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Comparison Analysis of AmoyDx® NGS panels on Saluseq Nimbo, Salus Pro, and Illumina NextSeq 500/550 sequencing platforms

Summary

This white paper compares the performance of the representative AmoyDx® NGS panels (Table 1) across Saluseq Nimbo, Salus Pro, and Illumina NextSeq 550Dx (RUO Mode) and NextSeq 500 platforms. Results demonstrate that Salus Nimbo and Pro deliver comparable data quality and panel coverage, supporting their suitability for reliable NGS panel testing in tumor mutation detection and research.

Table 1. AmoyDx® NGS panels used for performance assessment on Salus sequencers

Sample Type	Panel Name*	Technology	Variant Type	Sample Quantity	
				Pro	Nimbo
White Blood Cells	Hereditary	HANDLE	SNV, Indel,CNV	83	39
FFPE	Essential	ddCAP	SNV, Indel, CNV, Fusion	57	16
	HCOM	HANDLE	SNV, Indel, GSS, HD	27	4
	Classic	HANDLE	SNV, Indel, CNV, Fusion, MSI	61	31
cfDNA	Essential	ddCAP	SNV, Indel, Fusion	30	18

**Are the abbreviated panel names:*
Hereditary: AmoyDx® HANDLE Hereditary Cancer NGS Panel
Essential: AmoyDx® Essential NGS Panel
HCOM: AmoyDx® HRD Complete Panel
Classic: AmoyDx® HANDLE Classic NGS Panel

Methodology

1. Sample Collection

A total of three sample types: white blood cells (WBC), formalin-fixed paraffin-embedded (FFPE) tissues, and circulating cell-free DNA (cfDNA)—were collected and processed using the featured AmoyDx® NGS panels listed above.

Across all panels, various mutation types were interrogated, including single-nucleotide variants (SNVs), insertions/deletions (Indels), copy number variations (CNVs), gene fusions, microsatellite instability (MSI), homozygous deletions (HD), and genomic structural signatures (GSS), depending on the panel design.

1) White Blood Cells (WBC) Samples:

The WBC samples were analyzed with the Hereditary panel, including 83 samples sequenced on Pro and 39 on Nimbo.

2) Formalin-fixed Paraffin-embedded (FFPE) Tissue Samples:

The FFPE specimens were analyzed across multiple panels: the Essential panel (ddCAP-based) included 57 on Pro and 16 FFPE samples on Nimbo; 27 FFPE samples on Pro and 4 on Nimbo for HCOM panel detection; The Classic panel included 61 on Pro and 31 FFPE samples on Nimbo.

3) cfDNA Samples:

The cfDNA samples were analyzed with the Essential panel, encompassing 30 on Pro and 18 on Nimbo.

2. Extraction & Library Preparation

FFPE DNA and cfDNA extraction was conducted using the AmoyDx® DNA/RNA Extraction Kit and AmoyDx® Circulating DNA Kit. Library preparation was performed according to the standard protocol described in the instruction for use (IFU) of each NGS panel. Sequencing was carried out on the Salus Nimbo, Salus Pro, and NextSeq 550 platforms for comparative analysis.

3. Data Processing and Analysis

Variant calling was conducted using the associated analysis modules of each panel. Key metrics including quality control parameters, sequencing depth and variant frequency were evaluated to assess performance.

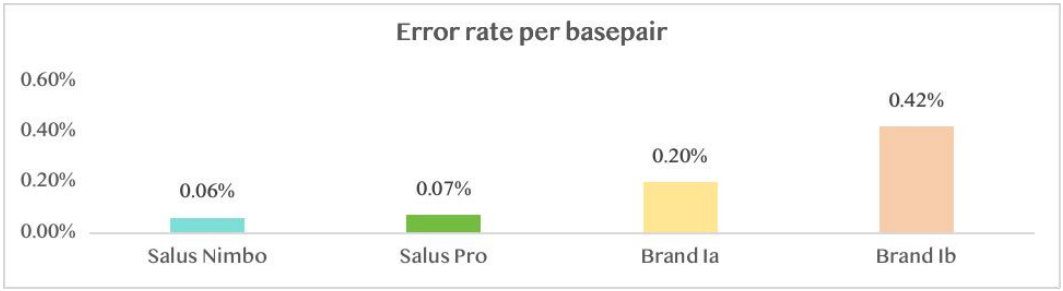
Results

Sequencing Performance Comparison

The sequencing error rate across the different platforms was calculated using the Hereditary panel data to exclude potential bias introduced by sample types. The testing results are as shown in Fig 1.

The error rate of Pro and Nimbo were below 0.1%. The Illumina sequencing platform NextSeq550Dx error rate is lower than that of NextSeq 500, which should be due to differences of sequencing reagent versions.

Fig 1. Overall sequencing error rate per basepairs



Hereditary Panel Testing Results

The SNV/InDel concordance rate of the both panels on Pro and Nimbo in germline variant detection are all greater than 99%. Testing results are as shown in Table 2.

