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Residual DNA Testing Market by Product & Service (Consumable, Instrument & Software), Technology (PCR), Test Type (Raw, Final, Bulk Lot Release Testing), Application (mAb, CGT, Vaccine), End User (Pharma & Biotech, CRO & CDMO) - Global Forecast to 2030

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Abstracts

The residual DNA testing market is projected to reach USD 0.37 billion by 2030 from USD 0.28 billion in 2025, at a CAGR of 6.0% during the forecast period. The expansion of this market is fueled by multiple factors, including the increasing frequency of approvals for biologics and biosimilars, as well as the implementation of rigorous regulatory frameworks governing the manufacture of biopharmaceutical products. Additionally, advancements in technologies related to residual DNA testing are anticipated to further bolster market growth throughout the forecast period.

By technology, the PCR segment accounted for the largest share of the residual DNA testing market in 2024.

By technology, the market is segmented into PCR, threshold Assays, DNA probe hybridization, and other technologies. In 2024, the Polymerase Chain Reaction (PCR) segment commanded the largest share of the market, reflecting its pivotal role in molecular diagnostics. This substantial market share can be primarily attributed to the high sensitivity and specificity offered by PCR, which enables the precise detection of even minute quantities of residual DNA. As a result, PCR effectively minimizes the risk of false positives, a critical factor in ensuring accurate test outcomes. Moreover, the versatility of the PCR technology plays a significant role in its widespread adoption. It can be easily adapted for various test types, making it applicable across a broad

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spectrum of biopharmaceutical applications. This adaptability, combined with its scalability, allows PCR to be employed in everything from small-scale research studies to large-scale clinical testing, catering to the evolving needs of the biopharmaceutical industry. With its exceptional performance characteristics and flexible applications, the PCR segment continues to be a cornerstone of advancements in molecular biology and diagnostics.

In 2024, by end user, the pharmaceutical & biotechnology companies segment accounted for the largest share of the residual DNA testing services market.

The residual DNA testing services market is categorized into two primary segments: pharmaceutical & biotechnology companies and academic & research institutes. As of 2024, the pharmaceutical & biotechnology companies segment holds the largest share of the market. This substantial growth can be attributed to the increasing emphasis on the development of biologics, which are innovative therapies aimed at treating a variety of diseases, including cancers, autoimmune disorders, and genetic conditions. As the industry evolves, pharmaceutical and biotechnology firms are required to adhere to stringent regulatory standards, which mandate the provision of comprehensive data concerning the entire manufacturing process. This includes the rigorous testing and validation of biological products to ensure their safety and efficacy. Consequently, the necessity for thorough quality inspections and regulatory approvals becomes paramount, driving the demand for residual DNA testing services. These services play a critical role in identifying and quantifying residual DNA left in biologics, ensuring that products meet safety guidelines and are free from contaminants that could pose risks to patients. Moreover, as companies invest in advanced biotechnological research and development, the demand for reliable and accurate testing methods continues to rise. This trend further augments the market for residual DNA testing services, highlighting its essential role in the pharmaceutical landscape. As the sector strives for innovation and compliance, the importance of these testing services will likely increase, underscoring their value in advancing medical science and patient safety.

In 2024, North America accounted for the largest share of the residual DNA testing market.

In 2024, North America emerged as the dominant force in the market, largely due to the strong presence of key industry leaders and a notable expansion in research initiatives aimed at innovating and developing biologics. This growth can be attributed to a significant increase in research and development investments within the life sciences sector, which, in turn, has escalated the demand for residual DNA testing products and

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services. Additionally, the region benefits from a concentration of numerous global entities, including pharmaceutical companies, biotech firms, and academic institutions, which collectively enhance its leadership position in the market. This collaborative environment fosters innovation and accelerates advancements in biologics, further solidifying North America's role as a pivotal hub for life sciences R&D.

The primary interviews conducted for this report can be categorized as follows:

By Respondent: Tier 1-25%, Tier 2-35%, and Tier 3- 40%

By Designation: CXOs and Directors- 30%, Managers- 45%, and Executives- 25%

By Region: North America -35%, Europe - 25%, Asia Pacific -15%, Latin America -10%, Middle East- 10%, and Africa- 5%

List of companies profiled in the report:

Thermo Fisher Scientific Inc. (US)

Merck KGaA (Germany)

Eurofins Scientific (Luxembourg)

Charles River Laboratories (US)

Bio-Rad Laboratories (US)

QIAGEN (Germany)

F. Hoffmann-La Roche Ltd (Switerland)

Maravai LifeSciences (US)

FUJIFILM Corporation (Japan)

SGS Soci?t? G?n?rale de Surveillance SA (Switzerland)

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Jiangsu Hillgene Biopharma Co.,Ltd (China)

Revvity (US)

Intertek Group plc (UK)

WuXi AppTec (China)

Sartorius AG (Germany)

Lonza (Switzerland)

Research Coverage:

This research report categorizes residual DNA testing market by offering (products and services), technology (PCR, threshold assay, DNA probe hybridization, and other technologies), test type (final product release testing, bulk lot release testing, and final product release testing), application (monoclonal antibodies, cell & gene therapy, vaccines, and other applications), end user for products (pharmaceutical & biotechnology companies, CROs & CDMOs, and academic & research institutes), end user for services (pharmaceutical & biotechnology companies and academic & research institutes), and region (North America, Europe, the Asia Pacific, Latin America, the Middle East, and Africa).

