Evaluation Report

proficiency test

DLA ptASW1 (2021)

Allergen Swab Test I:

Guten, Peanut, Milk and Soya

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Allgemeine Informationen zur Eignungsprüfung (EP)
General Information on the proficiency test (PT)

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EP-Bericht Freigabe *PT-Report Authorization*	Dr. Matthias Besler-Scharf (Technischer Leiter / Technical Manager) *- gezeichnet / signed M. Besler-Scharf* Alexandra Scharf MSc. (QM-Beauftragte / Quality Manager) *- gezeichnet / signed A. Scharf* Datum / Date: 9 August 2021
Unteraufträge *Subcontractors*	Im Rahmen dieser Eignungsprüfung wurden nachstehende Leistungen im Unterauftrag vergeben: Proteinbestimmung As part of the present proficency test the following services were subcontracted: protein determination
Vertraulichkeit *Confidentiality*	Die Teilnehmerergebnisse sind im EP-Bericht in anonymisierter Form mit Auswertenummern benannt. Daten einzelner Teilnehmer werden ausschließlich nach vorheriger Zustimmung des Teilnehmers an Dritte weitergegeben. Participant result are named anonymously with evaluation numbers in the PT report. Data of individual participants will be passed on to third parties only with prior consent of the participant.

Contents

1. Introduction

The participation in proficiency testing schemes is an essential element of the quality-management-system of every laboratory testing food and feed, cosmetics and food contact materials. The implementation of proficiency tests enables the participating laboratories to prove their own analytical competence under realistic conditions. At the same time they receive valuable data regarding the verification and/or validation of the particular testing method [1, 5].
The purpose of DLA is to offer proficiency tests for selected parameters in concentrations with practical relevance.
Realisation and evaluation of the present proficiency test follows the technical requirements of DIN EN ISO/IEC 17043 (2010) and DIN ISO 13528:2009 / ISO 13528:2015 [2, 3].

2. Realisation

2.1 Test material

Eight test surfaces were provided for the qualitative detection of allergens in the range of 80 – 120 µg per test surface.
To prepare the test surfaces coated with allergens premixes were used at levels of about 5-10% of the allergenic ingredients concerned.
The allergen premixes were suspended in aqueous surfactant-containing solutions and defined aliquots were each spread out in petri dishes made of polystyrene. The test areas were then dried at 40°C overnight. A total of 4 petri dishes with halved partial areas were used, so that a total of 8 test areas were obtained.

The composition of the allergen suspensions is given in table 1. These premixes were used to spike the PT test areas A - D (see Table 2). The areas A and B should be tested for gluten and peanut and the areas C and D should be tested for milk and soya.
Two sealed petri dishes were welded in into one metallized PET film bag.

Table 1: Composition of DLA-Samples

Ingredients	**Samples A - D**
surfactant containing aqueous solution	100 mL
Allergen-Vormischungen Ingredients: - Maltodextrin (80% - 94%) - Sodium sulfate (0,0% - 7,7%) - Silicon dioxide (1,0% - 2,2%) - allergens (5,0% - 10% each)	0,4 - 2,0 g

Table 2: Added amounts of allergenic ingredients, positive in brackets in µg/test surface (approx. 30 cm^2) ranges given as food item ** (cereals as total protein)

Ingredients *	**Surface A**	**Surface B**	**Surface C**	**Surface D**
Wheat: wheat flour type 550 (Protein 10,5%)	**negative**	**positive (80 - 120)**	-	-
Peanut: commercial nut butter (Protein 30%)	**positive (40 - 80)**	**negative**	-	-
Milk: Skimmed milk powder (protein 32%)	-	-	**negative**	**positive (80 - 120)**
Soya: soya flour, untoasted (Protein 37%)	-	-	**positive (60 - 100)**	**negative**

* Protein contents according to laboratory analysis (total nitrogen, Kjeldahl general factor F=6,25)
**Allergen contents of „food item" as indicated in the column of ingredients according gravimetric mixing
Note: *The metrological traceability of temperature, mass and volume during production of the PT samples is ensured by DAkkS calibrated reference materials.*

The detectability or absence of the allergens was tested by DLA using lateral flow assays. The results are in agreement with the spiking of the PT samples A-D (see Table 3).

Table 3: Verification of detectability of the added allergens by lateral flow assays (AgraStrip® LFD, Romer Labs®)

Lateral Flow Device (LFD)*	**Surface A**	**Surface B**	**Surface C**	**Surface D**
AgraStrip® Gluten	**negative**	**positive**	-	-
AgraStrip® Peanut	**positive**	**negative**	-	-
AgraStrip® Casein	-	-	**negative**	**positive**
AgraStrip® Soy	-	-	**positive**	**negative**

* Nachweisgrenze jeweils 1-5 µg/25 cm^2 / Limit of detection (LOD) 1-5 µg/25 cm^2 each

2.1.1 Homogeneity

The homogeneity of the samples was ensured by applying equal amounts of suspended sample solution to each test area. The test areas were examined qualitatively for the relevant allergens using the allergen swab test. Quantitative tests were not carried out.

2.1.2 Stability

The experience with various DLA test materials showed good storage stability with respect to the durability of the sample (spoilage) and the content of the PT parameters for dry and dried products.
The stability of the sample material was thus ensured during the investigation period under the specified storage conditions.
A water activity (a_W) of < 0,5 is an important factor to ensure the stability of dry or dried products during storage. Optimum conditions for storage is the a_W value range of 0,15 - 0,3. In this range the lowest possible degradation rate is to be expected [16].

2.2 Sample shipmend and information to the test

The portions of the test materials (sample A to D) were sent to every participating laboratory in the 11th week of 2021. The testing method was optional. The tests should be finished at May 14th 2021 the latest.

With the cover letter along with the sample shipment the following information was given to participants:

There are 4 plates (each with 2 test surfaces) possibly containing the allergenic parameters Gluten, Peanut, Milk and Soya. Two areas are to be tested per allergen (one of them spiked with the relevant allergen). The amounts are in the range of 10 – 100 µg/test area. The analysis methods are optional.
The evaluation of results is strictly qualitative (positive / negative).

*Important note: The test areas are labeled with the **parameter to be tested** on the **backside of the plates**. A test field is only to be tested for this parameter.*

Please note the attached information on the proficiency test.
(see documentation, section 5.2 Information on the PT)

2.3 Submission of results

The participants submitted their results in standard forms, which have been sent by email or were available on our website. The results given as positive/negative were evaluated.
Queried and documented were the indicated results and details of the test methods like specificities, test kit manufacturer and hints about the procedure.
In case participants submitted several results for the same parameter obtained by different methods these results were evaluated with the same evaluation number with a letter as a suffix and indication of the related method.

All 22 participants submitted at least one result.

