



CERTIFICATION

AOAC Research Institute *Performance Tested Methods*SM

Certificate No.
062401

The AOAC Research Institute hereby certifies the method known as:

PathoSEEK® Total Yeast & Mold Detection Assay

manufactured by

Medicinal Genomics
100 Cummings Center # 406L
Beverly, MA 01915

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.

A handwritten signature in black ink, appearing to read "Bradley A. Stawick".

Bradley A. Stawick, Senior Director
Signature for AOAC Research Institute

Issue Date
Expiration Date

October 26, 2024
December 31, 2025

METHOD NAME

PathoSEEK® Total Yeast & Mold Detection Assay

CATALOG NUMBERS

420001, 420206, 420201, 420103, 420303, 420145, 420144, 420143

ORIGINAL CERTIFICATION DATE

June 01, 2024

PRINCIPLE OF THE METHOD

PathoSEEK TYM Detection Assay combined with use of the Grim Reefer® Free DNA Removal process and the SenSATIVax TLP Extraction Enzyme purification protocol is a novel, real-time qPCR method that uses a multiplex system of primers to enumerate yeast and molds in cannabis matrixes.

SenSATIVax is a proprietary DNA isolation process that uses magnetic particles to isolate and purify both plant and microbial DNA from a raw, homogenized plant sample. The use of magnetic particles affords eight-tip or 96-tip automation, enabling both minimal entry costs and high throughput applications. DNA can be isolated from a single sample or a large batch in under 1 h. Hands-on time is less than 45 min.

The TYM Count Detection Assay and all components required to perform the method are intended for use by trained personnel familiar with laboratory techniques associated with pathogenic organism detection.

CERTIFIED CLAIM STATEMENT: The Medicinal Genomics PathoSEEK® Total Yeast & Mold Detection Assay with SenSATIVax® TLP purification and Grim Reefer® free DNA removal is certified for detection and enumeration of total yeast and mold within the scope of Tables 1 and 2.

Certification includes:

1. Agilent AriaMx G8830A Option 010, containing the following Optical Channels: FAM, HEX, and Cy5 with AriaMx Version 2.1 software.
2. Bio-Rad CFX96 Touch™ (Standard) with CFX Manager Version 3.1 software or CFX Maestro Version 2.2 software.

Table 1. Method Performance Claims

Qualitative				
Matrix	Test Portion	Diluent	SMPR	Claim
Dried cannabis flower (>0.3% THC) ^a	10 g	TSB ^b	2021.009 ^c	NSDD ^d
Quantitative				
Matrix	Test Portion	Diluent	SMPR	Claim
Dried cannabis flower (>0.3% THC) ^a	10 g	TSB ^b	2021.009	Eq ^e

^a Matrix tested by the method developer and the independent laboratory.

^b TSB = Tryptic soy broth.

^c *Standard Method Performance Requirements* (SMPRs) for Viable Yeast and Mold Count Enumeration in Cannabis and Cannabis Products (AOAC SMPR 2021.009).

^d NSDD = No statistical difference detected using SLV study design from OMA Appendix J (2012). The SLV qualitative method comparison study design from OMA Appendix J (2012) is not intended to demonstrate statistical equivalence. Expert opinion is that the method is appropriate for its intended use. For cannabis matrixes, comparison is only between presumptive and confirmed candidate method results. Confirmation by plating onto dichloran rose bengal chloramphenicol (DRBC) and acidified potato dextrose agar (PDA) spread plates for 5–7 days at 25°C.

^e Eq = Equivalence of candidate and cultural plating methods (DRBC and PDA spread plates for 5–7 days as 25°C demonstrated by 90% confidence interval on DOM contained entirely within -0.5 to 0.5 log₁₀.

Table 2. Method Selectivity

Enrichment			Inclusivity Strains		Exclusivity Species ^c	
Broth ^a	Temp., °C	Time, h	No. Tested	No. Positive ^b	No. Tested	No. Positive
TSB	20–28	48	55	51	31	0

^a Tryptic Soy Broth.

^b The strains not detected were *Botrytis cinerea*, *Scopulariopsis acremonium*, *Arthrinium arundinis*, and *Phytophthora infestans*. *Arthrinium arundinis*, and *Phytophthora infestans* did not grow on PDA.

^c Exclusivity organisms were cultured in non-selective broth under optimal conditions for growth depending on the strain.

Table 3. Method Summary

No.	Date	Summary	Supporting Data
1	June 2024	Original Certification.	Certification Report