

Global Gene Editing Off-Target NGS Assay Kits Supply, Demand and Key Producers, 2026-2032

<https://marketpublishers.com/r/G26716D35EDEEN.html>

Date: September 2026

Pages: 101

Price: US\$ 4,480.00 (Single User License)

ID: G26716D35EDEEN

Abstracts

The global Gene Editing Off-Target NGS Assay Kits market size is expected to reach \$ 234 million by 2032, rising at a market growth of 14.8% CAGR during the forecast period (2026-2032).

Gene editing off-target NGS assay kits are research-use reagent systems and custom targeted sequencing configurations designed to identify, localize, and quantify unintended genomic changes generated during genome editing. The category covers off-target site discovery and candidate-site confirmation for CRISPR-Cas nucleases, base editors, and other programmable editing systems. Typical offerings combine target design or probe/primer pools, DNA library preparation and indexing reagents, target-enrichment modules, and associated analysis workflows. Commercial workflows may use GUIDE-seq-type break-site tagging, multiplex amplicon sequencing, hybrid capture, in vitro cleavage enrichment, or whole-genome sequencing to detect small insertions and deletions, nucleotide substitutions, and selected structural abnormalities at high depth. This study focuses on NGS experimental products sold as kits or integrated library-preparation solutions, with the market boundary centered on sample preparation, target enrichment, and pre-sequencing library construction. The market is characterized by high customization, extended customer-validation cycles, and recurring consumable demand. The blended gross margin is approximately 65%.

Market Trends

The market is moving from isolated edit-efficiency checks toward staged and orthogonal safety-assessment workflows. Developers increasingly combine computational nomination, unbiased genome-wide discovery, high-depth targeted confirmation, and

broader genome-integrity assessment rather than relying on a single assay. Product development is therefore focused on higher multiplexing, lower DNA input, molecular-barcode error correction, improved performance in difficult genomic regions, and standardized analysis pipelines that can compare results across cell types, donors, and editing conditions. Demand is also expanding beyond conventional CRISPR nucleases to base editors, prime editors, and other programmable systems, which require assay designs capable of capturing substitutions, small insertions and deletions, and selected structural abnormalities. The FDA's 2026 draft guidance dedicated to NGS-based genome-editing safety assessment further reinforces the shift toward well-characterized methods, predefined acceptance criteria, traceable bioinformatics, and orthogonal confirmation. Commercial offerings are consequently evolving from stand-alone primer or probe pools into integrated systems combining custom panel design, library preparation, indexing, sequencing compatibility, quality-control materials, and automated data interpretation.

Drivers

Growth is driven primarily by the expanding clinical and preclinical pipeline for genome-edited cell and gene therapies, where off-target characterization and genome-integrity evidence are central to safety evaluation. More editing targets, cell types, donor backgrounds, and manufacturing changes increase the number of samples and conditions requiring confirmation, supporting recurring consumable demand rather than one-time testing. Regulatory expectations in the United States and Europe are also pushing sponsors to justify site-nomination strategies, analytical sensitivity, sample relevance, sequencing depth, and confirmation thresholds. Outside therapeutics, functional genomics and agricultural biotechnology add research demand for scalable assays that can verify multiple edited loci and distinguish intended edits from low-frequency unintended events.

Restraints

Market adoption is constrained by the high degree of assay customization and the absence of a single universally accepted workflow. Off-target profiles can vary with nuclease, guide sequence, delivery method, cell type, donor, and culture conditions, limiting direct transfer of panels between programs. Detecting rare events requires substantial sequencing depth, appropriate controls, and carefully validated error models, which increases reagent consumption and analytical cost. Complex or repetitive genomic regions can remain difficult to amplify or capture, while discordance

among nomination methods creates uncertainty over which candidate sites should enter targeted confirmation panels. Smaller laboratories may also lack the bioinformatics capability and quality systems needed to convert raw sequencing results into defensible safety conclusions.

Opportunities

The strongest opportunities lie in end-to-end and regulatory-ready assay packages that connect off-target nomination, custom panel design, wet-lab reagents, reference standards, automated analysis, and documented analytical validation. Suppliers can expand value capture by offering low-input and high-multiplex panels for primary cells, stem cells, and limited clinical specimens, as well as editor-specific designs for base and prime editing. Multi-platform compatibility and local manufacturing can improve access in regions where sequencing ecosystems differ from the dominant global platform. Additional opportunities exist in standardized positive controls, inter-laboratory comparability materials, longitudinal monitoring panels, and modular kits that allow customers to add new candidate sites without redesigning the full assay.

Challenges

The industry must balance sensitivity with specificity as deeper sequencing can increase detection of background errors and biologically irrelevant low-frequency signals. Establishing meaningful reporting thresholds remains difficult because technical detection limits do not automatically correspond to clinical risk. Validation also has to demonstrate performance across representative cell populations and manufacturing stages, creating long study cycles and demanding documentation requirements. Competitive pressure will come from integrated testing-service providers, broader whole-genome approaches, and improving long-read methods that may capture structural changes missed by targeted assays. Suppliers must therefore show that kit-based workflows provide reproducibility, transferability, turnaround time, and total-cost advantages without narrowing the assessment in ways that weaken safety conclusions.

Industry Chain Analysis

The upstream chain includes synthetic oligonucleotides, primers and capture probes, polymerases and ligases, library-preparation chemistry, indexes and unique molecular identifiers, magnetic beads, reference materials, sequencing consumables, and

bioinformatics components. Upstream quality directly influences amplification uniformity, background error, target recovery, and lot-to-lot consistency. The midstream segment converts these inputs into custom assay design, probe or primer pooling, enrichment chemistry, library construction kits, workflow optimization, quality control, and analytical software. Value creation is concentrated in design algorithms, multiplex balancing, sensitivity validation, difficult-region coverage, and technical documentation rather than in generic reagents alone.

Downstream customers include biopharmaceutical developers, contract research organizations, independent testing laboratories, academic and government institutes, and agricultural biotechnology companies. The commercial model combines initial design and validation revenue with recurring purchases of assay reagents, indexes, and library-preparation consumables. Complete kits and custom panels generally capture more value than stand-alone oligonucleotide pools because they reduce method-development work and transfer risk for customers. Suppliers with scalable manufacturing, rapid redesign, consistent lots, cross-platform support, and application expertise are better positioned to maintain margins and become embedded in long-duration development programs.

Segment Insights

Targeted candidate-site validation represents the largest routine-use segment because most development programs repeatedly quantify a defined set of nominated sites across optimization, process development, comparability, and release-support studies. Unbiased genome-wide discovery is strategically important at earlier stages but is used less frequently and often feeds candidates into targeted confirmation. By enrichment method, multiplex PCR has the broadest commercial adoption where speed, low input, and high sample throughput are priorities. Hybrid capture is favored for larger target collections, difficult genomic regions, or designs requiring more flexible probe placement, while tag-capture and in vitro cleavage-enrichment approaches remain important for initial site discovery. Workflows without target enrichment are mainly associated with whole-genome strategies and represent a smaller but technically influential segment.