3. Evaluation

Different ELISA- and PCR-methods for the determination of allergens in foods are eventually using different antibodies and target-DNA, are usually calibrated with different reference materials and may utilize differing extraction methods. Among others this can induce different valuation of the presence and/or content of the analyte [25, 26, 27, 28]. Furthermore matrix- and/or processing of samples can have strong impact on the detectability of allergens by ELISA and PCR methods.

Therefore in the present PT the allergenic ingredients were provided for analysis on a test surface made of polystyrene without further processing.

3.1 Agreement with consensus values from participants

The qualitative evaluation of the ELISA (or lateral flow) and PCR results of each participant was based on the agreement of the indicated results (positive or negative) with the **consensus values from participants**. A consensus value is determined if ≥ 75% positive or negative results are available for a parameter.
The assessment will be in the form that the number of matching results followed by the number of samples for which a consensus value was obtained is indicated. Behind that the agreement is expressed as the percentage in parentheses.

3.2 Agreement with spiking of samples

The qualitative evaluation of the ELISA (or lateral flow) and PCR results of each participant was based on the agreement of the indicated results (positive or negative) with the **spiking of the four PT-samples.**
The assessment will be in the form that the number of matching results followed by the number of samples is indicated. Behind that the agreement is expressed as the percentage in parentheses.

4. Results

All following tables are anonymized. With the delivering of the evaluation-report the participants are informed about their individual evaluation-number.

The qualitative evaluation is carried out for each parameter for ELISA (or lateral flow) and PCR methods separately. Results of lateral flow methods were valuated together with ELISA methods, because they are usually based on antibody detection.

The surfaces A and B should be tested for gluten / gluten-containing cereals and peanut, and the surfaces C and D should be tested for milk and soya as indicated on the 4 halfed petri dishes.

The participant results and evaluation are tabulated as follows:

Evaluation number	Surface A	Surface B	Surface C	Surface D	Qualitative Valuation	Qualitative Valuation	Method	Remarks
	pos/neg	pos/neg	pos/neg	pos/neg	Agreement with consensus value	Agreement with spiking of samples		

	Surface A	Surface B	Surface C	Surface D
Number positive				
Number negative				
Percent positive				
Percent negative				
Consensus value				
Spiking				

4.1 Proficiency Test Gluten (gluten-containing Cereals)

4.1.1 ELISA- and Lateral Flow Results: Gluten

Qualitative valuation of results

Evaluation number	Surface A	Surface B	Qualitative Valuation	Qualitative Valuation	Method	Remarks
	pos/neg	pos/neg	Agreement with consensus value	Agreement with spiking of samples		
11	negative	positive	2/2 (100%)	2/2 (100%)	AQ	
1	negative	positive	2/2 (100%)	2/2 (100%)	AS	
12	negative	positive	2/2 (100%)	2/2 (100%)	IFP	
16	negative	positive	2/2 (100%)	2/2 (100%)	IL	
18	negative	positive	2/2 (100%)	2/2 (100%)	IL	
2	negative	positive	2/2 (100%)	2/2 (100%)	RS	
3	negative	positive	2/2 (100%)	2/2 (100%)	RS	
4	negative	positive	2/2 (100%)	2/2 (100%)	RS	
6	negative	positive	2/2 (100%)	2/2 (100%)	RS	
7	negative	positive	2/2 (100%)	2/2 (100%)	RS	
14	negative	positive	2/2 (100%)	2/2 (100%)	RS	
17a	negative	positive	2/2 (100%)	2/2 (100%)	RS	
19	negative	positive	2/2 (100%)	2/2 (100%)	RS	
22	negative	positive	2/2 (100%)	2/2 (100%)	RS	
20	negative	positive	2/2 (100%)	2/2 (100%)	SP-Q	
13	negative	positive	2/2 (100%)	2/2 (100%)	SP-R5	
15	negative	positive	2/2 (100%)	2/2 (100%)	SP-R5	
17b	negative	positive	2/2 (100%)	2/2 (100%)	SP-R5	
5	negative	positive	2/2 (100%)	2/2 (100%)	VT	
8	negative	positive	2/2 (100%)	2/2 (100%)	VT-R2	
9	negative	positive	2/2 (100%)	2/2 (100%)	div	Lateral Flow

	Surface A	Surface B
Number positive	0	21
Number negative	21	0
Percent positive	0	100
Percent negative	100	0
Consensus value	negative	positive
Spiking	negative	positive

Methods:

AQ = AgraQuant, RomerLabs

AS = AgraStrip (Lateral Flow), RomerLabs

IFP = ELISA

IL = Immunolab

RS = Ridascreen®, R-Biopharm

SP-Q = SensiSpec Ingezim Gluten R5 Quick, Eurofins

SP-R5 = SensiSpec Ingezim Gluten R5, Eurofins

VT = Veratox, Neogen

VT-R5 = Veratox, Neogen

div = keine genaue Angabe / andere Methode

Comments:

The consensus values of results are in qualitative agreement with the spiking of the test surfaces.

4.1.2 PCR-Results: Gluten-containing Cereals

Qualitative valuation of results

Evaluation number	Surface A	Surface B	Qualitative Valuation	Qualitative Valuation	Method	Remarks
	pos/neg	pos/neg	Agreement with consensus value	Agreement with spiking of samples		
4a	negative	positive	2/2 (100%)	2/2 (100%)	SFA	Gluten-containing cereals
21	negative	positive	2/2 (100%)	2/2 (100%)	SFA	Gluten-containing cereals
4b	negative	positive	2/2 (100%)	2/2 (100%)	SFA-4p	Wheat

	Surface A	Surface B
Number positive	0	3
Number negative	3	0
Percent positive	0	100
Percent negative	100	0
Consensus value	negative	positive
Spiking	negative	positive

Methods:

SFA = Sure Food ALLERGEN, R-Biopharm / Congen

SFA-4p = Sure Food Allergen 4plex, R-Biopharm / Congen

Comments:

The consensus values of results are in qualitative agreement with the spiking of the test surfaces.

