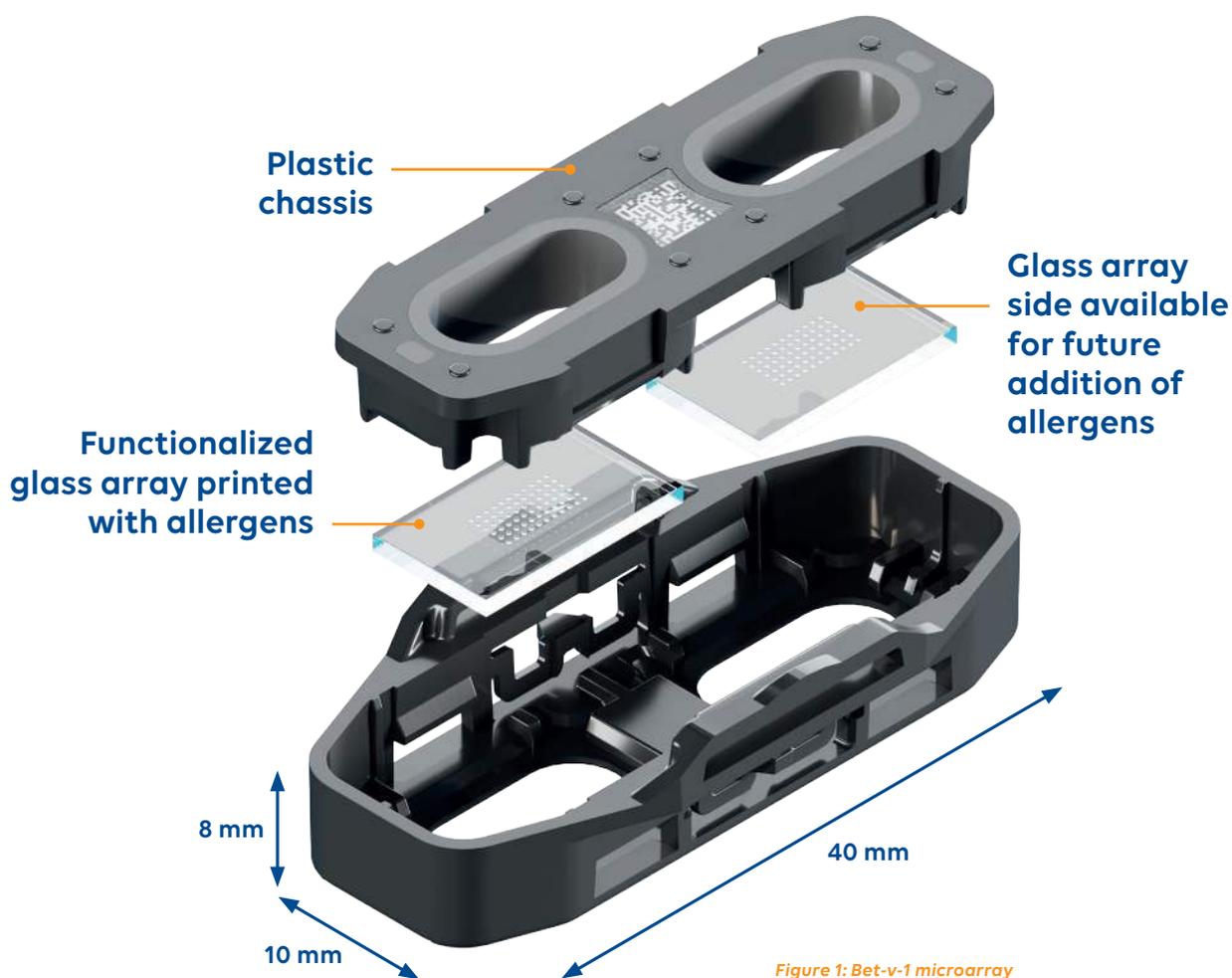


# Performance characteristics of a novel, fully automated immunoassay microarray for the qualitative serological detection of specific IgE directed against Bet v 1

Yasemin Ataman-Önal<sup>1</sup>, Brian Steele<sup>2</sup>, Gerber Gomez<sup>3</sup>, Rocio Pasion-Galvan<sup>4</sup>, Jose Santiago<sup>5</sup>, Michael Hausmann<sup>1</sup>, Christian Fischer<sup>3</sup>

1. Research & Development, AliveDx, Eysins, Switzerland; 2. Research & Development, AliveDx, Edinburgh, Scotland; 3. Scientific & Medical Affairs, AliveDx, Eysins, Switzerland; 4. Clinical Affairs, AliveDx, Eysins, Switzerland; 5. Scientific & Medical Affairs, AliveDx, Chicago, USA. Authors are AliveDx employees.

✉ gerber.gomez@alivedx.com



## 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
<b>Totaal</b>		<b>62</b>	<b>100</b>	<b>162</b>

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
<b>Lot A</b>	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)
<b>Lot B</b>	100	100	100	100
n/N	100/100	92/92	96/96	290/290
95% CI	(96.4, 100)	(96.1, 100)	(96.3, 100)	(98.7, 100)
<b>Lot C</b>	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
<b>Instrument S/N 101</b>	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)
<b>Instrument S/N 120</b>	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)
<b>Instrument S/N 122</b>	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
<b>Overall Day 1</b>	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)
<b>Overall Day 2</b>	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)
<b>Overall Day 3</b>	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)
<b>Overall Day 4</b>	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)
<b>Overall Day 5</b>	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)
<b>Overall Run 1</b>	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)
<b>Overall Run 2</b>	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.



Figure 2: MosaiQ® instrument

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