By supply format, custom panel kits and complete assay kits are gaining preference because they combine design, optimized pooling, library preparation, and analysis support in a transferable workflow. Probe or primer pools remain relevant for experienced laboratories that already operate validated library-preparation processes.

Illumina-compatible products have the broadest commercial availability, reflecting the installed base of short-read instruments, while multi-platform configurations are becoming more important for global studies and regional sequencing ecosystems. MGI-compatible offerings have particular expansion potential in China and selected Asian markets, whereas Ion Torrent-compatible products retain demand in laboratories with established semiconductor-sequencing workflows.

Downstream Market Opportunities

Biopharmaceutical companies provide the highest-value opportunity because therapeutic programs require repeated testing across guide selection, cell-line or donor selection, process optimization, nonclinical studies, and regulatory submissions. Contract research organizations and independent testing laboratories are benefiting from outsourcing as smaller developers seek specialized capabilities without building internal NGS and bioinformatics teams. Academic and government institutes remain important for method development and early validation, although purchasing is more project-based. Agricultural biotechnology creates a distinct opportunity for multi-locus and multi-species panels, but customers are generally more price-sensitive and regulatory requirements differ by jurisdiction. Suppliers that offer flexible panel sizes, rapid turnaround, technical transfer, and consistent interpretation across these customer groups can expand recurring demand.

Regional Insights

North America is the largest regional market, supported by a concentrated pipeline of genome-edited therapeutics, advanced NGS infrastructure, specialized contract laboratories, and active regulatory engagement. Europe is characterized by strong advanced-therapy research and rigorous expectations for quality and nonclinical evidence, which supports demand for validated and well-documented workflows but can lengthen purchasing and method-qualification cycles. Asia-Pacific has the strongest expansion potential as China, Japan, South Korea, and other markets increase investment in cell therapy, gene therapy, genomics, and local sequencing platforms. Regional growth will favor suppliers that can provide local assay design, faster delivery, platform-specific compatibility, and technical support in local languages. Other regions remain primarily research-led and are more dependent on imported reagents and centralized sequencing facilities.

Competitive Landscape Analysis

Competition is fragmented across established oligonucleotide and NGS-reagent suppliers, sequencing-platform companies, and specialized custom-panel developers. The market is not determined by catalog breadth alone; suppliers compete on off-target assay expertise, primer and probe design quality, multiplex capacity, low-input performance, analytical sensitivity, difficult-region coverage, workflow time, and data-analysis support. Larger life-science companies benefit from installed sequencing ecosystems, global distribution, and broad library-preparation portfolios, while specialized providers can differentiate through faster customization and application-focused validation. Competitive advantage increasingly depends on the ability to deliver an integrated and reproducible package with documented performance, cross-lot consistency, automation compatibility, and regulatory-support materials. Partnerships with contract laboratories and therapeutic developers can strengthen market access, but suppliers must avoid positioning generic custom panels as fully validated off-target solutions without program-specific evidence.

Report Scope

This report studies the global Gene Editing Off-Target NGS Assay Kits production, demand, key manufacturers, and key regions.

This report is a detailed and comprehensive analysis of the world market for Gene Editing Off-Target NGS Assay Kits and provides market size (US\$ million) and Year-over-Year (YoY) Growth, considering 2025 as the base year. This report explores demand trends and competition, as well as details the characteristics of Gene Editing Off-Target NGS Assay Kits that contribute to its increasing demand across many markets.

Highlights and key features of the study

Global Gene Editing Off-Target NGS Assay Kits total production and demand, 2021-2032, (Units)

Global Gene Editing Off-Target NGS Assay Kits total production value, 2021-2032, (USD Million)

Global Gene Editing Off-Target NGS Assay Kits production by region & country, production, value, CAGR, 2021-2032, (USD Million) & (Units), (based on production site)

Global Gene Editing Off-Target NGS Assay Kits consumption by region & country, CAGR, 2021-2032 & (Units)

U.S. VS China: Gene Editing Off-Target NGS Assay Kits domestic production, consumption, key domestic manufacturers and share

Global Gene Editing Off-Target NGS Assay Kits production by manufacturer, production, price, value and market share 2021-2026, (USD Million) & (Units)

Global Gene Editing Off-Target NGS Assay Kits production by Type, production, value, CAGR, 2021-2032, (USD Million) & (Units)

Global Gene Editing Off-Target NGS Assay Kits production by Application, production, value, CAGR, 2021-2032, (USD Million) & (Units)

This report profiles key players in the global Gene Editing Off-Target NGS Assay Kits market based on the following parameters - company overview, production, value, price, gross margin, product portfolio, geographical presence, and key developments. Key companies covered as a part of this study include Integrated DNA Technologies, Paragon Genomics, iGeneTech Bioscience, Illumina, Thermo Fisher Scientific, Twist Bioscience, Agilent Technologies, Roche, etc.

This report also provides key insights about market drivers, restraints, opportunities, new product launches or approvals.

Stakeholders would have ease in decision-making through various strategy matrices used in analyzing the World Gene Editing Off-Target NGS Assay Kits market

Detailed Segmentation:

Each section contains quantitative market data including market by value (US\$ Millions), volume (production, consumption) & (Units) and average price (US\$/Unit) by manufacturer, by Type, and by Application. Data is given for the years 2021-2032 by

year with 2025 as the base year, 2026 as the estimate year, and 2027-2032 as the forecast year.

Global Gene Editing Off-Target NGS Assay Kits Market, By Region:

United States

China

Europe

Japan

South Korea

ASEAN

India

Rest of World

Market Segmentation

Global Gene Editing Off-Target NGS Assay Kits Market, Segmentation by Type:

Unbiased Genome-Wide Discovery

Targeted Candidate-Site Validation

Global Gene Editing Off-Target NGS Assay Kits Market, Segmentation by Target Enrichment Method:

Multiplex PCR

Hybrid Capture

Double-Stranded Oligonucleotide Tag Capture

In Vitro Cleavage Enrichment

No Target Enrichment

Other

Global Gene Editing Off-Target NGS Assay Kits Market, Segmentation by Supply Format:

Complete Assay Kits

Library Preparation Kits

Probe or Primer Pools

Other

Global Gene Editing Off-Target NGS Assay Kits Market, Segmentation by Sequencing Platform Compatibility:

Illumina-Compatible

Ion Torrent-Compatible

MGI-Compatible

Multi-Platform

Other

Global Gene Editing Off-Target NGS Assay Kits Market, Segmentation

by Application:

Biopharmaceutical Companies

Independent Testing Laboratories

Academic and Government Institutes

Agricultural Biotechnology Companies

Other

Companies Profiled:

Integrated DNA Technologies

Paragon Genomics

iGeneTech Bioscience

Illumina

Thermo Fisher Scientific

Twist Bioscience

Agilent Technologies

Roche

Key Questions Answered

1. How big is the global Gene Editing Off-Target NGS Assay Kits market?
2. What is the demand of the global Gene Editing Off-Target NGS Assay Kits market?
3. What is the year over year growth of the global Gene Editing Off-Target NGS Assay Kits market?

