CERTIFICATION

AOAC® *Performance Tested*SM

Certificate No.

010902

The AOAC Research Institute hereby certifies the test kit known as:

BAX® System PCR Assay for Yeast and Mold

manufactured by

Hygiena
2 Boulden Circle
New Castle, DE 19720
USA

This method has been evaluated in the AOAC® *Performance Tested Methods*SM Program and found to perform as stated by the manufacturer contingent to the comments contained in the manuscript. This certificate means that an AOAC® Certification Mark License Agreement has been executed which authorizes the manufacturer to display the AOAC *Performance Tested*SM certification mark along with the statement - "THIS METHOD'S PERFORMANCE WAS REVIEWED BY AOAC RESEARCH INSTITUTE AND WAS FOUND TO PERFORM TO THE MANUFACTURER'S SPECIFICATIONS" - on the above mentioned method for a period of one calendar year from the date of this certificate (December 03, 2019 – December 31, 2020). Renewal may be granted at the end of one year under the rules stated in the licensing agreement.

Scott Coates

Scott Coates, Senior Director
Signature for AOAC Research Institute

December 03, 2019
Date

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New Castle, DE 19720
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KIT NAME(S)
DuPont™ Bax® System PCR Assay for Yeast and Mold
March 01, 2017, Bax® System PCR Assay for Yeast and Mold

CATALOG NUMBERS
KIT2015 (kit); KIT2014 (supplement)

INDEPENDENT LABORATORY
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[4] US FDA, CFSAN, College Park, MD, USA: July 2013 Modification only

APPLICABILITY OF METHOD
Target organism – Yeast and Mold (all genra, all species)

Matrices – (25 g) - Yogurt, corn starch, milk-based powdered infant formula

Performance claims - Threshold detection of contaminating fungi in specified matrices that is statistically indistinguishable from the FDA-BAM method for detecting Yeast and Mold [3].

REFERENCE METHOD
Tournas, V., Stack, M.E., Mislivec,P.B., Koch, H.A. and Bandler R. 1998. Bacteriological Analytical Manual Online. Revised 4/2000. US Food & Drug Administration, Center for Food Safety & Applied Nutrition. Chapter 18, *Yeasts, Molds and Mycotoxins*. http://www.cfsan.fda.gov/~ebam/bam-18.html Date of Access 6 Jan 2009. (2)

ORIGINAL CERTIFICATION DATE
January 29, 2009

CERTIFICATION RENEWAL RECORD
Renewed Annually through December 2020

METHOD MODIFICATION RECORD
1. **July 2013**
2. **March 2017 Level 2**
3. **January 2018 Level 1**
4. **May 2019 Level 1**

SUMMARY OF MODIFICATION
1. **Addition of Thermal Block for automated sample lysis.**
2. **Name change from DuPont Nutrition & Health to Qualicon Diagnostics LLC., a Hygiena company**
3. **Editorial update of labels, insert, and documents to Hygiena**
4. **Update to inserts and corporate address change**

Under this AOAC® *Performance Tested*℠ License Number, 010902 this method is distributed by:
NONE

Under this AOAC® *Performance Tested*℠ License Number, 010902 this method is distributed as:
NONE

PRINCIPLE OF THE METHOD (1)
Fungal Cell Disruption – Fungal cells are disrupted and their DNA is sheared into multiple pieces using a mechanical shearing device.
PCR Amplification - The BAX® system Yeast and Mold test kit uses the Polymerase Chain Reaction (PCR) to amplify specific fragments of fungal DNA, which are present in multiple copies per cell and are stable and unaffected by growth environment. The fragments are genetic sequences that are unique to the fungal genome, thus providing a highly reliable indicator that the organism is present. The BAX® system simplifies the PCR process by combining the requisite primers, polymerase and nucleotides into a stable, dry, manufactured tablet already packaged inside the PCR tubes. After amplification, these tubes remain sealed for the detection phase, thus significantly reducing the potential for contamination with one or more molecules of amplified PCR product [2].
Fluorescent Detection - The automated BAX® system uses fluorescent detection to analyze PCR product. Each PCR tablet contains a fluorescent dye, which binds with double-stranded DNA and emits a signal in response to excitation light. During the detection phase, the temperature of the samples is slowly increased to denature the DNA. This releases the dye and causes a drop in emission signal. The BAX® system measures the denaturation temperature and the magnitude of fluorescent signal change [3]. An analysis by the BAX® System software algorithm then evaluates that data to determine a positive or negative result which is displayed as described below.

