

New Independent comparison study **InviLisa® vs. market ELISAs**



The InviLisa® ELISA kits provide a comprehensive solution for the quantification of food allergens from a variety of sources, including different fresh and processed food products, rinse waters and environmental swab samples.

Comparative Performance of Commercial ELISA Kits for Allergen Detection in Food Matrices

Executive Summary

In an external laboratory study conducted by an accredited analytical laboratory, the performance of four Invitek Diagnostics allergen ELISA tests (gluten, milk, egg, and soya), was compared against ELISA test kits currently on the market from three other manufacturers.

Key findings

- Across the tested allergens, kits produced broadly similar quantitative results when normalized to the same units, but meaningful differences appeared by allergen and use-case.
- **Gluten:** Invitek Diagnostics showed the best precision and closest agreement to the calibrant; the Romer Labs assay over-estimated gluten and had the poorest precision.
- **Egg:** Invitek Diagnostics and Romer Labs aligned best to calibrant; Neogen had the poorest precision, while Neogen showed the best precision on proficiency and Internal quality control (IQC) materials.
- **Milk:** Invitek Diagnostics aligned best to calibrant; all kits showed wider dispersion on the proficiency cake mix.
- **Soya:** Invitek Diagnostics and R-Biopharm aligned similarly to calibrant and proficiency; Romer Labs showed larger variation and over-estimation vs calibrant.

1. Background

Food allergens such as gluten, egg, milk, and soya represent a significant concern in public health and food safety, particularly due to their potential to elicit adverse immunological responses in sensitized individuals. The accurate detection and quantification of these allergens in complex food matrices are essential for compliance with regulatory standards and for the protection of allergic consumers. Enzyme-linked immunosorbent assays (ELISAs) are among the most widely employed analytical methods for allergen detection, owing to their high sensitivity, specificity, and adaptability to routine laboratory workflows. However, the performance characteristics of ELISA kits can vary considerably across manufacturers and target analytes. This study presents a comparative evaluation of ELISA assays specific to gluten, egg, milk, and soya, from 4 different manufacturers with the aim of assessing their analytical robustness and practical applicability in food allergen monitoring.

2. Study Overview

The study was conducted by an accredited analytical laboratory (ISO 17025:2017) with an international reputation for its knowledge and experience of food and drink science and research. The aim of the study was to compare the performance of four Invitek Diagnostics allergen ELISA tests (gluten, milk, egg and soya) against ELISA test kits currently on the market from three other manufacturers (Neogen, R-Biopharm, Romer Labs).

The following four sample types were analysed for all four different allergens:

- (i) a blank incurred food matrix
- (ii) a proficiency material with a known consensus value
- (iii) an internal quality control (IQC) material
- (iv) a recognised calibration material

These samples were analysed with each of the different ELISA brands, by two independent analysts following the kit manufacturer instructions.

Result data were calculated from OD values as detailed in the assay instruction as well as by software associated with the plate reader with simple statistics (mean and % difference). Results have been standardised to the same reporting units using manufacturer provided conversion factors to assist comparison.

These reported results relate only to the materials tested. Any opinions and interpretations provided are not under any part of the external laboratory's accreditation or third-party certifications.

3. Materials & Methods

3.1 ELISA kits

The following ELISA kits were used in this study:

3.1.1 Gluten

Manufacturer	Product name	Product code	Lot number	Range of kit	Conversion factors
Invitek Diagnostics	InviLisa Gluten ELISA Kit	6032003200	E03C01240503	2.5 - 50 mg/kg gluten	None
Neogen	Veratox for Gliadin R5	8510	3000003006	2.5 – 40 mg/kg gliadin	Multiply by 2 for gliadin to gluten
R-Biopharm	RIDASCREEN Gliadin	R7001	21253	5 – 80 mg/kg gluten	Multiply by 2 for gliadin to gluten
Romer Labs	AgraQuant Gluten G12	10001994	1000059892	4 – 200 mg/kg gluten	None

Note: Neogen's Veratox for Gliadin R5 results data not included in study due to observed kit issues.