4. What is the total value of the global Gene Editing Off-Target NGS Assay Kits market?
5. Who are the Major Players in the global Gene Editing Off-Target NGS Assay Kits market?
6. What are the growth factors driving the market demand?

Contents

1 SUPPLY SUMMARY

- 1.1 Gene Editing Off-Target NGS Assay Kits Introduction
- 1.2 World Gene Editing Off-Target NGS Assay Kits Supply & Forecast
 - 1.2.1 World Gene Editing Off-Target NGS Assay Kits Production Value (2021 & 2025 & 2032)
 - 1.2.2 World Gene Editing Off-Target NGS Assay Kits Production (2021-2032)
 - 1.2.3 World Gene Editing Off-Target NGS Assay Kits Pricing Trends (2021-2032)
- 1.3 World Gene Editing Off-Target NGS Assay Kits Production by Region (Based on Production Site)
 - 1.3.1 World Gene Editing Off-Target NGS Assay Kits Production Value by Region (2021-2032)
 - 1.3.2 World Gene Editing Off-Target NGS Assay Kits Production by Region (2021-2032)
 - 1.3.3 World Gene Editing Off-Target NGS Assay Kits Average Price by Region (2021-2032)
 - 1.3.4 North America Gene Editing Off-Target NGS Assay Kits Production (2021-2032)
 - 1.3.5 Europe Gene Editing Off-Target NGS Assay Kits Production (2021-2032)
 - 1.3.6 China Gene Editing Off-Target NGS Assay Kits Production (2021-2032)
 - 1.3.7 Japan Gene Editing Off-Target NGS Assay Kits Production (2021-2032)
- 1.4 Market Drivers, Restraints and Trends
 - 1.4.1 Gene Editing Off-Target NGS Assay Kits Market Drivers
 - 1.4.2 Factors Affecting Demand
 - 1.4.3 Gene Editing Off-Target NGS Assay Kits Major Market Trends

2 DEMAND SUMMARY

- 2.1 World Gene Editing Off-Target NGS Assay Kits Demand (2021-2032)
- 2.2 World Gene Editing Off-Target NGS Assay Kits Consumption by Region
 - 2.2.1 World Gene Editing Off-Target NGS Assay Kits Consumption by Region (2021-2026)
 - 2.2.2 World Gene Editing Off-Target NGS Assay Kits Consumption Forecast by Region (2027-2032)
- 2.3 United States Gene Editing Off-Target NGS Assay Kits Consumption (2021-2032)
- 2.4 China Gene Editing Off-Target NGS Assay Kits Consumption (2021-2032)
- 2.5 Europe Gene Editing Off-Target NGS Assay Kits Consumption (2021-2032)
- 2.6 Japan Gene Editing Off-Target NGS Assay Kits Consumption (2021-2032)

- 2.7 South Korea Gene Editing Off-Target NGS Assay Kits Consumption (2021-2032)
- 2.8 ASEAN Gene Editing Off-Target NGS Assay Kits Consumption (2021-2032)
- 2.9 India Gene Editing Off-Target NGS Assay Kits Consumption (2021-2032)

3 WORLD MANUFACTURERS COMPETITIVE ANALYSIS

- 3.1 World Gene Editing Off-Target NGS Assay Kits Production Value by Manufacturer (2021-2026)
- 3.2 World Gene Editing Off-Target NGS Assay Kits Production by Manufacturer (2021-2026)
- 3.3 World Gene Editing Off-Target NGS Assay Kits Average Price by Manufacturer (2021-2026)
- 3.4 Gene Editing Off-Target NGS Assay Kits Company Evaluation Quadrant
- 3.5 Industry Rank and Concentration Rate (CR)
 - 3.5.1 Global Gene Editing Off-Target NGS Assay Kits Industry Rank of Major Manufacturers
 - 3.5.2 Global Concentration Ratios (CR4) for Gene Editing Off-Target NGS Assay Kits in 2025
 - 3.5.3 Global Concentration Ratios (CR8) for Gene Editing Off-Target NGS Assay Kits in 2025
- 3.6 Gene Editing Off-Target NGS Assay Kits Market: Overall Company Footprint Analysis
 - 3.6.1 Gene Editing Off-Target NGS Assay Kits Market: Region Footprint
 - 3.6.2 Gene Editing Off-Target NGS Assay Kits Market: Company Product Type Footprint
 - 3.6.3 Gene Editing Off-Target NGS Assay Kits Market: Company Product Application Footprint
- 3.7 Competitive Environment
 - 3.7.1 Historical Structure of the Industry
 - 3.7.2 Barriers of Market Entry
 - 3.7.3 Factors of Competition
- 3.8 New Entrant and Capacity Expansion Plans
- 3.9 Mergers, Acquisition, Agreements, and Collaborations

4 UNITED STATES VS CHINA VS REST OF THE WORLD

- 4.1 United States VS China: Gene Editing Off-Target NGS Assay Kits Production Value Comparison
 - 4.1.1 United States VS China: Gene Editing Off-Target NGS Assay Kits Production

Value Comparison (2021 & 2025 & 2032)

4.1.2 United States VS China: Gene Editing Off-Target NGS Assay Kits Production Value Market Share Comparison (2021 & 2025 & 2032)

4.2 United States VS China: Gene Editing Off-Target NGS Assay Kits Production Comparison

4.2.1 United States VS China: Gene Editing Off-Target NGS Assay Kits Production Comparison (2021 & 2025 & 2032)

4.2.2 United States VS China: Gene Editing Off-Target NGS Assay Kits Production Market Share Comparison (2021 & 2025 & 2032)

4.3 United States VS China: Gene Editing Off-Target NGS Assay Kits Consumption Comparison

4.3.1 United States VS China: Gene Editing Off-Target NGS Assay Kits Consumption Comparison (2021 & 2025 & 2032)

4.3.2 United States VS China: Gene Editing Off-Target NGS Assay Kits Consumption Market Share Comparison (2021 & 2025 & 2032)

4.4 United States Based Gene Editing Off-Target NGS Assay Kits Manufacturers and Market Share, 2021-2026

4.4.1 United States Based Gene Editing Off-Target NGS Assay Kits Manufacturers, Headquarters and Production Site (States, Country)

