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SH

Prof. Dr. med. W. Solbach • Ratzeburger Allee 160 • 23538 Lübeck, Germany

UNIVERSITY CLINIC
Schleswig-Holstein

Lübeck campus
Institute for Medicinal Microbiology and Hygiene
Prof. Dr. med. Werner Solbach
Tel: 0451 500-2801
Fax: 0451 500-2749
email: werner.solbach@uk-sh.de
Internet: www.hygiene-luebeck.uk-sh.de

Diagnostic laboratories
Information: 0451 500-2824
Accredited in accordance with DIN EN ISO 15189 and
DIN EN ISO/IEC 17025

Deutscher Akkreditierungs Rat
DAR

DGA-ML-6157.02.10

Date: 28.1.2011

Test report 101207-1

Contamination analysis of the proximal tube system upon repeated use of the Nomo adapter

1. Background

It is to be clarified as to whether bacteria that are expelled with the exhalation air contaminate the proximal tube system of the Nomo adapter. Depending on the results, harmlessness on repeated use is to be evaluated.

2. Principle of the test

A sidestream CO2/SpO2 [redacted] portable measuring device was provided with 5 airway adapters (REF 3090121002), 10 sampling tubes (REF 3090121001) and 5 Nomo adapters (REF 3090122009).

3. Procedure

3.1. Test germ: *Enterococcus* ***faecium*** **ATCC 6057**

3.2. 300 µl of a 24 h bouillon of the test germ (10^9/ml) was injected into the Nomo adapter(approx. 3 x 10^8 KBE/filter)

3.3. The Nomo adapter was connected to the CapnoTrue ASP device and left for approx. 18 hrs in a damp chamber at 37° C.

3.4. After incubation, the 2 m long sampling tube (ID: 1 mm) was rinsed with NaCl 0.9% and connected to the Nomo or airway adapter.

3.5. A respiration device (Oxilog 2000, Dräger company) was connected via the airway adapter. Setting: Air mix, MV 10 L / min, freq. 12/min, PEEP 0 mbar).

3.6. To simulate humid respiration air, approximately 5 ml NaCl 0.9% was also added to the breathing bag.

3.7. The device with the Nomo adapter was placed approx. 10 cm higher than the breathing bag during the approx. 5 hours respiration time.

3.8. The [redacted] device CO_2 sensor Capnon was not connected during the test.

3.9. After the preliminary test, the test was repeated three times (without cooking salt

3.10. solution in the breathing bag). The Nomo adapter was not reinoculated, but in each case was placed in the damp chamber for 18 h before the repeat tests.

See p. 3 for the test structure.

The test was carried out three times.

3.11. Evaluation

After the tests the sampling tube was cut into 10 cm sections, each of which was rinsed out with 5 x 0.1 ml NaCl 0.9%. The eluate was placed directly on a blood agar plate (Biomérieux COS Lot 869452301 2011-02-22) and incubated for 24 h at 37° C. The germ count was then determined.

In a corresponding manner, the plug area of the Nomo adapter was swabbed and the Nomo adapter was rinsed together with its fixed tube.