3.1.2 Egg

Manufacturer	Product name	Product code	Lot number	Range of kit	Conversion factors
Invitek Diagnostics	InviLisa Egg ELISA Kit	6032004200	E04C01240503	1 – 10 mg/kg whole egg powder	Multiply by 0.3 for egg white protein
Neogen	Veratox for Egg	8450	3000001990	2.5 – 25mg/kg whole egg	Multiply by 0.4805 for whole egg protein
R-Biopharm	RIDASCREEN Egg	R6411	23472	0.25 – 2 mg/kg whole egg powder	Multiply by 0.49 for whole egg protein Multiply by 0.263 for egg white protein
Romer Labs	AgraQuant Egg White	10002026	1000046520	0.4 – 10 mg/kg egg white protein	Multiply by 9.17 for egg white

3.1.3 Milk

Manufacturer	Product name	Product code	Lot number	Range of kit	Conversion factors
Invitek Diagnostics	InviLisa Milk ELISA Kit	6032002200	E02C01240430	0.5 – 10 mg/kg milk protein	None
Neogen	Veratox for Total Milk	8470	322851	2.5 – 25 mg/kg nonfat dried milk	Multiply by 0.36 for milk protein
R-Biopharm	RIDASCREEN FAST Milk	R4652	22193	2.5 – 67.5 mg/kg milk protein	Multiply by 2.84 for skim milk powder
Romer Labs	AgraQuant Milk	10002080	1000050823	0.4 – 10 mg/kg milk protein	Multiply by 2.86 for skim milk powder Multiply by 4.35 for whole milk powder

3.1.4 Soya

Manufacturer	Product name	Product code	Lot number	Range of kit	Conversion factors
Invitek Diagnostics	InviLisa Soya ELISA Kit	6032006200	E06C01240522	0.8 – 10 mg/kg soya protein	Multiply by 2.5 for soya flour
Neogen	Veratox for Soy	8410	324856	2.5 – 25 mg/kg soy flour	Multiply by 0.515 for soy protein
R-Biopharm	RIDASCREEN FAST Soya	R7102	22113	2.5 – 20 mg/kg soya protein	None
Romer Labs	AgraQuant Soy	10002015	1000056264	0.04 – 1 mg/kg soy trypsin inhibitor	Multiply by 6.67 for soy protein Multiply by 425 for soy flour (unroasted)

3.2 Samples

The following four sample types were analysed for all allergens by the four different ELISA test kit brands:

- (i) A blank incurred food matrix
- (ii) A proficiency material with a known consensus value
- (iii) An internal quality control (IQC) material
- (iv) A recognised calibration material

3.2.1 Incurred food matrix- Blank

Gluten free breadcrumbs. Product code: A13099 (PJ040)

Tested for all four allergens.

3.2.2 Proficiency materials

Gluten, egg and milk: proficiency material T27364B - cake mix.

Soya: proficiency material T27356B - wheat flour.

3.2.3. Internal quality control material (IQCM)

- (i) Biscuit crumb incurred with gluten, egg and milk (PI861)
- (ii) Wheat flour spiked with soya flour (PJ076)

3.2.4. Calibration materials

(i) Gluten: PWG-gliadin. Protein content is 96.9%, from WGPAT, Specification of PWG-Gliadin. Protein content taken into account when calculating required dilutions.

(ii) Egg: Reference material LGC7422- egg white powder sourced from LGC. Batch number: 001/sample 0094. Nitrogen content from Statement of Measurement sheet (Doc revision June 2022) is 13.49g/100g. Protein content is therefore 84.3g/100g (84.3% protein) (based on a nitrogen conversion factor of 6.25).

(iii) Milk: Reference material LGC7421- skimmed milk powder sourced from LGC. Batch number: 001/sample 0047. Nitrogen content from Statement of Measurement sheet (Doc revision June 2022) is 5.40g/100g. Protein content is therefore 34.5g/100g (34.5%) (based on a nitrogen conversion factor of 6.38)

(iv) Soya: Soybean flour, Type I. 54% protein. Sourced from Sigma Aldrich. Sigma product code: S9633. CBRI code: PJ106. Batch number: SLCJ6121.

Preparation of Calibrants

(i) **Gluten:** Using the PWG-gliadin a stock solution of 0.5mg/mL PWG-gliadin was prepared in 60% aqueous solution and stored at ambient in the dark. This stock solution was extracted 1/100 following the extraction method in the kit instructions. A series of dilutions were applied to the extract to target a result in the middle of each standard curve.

