NIBAPLEX®

Off-the-shelf solutions for viral vector characterisation

niba LABS
your trusted dPCR experts

MULTIPLEX AND SIMPLEX ASSAYS FOR VECTOR GENOME INTEGRITY & TITRE

NibaPlex® digital PCR (dPCR) assays have been developed for specific detection and quantification of a target panel of viral vector genome elements, empowering scientists in biopharma industry to address genome integrity and vector genome titre.

1 VECTOR GENOME INTEGRITY

Cutting-edge multiplex dPCR assays for genome integrity assessment

The key role of multiplex dPCR for the quantification of complete genomes in your viral vector product

Genome integrity results by multiplex dPCR show an excellent correlation of complete vector genomes to the results of biopotency, as presented in recent studies.

Our dedicated NibaPlex® multiplex dPCR assays have been developed for specific detection and quantification of complete and incomplete genomes, providing in-depth information on the genome integrity of viral vector products for gene therapy.

Our portfolio of NibaPlex® assays can provide detailed information on the quantity of complete genomes and the distribution of incomplete populations in AAV samples.

BENEFITS

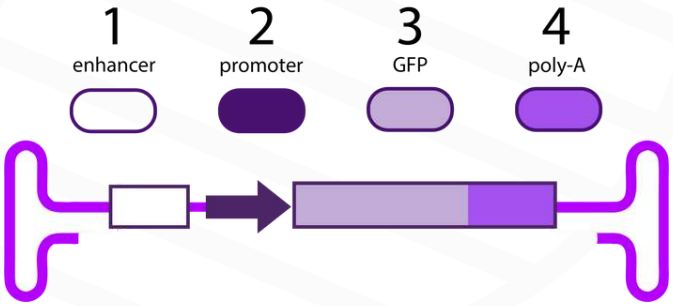
High throughput method to help you improve biopotency of viral vector products.

NIBAPLEX® 4-PLEX ASSAYS

First-of-its-kind assay with 4 target regions simultaneously targeted in one reaction mix

The NibaPlex® 4-plex assays are designed to simultaneously target 4 regions on the viral vector genome to obtain in-depth information on genome integrity. This enables the user to collect quantitative data of complete and incomplete vector genomes present in viral vector capsids and to determine the expected biopotency of viral vector products.

NibaPlex® 4-plex off-the-shelf offerings comprise various combinations of enhancer, promoter, and poly-A tail options with the model GFP gene.



NibaPlex® 4-plex assay	1 Enhancer	2 Promoter	3 GOI	4 poly-A tail
4.01	CMV	CMV	GFP	SV40
4.02	CMV	CMV	GFP	hGH
4.03	CMV	CMV	GFP	bGH

CUSTOM DESIGN & DEVELOPMENT OF 4-PLEX ASSAYS

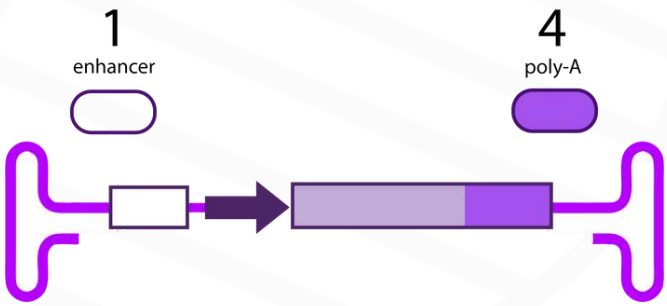
Niba Labs offers custom design of 4-plex assays for your specific regions & GOI upon request.

NIBAPLEX® DUPLEX ASSAYS

First-stage assessment of viral vector genome integrity

The NibaPlex® duplex assays are designed to simultaneously target the beginning and end of the viral vector genome to obtain high-level information on genome integrity based on quantitative data of complete and incomplete vector genomes present in viral vector capsids. This enables the user to quickly assess the general efficacy of the viral vector production process.

NibaPlex® duplex off-the-shelf offerings comprise various combinations of enhancer and poly-A tail options.



