700 Harris Street
Charlottesville, VA 22903
U.S.A.

Tel: (1) (434) 984-2304
Fax: (1) (434) 984-2709
www.inbio.com

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
Linearity (R^2)[1]	0.998	0.996	0.999	0.997	0.995	0.998	0.997	0.999	0.995
Range (ng/ml)[2]	20-0.01	250-0.12	125-0.06	12.5-0.02	200-0.10	50-0.10	500-0.98	50-0.02	250-0.12
Limit of Quantification[3]									
LLOQ (ng/ml)[3a]	0.01-0.02	0.12-0.98	0.06	0.02	0.20-0.78	0.10	0.98-3.91	0.02-0.10	0.12
ULOQ (ng/ml)[3b]	20-5	250	125	50-6.25	200-100	50	500-250	50	250-62.5
Accuracy (% Recovery)[4]									
Intra-assay (n=9)[4a]	101-119%	92-113%	89-101%	91-102%	83-106%	82-115%	89-132%	78-94%	89-132%
Inter-assay (n=36)[4b]	111%	101%	94%	97%	94%	92%	106%	85%	113%
Precision (%CV)[5]									
Intra-assay (n=9)[5a]	2-6%	1-13%	4-9%	3-6%	2-10%	4-6%	3-15%	3-6%	3-15%
Inter-assay (n=36)[5b]	5%	6%	7%	5%	7%	6%	7%	5%	6%

Allergen:	Gal d 1	Gal d 2	Gly m 5	Jug r 1	Pru du 6	Ses i 1	Shrimp Tropomyosin	Sin a 1
Linearity (R^2)[1]	0.992	0.997	0.998	0.999	1.000	0.998	0.997	0.999
Range (ng/ml)[2]	500-0.98	50-0.02	500-0.98	20-0.01	125-0.24	12.5-0.02	25-0.02	15-0.01
Limit of Quantification[3]								
LLOQ (ng/ml)[3a]	0.24-1.95	0.02	0.24-0.49	0.01	0.24	0.02-0.05	0.02	0.01-0.12
ULOQ (ng/ml)[3b]	500-250	50-12.5	500-125	20	125	12.5-6.25	50-12.5	15
Accuracy (% Recovery)[4]								
Intra-assay (n=9)[4a]	83-97%	97-118%	95-111%	80-131%	71-102%	79-117%	94-113%	72-131%
Inter-assay (n=36)[4b]	91%	106%	106%	98%	90%	96%	103%	97%
Precision (%CV)[5]								
Intra-assay (n=9)[5a]	4-8%	2-7%	3-9%	0-12%	4-15%	2-14%	4-6%	2-22%
Inter-assay (n=36)[5b]	6%	4%	6%	5%	7%	6%	5%	8%

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).