Kit	Range of standard curve	Target result	Total dilution of PWG-gliadin on top of the nominal*
InviLisa Gluten ELISA Kit	2.5 – 50 mg/kg gluten	25 mg/kg gluten	1/77,520
Veratox for Gliadin R5	2.5 – 50 mg/kg gluten	10 mg/kg gliadin	1/96,896
RIDASCREEN Gliadin	5 – 80 mg/kg gluten	40 mg/kg gluten	1/48,448
AgraQuant Gluten G12	4 – 200 mg/kg gluten	80 mg/kg gluten	1/24,225

**This is the total dilution (preparation of stock solution, extraction and dilution of extract) applied to the PWG-gliadin powder, on top of any nominal dilutions used in the ELISA kit, where the nominal dilutions are already taken into account to allow for direct reading of results from the standard curve.*

(ii) **Egg:** Egg white powder (LGC7422) was extracted 1/400 following the extraction method in the kit instructions. A series of dilutions were applied to the extract to target a result in the middle of each standard curve.

Kit	Range of standard curve	Target result	Total dilution of egg white powder on top of the nominal*
InviLisa Egg ELISA Kit	1 – 10 mg/kg whole egg powder	5 mg/kg whole egg powder	1/562,000
Veratox for Egg	2.5 – 25 mg/kg whole egg	5 mg/kg whole egg	1/562,000
RIDASCREEN Egg	0.25 – 2 mg/kg whole egg powder	1 mg/kg whole egg powder	1/6,540,000
AgraQuant Egg White	0.4 – 10 mg/kg egg white protein	1 mg/kg whole egg powder	1/210,750

**This is the total dilution (extraction and dilution of extract) applied to the egg white powder, on top of any nominal dilutions used in the ELISA kit, where the nominal dilutions are already taken into account to allow for direct reading of results from the standard curve.*

(iii) **Milk:** Skimmed milk powder (LGC7421) was extracted 1/400 following the extraction method in the kit instructions. A series of dilutions were applied to the extract to target a result in the middle of each standard curve.

Kit	Range of standard curve	Target result	Total dilution of skimmed milk powder on top of the nominal*
InviLisa Milk ELISA Kit	0.5 – 10 mg/kg milk protein	5 mg/kg milk protein	1/69,000
Veratox for Total Milk	2.5 – 25 mg/kg non-fat dried milk (NFDM)	10 mg/kg NFDM	1/95,800
RIDASCREEN FAST Milk	2.5 – 67.5 mg/kg milk protein	22.5 mg/kg milk protein	1/15,336
AgraQuant Milk	0.4 – 10 mg/kg milk protein	4 mg/kg milk protein	1/86,250

**This is the total dilution (extraction and dilution of extract) applied to the skimmed milk powder, on top of any nominal dilutions used in the ELISA kit, where the nominal dilutions were already taken into account to allow for direct reading of results from the standard curve*

(iv) **Soya:** Soybean flour (PJ106) was extracted 1/400 following the extraction method in the kit instructions and the extract diluted to target a result in the middle of each standard curve.

Kit	Range of standard curve	Target result	Total dilution of soybean flour on top of the nominal*
InviLisa Soya ELISA Kit	0.8 – 10 mg/kg soya protein	5 mg/kg soya protein	1/108,000
Veratox for Soy	2.5 – 25 mg/kg soy flour	10 mg/kg soy flour	1/100,000
RIDASCREEN FAST Soya	2.5 – 20 mg/kg soya protein	10 mg/kg soya protein	1/54,000
AgraQuant Soy	0.04 – 1 mg/kg soy trypsin inhibitor	1 mg/kg soy trypsin inhibitor	1/90,000

**This is the total dilution (extraction and dilution of extract) applied to the skimmed milk powder, on top of any nominal dilutions used in the ELISA kit, where the nominal dilutions were already taken into account to allow for direct reading of results from the standard curve.*

4. Results

4.1 General Results

Whilst interpretation of the data is limited to the materials tested, the following observations and conclusions have been drawn:

- All the test kit brands tested for quantitation of gluten, egg, milk, and soya provided broadly similar results when expressed in the same reporting units.
- Differences in performance observed related to the allergen, the brand, the degree of variation in the data by the analyst and between analysts; plus differences in accuracy relative to a calibrant and in some cases to a proficient material.
- Results whether determined using the curve fit software of the plate reader were broadly similar to the manufacturers own software.

4.2 Gluten

With gluten, the InviLisa Gluten ELISA Kit demonstrated the best precision and closeness in agreement to the calibrant compared to the Codex recommended Type 1 method and AOAC OM certified R5-based ELISA RIDASCREEN Gliadin and also the G12-based assay (AgraQuant Gluten G12, which had the poorest precision and over-estimated gluten).

%CV = Variation between operators.