4. Results

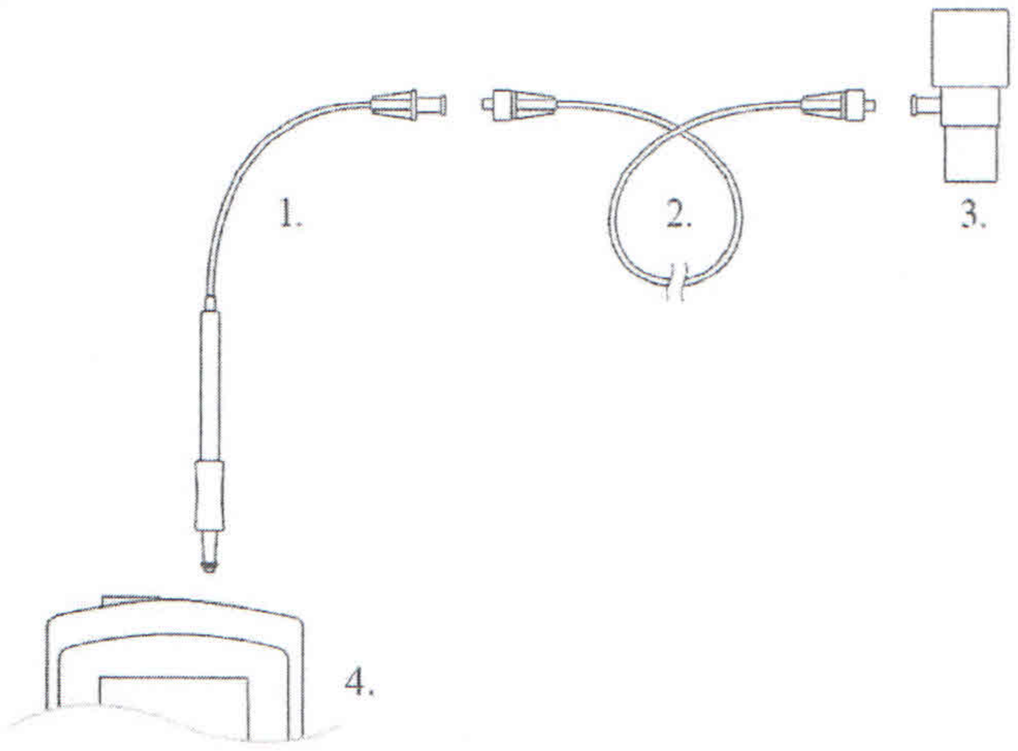
see Appendix 1

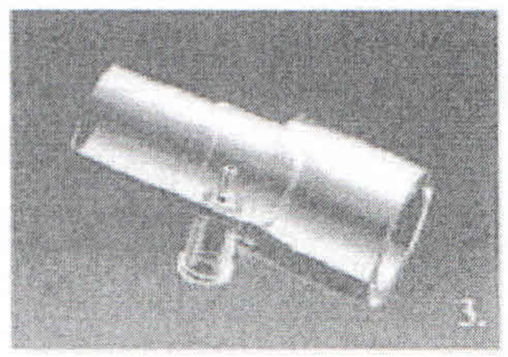
Evaluation

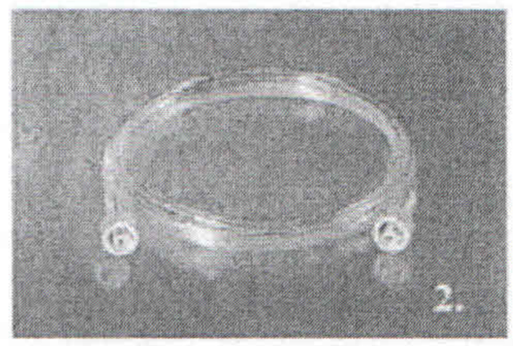
It was observed that even in the case of heavy contamination of the Nomo adapter with the test germ, only very small quantities entered the first section of the proximal portion of the adapter. No germs could be verified in the remaining part of the sampling tube. Repeated use of the adapter is harmless.

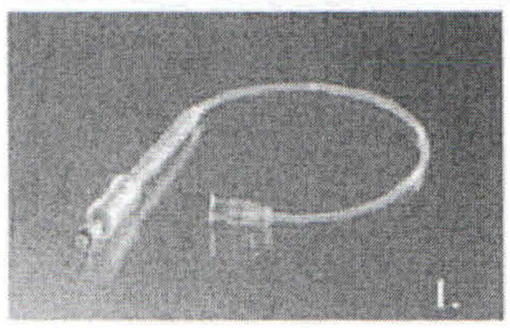
Test structure:

a)



