	Issue	
	Summary of Phadebact Stability Tests	
Issued	Approved	Date
Fredrik Johansson	Adam Mallkoo	2012-06-19

Stability of MKL Diagnostics AB product line Phadebact/Phadirect

The tests were performed in Bactus Quality control laboratory in Huddinge January 2008.


Test procedure according to the Directions for use.

The results are presented in the following tables (given in a 6-graded scale where 6 is the maximum response. Approved positive reaction = 4 - 6. Approved negative reaction ≤ 2).

Conclusion:

The test results are in compliance with the specifications. The shelf life of all products are 24 months (if stored at 2-8° C).

Adam Mallkoo, QA-Manager
2012-06-19, Sollentuna


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Streptococcus group A

Strain	Specification	0 test	4 months	9 months	17 months	24 months	29 months
A 1849	4-6	6	6	6	6	6	6
CDC 633	4-6	6	6	6	6	6	6
CDC 721	4-6	5	6	6	6	6	6
B III	≤2	0	0	0	0	0	0
C 1910	≤2	0	0	0	0	0	0
G 1911	≤2	0	0	0	0	0	0
Reagent only	0	0	0	0	0	0	0

Streptococcus group B

Strain	Specification	0 test	4 months	9 months	17 months	24 months	29 months
ATCC 12401	4-6	6	6	6	6	6	6
B III	4-6	6	6	6	6	6	6
CDC 617	4-6	6	6	6	6	6	6
A 1849	≤2	0	0	0	0	0	0
C 1910	≤2	0	0	0	0	0	0
G 1911	≤2	0	0	0	2	0	0
Reagent only	0	0	0	0	0	0	0


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Streptococcus group C

Strain	Specification	0 test	4 months	9 months	17 months	24 months	29 months
C 1910	4-6	6	6	6	6	6	6
C 74	4-6	6	6	6	6	6	6
CDC 1069	4-6	6	6	6	6	6	6
ATCC 12401	≤2	0	0	0	0	0	0
B III	≤2	0	0	0	0	0	0
G 1911	≤2	0	0	0	0	0	0
Reagent only	0	0	0	0	0	0	0

Streptococcus group G

Strain	Specification	0 test	4 months	9 months	17 months	24 months	29 months
G 1911	4-6	6	6	6	6	6	6
CDC 13	4-6	6	6	6	6	6	6
ATCC 12395	4-6	6	5	6	6	6	6
ATCC 12401	≤2	0	0	0	0	0	0
B III	≤2	0	0	0	0	0	0
C 1910	≤2	0	0	0	0	0	0
Reagent only	0	0	0	0	0	0	0


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Streptococcus group D

Strain	Specification	0 test	4 months	14 months	24 months
NCTC 8729	4-6	6	6	6	6
NCTC 7171	4-6	6	6	6	6
NCTC 8140	4-6	6	6	6	6
B III	≤2	0	0	0	0
C 1910	≤2	0	0	0	0
G 1911	≤2	0	0	0	0
Reagent only	0	0	0	0	0

Streptococcus group F

Strain	Specification	0 test	4 months	14 months	16 months	24 months
ATCC 9328	4-6	5	5	5	5	6
NCTC 10714	4-6	4	5	6	6	6
CDC 53	4-6	5	5	5	5	6
B III	≤2	0	0	0	0	0
C 74	≤2	0	0	0	0	0
NCTC 8729	≤2	0	0	0	0	0
Reagent only	0	0	0	0	0	0


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Haemophilus type b

Strain	Specification	0 test	4 months	17 months	24 months
NCTC 7279	4-6	6	6	6	6
SBL 342	4-6	6	6	6	6
SBL 344	4-6	6	6	6	6
NCTC 8465	≤2	0	0	0	0
ATCC 9008	≤2	0	0	0	0
NCTC 8473	≤2	0	0	0	0
Reagent only	0	0	0	0	0

Haemophilus type a,c-f

Strain	Specification	0 test	4 months	17 months	24 months
NCTC 8465	4-6	6	6	6	6
ATCC 9008	4-6	6	6	6	6
NCTC 8473	4-6	6	6	6	6
NCTC 7279	≤2	0	0	0	0
SBL 342	≤2	0	0	0	0
SBL 344	≤2	0	0	0	0
Reagent only	0	0	0	0	0

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Pneumococcus

Strain	Specification	0 test	4 months	17 months	24 months
SSI 1	4-6	5	5	5	6
SSI 4	4-6	6	6	6	6
SSI 6A	4-6	6	6	6	6
SSI 18C	4-6	6	6	6	6
alfa strep					
CDC 305	≤2	0	0	0	0
CDC 816	≤2	0	0	0	0
Reagent only	0	0	0	0	0

