

Evaluation of Sigma Transwab® With Foam Tip Swab According to CLSI M40-A2 Using Both Swab Elution and Roll Plate Methods

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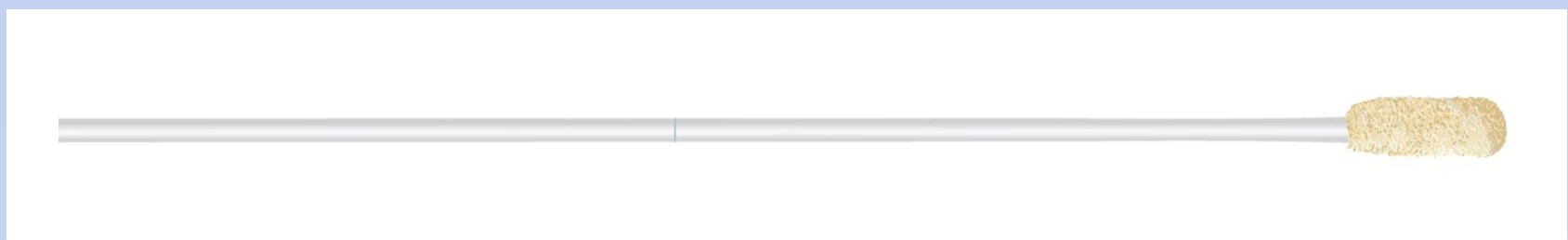
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Introduction

Transport swabs are critical components of the pre-analytical phase of the processing of microbiological specimens. It is essential to know that the swab transport system (STS) is fully capable of maintaining all target microorganisms in a viable condition until they can be processed in the laboratory. The Clinical and Laboratory Standards Institute (CLSI) M40-A2 standard has become the international benchmark for assessing the performance of STS.

Sigma-Transwab® is a liquid medium format transport swab designed for use on automated processing platforms. The Sigma swab has a bud of cellular polyurethane foam for efficient absorption and release of the specimen.



The CLSI M40-A2 standard includes two test methods, quantitative swab elution, and qualitative roll plate. The new standard also recommends that both quantitative and qualitative methods be used when testing foam or flock used in conjunction with liquid transport media due to the versatility of the STS; it can be used to inoculate agar directly via swab or liquid media or used by automated equipment. Use of both quantitative and qualitative methods ensures reliable performance under laboratory usage and accurate sensitivity.

