CERTIFICATION

AOAC Research Institute

Performance Tested Methods[SM]

Certificate No.

010902

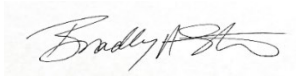
The AOAC Research Institute hereby certifies the method known as:

BAX® System PCR Assay for Yeast and Mold

manufactured by

Hygiena
2 Boulden Circle
New Castle, DE 19720
USA

This method has been evaluated and certified according to the policies and procedures of the AOAC *Performance Tested Methods*[SM] Program. This certificate indicates an AOAC Research Institute Certification Mark License Agreement has been executed which authorizes the manufacturer to display the AOAC Research Institute *Performance Tested Methods*[SM] certification mark on the above-mentioned method for the period below. Renewal may be granted by the Expiration Date under the rules stated in the licensing agreement.



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METHOD NAME
BAX® System PCR Assay for Yeast and Mold
Formerly known as DuPont™ BAX® System PCR Assay for Yeast and Mold

CATALOG NUMBERS
KIT2015 (kit); KIT2014 (supplement)

INDEPENDENT LABORATORY
Cherney Microbiological Services
1110 Huron Road
Green Bay, WI 54311 USA

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

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

Performance claims – Threshold detection of contaminating fungi in specified matrixes that is statistically indistinguishable from the FDA-BAM method for detecting Yeast and Mold [2].

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*. (2)

ORIGINAL CERTIFICATION DATE
January 29, 2009

CERTIFICATION RENEWAL RECORD
Renewed through December 2025.

METHOD MODIFICATION RECORD

1. **July 2013 Level 2**
2. **March 2017 Level 2**
3. **January 2018 Level 1**
4. **May 2019 Level 1**
5. **December 2021 Level 1**
6. **November 2022 Level 1**
7. **December 2023 Level 1**
8. **December 2024 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.**
5. **Updates to BAX manuals for Q7 and X5.**
6. **Editorial changes.**
7. **Addition of documents.**
8. **Editorial changes.**

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NONE

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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 can 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 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 matrixes such as a protein isolate that there is the possibility of a false positive event.

In food matrixes 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 MODIFICATION APPROVED JULY 2013 (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]		
Yeast and Mold	Yogurt	Low	17	12	0.71	0.44, 0.87	14	0.82	0.59, 0.94	0	-0.18, 0.18
		Control	17	0	0	0, 0.19	0	0	0, 0.19	-0.12	-.038, 0.17
		High	17	17	1	0.82, 1.0	17	1	0.82, 1.0	0	-0.19, 0.19
	Cornstarch	Low	17	7	0.41	0.22, 0.64	6	0.35	0.17, 0.59	0	-0.18, 0.18
		Control	17	0	0	0, 0.19	0	0	0, 0.19	0.059	-0.24, 0.35
		High	17	17	1	0.82, 1.0	17	1	0.82, 1.0	0	-0.19, 0.19
	Powdered infant formula	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

REFERENCES CITED

1. Burns, Frank, Andaloro, Bridget, Fleck, Lois, Davis, Eugene, Tice, George, and Wallace, Morgan., Evaluation of the DuPont™ Bax® System Test Kit for Detection of Yeast and Mold in Yogurt, Corn Starch, and Milk-based Powdered Infant Forumla, AOAC *Performance Tested Methods℠* certification number 010902.
2. 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.
3. AOAC International Official Methods of Analysis Program Manual May 2002 Appendix X http://www.aoac.org/vmeth/Manual_App_X.pdf Date of Access 6 Jan 2009.
4. Hoelzer, S., Wallace, F.M., Fleck, L, DiCosimo, D., Harris, J., Andaloro, B., Farnum, A., Davis, E., and Rohrbeck, J., Evaluation of the DuPont™ Thermal Block for Automated Sample Lysis with the BAX® System Method (Minor Modification), AOAC *Performance Tested Methods℠* certification number 010902. Approved July 2013.