4.2 Proficiency Test results Peanut

4.2.1 ELISA- and Lateral Flow-Results: Peanut

Qualitative valuation of results

Evaluation number	Surface A	Surface B	Qualitative Valuation	Qualitative Valuation	Method	Remarks
	pos/neg	pos/neg	Agreement with consensus value	Agreement with spiking of samples		
11	positive	negative	2/2 (100%)	2/2 (100%)	AQ	
14	positive	negative	2/2 (100%)	2/2 (100%)	AQ-P	
12	positive	negative	2/2 (100%)	2/2 (100%)	ASU	
17	positive	negative	2/2 (100%)	2/2 (100%)	MI	
3	positive	negative	2/2 (100%)	2/2 (100%)	RS-F	
4	positive	negative	2/2 (100%)	2/2 (100%)	RS-F	
6	positive	negative	2/2 (100%)	2/2 (100%)	RS-F	
8	positive	negative	2/2 (100%)	2/2 (100%)	RS-F	
13	positive	negative	2/2 (100%)	2/2 (100%)	SP	
18	positive	negative	2/2 (100%)	2/2 (100%)	SP	
5	positive	negative	2/2 (100%)	2/2 (100%)	VT	
20	positive	negative	2/2 (100%)	2/2 (100%)	VT	

	Surface A	Surface B
Number positive	12	0
Number negative	0	12
Percent positive	100	0
Percent negative	0	100
Consensus value	positive	negative
Spiking	positive	negative

Methods:

AQ = AgraQuant, RomerLabs

AQ-P = AgraQuant Plus, RomerLabs

ASU = ASU §64 Methode/method

MI = Morinaga Institute ELISA

RS-F= Ridascreen® Fast, R-Biopharm

SP = SensiSpec ELISA Kit, Eurofins

VT = Veratox, Neogen

Comments:

The consensus values of results are in qualitative agreement with the spiking of the test surfaces.

4.2.2 PCR-Results: Peanut

Qualitative valuation of results

Evaluation number	Surface A	Surface B	Qualitative Valuation	Qualitative Valuation	Method	Remarks
	pos/neg	pos/neg	Agreement with consensus value	Agreement with spiking of samples		
17	positive	negative	2/2 (100%)	2/2 (100%)	ASU	
2	positive	negative	2/2 (100%)	2/2 (100%)	SFA	
4	positive	negative	2/2 (100%)	2/2 (100%)	SFA	
19	positive	negative	2/2 (100%)	2/2 (100%)	SFA	
22	positive	negative	2/2 (100%)	2/2 (100%)	SFA-4p	
16	positive	negative	2/2 (100%)	2/2 (100%)	div	

	Surface A	Surface B
Number positive	6	0
Number negative	0	6
Percent positive	100	0
Percent negative	0	100
Consensus value	positive	negative
Spiking	positive	negative

Methods:

ASU = ASU §64 Methode/method

SFA = Sure Food ALLERGEN, R-Biopharm / Congen

SFA-4p = Sure Food Allergen 4plex, R-Biopharm / Congen

div = keine genaue Angabe / andere Methode

div = not indicated / other method

Comments:

The consensus values of results are in qualitative agreement with the spiking of the test surfaces.

4.3 Proficiency Test Results Milk

4.3.1 ELISA- and Lateral Flow-Results: Milk

Qualitative valuation of results

Evaluation number	Surface C	Surface D	Qualitative Valuation	Qualitative Valuation	Method	Remarks
	pos/neg	pos/neg	Agreement with consensus value	Agreement with spiking of samples		
4a	negative	positive	2/2 (100%)	2/2 (100%)	AQ	
11	negative	positive	2/2 (100%)	2/2 (100%)	AQ	
1	negative	positive	2/2 (100%)	2/2 (100%)	AS	Lateral Flow
10a	negative	positive	2/2 (100%)	2/2 (100%)	BA	Lateral Flow
4b	negative	positive	2/2 (100%)	2/2 (100%)	BC	β-Lactoglobulin
12	negative	positive	2/2 (100%)	2/2 (100%)	IFP	
16	negative	positive	2/2 (100%)	2/2 (100%)	IL	
15a	negative	positive	2/2 (100%)	2/2 (100%)	IN	β-Lactoglobulin
17a	negative	positive	2/2 (100%)	2/2 (100%)	MI	Casein
3	negative	positive	2/2 (100%)	2/2 (100%)	RS-F	
6	negative	positive	2/2 (100%)	2/2 (100%)	RS-F	
7	negative	positive	2/2 (100%)	2/2 (100%)	RS-F	
8	negative	positive	2/2 (100%)	2/2 (100%)	RS-F	
10b	negative	positive	2/2 (100%)	2/2 (100%)	RS-F	
14	negative	positive	2/2 (100%)	2/2 (100%)	RS-F	Casein
20	positive	negative	0/0 (0%)	0/0 (0%)	RS-F	Casein
22	negative	positive	2/2 (100%)	2/2 (100%)	RS-F	
13	negative	positive	2/2 (100%)	2/2 (100%)	SP	
15b	negative	positive	2/2 (100%)	2/2 (100%)	SP	Casein
17b	negative	positive	2/2 (100%)	2/2 (100%)	SP	
18	negative	positive	2/2 (100%)	2/2 (100%)	SP	
2	negative	positive	2/2 (100%)	2/2 (100%)	VT	
5	negative	positive	2/2 (100%)	2/2 (100%)	VT	

	Surface C	Surface D
Number positive	1	22
Number negative	22	1
Percent positive	4	96
Percent negative	96	4
Consensus value	negative	positive
Spiking	negative	positive

Methods:

AQ = AgraQuant, RomerLabs
AS = AgraStrip (Lateral Flow), RomerLabs
BA = Bioavid (Lateral Flow), R-Biopharm
BC = BioCheck ELISA
IFP = ELISA Total Milk
IN = INgezim beta-Lactoglobulin, Ingenasa
MI = Morinaga Institute ELISA
SP = SensiSpec ELISA Kit, Eurofins
VT = Veratox, Neogen

Comments:
The consensus values of results are in qualitative agreement with the spiking of the test surfaces.

4.3.2 PCR-Results: Milk

Qualitative valuation of results

Comments: There are no PCR results available for the parameter Milk.

4.4 Proficiency Test Results Soya

4.4.1 ELISA- and Lateral Flow-Results: Soya

Qualitative valuation of results

Evaluation number	Surface C	Surface D	Qualitative Valuation	Qualitative Valuation	Method	Remarks
	pos/neg	pos/neg	Agreement with consensus value	Agreement with spiking of samples		
3	positive	negative	2/2 (100%)	2/2 (100%)	AQ	
11	positive	negative	2/2 (100%)	2/2 (100%)	AQ	
1	positive	negative	2/2 (100%)	2/2 (100%)	AS	Lateral Flow
20	negative	positive	0/0 (0%)	0/0 (0%)	ES	
12	positive	negative	2/2 (100%)	2/2 (100%)	IFP	
14	positive	negative	2/2 (100%)	2/2 (100%)	MI	
17	positive	negative	2/2 (100%)	2/2 (100%)	MI	
6	positive	negative	2/2 (100%)	2/2 (100%)	RS-F	
7	positive	negative	2/2 (100%)	2/2 (100%)	RS-F	
8	positive	negative	2/2 (100%)	2/2 (100%)	RS-F	
13	positive	negative	2/2 (100%)	2/2 (100%)	SP	
18	positive	negative	2/2 (100%)	2/2 (100%)	SP	
4	positive	negative	2/2 (100%)	2/2 (100%)	VT	
5	positive	negative	2/2 (100%)	2/2 (100%)	VT	

	Surface C	Surface D
Number positive	13	1
Number negative	1	13
Percent positive	93	7
Percent negative	7	93
Consensus value	positive	negative
Spiking	positive	negative

Methods:

AQ = AgraQuant, RomerLabs

AS = AgraStrip (Lateral Flow), RomerLabs

ES = ELISA-Systems

IFP = ELISA Total Milk

MI = Morinaga Institute ELISA

RS-F= Ridascreen® Fast, R-Biopharm

SP = SensiSpec ELISA Kit, Eurofins

VT = Veratox, Neogen

Comments:

The consensus values of results are in qualitative agreement with the spiking of the test surfaces.