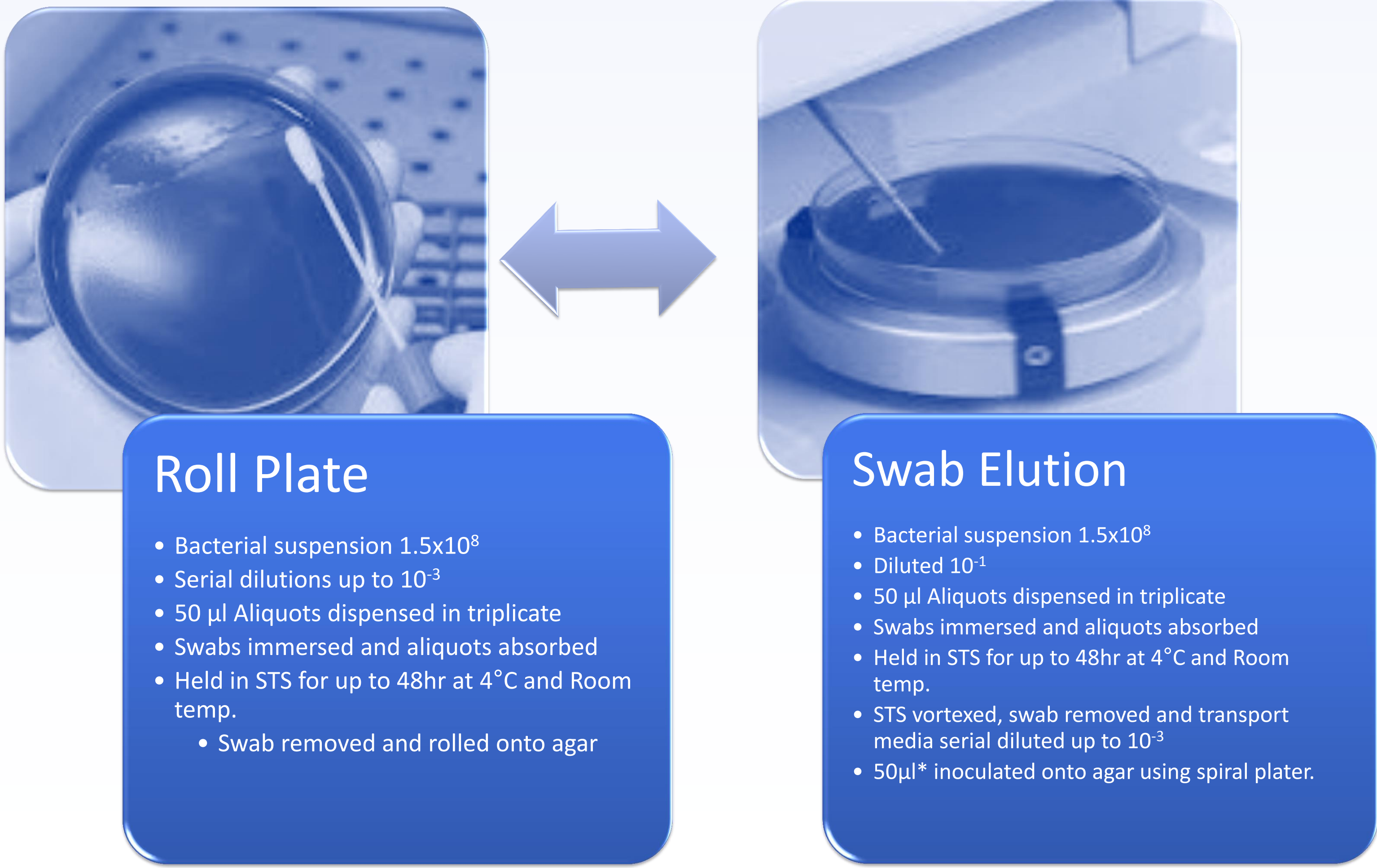
In this study, the viability of the ten M40-A2 bacteria was assessed using the Sigma-Transwab® with the qualitative (Roll plate) and quantitative (Swab Elution) method in accordance with CLSI M40-A2 standard.

Methods

Table 1. Growth conditions for M40-A2 test organisms

M40-A2 test organisms	Atmosphere	Media	Incubation time (hours)
<i>Pseudomonas aeruginosa</i> ATCC BAA-427	Aerobic	TSA	48
<i>Streptococcus pyogenes</i> ATCC 19615	5% CO ₂	CBA	48
<i>Streptococcus pneumonia</i> ATCC 6305	5% CO ₂	CBA	48
<i>Haemophilus influenzae</i> ATCC 10211	5% CO ₂	CA	48
<i>Bacteroides fragilis</i> ATCC 25285	Anaerobic	CBA	48
<i>Peptostreptococcus anaerobius</i> ATCC 27337	Anaerobic	CBA	48
<i>Fusobacterium nucleatum</i> ATCC 25586	Anaerobic	CBA	48
<i>Propionibacterium acnes</i> ATCC 6919	Anaerobic	CBA	48
<i>Prevotella melaninogenica</i> ATCC 25845	Anaerobic	CBA	48
<i>Neisseria gonorrhoeae</i> ATCC 43069	5% CO ₂	CA	24

Abbreviation: ATCC – American Type Culture Collection
TSA - Tryptic Soy Agar; CBA: Columbia Base Agar; CA: Chocolate Agar



Results

Table 2. M40-A2 Viability and overgrowth compliance for Sigma Transwab® using Qualitative and Qualitative Methods

