

PathoSEEK Total Yeast and Mold (TYM) Screening Assay with MaGiC Lysis

Method Developer Validation

Table of Contents

Abstract.....	3
Study Design.....	3
Action Limit Determination.....	4
Oil Matrix.....	4
Chocolate Matrix.....	5
Gummy Matrix — Initial Action Limit Screen.....	6
Gummy Matrix — Confirmatory Testing at Elevated Spike Levels.....	7
Detection Rate Summary — All Matrices.....	8
Robustness Testing.....	9
Assay Controls.....	10
Action Limit Summary.....	11
Matrix Specific Results.....	11
Matrix.....	11
Enrichment Time.....	11
Study Interpretation.....	11
Application to Action Limits.....	11
Proficiency Testing / Certified Reference Materials Results.....	12
Hemp Matrix.....	12
Chocolate/Edible Matrix.....	12
Oil Matrix.....	13
PT CRM Interpretation.....	13
Conclusions.....	13
Revision History.....	14
Disclaimer.....	14

Abstract

Background

Yeast and mold contamination is a key indicator of overall product quality and shelf stability in cannabis and hemp-derived products, particularly marijuana-infused products (MIPs) such as oils, gummies, and chocolates, which can support the growth of osmotolerant/xerophilic fungal organisms during storage and distribution. Total yeast and mold (TYM) counts are a standard quality and safety specification required by many state cannabis testing programs.

The TYM Screening Assay is a qPCR-based detection assay intended for the rapid screening of total yeast and mold contamination in MIP matrices as an alternative to traditional culture-based plating methods.

Objective

To evaluate the TYM Screening Assay, using MaGiC Lysis extraction, for detection of representative yeast (*Candida albicans*) and mold (*Aspergillus brasiliensis*) organisms spiked into oil, gummy, and chocolate after 24 and 48 hours of enrichment, and to characterize matrix-specific detection performance under the conditions tested.

Results

Detection performance depended on matrix and enrichment time. MCT oil supported consistent detection at the lowest level evaluated after 24 hours, while chocolate required 48 hours to achieve consistent detection at the same level. Gummy was the most challenging formulation for *C. albicans* and required either a higher target level at 24 hours or extended enrichment.

Study Design

The TYM Screening Assay targets total yeast and mold nucleic acid in the FAM channel (“TYM”), with an internal amplification control (IC) monitored in the HEX channel to assess extraction efficiency and PCR inhibition on a per-sample basis. All extractions in this study were performed using MaGiC Lysis.

Three MIP matrices representative of the assay's intended use—oil, gummy, and chocolate—were spiked with known quantities of *C. albicans* and *A. brasiliensis* prepared from NSI reference pellets of known CFU per pellet and serially diluted to the target concentrations. Unspiked matrix blanks, a positive amplification control, and a no-template control (NTC) were included. Spiked and blank samples were enriched for 24 and 48 hours before extraction and qPCR analysis. Three replicates were evaluated at each spike level and timepoint to identify the lowest tested level that produced detection in all three replicates under the conditions evaluated.

Actual delivered CFU levels for each spiked inoculum were confirmed by parallel plate counting (colony counts on solid media); plate count images are retained as supporting raw data and are referenced but not reproduced in this report.

Action Limit Determination

Oil Matrix

C. albicans and *A. brasiliensis* were independently spiked into MCT oil at 500, 250, and 100 CFU, with triplicate blanks, and enrichment for 24 and 48 hours prior to extraction and qPCR.

