Successful launch of the MammaPrint and BluePrint NGS kit at decentralized sites

Leonie JMJ Delahaye[1], Anke T Witteveen[1], Mireille HJ Snel[1], Tyson Cavness[2], Bob Chan[1], Lorenza Mittempergher[1], Annuska M Glas[1]

[1]Agendia NV, Department of Research and Development, the Netherlands;[2] Agendia Inc, Laboratory Operations Department, the United States

Background

Centralized MammaPrint (MP) and BluePrint (BP) microarray-based genomic tests on FFPE RNA were successfully translated to a targeted RNA NGS kit that can be performed locally at decentralized sites. Since the launch of the CE-marked MP and BP NGS kit, more data has been generated on this platform with matching results on the established FDA-cleared microarray platform. Furthermore, decentralized sites worldwide have been onboarded and are certified to locally run the MP and BP NGS kit.

Methods

The paired MP and BP results were generated from FFPE RNA samples using the standard microarray as well as the MP and BP NGS kit *(Figure 1)*. The results from both platforms were compared to assess the concordance. Since the launch of the MP and BP NGS kit several decentralized sites underwent the onboarding process. As part of the onboarding, these sites processed a set of RNA and FFPE tissue samples previously processed at Agendia using the MP and BP NGS kit. The FASTQ files generated at the sites were uploaded into the cloud-based Agendia Data Analysis Pipeline Tool (ADAPT) to generate MP and BP results. A site could only be certified if NGS data passed the quality thresholds and results showed a 100% concordance with the Agendia results.

Results

To date, over 450 FFPE samples have been processed with both microarray and NGS kit at Agendia *(partly published by Mittempergher L, et.al. JMD, 2019)* shown here are 163 additional FFPE RNA samples showing a concordance for MammaPrint of 97% and the concordance of BluePrint was the same *(Figure 2).* A comparison of NGS kit results from 29 onboarding samples was also performed, starting from FFPE tissue. The concordance for MammaPrint between Agendia's central laboratory and the decentralized laboratories was 100%. The concordance for BluePrint was the same *(Figure 3).*

Conclusions

Agendia's CE-marked NGS kit delivers MammaPrint and BluePrint results equivalent to the standard microarray test. Additionally, decentralized sites using Agendia's CE-marked kit are able to generate results equivalent to Agendia's. These results confirm the high quality and robustness of the MP and BP NGS test.

Figure 1.NGS Pipeline

Sample Preparation → Library Preparation → Target Enrichment → Sequencing → FASTQ files →

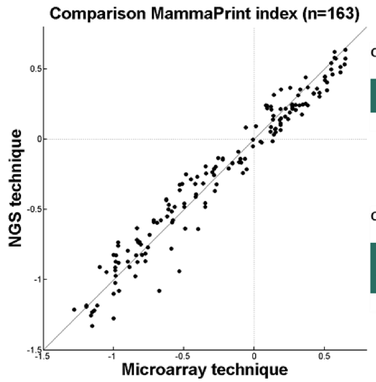
ADAPT

- Raw expression counts
- Log_2 expression counts
- Floor expression counts
- Normalize expression counts
- Compare to MammaPrint and BluePrint templates

Technical Report

Explanation of Results

Figure 2.Microarray vs NGS



Concordance table MP

		Microarray technique		
		High Risk	Low Risk	Total
NGS technique	High Risk	94	4	98
	Low Risk	1	64	65
	Total	95	68	163

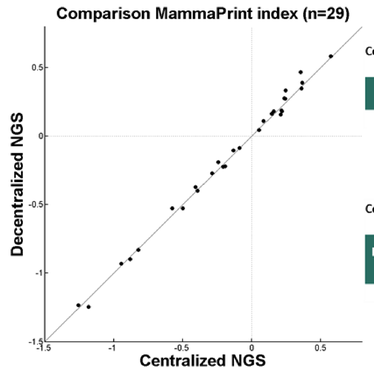
Concordance	97%

Concordance table BP

		Microarray technique			
		Luminal-type	HER2-type	Basal-type	Total
NGS technique	Luminal-type	86	2	0	88
	HER2-type	1	38	0	39
	Basal-type	2	0	34	36
	Total	89	40	34	163

Concordance	97%

Figure 3.Centralized NGS vs Decentralized NGS



Concordance table MP

		Centralized NGS		
		High Risk	Low Risk	Total
Decentralized NGS	High Risk	15	0	15
	Low Risk	0	14	14
	Total	15	14	29

Concordance	100%

Concordance table BP

		Centralized NGS			
		Luminal-type	HER2-type	Basal-type	Total
Decentralized NGS	Luminal-type	22	0	0	22
	HER2-type	0	3	0	3
	Basal-type	0	0	4	4
	Total	22	3	4	29

Concordance	100%

Contact Leonie.Delahaye@agendia.com/Annuska.Glas@agendia.com