Amies swab	3.79×10^6	5.33×10^6 (140)	5.23×10^6 (137)
Escherichia coli 4ºC	Sigma-Swab	8.30×10^6	1.25×10^7 (150)	1.55×10^7 (186)
	Amies swab	9.68×10^6	1.79×10^7 (184)	2.11×10^7 (217)
Staphylococcus aureus RT	Sigma-Swab	3.76×10^6	2.31×10^7 (614)	4.20×10^7 (1117)
	Amies swab	3.79×10^6	2.91×10^7 (768)	5.11×10^7 (1348)
Escherichia coli RT	Sigma-Swab	8.30×10^6	3.20×10^7 (385)	3.55×10^7 (427)
	Amies swab	9.68×10^6	5.31×10^7 (548)	6.58×10^7 (680)

Both the Sigma-Swab and HTL were considered acceptable by CSLI M40-A criteria for both strains at 48h, but the Sigma-swab performed better using *E.coli.* The Sigma-swab released more CFU than HTL for the specimens processed by the standard procedure. For specimens processed by the modified method the release of bacteria was similar. Overgrowth was observed at 24h and 48h for both strains incubated at RT and processed by standard procedure and 4ºC and RT for samples incubated in the presence of nutrients.

Figure 2. *S. aureus and E.coli mixture in ratio 1:1 after incubation at 4ºC for 48h.*

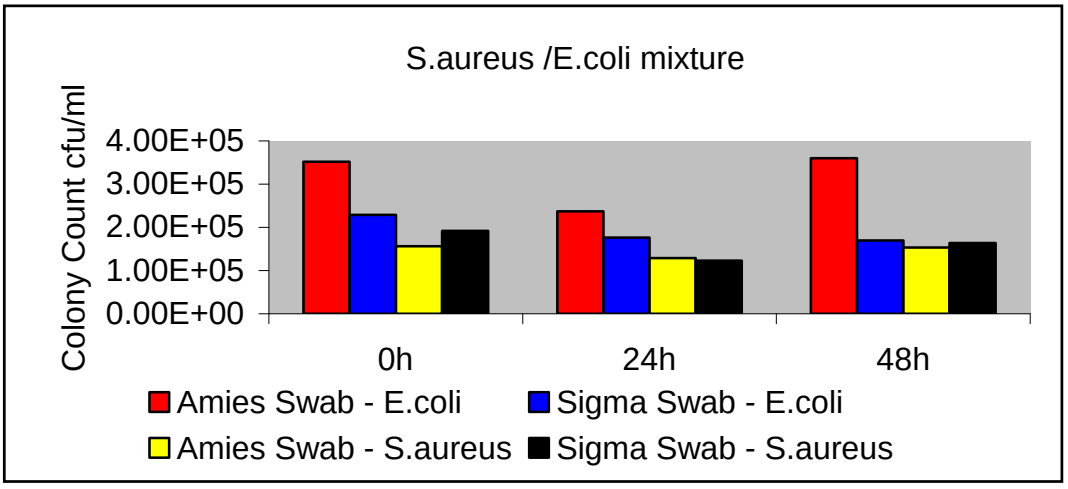
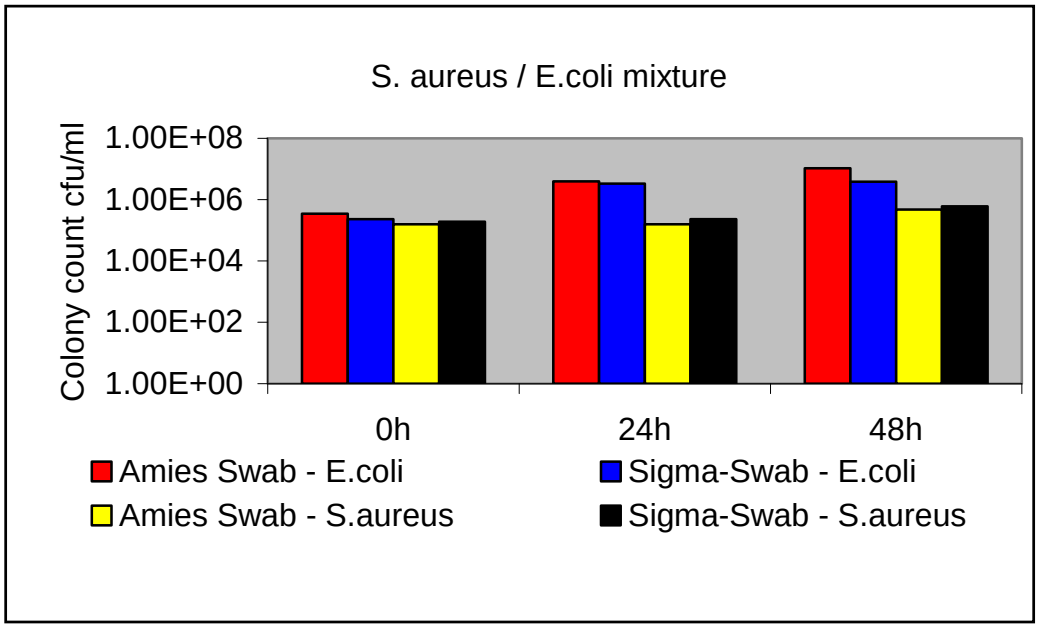


Figure 3. *S.aureus and E.coli mixture in ratio 1:1 after Incubation at room temperature for 48h. 1.8 log overgrowth of Escherichia coli on Amies swab comparing to 1.1 log overgrowth on Sigma-Swab.*



Discussion/ Conclusion

Loss of viability during transport will have a negative effect on bacterial culture results, especially when they are present in low numbers, also, the presence of nutrients can cause overgrowth during the transport. The perfect transport device should maintain viability of bacteria and prevent overgrowth. The Sigma-swab and Amies swab met acceptance criteria for all isolates tested, but the Medical Wire Sigma-swab medium free transport system maintained viability of bacteria optimally compared to the Copan HealthLink Amies swab.

References

1.Quality Control of Microbiological Transport Systems: Approved Standard. NCCLS document M40-A. 2003.

2. Sarina M, Lawrence D.M. Comparative Evaluation of Two New Amies Swab Transport Systems BD CultureSwab MaxV(+) (Copan) and the Fisherfinest (Starplex) Swab. ASM 105th General Convention, Atlanta 2005.

Manchester Metropolitan University

mwe medical wire

Maintaining Viability of Aerobic and Anaerobic Bacteria from Wounds Using the New Sigma-Swab Transport System.

Stuczen M, Edwards-Jones V, Manchester Metropolitan University, United Kingdom

Monika Stuczen
Manchester Metropolitan University
Chester Street, Manchester
M1 5GD, UK
Phone:00441612471153
m.stuczen@mmu.ac.uk

Abstract

Background: A crucial step for effective laboratory diagnosis of infection is adequate collection and transport of specimens. Three quantifiable parameters influence the performance of specimen transport: time, temperature and quality of transport medium. In this study, these parameters were evaluated for a novel dry specimen transport system, Sigma-swab (Medical Wire). Additionally, the standard M40-A method (CLSI) was compared with a modified method that assessed the effect of nutrients and mixtures of bacteria on their recovery which would reflect a clinical situation. **Methods:** Viability of common pathogens isolated from wounds; *Staphylococcus aureus*, *Escherichia coli*, *Pseudomonas aeruginosa*, *Bacteroides fragilis* and their mixtures were evaluated using the Sigma swab (Medical Wire, UK). Known numbers of bacteria were added to the swab and quantified using serial dilution at 0h, 24h and 48h, after storage at 4 ºC and RT, in the presence and absence of nutrients in pure culture and in mixtures. **Results:** All bacteria were recovered from the Sigma-Swab for up to 48h of incubation at RT and 4 ºC in the presence and absence of nutrients. There was a 1.15 log and 0.5 log increase in numbers of *S. aureus* at RT in the presence and absence of nutrients (respectively). With *E. coli* there was a similar increase seen for the same conditions (1.0 log and 0.7 log increase). No difference in numbers was observed at 24h at RT or at 4 ºC . The numbers of *P. aeruginosa* and *B. fragilis* remained stable for 48h in all conditions. Mixtures of organisms were recovered for up to 48h of incubation in all conditions without significant effect on viability. **Conclusion:** Many laboratories use transport medium to maintain the viability of the bacteria from clinical samples whilst swab is transported. This is especially problematic when bacteria are present in low numbers. The Sigma-Swab met acceptance criteria at both storage temperatures for all isolates tested in the presence and absence of nutrients. Additionally there was no overgrowth of any bacteria tested even in mixed culture.

