

QualityXplorer

Lot 3100004

Release date of expected values: February 18th 2025

DESCRIPTION:

The QualityXplorer can be used as an internal quality control material to monitor the test performance of ALEX², ALEX Air, ALEX Food or ALEX³ in your laboratory. The control should be processed like a standard patient serum sample according to the Instructions for Use of the respective product used. The values for the acceptance ranges in Table 1 are based on testing five batches per method (MAX9K, MAX45K, ImageXplorer), with five replicates per batch, giving a total of 75 measurements. The complete list of allergens below applies to ALEX² and ALEX³, the allergen panels ALEX Air and ALEX Food cover a subset of the listed allergens.

Please find expected values and acceptance ranges in the table below:

Allergen	Code	Expected min (kU _A /L)	Expected max (kU _A /L)
Asp f 4	m221	4,9	21,32
Fel d 1	e94	3,37	13,65
Jug r 3	f539	4,58	20,83
Mal d 3	f435	5,87	37,07
Mus m 1	e103	2,59	9,83
Ory c 2	e310	4,57	33,05
Pen m 3	f552	7,78	47,85
Phl p 5.0101	g215	4,08	15,15
Pla a 3	t302	0,5	8,89
Zea m 14	f523	4,84	24,19

Table 1.: Expected values and acceptance ranges for QualityXplorer Lot 3100004.

Note: After a minimum number of measurements (e.g., 20 measurements), instrument-specific intervals (2 and 3 standard deviations) can be displayed via the QC module in RAPTOR SERVER Analysis Software. In this way, the laboratory-specific intervals for each allergen can be determined more precisely. The reference values are for informational purposes only and should not be regarded as rejection criteria if not met during a single run.