Multiskan based results

Name	Description	InviLisa Gluten ELISA Kit (mg gluten/kg)			RIDASCREEN Gliadin (mg gluten/kg)			AgraQuant Gluten G12 (mg gluten/kg)		
		%CV	Mean	Assigned	%CV	Mean	Assigned	%CV	Mean	Assigned
Blank	Blank breadcrumbs		<2.5			<5			5.1	
Proficiency	Cake mix T27364B	8.7	42.2		20.3	35.1		40.1	98.2	
Proficiency	Cake mix T27364B	2.7	50.6		27.3	45.6		39.5	80.9	
IQCM	Incurred biscuit crumb	25.6	20.4		1.5	23.9		41.3	37.0	
Calibrant	PWG-gliadin	8.7	23.6	25.0	5.2	32.7	40.0	1.5	104.5	80.0

4.3 Egg

With egg, the InviLISA Egg ELISA Kit and AgraQuant Egg White showed similar levels of trueness to the calibrant and the Veratox for Egg the least, with large variation in the data between operators as with the RIDASCREEN kit. However, the Veratox ELISA did demonstrate the best levels of precision with the proficiency and IQCM materials. The RIDASCREEN Egg is designed to be suitable for detecting processed egg, like the InviLISA Egg ELISA Kit, though with these samples this difference was not apparent.

%CV = Variation between operators.

Multiskan based results

		InviLISA Egg ELISA Kit (mg whole egg protein/kg)			Veratox for Egg (mg whole egg protein/kg)			RIDASCREEN Egg (mg whole egg protein/kg)			AgraQuant Egg White (mg whole egg protein/kg)		
Name	Description	%CV	Mean	Assigned	%CV	Mean	Assigned	%CV	Mean	Assigned	%CV	Mean	Assigned
Blank	Blank breadcrumbs	<0.5			<1.2			<0.1			<0.8		
Proficiency	Cake mix T27364B	7.3	20.9		3.5	26.2	22.1	14.2	22.4		12.7	15.6	
Proficiency	Cake mix T27364B	15.8	19.6		10.2	26.6	22.1	10.9	23.0		21.3	16.9	
IQCM	Incurred biscuit crumb	2.5	16.7		7.0	18.8		6.3	42.4		7.7	8.5	
Calibrant	Egg white powder	3.2	3.0	2.5	30.5	4.2	2.4	36.3	0.3	0.5	2.6	9.9	8.0

4.4 Milk

With milk, the InviLISA Milk ELISA Kit was the best aligned with the calibrant, however there was a wide dispersion of results for the proficiency cake mix sample with all the kits. Variation of data between operators was similar for all brands.

%CV = Variation between operators.

Multiskan based results

		InviLISA Milk ELISA Kit (mg milk protein/kg)			Veratox for Total Milk (mg milk protein/kg)			RIDASCREEN FAST Milk (mg milk protein/kg)			AgraQuant Milk (mg milk protein/kg)		
Name	Description	%CV	Mean	Assigned	%CV	Mean	Assigned	%CV	Mean	Assigned	%CV	Mean	Assigned
Blank	Blank breadcrumbs	<0.5			<0.9			<2.5			<0.4		
Proficiency	Cake mix T27364B	7.4	16.5		2.3	49.5	48.6	17.8	61.2	66.1	2.3	25.4	37.0
Proficiency	Cake mix T27364B	5.3	15.9		7.0	54.1	48.6	5.5	57.3	66.1	4.1	25.5	37.0
IQCM	Incurred biscuit crumb	3.4	19.7		33.6	19.2		35.4	39.5		3.9	23.1	
Calibrant	Skimmed milk powder	0.1	4.8	5.0	27.4	4.8	3.6	20.5	43.4	22.5	27.5	2.8	4.0

4.5 Soya

With soya, the InviLisa Soya ELISA Kit and the RIDASCREEN FAST Soya demonstrated similar levels of alignment with the calibrant and results with the proficiency sample. Conversely, the AgraQuant kit demonstrated large variation and over-estimation versus the calibrant.

%CV = Variation between operators.