Table 2. Testing result summary of Hereditary Panel

Platform	Mutation	Pro			Nimbo		
		Total Variants	divergent result	OPA	Total Variants	divergent result	OPA
NextSeq 500	SNV/InDel	10193	37	99.63%	10214	35	99.65%
	CNV	5	0	100%	5	0	100%

Classic Panel Testing Results

In Classic panel, the concordance rate of each mutation type for both Pro and Nimbo platforms are all greater than 99%. Testing results are as shown in Table 3.

Table 3. Testing result summary of HANDLE Classic Panel

Platform	Mutation	Pro			Nimbo		
		Total Variants	divergent result	OPA	Total Variants	divergent result	OPA
NextSeq 500Dx	SNV/InDel	-	-	-	484	2	99.29%
	CNV	-	-	-	3	0	100%
	MSI	-	-	-	19	0	100%
	Fusion	-	-	-	17	0	100%
	Chemotherapy	-	-	-	133	0	100%

HCOM Panel Testing Results

The concordance rate of SNV/InDel detection meets the performance qualification criteria. The GSS evaluation shows highly robust performance cross different sequencing platforms, with a concordance rate of 100%. Testing results are as shown in Table 4.

Table 4. Testing result summary of HRD Complete Panel

Platform	Mutation	Pro			Nimbo		
		Total Variants	divergent result	OPA	Total Variants	divergent result	OPA
NextSeq 500	SNV/InDel	1121	31	97.23%	178	5	97.19%
	GSS	25	0	100%	4	0	100%
	HD	25	0	100%	4	0	100%

Essential Panel Testing Results

In the Essential panel FFPE sample test, it is observed that the SNV/Indel variant frequency fluctuates when they are around the limit of detection (LoD), and the overall concordance rate meets the performance requirements; the CNV concordance rate is 100%. Some fusions allele frequency are near the LoD, and it is non-related to different platforms (0.2~0.4%), and with no clinically significance. Testing results are as shown in Table 5.

Table 5. Testing result summary of Essential panel for FFPE samples

Platform	Mutation	Pro			Nimbo		
		Total Variants	divergent result	OPA	Total Variants	divergent result	OPA
NextSeq 500	SNV/InDel	60	0	100%	43	0	100%
	CNV	23	0	100%	16	0	100%
	Fusion	6	0	100%	9	1	88.89%

In the Essential panel plasma sample test, the overall concordance rate meets the performance requirements. There was one divergent case of fusion variant near LoD tested in both Pro and NextSeq 500 platforms, with a mutation frequency of approximately 0.2%, and the fusion type had no clinical significance (Table 7).

Testing results are as shown in Table 6.

Table 7. Testing result summary of Essential panel for plasma samples

Platform	Mutation	Pro			Nimbo		
		Total Variants	divergent result	OPA	Total Variants	divergent result	OPA
NextSeq 500	SNV/InDel	62	0	100%	23	0	100%
	Fusion	2	2	0%	1	1	0%

Table 7. Testing result of the divergent fusion variant

Platform	Sample	InferredFusion	Depth	Freq
Pro	LC-BS010	ALK:exon19-CTNNB1:exon14	6,976	0.29%
NextSeq 500	LC-BSH01	CD79B:exon5-RET:exon12	6,053	0.20%

Discussion

The comparative analysis highlights several key findings:

Sequencing Quality:

The Slaus Pro and Nimbo sequencing platforms have been evaluated and exhibit base-level error rates below 0.1%, indicating high sequencing accuracy and data quality. This level of performance supports their compatibility with AmoyDx® NGS panel applications. Comparative analysis shows that the

sequencing accuracy of Pro and Nimbo is on par with established clinical platforms such as the Illumina 500/550 platforms.

Detection Performance:

Across all panels tested on the Salus Pro and Nimbo platforms, the concordance rate for SNV/InDel detection in germline and somatic variant calling consistently exceeded 99%, meeting performance qualification criteria.

GSS and HD evaluation confirmed high cross-platform robustness with a 100% concordance rate. The minor discrepancies observed in fusions were caused by the gene break-point offsets, which is inherent to algorithmic resolution of structural variants near complex regions, and is not attributable to differences between sequencing platforms.

Sample type analysis using the Essential panel demonstrated consistent and robust performance across both FFPE and plasma samples on the tested sequencing platforms. In FFPE samples, SNV/InDel variant frequencies exhibited understandable variability near the LoD; however, overall concordance remained within acceptable performance thresholds. CNV detection achieved 100% concordance, and low-frequency fusion variants (0.2-0.4%) observed near the LoD were clinically insignificant and not attributable to platform differences. Similarly, plasma sample testing showed high concordance across platforms. Collectively, these results support the compatibility of both FFPE and plasma sample types with the evaluated sequencing platforms.

Conclusion

The study confirms that the AmoyDx® NGS Panel performs exceptionally well on both Salus sequencer Nimbo and Pro, and Illumina NextSeq platforms. The Salus sequencer demonstrated superior sequencing quality and comparable accuracy in mutation frequency detection. These findings validate Salus sequencer Nimbo and Pro as robust and reliable platform for detect the target region of tumor genes from the AmoyDx® NGS panels in both clinical and research applications.