Table 1: Oil Matrix Action Limit Results (*C. albicans* and *A. brasiliensis*)

Organism	Matrix	Spike (CFU)	FAM 24 hr (TYM)	FAM 48 hr (TYM)	HEX 24 hr (IC)	HEX 48 hr (IC)
<i>C. albicans</i>	Oil	500	33.16	30.05	29.62	29.44
<i>C. albicans</i>	Oil	500	32.39	29.96	29.29	29.49
<i>C. albicans</i>	Oil	500	33.35	29.83	29.65	29.23
<i>C. albicans</i>	Oil	250	33.36	29.34	29.48	29.65
<i>C. albicans</i>	Oil	250	33.92	29.64	29.20	29.41
<i>C. albicans</i>	Oil	250	33.04	29.68	30.22	29.21
<i>C. albicans</i>	Oil	100	33.12	30.17	29.50	29.85
<i>C. albicans</i>	Oil	100	33.55	30.92	29.17	34.74
<i>C. albicans</i>	Oil	100	32.72	30.93	29.40	28.81
<i>A. brasiliensis</i>	Oil	500	28.59	27.25	29.52	29.38
<i>A. brasiliensis</i>	Oil	500	29.17	27.51	29.48	29.21
<i>A. brasiliensis</i>	Oil	500	29.21	26.90	29.20	29.18
<i>A. brasiliensis</i>	Oil	250	29.67	27.16	29.18	29.19
<i>A. brasiliensis</i>	Oil	250	28.70	26.81	29.34	29.27
<i>A. brasiliensis</i>	Oil	250	30.09	27.28	29.01	29.34
<i>A. brasiliensis</i>	Oil	100	29.04	28.39	29.15	29.61
<i>A. brasiliensis</i>	Oil	100	25.24	27.21	29.09	28.99
<i>A. brasiliensis</i>	Oil	100	28.83	26.39	29.32	29.45
Blank	Oil	0	ND	ND	29.18	29.97
Blank	Oil	0	ND	ND	29.43	29.24
Blank	Oil	0	ND	ND	29.24	29.41
Blank	Oil	0	ND	ND	29.39	29.40
Blank	Oil	0	ND	ND	29.56	29.14
Blank	Oil	0	ND	ND	29.23	29.61

Result: Both organisms were detected in all replicates (3/3) at every spike level (100–500 CFU) at both 24 and 48 hours of enrichment. All unspiked blanks were negative (ND) at both timepoints. The internal control (IC) amplified consistently across all wells, confirming absence of extraction failure or PCR inhibition in the oil matrix.

Chocolate Matrix

C. albicans and *A. brasiliensis* were independently spiked into chocolate at 500, 250, and 100 CFU, with triplicate blanks, and enrichment for 24 and 48 hours prior to extraction and qPCR.

Table 2: Chocolate Matrix Action Limit Results (*C. albicans* and *A. brasiliensis*)

Organism	Matrix	Spike (CFU)	FAM 24 hr (TYM)	FAM 48 hr (TYM)	HEX 24 hr (IC)	HEX 48 hr (IC)
<i>C. albicans</i>	Chocolate	500	34.31	31.55	30.84	32.25
<i>C. albicans</i>	Chocolate	500	34.58	32.05	31.18	27.41
<i>C. albicans</i>	Chocolate	500	35.02	31.46	30.71	32.54
<i>C. albicans</i>	Chocolate	250	37.16	31.07	31.25	30.28
<i>C. albicans</i>	Chocolate	250	37.19	31.01	29.48	31.65
<i>C. albicans</i>	Chocolate	250	ND	31.10	31.56	32.08
<i>C. albicans</i>	Chocolate	100	ND	33.32	32.22	30.56
<i>C. albicans</i>	Chocolate	100	ND	34.37	31.17	30.01
<i>C. albicans</i>	Chocolate	100	38.25	34.34	31.50	31.18
<i>A. brasiliensis</i>	Chocolate	500	34.13	32.95	30.97	30.72
<i>A. brasiliensis</i>	Chocolate	500	34.35	33.25	30.87	31.99
<i>A. brasiliensis</i>	Chocolate	500	34.24	32.66	31.01	32.91
<i>A. brasiliensis</i>	Chocolate	250	34.20	33.00	31.40	31.88
<i>A. brasiliensis</i>	Chocolate	250	33.73	34.12	31.08	31.08
<i>A. brasiliensis</i>	Chocolate	250	34.13	33.08	31.02	32.44
<i>A. brasiliensis</i>	Chocolate	100	36.03	32.08	31.20	31.96
<i>A. brasiliensis</i>	Chocolate	100	38.08	31.34	31.17	31.95
<i>A. brasiliensis</i>	Chocolate	100	ND	31.58	31.04	31.07
Blank	Chocolate	0	ND	ND	31.04	30.56
Blank	Chocolate	0	ND	ND	31.29	32.14
Blank	Chocolate	0	ND	38.90	31.33	30.53
Blank	Chocolate	0	ND	ND	31.19	30.67
Blank	Chocolate	0	ND	ND	31.19	31.65
Blank	Chocolate	0	ND	ND	31.03	31.48