Multiskan based results

Name	Description	InviLisa Soya ELISA Kit (mg soy protein/kg)			Veratox for Soy (mg soy protein/kg)			RIDASCREEN FAST Soya (mg soy protein/kg)			AgraQuant Soy (mg soy protein/kg)		
		%CV	Mean	Assigned	%CV	Mean	Assigned	%CV	Mean	Assigned	%CV	Mean	Assigned
Blank	Blank breadcrumbs	<0.8			<1.3			9.0			0.4		
Proficiency	Wheat flour	1.6	41.5		7.6	35.8	34.8	33.5	38.9	29.0	18.0	11.5	
Proficiency	Wheat flour	17.9	37.9		0.5	34.0	34.8	9.8	32.7	29.0	42.4	11.2	
IQCM	Wheat flour	0.5	36.9		11.0	23.8		15.9	27.3		36.5	8.5	
Calibrant	Soybean flour	3.6	4.5	5.0	18.7	7.6	5.2	1.3	9.0	10.0	47.1	2.8	1.0

5. Conclusion

The InviLisa® ELISA kits demonstrated strong precision, reliable alignment with calibrants, and consistent performance across gluten, egg, milk, and soya detection. Compared to other manufacturers' kits, Invitek Diagnostics' assays showed superior accuracy and lower variability between analysts. These results prove their suitability for dependable allergen quantitation in diverse food matrices.

6. Appendix

6.1 Calculation of results

Results were calculated using the Multiskan Ascent plate reader and its associated software. For those manufacturers with their own calculation spreadsheets/software, results were also calculated using these.

Manufacturer	Kit	Manufacturer's calculation software	Type of standard curve
Invitek Diagnostics	Gluten	None	4 Parameter logistic
	Egg		Cubic Spline
	Milk		Cubic Spline
	Soy		Cubic Spline
Neogen	Gluten	Veratox for Windows v3.9	Log-logit
	Egg		Log-logit
	Milk		Log-logit
	Soy		Log-logit
R-Biopharm	Gluten	RIDASOFT Win.Net version 1.4.1	Cubic Spline
	Egg		4 Parameter logistic
	Milk		Cubic Spline
	Soy		Cubic Spline
Romer Labs	Gluten	Romer spreadsheet v04	Cubic Spline
	Egg		4 Parameter logistic
	Milk		4 Parameter logistic
	Soy		4 Parameter logistic

6.2 Results of Multiskan vs. Manufacturer Software

6.2.1 Gluten

Invitek Diagnostics:

Test Kit		InviLisa Gluten ELISA Kit				
Samples		Multiskan Ascent results (mg gluten/kg)				Assigned Value (mg gluten /kg)
Name	Description	A1	A2	Operator %CV	Mean	
Blank	Blank breadcrumbs	<2.5	<2.5		<2.5	
Proficiency	Cake mix T27364B	44.9	39.6	8.7	42.2	
Proficiency	Cake mix T27364B	49.7	51.6	2.7	50.6	
IQCM	Incurred biscuit crumb	24.1	16.7	25.6	20.4	
Calibrant	PWG-gliadin	22.2	25.1	8.7	23.6	25.0

Note: A1= Analyst 1 A2= Analyst 2

R-Biopharm:

Test Kit		RIDASCREEN Gliadin								
Samples		Multiskan Ascent results (mg gluten/kg)				Manufacturer software results (mg gluten/kg)				Assigned Value (mg gluten/kg)
Name	Description	A1	A2	Operator %CV	Mean	A1	A2	Operator %CV	Mean	
Blank	Blank breadcrumbs	<5	<5		<5	<5	<5		<5	
Proficiency	Cake mix T27364B	30.0	40.1	20.3	35.1	30.4	40.2	19.8	35.3	41.6
Proficiency	Cake mix T27364B	36.8	54.4	27.3	45.6	36.9	55.6	28.6	46.3	41.6
IQCM	Incurred biscuit crumb	24.1	23.6	1.5	23.9	24.4	23.2	3.5	23.8	
Calibrant	PWG-gliadin	31.5	33.9	5.2	32.7	32.0	33.4	3.1	32.7	40.0

Note: A1= Analyst 1 A2= Analyst 2

Romer Labs:

Test Kit		AgraQuant Gluten G12								
Samples		Multiskan Ascent results (mg gluten/kg)				Manufacturer software results (mg gluten/kg)				Assigned Value (mg gluten/kg)
Name	Description	A1 mean	A2 mean	Operator %CV	Mean	A1 mean	A2 mean	Operator %CV	Mean	
Blank	Blank breadcrumbs	4.6	<4.0			5.1	<4.0		5.1	
Proficiency	Cake mix T27364B	126.1	70.3	40.1	35.1	105.9	76.5	46.3	113.7	
Proficiency	Cake mix T27364B	103.5	58.3	39.5	45.6	36.9	63.0	42.6	90.2	
IQCM	Incurred biscuit crumb	47.8	26.2	41.3	23.9	24.4	28.3	37.8	38.6	
Calibrant	PWG-gliadin	105.6	103.3	1.5	32.7	32.0	119.9	3.5	122.9	80.0

