

Medical Wire – Compliance with CLSI M40-A

Since the launch in 1975 of Transwab[®], the world's first commercially produced all-in-one transport swab, Medical Wire has remained committed to the quality of its products, ensuring reliable handling of the patient's specimen, and dependable performance for all of our laboratory colleagues.

Accordingly, Medical Wire was one of the early adopters of CLSI's M40-A standard, implementing the requirements of the then proposed standard (M40-P) in 2001. We have always seen it as an essential reference to measure and where possible improve the performance of existing products, and for the development of new transport devices.

This document provides details of those of our products for which M40-A is relevant, with details of compliance.

Reference

CLSI. 'Quality Control of Microbiological Transport Systems'; *Approved Standard M40-A*. CLSI (formerly NCCLS) document M40-A [ISBN 1-56238-520-8]. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2003.

Purpose of M40-A

CLSI's^a document M40-A was first published as an approved standard in 2003^b by the then NCCLS^c. It set out criteria for the guidance of manufacturers of microbiological transport devices, including urine specimen containers, blood culture bottles, and transport swabs. These same criteria were also intended to assist end users in assessing the relative performance characteristics of available devices.

The essential requirement of M40-A is to show that the microbiological quality of a patient's

specimen is being maintained in a stable manner during the anticipated transport period and conditions. In the case of transport swabs where live microorganisms are required to remain viable without drastic increase or decrease in numbers, the performance is assessed with a set of ten specified ATCC strains of bacteria in categories of aerobes, anaerobes, and fastidious organisms. Survival is assessed for up to 48 hours at either ambient or refrigeration temperatures. Swabs for virology are assessed using specified viruses. Transport swabs which are intended for a more restricted set of criteria can be assessed, but the limitations of any claims must be clearly stated.

Since publication, M40-A has become established as the international benchmark for transport devices, perhaps particularly in relation to transport swabs for bacteriology and virology. Many studies have been presented or published invoking its requirements, although sadly not all such "studies" are genuine, and may show conclusions which cannot be reconciled with the data presented.

Notes

- a. CLSI : Clinical Laboratory Standards Institute
- b. M40-A is currently being revised, and will be reissued in the near future as CLSI M40-A2
- c. NCCLS: National Committee for Clinical Laboratory Standards

Please note CLSI M40-A is a copyrighted document and copies can be purchased from Clinical Laboratory Standards Institute at www.clsi.org



M40-A Compliance

	MW169C	MW169P	MW170	MW171	MW172C	MW172P	MW173C	MW173P	MW175C	MW175P	MW176S MW176S3	MW167S Σ- Transwab®	MW177S Σ- Transwab®	MW910S+ Σ-VCM™	MW950S+ Σ-Virocult®	MW950+ Virocult®
Test Organism	Transwab®	Transwab®	Transwab®	Transwab®	Transwab®	Transwab®	Transwab®	Transwab®	Transwab®	Transwab®	Σ-Transwab®	Σ- Transwab®	Σ- Transwab®	Σ-VCM™	Σ-Virocult®	Virocult®
<i>Pseudomonas aeruginosa</i> (ATCC® BAA-427)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			
<i>Streptococcus pyogenes</i> (ATCC® 19615)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			
<i>Streptococcus pneumoniae</i> (ATCC® 6305)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			
<i>Haemophilus influenzae</i> (ATCC® 10211)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			
<i>Bacteroides fragilis</i> (ATCC® 25285)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			
<i>Peptostreptococcus anaerobius</i> (ATCC® 27337)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			
<i>Fusobacterium nucleatum</i> (ATCC® 25586)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			
<i>Prevotella melaninogenica</i> (ATCC® 25845)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			
<i>Propionibacterium acnes</i> (ATCC® 6919)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			
<i>Neisseria gonorrhoeae</i> (ATCC® 43069)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
<i>Adenovirus</i>														✓	✓	✓
Influenza A														✓	✓	✓
Herpes Simplex Virus Type 2														✓	✓	✓
Respiratory Syncytial Virus														✓	✓	✓
<i>Mycoplasma hominis</i>														✓		
<i>Ureaplasma urealyticum</i>														✓		
<i>Chlamydia trachomatis</i>														✓		

*Results for Sigma VCM™, Sigma Virocult® & Virocult are also valid for all variants