Staph Aureus

Strain	Specification	0 test	9 months	19 months	24 months	35 months
8884	2-4	4	4	4	4	4
ORSA 12094	2-4	4	4	4	4	4
ATCC 6538	2-4	4	4	4	4	4
ATCC 25923	2-4			4		4
ATCC 29887	0	0	0	0	0	0
12228	0	ND	ND	0	ND	0
Reagent only	0	0	0	0	0	0




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CSF Meningococcus

Strain	Specification	0 test	14 months	18 months	24 months
NCTC 1002510 ⁸	4-6	6	6	6	6
NCTC 10025 10 ⁷	4-6	5	5	5	5
NCTC 8554 10 ⁸	4-6	6	5	5	5
NCTC 855410 ⁷	4-6	5	5	5	5
NCTC 11203 10 ⁸	4-6	6	5	5	5
SSI 4	≤ 2	0	0	0	0
SSI 14	≤ 2	0	0	0	0
NCTC 8467 10 ⁸	≤ 2	0	0	0	0
NCTC 1021110 ⁸	≤ 2	0	0	0	0
CDC 617	≤ 2	0	0	0	0
ATCC 12387	≤ 2	0	0	0	0
Reagent only	0	0	0	0	0

CSF Streptococcus group B

Strain	Specification	0 test	14 months	18 months	24 months
CDC 617	4-6	6	5	5	5
ATCC 12387	4-6	5	5	5	5
B1a	4-6	6	5	6	6
NCTC 1002510 ⁸	≤ 2	0	0	0	0
NCTC 8554 10 ⁸	≤ 2	0	0	0	0
SSI 4	≤ 2	0	0	0	0
SSI 14	≤ 2	0	0	0	0
NCTC 8467 10 ⁸	≤ 2	0	0	0	0
NCTC 1021110 ⁸	≤ 2	0	0	0	0
Reagent only	0	0	0	0	0


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CSF Haemophilus type b

Strain	Specification	0 test	14 months	18 months	24 months
ATCC 10211 10 ⁸	4-6	6	6	6	6
ATCC 10211 10 ⁷	4-6	5	5	5	5
NCTC 8467 10 ⁸	4-6	6	6	6	6
NCTC 8467 10 ⁷	4-6	5	5	5	5
NCTC 8468 10 ⁸	4-6	6	6	6	6
NCTC 8468 10 ⁷	4-6	5	5	5	5
ATCC 12387	≤ 2	0	0	0	0
B1a	≤ 2	0	0	0	0
NCTC 10025 10 ⁸	≤ 2	0	0	0	0
NCTC 8554 10 ⁸	≤ 2	0	0	0	0
SSI 4	≤ 2	0	0	0	0
SSI 14	≤ 2	0	0	0	0
Reagent only	0	0	0	0	0

CSF Pneumococcus

Strain	Specification	0 test	14 months	18 months	24 months
SSI 4	4-6	5	4	4	4
SSI 14	4-6	4	4	4	4
SSI 19 C	4-6	4	4	4	4
ATCC 12387	≤ 2	0	0	0	0
B1a	≤ 2	0	0	0	0
NCTC 10025 10 ⁸	≤ 2	0	0	0	0
NCTC 8554 10 ⁸	≤ 2	0	0	0	0
ATCC 10211 10 ⁸	≤ 2	0	0	0	0
NCTC 8467 10 ⁸	≤ 2	0	0	0	0
Reagent only	0	0	0	0	0


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Phadirect Streptococcus group A

Strain	Specification	0 test	7 months	14 months	24 months
CDC 633 10 ⁷	4-6	5	5	5	5
CDC 633 10 ⁶	4-6	4	4	4	5
CDC 721 10 ⁷	4-6	5	5	5	5
CDC 721 10 ⁶	4-6	4	4	4	4
CDC 754 10 ⁷	4-6	5	5	5	5
CDC 754 10 ⁶	4-6	4	4	4	4
C74	≤ 2	0	0	0	0
C1860	≤ 2	0	0	0	0
Reagent only	0	0	0	0	0

ETEC-LT

Strain	Specification	0 test	17 months	28 months
T 63	4-6	6	6	6
B 96-8	4-6	6	6	6
4421-d	4-6	6	6	6
342-17	≤ 2	0	0	0
B 34212j	≤ 2	0	0	0
C-922-a	≤ 2	0	0	0
Reagent only	0	0	0	0

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CSF pos control Meningococcus

Reagent	Specification	0 test	12 months	19 months	24 months
Meningococcus	4-6	6	6	6	6
Pneumococcus	≤ 2	0	0	0	0
Haemophilus type b	≤ 2	0	0	0	0
Streptococcus group B	≤ 2	0	0	0	0

CSF pos control Pneumococcus


Reagent	Specification	0 test	12 months	19 months	24 months
Pneumococcus	4-6	5	5	5	5
Meningococcus	≤ 2	0	0	0	0
Haemophilus type b	≤ 2	0	0	0	0
Streptococcus group B	≤ 2	0	0	0	0

