

**Title: 3M™ Hydrated-Sponges:
Compatibility with BioMérieux VIDAS® and DuPont Qualicon BAX®
Systems Performance Summary**

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Technology Platform: Sample Handling – 3M™ Sponge Products
Originating Location: St. Paul, Minnesota

3M™ Sponge Products make environmental testing and product sampling easier and more convenient. That's because 3M™ Sponge-Stick and 3M™ Hydrated-Sponge products are compatible with several assays including BioMérieux VIDAS® and DuPont Qualicon BAX® systems.

Performance of the 3M Sponge products was evaluated for compatibility with the BioMérieux VIDAS® and DuPont Qualicon BAX® systems for *Salmonella*, *Listeria*, and *E. coli* assays.



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Study Design:

Testing was performed to determine organism viability after rapid assay media enrichment and processing with rapid assay systems.

Using a 3M™ Hydrated-Sponge, a low level inoculum (approximately 10 colony forming units - CFUs) of the culture strain was added to the sponge and then incubated according to the DuPont Qualicon BAX® and BioMérieux VIDAS® assay procedure. Media controls were also inoculated and processed in this same manner.

After incubation, samples were analyzed on the BioMérieux VIDAS® and DuPont Qualicon BAX® systems for positive or negative detection. Quantitative assessment of the enriched media (with inoculated sponge) was performed to determine level of microbial growth. In addition, a qualitative assessment of the enrichment media (with inoculated sponge) was performed by streaking onto selective agar to determine presence/absence of the target organism. A Percentage Agreement test was used to compare the results from the rapid assay with the selective agar for each organism.

Experiment:

Inoculated Samples: 3M Hydrated-sponge samples were inoculated with approximately less than 10 CFUs of the target organism. The inoculated sample was processed according to the corresponding rapid assay procedure.

The testing was performed for the following sponges:

- 3M™ Hydrated Sponges with Dey Engley Broth (DEB)
- 3M™ Hydrated Sponges with Neutralizing Buffer (NB)
- 3M™ Hydrated Sponges with Letheen Broth (LET)
- 3M™ Hydrated Sponges with Buffered Peptone Water Broth (BPW)

Testing was performed with ten replicates for each sample per each organism for each of the corresponding rapid assays.



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The organisms used for inoculation were:

Listeria monocytogenes, ATCC# 19114
Salmonella enterica, ATCC# 35640
Escherichia coli – O157, ATCC# 43888

The rapid assay procedures used for testing were:

DuPont Qualicon BAX® System PCR Assay for Salmonella
DuPont Qualicon BAX® System PCR Assay for Screening *E. coli* O157:H7 MP
DuPont Qualicon BAX® System PCR Assay for Genus *Listeria* 24E
BioMérieux VIDAS® SLM
BioMérieux VIDAS® UP *E. coli* O157 ECPT
BioMérieux VIDAS® LIS

The selective agar media used for testing were:

Oxford (OX) Agar for *Listeria* isolation
Xylose Lysine Deoxycholate (XLD) Agar for *Salmonella* isolation
MacConkey (MAC) Agar for *E. coli* isolation

Negative Control: 3M Hydrated-Sponge samples with no inoculation were processed according to the specific rapid assay procedure.

Media Controls: The 3M hydration diluents (with no sponge) were inoculated with approximately less than 10 CFUs of a specific organism. The inoculated sample was then processed according to the specific rapid assay procedure.



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Results:

Qualitative: Percentage agreement results demonstrated that there were no statistically significant differences between the results of the DuPont Qualicon BAX® and BioMérieux VIDAS® assays to the selective agar plates when the sample results were pooled for each organism.

Organism	Rapid Assay to Agar Confirmation	P Value	Statistically Significant Difference (p value <0.05)?
<i>Listeria monocytogenes</i>	BAX®:OX	1.000	No
	VIDAS®:OX	0.356	No
<i>Salmonella enterica</i>	BAX®:XLD	0.356	No
	VIDAS®:XLD	N/A – since there was 100% agreement	No
<i>Escherichia coli</i> – O157	BAX®: MAC	0.356	No
	VIDAS®:MAC	0.177	No

Quantitative: For all organisms with the various rapid assay enrichment media, the CFU average was greater than 10^4 . The range in log difference between the average CFU results of the various inoculated 3M Hydrated-Sponges and the Media Positive Controls was: -1.0 to 0.92.

Conclusion of Testing:

Overall conclusion: the 3M Hydrated-Sponges are compatible for use with the DuPont Qualicon BAX® and/or BioMérieux VIDAS® rapid assays.

Culture growth level in the rapid assay enrichment media was on average greater than 10^4 CFU. When compared to the Media Positive Controls, there was no larger than a one log difference between culture enrichment levels.