April 2009

Dear BacT/ALERT® Customer,

bioMérieux is pleased to announce the new BacT/ALERT® iFA, BacT/ALERT® iFN and BacT/ALERT® iPF culture bottles are *NOW* available. These new bottles will replace the current BacT/ALERT® FA, BacT/ALERT® FN and BacT/ALERT® PF culture bottles for INDUSTRY applications.

The new BacT/ALERT bottles include package inserts with intended use statements that support INDUSTRY applications. These bottles were performance tested using the USP and EP compendial microorganisms with results that appear in the package inserts. The new bottles are provided with the same media formulation and package size as the current product you purchase. In addition, each lot is produced in specific batches to allow full traceability of product in the field. Internal tests demonstrated performance of the new BacT/ALERT iFA, BacT/ALERT iFN and BacT/ALERT iPF culture bottles as equivalent to the currently marketed BacT/ALERT FA, BacT/ALERT FN and BacT/ALERT PF culture bottles.

New product numbers are below:

New BacT/ALERT Culture Bottles	New Product Number	Old BacT/ALERT Culture Bottles	Old Product Number
BacT/ALERT iFA	251062	BacT/ALERT FA	259791
BacT/ALERT iFN	251063	BacT/ALERT FN	259793
BacT/ALERT iPF	251061	BacT/ALERT PF	259794

In order to use the new culture bottles, your BacT/ALERT system must be programmed using the barcodes included within the BacT/ALERT iFA, BacT/ALERT iFN and BacT/ALERT iPF *Bottle Barcode Activation Instructions* (514550-1EN1). These barcodes provide the programming needed for your BacT/ALERT to recognize these bottles and therefore use the correct detection algorithm.

The new BacT/ALERT culture bottles also contain a new supply of activated charcoal. Tests conducted at bioMérieux have demonstrated equivalence of the new charcoal supply with that in the current FA and FN bottles. bioMérieux will maintain inventory of the old BacT/ALERT FA, BacT/ALERT FN and BacT/ALERT PF bottles for any potential studies you wish to conduct. Any old BacT/ALERT bottles required for your studies must be ordered by May 30, 2009.

Thank you for your continued use of bioMérieux products, and please do not hesitate to contact your bioMérieux representative with any questions at 800-634-7656.

Sincerely,

Ray T. Turnley

Ray T. Turnley
Senior Product Manager, BacT/ALERT® 3D
bioMérieux INDUSTRY

P/N 702454-2

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BacT/ALERT® Raw Material Summary

bioMérieux will substitute the activated charcoal currently used in the BacT/ALERT® FA (Product number 259791), BacT/ALERT® FN (Product number 259793) and BacT/ALERT® PF (Product number 259794) culture bottles for an equivalent activated charcoal with the launch of the new BacT/ALERT® iFA (Product number 251062), BacT/ALERT® iFN (Product number 251063) and BacT/ALERT® iPF (Product number 251061) culture bottles. Validation of the activated charcoal substitution is complete and equivalency between the two charcoal supplies has been established. Recovery and detection times of microorganisms from the United States Pharmacopoeia <51> and <71>, European Pharmacopoeia 2.6.1 and 2.6.27 and 21 CFR 610.12 demonstrate substitution of the activated charcoal does not impact performance of the aforementioned products. All bottles used in the study were manufactured according to bioMérieux quality procedures and specifications. Consult package inserts for any specific bottle limitations.

Tables 1, 2 and 3 list the results of the seeded studies used to demonstrate performance:

Table 1: BacT/ALERT iFA vs. BacT/ALERT FA

			Detection Time (hrs) Avg. of 5 Replicates at 32.5°C	
Microorganism	Theoretical Inoculum (CFU/ml)	Actual Inoculum (CFU/ml)	BacT/ALERT iFA Culture Bottle	BacT/ALERT FA Culture Bottle
Staphylococcus aureus ATCC 6538	25	32	21.2	20.7
Bacillus subtilis ATCC 6633	25	16	18.6	18.2
Escherichia coli ATCC 8739	25	44	23.0	18.4
Streptococcus pyogenes ATCC 19615	25	45	24.5	23.3
Yersinia enterocolitica ATCC 9610	25	24	31.0	25.9
Pseudomonas aeruginosa ATCC 9027	25	48	21.8	20.9
Micrococcus luteus ATCC 9341	25	98	31.4	28.6
Candida albicans ATCC 10231	25	38	34.8	33.2
Aspergillus niger ATCC16404	25	6	55.8[1]	53.3

[1] Average of 4 Replicates

The BacT/ALERT iFA and BacT/ALERT FA culture bottles recovered microorganisms recommended for testing by the USP <51>, <71>, EP 2.6.1 and 2.6.27 and 21CFR 610.12. Time of detection was equivalent between the two charcoal types.

Table 2: BacT/ALERT iFN vs. BacT/ALERT FN

Microorganism	Theoretical Inoculum (CFU/ml)	Actual Inoculum (CFU/ml)	Detection Time (hrs) Avg. of 5 Replicates at 32.5°C	
			BacT/ALERT iFN Culture Bottle	BacT/ALERT FN Culture Bottle
Staphylococcus aureus ATCC 6538	25	32	20.2	21.3
Escherichia coli ATCC 8739	25	44	13.6	13.8
Clostridium sporogenes ATCC 11437	25	26	27.7	21.9
Bacteroides vulgatus ATCC 8482	25	5	8.1[1,2]	9.0[1]
Clostridium sporogenes ATCC 19404	25	42	28.6	23.2
Bacteroides fragilis ATCC 25285	25	15	6.5[1]	7.0[1]
Streptococcus pyogenes ATCC 19615	25	45	27.1	29.6
Yersinia enterocolitica ATCC 9610	25	24	22.7	23.5

[1] Time to Detection (days)
[2] Average of 4 Replicates

The BacT/ALERT iFN and BacT/ALERT FN non-vented culture bottles recovered microorganisms recommended for testing by the USP <51>, <71>, EP 2.6.1 and 2.6.27 and 21CFR 610.12. Time of detection was equivalent between the two charcoal types.

Table 3: BacT/ALERT iPF vs. BacT/ALERT PF

Microorganism	Theoretical Inoculum (CFU/ml)	Actual Inoculum (CFU/ml)	Detection Time (hrs) Avg. of 5 Replicates at 32.5°C	
			BacT/ALERT iPF Culture Bottle	BacT/ALERT PF Culture Bottle
Staphylococcus aureus ATCC 6538	25	32	20.5	20.3
Bacillus subtilis ATCC 6633	25	16	17.9	17.8
Escherichia coli ATCC 8739	25	44	22.4	21.4
Streptococcus pyogenes ATCC 19615	25	45	23.8	23.0
Yersinia enterocolitica ATCC 9610	25	24	29.5	26.4
Pseudomonas aeruginosa ATCC 9027	25	48	20.7	20.4
Micrococcus luteus ATCC 9341	25	98	31.9	31.2
Candida albicans ATCC 10231	25	38	34.1	33.6
Aspergillus niger ATCC16404	25	6	51.4	50.8

The BacT/ALERT iPF and BacT/ALERT PF culture bottles recovered microorganisms recommended

for testing by the USP <51>, <71>, EP 2.6.1 and 2.6.27 and 21CFR 610.12. Time of detection was equivalent between the two charcoal types.