



CERTIFICATION

AOAC Research Institute
Performance Tested MethodsSM

Certificate No.

072502

The AOAC Research Institute hereby certifies the method known as:

PathoSEEK[®] Aspergillus Multiplex Assays with MaGiC Lysis

manufactured by

Medicinal Genomics Corp.
100 Cummings Center, Suite 406L
Beverly, MA 01915 USA

This method has been evaluated and certified according to the policies and procedures of the AOAC *Performance Tested MethodsSM* 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 MethodsSM* 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, AOAC Research Institute Senior Director

Issue Date

December 15, 2025

Expiration Date

December 31, 2026

METHOD NAME	CATALOG NUMBERS	ORIGINAL CERTIFICATION DATE
PathoSEEK® Aspergillus Multiplex Assays with MaGiC Lysis	420523, 420518, 420519	July 17, 2025

PRINCIPLE OF THE METHOD

The PathoSEEK 2-Color and 5-Color Aspergillus Multiplex Detection Assays use a multiplexing strategy with an internal cannabis control (ICC) that is introduced at the lysis step to ensure accurate detection of four species of *Aspergillus* as well as the internal control DNA in every reaction. Unlike other techniques, this multiplexing strategy verifies the performance of the assay when detecting pathogens, resulting in the minimization of false negative results due to reaction setup errors or failing experimental conditions.

The PathoSEEK 2-Color Aspergillus Multiplex Detection Assay v2 is compatible with qPCR instruments that support HEX and FAM and has been validated on the BioMolecular Systems Mic, Agilent AriaMX, and Bio-RAD CFX96. The PathoSEEK 5-Color Aspergillus Multiplex (AriaMX) Detection Assay v2 for use on the AriaMx Real-Time PCR Thermal cycler (Agilent) uses the FAM Fluorophore for the detection of *Aspergillus fumigatus*, ROX Fluorophore for the detection of *Aspergillus niger*, CY5 Fluorophore for the detection of *Aspergillus flavus*, and the ATTO 425 Fluorophore for detection of the *Aspergillus terreus*, while the PathoSEEK 5-Color Aspergillus Multiplex (CFX) Detection Assay v2, for use on the CFX96 (Bio-Rad), uses the FAM Fluorophore for the detection of *Aspergillus fumigatus*, ROX Fluorophore for the detection of *Aspergillus niger*, CY5 Fluorophore for the detection of *Aspergillus flavus*, and the Cy5.5 Fluorophore for the detection of *Aspergillus terreus*.

CERTIFIED CLAIM STATEMENT: The PathoSEEK® Aspergillus Multiplex Assays with MaGiC Lysis is certified for the detection of *Aspergillus niger*, *A. flavus*, *A. fumigatus* and *A. terreus* within the scope of Tables 1 and 2.

Certified method includes:

- 1. PathoSEEK® 2-Color Aspergillus Multiplex Assay
 - a. Bio-Rad CFX96 Touch™ Real-Time System, software version 10.0.26100, standard
 - b. Agilent AriaMx Real-Time PCR System G8830A, software version 3.1.2306.0602, standard
 - c. Bio Molecular Systems (BMS) Mic 4-Channel PCR Instrument, software version 1.4.10, standard
- 2. PathoSEEK® 5-Color Aspergillus Multiplex Assay
 - a. Bio-Rad CFX96 Touch™ Real-Time System, software version 10.0.26100, standard
 - b. Agilent AriaMx Real-Time PCR System G8830A, software version 3.1.2306.0602, standard
- 3. Optional use of Grim Reefer Free DNA Removal step after 48 and 54 h of enrichment.

Table 1. Method Performance Claims

Matrix	Test Portion	Enrichment Conditions				SMPR ^b	Test Kit	Claim ^e
		Broth ^a	Volume	Temperature	Time			
Dried cannabis flower (>0.3% THC)	10 g	PDB + C	90 mL	37 ± 1°C	24-48 h	2019.001	2-Color	Eq
	10 g	PDB + C	90 mL	37 ± 1°C	24-48 h	2019.001	5-Color	Eq
THC-infused oil	5 g	PDB + C	45 mL	37 ± 1°C	48-54 h	2019.001	2-Color	Eq
	5 g	PDB + C	45 mL	37 ± 1°C	48-54 h	2019.001	5-Color	Eq

^a PDB + C = Potato Dextrose Broth plus Chloramphenicol (0.66 mg/L).
^b SMPR = Standard Method Performance Requirements.
^c Eq = Equivalence of candidate method presumptive and confirmed results demonstrated by 90% confidence interval on dPOD_{CC} meeting the criteria according to TR364 (Least Cost Formulations, Virginia Beach, VA). For cannabis matrixes, comparison is only between presumptive and confirmed (paired) candidate method results.

Table 2. Method Selectivity^a

Broth ^b	Temperature	Inclusivity Strains		Exclusivity Strains	
		No. Tested	No. Positive	No. Tested	No. Positive
PDB + C	37 ± 1°C	50 ^c	50	38 ^d	3 ^e

^a Results were identical for both the PathoSEEK 2-Color Aspergillus Multiplex Assay and the PathoSEEK 5-Color Aspergillus Multiplex Assay.
^b PDB + C = Potato Dextrose Broth plus chloramphenicol (0.66 mg/L).
^c Comprising *Aspergillus flavus* (13), *A. fumigatus* (13), *A. niger* (11), and *A. terreus* (13).
^d Comprised of 22 strains of non-target *Aspergillus* species and 16 additional yeast and mold species.
^e *Aspergillus oryzae*, *Aspergillus parasiticus*, and *Aspergillus pseudoterreus* tested positive.

Table 3. Method History

No.	Date	Summary	Supporting Data
1	June 2025	Original Certification	Certification Report