Result: At 24 hours, detection was incomplete at the lower spike levels for both organisms (*C. albicans*: 1/3 at 100 CFU and 2/3 at 250 CFU; *A. brasiliensis*: 2/3 at 100 CFU). Detected wells at these levels had late Cq values (>37). At 48 hours, both organisms were detected in 3/3 replicates at every spike level, with target Cq values approximately 3–6 cycles earlier. All blanks were ND at 24 hours; one 48-hour blank produced a late FAM signal (Cq 38.9), while the remaining blanks were ND. Under the conditions evaluated, 48 hours of enrichment was required for consistent detection at 100 CFU in chocolate.

Gummy Matrix — Initial Action Limit Screen

C. albicans and *A. brasiliensis* were each spiked into gummy at 500, 250, and 100 CFU (same run as the oil matrix above), with triplicate blanks, and enrichment for 24 and 48 hours.

Table 3: Gummy Matrix Initial Action Limit Screen (*C. albicans* and *A. brasiliensis*)

Organism	Matrix	Spike (CFU)	FAM 24 hr (TYM)	FAM 48 hr (TYM)	HEX 24 hr (IC)	HEX 48 hr (IC)
<i>C. albicans</i>	Gummy	500	ND	32.15	29.69	29.85
<i>C. albicans</i>	Gummy	500	ND	31.87	29.73	29.99
<i>C. albicans</i>	Gummy	500	38.78	31.56	29.49	29.66
<i>C. albicans</i>	Gummy	250	38.95	33.68	29.46	30.08
<i>C. albicans</i>	Gummy	250	ND	31.22	29.51	29.69
<i>C. albicans</i>	Gummy	250	ND	32.97	29.45	30.07
<i>C. albicans</i>	Gummy	100	ND	ND	29.55	29.62
<i>C. albicans</i>	Gummy	100	ND	32.78	30.06	29.66
<i>C. albicans</i>	Gummy	100	ND	33.85	29.43	29.55
<i>A. brasiliensis</i>	Gummy	500	34.21	28.86	29.58	29.92
<i>A. brasiliensis</i>	Gummy	500	33.20	29.36	29.65	29.68
<i>A. brasiliensis</i>	Gummy	500	30.82	21.74	29.88	29.91
<i>A. brasiliensis</i>	Gummy	250	33.35	29.71	29.94	30.13
<i>A. brasiliensis</i>	Gummy	250	32.14	30.63	29.85	29.50
<i>A. brasiliensis</i>	Gummy	250	32.65	30.11	29.65	29.75
<i>A. brasiliensis</i>	Gummy	100	37.09	30.07	29.73	29.35
<i>A. brasiliensis</i>	Gummy	100	37.81	30.51	29.89	29.49
<i>A. brasiliensis</i>	Gummy	100	37.58	29.62	29.77	29.32
Blank	Gummy	0	ND	ND	29.70	29.52
Blank	Gummy	0	ND	ND	29.36	29.82
Blank	Gummy	0	ND	ND	29.58	30.03
Blank	Gummy	0	ND	ND	29.44	30.02
Blank	Gummy	0	ND	38.87	30.11	29.55
Blank	Gummy	0	ND	ND	30.02	29.95