Bacteria	Temp	Qualitative (Roll Plate) CFU				Quantitative (Swab Elution) CFU/ml			
		0hr	24hr	48hr	M40-A2 Compliance	0hr	24hr	48hr	M40-A2 Compliance
<i>Pseudomonas aeruginosa</i> ATCC® BAA-427	Room temp.	NA	NA	NA	NA	NA	NA	NA	NA
	4°C	20	87	109	✓	3.27 x10 ⁷	8.73 x10 ⁷	3.3 x10 ⁸	✓
<i>Haemophilus Influenzae</i> ATCC® 10211	Room temp.	168	11	7	✓	3.27 x10 ⁷	1.10 x10 ⁶	2.17 x10 ⁵	✓
	4°C		42	11	✓		1.16 x10 ⁶	1.19 x10 ⁵	✓
<i>Streptococcus pneumoniae</i> ATCC® 6305	Room temp.	225	131	74	✓	6.27 x10 ⁶	6.40 x10 ⁶	1.37 x10 ⁶	✓
	4°C		216	202	✓		1.73 x10 ⁶	7.60 x10 ⁶	✓
<i>Streptococcus pyogenes</i> ATCC® 19615	Room temp.	201	43	12	✓	8.30 x10 ⁶	4.53 x10 ⁶	2.67 x10 ⁶	✓
	4°C		108	23	✓		6.70 x10 ⁶	7.37 x10 ⁶	✓
<i>Prevotella melaninogenica</i> ATCC® 25845	Room temp.	73	95	38	✓	1.03 x10 ⁷	5.20 x10 ⁶	9.3 x10 ⁶	✓
	4°C		92	80	✓		6.07 x10 ⁶	6.5 x10 ⁶	✓
<i>Bacteroides fragilis</i> ATCC® 25285	Room temp.	187	108	80	✓	9.83 x10 ⁷	1.63 x10 ⁷	7.10 x10 ⁶	✓
	4°C		105	74	✓		4.57 x10 ⁷	9.41 x10 ⁶	✓
<i>Peptostreptococcus anaerobius</i> ATCC® 27337	Room temp.	301	176	105	✓	2.56 x10 ⁸	7.01 x10 ⁶	2.04 x10 ⁶	✓
	4°C		165	135	✓		9.56 x10 ⁷	2.30 x10 ⁷	✓
<i>Propionibacterium acnes</i> ATCC® 6919	Room temp.	187	78	31	✓	7.04 x10 ⁷	6.2 x10 ⁶	4.31x10 ⁶	✓
	4°C		69	52	✓		1.2 x10 ⁷	6.96x10 ⁶	✓
<i>Fusobacterium nucleatum</i> ATCC® 25586	Room temp.	297	215	108	✓	4.35 x10 ⁸	4.71 x10 ⁷	9.09 x10 ⁶	✓
	4°C		246	178	✓		9.09 x10 ⁷	5.41 x10 ⁷	✓
<i>Neisseria gonorrhoeae</i> ATCC® 43069	Room temp.	267	52	n/a	✓	8.13 x10 ⁶	4.67 x10 ⁵	n/a	✓
	4°C		65	n/a	✓		1.20 x10 ⁶	n/a	✓

Conclusions

The criteria set by the new M40-A2 standard for the Roll plate method standard states that for compliance of viability, any specimen held at 4 °C and RT should yield ≥ 5 CFU after the specified holding period and for the Swab elution method, specimens held at 4 °C and RT should not yield any more than 3-log decline in CFU between time zero and the specified holding period. For overgrowth studies, specimens held at 4 °C, should not yield any more than 1-log increase in CFU between time zero and the specified holding period.

The Sigma-Transwab® met CLSI acceptance criteria for all M40-A2 bacteria after the specified holding periods for both Qualitative (Roll Plate) and Quantitative (Swab Elution) methods as it was able to recover all specified strains at both room temperature and at 4 °C in full compliance with M40-A2.

We recommend that liquid media transport systems used in conjunction with foam swabs currently available commercially are internally reevaluated to ensure full M40-A2 adherence using both qualitative and quantitative methods. This will provide support for clinical diagnosis as identification of highly sensitive bacteria such as *N. gonorrhoeae* will be improved.

References

1.Clinical and Laboratory Standards Institute (CLSI). *Quality Control of Microbiological Transport Systems; Approved Standard- Second Edition*. CLSI document M40-A2

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