4.4.2 PCR-Results: Soya

Qualitative valuation of results

Evaluation number	Surface C	Surface D	Qualitative Valuation	Qualitative Valuation	Method	Remarks
	pos/neg	pos/neg	Agreement with consensus value	Agreement with spiking of samples		
2	positive	negative	2/2 (100%)	2/2 (100%)	SFA	
4	positive	negative	2/2 (100%)	2/2 (100%)	SFA	
22	positive	negative	2/2 (100%)	2/2 (100%)	SFA	
19	positive	negative	2/2 (100%)	2/2 (100%)	SFA-4p	
21	positive	negative	2/2 (100%)	2/2 (100%)	SFA-4p	
16	positive	negative	2/2 (100%)	2/2 (100%)	div	
17	positive	negative	2/2 (100%)	2/2 (100%)	div	

	Surface C	Surface D
Number positive	7	0
Number negative	0	7
Percent positive	100	0
Percent negative	0	100
Consensus value	positive	negative
Spiking	positive	negative

Methods:

SFA = Sure Food ALLERGEN, R-Biopharm / Congen

SFA-4p = Sure Food Allergen 4plex, R-Biopharm / Congen

div = keine genaue Angabe / andere Methode

div = not indicated / other method

Comments:

The consensus values of results are in qualitative agreement with the spiking of the test surfaces.

5. Documentation

5.1 Details by the participants

Note: Information given in German was translated by DLA to the best of our knowledge (without guarantee of correctness).

5.1.1 ELISA: Gluten

Primary Data

Meth. Abr.	Evaluation number	Date of analysis	Result Surface A	Result Surface B	Result Surface C	Result Surface D	Limit of detection	Limit of detection given as	Method
		Day/ Month	qualitative	qualitative	qualitative	qualitative	mg/kg	e.g. food / food protein	Test-Kit + Provider
AQ	11	31.03.21	negative	positive	X	X	0,1	Gluten	AQ = AgraQuant, RomerLabs
AS	1		negative	positive	X	X			Romer Labs AgraStrip Gluten Test Kit
IFP	12		negative	positive	X	X	0,006	Gluten	IFP 002822 (ELISA) : 2020-07 (a)
IL	16	13.05.21	negative	positive	X	X	0.008	Gluten	IL = Immunolab
IL	18	31.03.21	negative	positive	X	X		Gliadin	IL = Immunolab
RS	2	29.03.21	negative	positive	X	X		Gluten	RS = Ridascreen®, R-Biopharm
RS	3	27.04.21	negative	positive	X	X	1	Gluten	RS = Ridascreen®, R-Biopharm
RS	4	03.05.21	negative	positive	X	X	3ug/Sw ab	Gluten	RS = Ridascreen®, R-Biopharm
RS	6	04.05.	negative	positive	X	X		Gluten	RS = Ridascreen®, R-Biopharm
RS	7	22.04.21	negative	positive	X	X	50ng/surface	Gluten	RS = Ridascreen®, R-Biopharm
RS	14	11.05.21	negative	positive	X	X	3	Gluten	RS = Ridascreen®, R-Biopharm
RS	17a	14.04.21	negative	positive	x	x	0,125	Gluten	RS = Ridascreen®, R-Biopharm
RS	19		negative	positive	X	X		Please select!	RS = Ridascreen®, R-Biopharm
RS	22		negative	positive	X	X		Gluten	RS = Ridascreen®, R-Biopharm
SP-Q	20		negative	positive	X	X	3	Gluten	SP = SensiSpec, Eurofins Technologies
SP-R5	13		negative	positive	X	X		Please select!	other: please fill in!
SP-R5	15	13.05.21	negative	positive	X	X	0,125	Gluten	SP = SensiSpec, Eurofins Technologies
SP-R5	17b	30.04.21	negative	positive	X	X	0,078	Gluten	SP = SensiSpec, Eurofins Technologies
VT	5	13.04.21	negative	positive	X	X	16	Gluten	VT = Veratox, Neogen
VT-R2	8		negative	positive	X	X		Gluten	VT-R5 = Veratox, Neogen
div	9	05.05.21	negative	positive	X	X		Gluten	Lateral Flow Device

Other details to the Methods

Meth. Abr.	Evaluation number	Method-No./ Test-Kit No.	Specifity	Remarks to the Method (Extraction and Determination)	Further Remarks
		Article-No. / ASU-No.	Antibody	e.g. extraction solution / time / temperature	
AQ	11	10001994			
AS	1	10002000			
IFP	12	IFP 002822 (ELISA) : 2020-07 (a)	R5	according to TKB	
IL	16	MEI 10.01 / GLU-E02	ND	Short Application Protocol for Swab Test in Combination with the Immunolab Gliadin ELISA, GLU-E02	
IL	18				
RS	2	R7001	R5		Analytical limit of detection: 5 ppm
RS	3				
RS	4	R7001	As per kit Instructions	As per kit instructions	
RS	6	R7001 RIDASCREEN® GliadinR7001 RIDASCREEN® Gliadin		Surface swabed with Ethanol 80%, measured as per kit instructions	
RS	7	R7001		swab B result/surface= 489 ng	Sample B multiplied for swabing efficiency(20%) by a factor of 5
RS	14	R 7001			
RS	17a	R7001	R5 of Mendez, detects prolamins (Gliadins) from wheat, rye and barley	surface swabed according to kit instructions of SENSISwab Swab Test Kit, swab extracted and solution submitted to test	A: <0,125; B: >0,625
RS	19	R7001	specific gliadin fractions from wheat	Cocktail solution, 50°C	
RS	22				
SP-Q	20	Ingezim Gluten Quick 30.GL2.K.2			
SP-R5	13			KIT Ingezim gluten	
SP-R5	15	30.GLU.K.2	R5	The extraction has been done whit 2ml of the sensiswab buffer kit. Article: Hu0030101	
SP-R5	17b	IT-G-157	R5 of Mendez, detects prolamins (Gliadins) from wheat, rye and barley	surface swabed according to kit instructions of SENSISwab Swab Test Kit, swab extracted and solution submitted to test	in additional material; A: <0,078; B: >1,25
VT	5	8510	ELISA SANDWICH	gliadin renaturing cocktail solution/ 40min/50C	
VT-R2	8	8510			
div	9				