Result: *A. brasiliensis* was detected in 3/3 replicates at all spike levels and both timepoints, although the mean Cq at 100 CFU after 24 hours was late (37.5). *C. albicans* detection was less consistent: at 24 hours, detection was 1/3 at 500 and 250 CFU and 0/3 at 100 CFU; at 48 hours, detection improved to 3/3 at 500 and 250 CFU but remained 2/3 at 100 CFU. Reduced recovery or detection of *C. albicans* was therefore observed in the gummy formulation, prompting confirmatory testing at higher spike levels.

Gummy Matrix — Confirmatory Testing at Elevated Spike Levels

Based on the reduced sensitivity observed for *C. albicans* in gummy above, *C. albicans* was re-tested in gummy at 1,000 and 750 CFU, with triplicate blanks, at 24 and 48 hours of enrichment.

Table 4: Gummy Matrix Confirmatory Testing — *C. albicans* at Elevated Spike Levels

Organism	Matrix	Spike (CFU)	FAM 24 hr (TYM)	FAM 48 hr (TYM)	HEX 24 hr (IC)	HEX 48 hr (IC)
<i>C. albicans</i>	Gummy	1000	35.83	29.64	29.13	28.94
<i>C. albicans</i>	Gummy	1000	35.41	30.20	29.12	27.47
<i>C. albicans</i>	Gummy	1000	36.16	29.74	29.65	27.25
<i>C. albicans</i>	Gummy	750	33.91	30.36	29.53	28.66
<i>C. albicans</i>	Gummy	750	34.40	29.97	28.91	28.19
<i>C. albicans</i>	Gummy	750	35.17	30.13	28.99	28.83
Blank	Gummy	0	ND	ND	28.14	28.69
Blank	Gummy	0	ND	ND	29.52	28.42
Blank	Gummy	0	ND	ND	28.73	28.41

Result: *C. albicans* was detected in 3/3 replicates at 750 and 1,000 CFU after both 24 and 48 hours. All blanks were ND. In combination with the initial screen, the lowest tested level with 3/3 detection was 750 CFU after 24 hours and 250 CFU after 48 hours. These observations describe performance at the concentrations tested and do not constitute a statistically determined absolute LOD.

Detection Rate Summary — All Matrices

The table below consolidates replicate detection rates and mean Cq values (of detected replicates only) at both 24 and 48 hours, across all matrices, organisms, and spike levels evaluated in the Action Limit study.

Table 5: Detection Rate Summary Across Oil, Gummy, and Chocolate Matrices

Organism	Matrix	Spike (CFU)	Det. 24 hr	Det. 48 hr	Mean Cq 24 hr	Mean Cq 48 hr
C. albicans	Oil	500	3/3	3/3	32.97	29.95
C. albicans	Oil	250	3/3	3/3	33.44	29.55
C. albicans	Oil	100	3/3	3/3	33.13	30.67
C. albicans	Gummy	1000	3/3	3/3	35.80	29.86
C. albicans	Gummy	750	3/3	3/3	34.49	30.15
C. albicans	Gummy	500	1/3	3/3	38.78	31.86
C. albicans	Gummy	250	1/3	3/3	38.95	32.62
C. albicans	Gummy	100	0/3	2/3	—	33.31
C. albicans	Chocolate	500	3/3	3/3	34.64	31.69
C. albicans	Chocolate	250	2/3	3/3	37.17	31.06
C. albicans	Chocolate	100	1/3	3/3	38.25	34.01
A. brasiliensis	Oil	500	3/3	3/3	28.99	27.22
A. brasiliensis	Oil	250	3/3	3/3	29.49	27.08
A. brasiliensis	Oil	100	3/3	3/3	27.70	27.33
A. brasiliensis	Gummy	500	3/3	3/3	32.74	26.65
A. brasiliensis	Gummy	250	3/3	3/3	32.71	30.15
A. brasiliensis	Gummy	100	3/3	3/3	37.49	30.07
A. brasiliensis	Chocolate	500	3/3	3/3	34.24	32.95
A. brasiliensis	Chocolate	250	3/3	3/3	34.02	33.40
A. brasiliensis	Chocolate	100	2/3	3/3	37.05	31.67