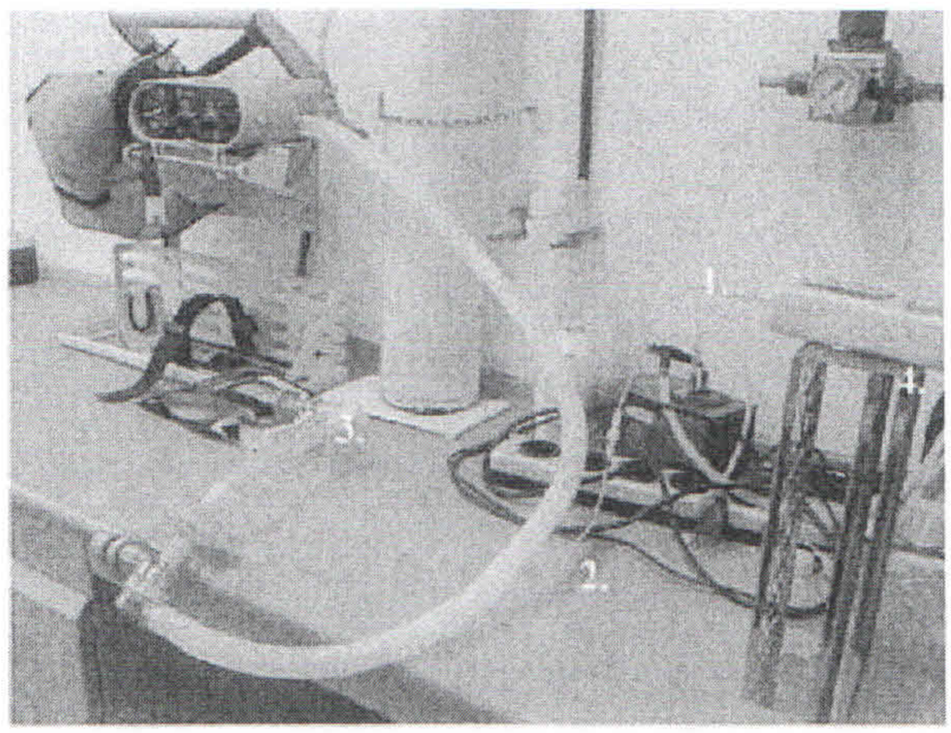






1 = Nomo adapter
2 = Sampling tube
3 = Airway adapter
4 = Sidestream CO2/SpO2 — [redacted] portable measuring device

b)



Appendix 1

Results

	Preliminary test 18.01.2011	**Test 1** 19.01.2011	**Test 2** 20.01.2011	**Test 3** 21.01.201
1st section (after Nomo adapter)	**123***	**0**	**9**	**1**
2. section	**1**	**0**	**0**	**0**
3. section	**0**	**0**	**0**	**0**
4. section	**0**	**0**	**0**	**0**
5. section	---	**0**	**0**	**0**
6. section		**0**	**0**	**0**
7. section	---	**0**	**0**	**0**
8. section	---	**0**	**0**	**0**
9. section	---	**0**	**0**	**0**
10. section	---	**0**	**0**	**0**
11. section	---	**0**	**0**	**0**
12. section	---	**0**	**0**	**0**
13. section	---	**0**	**0**	**0**
14. section	---	**0**	**0**	**0**
15. section	---	**0**	**0**	**0**
16. section	---	**0**	**0**	**0**
17. section	---	**0**	**0**	**0**
18. section	---	**0**	**0**	**0**
19. section	---	**0**	**0**	**0**
20. section (before the airway adapter)	---	**0**	**0**	**0**

* Figures indicate the number of proven test germs *(E. faecium* ATCC 6057).

Proof of test germs at the Nomo adapter after 4 tests	
	Test germ proof KBE/ test part
Nomo adapter plug to the device **swabbed**	**negative**
Plug area of the Nomo adapter **swabbed**	**negative**
Nomo adapter filter **rinsed out** in 10 ml NaCl	100*
Nomo adapter tube **rinsed out** with 2 ml NaCl	< 4

* Figures indicate the number of proven test germs *(E. faecium* ATCC 6057).

Controls

Contamination with 300 µl test germ suspension (approx. 3 x 10^8 KBE), followed by 18 h in a damp chamber, 37°C

	Test germ proof KBE/ test part
2 m tube Inoculated for KBE check	6.65 x 10^8
rinsed Nomo adapter filter (after 4 tests) reinoculated	4.20 x 10^6
Nomo adapter filter new	8.75 x 10^6
Nomo adapter tube	9.80 x 10^6

* Figures indicate the number of proven test germs *(E. faecium* ATCC 6057).