5.1.2 PCR: Gluten-containing Cereals

Primary data

Meth. Abr.	Evaluation number	Date of analysis	Result Surface A	Result Surface B	Result Surface C	Result Surface D	Limit of detection	Limit of detection given as	Method
		Day/ Month	qualitative	qualitative	qualitative	qualitative	mg/kg	e.g. food / food protein	Test-Kit + Provider
SFA	4a	24.04.21	negative	positive	-	-	10ug/Swab	Food item, total	SFA = Sure Food ALLERGEN, R-Biopharm / Congen
SFA	21	25.06.21	negative	positive	X	X		Please select!	SFA = Sure Food ALLERGEN, R-Biopharm / Congen
SFA-4p	4b	24.04.21	negative	positive	-	-	10ug/Swab	Food item, total	SFA-4p = Sure Food Allergen 4plex, R-Biopharm / Congen

Other details to the Methods

Meth. Abk.	Auswerte-nummer	Methoden-Nr./ Test-Kit Nr.	Spezifität	Hinweise zur Methode (Extraktion und Bestimmung)	Sonstige Hinweise
		Artikel-Nr. / ASU-Nr.	Target-Sequenz / -DNA	z.B. Extraktion / Enzyme / Clean-Up / Real Time PCR / Gelelektrophorese / Cyclen	
SFA	4a	S3606	As per kit Instructions	As per kit instructions	
SFA	21	S3606		CTAB Isolation/Real Time PCR	Surface swab with liquid swab
SFA-4p	4b	S7006	As per kit Instructions	As per kit instructions	

5.1.3 ELISA and Lateral Flow: Peanut

Primary data

Meth. Abr.	Evaluation number	Date of analysis	Result Surface A	Result Surface B	Result Surface C	Result Surface D	Limit of detection	Limit of detection given as	Method
		Day/ Month	qualitative	qualitative	qualitative	qualitative	mg/kg	e.g. food / food protein	Test-Kit + Provider
AQ	11	31.03.21	positive	negative	X	X	0,005	Peanut	AQ = AgraQuant, RomerLabs
AQ-P	14	13.05.21	positive	negative	X	X	0,1	Peanut	AQ-P = AgraQuant Plus, RomerLabs
ASU	12		positive	negative	X	X	0,001	Peanut	ASU L 00.00-69 : 2003-12 (a)
MI	17	14.04.21	positive	negative	X	X	0,01	Peanutprotein	MI = Morinaga Institute ELISA
RS-F	3	09.04.21	positive	negative	X	X	0,13	Peanut	RS-F= Ridascreen® Fast, R-Biopharm
RS-F	4	08.04.21	positive	negative	X	X	2.5ug/Swab	Peanut	RS-F= Ridascreen® Fast, R-Biopharm
RS-F	6	03.05.	positive	negative	X	X		Peanut	RS-F= Ridascreen® Fast, R-Biopharm
RS-F	8		positive	negative	X	X		Peanut	RS-F= Ridascreen® Fast, R-Biopharm
SP	13		positive	negative	X	X		Please select!	SP = SensiSpec, Eurofins Technologies
SP	18	31.03.21	positive	negative	X	X		Peanut	SP = SensiSpec, Eurofins Technologies
VT	5	13.04.21	positive	negative	X	X	10	Peanut protein	VT = Veratox, Neogen
VT	20		positive	negative	X	X	1	Peanut	VT = Veratox, Neogen

Other details to the Methods

Meth. Abr.	Evaluation number	Method-No./ Test-Kit No.	Specifity	Remarks to the Method (Extraction and Determination)	Further Remarks
		Article-No. / ASU-No.	Antibody	e.g. extraction solution / time / temperature	
AQ	11	10001990			
AQ-P	14	COKAL0148F			
ASU	12	PV-28-PCR-PF-229 : 2014-11 (a)	peanutprotein, polyclonal	according TKB	
MI	17	M2120	detects peanutproteins	surface swabed according to kit instructions of SENSISwab Swab Test Kit, swab extracted and solution submitted to test	A: >0,5, B:<0,01
RS-F	3				
RS-F	4	R6202	As per kit Instructions	As per kit instructions	
RS-F	6	R6902 RIDASCREEN® FAST Peanut		Surface swabbed with diluted extraction buffer, measurement as per kit instructions	
RS-F	8	R6202			
SP	13				
SP	18				
VT	5	8430	ELISA SANDWICH	PBS/15min/60C	
VT	20	8430			

5.1.4 PCR: Peanut

Primary data

Meth. Abr.	Evaluation number	Date of analysis	Result Surface A	Result Surface B	Result Surface C	Result Surface D	Limit of detection	Limit of detection given as	Method
		Day/ Month	qualitative	qualitative	qualitative	qualitative	mg/kg	e.g. food / food protein	Test-Kit + Provider
ASU	17	07.05.21	positive	negative	X	X	10	Food item, DNA	ASU = ASU §64 Methode/method
SFA	2	25.03.21	positive	negative	X	X		Food item, DNA	SFA = Sure Food ALLERGEN, R-Biopharm / Congen
SFA	4	09.04.21	positive	negative	X	X	1ug/Swab	Food item, total	SFA = Sure Food ALLERGEN, R-Biopharm / Congen
SFA	19	22.03.21	positive	negative	X	X		Bitte auswählen!	SFA = Sure Food ALLERGEN, R-Biopharm / Congen
SFA-4p	22		positive	negative	X	X		Food item, DNA	SFA-4p = Sure Food Allergen 4plex, R-Biopharm / Congen
div	16	13.05.21	positive	negative	X	X		LD PCR=15 pg DNA (<10mg / kg for reference material)	Real Time PCR Internal Method: MEB66

Other details to the Methods

Meth. Abr.	Evaluation number	Method-No./ Test-Kit No.	Specifity	Remarks to the Method (Extraction and Determination)	Further Remarks
		Article-No. / ASU-No.	Target-Sequence/ DNA	e.g. Extraction / enzymes / clean-up / real time PCR / gel electrophoresis / cycles	
ASU	17	§ 64 LFGB L 00.00-169:2019-07		CTAB / Proteinase K / Rnase A / Maxwell / Real-time PCR 45 Cycles	in additional material
SFA	2	S3603			Analytical limit of detection: 0,4 ppm
SFA	4	S3603	As per kit Instructions	As per kit instructions	
SFA	19	S3603	Arachis hypogaea	Extraction with: SureFood® PREP Advanced, Art. No. S1053	
SFA-4p	22				
div	16	Internal Method: MEB66	Ara h 2 gene	Extraction performed using the DNeasy Mericon Qiacube HT kit. Detection performed by Real-Time PCR (50 cycles of amplification)	