Introduction

Different swab systems are used to transport a variety of specimen types to the diagnostic laboratory and these systems often differ depending upon the category of organism being investigated e.g. bacteria, viruses or fungi. The ideal swab system must absorb organisms from the infection site, maintain viability during transport and allow release of organisms from the swab to the appropriate media during cultural techniques. Liquid and gel-based swab systems have been used for many years, but have limitations as the specimen is diluted by immersion within the liquid or gel. The Sigma-swab is a new, medium free transport system and the absence of transport medium means there is no dilution of the specimen. Also, this swab system can be used for bacterial, viral and fungal culture and additionally can be used in modern molecular testing methods, e.g. PCR.

Three quantifiable parameters influence the performance of specimen transport: time, temperature and quality of transport swab. Additionally, during wound surface swabbing it is likely, that nutrients (bodily fluids and skin cells) as well as bacteria will be transferred to swab causing overgrowth during transport.

In this study, these parameters were evaluated using the standard M40-A (CLSI) method and the effect of nutrients and mixtures of bacteria, reflecting a clinical situation was also assessed.

Methods

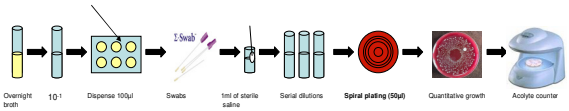


Figure 1. Method of processing the swab for evaluation of bacteria viability.

- A suspension from a freshly grown isolate of each strain (*Staphylococcus aureus* - NCTC 6571, *Escherichia coli* ATCC 8739, *Pseudomonas aeruginosa* NCTC 6749*)* and *Bacteroides fragilis* – NCTC 9343) was prepared in sterile saline diluted 1:10. Serial 10-fold dilutions were prepared from the suspension and plated onto nutrient agar. The plates were incubated at 37 ºC for 24h, and colony forming units counted to confirm inoculum concentration.
- Swabs were placed into the saline suspension for 10 sec allowing the fluid to absorb and then inserted back into the transport device.
- Swabs were incubated at room temperature and at 4 ºC for 0, 24h and 48h.
- After the appropriate incubation period each swab was removed and placed into 1 ml of sterile saline and mixed for 1 min.
- Serial dilutions were inoculated onto the nutrient agar using spiral plater (Don Whitley Scientific, BS5687).
- All plates were incubated at 37 ºC for 24h in appropriate aerobic and anaerobic conditions.
- After incubation, a quantitative count was performed using Acolyte counter (Don Whitley Scientific).
- All experiments were carried out in triplicate.
- All experiments were repeated using nutrient broth instead of saline to reflect for the effect of nutrients.
- All experiments were repeated using mixtures of the four organisms.

Results

Bacteria mixtures in ratio 1:1		Incubation period	
	0h	24h	48h
S.aureus	1.82 x 10^5	2.42 x 10^5	3.41 x 10^5
E.coli	2.91 x 10^5	1.80 x 10^5	7.78 x 10^5
S.aureus	2.96 x 10^5	5.14 x 10^5	4.70 x 10^5
P.aeruginosa	9.62 x 10^5	9.97 x 10^5	3.96 x 10^6
S.aureus	3.48 x 10^5	2.72 x 10^5	5.05 x 10^6
B.fragilis	5.18 x 10^6	3.22 x 10^6	2.86 x 10^6
E.coli	3.66 x 10^5	6.11 x 10^5	9.06 x 10^5
B.fragilis	3.26 x 10^6	3.54 x 10^6	3.35 x 10^6
E.coli	2.34 x 10^5	1.58 x 10^5	8.35 x 10^5
P.aeruginosa	1.96 x 10^5	8.20 x 10^5	2.88 x 10^6
P.aeruginosa	4.36 x 10^5	1.84 x 10^5	4.42 x 10^5
B.fragilis	1.13 x 10^6	2.60 x 10^6	4.03 x 10^6

Table 5. Results of the recovery of bacteria mixtures incubated at 4ºC and processed by standard procedure. **Mixtures of organisms were recovered for up to 48h without significant effect on viability.**

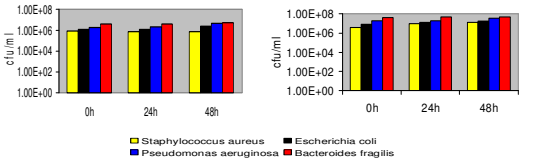


Table1. Recovery of bacteria incubated at 4ºC and processed by standard method.

Table 2. Recovery of bacteria incubated at RT and processed by standard method.

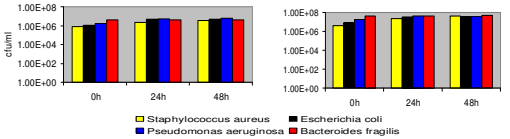


Table 3. Recovery of bacteria incubated at 4ºC and processed by modified method.

Table 4. Recovery of bacteria incubated at RT and processed by modified method.

All strains were recovered from the Sigma-swab for up to 48h of incubation at room temperature and 4ºC in the presence and absence of nutrients. There was a 1.15 log and 0.5 log increase in numbers of *S.aureus* at RT in the presence and absence of nutrients (respectively). With *E.coli* there was a similar increase seen for the same conditions (1.0 log and 0.7log increase). The numbers of *P.aeruginosa* and *B.fragilis* remained stable for 48h in all conditions.

Discussion/ Conclusion

Loss of viability during transport will have a negative effect on bacterial culture results, especially when they are present in low numbers, also, the presence of nutrients can cause overgrowth during the transport. The perfect transport device should maintain viability of bacteria and prevent overgrowth. The Medical Wire Sigma-swab met acceptance criteria at both storage temperatures for all isolates tested with excellent results of recovery.

References

1.Quality Control of Microbiological Transport Systems: Approved Standard. NCCLS document M40-A. 2003.
2. Sarina M, Lawrence D.M. Comparative Evaluation of Two New Amies Swab Transport Systems BD CultureSwab MaxV(+) (Copan) and the Fisherfinest (Starplex) Swab. ASM 105th General Convention, Atlanta 2005.

The Sigma Swabs were provided by Medical Wire & Equipment.

POSTER P37 EUROPEAN WOUND MANAGEMENT ASSOCIATION
19TH CONFERENCE, HELSINKI, MAY 2009

Efficacy of a New Sigma-Swab Transport System (Medical Wire) in Maintaining Viability of Wound Pathogens.

Edwards-Jones V, Stuczen M, Manchester Metropolitan University, United Kingdom

Introduction

Different swab systems are used to transport a variety of specimen types to the diagnostic laboratory and these systems often differ depending upon the category of organism being investigated e.g. bacteria, viruses or fungi. The ideal swab system must absorb organisms from the infection site, maintain viability during transport and allow release of organisms from the swab to the appropriate media during cultural techniques. Liquid and gel-based swab systems have been used for many years, but have limitations as the specimen is diluted by immersion within the liquid or gel. The Sigma-swab is a new, medium free transport system and the absence of transport medium means there is no dilution of the specimen. Also, this swab system can be used for bacterial, viral and fungal culture and additionally can be used in modern molecular testing methods, e.g. PCR.