Note: A1= Analyst 1 A2= Analyst 2

6.2.2 Egg

Invitex Diagnostics:

Test Kit		InviLisa Egg ELISA Kit					
Samples		Multiskan Ascent results (mg whole egg protein/kg)				Assigned Value (mg/kg whole egg protein)	
Name	Description	A1	A2	Operator %CV	Mean		
Blank	Blank breadcrumbs	<0.5	<0.5		<0.5		
Proficiency	Cake mix 27364B	19.8	22.0	7.3	20.9		
Proficiency	Cake mix 27364B	17.4	21.8	15.8	19.6		
IQCM	Incurred biscuit crumb	16.5	17.0	2.5	16.7		
Calibrant	Egg white powder	2.9	3.0	3.2	3.0	2.5	

Note: A1= Analyst 1 A2= Analyst 2

Neogen:

Test Kit		Veratox for Egg								
Samples		Multiskan Ascent results (mg whole egg protein/kg)				Manufacturer software results (mg whole egg protein/kg)				Assigned Value (mg whole egg protein/kg)
Name	Description	A1 mean	A2 mean	Operator %CV	Mean	A1 mean	A2 mean	Operator %CV	Mean	
Blank	Blank breadcrumbs	<1.2	<1.2		<1.2	<1.2	<1.2		<1.2	
Proficiency	Cake mix 27364B	26.8	25.5	3.5	26.2	26.2	25.3	2.5	25.7	22.1
Proficiency	Cake mix 27364B	24.7	28.5	10.2	26.6	26.6	28.0	10.4	26.1	22.1
IQCM	Incurred biscuit crumb	17.9	19.8	7.0	18.8	18.8	20.0	7.5	19.0	
Calibrant	Egg white powder	3.3	5.1	30.5	4.2	4.2	5.2	31.8	4.3	2.4

Note: A1= Analyst 1 A2= Analyst 2

R-Biopharm:

Test Kit		RIDASCREEN Egg								
Samples		Multiskan Ascent results (mg whole egg protein/kg)				Manufacturer software results (mg whole egg protein/kg)				Assigned Value (mg whole egg protein/kg)
Name	Description	A1	A2	Operator %CV	Mean	A1	A2	Operator %CV	Mean	
Blank	Blank breadcrumbs	<0.1	<0.1		<0.1	<0.1	<0.1		<0.1	
Proficiency	Cake mix 27364B	20.2	24.7	14.2	22.4	20.3	24.7	14.0	22.5	
Proficiency	Cake mix 27364B	21.2	24.8	10.9	23.0	21.4	24.8	10.6	23.1	
IQCM	Incurred biscuit crumb	44.3	40.5	6.3	42.4	44.6	40.5	6.8	42.6	
Calibrant	Egg white powder	0.2	0.4	36.3	0.3	0.2	0.4	37.8	0.3	0.5

Note: A1= Analyst 1 A2= Analyst 2

Romer Labs:

Test Kit		AgraQuant Egg White								
Samples		Multiskan Ascent results (mg whole egg protein/kg)				Manufacturer software results (mg whole egg protein/kg)				Assigned Value (mg whole egg protein/kg)
Name	Description	A1	A2	Operator %CV	Mean	A1	A2	Operator %CV	Mean	
Blank	Blank breadcrumbs	<0.8	<0.8		<0.8	<0.8	<0.8		<0.8	
Proficiency	Cake mix 27364B	17.0	14.2	12.7	15.6	17.8	15.0	12.1	16.4	
Proficiency	Cake mix 27364B	19.5	14.4	21.3	16.9	21.8	15.0	26.3	18.4	
IQCM	Incurred biscuit crumb	9.0	8.0	7.7	8.5	9.6	8.0	13.0	8.8	
Calibrant	Egg white powder	10.1	9.8	2.6	9.9	11.4	10.9	2.9	11.1	8

Note: A1= Analyst 1 A2= Analyst 2

6.2.3 Milk

Invitex Diagnostics:

Test Kit		InviLisa Milk ELISA Kit					
Samples		Multiskan Ascent results (mg milk protein/kg)				Assigned Value (mg/kg milk protein)	
Name	Description	A1	A2	Operator %CV	Mean		
Blank	Blank breadcrumbs	<0.5	<0.5		<0.5		
Proficiency	Cake mix 27364B	17.4	15.7	7.4	16.5		
Proficiency	Cake mix 27364B	15.3	16.5	5.3	15.9		
IQCM	Incurred biscuit crumb	19.2	20.2	3.4	19.7		
Calibrant	Skimmed milk powder	4.8	4.8	0.1	4.8	5.0	

