United States Department of Agriculture
Agricultural Marketing Service
Federal Grain Inspection Service

# Criteria & Specifications

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**Design Criteria and Test Performance Specifications for Biotechnology Rapid Test Kits**

## Contents

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Effective Date: 5/17/2017

United States Department of Agriculture
Agricultural Marketing Service
Federal Grain Inspection Service
Technology and Science Division

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Acting Deputy Director
Technology and Science Division

## 1. PURPOSE AND SCOPE

To meet the grain industry's demand for accurate and reliable qualitative testing for genetically engineered (GE) traits in grains and oilseeds, test kit manufacturers have asked the United States Department of Agriculture's Federal Grain Inspection Service (FGIS to maintain a program to verify test kit performance claims and subsequently issue Certificates of Performance (COP) for test kits meeting these claims. In response to this request, FGIS has established a program for verifying the performance of these qualitative rapid test kits.

## 2. SUMMARY OF TEST KIT EVALUATION PROCESS

The Rapid Test Kit Performance Evaluation Program established by FGIS is a basic four step process where:

a. The rapid test kit manufacturer submits a data package supporting their claims;

b. FGIS staff reviews the data submitted by the manufacturer;

c. If FGIS determines the data package is complete and the claims of the rapid test kits are supported by the data, FGIS conducts an in-house performance verification of the rapid test;

d. If the manufacturer's claims are verified by FGIS's in-house performance testing, a Certificate of Performance (COP) is issued to the manufacturer for the rapid test.

The COP will be valid for three years from its date of issuance. Renewal of a COP requires a full submission and evaluation.

If the test kit fails to meet all of the criteria specified herein, the test kit can be resubmitted after a three-month waiting period. When the test kit is resubmitted, the applicant must state the corrective action that was taken to bring the test kit into conformance with FGIS requirements.

## 3. PROGRAM CONTACT INFORMATION

For any questions regarding the program, contact the Biotechnology Laboratory Program Leader, Dr. Brian Beecher by email or via telephone at: Brian.S.Beecher@usda.gov, 816-891-0453. Submission packets should also be sent to the email address above.

FGIS will assess a fee for evaluating the test kit, including all documentation reviews. Payment is required within thirty days of the invoice date.

## 4. DEFINITIONS

***Genetically Engineered Grains and Oilseeds***. Grains and oilseeds that are products of modern biotechnology (genetic engineering) to modify agronomic and/or quality characteristics.

***Limit of detection***. The lowest concentration of a genetically engineered protein/or DNA that can be reliably detected by a rapid test kit. This concentration will be specified by the manufacturer upon submission.

***Fortified Samples***. Samples of grain or oilseeds containing a predetermined concentration of genetically engineered grain due to the addition of known quantities of the corresponding genetically engineered grain or oilseed, as applicable.

## 5. TEST KIT EVALUATION REQUIREMENTS

### Manufacturer Information

**a. Limit of Detection**

The manufacturer is required to submit data that supports the claims they make regarding the performance of the rapid test kit. The test kit must reliably detect the presence of genetically engineered material in the grain/oilseed at the limit of detection claimed by the manufacturer.

**b. General Information**

To submit a rapid test kit to FGIS for performance verification, the manufacturer must submit the following information to the Biotechnology Laboratory Program Leader.

- Manufacturer name and address
- Manufacturer point of contact
- Telephone number
- Fax Number
- E-mail address
- Test Format: Lateral slow strip, microtiter well assay, or other (specify)
- Matrix: corn, soybeans, other (specify)
- Protein/DNA detected and the corresponding trait
- Limit of detection
- User instructions for the rapid test kit

**c. Manufacturer Data Submission**

To support claims with respect to the particular rapid test kit, the manufacturer is required to submit the following data to FGIS:

- Control Samples

  One hundred fifty-six (156) independent analyses performed using thirteen (13) different negative samples tested across three (3) manufacturing lots, at four (4) replicates per sample. A minimum of one hundred fifty three (153) of the test results must be negative for the genetically engineered material of interest.