DISCUSSION OF THE ORIGINAL VALIDATION STUDY (1)

The BAX ® System PCR Assay for Screening Yeast and Mold demonstrates slightly, though not statistically significantly, greater sensitivity than the reference FDA BAM plating method. The test kit is able to be tuned to achieve comparable threshold level contamination detection when compared with plating methods by adjusting the amount of sample homogenate added to the growth/disrupter tube(s). Since by its nature, the BAX assay is a +/- result whose sensitivity is determined by the amount of sample homogenate evaluated, its use is limited in cases where a product of interest is frequently contaminated at a level near the specified cutoff. In such cases, the time saved by performing the rapid test will often be negated by having to perform many reference method analyses to determine the true level of contamination before product can be released. Conversely, the test kit is most useful in the testing of product where either there is usually no fungal contamination of the food matrix, or where if a fungal contaminate is present, it is there in levels much greater than the specified acceptable cutoff level. In both of these cases, significant time savings can be achieved as a faster release of most lots of product will be possible.

Initial studies performed on soy-based infant formula revealed sporadic low level positive results on non-spiked samples. The sample matrix for this sample type could not be confirmed as culture positive. It is possible that these false positive results are due to a particular property of this product type associated with it's method of manufacture. Soy protein is isolated in part through alcohol precipitation steps. This alcohol preparation will have as a potential side effect the preservation of naturally occurring fungal DNA that may survive through to disruption and thus lead to false positive results using this test kit.

The signal seen in this case is a weak positive, and an end user could potentially adjust the target to target plus internal control peak ratio that they would accept as a positive result from the assay. Should a user desire to internally validate a protocol of this nature, they should contact Qualicon for assistance. Because the modification will likely be product specific, this alternative protocol will not be validated through the AOAC-RI validation process. Other plant material produced in a similar fashion to soy protein isolate destined for soy-based infant formula with an early in the production process alcohol-based extraction could demonstrate similar results. Due to the sensitivity of the assay, as few as 10 intact fungal genomes in a disrupter tube following the incubation step would be expected to result in a low level positive result. Fungal DNA in foods at any level would not normally be detected by the assay as validated in this study report due to the fragility of nucleic acid in aqueous environments. Since the methods validated in this study only used the enriched protocol (as opposed to the non-AOAC validated direct testing method described in the BAX ® User Guide) that included a 44 hr enrichment step in the disrupter tubes, any free DNA from non-viable cells would be expected to be degraded and not detected. It is only when the fungal DNA is precipitated and preserved in matrices such as a protein isolate that there is the possibility of a false positive event.

In food matrices that can start out with a high fungal burden (such as the raw materials for corn starch), Qualicon customers have not found false positive results to be a problem, since any contaminating DNA is not protected and is degraded in either the aqueous starch preparation process of in the BAX ® enrichment process.

Table 1. BAX ® system inclusivity (*Yeast and Mold* assay) (1)