Three quantifiable parameters influence the performance of specimen transport: time, temperature and quality of transport swab. Additionally, during wound surface swabbing it is likely, that nutrients (bodily fluids and skin cells) as well as bacteria will be transferred to swab causing overgrowth during transport.

In this study, these parameters were evaluated using the standard M40-A (CLSI) method and the effect of nutrients and mixtures of bacteria, reflecting a clinical situation was also assessed.

Methods

- A suspension from a freshly grown isolate of each strain (*Staphylococcus aureus* - NCTC 6571, *Escherichia coli* – ATCC 8739, *Pseudomonas aeruginosa* – NCTC 6749*)* and *Bacteroides fragilis* – NCTC 9343) was prepared in sterile saline diluted 1:10. Serial 10-fold dilutions were prepared from the suspension and plated onto nutrient agar. The plates were incubated at 37℃ for 24h, and colony forming units counted to confirm inoculum concentration.
- Swabs were placed into the saline suspension for 10 sec allowing the fluid to absorb and then inserted back into the transport device.
- Swabs were incubated at room temperature and at 4℃ for 0, 24h and 48h.
- After the appropriate incubation period each swab was removed and placed into 1 ml of sterile saline and mixed for 1 min.
- Serial dilutions were inoculated onto the nutrient agar using spiral plater (Don Whitley Scientific, BS5687).
- All plates were incubated at 37℃ for 24h in appropriate aerobic and anaerobic conditions.
- After incubation, a quantitative count was performed using Acolyte counter (Don Whitley Scientific).
- All experiments were carried out in triplicate.
- All experiments were repeated using nutrient broth instead of saline to reflect for the effect of nutrients.
- All experiments were repeated using mixtures of the four organisms.

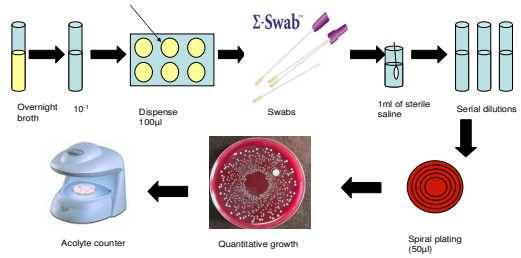


Figure 1. Method of processing the swab for evaluation of bacteria viability.

Results

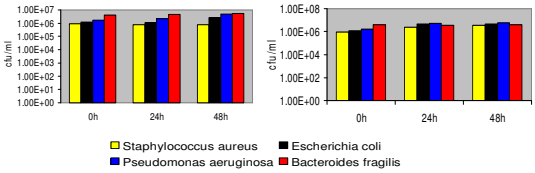


Table1. Recovery of bacteria incubated at 4ºC and processed by standard method.

Table 2. Recovery of bacteria incubated at room temp. and processed by standard method.

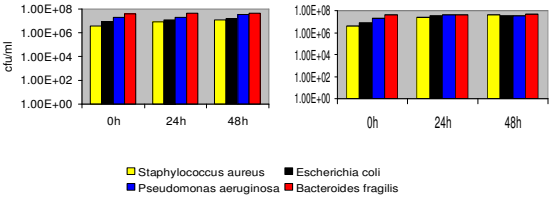


Table 3. Recovery of bacteria incubated at 4ºC and processed by modified method.

Table 4. Recovery of bacteria incubated at room temp. and processed by modified method.

All strains were recovered from the Sigma-swab for up to 48h of incubation at room temperature and 4ºC in the presence and absence of nutrients. There was a 1.15 log and 0.5 log increase in numbers of *S.aureus* at RT in the presence and absence of nutrients (respectively). With *E.coli* there was a similar increase seen for the same conditions (1.0 log and 0.7log increase). The numbers of *P.aeruginosa* and *B.fragilis* remained stable for 48h in all conditions.

Bacteria mixtures in ratio 1:1		Incubation period	
	0h	24h	48h
S.aureus	1.82 x 10⁵	2.42 x 10⁵	3.41 x 10⁵
E.coli	2.91 x 10⁵	1.80 x 10⁵	7.78 x 10⁵
S.aureus	2.96 x 10⁵	5.14 x 10⁵	4.70 x 10⁵
P.aeruginosa	9.62 x 10⁵	9.97 x 10⁵	3.96 x 10⁶
S.aureus	3.48 x 10⁵	2.72 x 10⁵	5.05 x 10⁶
B.fragilis	5.18 x 10⁶	3.22 x 10⁶	2.86 x 10⁶
E.coli	3.66 x 10⁵	6.11 x 10⁵	9.06 x 10⁵
B.fragilis	3.26 x 10⁶	3.54 x 10⁶	3.35 x 10⁶
E.coli	2.34 x 10⁵	1.58 x 10⁵	8.35 x 10⁵
P.aeruginosa	1.96 x 10⁵	8.20 x 10⁵	2.88 x 10⁶
P.aeruginosa	4.36 x 10⁵	1.84 x 10⁵	4.42 x 10⁵
B.fragilis	1.13 x 10⁶	2.60 x 10⁶	4.03 x 10⁶

Table 5.Results of the recovery of bacterial mixtures incubated at 4ºC and processed by standard procedure.

Mixtures of organisms were recovered for up to 48h of incubation without significant effect on viability.

Discussion/ Conclusion

Loss of viability during transport will have a negative effect on bacterial culture results, especially when they are present in low numbers, also, the presence of nutrients can cause overgrowth during the transport. The perfect transport device should maintain viability of bacteria and prevent overgrowth. The Medical Wire Sigma-swab met acceptance criteria at both storage temperatures for all isolates tested with excellent results of recovery.

References

1.Quality Control of Microbiological Transport Systems: Approved Standard. NCCLS document M40-A. 2003.
2. Sarina M, Lawrence D.M. Comparative Evaluation of Two New Amies Swab Transport Systems BD CultureSwab MaxV(+) (Copan) and the Fisherfinest (Starplex) Swab. ASM 105th General Convention, Atlanta 2005.

The Sigma Swabs were provided by Medical Wire & Equipment.

Sigma Swab 4C			
Sigma	0h	24h	48h
MRSA	2.67E+05	2.42E+05	2.22E+05
P.aeruginosa	3.00E+06	1.79E+06	1.91E+06
S.pneumoniae	2.90E+04	2.93E+04	1.73E+04

E-Swab 4C			
E-swab	0h	24h	48h
MRSA	3.97E+06	3.25E+06	3.63E+06
P.aeruginosa	6.20E+06	8.75E+06	9.43E+06
S.pneumoniae	1.41E+05	1.74E+05	2.80E+05

Sigma swab RT			
Sigma	0h	24h	48h
MRSA	2.67E+05	7.15E+05	3.17E+06
P.aeruginosa	3.00E+06	8.55E+06	7.13E+06
S. pneumoniae	2.90E+04	6.93E+04	6.33E+04

E-Swab RT			
E-swab	0h	24h	48h
MRSA	3.97E+06	8.75E+06	2.03E+07
P.aeruginosa	6.20E+06	4.17E+07	8.58E+07
S.pneumoniae	1.41E+05	6.17E+05	7.80E+05

Conclusion

The Dry Sigma Swab picked up a smaller sample but was as successful at maintaining the 3 pathogens at stable numbers

Manchester
Jul-09

Clinical Performance of Foam vs Flocked Swabs

collected from the anterior nares in a rapid antigen test for influenza A & B

Kathy Mack, Douglas Salamon, Erin Stoner, Jose Cuatas, Kimberley Scansen,
Bema Bonsu, Amy Leber, & Mario Marcon
Departments of Emergency Medicine, Nationwide Children's Hospital, Columbus, Ohio, USA
Poster M8 at Pan American Society for Clinical Virology24th Clinical Virology Symposium
April 27 - 30, 2008 Daytona Beach, Florida, USA

Background: Posterior nasopharyngeal (NP) secretions collected by aspiration, wash or swab are preferred for laboratory testing to diagnose respiratory viral infections including influenza. However, anterior nares (AN) swabs are easier to collect and better tolerated by patients, and some rapid influenza antigen tests are FDA-cleared for this specimen type. There are limited data on the performance of such tests with respect to the effects of swab composition.