- Fortified Samples

  One hundred fifty-six (156) independent analyses performed using thirteen (13) different samples fortified at the claimed detection threshold. Samples will be tested across three (3) manufacturing lots, at four (4) replicates per sample. A minimum of one hundred fifty three (153) of the test results must be positive for the genetically engineered material of interest.

**d. Performance of Rapid Test at 18° C and 30° C**

Data must be provided demonstrating reliable performance of the test at 18° C and 30° C if the detection apparatus is not temperature controlled. Samples, equipment, and testing materials must be equilibrated at the testing temperature for one hour prior to conducting the analyses.

(1) Control sample analyses at 18° C.

Twenty (20) independent analyses. All test results must be negative for the genetically engineered material of interest.

(2) Fortified sample analyses at 18° C.

Twenty (20) independent analyses. All test results must be positive for the genetically engineered material of interest.

(3) Control sample analyses at 30° C.

Twenty (20) independent analyses. All test results must be negative for the genetically engineered material of interest.

(4) Fortified sample analyses at 30° C.

Twenty (20) independent analyses. All test results must be positive for the genetically engineered material of interest.

**e. Cross-reactivity with Other Genetically Engineered Proteins/DNA.**

For protein-based tests, data shall be provided from five (5) independent tests of all other genetically engineered proteins in commercial production in the U.S. demonstrating that the test is specific for the protein of interest, but not necessarily trait-specific. All tests must be negative for test samples that do not contain the target protein. If multiple events express the same protein, these events and their corresponding protein expression levels must be indicated on the submission data package and in the final instructions included in the manufactured test kit.

**f. FGIS Review and Performance Verification**

Upon receipt of the data submission from the manufacturer, FGIS will:
Review the data submission for completeness and compliance with FGIS performance standards as stated above and will advise the manufacturer that the test meets or did not meet the performance specifications.

If the test kit meets all performance specifications, FGIS will contact the manufacturer and identify a mutually agreeable date for the manufacturer to train FGIS staff in the operation of the test. While training of FGIS staff is advisable, it can be waived at the manufacturer's discretion.

Reference material (whole kernel or seed) is required to perform test kit verification. The test kit manufacturer will be asked to obtain negative material as well as positive reference material from the appropriate life science company in order to verify the claims of the kit. FGIS reserves the right to characterize the integrity of the provided materials by appropriate laboratory analysis.

The performance verification will consist of the FGIS analysis of control and fortified samples as specified below:

(1) Control Samples.

One hundred fifty-six (156) independent analyses performed using thirteen (13) different negative samples tested across three (3) manufacturing lots, at four (4) replicates per sample. A minimum of one hundred fifty three (153) of the test results must be negative for the genetically engineered material of interest. (2) Fortified Samples

(2) Fortified Samples

One hundred fifty-six (156) independent analyses performed using thirteen (13) different fortified samples. Samples will be fortified by FGIS personnel at the manufacturer's stated limit of detection. Samples will be tested across three (3) manufacturing lots, at four (4) replicates per sample. A minimum of one hundred fifty three (153) of the test results must be positive for the genetically engineered material of interest.

If the test kit fails the performance verification, the test kit must be resubmitted with new supporting performance data.

## 6. CERTIFICATE OF PERFORMANCE

A rapid test kit that successfully demonstrates conformance with the manufacturer's claims will be awarded a Certificate of Performance. The Certificate of Performance automatically expires three (3) years from the date of issue. The manufacturer will be required to resubmit new performance data to FGIS prior to the expiration date to have the Certificate of Performance renewed for an additional three years.

FGIS reserves the right to rescind the Certificate of Performance if:

- The manufacturer fails to notify FGIS of changes or alterations to the test kit
- The test kit is found to produce invalid results identified by users, or through some other program.