



Genetic characterization



Detection of adventitious agents



Custom solutions

Genetic Characterization

Guarantee the safety of your biologics development and manufacturing pipelines

Due to safety concerns, regulatory bodies worldwide require a thorough genetic characterization of all biologically derived materials that are commonly used across the entire manufacturing process. Are you interested in characterizing your (viral) vector? Are you required to evaluate the integration site introduced to your producer cell line? Look no further!

GenomeScan offers comprehensive and cost-effective Next Generation Sequencing (NGS)-based QC solutions that guarantee in-depth evaluation of the identity and stability of your target. Whether it is a viral vector, Master Cell Bank (MCB), Working Cell Bank (WCB) or End of Production Cell Bank (EOPC), our range of genetic QC characterization services are here to enhance the safety of your product development and manufacturing pipelines. Our proprietary RNA and DNA library preparation protocols combined with short (Illumina) or long-read (PacBio, ONT) sequencing solutions are compatible with a wide range of samples and can be easily adapted to address your specific needs.

Key benefits

Our NGS-based solutions for genetic characterization:

- Are GMP compliant
- Are compatible with a wide range of input materials
- Are faster, more comprehensive, and more affordable than traditionally used tests
- Aid stable and consistent production
- Accelerate your manufacturing processes

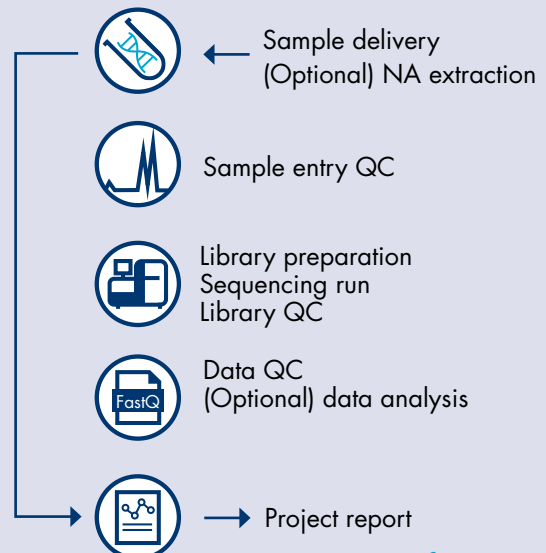
Trustworthy results

Data quality guarantee

Sequence quality control is an essential tool in our workflow. Using our in-house validated pipelines, we minimize intra- and inter-experiment variability, and ensure that you always receive data of the highest possible quality.

In most of our workflows that include PCR amplification, we incorporated unique molecular identifiers (UMIs), which allow distinguishing PCR duplicates from true identical input molecules.

Genetic characterization workflow

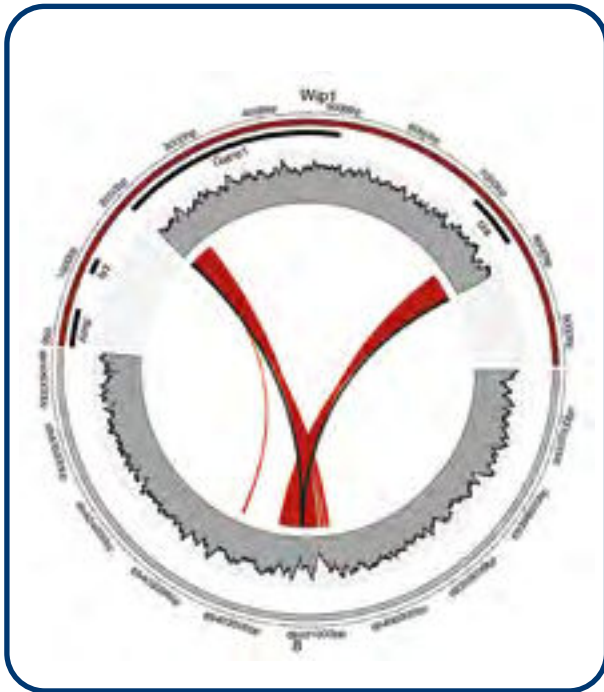


Professional reporting

We deliver comprehensive, consistent, and transparent project reports that describe all experimental procedures and include relevant QC metrics.

Data analysis options

Our data analysis workflows are based on state-of-the-art bioinformatics tools that conduct exhaustive analyses with insightful data visualization outputs. This way, we provide you with easily comprehensible and ready-to-publish results. Depending on your research question, we can perform various analyses. For example, your data analysis report can include tables of variant calling results with clinical grade annotations. You can also view your report in html format to make use of the interactive elements, such as visualizations of structural variants or putative vector integration sites.



Circos plot of putative vector integration site

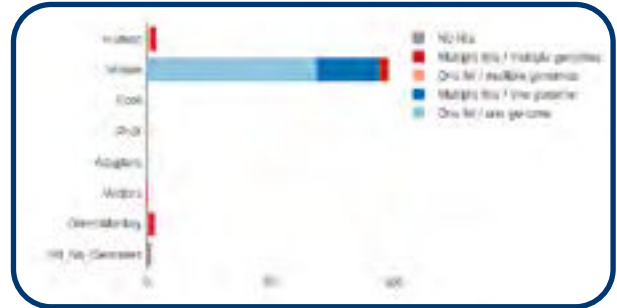
Genetic characterization insights

Our genetic characterization services aid, amongst others:

- Verification of the vector and viral sequences
- Evaluation of genomic integration site
- Cell line purity assessment
- Cell line identification
- Cell line authentication

Custom solutions

At GenomeScan, we continuously improve our services and validate new solutions. Take advantage of our pilot program in which bioinformatics pipelines can be tailored to your specific needs, allowing more in-depth mining of your dataset. In addition to that, we offer various customizable publication grade visualization options to present your results.



Bar plot displaying sample purity

About GenomeScan

As an ISO-accredited leading Dutch Next Generation Sequencing service provider, GenomeScan develops customizable NGS solutions for pharmaceutical and biotech companies, healthcare providers and academic institutions. By providing state-of-the-art tools to analyze genetic disorders fast, affordably, and effectively, GenomeScan fosters innovation through partnership with medical centers and research laboratories.

| AnnotSV ID | ACMG class | SV type | Annotation mode | Gene name | Overlapped regulatory elements | Pathogenic SV |
|---------------------------------------|------------|---------|-----------------|---|--|--|
| 10_7541599 5_75782392 _<DUP>_1 | 5 | <DUP> | full | AGAP5; BMS1P4; BMS1P4-AGAP5; C10orf55; CAMK2G; [...14genes] | MRPS16 (morbid/RE=EA_enhancer+GH_enhancer); F[...] | 10:75659016-75736953 |
| 21_4420710 5_44623455 _<DUP>_1 | 5 | <DUP> | full | CBS; CBSL; CRYAA; CRYAA2; ERVH48-1; [...13genes] | ATXN1 (morbid/RE=mTL_miRNA); SDHD (HI=3/morbi[...]) | 21:44480531-44482525; 21:44485538-44485959 |
| 7_15790815 2_15898266 1_<DUP>_1 | 5 | <DUP> | full | DYNC211; ESYT2; LINC01022; MIR5707; [...9genes] | CHEK2 (HI+3/morbid/RE=RE=mTL_miRNA); HOXC13 (mor[...]) | 7:158395932-158901010 |

Annotated structural and copy number variants