4.4.2 United States Based Manufacturers Gene Editing Off-Target NGS Assay Kits Production Value (2021-2026)

4.4.3 United States Based Manufacturers Gene Editing Off-Target NGS Assay Kits Production (2021-2026)

4.5 China Based Gene Editing Off-Target NGS Assay Kits Manufacturers and Market Share

4.5.1 China Based Gene Editing Off-Target NGS Assay Kits Manufacturers, Headquarters and Production Site (Province, Country)

4.5.2 China Based Manufacturers Gene Editing Off-Target NGS Assay Kits Production Value (2021-2026)

4.5.3 China Based Manufacturers Gene Editing Off-Target NGS Assay Kits Production (2021-2026)

4.6 Rest of World Based Gene Editing Off-Target NGS Assay Kits Manufacturers and Market Share, 2021-2026

4.6.1 Rest of World Based Gene Editing Off-Target NGS Assay Kits Manufacturers, Headquarters and Production Site (State, Country)

4.6.2 Rest of World Based Manufacturers Gene Editing Off-Target NGS Assay Kits Production Value (2021-2026)

4.6.3 Rest of World Based Manufacturers Gene Editing Off-Target NGS Assay Kits Production (2021-2026)

5 MARKET ANALYSIS BY TYPE

5.1 World Gene Editing Off-Target NGS Assay Kits Market Size Overview by Type:
2021 VS 2025 VS 2032

5.2 Segment Introduction by Type

5.2.1 Unbiased Genome-Wide Discovery

5.2.2 Targeted Candidate-Site Validation

5.3 Market Segment by Type

5.3.1 World Gene Editing Off-Target NGS Assay Kits Production by Type (2021-2032)

5.3.2 World Gene Editing Off-Target NGS Assay Kits Production Value by Type
(2021-2032)

5.3.3 World Gene Editing Off-Target NGS Assay Kits Average Price by Type
(2021-2032)

6 MARKET ANALYSIS BY TARGET ENRICHMENT METHOD

6.1 World Gene Editing Off-Target NGS Assay Kits Market Size Overview by Target
Enrichment Method: 2021 VS 2025 VS 2032

6.2 Segment Introduction by Target Enrichment Method

6.2.1 Multiplex PCR

6.2.2 Hybrid Capture

6.2.3 Double-Stranded Oligonucleotide Tag Capture

6.2.4 In Vitro Cleavage Enrichment

6.2.5 No Target Enrichment

6.2.6 Other

6.3 Market Segment by Target Enrichment Method

6.3.1 World Gene Editing Off-Target NGS Assay Kits Production by Target Enrichment
Method (2021-2032)

6.3.2 World Gene Editing Off-Target NGS Assay Kits Production Value by Target
Enrichment Method (2021-2032)

6.3.3 World Gene Editing Off-Target NGS Assay Kits Average Price by Target
Enrichment Method (2021-2032)

7 MARKET ANALYSIS BY SUPPLY FORMAT

7.1 World Gene Editing Off-Target NGS Assay Kits Market Size Overview by Supply
Format: 2021 VS 2025 VS 2032

7.2 Segment Introduction by Supply Format

- 7.2.1 Complete Assay Kits
- 7.2.2 Library Preparation Kits
- 7.2.3 Probe or Primer Pools
- 7.2.4 Other

7.3 Market Segment by Supply Format

- 7.3.1 World Gene Editing Off-Target NGS Assay Kits Production by Supply Format (2021-2032)
- 7.3.2 World Gene Editing Off-Target NGS Assay Kits Production Value by Supply Format (2021-2032)
- 7.3.3 World Gene Editing Off-Target NGS Assay Kits Average Price by Supply Format (2021-2032)

8 MARKET ANALYSIS BY SEQUENCING PLATFORM COMPATIBILITY

8.1 World Gene Editing Off-Target NGS Assay Kits Market Size Overview by Sequencing Platform Compatibility: 2021 VS 2025 VS 2032

8.2 Segment Introduction by Sequencing Platform Compatibility

- 8.2.1 Illumina-Compatible
- 8.2.2 Ion Torrent-Compatible
- 8.2.3 MGI-Compatible
- 8.2.4 Multi-Platform
- 8.2.5 Other

8.3 Market Segment by Sequencing Platform Compatibility

- 8.3.1 World Gene Editing Off-Target NGS Assay Kits Production by Sequencing Platform Compatibility (2021-2032)
- 8.3.2 World Gene Editing Off-Target NGS Assay Kits Production Value by Sequencing Platform Compatibility (2021-2032)
- 8.3.3 World Gene Editing Off-Target NGS Assay Kits Average Price by Sequencing Platform Compatibility (2021-2032)

9 MARKET ANALYSIS BY APPLICATION

9.1 World Gene Editing Off-Target NGS Assay Kits Market Size Overview by Application: 2021 VS 2025 VS 2032

9.2 Segment Introduction by Application

- 9.2.1 Biopharmaceutical Companies
- 9.2.2 Independent Testing Laboratories
- 9.2.3 Academic and Government Institutes
- 9.2.4 Agricultural Biotechnology Companies

9.2.5 Other

9.3 Market Segment by Application

9.3.1 World Gene Editing Off-Target NGS Assay Kits Production by Application (2021-2032)

9.3.2 World Gene Editing Off-Target NGS Assay Kits Production Value by Application (2021-2032)

9.3.3 World Gene Editing Off-Target NGS Assay Kits Average Price by Application (2021-2032)

10 COMPANY PROFILES

10.1 Integrated DNA Technologies

10.1.1 Integrated DNA Technologies Details

10.1.2 Integrated DNA Technologies Major Business

10.1.3 Integrated DNA Technologies Gene Editing Off-Target NGS Assay Kits Product and Services

10.1.4 Integrated DNA Technologies Gene Editing Off-Target NGS Assay Kits Production, Price, Value, Gross Margin and Market Share (2021-2026)

10.1.5 Integrated DNA Technologies Recent Developments/Updates

10.1.6 Integrated DNA Technologies Competitive Strengths & Weaknesses

10.2 Paragon Genomics

10.2.1 Paragon Genomics Details

10.2.2 Paragon Genomics Major Business

10.2.3 Paragon Genomics Gene Editing Off-Target NGS Assay Kits Product and Services

10.2.4 Paragon Genomics Gene Editing Off-Target NGS Assay Kits Production, Price, Value, Gross Margin and Market Share (2021-2026)

10.2.5 Paragon Genomics Recent Developments/Updates

10.2.6 Paragon Genomics Competitive Strengths & Weaknesses

10.3 iGeneTech Bioscience

10.3.1 iGeneTech Bioscience Details

10.3.2 iGeneTech Bioscience Major Business

10.3.3 iGeneTech Bioscience Gene Editing Off-Target NGS Assay Kits Product and Services