Objective: This study compared the clinical sensitivity and specificity of a high absorbency polyurethane foam swab versus a high surface area nylon flocked swab collected from the AN for detecting influenza antigen.

Methods: For this prospective study, 100 children with symptoms suggesting influenza were recruited with informed consent from a large academic pediatric Emergency Department during the 2006-07 and 2007-08 influenza seasons. For each subject, a high absorbency foam (**Medical Wire Σ – Swab™**) and high surface area flocked nylon fiber (Copan USA) swab specimen was obtained from left and right AN and placed in a transport tube (no transport medium). A polyester swab specimen was also collected from the posterior NP on each subject and placed in M4 transport medium. The AN specimens were tested for influenza antigen in the main hospital laboratory using the Quidel QuickVue® Influenza A+B Test. The posterior NP specimens in M4 were tested by culture, DFA, and RT-PCR (Prodesse). The results of the latter tests were used to establish the clinical performance of the Quidel test performed on the two AN swab types.

Results: Influenza was diagnosed by culture and/or DFA in 49 subjects- 34 influenza A and 15 B. Influenza was diagnosed by RT-PCR in 56 subjects- 37 influenza A and 19 B.

Standard Method	Swab Type	Antigen Test Sensitivity (%)	Antigen Test Specificity (%)
Culture and DFA	Foam	78 (38/49)	94 (48/51)
	Flocked	61 (30/49)	98 (50/51)
RT-PCR	Foam	71 (40/56)	98 (43/44)
	Flocked	54 (30/56)	98 (43/44)

The intensity of the test band on most of the positive tests was greater with the foam swab.

Conclusions: High absorbency polyurethane foam swabs are preferable to high surface area nylon flocked fiber swabs for detection of influenza virus in the Quidel QuickVue® Influenza A+B Test.

Influenza Virus

The table shows recovery of live influenza virus for up to 4 days (J+4) in cell culture using only Sigma Swab (Full details in Sigma Virocult section)

Culture	J0		+	
	J+1	+		+
	J+2	+		+
	J+3	+		+
	J+4	+		+

Mycoplasma

Sigma swabs maintained Mycoplasma & Ureaplasma for 72 hours at 2-8^{O}C

Testing of Sigma Swab for cytotoxicity

by Iso Elution Method

Extracted into cell culture medium, inoculated onto confluent monolayers of fibroblast cells, together with positive and negative controls, monolayers examined at 48hours for any changes to cell morphology

1. Adhesive NO EVIDENCE OF TOXICITY
2. Swab & Stick NO EVIDENCE OF TOXICITY

No contact dermatitis in guinea pigs

No contact dermatitis in humans

∑-Swab™ - The Ideal M40-A Device?

The principal function of a transport swab is to maintain microorganisms in a viable and numerically stable condition. If some organisms die off too rapidly they will not be detectable at the laboratory, but it is also well understood that some bacteria have a tendency to overgrow, even in a well-defined transport medium without nutrients, giving a distorted representation of the relative populations in the original specimens.

CLSI's M40-A standard recognises this problem. It requires that organism numbers should not drop by more than 3 logs during the maximum transport period specified by the manufacturer, whether transport is at ambient or refrigerated temperatures. It also requires that numbers should not increase by more than 1 log during the maximum transport period, but in this case this requirement only applies for transport at refrigerated temperatures.
In some ways this seems a pointless requirement since very few organisms are capable of multiplying at all at low temperatures, and even those which do, such as *Listeria* will do so relatively slowly. It seems to have been accepted that the overgrowth standard cannot be met at ambient temperatures, although those are the conditions in which many specimens have to be transported.

Medical Wire's new ∑-Swab™ (Sigma Swab) is a dry swab without transport medium which meets the M40-A criteria for keeping bacterial numbers stable at ambient as well as refrigerated temperatures. Studies to be presented in the coming months will show that ∑-Swab™ will keep the numbers of many common organisms stable for 48 hours, neither increasing nor decreasing. These include many of the organisms present in wound infections such as *Staphylococcus aureus*, *Pseudomonas aeruginosa,* and *Escherichia coli*. Anaerobes such as *Bacteroides fragilis* have also been shown to survive in stable numbers for up to 48 hours. Even fastidious organisms will show some limited survival at 24 hours, although for these the assistance of a transport medium would still be recommended.

The secret of ∑-Swab™'s performance is in the bud, which is made from a soft synthetic foam. Unlike conventional swabs with a tightly wound fibre bud, ∑-Swab™'s bud is an open-cell structure. The cells have a uniform icosahedral shape which makes the material highly absorbent, protecting the bacteria within their own micro-environment, yet allowing complete flow-through for reagents for optimum performance for both conventional laboratory procedures, and the many newer molecular methods.

The ability to keep organism numbers stable means that ∑-Swab™ could be the ideal device for many routine specimens such as post-operative wounds, leg ulcers, and MRSA screening.

Using a dry swab has a number of technical advantages. The specimen is not diluted into a transport medium, there are no non-viable bacteria from the medium to interfere with Gram-stains, and there is no overgrowth.

There are also practical and environmental advantages. ∑-Swab™ has a five year shelf-life, since there is no medium to dry out. Tubed dry swabs are considerably less bulky for storage than the peel pouches required for transport swabs, and with less packaging to dispose of. ∑-Swab™ Duo is now also available in a labelled tube.

∑-Swab™ is the ideal specimen collection device for many routine applications, meeting M40-A criteria for survival for many common pathogens, and exceeding the criteria for overgrowth by keeping numbers stable at ambient temperatures. The inert open-celled bud allows improved reactions and sensitivities for conventional and molecular procedures. Extended shelf-life, and reduced packaging assist with stock management and environmental concerns.

Reference

1. CLSI. Quality Control of Microbiological Transport Systems; Approved Standard, CLSI document M40-A [ISBN 1-56238-520-8].

Σ-Transwab®

mwe
medical wire

Σ-Transwabs
Preliminary Study

Samples of Σ-Transwabs were provided to 3 clinical microbiology laboratories experienced in the evaluation of transport devices. Swabs were inoculated with diluted suspensions of test organisms, either lab or ATCC strains.

This was a preliminary study rather than a full M40-type validation. The organisms are chosen by the laboratories as typical of the daily workflow, and the dilutions were chosen to show quantitatively the relative decrease or increase in numbers over the holding time of 1 or 2 days.

