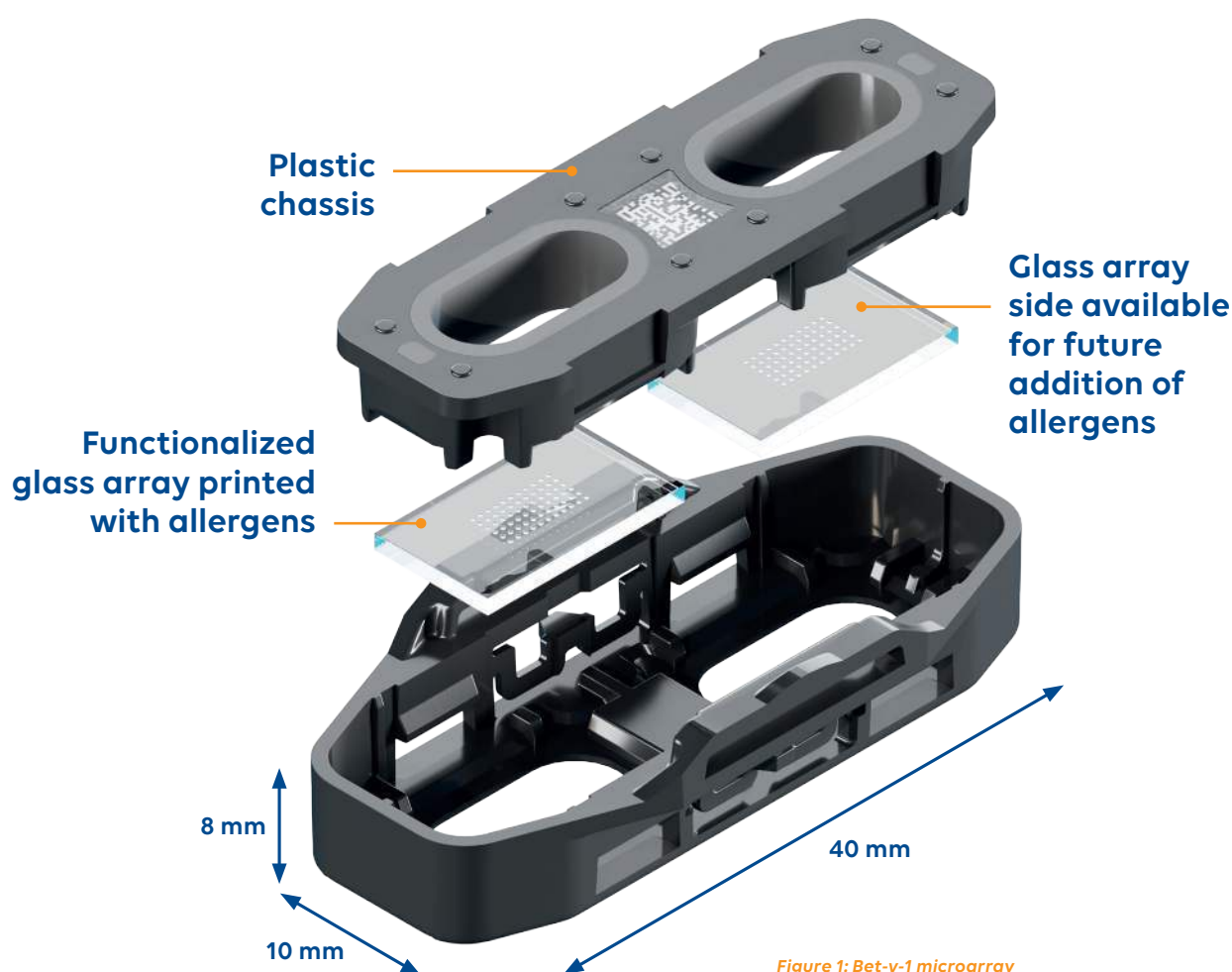


Performance characteristics of a novel, fully automated immunoassay microarray for the qualitative serological detection of specific IgE directed against Bet v 1

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Purpose

Bet v 1 (main allergen from the Birch tree pollen) is an important contributor to IgE-mediated allergic disorders. We report the performance characteristics of a novel, single-use, microarray immunoassay (MosaiQ® Allergy Bet v 1, AliveDx, Eysins, Switzerland) (Bet-v-1-Microarray) when used with the fully automated MosaiQ® system, for the qualitative detection of specific IgE (sIgE) directed against Bet v 1, compared with ImmunoCAP™ Specific IgE (Phadia AB). Assay's reproducibility and repeatability were also assessed.

Methods

Investigational device: Bet-v-1 microarrays (Figure 1), sized 40 mm x 10 mm x 8 mm, were prepared by printing Bet v 1 allergens onto functionalized glass chips and assembled into magazines for automatic processing on the MosaiQ instrument (Figure 2).

Samples for method comparison: 163 anonymized, residual serum samples, characterized by the comparator method as reactive (n=63) or as non-reactive (n=100) were tested with the investigational device.

