

**U.S. DEPARTMENT OF AGRICULTURE
Agricultural Marketing Service
Federal Grain Inspection Service**

CERTIFICATE NO.: FGIS 2023-B001 QL

CERTIFICATE OF PERFORMANCE

Qualitative test kit for CP4 EPSPS (RR) transgenic protein in soybean, CP4 EPSPS (RR) ImmunoStrip® Test

For: Agdia, Inc.
Method: Lateral Flow Strip

Submitted by: Agdia, Inc.
52642 County Road 1
Elkhart, IN 46514
Telephone: 574-327-6068
Contact: Mr. Dave Rambow

Standard Features and Options

Model: CP4 EPSPS (RR) ImmunoStrip® Test, Product # STX 74000
Sample Preparation: Grind
Extraction Method: Water
Temperature Range: 18 – 30 °C (64 – 86 °F)
Event(s) Detected: Genetic events expressing the CP4 EPSPS (RR)
Detection Threshold: 1 transgenic CP4 EPSPS (RR) seed in 1000 soybean seeds (0.1%)
Detection Technique: Visual

Test kits must be operated according to the manufacturer's instructions.

This qualitative lateral flow strip test kit has undergone an initial verification of performance under the authority of Section 7B(c) of the United States Grain Standards Act, as amended, and was found to meet all test performance criteria as defined in the "Design Criteria and Test Performance Specifications for Biotechnology Rapid Test Kits," May 2017 version. Evaluation tests that passed are summarized in Attachment I.

For further information, contact:

USDA, AMS, Federal Grain Inspection Service
Technology and Science Division
Biotechnology and Analytical Services Branch
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Kansas City, Missouri 64153-1394 Telephone: (816) 702-3800

Edward Jhee, Director
Technology and Science Division

Date: _____

Certificate Expires Three Years from the Date Signed

Note: The mention of firm name or trade products does not imply that they are endorsed or recommended by the United States Department of Agriculture over other firms or similar products not mentioned.

Type Evaluation
Certificate No.: FGIS 2023-B001 QL

ATTACHMENT I

Manufacturer: Agdia, Inc.
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Elkhart, IN 46514
Telephone: 574-327-6068
Contact: Mr. Dave Rambow

TEST 1: CAPABILITY OF ANALYZING FOR THE CP4 EPSPS (RR) TRANSGENIC PROTEIN.

Data submitted by the manufacturer supported the test kit's capability of reliably detecting the CP4 EPSPS (RR) transgenic protein at a detection threshold of 1 transgenic CP4 EPSPS (RR) soybean seed in 1000 non-transgenic soybean seeds (0.1%).

TEST 2: CROSS-REACTIVITY.

Data from five (5) independent tests submitted by the manufacturer supported the claim that the test kit does not cross react with any other biotechnology-derived proteins in commercial production in the U.S., demonstrating the test is specific for the protein of interest, but not necessarily trait-specific.

TEST 3: TEMPERATURE SENSITIVITY.

Data submitted by the test kit manufacturer supported performance of the kit at 18 °C and 30 °C.

TEST 4: FGIS-TSD PERFORMANCE VERIFICATION.

Data generated by FGIS-TSD staff showed the test kit is capable of detecting the CP4 EPSPS (RR) transgenic protein at a detection threshold of 1 transgenic CP4 EPSPS (RR) soybean seed in 1000 non-transgenic soybean seeds (0.1%). The evaluation was conducted by visual examination of the lateral flow strips. Cross reactivity data submitted by the manufacturer was not verified by FGIS-TSD.