Lab 1

Organism	Inoculum	Control Plate	Room Temperature		$4^{O}C$	
			24hr	48hr	24hr	48hr
H.influenza	1.5×10^{6}	>1000	80	0	>100	100
	1.5×10^{7}	>1000	>100	10	>500	>200
S. aureus	1.5×10^{6}	>500	>500	>500	>500	>500
	1.5×10^{7}	>1000	>1000	>1000	>1000	>1000
Beta-haemolytic strep.	1.5×10^{5}	>200	44	40	50	16
	1.5×10^{6}	>500	>200	>200	>200	>100
	1.5×10^{7}	>1000	>500	>500	>500	>200

Lab 2

Organism	T0 (average)		T24 (average)		T48 (average)	
	RT	FT	RT	FT	RT	FT
E. coli	90	90	>1000	100	>1000	100
MRSA	180	200	80	120	75	110
Candida	5	5	120	2	200	1
S. pneumoniae	20	20	15	20	15	15
BHS gpA	120	120	120	120	80	80
Bacteroides sp	160	160	160	140	80	130

Lab 3

Swabs inoculated with overnight broth cultures of GC, MRSA and C.albicans (all ATTC strains). Subcultured at time 0hr, 24hr, 48hr and 72hr.(Room Temperature) (GC 24 hr only as per M40)

GC
0hr: +++ growth
24hr: +

MRSA
0hr: +++
24hr: +++
48hr: +++
72hr: +++

C.albicans
0hr: +++
24hr: +++
48hr: +++
72hr: +++

Conclusion
The results show good survival without overgrowth of the organisms tested over the periods required for M40.

Σ-Virocult®

mwe medical wire

World Health Organization
Collaborating Centre for Virus Reference and Research

Centre National de Référence des Virus Influenza Région Sud
Centre de Biologie & Pathologie Est
Institut de Microbiologie
Laboratoire de Virologie
Bât. A3 – 59 boulevard Pinel
69677 BRON CEDEX

Professeur Bruno LINA
bruno.lina@chu-lyon.fr
Docteur Martine VALETTE
martine.valette@chu-lyon.fr
☎ 04 72 12 96 17
🖷 04 72 12 95 00

MILIEU DE TRANSPORT & PERSISTANCE du VIRUS GRIPPAL
2ème ESSAI

1/ Choix de la souche :

Souche prototype vaccinale hiver 2008-09 : **A/H3N2/Uruguay/716/2007** *P4MDCK* du 23/04/2008
Préparer une culture à utiliser le jour de la préparation des essais :
* le vendredi 5 décembre 2008 : inoculer la souche aux dilution 10^{-4} –> 10^{-8} sur boîte 25 cm^2.
* le lundi 8 décembre 2008 : titrer et récolter la culture – P5 MDCK HA=HAc=128 inoculée à 10^{-8} avec un ECP proche de 50 %.

2/ Kits de prélèvement :

Ecouvillons : **Virocult**
Σ-Swab
Milieu liquide : **Σ-Virocult**

3/ Choix des dilutions :

1/ Culture non diluée, notée « PUR »
2/ Dilution 10^{-2}

La dilution est préparée en milieu MDCK et cellules MDCK, à une concentration de 0,1 M/ml. On procède à une dilution en cascade.
Prélever 100µl de culture ou dilution par écouvillon.
Chaque concentration sera déposée sur :
* 2 x 7 écouvillons : **Virocult**
* 2 x 7 écouvillons : **Σ-Swab**
* 2 x 7 tubes de milieu **Σ-Virocult**

4/ Délai et Température de contact :

1/ Temps de contact suivants : J0 – J+1 – J+2 – J+3 – J+4 – J+5 – J+7
2/ Température : Température ambiante : laisser les écouvillons sur la paillasse +4°C réfrigérateur
Rq : Le J0 servira de témoin.

5/ Inoculation sur cellules MDCK - ICE:

Traiter les échantillons comme un prélèvement « GROG »
Prélever pour ICE (P0) : 250µl
Prélever 210µl pour RT-PCR et congeler à -80°C.
Inoculer sur plaque MDCK chaque **Virocult**/ **Σ-Swab** / **Σ-Virocult** sur 1 cupule puis les surnageants seront testés après 3-5 jours de culture par ICE.

Lorsque les cultures seront testées par ICE prélever 1 aliquot (210µl) pour RT-PCR

MILIEU DE TRANSPORT & PERSISTANCE du VIRUS GRIPPAL

2ème ESSAI

08/12/2008

		Σ-Swab				Virocult				Σ-Virocult			
		Non Dilué		10^{-2}		Non Dilué		10^{-2}		Non Dilué		10^{-2}	
		+4℃	Ambiant	+4℃	Ambiant	+4℃	Ambiant	+4℃	Ambiant	+4℃	Ambiant	+4℃	Ambiant
Détection ICE	J0	±		-		±		-		+		-	
	J+1	+	+	-	-	+	+	-	-	+	+	-	-
	J+2	±	-	-	-	-	-	-	-	+	±	-	-
	J+3	+	+	-	-	+	+	-	-	+	+	-	-
	J+4	+	+	-	-	+	+	-	-	+	+	-	-
	J+5	-	-	-		-	-	-	-	+	±	-	-
Culture	J0	+		+		+		+		+		+	
	J+1	+	+	+	+/+	+	+	+	+	+	+	+	+
	J+2	+	+	+	+	+	+	+	+	+	+	+	+
	J+3	+	+	+	-/-	+	+	+	+	+	+	+	+
	J+4	+	+	+	-/+	+	+	+	-/+	+	+	+	+

Culture : MDCK plaques 24 cupules

Rq : P0 J0 & J+2 ont été congelés avant d'être testés ICE.

Dates ICE : 09/12 - 12/12 - 15/12 - 19/12

CI : les 2 écouvillons st équivalents - Le Σ-Virocult semble supérieur.

Transport Medium & Survival of Influenza Virus

2nd Trial

1. Choice of strain

   Prototype strain for vaccine winter 2008-09: A/H3N2/Uraguay/716/2007 P4 MDCK (23rd April, 2008)

   Preparation of culture for use on day of trial:

   Friday 5/12/08 – inoculate strain (dilutions 10^{-4} – 10^{-8}) in a 25cm^2 flask

   Monday 8/12/08 - titrate and harvest culture – P5 MDCK HA=Hac+128 inoculated to 10^{-8} yieded 50% CPE

2. Sampling kits:

   Virocult

   Σ-Swab (swab only)

   Σ-Virocult

3. Dilutions used

   i) Non-diluted (PUR)

   ii) 10^{-2}

   The dilution is prepared in MDCK medium and MDCK cells, at a concentration of 0.1M/ml. [10^5 per ml? = 10^5 $TCID_{50}$ /ml], then prepared in serial dilution.

   Sample 100µl culture or dilution with each swab.

   Each concentration is inoculated onto 2 x 7 swabs each for Virocult , Σ-Swab, and Σ-Virocult.

4. Holding times and temperatures

   i) Holding time after inoculation: 0 days (J0), 1 day (J+1), 2 days (J+2), 3 days (J+3), 4 days (J+4), 5 days (J+5), and 7 days (J+7)

   ii) Temperature: Room Temperature (Ambiant) & Fridge Temperature (+4^{O}C)

   J0 is the control

5. Cell culture & ICE

The samples are treated as for GROG specimens

ICE (P0) 250 μl

RT-PCR 210 μl frozen at -80 ^{O}C

Inoculate each Virocult , Σ-Swab, or Σ-Virocult into a cell layer (MDCK) tube or well. After 3-5 days culture the supernatant is tested by ICE.

While the cultures are being tested by ICE, take a 210 μl aliquot for RT-PCR.

Σ-VCM®

mwe
medical wire

PERFORMANCE OF VCM MEDIUM (In House)

Product	Organism	0 hour	24 hour time (4C)
Universal media + sigma swab	**GC**	3++	3+, 2+

Date of testing 28/4/2009

mwe
medical wire

The new generation of preanalyticals

Σ-Transwab®

Σ-Virocult®

Σ-VCM®

Σ-Swab®

Multipurpose collection and transportation systems

CE 0800

mwe
medical wire

Σ-Transwab,® liquid transport for automated & conventional processing.