5.1.5 ELISA and Lateral Flow: Milk

Primary data

Meth. Abr.	Evaluation number	Date of analysis	Result Surface A	Result Surface B	Result Surface C	Result Surface D	Limit of detection	Limit of detection given as	Method
		Day/ Month	qualitative	qualitative	qualitative	qualitative	mg/kg	e.g. food / food protein	Test-Kit + Provider
AQ	4a	09.04.21	X	X	negative	positive	0.4ug/Sw ab	Milkprotein	AQ = AgraQuant, RomerLabs
AQ	11	01.04.21	X	X	negative	positive	0,0025	Milkprotein	AQ = AgraQuant, RomerLabs
AS	1		X	X	negative	positive			Romer Labs AgraStrip Milk Test Kit
BA	10a		X	X	negative	positive			BA = Bioavid (Lateral Flow), R-Biopharm
BC	4b	11.04.21	-	-	negative	positive	10ng/Sw ab	other: please fill in!	BC = BioCheck ELISA
IFP	12		X	X	negative	positive	0,002	Skimmed milk powder	IFP 002822 (ELISA) : 2020-07 (a) total Milk
IL	16	13.05.21	X	X	negative	positive	0.02	Milkprotein	IL = Immunolab
IN	15a	12.05.21	-	-	negative	positive	0,0025	beta-lactoglobulin	INGENASA= Ingezim b-lactoglobulin
MI	17a	07.05.21	X	X	negative	positive	0,0125	Casein	MI = Morinaga Institute ELISA
RS-F	3	28.04.21	X	X	negative	positive	0,7	Milk	RS-F= Ridascreen® Fast, R-Biopharm
RS-F	6	07.05.	X	X	negative	positive		Milkprotein	RS-F= Ridascreen® Fast, R-Biopharm
RS-F	7	30.04.21	X	X	negative	positive	0,167	Milkprotein	RS-F= Ridascreen® Fast, R-Biopharm
RS-F	8		X	X	negative	positive		other: Casein &beta-Lactoglobulin	RS-F= Ridascreen® Fast, R-Biopharm
RS-F	10b		X	X	negative	positive		Milkprotein	RS-F= Ridascreen® Fast, R-Biopharm
RS-F	14	12.05.21	X	X	negative	positive	0,3	Casein	RS-F= Ridascreen® Fast, R-Biopharm
RS-F	20		X	X	positive	negative	0,5	Casein	RS-F= Ridascreen® Fast, R-Biopharm
RS-F	22		X	X	negative	positive		Milk	RS-F= Ridascreen® Fast, R-Biopharm
SP	13		X	X	negative	positive		Please select!	SP = SensiSpec, Eurofins Technologies
SP	15b	12.05.21	-	-	negative	positive	0,01	casein	SP = SensiSpec, Eurofins Technologies
SP	17b	07.05.21	x	x	negative	positive	0,02	Milkprotein	SP = SensiSpec, Eurofins Technologies
SP	18	31.03.21	X	X	negative	positive		Milkprotein	SP = SensiSpec, Eurofins Technologies
VT	2	30.03.21	X	X	negative	positive		Skimmed milk powder	VT = Veratox, Neogen
VT	5	12.04.21	X	X	negative	positive	15	Milkprotein	VT = Veratox, Neogen

Other details to the Methods

Meth. Abr.	Evaluation number	Method-No./ Test-Kit No.	Specifity	Remarks to the Method (Extraction and Determination)	Further Remarks
		Article-No. / ASU-No.	Antibody	e.g. extraction solution / time / temperature	
AQ	4a	COKAL2448	As per kit Instructions	As per kit instructions	
AQ	11	10002080			
AS	1	10002078			
BA	10a				
BC	4b	R6036	As per kit Instructions	As per kit instructions	LOD as B-lactoglobulin
IFP	12	IFP 002822 (ELISA) : 2020-07 (a)	Milk protein, polyclonal	according TKB	
IL	16	MEI 10.01 / MIL-E01	ND	Short Application Protocol for Swab Test in Combination with Immunolab Food Allergen ELISAs	
IN	15a	30.BLG.K.2	-	The extraction has been done whit 2ml of the sensiswab buffer kit. Article: Hu0030101	
MI	17a	M2113	detects cow's milk casein	surface swabed according to kit instructions of SENSISwab Swab Test Kit, swab extracted and solution submitted to test	
RS-F	3				
RS-F	6	R4652 RIDASCREEN® FAST Milk		Surface swabbed with diluted extraction buffer, preparation with 250µl diluted extractor 2 and 750µl diluted A-AEP, measurement as per kit instructions	
RS-F	7	R4912		swab D result/surface= 0,33 µg b-lactoglobulin and 0,69 µg cazein	result not corrected for efficiency
RS-F	8	R4612 (Casein) R4912 (beta-Lactoglobulin)R4612 (Casein) R4912 (beta-Lactoglobulin)			2 separate analysis
RS-F	10b				
RS-F	14	R4612			
RS-F	20	R4612			
RS-F	22				
SP	13				
SP	15b	HU0030003	-	The extraction has been done whit 2ml of the sensiswab buffer kit. Article: Hu0030101	
SP	17b	HU0030038	detects cow's milk casein	surface swabed according to kit instructions of SENSISwab Swab Test Kit, swab extracted and solution submitted to test	in additional material; C: <0,02; D: >0,3
SP	18				
VT	2	8470	Casein, whey proteins		Analytical limit of detection: 2,5 ppm
VT	5	8470	ELISA SANDWICH	PBS/15min/60C	

5.1.6 ELISA and Lateral Flow: Soya

Primary data

Meth. Abr.	Evaluation number	Date of analysis	Result Surface A	Result Surface B	Result Surface C	Result Surface D	Limit of detection	Limit of detection given as	Method
		Day/ Month	qualitative	qualitative	qualitative	qualitative	mg/kg	e.g. food / food protein	Test-Kit + Provider
AQ	3	28.04.21	X	X	positive	negative	0,11	Soyprotein	AQ = AgraQuant, RomerLabs
AQ	11	01.04.21	X	X	positive	negative	0,0008	Soy-Trypsin-Inhibitor protein	AQ = AgraQuant, RomerLabs
AS	1		X	X	positive	negative			Romer Labs AgraStrip Soy Test Kit
ES	20		X	X	negative	positive	2,5	Soyprotein	ES = ELISA-Systems
IFP	12		X	X	positive	negative	0,002	Soyflour	IFP 002822 (ELISA) : 2020-07 (a)
MI	14	10.05.21	X	X	positive	negative	0,3	Soyprotein	MI = Morinaga Institute ELISA
MI	17	14.04.21	X	X	positive	negative	0,0625	Soyprotein	MI = Morinaga Institute ELISA
RS-F	6	05.05.	X	X	positive	negative		Soyprotein	RS-F= Ridascreen® Fast, R-Biopharm
RS-F	7	23.04.21	X	X	positive	negative	0,625 µg/surface	Soyprotein	RS-F= Ridascreen® Fast, R-Biopharm
RS-F	8		X	X	positive	negative		Soyprotein	RS-F= Ridascreen® Fast, R-Biopharm
SP	13		X	X	positive	negative		Please select!	SP = SensiSpec, Eurofins Technologies
SP	18	31.03.21	X	X	positive	negative		Soyprotein	SP = SensiSpec, Eurofins Technologies
VT	4	09.04.21	X	X	positive	negative	2.5ug/Sw ab	Soyflour	VT = Veratox, Neogen
VT	5	12.04.21	X	X	positive	negative	13,9	Soyprotein	VT = Veratox, Neogen