10.3.4 iGeneTech Bioscience Gene Editing Off-Target NGS Assay Kits Production, Price, Value, Gross Margin and Market Share (2021-2026)

10.3.5 iGeneTech Bioscience Recent Developments/Updates

10.3.6 iGeneTech Bioscience Competitive Strengths & Weaknesses

10.4 Illumina

- 10.4.1 Illumina Details
- 10.4.2 Illumina Major Business
- 10.4.3 Illumina Gene Editing Off-Target NGS Assay Kits Product and Services
- 10.4.4 Illumina Gene Editing Off-Target NGS Assay Kits Production, Price, Value, Gross Margin and Market Share (2021-2026)
- 10.4.5 Illumina Recent Developments/Updates
- 10.4.6 Illumina Competitive Strengths & Weaknesses
- 10.5 Thermo Fisher Scientific
 - 10.5.1 Thermo Fisher Scientific Details
 - 10.5.2 Thermo Fisher Scientific Major Business
 - 10.5.3 Thermo Fisher Scientific Gene Editing Off-Target NGS Assay Kits Product and Services
 - 10.5.4 Thermo Fisher Scientific Gene Editing Off-Target NGS Assay Kits Production, Price, Value, Gross Margin and Market Share (2021-2026)
 - 10.5.5 Thermo Fisher Scientific Recent Developments/Updates
 - 10.5.6 Thermo Fisher Scientific Competitive Strengths & Weaknesses
- 10.6 Twist Bioscience
 - 10.6.1 Twist Bioscience Details
 - 10.6.2 Twist Bioscience Major Business
 - 10.6.3 Twist Bioscience Gene Editing Off-Target NGS Assay Kits Product and Services
 - 10.6.4 Twist Bioscience Gene Editing Off-Target NGS Assay Kits Production, Price, Value, Gross Margin and Market Share (2021-2026)
 - 10.6.5 Twist Bioscience Recent Developments/Updates
 - 10.6.6 Twist Bioscience Competitive Strengths & Weaknesses
- 10.7 Agilent Technologies
 - 10.7.1 Agilent Technologies Details
 - 10.7.2 Agilent Technologies Major Business
 - 10.7.3 Agilent Technologies Gene Editing Off-Target NGS Assay Kits Product and Services
 - 10.7.4 Agilent Technologies Gene Editing Off-Target NGS Assay Kits Production, Price, Value, Gross Margin and Market Share (2021-2026)
 - 10.7.5 Agilent Technologies Recent Developments/Updates
 - 10.7.6 Agilent Technologies Competitive Strengths & Weaknesses
- 10.8 Roche
 - 10.8.1 Roche Details
 - 10.8.2 Roche Major Business
 - 10.8.3 Roche Gene Editing Off-Target NGS Assay Kits Product and Services
 - 10.8.4 Roche Gene Editing Off-Target NGS Assay Kits Production, Price, Value,

Gross Margin and Market Share (2021-2026)

10.8.5 Roche Recent Developments/Updates

10.8.6 Roche Competitive Strengths & Weaknesses

11 INDUSTRY CHAIN ANALYSIS

11.1 Gene Editing Off-Target NGS Assay Kits Industry Chain

11.2 Gene Editing Off-Target NGS Assay Kits Upstream Analysis

11.2.1 Gene Editing Off-Target NGS Assay Kits Core Raw Materials

11.2.2 Main Manufacturers of Gene Editing Off-Target NGS Assay Kits Core Raw Materials

11.3 Midstream Analysis

11.4 Downstream Analysis

11.5 Gene Editing Off-Target NGS Assay Kits Production Mode

11.6 Gene Editing Off-Target NGS Assay Kits Procurement Model

11.7 Gene Editing Off-Target NGS Assay Kits Industry Sales Model and Sales Channels

11.7.1 Gene Editing Off-Target NGS Assay Kits Sales Model

11.7.2 Gene Editing Off-Target NGS Assay Kits Typical Distributors

12 RESEARCH FINDINGS AND CONCLUSION

13 APPENDIX

13.1 Methodology

13.2 Research Process and Data Source

13.3 Disclaimer

List Of Tables

LIST OF TABLES

Table 1. World Gene Editing Off-Target NGS Assay Kits Production Value by Region (2021, 2025 and 2032) & (USD Million)

Table 2. World Gene Editing Off-Target NGS Assay Kits Production Value by Region (2021-2026) & (USD Million)

Table 3. World Gene Editing Off-Target NGS Assay Kits Production Value by Region (2027-2032) & (USD Million)

Table 4. World Gene Editing Off-Target NGS Assay Kits Production Value Market Share by Region (2021-2026)

Table 5. World Gene Editing Off-Target NGS Assay Kits Production Value Market Share by Region (2027-2032)

Table 6. World Gene Editing Off-Target NGS Assay Kits Production by Region (2021-2026) & (Units)

Table 7. World Gene Editing Off-Target NGS Assay Kits Production by Region (2027-2032) & (Units)

Table 8. World Gene Editing Off-Target NGS Assay Kits Production Market Share by Region (2021-2026)

Table 9. World Gene Editing Off-Target NGS Assay Kits Production Market Share by Region (2027-2032)

Table 10. World Gene Editing Off-Target NGS Assay Kits Average Price by Region (2021-2026) & (US\$/Unit)

Table 11. World Gene Editing Off-Target NGS Assay Kits Average Price by Region (2027-2032) & (US\$/Unit)

Table 12. Gene Editing Off-Target NGS Assay Kits Major Market Trends

Table 13. World Gene Editing Off-Target NGS Assay Kits Consumption Growth Rate Forecast by Region (2021 & 2025 & 2032) & (Units)

Table 14. World Gene Editing Off-Target NGS Assay Kits Consumption by Region (2021-2026) & (Units)

Table 15. World Gene Editing Off-Target NGS Assay Kits Consumption Forecast by Region (2027-2032) & (Units)

Table 16. World Gene Editing Off-Target NGS Assay Kits Production Value by Manufacturer (2021-2026) & (USD Million)

Table 17. Production Value Market Share of Key Gene Editing Off-Target NGS Assay Kits Producers in 2025

Table 18. World Gene Editing Off-Target NGS Assay Kits Production by Manufacturer (2021-2026) & (Units)

Table 19. Production Market Share of Key Gene Editing Off-Target NGS Assay Kits Producers in 2025

Table 20. World Gene Editing Off-Target NGS Assay Kits Average Price by Manufacturer (2021-2026) & (US\$/Unit)

Table 21. Global Gene Editing Off-Target NGS Assay Kits Company Evaluation Quadrant

Table 22. World Gene Editing Off-Target NGS Assay Kits Industry Rank of Major Manufacturers, Based on Production Value in 2025

Table 23. Head Office and Gene Editing Off-Target NGS Assay Kits Production Site of Key Manufacturer

