

## MARIA® for Foods – Validated Performance Parameters

Allergen:	Ana o 3	Ara h 1	Ara h 3	Ara h 6	Api g 1	Bos d 5 (Native)	Bos d 11	Cor a 9	Cyp c 1
<b>Linearity (R<sup>2</sup>)<sup>1</sup></b>	0.998	0.996	0.999	0.997	0.995	0.998	In progress	0.999	0.995
<b>Range (ng/ml)<sup>2</sup></b>	20-0.01	250-0.12	125-0.06	12.5-0.02	200-0.10	50-0.02	500-0.98	50-0.02	250-0.12
<b>Limit of Quantification<sup>3</sup></b>									
<i>LLOQ (ng/ml)<sup>3a</sup></i>	0.02-0.01	0.12-0.98	0.06	0.02	0.78-0.20	0.02	In progress	0.10-0.02	0.12
<i>ULOQ (ng/ml)<sup>3b</sup></i>	20-5	250	125	50-6.25	200-100	50	In progress	50	250-62.5
<b>Accuracy (% Recovery)<sup>4</sup></b>									
<i>Intra-assay (n=9)<sup>4a</sup></i>	101-119%	92-113%	89-101%	91-102%	83-106%	82-115%	In progress	78-94%	89-132%
<i>Inter-assay (n=36)<sup>4b</sup></i>	111%	101%	94%	97%	94%	92%	In progress	85%	113%
<b>Precision (%CV)<sup>5</sup></b>									
<i>Intra-assay (n=9)<sup>5a</sup></i>	2-6%	1-13%	4-9%	3-6%	2-10%	4-6%	In progress	3-6%	3-15%
<i>Inter-assay (n=36)<sup>5b</sup></i>	5%	6%	7%	5%	7%	6%	In progress	5%	6%

Allergen:	Gal d 1	Gal d 2	Gly m 5	Jug r 1	Shrimp Tropomyosin	Ses i 1	Sin a 1	Tri a 19
<b>Linearity (R<sup>2</sup>)<sup>1</sup></b>	0.992	0.997	0.998	0.999	0.997	In progress	0.999	0.999
<b>Range (ng/ml)<sup>2</sup></b>	500-0.49	50-0.02	500-0.49	20-0.01	25-0.02	12.5-0.01	15-0.01	300-0.15
<b>Limit of Quantification<sup>3</sup></b>								
<i>LLOQ (ng/ml)<sup>3a</sup></i>	1.95-0.24	0.02	0.49-0.24	0.01	0.02	In progress	0.01-0.12	0.59-1.17
<i>ULOQ (ng/ml)<sup>3b</sup></i>	500-250	50-12.5	500-125	20	50-12.5	In progress	15	300-37.5
<b>Accuracy (% Recovery)<sup>4</sup></b>								
<i>Intra-assay (n=9)<sup>4a</sup></i>	83-97%	97-118%	95-111%	80-131%	94-113%	In progress	72-131%	75-100%
<i>Inter-assay (n=36)<sup>4b</sup></i>	91%	106%	106%	98%	103%	In progress	97%	88%
<b>Precision (%CV)<sup>5</sup></b>								
<i>Intra-assay (n=9)<sup>5a</sup></i>	4-8%	2-7%	3-9%	0-12%	4-6%	In progress	2-22%	2-21%
<i>Inter-assay (n=36)<sup>5b</sup></i>	6%	4%	6%	5%	5%	In progress	8%	7%

### **Validation Notes:**

1. **Linearity** is the mean  $R^2$  of four MARIA plates for control curves generated using 4-parameter logistic fit.
2. **Range** is the average usable range of control curves from four MARIA plates that have a value of 70-130% of the expected concentration, with %CV < 15 between duplicate points.
3. **Limit of Quantification**
  - 3a. LLOQ - The lowest concentration points of four control curves with a recovery of 70-130% and %CV < 15, expressed as a range.
  - 3b. ULOQ - The highest concentration points of four control curves with a recovery of 70-130% and %CV < 15, expressed as a range.
4. **Accuracy**
  - 4a. Intra-assay - The range of average percent recovery of samples A, B, and C run in triplicate from four MARIA plates (n=9).
  - 4b. Inter-assay - The overall average percent recovery of samples A, B, and C run in triplicate from four MARIA plates (n=36).
5. **Precision**
  - 5a. Intra-assay - The range of average percent coefficient of variation of samples A, B, and C run in triplicate from four MARIA plates (n=9).
  - 5b. Inter-assay - The overall average percent coefficient of variation of samples A, B, and C run in triplicate from four MARIA plates (n=36).