M40 COMPLIANT

New collection vial

- Screw cap – for sample integrity and security
- Compatible with most automatic decapping systems
- Integral swab capture – no further manual handling of swab shaft required
- Colour coded caps according to format and application
- Self-standing for convenience
- Inner conical base – can be centrifuged
- Shatterproof polypropylene

New Sigma-swab®

- Soft polyurethane foam bud preferred by patients
- High absorbency for optimum sample uptake
- Open cell for complete flow through of medium and reagents [24-28]
- Maximum release of microorganism
- Entire specimen is released into liquid phase
- Breakpoint for easy handling, ensures exact fit of swab in tube and swab capture
- Fine-tip option available for urethral and nasopharyngeal specimens

New transport medium

- Liquid Amies for automated and conventional processing
- Liquid Amies provides suspension for quick Gram stain and multiple cultures
- Liquid Amies maintains viability of Aerobes, Anaerobes, and Fastidious bacteria for up to 48 hours at ambient and refrigerated temperatures (as required for M40 compliance)[1,3,29]
- Rapid elution of specimen allows accurate and quantitative dilutions
- Stable at room temperature for 24 months

The transport system for microbiology

Σ-Transwab®

Σ-Transwab®- The all new system for specimen collection and transport.

Transwab® was the first commercially produced gel transport swab, and for many years has led the field for reliable microbiological specimen collection and transport. A programme of continous development has kept Transwab® ahead of changes in laboratory science and regulatory requirements, so that it remains a trusted partner in the diagnosis of infectious disease[1-8]. Sigma-Transwab® combines all of this experience in an all-new format and technology for the new era of liquid preanalytical microbiology, while remaining completly suitable for conventional methodologies.

The specimen is collected by swab into the tube containing 1 ml of Liquid Amies Transport Medium. The microorganisms from the initial specimen are dispersed throughout the medium, producing a uniform suspension ready for use, either in an automatic sampling and inoculation system, or directly with any of the many rapid molecular tests currently available. The process is enhanced by the incorporation of an open-celled foam-tipped swab which allows complete flow through of the liquid medium, reagents, and microorganism. This increases the sensitivity of any diagnostic procedures.

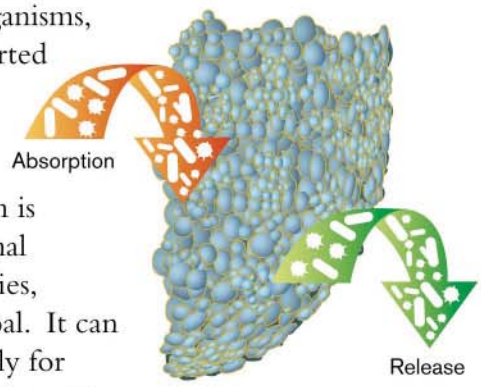
The vial, made from shatterproof polypropylene, has a conical base, and can be centrifuged if required. The base is skirted, so the tube is free standing for convenience of use at the bench, while the new screw cap ensures secure containment of liquids. The cap also incorporates an ingenious swab capture mechanism. Thus when the swab is placed in the tube, snapped at its break point and broken, and the cap screwed home, the swab is "captured" securely, so that when the cap is removed, whether manually or mechanically, the swab is automatically removed with the cap.

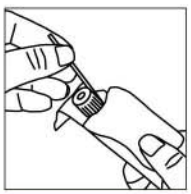
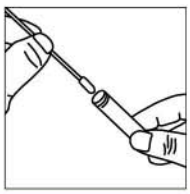
Sigma-Transwab® is also available in two further formats with colour coded caps.

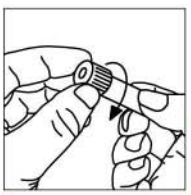
Sigma-Transwab® (dual format) has two standard swabs with breakpoints, and is convenient when a patient is being swabbed at multiple sites, such as for MRSA-screening. The dual format does not use the swab capture mechanism.

Sigma-Transwab® (mini-tip format) uses a narrow fine-tip shaft, also with a foam tip, and is particularly suited for nasopharyngeal and urethral specimens. This does not use the swab capture mechanism.

All variants of Sigma-Transwab® are M40-A compliant, suitable for aerobic, anaerobic and fastidious microorganisms, and can be transported at ambient or refrigerator temperatures. The liquid medium is based on the original formulation of Amies, but without charcoal. It can be used immediately for Gram stains at the time of collecting the specimen, and transported securely whether by external courier or internal pneumatic system. All Sigma-Transwabs® are CE-marked, and conform to the requirements of the European Medical Devices Directive and In Vitro Medical Devices Directives[31,32].





0088 CE

mwe medical wire

Σ-VCM®, for Viruses, Chlamydia, Mycoplasmas & Ureaplasmas

Sigma- VCM®

- Sigma-Swab®, with new VCM® medium for viruses, Chlamydia, Mycoplasmas & Ureaplasmas

Sigma-Swab®

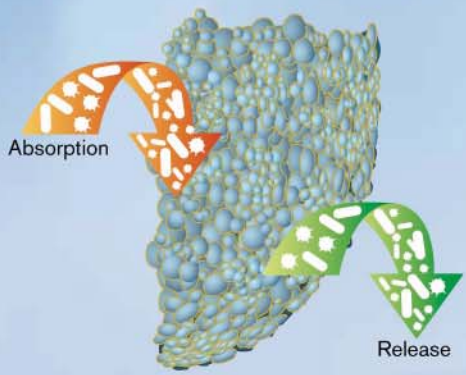
- Open-celled foam bud
- Optimum absorption and release
- Optimum performance with molecular test systems [24-28]

VCM medium

- Optimum recovery of target organisms
- Optimum compatibility with molecular test systems
- Antibiotics inhibit contaminating bacteria and fungi
- Choise of fill volume

New collection vials

- Screw cap – for sample integrity and security
- Compatible with most automatic decapping systems
- Self-standing for convenience
- Inner conical base – can be centrifuged
- Shatterproof polypropylene



Σ-Swab® features unique open cell structure for optimum absorbance and realease of microorganisms and reagents.

Transport systems for Viruses, Chlamydia, My

Σ-VCM®

Σ-VCM ,® with new VCM™ medium for Viruses, Chlamydia, Mycoplasma & Ureaplasmas

Sigma-VCM® retains the qualities of Viroculț® medium[9-23], but has been adapted to make it suitable not only for viruses, but also for chlamydia, mycoplasma, ureaplasmas, and certain important fastidious bacteria. The base medium allows survival and recovery of the target organisms, while a new cocktail of antimicrobials prevents the growth of most contaminating bacteria and fungi in the specimen which could compromise its integrity.

Glass beads in the medium, when vortexed, help to break open cells for the release of intracellular organisms, such as chlamydia & viruses. A version without beads is also available.

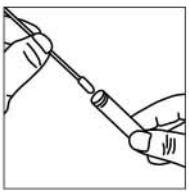
Sigma-VCM® is supplied with Sigma-swabs®[24-28], the open cell foam tipped swabs which allow optimum uptake and release of target microorganisms, and complete flow-through of reagents for optimum sensitivity for molecular test protocols. Standard Sigma-swab® is suitable for general swab applications such as skin lesions, nose and throat. Mini-tip Sigma-swabs® are suitable for nasopharyngeal and urethral sampling.

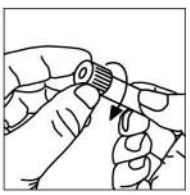
Internal studies have shown that Sigma-VCM® will recover viruses, chlamydia, mycoplasmas and ureaplasmas so that they can be identified, either by gold standard culture methods, and by the new molecular techniques that have become routine for most laboratories.