Robustness Testing

An additional round of testing challenged the assay at higher spike levels representative of gross contamination and evaluated reproducibility. *A. brasiliensis* was spiked at 10,000 CFU and *C. albicans* at 1,000, 500, and 100 CFU into gummy and MCT oil. Samples were evaluated after 24 and 48 hours of enrichment.

Table 6: Applications Testing Results — Gummy and MCT Oil

Organism	Matrix	Spike (CFU)	FAM 24 hr (TYM)	FAM 48 hr (TYM)	HEX 24 hr (IC)	HEX 48 hr (IC)
<i>C. albicans</i>	Gummy	1000	33.76	28.89	29.55	28.37
<i>C. albicans</i>	Gummy	1000	34.15	27.48	29.78	28.39
<i>C. albicans</i>	Gummy	1000	33.73	27.58	29.72	28.49
<i>C. albicans</i>	Gummy	500	34.32	28.92	29.50	28.31
<i>C. albicans</i>	Gummy	500	35.24	28.67	29.67	29.02
<i>C. albicans</i>	Gummy	500	34.38	27.25	29.62	28.09
<i>C. albicans</i>	Gummy	100	ND	34.60	29.72	28.56
<i>C. albicans</i>	Gummy	100	ND	34.36	29.43	28.78
<i>C. albicans</i>	Gummy	100	ND	32.93	29.47	28.50
<i>A. brasiliensis</i>	Gummy	10,000	27.90	24.75	29.13	28.40
<i>A. brasiliensis</i>	Gummy	10,000	27.28	23.70	29.40	28.24
<i>A. brasiliensis</i>	Gummy	10,000	27.05	25.78	29.33	28.58
<i>C. albicans</i>	MCT Oil	1000	34.24	27.91	29.88	27.05
<i>C. albicans</i>	MCT Oil	1000	33.78	28.32	29.45	26.74
<i>C. albicans</i>	MCT Oil	1000	34.19	27.49	29.51	27.01
<i>C. albicans</i>	MCT Oil	500	35.08	27.79	29.94	27.15
<i>C. albicans</i>	MCT Oil	500	37.17	28.10	29.48	27.29
<i>C. albicans</i>	MCT Oil	500	36.18	27.07	29.64	26.72
<i>C. albicans</i>	MCT Oil	100	37.21	27.93	29.66	27.17
<i>C. albicans</i>	MCT Oil	100	37.28	28.22	29.82	27.27
<i>C. albicans</i>	MCT Oil	100	36.31	28.30	29.75	27.09
<i>A. brasiliensis</i>	MCT Oil	10,000	33.06	29.95	29.94	27.48
<i>A. brasiliensis</i>	MCT Oil	10,000	32.99	30.08	29.67	27.51
<i>A. brasiliensis</i>	MCT Oil	10,000	33.25	27.76	29.97	27.26

Result: *A. brasiliensis* was reliably detected (3/3) at 10,000 CFU in both gummy and MCT oil at both 24 and 48 hours, with Cq values decreasing (as expected) with additional enrichment time. *C. albicans* was reliably detected (3/3) at 1,000 and 500 CFU in both matrices at both timepoints, with later Cq values in MCT oil than in gummy at the equivalent spike level at 24 hours. At the 100 CFU challenge level, *C. albicans* was not detected (0/3) in gummy at 24 hours — consistent with the higher Action Limit for *C. albicans* in gummy established above — but was detected (3/3) by 48 hours; MCT oil detected *C. albicans* at 100 CFU at 24 hours already (3/3, Cq ~36–37), improving further by 48 hours.