Note: A1= Analyst 1 A2= Analyst 2

Neogen:

Test Kit		Veratox for Total Milk								
Samples		Multiskan Ascent results (mg milk protein/kg)				Manufacturer software results (mg milk protein/kg)				Assigned Value (mg milk protein/kg)
Name	Description	A1	A2	Operator %CV	Mean	A1	A2	Operator %CV	Mean	
Blank	Blank breadcrumbs	<0.9	<0.9		<0.9	<0.9	<0.9		<0.9	
Proficiency	Cake mix 27364B	50.3	48.7	2.3	49.5	54.1	49.8	5.8	51.9	48.6
Proficiency	Cake mix 27364B	51.5	56.8	7.0	54.1	54.7	57.7	3.8	56.2	48.6
IQCM	Incurred biscuit crumb	23.7	14.6	33.6	19.2	25.7	14.7	38.6	20.2	
Calibrant	Skimmed milk powder	3.8	5.7	27.4	4.8	4.1	5.8	23.6	5.0	3.6

Note: A1= Analyst 1 A2= Analyst 2

R-Biopharm:

Test Kit		RIDASCREEN FAST Milk								
Samples		Multiskan Ascent results (mg milk protein/kg)				Manufacturer software results (mg milk protein/kg)				Assigned Value (mg milk protein/kg)
Name	Description	A1	A2	Operator %CV	Mean	A1	A2	Operator %CV	Mean	
Blank	Blank breadcrumbs	<2.5	<2.5		<2.5	<2.5	<2.5		<2.5	
Proficiency	Cake mix 27364B	52.7	66.4	16.2	59.6	53.5	68.9	17.8	61.2	66.1
Proficiency	Cake mix 27364B	58.1	54.2	4.9	56.2	59.5	55.1	5.5	57.3	66.1
IQCM	Incurred biscuit crumb	30.2	49.0	33.7	39.6	29.6	49.3	35.4	39.5	
Calibrant	Egg white powder	35.6	47.3	20.0	41.5	37.1	49.7	20.5	43.4	22.5

Note: A1= Analyst 1 A2= Analyst 2

Romer Labs:

Test Kit		AgraQuant Milk								
Samples		Multiskan Ascent results (mg milk protein/kg)				Manufacturer software results (mg milk protein/kg)				Assigned Value (mg milk protein/kg)
Name	Description	A1	A2	Operator %CV	Mean	A1	A2	Operator %CV	Mean	
Blank	Blank breadcrumbs	<0.4	<0.4		<0.4	<0.4	<0.4		<0.4	
Proficiency	Cake mix 27364B	24.9	25.8	2.3	25.4	25.69	26.32	1.7	26.0	37.0
Proficiency	Cake mix 27364B	26.2	24.8	4.1	25.5	26.6	25.55	2.8	26.1	37.0
IQCM	Incurred biscuit crumb	22.5	23.8	3.9	23.1	25.1	26.5	3.8	25.8	
Calibrant	Skimmed milk powder	2.2	3.3	27.5	2.8	2.51	3.49	23.1	3.0	4.0

Note: A1= Analyst 1 A2= Analyst 2

6.2.4 Soya

Invitex Diagnostics:

Test Kit		InviLisa Soya ELISA Kit					
Samples		Multiskan Ascent results (mg soya protein/kg)				Assigned Value (mg/kg soya protein)	
Name	Description	A1	A2	Operator %CV	Mean		
Blank	Blank breadcrumbs	<0.8	<0.8		<0.8		
Proficiency	Wheat flour	41.0	42.0	1.6	41.5		
Proficiency	Wheat flour	42.7	33.1	17.9	37.9		
IQCM	Wheat flour	37.0	36.7	3.4	36.9		
Calibrant	Soybean flour	4.4	4.6	3.6	4.5	5.0	

Note: A1= Analyst 1 A2= Analyst 2

Neogen:

Test Kit		Veratox for Soy								
Samples		Multiskan Ascent results (mg soya protein/kg)				Manufacturer software results (mg soya protein/kg)				Assigned Value (mg soya protein/kg)
Name	Description	A1	A2	Operator %CV	Mean	A1	A2	Operator %CV	Mean	
Blank	Blank breadcrumbs	<1.3	<1.3		<1.3	<1.3	<1.3		<1.3	
Proficiency	Wheat flour	37.7	33.9	7.6	35.8	39.6	37.0	4.7	36.3	34.8
Proficiency	Wheat flour	34.1	33.8	0.5	34.0	35.5	37.0	2.8	36.3	34.8
IQCM	Wheat flour	25.6	21.9	11.0	23.8	27.0	23.8	8.7	25.4	
Calibrant	Soybean flour	6.6	8.6	18.7	7.6	6.9	8.5	14.7	7.7	5.2