Table 24. Gene Editing Off-Target NGS Assay Kits Market: Company Product Type Footprint

Table 25. Gene Editing Off-Target NGS Assay Kits Market: Company Product Application Footprint

Table 26. Gene Editing Off-Target NGS Assay Kits Competitive Factors

Table 27. Gene Editing Off-Target NGS Assay Kits New Entrant and Capacity Expansion Plans

Table 28. Gene Editing Off-Target NGS Assay Kits Mergers & Acquisitions Activity

Table 29. United States VS China Gene Editing Off-Target NGS Assay Kits Production Value Comparison, (2021 & 2025 & 2032) & (USD Million)

Table 30. United States VS China Gene Editing Off-Target NGS Assay Kits Production Comparison, (2021 & 2025 & 2032) & (Units)

Table 31. United States VS China Gene Editing Off-Target NGS Assay Kits Consumption Comparison, (2021 & 2025 & 2032) & (Units)

Table 32. United States Based Gene Editing Off-Target NGS Assay Kits Manufacturers, Headquarters and Production Site (States, Country)

Table 33. United States Based Manufacturers Gene Editing Off-Target NGS Assay Kits Production Value, (2021-2026) & (USD Million)

Table 34. United States Based Manufacturers Gene Editing Off-Target NGS Assay Kits Production Value Market Share (2021-2026)

Table 35. United States Based Manufacturers Gene Editing Off-Target NGS Assay Kits Production (2021-2026) & (Units)

Table 36. United States Based Manufacturers Gene Editing Off-Target NGS Assay Kits Production Market Share (2021-2026)

Table 37. China Based Gene Editing Off-Target NGS Assay Kits Manufacturers, Headquarters and Production Site (Province, Country)

Table 38. China Based Manufacturers Gene Editing Off-Target NGS Assay Kits Production Value, (2021-2026) & (USD Million)

Table 39. China Based Manufacturers Gene Editing Off-Target NGS Assay Kits

Production Value Market Share (2021-2026)

Table 40. China Based Manufacturers Gene Editing Off-Target NGS Assay Kits Production, (2021-2026) & (Units)

Table 41. China Based Manufacturers Gene Editing Off-Target NGS Assay Kits Production Market Share (2021-2026)

Table 42. Rest of World Based Gene Editing Off-Target NGS Assay Kits Manufacturers, Headquarters and Production Site (State, Country)

Table 43. Rest of World Based Manufacturers Gene Editing Off-Target NGS Assay Kits Production Value, (2021-2026) & (USD Million)

Table 44. Rest of World Based Manufacturers Gene Editing Off-Target NGS Assay Kits Production Value Market Share (2021-2026)

Table 45. Rest of World Based Manufacturers Gene Editing Off-Target NGS Assay Kits Production, (2021-2026) & (Units)

Table 46. Rest of World Based Manufacturers Gene Editing Off-Target NGS Assay Kits Production Market Share (2021-2026)

Table 47. World Gene Editing Off-Target NGS Assay Kits Production Value by Type, (USD Million), 2021 & 2025 & 2032

Table 48. World Gene Editing Off-Target NGS Assay Kits Production by Type (2021-2026) & (Units)

Table 49. World Gene Editing Off-Target NGS Assay Kits Production by Type (2027-2032) & (Units)

Table 50. World Gene Editing Off-Target NGS Assay Kits Production Value by Type (2021-2026) & (USD Million)

Table 51. World Gene Editing Off-Target NGS Assay Kits Production Value by Type (2027-2032) & (USD Million)

Table 52. World Gene Editing Off-Target NGS Assay Kits Average Price by Type (2021-2026) & (US\$/Unit)

Table 53. World Gene Editing Off-Target NGS Assay Kits Average Price by Type (2027-2032) & (US\$/Unit)

Table 54. World Gene Editing Off-Target NGS Assay Kits Production Value by Target Enrichment Method, (USD Million), 2021 & 2025 & 2032

Table 55. World Gene Editing Off-Target NGS Assay Kits Production by Target Enrichment Method (2021-2026) & (Units)

Table 56. World Gene Editing Off-Target NGS Assay Kits Production by Target Enrichment Method (2027-2032) & (Units)

Table 57. World Gene Editing Off-Target NGS Assay Kits Production Value by Target Enrichment Method (2021-2026) & (USD Million)

Table 58. World Gene Editing Off-Target NGS Assay Kits Production Value by Target Enrichment Method (2027-2032) & (USD Million)

Table 59. World Gene Editing Off-Target NGS Assay Kits Average Price by Target Enrichment Method (2021-2026) & (US\$/Unit)

Table 60. World Gene Editing Off-Target NGS Assay Kits Average Price by Target Enrichment Method (2027-2032) & (US\$/Unit)

Table 61. World Gene Editing Off-Target NGS Assay Kits Production Value by Supply Format, (USD Million), 2021 & 2025 & 2032

Table 62. World Gene Editing Off-Target NGS Assay Kits Production by Supply Format (2021-2026) & (Units)

Table 63. World Gene Editing Off-Target NGS Assay Kits Production by Supply Format (2027-2032) & (Units)

Table 64. World Gene Editing Off-Target NGS Assay Kits Production Value by Supply Format (2021-2026) & (USD Million)

Table 65. World Gene Editing Off-Target NGS Assay Kits Production Value by Supply Format (2027-2032) & (USD Million)

Table 66. World Gene Editing Off-Target NGS Assay Kits Average Price by Supply Format (2021-2026) & (US\$/Unit)

Table 67. World Gene Editing Off-Target NGS Assay Kits Average Price by Supply Format (2027-2032) & (US\$/Unit)

Table 68. World Gene Editing Off-Target NGS Assay Kits Production Value by Sequencing Platform Compatibility, (USD Million), 2021 & 2025 & 2032

Table 69. World Gene Editing Off-Target NGS Assay Kits Production by Sequencing Platform Compatibility (2021-2026) & (Units)

Table 70. World Gene Editing Off-Target NGS Assay Kits Production by Sequencing Platform Compatibility (2027-2032) & (Units)

Table 71. World Gene Editing Off-Target NGS Assay Kits Production Value by Sequencing Platform Compatibility (2021-2026) & (USD Million)

Table 72. World Gene Editing Off-Target NGS Assay Kits Production Value by Sequencing Platform Compatibility (2027-2032) & (USD Million)

Table 73. World Gene Editing Off-Target NGS Assay Kits Average Price by Sequencing Platform Compatibility (2021-2026) & (US\$/Unit)

Table 74. World Gene Editing Off-Target NGS Assay Kits Average Price by Sequencing Platform Compatibility (2027-2032) & (US\$/Unit)

Table 75. World Gene Editing Off-Target NGS Assay Kits Production Value by Application, (USD Million), 2021 & 2025 & 2032

Table 76. World Gene Editing Off-Target NGS Assay Kits Production by Application (2021-2026) & (Units)