Source	Strain	Source	ID	BAX Result
ATCC	**18577**	**Soil**	*Debaryomyces ploymorphus*	*POS*
ATCC	**10259**	**Unknown**	*Candida albicans*	*POS*
ATCC	**14056**	**Human**	*Candida tropicalis*	*POS*
ATCC	**9451**	**Air**	*Rhodotorula mucilaginosa*	*POS*
ATCC	**15125**	**Unknown**	*Rhodotorula glutinis*	*POS*
ATCC	**10651**	**Buttermilk**	*Pichia fermentans Lodder*	*POS*
ATCC	**34517**	**Raw Sugar**	*Zygosaccharomyces rouxii*	*POS*
ATCC	**36240**	**Grapes**	*Torulaspora delbrueckii*	*POS*
ATCC	**76455**	**Unknown**	*Saccharomyces cerevisiae*	*POS*
ATCC	**6989**	**Cheese**	*Penicillium roquefortii*	*POS*
ATCC	**32079**	**Rotten Orange**	*Penicillium italicum*	*POS*
ATCC	**34928**	**Sweet Potato**	*Rhizopus stolonifer*	*POS*
ATCC	**26195**	**Sand**	*Geotrichum candidum*	*POS*
ATCC	**18003**	**Soil**	*Trichothecium roseum*	*POS*
ATCC	**36963**	**Soil**	*Eurotium repens var. columnaris*	*POS*
ATCC	**200095**	**Asparagus**	*Fusarium oxysporum f. sp. asparagi*	*POS*
ATCC	**20476**	**Plum Tree**	*Trichoderma viride*	*POS*
ATCC	**34892**	**Fermented Red Rice**	*Monascus purpureus*	*POS*
ATCC	**34668**	**Carrot Seed**	*Cladosporium cladosporioides*	*POS*
ATCC	**13696**	**Unknown**	*Aspergillus parasiticus*	*POS*
ATCC	**1011**	**Unknown**	*Aspergillus oryzae*	*POS*
ATCC	**10058**	**Dung**	*Aspergillus clavatus*	*POS*
ATCC	**10864**	**Chinese Galls**	*Aspergillus niger*	*POS*
ATCC	**204446**	**Tomato**	*Botrytis cinerea bc-1*	*POS*
ATCC	**28987**	**Onion**	*Cladosporium herbarum*	*POS*
ATCC	**10141**	**Peas**	*Acremonium strictum*	*POS*
ATCC	**6663**	**Unknown**	*Alternaria alternata*	*POS*
ATCC	**24905**	**Rice Fermentation**	*Amylomyces rouxii*	*POS*
ATCC	**28064**	**Unknown**	*Anthrodema benhamiae*	*POS*
ATCC	**36607**	**Clinical**	*Aspergillus fumigatus*	*POS*
ATCC	**10535**	**Painted Pine Board**	*Aspergillus niger*	*POS*
ATCC	**14895**	**Soy Sauce**	*Aspergillus oryzae*	*POS*
ATCC	**24951**	**Unknown**	*Emmonsia crescens*	*POS*

