



The AlerTox® ELISA Soy Kit Detects Soy Protein in Wheat

Highlights of Fapas® Proficiency Testing Studies 27244 and 27255

Soy and Soy Cross-Contamination

For wheat flour processors, soy is a common cross-contaminant. Storage facilities, transport vehicles as well as harvesting and milling works often handle both soy and wheat. Therefore, processors need to test for soy to make sure the allergen is not present in their wheat products.

Description of the AlerTox ELISA Soy Kits

The AlerTox® ELISA Soy Kit is an immunosorbent assay designed for the quantitative determination of soy proteins based on STI (Soy Trypsin Inhibitor) in raw materials and final products. The kit is based on the ELISA sandwich technique that is often used to analyze substances found at very low concentrations. This method, combined with the high specificity and sensitivity of the antibody used in these tests, allows this kit to precisely quantify soy protein in all types of food and drinks. The limit of detection (LOD) is 16 ppb, and the limit of quantification (LOQ) is 50 ppb.

Proficiency Testing Method

Using its AlerTox ELISA Soy Kit, Hygiena® participated in Fapas® proficiency studies organized by Fera Science, an accredited proficiency testing (PT) provider that has been supporting food and water PT since 1990.

PT is a way to compare the performance of detection kits on equal terms. PT rounds are organized by independent organizations that send the same samples to all participants, collect their results, analyze the data and produce reports. In these reports, samples are assigned a consensus allergen level (in ppm) for each kit participating in the round. In this way, participants can compare how well their kits have performed in detecting the correct amount of allergen.

In both rounds of testing (Round 1, Study 27244 and Round 2, Study 27255), a sample material consisted of organic wheat flour with and without the addition of ground organic soya beans. Seventy-eight (78) laboratories, including two that used AlerTox ELISA Soy Kits, submitted results in Round 1. Ninety (90) laboratories, including two that used AlerTox ELISA Soy Kits, submitted results in Round 2.

Results

Qualitative Results

In agreement with almost all other participants' test results, the AlerTox ELISA Soy Kit detected soy in wheat samples containing soy and did not detect soy in wheat samples without soy (Table 1).

**Table 1. Overview of Qualitative Results for Fapas Proficiency Testing to Detect Soy.**

Submitted Sample	AlerTox ELISA Soy Results		Consensus [†]	Match?
Round 1	Lab 073	Lab 075		
Positive (Test material A)	+*	+*	100%	Yes
Negative (Test material B)	—*	—*	100%	Yes
Round 2	Lab 075	Lab 088		
Positive (Test material A)	+ [#]	+*	100%	Yes
Negative (Test material B)	— [#]	—*	97%	Yes

[†] Consensus = percent of study participants submitting an accurate qualitative result (positive or negative)

* LOD = 0.27 ppm soy protein; LOQ = 0.85 ppm soy protein

LOD = 0.2 ppm soy protein; LOQ = 0.8 ppm soy protein

Quantitative Tests

A “Z-score” was calculated to compare how a single test result compares to a set of test results. Compared to other testing kits, 100 percent of the cases had a satisfactory Z-score value. In all rounds, AlerTox ELISA Soy test results had Z-scores that fell within the –2 to +2 range, meaning its results were reliable indicators of soy content (Table 2).

Table 2. Comparison of Results from AlerTox ELISA Soy Kit with Another Kit.

Laboratory Number	AlerTox ELISA Soy Kit (ppm soy protein)	Value from the Most-Used Kit (ppm soy protein)	Z-score*
Round 1			
073	15.8	25.6	–1.53
075	14.1	25.6	–1.8
Round 2			
075	31.78	30.5	0.17
088	32.8	30.5	0.3

* Z-score for the AlerTox ELISA Soy Kit measurement compared to the value from the most used kit in the study.

Conclusions

Fapas tests of submitted AlerTox ELISA Soy samples showed that the tests for soy protein were reliable and accurate. The results showed that it could detect if soy in wheat flour fell below acceptable levels. Hygiena and other users of our Allergen kits regularly participate in proficiency testing studies such as the one offered by FAPA or BIPEA to assess the performance of their laboratories for a specific test, giving them ongoing opportunities to compare their data with others and ensure the accuracy and robustness of their results.

Qualitative and quantitative results showed that the AlerTox ELISA Soy Kit was fit for purpose for detecting soy in food samples.