CERTIFICATION

AOAC Research Institute
Performance Tested Methods℠

Certificate No.

021402

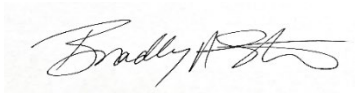
The AOAC Research Institute hereby certifies the method known as

HistaSure™ ELISA Fast Track

manufactured by

Labor Diagnostika Nord GmbH & Co KG
Am Eichenhain 1
48531 Nordhorn
Germany

This method has been evaluated and certified according to the policies and procedures of the AOAC *Performance Tested Methods*℠ 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*℠ 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.



Bradley A. Stawick, AOAC Research Institute Senior Director

Issue Date	November 11, 2025
Expiration Date	December 31, 2026

METHOD NAME
HistaSure™ ELISA Fast Track

CATALOG NUMBERS
FC E-3600; FC E-3900

ORIGINAL CERTIFICATION DATE
February 03, 2014

PRINCIPLE OF THE METHOD

Histamine is extracted from the fish using a simple water extraction. After filtration or centrifugation, the clear supernatant is used for the subsequent step, the derivatization of histamine. Using the acylation reagent, histamine from the calibrators and histamine from the food extracts are quantitatively derivatized into N-acylhistamine. The competitive Histamine ELISA kit uses the microtiter plate format. Histamine is bound to the solid phase of the microtiter plate. Acylated histamine and solid phase bound histamine compete for a fixed number of antiserum binding sites. When the system is in equilibrium, free antigen and free antigen-antiserum-peroxidase complexes are removed by washing. The substrate TMB/peroxidase reaction is monitored at 450 nm. The amount of antibody bound to the solid phase histamine is inversely proportional to the histamine concentration of the sample.

CERTIFIED CLAIM STATEMENT: The HistaSure™ ELISA Fast Track method is certified for the determination of histamine within the scope of Tables 1 and 2.

Table 1. Method Performance Claims

				Performance supporting certification			
Matrix	Test Portion	Solvent	Range, mg/kg	LOD, mg/kg	LOQ, mg/kg	Recovery, %	RSD_r, %
Fresh/Frozen Tuna	10 g	Water	5-250	ND[a]	ND	85.2-99.6	4.13-10.8
Canned Tuna	10 g	Water	5-250	0.4	1.3	91.0-119	2.50-13.9
Frozen Mahi-Mahi	10 g	Water	5-250	ND	ND	79.1-103	2.97-9.56
Canned Sardines	10 g	Water	5-250	ND	ND	76.8-99.7	1.80-9.22
Fish Meal	10 g	Water	5-250	ND	ND	79.0-93.9	2.09-7.92

[a] ND = Not determined.

Table 2. Method Selectivity

		No. Compounds Interfering	
Compounds	Concentration	0 mg/kg Histamine	25 mg/kg Histamine
11 Amines[a]	1000 mg/kg	3[b]	3[b]

[a] Comprising 3-methylhistamine, tyramine, l-phenylalanine, l-histidine, l-tyrosine, tryptamine, l-tryptophan, cadaverine, spermine, putrescine, and trimethylamine.

[b] Cross-reactivity tested as <1% for 3-methylhistamine, tyramine, and cadaverine.

Table 3. Method History

No.	Date	Summary	Supporting Data
1	February 2014	Original Certification.	Certification Report
2	June 2025	Addition of Supplemental Data.	Supplemental 1 Data