Assay Controls

A positive amplification control (TYM target, no IC template) and a no-template control (NTC, both channels) were included with each qPCR run.

Table 7: Positive Control and NTC Performance — Action Limit Study Runs

Control Type	Table	FAM 24 hr	FAM 48 hr	HEX 24 hr	HEX 48 hr
NTC	Tables 1, 3	ND	ND	ND	ND
NTC	Tables 1, 3	ND	ND	ND	ND
NTC	Table 2	ND	ND	ND	ND
NTC	Table 4	ND	ND	ND	ND
Positive Control	Tables 1, 3	14.57	14.26	ND	ND
Positive Control	Tables 1, 3	14.24	14.25	ND	ND
Positive Control	Table 2	14.26	14.09	ND	ND
Positive Control	Table 4	14.41	14.09	ND	ND

Result: All assay positive and negative controls (NTCs) performed as expected.

Action Limit Summary

The table below summarizes the lowest concentration tested that produced detection in all three replicates for both challenge organisms, or for the more limiting organism when performance differed. These levels describe observed performance under the study conditions and are not statistically determined absolute limits of detection.

Matrix Specific Results

Matrix	Enrichment Time	Lowest Tested Level With 3/3 Detection	Study Interpretation
MCT Oil	24 hours	100 CFU per test portion	Both <i>C. albicans</i> and <i>A. brasiliensis</i> were detected in all three replicates at the lowest concentration evaluated.
Chocolate	48 hours	100 CFU per test portion	Both organisms were detected in all three replicates at 100 CFU after 48 hours. Detection at 24 hours was incomplete at the lower inoculum levels.
Gummy	24 hours	750 CFU per test portion	<i>C. albicans</i> , the more limiting challenge organism in this matrix, was detected in all three replicates at 750 CFU during confirmatory testing.
Gummy	48 hours	250 CFU per test portion	<i>C. albicans</i> was detected in all three replicates at 250 CFU. At 100 CFU, detection occurred in two of three replicates and was not considered consistently demonstrated.

Application to Action Limits

The matrix-specific enrichment time should be selected according to the applicable regulatory or laboratory-established action limit. The conditions summarized above are supported only for the matrices and formulations evaluated in this study.

Laboratories should verify that the selected enrichment time provides adequate detection at the applicable action limit for the matrix tested. Additional verification may be warranted for alternative matrices or formulations.

Proficiency Testing / Certified Reference Materials Results

Three different CRMs supplied by NSI were used:

1. Quantitative Mold in Oil (CMQC-033, Lot 260305)
2. Quantitative Yeast/Mold in Edible (CMQC-059, lot 241021)
3. Quantitative Yeast/Mold in Hemp (CMQC-085, Lot H0924)

A total of 9 mL of PDB was added to each vial of Oil, Hemp, or Edible CRM. The contents of each vial were then transferred to a Whirl-Pak® bag and enriched for 24 hours at 37°C. Following enrichment, samples were extracted using MaGiC™ Lysis according to the Total Yeast & Mold Screening Assay with MaGiC Lysis User Guide.

Summary of Matrix Performance

Matrix	Material Evaluated	Testing Design	TYM Detection	Overall Result
Oil	5 individual PT vials, % Positives	Triplicate lysis testing; 1:10 dilution also evaluated	Correct final classification of all 5 PT samples	5/5 (100%) agreement with 1:10 dilution of lysates
Hemp	1 PT/CRM vial	3 independent lysis preparations	TYM detected in 3/3 preparations	Detected in 3/3, no dilution needed
Chocolate/Edible	1 PT/CRM vial	3 independent lysis preparations	TYM detected in 3/3 preparations	Detected in 3/3, no dilution needed

Note: The three hemp and chocolate results represent independent lysis preparations from a single PT/CRM vial for each matrix and are not counted as three independent PT samples.