ATCC	**48112**	**Unknown**	*Fusarium oxysporum*	*POS*
ATCC	**16222**	**Wheat Field Soil**	*Geomyces pannorum var. pannorum*	*POS*
ATCC	**34614**	**Clotted Carrot**	*Geotrichum candidum*	*POS*
ATCC	**10333**	**Unknown**	*Neurospora crassa*	*POS*
ATCC	**10002**	**Unknown**	*Penicillium chrosogenum*	*POS*
ATCC	**9179**	**Culture Contaminant**	*Penicillium notatum*	*POS*
ATCC	**10110**	**Cheese**	*Penicillium roquefortii*	*POS*
ATCC	**36779**	**Unknown**	*Pilaira anomala*	*POS*
ATCC	**22959**	**Unknown**	*Rhizopus oligosporus*	*POS*
ATCC	**66034**	**Unknown**	*Rhizopus stolonifer*	*POS*
ATCC	**14284**	**Human**	*Sporothrix schenckii*	*POS*
ATCC	**9182**	**Unknown**	*Stachybotrys chartarum*	*POS*
ATCC	**28185**	**Unknown**	*Trichophyton mentagrophytes*	*POS*
ATCC	**9773**	**Unknown**	*Yarrow lipolytica*	*POS*
DuPont	**FS34.3**	**Buttermilk Biscuit Mix**	*Alternaria alternate*	*POS*
DuPont	**FS37.4**	**Peanut Butter Cookie Mix**	*Alternaria infectoria*	*POS*
DuPont	**FS31.3**	**Three Cheese Biscuit Mix**	*Aschersonia* sp	*POS*
DuPont	**FS34.5**	**Buttermilk Biscuit Mix**	*Aschersonia* sp	*POS*
DuPont	**FS20.1**	**Raisins**	*Aspergillus awamori*	*POS*
DuPont	**FS64.1**	**Nut & Berry Mix**	*Aspergillus awamori*	*POS*
DuPont	**FS9.1**	**Brown rice flour**	*Aspergillus candidus*	*POS*
DuPont	**FS31.5**	**Three Cheese Biscuit Mix**	*Aspergillus candidus*	*POS*
DuPont	**FS55.1**	**Corn Grits**	*Aspergillus candidus*	*POS*
DuPont	**FS28.1**	**Flour - Bread**	*Aspergillus flavus*	*POS*
DuPont	**FS65.1**	**Candied Pecans**	*Aspergillus flavus*	*POS*
DuPont	**FS29.3**	**Unbleached Flour**	*Aspergillus flavus*	*POS*
DuPont	**FS66.2**	**Shelled Pecan Halves**	*Aspergillus flavus*	*POS*
DuPont	**FS1.2**	**Oregano**	*Aspergillus phoenicis*	*POS*
DuPont	**FS2.1**	**Sesame Seeds**	*Aspergillus phoenicis*	*POS*
DuPont	**FS19.1**	**Cereal**	*Aspergillus pseudodeflectus*	*POS*
DuPont	**FS53.4**	**Buckwheat Pancake Mix**	*Bipolaris micropus*	*POS*
DuPont	**FS48.1**	**Water Crackers**	*Bipolaris micropus*	*POS*
DuPont	**FS49.1**	**Raisins**	*Bipolaris micropus*	*POS*
DuPont	**FS12.1**	**Rolled Oats**	*Bipolaris panici-milacei*	*POS*
DuPont	**FS31.2**	**Three Cheese Biscuit Mix**	*Bipolaris panici-milacei*	*POS*
DuPont	**FS16.1**	**Dried Basil & Tomato**	*Candida krissii*	*POS*
DuPont	**FS14.1**	**Crackers**	*Candida osormensis*	*POS*
DuPont	**FS25.1**	**Thyme**	*Cryptococcus albidus*	*POS*
DuPont	**FS59.2**	**French Thyme**	*Cryptococcus albidus*	*POS*
DuPont	**FS28.3**	**Flour - Bread**	*Cryptococcus alter*	*POS*
DuPont	**FS33.1**	**Cookie Mix**	*Cryptococcus alter*	*POS*
DuPont	**FS50.1**	**Honey Butter Biscuit Mix**	*Cryptococcus alter*	*POS*
DuPont	**FS3.2**	**Rosemary**	*Cryptococcus oeirensis*	*POS*
DuPont	**FS6.1**	**Cereal**	*Cryptococcus sp*	*POS*
DuPont	**FS30.2**	**Cornbread & Muffin Mix**	*Cryptococcus sp*	*POS*
DuPont	**FS15.1**	**Cheese**	*Debaromyces hansenii hansenii*	*POS*
DuPont	**FS17.1**	**Cheese**	*Debaromyces hansenii hansenii*	*POS*
DuPont	**FS18.6**	**Whole Wheat Flour**	*Emericella nidulans*	*POS*
DuPont	**FS1.1**	**Oregano**	*Eurotium rubrum*	*POS*
DuPont	**FS52.1**	**Gingerbread Mix**	*Fusarium gramnearum*	*POS*
DuPont	**FS8.1**	**Waffle Mix**	*Fusarium proliferatum var. proliferatum*	*POS*
DuPont	**FS24.1**	**Cornmeal Yellow**	*Fusarium proliferatum var. proliferatum*	*POS*
DuPont	**FS40.4**	**Blueberry Muffin Mix**	*Mycospaerella aronici*	*POS*
DuPont	**FS54.1**	**Gluten Free Flour**	*Mycospaerella aronici*	*POS*
DuPont	**FS57.1**	**Dill**	*Mycospaerella aronici*	*POS*
DuPont	**FS29.2**	**Unbleached Flour**	*Penicillium camembertii*	*POS*
DuPont	**FS30.1**	**Cornbread & Muffin Mix**	*Penicillium camembertii*	*POS*
DuPont	**FS45.1**	**Flaxseed Meal**	*Penicillium camembertii*	*POS*
DuPont	**FS44.1**	**Oregano**	*Penicillium chrysogenium*	*POS*
DuPont	**FS59.3**	**French Thyme**	*Penicillium chrysogenium*	*POS*