Sigma-VCM® will also recover certain fastidious bacteria such as *Neisseria gonorrhoeae*, making it the ideal swab device for STD clinics.

Sigma-VCM® is available in a range of formats, reflecting the many applications for which it can be used. It is supplied as a sterile device comprising a self-standing conical based vial with 1ml or 3ml of VCM™ medium, and a choice of 1 or 2 Sigma-swabs®, 1 or 2 mini-tip Sigma-swabs®, or one of each. All standard versions come with glass beads in the medium. It is also possible to have Sigma-VCM® without beads, or to have tubes containing 1ml or 3ml of VCM™ medium (with beads).







CE 0800

coplasmas & Ureaplasmas

mwe
medical wire

Σ-Virocult,® with classic Virocult® medium for virus isolation and identification

M40 COMPLIANT

Sigma-Swab®

- Open-celled foam bud
- Optimum absorption and release
- Optimum performance with molecular test systems
- Standard shaft or ENT/urethral

Virocult® medium

- Optimum recovery of target organisms
- Optimum compatibility with molecular test systems
- Antibiotics inhibit bacteria and fungi
- Recovers wide range of respiratory, genital and enteric viruses
- Transport specimens at ambient temperatures
- Choise of fill volume

Sigma-Virocult® combines Medical Wire's open cell bud Sigma-Swab®[24-28] with Virocult® medium[9-23], for long the leading transport medium for virus specimens. Virocult® medium can be used with traditional cell culture techniques, or the many current molecular techniques.

Virocult® has long been recognised as one of the best transport devices for viruses, demonstrating survival of many types of virus at ambient temperatures, including Herpes Simplex Virus, Varicella-Zoster Virus, Influenza Type A (including Novel H1N1, H5N1, and H3N2) , Influenza Type B, respiratory syncytial virus, mumps virus, adenovirus, rhinovirus, and various enterovirus.

Virocult® medium stabilises the virus particles allowing long survival, and also contains antimicrobials to prevent the growth of any bacteria and fungi present in the specimen. These features make it suitable for cell culture based analysis, but

The transport system for viruses

CE 0086

Σ-Virocult®

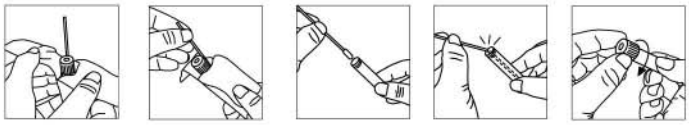
For virus isolation and identification

many studies in recent years have shown Virocult® to be completely compatible with many of the newer molecular techniques such as DFA, ELISA and PCR.

Virocult® & Sigma-Virocult® have been validated according to CLSI's M40-A standard for viral culture transport devices, which requires survival of reference strains for at least 96 hours at ambient or refrigerated temperatures.

Sigma-Virocult® is supplied with Sigma-Swab®, the open cell foam tipped swabs which allows optimum uptake and release of target microorganisms, and complete flow-through of reagents for optimum sensitivity for molecular test protocols. Standard Sigma-Swab® is suitable for general swab applications such as skin lesions, nose and throat. Sigma-Swab® ENT /urethral is suitable for nasopharyngeal and urethral sampling.

Sigma-Virocult® is supplied as a sterile device comprising a self-standing conical based vial with 2ml of Virocult® medium, and a choice of 1 or 2 standard Sigma-Swab®, 1 fine-tip Sigma-Swab® ENT/urethral , or one of each. It is stored at room temperature, with a shelf life of 1 year.



Specimens, once collected, can be transported under ambient or refrigerator temperature conditions. Sigma-Virocult® is CE-marked, and conforms to the requirements of the European Medical Devices Directive and In Vitro Medical Devices Directives.

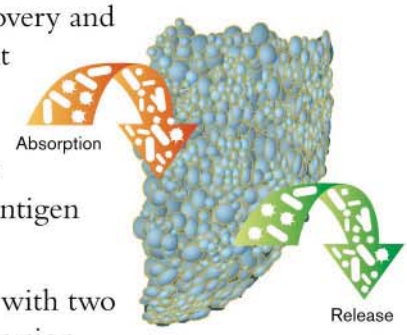
Σ-Swab®

Σ-Swab®- the medium free transport system

- No dilution of sample
- No overgrowth
- No non-viables
- Suitable for bacteria, fungi, viruses
- Open-celled, inert structure allows free access to reagents for direct testing

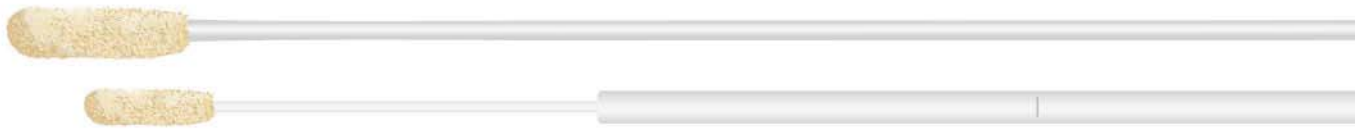
Sigma-Swabs®.
Medical Wire's Sigma-Swab® features a special polyurethane foam tip (standard or ENT fine-tip). Studies have shown that a dry polyurethane foam-tipped swab can be used for the transport of many micro-organisms. The soft-foam bud is more comfortable for patients, and has significant advantages for both conventional and molecular methods[23-28].

In-house and published studies show that Sigma-Swab® maintains many classes of organisms in stable numbers, including bacteria[26-28], fungi, viruses[23] , and mycoplasma. It is particularly useful for MRSA screening, with good recovery and no overgrowth. Absorbent foam-tipped swabs have been shown to be superior to flocked swabs when used with a rapid antigen test for influenza[24].



Sigma-Swab® is available with two bud types. The standard version has a normal sized bud suitable for general purpose swabbing such as wounds, including surgical wounds, skin, mouth, nose and throat. The fine-tip version (Mini Sigma-Swab®) has a narrow shaft and is especially suited for urethral and nasopharyngeal sampling.

Sigma-Swab® and Mini Sigma-Swab® are supplied sterile in peel pouch, tubed and tubed-duo formats.



Ordering information

Code	Vial	Fill	Swab Configuration*	Cap
Sigma Transwab				
MW167S	Small	1.0ml	2 Standard Sigma Swabs with break point	White
MW176S	Small	1.0ml	1 Standard Sigma Swab with break point	Purple
MW177S	Small	1.0ml	1 Mini tip Sigma Swab with break point	Orange
Sigma VCM				
MW910S	Small	1.0ml	1 Standard Sigma Swab with break point	Red
MW911S	Small	1.0ml	1 Mini tip Sigma Swab with break point	Red
MW912S	Small	1.0ml	1 Standard, 1 Mini tip Sigma Swab with break point	Red
MW915T	Small	1.0ml	Tube Only	Red
MW916T	Small	3.0ml	Tube Only	Red
MW918S	Large	3.0ml	1 Standard Sigma Swab with break point	Red
MW919S	Large	3.0ml	1 Mini tip Sigma Swab with break point	Red
MW920S	Large	3.0ml	1 Standard, 1 Mini tip Sigma Swab with break point	Red
MW921S	Large	3.0ml	2 Standard Sigma Swabs with break point	Red
MW924S	Large	1.5ml	2 Standard Sigma Swabs with break point, no glass beads	Red
MW925	Large	3.0ml	1 Standard Rayon Swab with break point	Red
MW926T	Large	3.0ml	Tube Only	Red
Sigma Virocult				
MW950S	Large	2.0ml	1 Standard Sigma Swab with break point	Green
MW950SENT	Large	2.0ml	1 Mini tip Sigma Swab with break point	Green
MW950S2	Large	2.0ml	2 Standard Sigma Swabs with break point	Green
MW950SE2	Large	2.0ml	1 Standard, 1 Mini tip Sigma Swab with break point	Green
MW950T	Large	2.0ml	Tube Only	Green
MW951S	Small	1.0ml	1 Standard Sigma Swab with break point	Green
MW951SENT	Small	1.0ml	1 Mini tip Sigma Swab with break point	Green
MW951T	Small	1.0ml	Tube Only	Green
Sigma Swab				
MW940			Sigma Swab and Peel Pouch	
MW941			Sigma Swab Individually Tubed and Labelled	
MW942			Duo Sigma Swab in Single Tube and Labelled	
MW943			Mini tip Sigma Swab and Peel Pouch	
MW944			2 Sigma Swabs and Peel Pouch	
MW945			1 Standard , 1 Mini Sigma Swab and Peel Pouch	