Table 77. World Gene Editing Off-Target NGS Assay Kits Production by Application (2027-2032) & (Units)

Table 78. World Gene Editing Off-Target NGS Assay Kits Production Value by

Application (2021-2026) & (USD Million)

Table 79. World Gene Editing Off-Target NGS Assay Kits Production Value by Application (2027-2032) & (USD Million)

Table 80. World Gene Editing Off-Target NGS Assay Kits Average Price by Application (2021-2026) & (US\$/Unit)

Table 81. World Gene Editing Off-Target NGS Assay Kits Average Price by Application (2027-2032) & (US\$/Unit)

Table 82. Integrated DNA Technologies Basic Information, Manufacturing Base and Competitors

Table 83. Integrated DNA Technologies Major Business

Table 84. Integrated DNA Technologies Gene Editing Off-Target NGS Assay Kits Product and Services

Table 85. Integrated DNA Technologies Gene Editing Off-Target NGS Assay Kits Production (Units), Price (US\$/Unit), Production Value (USD Million), Gross Margin and Market Share (2021-2026)

Table 86. Integrated DNA Technologies Recent Developments/Updates

Table 87. Integrated DNA Technologies Competitive Strengths & Weaknesses

Table 88. Paragon Genomics Basic Information, Manufacturing Base and Competitors

Table 89. Paragon Genomics Major Business

Table 90. Paragon Genomics Gene Editing Off-Target NGS Assay Kits Product and Services

Table 91. Paragon Genomics Gene Editing Off-Target NGS Assay Kits Production (Units), Price (US\$/Unit), Production Value (USD Million), Gross Margin and Market Share (2021-2026)

Table 92. Paragon Genomics Recent Developments/Updates

Table 93. Paragon Genomics Competitive Strengths & Weaknesses

Table 94. iGeneTech Bioscience Basic Information, Manufacturing Base and Competitors

Table 95. iGeneTech Bioscience Major Business

Table 96. iGeneTech Bioscience Gene Editing Off-Target NGS Assay Kits Product and Services

Table 97. iGeneTech Bioscience Gene Editing Off-Target NGS Assay Kits Production (Units), Price (US\$/Unit), Production Value (USD Million), Gross Margin and Market Share (2021-2026)

Table 98. iGeneTech Bioscience Recent Developments/Updates

Table 99. iGeneTech Bioscience Competitive Strengths & Weaknesses

Table 100. Illumina Basic Information, Manufacturing Base and Competitors

Table 101. Illumina Major Business

Table 102. Illumina Gene Editing Off-Target NGS Assay Kits Product and Services

Table 103. Illumina Gene Editing Off-Target NGS Assay Kits Production (Units), Price (US\$/Unit), Production Value (USD Million), Gross Margin and Market Share (2021-2026)

Table 104. Illumina Recent Developments/Updates

Table 105. Illumina Competitive Strengths & Weaknesses

Table 106. Thermo Fisher Scientific Basic Information, Manufacturing Base and Competitors

Table 107. Thermo Fisher Scientific Major Business

Table 108. Thermo Fisher Scientific Gene Editing Off-Target NGS Assay Kits Product and Services

Table 109. Thermo Fisher Scientific Gene Editing Off-Target NGS Assay Kits Production (Units), Price (US\$/Unit), Production Value (USD Million), Gross Margin and Market Share (2021-2026)

Table 110. Thermo Fisher Scientific Recent Developments/Updates

Table 111. Thermo Fisher Scientific Competitive Strengths & Weaknesses

Table 112. Twist Bioscience Basic Information, Manufacturing Base and Competitors

Table 113. Twist Bioscience Major Business

Table 114. Twist Bioscience Gene Editing Off-Target NGS Assay Kits Product and Services

Table 115. Twist Bioscience Gene Editing Off-Target NGS Assay Kits Production (Units), Price (US\$/Unit), Production Value (USD Million), Gross Margin and Market Share (2021-2026)

Table 116. Twist Bioscience Recent Developments/Updates

Table 117. Twist Bioscience Competitive Strengths & Weaknesses

Table 118. Agilent Technologies Basic Information, Manufacturing Base and Competitors

Table 119. Agilent Technologies Major Business

Table 120. Agilent Technologies Gene Editing Off-Target NGS Assay Kits Product and Services

Table 121. Agilent Technologies Gene Editing Off-Target NGS Assay Kits Production (Units), Price (US\$/Unit), Production Value (USD Million), Gross Margin and Market Share (2021-2026)

Table 122. Agilent Technologies Recent Developments/Updates

Table 123. Agilent Technologies Competitive Strengths & Weaknesses

Table 124. Roche Basic Information, Manufacturing Base and Competitors

Table 125. Roche Major Business

Table 126. Roche Gene Editing Off-Target NGS Assay Kits Product and Services

Table 127. Roche Gene Editing Off-Target NGS Assay Kits Production (Units), Price (US\$/Unit), Production Value (USD Million), Gross Margin and Market Share

(2021-2026)

Table 128. Roche Recent Developments/Updates

Table 129. Roche Competitive Strengths & Weaknesses

Table 130. Global Key Players of Gene Editing Off-Target NGS Assay Kits Upstream
(Raw Materials)

Table 131. Global Gene Editing Off-Target NGS Assay Kits Typical Customers

Table 132. Gene Editing Off-Target NGS Assay Kits Typical Distributors

List Of Figures

LIST OF FIGURES

Figure 1. Gene Editing Off-Target NGS Assay Kits Picture

Figure 2. World Gene Editing Off-Target NGS Assay Kits Production Value: 2021 & 2025 & 2032, (USD Million)

Figure 3. World Gene Editing Off-Target NGS Assay Kits Production Value and Forecast (2021-2032) & (USD Million)

Figure 4. World Gene Editing Off-Target NGS Assay Kits Production (2021-2032) & (Units)

Figure 5. World Gene Editing Off-Target NGS Assay Kits Average Price (2021-2032) & (US\$/Unit)

Figure 6. World Gene Editing Off-Target NGS Assay Kits Production Value Market Share by Region (2021-2032)

Figure 7. World Gene Editing Off-Target NGS Assay Kits Production Market Share by Region (2021-2032)

Figure 8. North America Gene Editing Off-Target NGS Assay Kits Production (2021-2032) & (Units)

Figure 9. Europe Gene Editing Off-Target NGS Assay Kits Production (2021-2032) & (Units)

Figure 10. China Gene Editing Off-Target NGS Assay Kits Production (2021-2032) & (Units)

Figure 11. Japan Gene Editing Off-Target NGS Assay Kits Production (2021-2032) & (Units)

Figure 12. Gene Editing Off-Target NGS Assay Kits Market Drivers

Figure 13. Factors Affecting Demand

Figure 14. World Gene Editing Off-Target NGS Assay Kits Consumption (2021-2032) & (Units)