DuPont	**FS10.1**	**Soy flour**	*Penicillum commune*	*POS*
DuPont	**FS66.1**	**Shelled Pecan Halves**	*Penicillum commune*	*POS*
DuPont	**FS62.1**	**Truffle Mix**	*Rhodotorula graminis*	*POS*
DuPont	**FS32.1**	**Chocolate Chip Cookie Mix**	*Saccharomyces cerevisiae*	*POS*

Table 2. BAX ® system exclusivity (*Yeast and Mold* assay) (1)

Strain ID	Source	ID Species	BAX Result
ATCC19433	type strain	*Enterococcus faecalis*	Negative
ATCC13883	type strain	*Klebsiella pneumoniae*	Negative
ATCC13047	type strain clinical	*Enterobacter cloacae*	Negative
DD379	unknown	*Bacillus subtilis*	Negative
ATCC15313	rabbit	*Listeria monocytogenes*	Negative
ATCC6539	clinical	*Salmonella typhi*	Negative
ATCC9610	clinical	*Yersinia enterocolitica*	Negative
ATCC27664	unknown	*Staphylococcus aureus*	Negative
ATCC12706	cured meat	*Lactobacillus viridescens*	Negative
ATCC43889	human clinical	*Escherichia coli*	Negative
ATCC29930	human clinical	*Shigella sonnei*	Negative
7AS	poultry	*Proteus mirabilis*	Negative
ATCC13337	unknown	*Hafnia alvei*	Negative
DD2416	plant material	*Serratia liquefaciens*	Negative
ATCC43864	unknown	*Citrobacter freundii*	Negative
ATCC35654	unknown	*Aeromonas species*	Negative
ATCC33379	dead puffin	*Edwardsiella hoshinae*	Negative
DD3064	unknown	*Morganella morganii*	Negative
ATCC27853	human clinical	*Pseudomonas aeruginosa*	Negative
ATCC4356	human	*Lactobacillus acidophilus*	Negative
TD4523	unknown	*Vibrio tubiashii*	Negative
DD5425	Cheese	*Listeria monocytogenes*	Negative
DD3019	unknown	*Salmonella dublin*	Negative
DD3411	hamburger	*Listeria welshimeri*	Negative
DD3327	cheese	*Listeria seeligeri*	Negative
DD1979	hamburger	*Escherichia coli* O157:H7	Negative
DD9775	human clinical	*Staphylococcus aureus*	Negative
TD3136	unknown	*Vibrio mimicus*	Negative
DD1144	cheese	*Listeria monocytogenes*	Negative
ATCC8739	unknown	*Escherichia coli*	Negative

Table 5 Method performance for the detection of *Yeast and Mold* from yogurt, milk-based infant formula, and corn starch by the BAX ® System. (1)

Matrix and Organism	Target Level (cfu/g)	Actual Level	Total Samples (each treatment)	BAX ® Presumptive (# > threshold)	BAX ® Confirmed[1]	Reference Method (# > threshold)	Sensitivity %[2]	Specificity %[3]	False Negative %[4]	False Positive %[5]	X^2 Value [6]
Yogurt *A. niger*	Aggregate data	-	20	14	NA	14	NA	NA	0	0	0
	> 50	390	5	5	NA	5	NA	NA	0	0	0
	10-50	53	5	5	NA	5	NA	NA	0	0	0
	1-10	12	5	4	NA	4	NA	NA	0	0	0
	0	0	5	0	NA	0	NA	NA	0	0	0
Yogurt (Independent Laboratory) *C. albicans*	Aggregate data	-	20	12	12	10	100	100	0	0	0.39
	> 50	54	5	5	5	3	100	100	0	0	2.25
	10-50	30	5	4	4	5	100	100	0	0	1.00
	1-10	10	5	3	3	2	100	100	0	0	0.36
	0	0	5	0	0	0	100	100	0	0	0
Powdered Infant Formula – Milk-Based *S. cerevisiae*	Aggregate data	-	20	14	14	10	100	100	0	0	1.63
	> 50	172	5	5	5	5	100	100	0	0	0
	10-50	47	5	5	5	4	100	100	0	0	1.00
	1-10	7	5	4	4	1	100	100	0	0	3.24
	0	0	5	0	0	0	100	100	0	0	0
Corn Starch *P. chrysogenum*	Aggregate data	-	20	12	NA	11	NA	NA	0	0	0.10
	> 50	191	5	5	NA	5	NA	NA	0	0	0
	10-50	68	5	5	NA	5	NA	NA	0	0	0
	1-10	2	5	2	NA	1	NA	NA	0	0	0.42
	0	0	5	0	NA	0	NA	NA	0	0	0