Precision evaluation:

- Magazine lot reproducibility was assessed over five days, on three magazine lots, across two instruments.
- Instrument reproducibility was evaluated over five days, on one magazine lot, across three instruments.
- Repeatability was assessed on one instrument and one magazine lot, two runs per day, over five days.
- Reproducibility panels were composed of three samples (non-reactive, low-reactive, high-reactive).

Results

Method comparison

After the protocol exclusion of 1 reactive sample, the investigational device identified as reactive 60 out of 62 characterized reactive samples by the comparator and all 100 non-reactive samples; for a positive, negative and overall agreement of 96.8%, 100% and 98.8%, respectively **Table 1**.

Table 1. Percentage Agreement of Bet-v-1-Microarray versus Comparator

		Comparator		Total
		R	NR	
Bet v 1 Microarray	R	60	0	60
	EQV	0	0	0
	NR	2	100	102
Total		62	100	162

Summary	Calculation	Agreement (%)	95% CI
PPA	60/62 * 100	96.8	(88.8, 99.6)
NPA	100/100 * 100	100	(96.4, 100)
OPA	160/162 * 100	98.8	(95.6, 99.9)

R: reactive
NR: non-reactive
EQV: equivocal
PPA: positive percentage agreement
NPA: negative percentage agreement
OPA: overall percentage agreement
CI: confidence interval

Precision evaluation

Agreement of the investigational device with expected results in the evaluations of reproducibility by lot (869 data points, **Table 2**) and by instrument (435 data points, **Table 3**) as well as in the assessment of repeatability across days and runs (291 data points, **Table 4**) were all 100%.

Reproducibility Agreement with Expected Results (Tables 2 and 3)
Table 2. by Magazine Lot

Magazine Lot		Negative Agreement	Low positive Agreement	High positive Agreement	Overall Agreement
Lot A	%	100	100	100	100
	n/N	97/97	97/97	98/98	292/292
	95% CI	(96.3, 100)	(36.3, 100)	(96.3, 100)	(98.7, 100)
Lot B	%	100	100	100	100
	n/N	100/100	92/92	96/96	290/290
	95% CI	(96.4, 100)	(96.3, 100)	(96.3, 100)	(98.7, 100)
Lot C	%	100	100	100	100
	n/N	99/99	94/94	94/94	287/287
	95% CI	(96.3, 100)	(96.2, 100)	(96.2, 100)	(93.8, 100)

Table 3. by Instrument

Instrument S/N		Negative Agreement	Low positive Agreement	High positive Agreement	Overall Agreement
Instrument S/N 101	%	100	100	100	100
	n/N	49/49	46/46	48/48	143/143
	95% CI	(92.7, 100)	(92.3, 100)	(92.6, 100)	(97.5, 100)
Instrument S/N 120	%	100	100	100	100
	n/N	48/48	50/50	49/49	147/147
	95% CI	(92.6, 100)	(92.9, 100)	(92.7, 100)	(97.5, 100)
Instrument S/N 122	%	100	100	100	100
	n/N	49/49	47/47	94/94	145/145
	95% CI	(92.7, 100)	(92.5, 100)	(92.7, 100)	(97.5, 100)

Repeatability Agreement with Expected Results
Table 4. by Day / Run

Day		Negative Agreement	Low positive Agreement	High positive Agreement	Overall Agreement
Overall Day 1	%	100	100	100	100
	n/N	20/20	19/19	19/19	58/58
	95% CI	(83.2, 100)	(82.4, 100)	(82.4, 100)	(93.8, 100)
Overall Day 2	%	100	100	100	100
	n/N	19/19	19/19	19/19	57/57
	95% CI	(82.4, 100)	(82.4, 100)	(82.4, 100)	(93.7, 100)
Overall Day 3	%	100	100	100	100
	n/N	19/19	19/19	20/20	58/58
	95% CI	(82.4, 100)	(82.4, 100)	(82.4, 100)	(93.8, 100)
Overall Day 4	%	100	100	100	100
	n/N	20/20	19/19	20/20	59/59
	95% CI	(83.2, 100)	(82.4, 100)	(83.2, 100)	(93.9, 100)
Overall Day 5	%	100	100	100	100
	n/N	20/20	19/19	20/20	59/59
	95% CI	(83.2, 100)	(82.4, 100)	(83.2, 100)	(93.9, 100)
Overall Run 1	%	100	100	100	100
	n/N	49/49	46/46	48/48	143/143
	95% CI	(92.7, 100)	(92.3, 100)	(92.6, 100)	(97.5, 100)
Overall Run 2	%	100	100	100	100
	n/N	49/49	49/49	50/50	148/148
	95% CI	(92.7, 100)	(92.7, 100)	(92.9, 100)	(97.5, 100)

Conclusions

- Bet-v-1-Microarray showed high concordance with the compared device for the qualitative detection of Bet v 1 sIgE. Moreover, Bet-v-1-Microarray demonstrated a high degree of precision in the reproducibility and repeatability evaluations.
- This platform has the potential to multiplex and contribute to the comprehensive assessment of allergic disorders. Further ongoing steps include the addition of other allergens to the microarray.

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Figure 2: MosaiQ® instrument