CSF pos control Haemophilus type b

Reagent	Specification	0 test	12 months	19 months	24 months
Haemophilus type b	4-6	6	6	6	5
Meningococcus	≤ 2	0	0	0	0
Pneumococcus	≤ 2	0	0	0	0
Streptococcus group B	≤ 2	0	0	0	0

CSF pos control Streptococcus group B

Reagent	Specification	0 test	12 months	19 months	24 months
Streptococcus group B	4-6	6	6	5	5
Meningococcus	≤ 2	0	0	0	0
Pneumococcus	≤ 2	0	0	0	0
Haemophilus type b	≤ 2	0	0	0	0


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GC WI

Strain	Specification	0 test	4 months	16 months	26 months
R 11	4-6	6	6	6	6
E 5	4-6	6	6	6	6
W 16	4-6	5	6	6	6
C 3	≤2	0	0	0	0
5288	≤2	0	0	0	0
5293	≤2	0	0	0	0
Reagent only	0	0	0	0	0

GC WII/III

Strain	Specification	0 test	4 months	16 months	26 months
C 3	4-6	5	6	6	6
5288	4-6	6	6	6	6
5293	4-6	5	6	6	6
R 11	≤2	0	0	0	0
E 5	≤2	0	0	0	0
W 16	≤2	0	0	0	0
Reagent only	0	0	0	0	0

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GC pos control

Reagent	Specification	0 test	23 months	31 months
Gc WI	4-6	6	6	6
Gc WII/III	4-6	6	6	6

Streptococcus group A positive control

Reagent	Specification	0 test	26 months	36 months
Streptococcus group A	4-6	6	6	6

Streptococcus group B positive control

Streptococcus group B	4-6	6	6	6
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Streptococcus group C positive control

Streptococcus group C	4-6	6	6	6
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Streptococcus group D positive control


Streptococcus group D	4-6	6	6	6
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Streptococcus group F positive control

Streptococcus group F	4-6	6	6	6
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Streptococcus group G positive control

Streptococcus group G	4-6	6	6	6
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Salmonella group O:2

Strain	Specification	0 test	9 months	12 months	24 months
S.paratyphi A	4-6	6	6	6	6
Var. Durazzo	4-6	6	6	6	6
S.reading	≤2	0	0	0	0
S.thompson	≤2	0	0	0	0
S.muenchen	≤2	0	0	0	0
S.enteritidis	≤2	0	0	0	0
S.london	≤2	0	0	0	0
Reagent only	0	0	0	0	0

Salmonella group O:4

Strain	Specification	0 test	9 months	12 months	24 months
S.reading	4-6	5	6	6	5
S.typhimurium	4-6	4	6	6	5
S.bredeney	4-6	5	6	6	5
S.paratyphi A	≤2	0	0	0	0
S.thompson	≤2	0	0	0	0
S.muenchen	≤2	1	0	0	0
S.enteritidis	≤2	0	0	0	0
S.london	≤2	0	0	0	0
Reagent only	0	0	0	0	0


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Salmonella group O:7

Strain	Specification	0 test	9 months	12 months	24 months
S.thompson	4-6	6	6	6	6
S.montevideo	4-6	6	6	6	5
S.paratyphi C	4-6	6	6	6	6
S.paratyphi A	≤2	0	0	0	0
S.reading	≤2	0	0	0	0
S.muenchen	≤2	0	0	0	0
S.enteritidis	≤2	0	0	0	0
S.london	≤2	0	0	0	0
Reagent only	0	0	0	0	0

Salmonella group O:8

Strain	Specification	0 test	9 months	12 months	24 months
S.muenchen	4-6	6	6	6	6
S.newport	4-6	6	6	6	6
S.hadar	4-6	6	6	6	6
S.paratyphi A	≤2	0	0	0	0
S.reading	≤2	0	0	0	0
S.paratyphi C	≤2	0	0	0	0
S.enteritidis	≤2	0	0	0	0
S.london	≤2	0	0	0	0
Reagent only	0	0	0	0	0

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Salmonella group O:9

Strain	Specification	0 test	9 months	12 months	24 months
S.enteritidis	4-6	6	6	6	6
S.typhi	4-6	6	6	6	5
S.strasbourg	4-6	6	6	6	6
S.paratyphi A	≤2	0	0	0	0
S.reading	≤2	0	0	0	0
S.paratyphi C	≤2	0	0	0	0
S.muenchen	≤2	0	0	0	0
S.london	≤2	0	0	0	0
Reagent only	0	0	0	0	0

Salmonella group O:3

Strain	Specification	0 test	9 months	12 months	24 months
S.london	4-6	5	6	6	6
S.anatum(IS78)	4-6	6	6	6	6
S.taksony	4-6	6	4	6	5
S.paratyphi A	≤2	0	0	0	0
S.reading	≤2	0	0	0	0
S.paratyphi C	≤2	0	0	0	0
S.muenchen	≤2	0	0	0	0
S.enteritidis	≤2	0	0	0	0
Reagent only	0	0	0	0	0