[1] Fungi which grow as yeasts are able to be recovered from disrupter tubes. Since Fungi which grow as molds in solution grow as hyphal masses, no confirmation is possible.
[2] Sensitivity is calculated as 100% – false negative rate
[3] Specificity is calculated as 100% – false positive rate
[4] False negative rate is calculated as BAX (-) Ref (+) BAX enrichment samples / Tot Ref (+) samples
[5] False positive rate is calculated as BAX (+) Ref (-) / Tot Ref (-) samples
[6] Mantel-Haenszel Chi-Square test statistic calculated for un-paired samples

$$X^2 = \frac{(n-1)(ad-bc)^2}{\text{----------}}$$

DISCUSSION OF JULY 2013 MODIFICATION (4)

The results of the method comparison between the digital DuPont™ Thermal Block and the analog heating/cooling blocks are provided in Table 3 below. For all sample types and BAX® System assays evaluated, the results for samples processed with the DuPont™ Thermal Block and the original heating/cooling blocks demonstrated no significant statistical difference as indicated by POD analysis (the 95% confidence interval of the dPOD included 0 in all cases). For additional figures illustrating the target responses of the individual BAX® System assays, see Appendix B.

All 544 samples inoculated with high levels of the target organism returned positive results with the BAX® System using both sample preparation methods, and all 544 samples tested as unspiked negative controls returned negative results with the BAX® System using both sample preparation methods with the exception of the non-inoculated poultry rinse samples that gave positive results *for Campylobacer jejuni*, while giving negative results for the target *C. coli* that was spiked into the test samples. For samples inoculated with low levels of target organism, the two preparation methods returned identical results for 530 of the 544 samples tested. The results for the 14 samples that returned different results between the two methods are summarized in Table 3. Because the low-spike samples were tested at levels near the limit of detection for the BAX® System assays, some discrepancy between the two methods is expected based on factors such as the distribution of the target organism within the sample.

Analysis of target response in cases where a fractional response was not generated, while demonstrating significant differences from a statistical standpoint in some cases, were not indicative of any difference that would likely be significant in a practical sense. All average differences were less than 10% for melt curve based target peak height, or target peak area to target plus internal control peak areas (for the Yeast and Mold assay) and all average C_t differences were less than 1 for all real time assay.

Because the difference in results between the two methods demonstrated no significant statistical difference as indicated by the POD analysis, these differences are found to be acceptable in this study for demonstrating equivalency between the two methods.

Table 3. BAX® System Results – DuPont™ Thermal Block vs. Analog Heating/Cooling Blocks (4)

BAX® System Assay	Sample Type	Spike Level	Test Portions	Heating/Cooling Blocks			DuPont™ Thermal Block			$dPOD_{TB}$ [d]	95% CI[e]
				X[a]	POD_{2B}[b]	95% CI[e]	X[a]	POD_{TB}[c]	95% CI[e]		
										0	-0.18, 0.18
Yeast and Mold	Yogurt	Low	17	12	0.71	0.44, 0.87	14	0.82	0.59, 0.94	-0.12	-.038, 0.17
		Control	17	0	0	0, 0.19	0	0	0, 0.19	0	-0.19, 0.19
		High	17	17	1	0.82, 1.0	17	1	0.82, 1.0	0	-0.18, 0.18
	Cornstarch	Low	17	7	0.41	0.22, 0.64	6	0.35	0.17, 0.59	0.059	-0.24, 0.35
		Control	17	0	0	0, 0.19	0	0	0, 0.19	0	-0.19, 0.19
	Powdered infant formula	High	17	17	1	0.82, 1.0	17	1	0.82, 1.0	0	-0.18, 0.18
		Low	17	17	1	0.82, 1.0	17	1	0.82, 1.0	0	-0.18, 0.18
		Control	17	0	0	0, 0.19	0	0	0, 0.19	0	-0.19, 0.19

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