** The position of the breakpoint varies according to product. For variants with swab capture, the breakpoint is set to ensure that after breaking, the swab fits into the cap. For variants without swab capture, the breakpoint is set to allow the swab to sit within the vial without contact with the cap.*

References

1 Amies CR. Canadian Journal of Public Health 1967; 58: 296-300

2 Cassity, T.R., 1982, Comparison of Swabs for the Collection of Clinical Specimens for Anaerobic Cultures, Poster, Scioto Memorial Hospital, Portsmouth, Ohio

3 Graver, M.A., and J.J. Wade, 2003, Refrigeration Does Not Impair The Recovery Of *Neisseria Gonorrhoeae* From Charcoal Transport Medium. Poster, 43rd Annual Interscience Conference on Antimicrobial Agents and Chemotherapy, Chicago

4 Rishmawi, N. et al, 2007, Survival of Fastidious and Non- Fastidious Anaerobic Bacteria in Three Bacterial Transport Swab Systems. J.Clin. Micro. 45, 1278-83

5 Inverarity, D. , M. Diggle, G. Edwards, & T. Mitchell, 2006, An Evaluation of Media Suitable for the Transportation by Air of Streptococcus pneumoniae. Federation of Infection Societies Conference, Cardiff

6 Birrell, K., 2007, Comparative Study of Copan Venturi Transystem & Medical Wire & Equipment Transwab Microbiological Swabs using the Roll-Plate Method, Poster P1153, ECCMID 2007, Munich

7 Birrell, K., 2007, Investigation Of The Ability Of Transport Swabs To Release Collected Micro-Organisms - Using The Roll Plate Method, Poster C-369 / 076, 107th General Meeting of American Society for Microbiology, Toronto

8 Lindsay, G., 2008, Evaluation of the survival and recovery of *Neisseria gonorrhoeae* from four commercial swab transport systems media and a flock type swab ,Personal communication

9 Porterfield J.N., Hume R.D. Evaluation of Virocult collection and transport device. American Society of Microbiology AGM 1979

10 Johnson F.B., Leavitt R.W., Richards D.F., Evaluation of Virocult transport tube for isolation of Herpes simplex virus from clinical specimens. J.Clin Microbiol 1984: 20: 120-122

11 Johnson F. B., 1990, Transport of Viral Specimens, p. 120 – 131. Clinical Microbiology Reviews, 3, 120-131

12 Arvin A.M., Prober, C.G. Herpes Simplex Viruses in Manual of Clinical Microbiology, 7th Edition, 1999, American Society of Microbiology

13 Chapin, K.C., & F.W. Westenfeld, 2003, Reagents, Stains, Media, and Cell Lines: Virology, p.1250 in Murray P.R., E.J. Baron, J.H. Jorgensen, M.A. Pfaller, & R.H. Yolken, 2003, Manual of Clinical Microbiology, 8th Edition, ASM Press, Washington D.C.

14 Rudsdale, A., 2009, Evaluation Of A Virology Specimen Transport Device With Six Viruses Using CLSI Standard M40-A, Poster C-053 ASM 109th General Meeting, Philadelphia

15 Rudsdale, A., and D.J Shedden, 2009, Investigation Of The Suitability Of The Virocult® Swab Transport Device For Influenza A Specimens Which Are To Be Analyzed By Cell Culture Or Molecular Techniques, Poster M42 ,25th Annual Clinical Virology Symposium, Daytona Beach

16 Lina, B. et al, 1996, Surveillance of Community-Acquired Viral Infections Due to Respiratory Viruses in Rhone-Alpes (France) during Winter 1994 to 1995, J. Clin. Microbiol., 34: 3007-3011

17 Lina, B., 2005, Test Evaluation Report Medix Biochemica Infl uenza A & B

(Ref 2832ETMB) Actim Influenza A & B (Ref 32832ETAC), World Health Organization Collaborating Centre for Virus Reference and Research

18 Magnard, C., et al, 1999, Comparison of Two Nested PCR, Cell Culture, and Antigen Detection for the Diagnosis of Upper Respiratory Tract Infections due to Influenza Viruses, J. Medical Virol., 59: 215-220

19 Rezza, G., et al, 2006, Respiratory Viruses and Influenza-Like Illness: A Survey in the Area of Rome, Winter 2004-2005, Eurosurveillance 11 (10), 01 October 2006

20 Schweiger, B., et al, 2000, Application of a Fluorogenic PCR Assay for Typing and Subtyping of Influenza Viruses in Respiratory Samples, J. Clin. Microbiol. 38: 1552-1558

21 Esposito, S.,et al, 2008, Impact of Human Bocavirus on Children and Their Families, J. Clin. Microbiol. 46: 1337-1342

22 Schmutzard, J., et al, 2004, Detection of Herpes Simplex Virus Type 1, Herpes Simplex Virus Type 2, and Varicella-Zoster Virus in Skin Lesions. Comparison of Real Time PCR, Nested PCR, and Virus Isolation, J. Clin. Virol., 29:120-126

23 Valette, M., & B. Lina, 2009, Milieu de Transport et Persistance du Virus Grippal. (Personal communication)

24 Mack, K. et al, 2008, Clinical Performance of Foam vs Flocked Swabs collected from the anterior nares in a rapid antigen test for influenza A & B, Poster M8 at Pan American Society for Clinical Virology 24th Clinical Virology Symposium

25 Beall, A.R., 2003, Evaluation of Six Swab Transport Systems: Recovery of clinically relevant anaerobes. Poster C-051 at American Society for Microbiology 103rd General Meeting, Washington D.C.

26 Stuczen M, and V. Edwards-Jones, 2009, Comparison of Medical Wire's new Sigma-Swab With HealthLink Amies Transport System (Copan) for maintenance of microorganisms viability, NVvM Spring Meeting, Papendal, Netherlands

27 Stuczen M, and V. Edwards-Jones ,Maintaining Viability of Aerobic and Anaerobic Bacteria from Wounds Using the New Sigma-Swab Transport System Poster C-052 ASM 109th General Meeting, Philadelphia

28 Edwards-Jones V, and M. Stuczen, 2009, Efficacy of a New Sigma-Swab Transport System (Medical Wire) in Maintaining Viability of Wound Pathogens, Poster P37, European Wound Management Association 19th Conference, Helsinki

29 CLSI. 'Quality Control of Microbiological Transport Systems'; Approved Standard M40-A. CLSI (formerly NCCLS) document M40-A. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2003.

30 CLSI, 2006, Viral Culture; Approved Guideline. CLSI Document M41A. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2003.

31 European Medical Devices Directive 93/42/EEC

32 European In Vitro Diagnostic Devices Directive 98/79/EC

mwe medical wire

Corsham, Wiltshire, SN13 9RT, U.K.
Telephone: 01225 810361 Fax: 01225 810153
E-mail: info@mwe.co.uk www.mwe.co.uk