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ELISA 2.0 – Validated Performance Parameters

Food Allergens:

	FOODS											
Allergen:	**Ana o 3**	**Ara h 1**	**Ara h 2**	**Ara h 3**	**Ara h 6**	**Ara h 8**	**Cor a 9**	**Gal d 1**	**Gal d 2**	**Gly m 5**	**Native Bos d 5**	**Shrimp Tropomyosin**
Linearity (R^2)[1]	1.0	1.0	0.999	0.999	1.0	1.0	0.998	1.0	1	1.0	1.0	0.999
Range (ng/ml)[2]	20-0.16	1000-31.25	125-0.98	62.5-0.49	25-0.05	12.5-0.20	50-0.39	250-7.81	50-0.39	250-1.95	12.5-0.10	25-0.20
Limit of Quantification[3]												
LLOQ (ng/ml)[3a]	0.16	31.25-15.63	3.91-0.49	1.95-0.49	0.20-0.05	1.56-0.20	0.78-0.39	7.80-3.90	0.78-0.39	3.91-1.95	0.78-0.10	0.39-0.10
ULOQ (ng/ml)[3b]	20-5	1000	250-31.25	62.5-31.25	25-12.5	25-6.25	100-12.5	250	100-25	250-62.5	25-12.5	25-6.25
Accuracy (% Recovery)[4]												
Intra-assay (n=9)[4a]	85-110%	82-124%	80-116%	74-127%	105-113%	100-109%	75-112%	89-101%	91-132%	93-119%	84-120%	95-115%
Inter-assay (n=54)[4b]	99%	109%	101%	97%	108%	102%	93%	95%	104%	105%	103%	108%
Precision (%CV)[5]												
Intra-assay (n=9)[5a]	4-10%	3-12%	7-14%	3-11%	7-13%	3-15%	5-15%	8-13%	5-16%	5-11%	4-9%	4-14%
Inter-assay (n=54)[5b]	8%	8%	10%	5%	8%	8%	10%	9%	11%	8%	6%	7%

1. **Linearity** is the mean R^2 of six ELISA plates for control curves generated using 4-parameter logistic fit.
2. **Range** is the average usable range of control curves from six ELISA 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 six control curves with a recovery of 70-130% and %CV <15, expressed as a range.
   - 3b. ULOQ - The highest concentration points of six 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 six ELISA plates (n=9).
   - 4b. Inter-assay - The overall average percent recovery of samples A, B, and C run in triplicate from six ELISA plates (n=54).
5. **Precision**
   - 5a. Intra-assay - The range of average percent coefficient of variation of samples A, B, and C run in triplicate from six ELISA plates (n=9).
   - 5b. Inter-assay - The overall average percent coefficient of variation of samples A, B, and C run in triplicate from six ELISA plates (n=54).