Note: A1= Analyst 1 A2= Analyst 2

R-Biopharm:

Test Kit		RIDASCREEN FAST Soya								
Samples		Multiskan Ascent results (mg soya protein/kg)				Manufacturer software results (mg soya protein/kg)				Assigned Value (mg soya protein/kg)
Name	Description	A1	A2	Operator %CV	Mean	A1	A2	Operator %CV	Mean	
Blank	Blank breadcrumbs	9.44	8.51		9.0	9.4	8.52		9.0	
Proficiency	Wheat flour	48.1	29.7	33.5	38.9	48.0	29.2	34.4	38.6	29.0
Proficiency	Wheat flour	35.0	30.5	9.8	32.7	34.6	30.0	10.2	32.3	29.0
IQCM	Wheat flour	30.3	24.2	15.9	27.3	30.0	23.8	16.3	26.9	
Calibrant	Soybean flour	8.9	9.1	1.3	9.0	8.9	9.0	1.0	8.9	10.0

Note: A1= Analyst 1 A2= Analyst 2

Romer Labs:

Test Kit		AgraQuant Soy								
Samples		Multiskan Ascent results (mg soya protein/kg)				Manufacturer software results (mg soya protein/kg)				Assigned Value (mg soya protein/kg)
Name	Description	A1	A2	Operator %CV	Mean	A1	A2	Operator %CV	Mean	
Blank	Blank breadcrumbs	0.3	0.5		0.4	0.27	0.47		0.4	
Proficiency	Wheat flour	10.1	13.0	18.0	11.5	12.3	14.9	13.5	13.6	
Proficiency	Wheat flour	7.9	14.6	42.4	11.2	8.9	16.7	42.7	12.8	
IQCM	Wheat flour	6.3	10.7	36.5	8.5	6.5	5.9	6.8	6.2	
Calibrant	Soybean flour	1.9	3.77	47.1	2.8	2.2	4.1	43.2	3.2	1.0

Note: A1= Analyst 1 A2= Analyst 2

6.3 Additional Sample Dilutions

(i) Additional dilutions in the gluten assays

The table below details additional dilutions applied to the sample extracts above the nominal dilution stated for each kit.

Test Kit	Sample	Additional dilution	
		A1	A2
InviLisa Gluten ELISA Kit	27364B	1/2	1/2
Veratox for Gliadin R5	27364B	1/3	1/3

(ii) Additional dilutions in the egg assays

The table below details additional dilutions applied to the sample extracts above the nominal dilution stated for each kit.

Test Kit	Sample	Additional dilution	
		A1	A2
InviLisa Egg ELISA Kit	A5107	1/50	1/50
	27364B	1/20	1/20
	PI861	1/10	NA
Veratox for Egg	A5107	1/2	1/2
	27364B	1/3	1/3
	PI861	1/10	1/10
RIDASCREEN Egg	A5107	1/500	1/2000
	27364B	1/50	1/50
	PI861	1/100	1/100
AgraQuant Egg White	27364B	1/2	1/2

(iii) Additional dilutions in the milk assays

The table below details additional dilutions applied to the sample extracts above the nominal dilution stated for each kit.

Test Kit	Sample	Additional dilution	
		A1	A2
InviLisa Milk ELISA Kit	27364B	1/2	1/2
	PI861	1/10	1/10
Veratox for Total Milk	27364B	1/10	1/10
	PI861	1/5	1/5
RIDASCREEN FAST Milk	27364B	1/2	1/2
	PI861	1/2	1/2
AgraQuant Milk	27364B	1/7	1/7
	PI861	1/10	1/10

(iv) Additional dilutions in the soya assays

The table below details additional dilutions applied to the sample extracts above the nominal dilution stated for each kit.

Test Kit	Sample	Additional dilution	
		A1	A2
InviLisa Soya ELISA Kit	27356B	1/10	1/10
	PJ076	1/8	1/8
Veratox for Soy	27356B	1/10	1/10
	PJ076	1/6	1/6
RIDASCREEN FAST Soya	27356B	1/5	1/5
	PJ076	1/4	1/4
	A5107	1/100	1/100
AgraQuant Soy	27356B	1/10	1/10
	PJ076	1/12	1/12



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