Other details to the Methods

Meth. Abr.	Evaluation number	Method-No./ Test-Kit No.	Specifity	Remarks to the Method (Extraction and Determination)	Further Remarks
		Article-No. / ASU-No.	Antibody	e.g. extraction solution / time / temperature	
AQ	3				
AQ	11	10002015			
AS	1	10002010			
ES	20	ESSOYPRD-48			
IFP	12	PV-28-PCR-PF-239 : 2014-11 (a)	Soyprotein, monoclonal	according to TKB	
MI	14				
MI	17	M2117	detects the soyprotein beta-conglycinin	surface swabed according to kit instructions of SENSISwab Swab Test Kit, swab extracted and solution submitted to test	C:>0,9; D: <0,0625
RS-F	6	R7102 RIDASCREEN® FAST Soya		Surface swabbed with diluted extraction buffer, preparation with 125µl extraction 3 and 875µl diluted extraction buffer, measurement as per kit instructions	
RS-F	7	R7102		swabC result= 7,0 µg/ surface	Sample C multiplied for swabing efficiency(20%) by a factor of 5
RS-F	8	R7102			
SP	13				
SP	18				
VT	4	8410	As per kit Instructions	As per kit instructions	
VT	5	8410	ELISA SANDWICH	PBS/15min/60C	

5.1.7 PCR: Soya

Primary data

Meth. Abr.	Evaluation number	Date of analysis	Result Surface A	Result Surface B	Result Surface C	Result Surface D	Limit of detection	Limit of detection given as	Method
		Day/ Month	qualitative	qualitative	qualitative	qualitative	mg/kg	e.g. food / food protein	Test-Kit + Provider
SFA	2	25.03.21	X	X	positive	negative		Food item, DNA	SFA = Sure Food ALLERGEN, R-Biopharm / Congen
SFA	4	07.04.21	X	X	positive	negative	1ug/Swab	Food item, total	SFA = Sure Food ALLERGEN, R-Biopharm / Congen
SFA	22		X	X	positive	negative		Food item, DNA	SFA = Sure Food ALLERGEN, R-Biopharm / Congen
SFA-4p	19	22.03.21	X	X	positive	negative		Please select!	SFA-4p = Sure Food Allergen 4plex, R-Biopharm / Congen
SFA-4p	21	24.06.21	X	X	positive	negative		Please select!	SFA-4p = Sure Food Allergen 4plex, R-Biopharm / Congen
div	16	13.05.21	X	X	positive	negative		LD PCR=150 pg DNA (0.1% relative to reference material)	Real Time PCR Internal Method: MEB61
div	17	07.05.21	X	X	positive	negative	10	Food item, DNA	other: please fill in!

Other details to the Methods

Meth. Abr.	Evaluation number	Method-No./ Test-Kit No.	Specifity	Remarks to the Method (Extraction and Determination)	Further Remarks
		Article-No. / ASU-No.	Target-Sequence/ DNA	e.g. Extraction / enzymes / clean-up / real time PCR / gel electrophoresis / cycles	
SFA	2	S3601			Analytical limit of detection: 0,4 ppm
SFA	4	S3601	As per kit Instructions	As per kit instructions	
SFA	22				
SFA-4p	19	S3401	Glycine max	Extraction with: SureFood® PREP Advanced, Art. No. S1053	
SFA-4p	21	S3401		CTAB Isolation/Real Time PCR	Surface swab with liquid swab
div	16	Internal Method: MEB61	Le1 gene	Extraction performed using the DNeasy Mericon Qiacube HT kit. Detection performed by Real-Time PCR (45 cycles of amplification)	
div	17	internal Method		CTAB / Proteinase K / Rnase A / Maxwell / Real-time PCR 45 Cycles	in additional material

5.2 Information on the Proficiency Test (PT)

Before the PT the participants received the following information in the sample cover letter:

PT number	***DLA ptASW1 (2021)***
PT name	***Allergen Swab Test I: Gluten, Peanut, Milk and Soya***
Sample matrix	*Plates A, B, C and D: 2 x 4 Test areas* *Plastic trays / ingredients: additives and allergenic foods*
Number of samples and sample amount	*4 Plates with 8 different test areas of approx. 30 cm².*
Storage	*Samples A + B:* *room temperature (PT period), cooled 2 - 10°C (long term)*
Intentional use	*Laboratory use only (quality control samples)*
Parameter	*qualitative: **Gluten and Peanut** (Plates A and B)* *qualitative: **Milk and Soya** (Plates C and D)* *Levels: approx. 10 - 100 µg / test area*
Methods of analysis	*Swab test with optional analytical method.*
Notes to analysis	*The analysis of PT samples should be performed like a routine laboratory analysis. The test areas are labeled with the allergen to be tested. It is recommended to sample the entire test area (half the area of a plate) according to the instructions of the swab test method applied.*
Result sheet	*For each parameter two different test areas should be examined and one result each should be determined per test area.* *The results should be filled in the result submission file.*
Units	*posititv / negativ (limit of detection in µg/cm²)*
Number of digits	*at least 2*
Result submission	*The result submission file should be sent by e-mail to:* ***pt@dla-lvu.de***
Last Deadline	***the latest May 14th 2021***
Evaluation report	*The evaluation report is expected to be completed 6 weeks after deadline of result submission and sent as PDF file by e-mail.*
Coordinator and contact person of PT	*Matthias Besler-Scharf PhD*

** Control of mixture homogeneity and qualitative testings are carried out by DLA. Any testing of the content, homogeneity and stability of PT parameters is subcontracted by DLA.*

6. Index of participant laboratories

Teilnehmer / Participant	Ort / Town	Land / Country
		SPAIN
		Germany
		Germany
		ITALY
		PORTUGAL
		Germany
		ITALY
		SPAIN
		SWEDEN
		Germany
		GREECE
		Germany
		ITALY
		GREAT BRITAIN
		Germany
		ITALY
		Germany
		Germany
		Germany
		USA
		USA
		GREECE

[Die Adressdaten der Teilnehmer wurden für die allgemeine Veröffentlichung des Auswerte-Berichts nicht angegeben.]