Figure 15. World Gene Editing Off-Target NGS Assay Kits Consumption Market Share by Region (2021-2032)

Figure 16. United States Gene Editing Off-Target NGS Assay Kits Consumption (2021-2032) & (Units)

Figure 17. China Gene Editing Off-Target NGS Assay Kits Consumption (2021-2032) & (Units)

Figure 18. Europe Gene Editing Off-Target NGS Assay Kits Consumption (2021-2032) & (Units)

Figure 19. Japan Gene Editing Off-Target NGS Assay Kits Consumption (2021-2032) & (Units)

Figure 20. South Korea Gene Editing Off-Target NGS Assay Kits Consumption (2021-2032) & (Units)

Figure 21. ASEAN Gene Editing Off-Target NGS Assay Kits Consumption (2021-2032) & (Units)

Figure 22. India Gene Editing Off-Target NGS Assay Kits Consumption (2021-2032) & (Units)

Figure 23. Producer Shipments of Gene Editing Off-Target NGS Assay Kits by Manufacturer Revenue (\$MM) and Market Share (%): 2025

Figure 24. Global Four-firm Concentration Ratios (CR4) for Gene Editing Off-Target NGS Assay Kits Markets in 2025

Figure 25. Global Four-firm Concentration Ratios (CR8) for Gene Editing Off-Target NGS Assay Kits Markets in 2025

Figure 26. United States VS China: Gene Editing Off-Target NGS Assay Kits Production Value Market Share Comparison (2021 & 2025 & 2032)

Figure 27. United States VS China: Gene Editing Off-Target NGS Assay Kits Production Market Share Comparison (2021 & 2025 & 2032)

Figure 28. United States VS China: Gene Editing Off-Target NGS Assay Kits Consumption Market Share Comparison (2021 & 2025 & 2032)

Figure 29. United States Based Manufacturers Gene Editing Off-Target NGS Assay Kits Production Market Share 2025

Figure 30. China Based Manufacturers Gene Editing Off-Target NGS Assay Kits Production Market Share 2025

Figure 31. Rest of World Based Manufacturers Gene Editing Off-Target NGS Assay Kits Production Market Share 2025

Figure 32. World Gene Editing Off-Target NGS Assay Kits Production Value by Type, (USD Million), 2021 & 2025 & 2032

Figure 33. World Gene Editing Off-Target NGS Assay Kits Production Value Market Share by Type in 2025

Figure 34. Unbiased Genome-Wide Discovery

Figure 35. Targeted Candidate-Site Validation

Figure 36. World Gene Editing Off-Target NGS Assay Kits Production Market Share by Type (2021-2032)

Figure 37. World Gene Editing Off-Target NGS Assay Kits Production Value Market Share by Type (2021-2032)

Figure 38. World Gene Editing Off-Target NGS Assay Kits Average Price by Type (2021-2032) & (US\$/Unit)

Figure 39. World Gene Editing Off-Target NGS Assay Kits Production Value by Target Enrichment Method, (USD Million), 2021 & 2025 & 2032

Figure 40. World Gene Editing Off-Target NGS Assay Kits Production Value Market

Share by Target Enrichment Method in 2025

Figure 41. Multiplex PCR

Figure 42. Hybrid Capture

Figure 43. Double-Stranded Oligonucleotide Tag Capture

Figure 44. In Vitro Cleavage Enrichment

Figure 45. No Target Enrichment

Figure 46. Other

Figure 47. World Gene Editing Off-Target NGS Assay Kits Production Market Share by Target Enrichment Method (2021-2032)

Figure 48. World Gene Editing Off-Target NGS Assay Kits Production Value Market Share by Target Enrichment Method (2021-2032)

Figure 49. World Gene Editing Off-Target NGS Assay Kits Average Price by Target Enrichment Method (2021-2032) & (US\$/Unit)

Figure 50. World Gene Editing Off-Target NGS Assay Kits Production Value by Supply Format, (USD Million), 2021 & 2025 & 2032

Figure 51. World Gene Editing Off-Target NGS Assay Kits Production Value Market Share by Supply Format in 2025

Figure 52. Complete Assay Kits

Figure 53. Library Preparation Kits

Figure 54. Probe or Primer Pools

Figure 55. Other

Figure 56. World Gene Editing Off-Target NGS Assay Kits Production Market Share by Supply Format (2021-2032)

Figure 57. World Gene Editing Off-Target NGS Assay Kits Production Value Market Share by Supply Format (2021-2032)

Figure 58. World Gene Editing Off-Target NGS Assay Kits Average Price by Supply Format (2021-2032) & (US\$/Unit)

Figure 59. World Gene Editing Off-Target NGS Assay Kits Production Value by Sequencing Platform Compatibility, (USD Million), 2021 & 2025 & 2032

Figure 60. World Gene Editing Off-Target NGS Assay Kits Production Value Market Share by Sequencing Platform Compatibility in 2025

Figure 61. Illumina-Compatible

Figure 62. Ion Torrent-Compatible

Figure 63. MGI-Compatible

Figure 64. Multi-Platform

Figure 65. Other

Figure 66. World Gene Editing Off-Target NGS Assay Kits Production Market Share by Sequencing Platform Compatibility (2021-2032)

Figure 67. World Gene Editing Off-Target NGS Assay Kits Production Value Market

Share by Sequencing Platform Compatibility (2021-2032)

Figure 68. World Gene Editing Off-Target NGS Assay Kits Average Price by Sequencing Platform Compatibility (2021-2032) & (US\$/Unit)

Figure 69. World Gene Editing Off-Target NGS Assay Kits Production Value by Application, (USD Million), 2021 & 2025 & 2032

Figure 70. World Gene Editing Off-Target NGS Assay Kits Production Value Market Share by Application in 2025

Figure 71. Biopharmaceutical Companies

Figure 72. Independent Testing Laboratories

Figure 73. Academic and Government Institutes

Figure 74. Agricultural Biotechnology Companies

Figure 75. Other

Figure 76. World Gene Editing Off-Target NGS Assay Kits Production Market Share by Application (2021-2032)

Figure 77. World Gene Editing Off-Target NGS Assay Kits Production Value Market Share by Application (2021-2032)

Figure 78. World Gene Editing Off-Target NGS Assay Kits Average Price by Application (2021-2032) & (US\$/Unit)

Figure 79. Gene Editing Off-Target NGS Assay Kits Industry Chain

Figure 80. Gene Editing Off-Target NGS Assay Kits Procurement Model

Figure 81. Gene Editing Off-Target NGS Assay Kits Sales Model

Figure 82. Gene Editing Off-Target NGS Assay Kits Sales Channels, Direct Sales, and Distribution

Figure 83. Methodology

Figure 84. Research Process and Data Source

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