NibaPlex® duplex assay	1 Enhancer	2 Promoter	3 GOI	4 poly-A tail
2.01	CMV	-	-	SV40
2.02	CMV	-	-	hGH
2.03	CMV	-	-	bGH

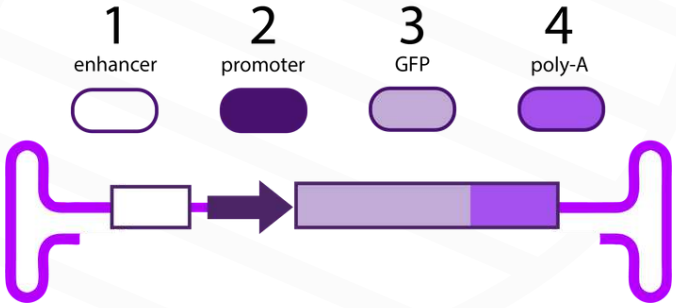
CUSTOM DESIGN & DEVELOPMENT OF DUPLEX ASSAYS

Niba Labs offers custom design of duplex assays for your specific vector genome sequence.

2 VECTOR GENOME TITRE

Simplex dPCR assays for quantification of viral vector genomes

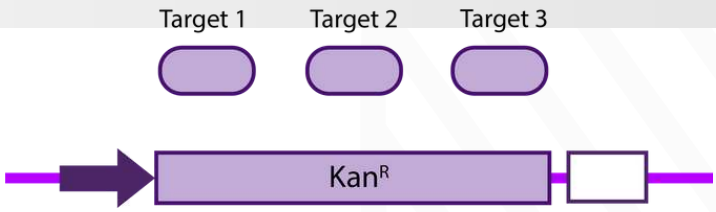
The NibaPlex® simplex assays are highly-optimized to target a single element of the viral vector genome, enabling the user to determine the titer of the viral genomes with great accuracy and precision. Our broad portfolio includes assays targeting the most common viral vector genome elements, rendering them appropriate for the quantification of commercial viral vector products.



NibaPlex® simplex assay	1 Enhancer	2 Promoter	3 GOI	4 poly-A tail
1.01	CMV	-	-	-
1.02	-	CMV	-	-
1.03	-	-	GFP	-
1.04	-	-	-	SV40
1.05	-	-	-	hGH
1.06	-	-	-	bGH

3 PROCESS-RELATED IMPURITIES

Simplex and multiplex dPCR assays for analysis of impurities in viral vector products



The NibaPlex® Kan^R assays are specifically designed to enable the accurate determination of the presence, quantity, and fragmentation of residual Kan^R gene in all stages of the viral vector production process.

The NibaPlex® Kan^R multiplex dPCR assays are based on an innovative approach for assessment of complete and incomplete populations of the plasmid-derived kanamycin resistance gene (nptII). The duplex assay targeting the start and end of the Kan^R gene provides high-level information on the complete and incomplete gene sequences, with the triplex assay enabling further assessment of their fragmentation. Our NibaPlex® Kan^R simplex assay targeting the middle of the Kan^R gene enables its general titration.

NibaPlex® Kan^R assay	Assay	Use	Kan^R Target 1	Kan^R Target 2	Kan^R Target 3
1.07	simplex	Quantification of Kan^R gene	-	Middle of gene	-
2.04	duplex	High-level determination of Kan^R gene integrity	Start of gene	-	End of gene
3.01	triplex	In-depth determination of Kan^R gene integrity	Start of gene	Middle of gene	End of gene

OFF-THE-SHELF NIBAPLEX® ASSAYS

Exceptionally user friendly:
optimised assays, ready-to-use &
all reagents in one tube

Assays are provided as single tube containing ready-to-use, 20x-concentrated reference assay

Cat. No. / ID	Item	Type of assay	Target region	Dye	Number of reactions
	4-PLEX				
400011	NibaPlex 4.01	Vector Genome Integrity	CMV enhancer CMV promoter GFP SV40 poly-A	FAM Cy5 Texas Red HEX	sufficient for 1x96 dPCR reactions of 12 µl each
400015	NibaPlex 4.01	Vector Genome Integrity	CMV enhancer CMV promoter GFP SV40 poly-A	FAM Cy5 Texas Red HEX	sufficient for 5x96 dPCR reactions of 12 µl each
400021	NibaPlex 4.02	Vector Genome Integrity	CMV enhancer CMV promoter GFP hGH poly-A	FAM Cy5 Texas Red HEX	sufficient for 1x96 dPCR reactions of 12 µl each
400025	NibaPlex 4.02	Vector Genome Integrity	CMV enhancer CMV promoter GFP hGH poly-A	FAM Cy5 Texas Red HEX	sufficient for 5x96 dPCR reactions of 12 µl each
400031	NibaPlex 4.03	Vector Genome Integrity	CMV enhancer CMV promoter GFP bGH poly-A	FAM Cy5 Texas Red HEX	sufficient for 1x96 dPCR reactions of 12 µl each
400035	NibaPlex 4.03	Vector Genome Integrity	CMV enhancer CMV promoter GFP bGH poly-A	FAM Cy5 Texas Red HEX	sufficient for 5x96 dPCR reactions of 12 µl each
	TRIPLEX				
300011	NibaPlex 3.01	Process-Related Impurities	Kanamycin (three regions)	FAM Cy5 HEX	sufficient for 1x96 dPCR reactions of 12 µl each
300015	NibaPlex 3.01	Process-Related Impurities	Kanamycin (three regions)	FAM Cy5 HEX	sufficient for 5x96 dPCR reactions of 12 µl each