[The address data of the participants were deleted for publication of the evaluation report.]

7. Index of references

1. DIN EN ISO/IEC 17025:2005; Allgemeine Anforderungen an die Kompetenz von Prüf- und Kalibrierlaboratorien / General requirements for the competence of testing and calibration laboratories
2. DIN EN ISO/IEC 17043:2010; Konformitätsbewertung – Allgemeine Anforderungen an Eignungsprüfungen / Conformity assessment – General requirements for proficiency testing
3. ISO 13528:2015 & DIN ISO 13528:2009; Statistische Verfahren für Eignungsprüfungen durch Ringversuche / Statistical methods for use in proficiency testing by inter-laboratory comparisons
4. ASU §64 LFGB: Planung und statistische Auswertung von Ringversuchen zur Methoden-validierung / DIN ISO 5725 series part 1, 2 and 6 Accuracy (trueness and preci-sion) of measurement methods and results
5. Verordnung / Regulation 882/2004/EU; Verordnung über über amtliche Kontrollen zur Überprüfung der Einhaltung des Lebensmittel- und Futtermittelrechts sowie der Bestimmungen über Tiergesundheit und Tierschutz / Regulation on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
6. Evaluation of analytical methods used for regulation of food and drugs; W. Hor-witz; Analytical Chemistry, 54, 67-76 (1982)
7. The International Harmonised Protocol for the Proficiency Testing of Ananlytical Laboratories ; J.AOAC Int., 76(4), 926 – 940 (1993)
8. A Horwitz-like funktion describes precision in proficiency test; M. Thompson, P.J. Lowthian; Analyst, 120, 271-272 (1995)
9. Protocol for the design, conduct and interpretation of method performance studies; W. Horwitz; Pure & Applied Chemistry, 67, 331-343 (1995)
10. Recent trends in inter-laboratory precision at ppb and sub-ppb concentrations in relation to fitness for purpose criteria in proficiency testing; M. Thompson; Ana-lyst, 125, 385-386 (2000)
11. The International Harmonised Protocol for the Proficiency Testing of Analytical Chemistry Laboratories; Pure Appl Chem, 78, 145 – 196 (2006)
12. AMC Kernel Density - Representing data distributions with kernel density estim-ates, amc technical brief, Editor M Thompson, Analytical Methods Committee, AMCTB No 4, Revised March 2006 and Excel Add-in Kernel.xla 1.0e by Royal Society of Chemistry
13. EURACHEM/CITAC Leitfaden, Ermittlung der Messunsicherheit bei analytischen Messun-gen (2003); Quantifying Uncertainty in Analytical Measurement (1999)
14. GMP+ Feed Certification scheme, Module: Feed Safety Assurance, chapter 5.7 Check-ing procedure for the process accuracy of compound feed with micro tracers in GMP+ BA2 Control of residues, Version: 1st of January 2015 GMP+ International B.V.
15. MTSE SOP No. 010.01 (2014): Quantitative measurement of mixing uniformity and carry-over in powder mixtures with the rotary detector technique, MTSE Micro Tracers Services Europe GmbH
16. Homogeneity and stability of reference materials; Linsinger et al.; Accred Qual Assur, 6, 20-25 (2001)
17. AOAC Official Methods of Analysis: Guidelines for Standard Method Performance Re-quirements, Appendix F, p. 2, AOAC Int (2016)
18. Codex Alimentarius Commission (2010) - Guidelines on performance criteria and validation of methods for detection, identification and quantification of specific DNA sequences and specific protiens in foods, CAC/GL 74-2010
19. DIN EN ISO 15633-1:2009; Nachweis von Lebensmittelallergenen mit immunologischen Verfahren - Teil 1: Allgemeine Betrachtungen / Foodstuffs - Detection of food allergens by immunological methods - Part 1: General considerations
20. DIN EN ISO 15634-1:2009; Nachweis von Lebensmittelallergenen mit molekularbiologischen Verfahren - Teil 1: Allgemeine Betrachtungen / Foodstuffs - Detection of food allergens by molecular biological methods - Part 1: General considerations
21. DIN EN ISO 15842:2010 Lebensmittel – Nachweis von Lebensmittelallergenen – Allgemeine Betrachtungen und Validierung von Verfahren / Foodstuffs - Detection of food allergens - General considerations and validation of methods
22. Ministry of Health and Welfare, JSM, Japan 2006
23. Working Group Food Allergens, Abbott et al., Validation Procedures for Quantitative Food Allergen ELISA Methods: Community Guidance and Best Practices JAOAC Int. 93:442-50 (2010)

24. Working Group on Prolamin Analysis and Toxicity (WGPAT): Méndez et al. Report of a collaborative trial to investigate the performance of the R5 enzyme linked immunoassay to determine gliadin in gluten-free food. Eur J Gastroenterol Hepatol. 17:1053-63 (2005)
25. DLA Publikation: Performance of ELISA and PCR methods for the determination of allergens in food: an evaluation of six years of proficiency testing for soy (Glycine max L.) and wheat gluten (Triticum aestivum L.); Scharf et al.; J Agric Food Chem. 61(43):10261-72 (2013)
26. EFSA (2014) Scientific Opinion on the evaluation of allergenic foods and food ingredients for labelling purposes1, EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), European Food Safety Authority (EFSA), Parma, Italy, EFSA Journal 2014;12(11):3894
27. IRMM, Poms et al.; Inter-laboratory validation study of five different commercial ELISA test kits for determination of peanut residues in cookie and dark chocolate; European Commission, Joint Research Centre, Belgium; GE/R/FSQ/D08/05/2004
28. Jayasena et al. (2015) Comparison of six commercial ELISA kits for their specificity and sensitivity in detecting different major peanut allergens. J Agric Food Chem. 2015 Feb 18;63(6):1849-55
29. ASU §64 LFGB L 06.00-56 Bestimmung von Sojaprotein in Fleisch und Fleischerzeugnissen Enzymimmunologisches Verfahren (2007) [Determination of soyprotein in meat and meat products by enzyme immunoassay]
30. ASU §64 LFGB L 00.00-69 Bestimmung von Erdnuss-Kontaminationen in Lebensmitteln mittels ELISA im Mikrotiterplattensystem (2003) [Foodstuffs, determination of peanut contamintions in foodstuffs by ELISA in microtiterplates]
31. ASU §64 LFGB L 44.00-7 Bestimmung von Haselnuss-Kontaminationen in Schokolade und Schokoladenwaren mittels ELISA im Mikrotiterplattensystem (2006) [Foodstuffs, determination of hazelnut contamintions in chocolate and chocolate products by ELISA in microtiterplates]