Hemp Matrix

One hemp PT/CRM sample was processed using three independent lysis preparations to assess consistency of TYM detection across replicate sample preparations.

Lysis Replicate	TYM (FAM) Cq	Internal Control (HEX) Cq	TYM Result
1	27.03	30.11	Detected
2	26.77	30.12	Detected
3	25.58	29.76	Detected
Mean	26.46	30.00	3/3 Detected

TYM was detected in all three independently prepared lysates, with consistent amplification of both the TYM target and internal control.

Chocolate/Edible Matrix

One chocolate/edible PT/CRM sample was processed using three independent lysis preparations.

Lysis Replicate	TYM (FAM) Cq	Internal Control (HEX) Cq	TYM Result
1	31.04	32.86	Detected
2	30.82	33.28	Detected

3	30.50	34.16	Detected
Mean	30.78	33.43	3/3 Detected

TYM was detected in all three independently prepared chocolate/edible lysates. Internal control amplification was also observed in all three preparations.

Oil Matrix

Five individual oil PT samples were evaluated. Three samples were expected to be negative for TYM and two were expected to be positive.

The two positive samples demonstrated inconsistent TYM detection when tested without dilution, with target amplification observed in 1 of 3 replicates for each positive sample. Following a 1:10 dilution, TYM was consistently detected in 3 of 3 replicates for both positive samples. All three negative PT samples remained negative.

PT Sample	Expected	Initial TYM Detection	1:10 Dilution	Final Result
Vial 1	Positive	1/3	3/3	Correct
Vial 2	Negative	0/3	0/3	Correct
Vial 3	Negative	0/3	0/3	Correct
Vial 4	Positive	1/3	3/3	Correct
Vial 5	Negative	0/3	0/3	Correct

The improved detection following dilution is consistent with a matrix-associated inhibitory effect in the oil matrix. A 1:10 dilution effectively mitigated the observed inhibition and resulted in correct classification of all five PT samples.

PT CRM Interpretation

The PT/CRM testing produced the expected final classifications across the oil, hemp, and chocolate/edible materials evaluated. Hemp and chocolate/edible were detected in all three independent lysis preparations. In oil, a 1:10 lysate dilution improved detection of the two positive samples from 1/3 to 3/3 replicates, while all three negative samples remained negative, supporting dilution as an inhibition-mitigation step for the materials tested. As a result, users are instructed to prepare two qPCR reactions: One un-diluted qPCR reaction and one qPCR reaction diluted 1:10, except for chocolate matrices which require a single qPCR reaction at a 1:100 dilution.

Conclusions

The TYM Screening Assay with MaGiC Lysis detected representative yeast and mold targets in oil, gummy, and chocolate, with performance dependent on matrix, organism, and enrichment duration. The lowest tested levels producing 3/3 detection and the supported enrichment conditions are summarized in the Action Limit Summary. Laboratories should verify performance at the applicable action limit and enrichment time for each matrix implemented.

Revision History

Version	Date	Description
v1	September 2026	Initial method developer validation — Action Limit determination (oil, gummy, chocolate) using MaGiC Lysis extraction

Disclaimer

This test was developed and its performance characteristics were determined by Medicinal Genomics for laboratory use. Deviations from this protocol are not supported by Medicinal Genomics.

This test has not been validated on remediated (irradiated, ozone-treated, acid-treated, hydrogen peroxide-treated, etc.) samples. Samples that have undergone remediation may cause discordant results between plating methods and this assay. When remediated samples produce a result above the action limit on qPCR, we recommend confirming viability with an approved plating method.

Results may vary based on laboratory conditions. Altitude and humidity are factors known to affect the growth of yeast and mold species.

Limited Use Label License

© 2026 Medicinal Genomics. All rights reserved.

* All trademarks are property of their respective owners.