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Cat. No. / ID	Item	Type of assay	Target region	Dye	Number of reactions
	DUPLEX				
200011	NibaPlex 2.01	Vector Genome Integrity	CMV enhancer SV40 poly-A	FAM HEX	sufficient for 1x96 dPCR reactions of 12 µl each
200015	NibaPlex 2.01	Vector Genome Integrity	CMV enhancer SV40 poly-A	FAM HEX	sufficient for 5x96 dPCR reactions of 12 µl each
200021	NibaPlex 2.02	Vector Genome Integrity	CMV enhancer hGH poly-A	FAM HEX	sufficient for 1x96 dPCR reactions of 12 µl each
200025	NibaPlex 2.02	Vector Genome Integrity	CMV enhancer hGH poly-A	FAM HEX	sufficient for 5x96 dPCR reactions of 12 µl each
200031	NibaPlex 2.03	Vector Genome Integrity	CMV enhancer bGH poly-A	FAM HEX	sufficient for 1x96 dPCR reactions of 12 µl each
200035	NibaPlex 2.03	Vector Genome Integrity	CMV enhancer bGH poly-A	FAM HEX	sufficient for 5x96 dPCR reactions of 12 µl each
200041	NibaPlex 2.04	Process-Related Impurities	Kanamycin (beginning and end of gene)	FAM HEX	sufficient for 1x96 dPCR reactions of 12 µl each
200045	NibaPlex 2.04	Process-Related Impurities	Kanamycin (beginning and end of gene)	FAM HEX	sufficient for 5x96 dPCR reactions of 12 µl each

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Cat. No. / ID	Item	Type of assay	Target region	Dye	Number of reactions
	SIMPLEX				
100011	NibaPlex 1.01	Vector Genome Titer	CMV enhancer	FAM	sufficient for 1x96 dPCR reactions of 12 µl each
100015	NibaPlex 1.01	Vector Genome Titer	CMV enhancer	FAM	sufficient for 5x96 dPCR reactions of 12 µl each
100021	NibaPlex 1.02	Vector Genome Titer	CMV promoter	Cy5	sufficient for 1x96 dPCR reactions of 12 µl each
100025	NibaPlex 1.02	Vector Genome Titer	CMV promoter	Cy5	sufficient for 5x96 dPCR reactions of 12 µl each
100031	NibaPlex 1.03	Vector Genome Titer	GFP	Texas Red	sufficient for 1x96 dPCR reactions of 12 µl each
100035	NibaPlex 1.03	Vector Genome Titer	GFP	Texas Red	sufficient for 5x96 dPCR reactions of 12 µl each
100041	NibaPlex 1.04	Vector Genome Titer	SV40 poly-A	HEX	sufficient for 1x96 dPCR reactions of 12 µl each
100045	NibaPlex 1.04	Vector Genome Titer	SV40 poly-A	HEX	sufficient for 5x96 dPCR reactions of 12 µl each
100051	NibaPlex 1.05	Vector Genome Titer	hGH poly-A	HEX	sufficient for 1x96 dPCR reactions of 12 µl each
100055	NibaPlex 1.05	Vector Genome Titer	hGH poly-A	HEX	sufficient for 5x96 dPCR reactions of 12 µl each
100061	NibaPlex 1.06	Vector Genome Titer	bGH poly-A	HEX	sufficient for 1x96 dPCR reactions of 12 µl each
100065	NibaPlex 1.06	Vector Genome Titer	bGH poly-A	HEX	sufficient for 5x96 dPCR reactions of 12 µl each
100071	NibaPlex 1.07	Process-Related Impurities	Kanamycin	Cy5	sufficient for 1x96 dPCR reactions of 12 µl each
100075	NibaPlex 1.07	Process-Related Impurities	Kanamycin	Cy5	sufficient for 5x96 dPCR reactions of 12 µl each