The report offers an in-depth examination of the critical elements shaping the residual DNA testing market, including key drivers, constraints, challenges, and emerging opportunities. It presents a comprehensive analysis of leading industry players, detailing their business models, product and service offerings, strategic initiatives, new launches, acquisitions, and recent advancements pertinent to the residual DNA testing sector. Additionally, this report includes a competitive landscape assessment of emerging startups within the residual DNA testing ecosystem.

Key Benefits of Buying the Report:

The report will help market leaders/new entrants by providing the closest approximations of the revenue numbers for the residual DNA testing market and its subsegments. It will also help stakeholders better understand the competitive landscape and gain more insights to position their business and make suitable go-to-market strategies. This report will enable stakeholders to understand the market's pulse and provide information on the key market drivers, restraints, challenges, trends, and opportunities.

The report provides insights on the following:

Analysis of key drivers (Increase in biologics and biosimilars approvals, stringent regulatory compliance requirements, technological advancements in DNA quantification and detection, increasing cell culture contamination risks, rising investments in R&D spending), restraints (high cost of advanced testing techniques, lack of standardization across testing protocols), opportunities (application in novel modalities such as mRNA vaccines, cell therapies, and gene therapies, growth opportunities in emerging markets, integration with continuous and accelerated bioprocessing, rising outsourcing to CROs and CDMOs), and challenges (complexity in sample preparation and assay validation) are influencing the growth of the residual DNA testing market.

Product Development/Innovation: Detailed insights on newly launched products of the residual DNA testing market.

Market Development: Comprehensive information about lucrative markets – the report analyses the residual DNA testing market across varied regions.

Market Diversification: Exhaustive information about new products and services, recent developments, and investments in the residual DNA testing market.

Competitive Assessment: In-depth assessment of market shares, growth strategies, and product offerings of leading players, including Thermo Fisher Scientific Inc. (US), Merck KGaA (Germany), and Eurofins Scientific (Luxembourg), among others, offering products and services for the residual DNA testing market. Other companies in this market include TransGen Biotech Co., Ltd. (China), Vazyme International LLC (China), and EagleBio (US).

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Contents

1 INTRODUCTION

1.1 STUDY OBJECTIVES
1.2 MARKET DEFINITION
1.3 STUDY SCOPE
  1.3.1 MARKET SEGMENTATION & REGIONAL SCOPE
  1.3.2 INCLUSIONS & EXCLUSIONS
  1.3.3 YEARS CONSIDERED
  1.3.4 CURRENCY CONSIDERED
1.4 STAKEHOLDERS

2 RESEARCH METHODOLOGY

2.1 RESEARCH DATA
  2.1.1 SECONDARY DATA
    2.1.1.1 Key sources of secondary data
    2.1.1.2 Key objectives of secondary research
  2.1.2 PRIMARY DATA
    2.1.2.1 Breakdown of primaries
    2.1.2.2 Key objectives of primary research
2.2 MARKET ESTIMATION METHODOLOGY
  2.2.1 MARKET ESTIMATION
    2.2.1.1 Company revenue analysis (bottom-up approach)
    2.2.1.2 Insights of primary experts
  2.2.2 SEGMENTAL MARKET SIZE ESTIMATION (TOP-DOWN APPROACH)
2.3 MARKET GROWTH RATE PROJECTIONS
2.4 DATA TRIANGULATION
2.5 STUDY ASSUMPTIONS
2.6 RESEARCH LIMITATIONS
2.7 RISK ANALYSIS

3 EXECUTIVE SUMMARY

4 PREMIUM INSIGHTS

4.1 RESIDUAL DNA TESTING MARKET OVERVIEW
4.2 NORTH AMERICA: RESIDUAL DNA TESTING MARKET, BY TEST TYPE AND

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COUNTRY
4.3 RESIDUAL DNA TESTING PRODUCTS MARKET SHARE, BY END USER, 2024
4.4 RESIDUAL DNA TESTING MARKET: GEOGRAPHIC GROWTH OPPORTUNITIES

5 MARKET OVERVIEW

5.1 INTRODUCTION
5.2 MARKET DYNAMICS
  5.2.1 DRIVERS
    5.2.1.1 Increasing number of biologics and biosimilar approvals
    5.2.1.2 Stringent regulatory compliance requirements
    5.2.1.3 Technological advancements in DNA quantification and detection
    5.2.1.4 Increasing risk of cell culture contamination
    5.2.1.5 Rising biopharmaceutical R&D investments
  5.2.2 RESTRAINTS
    5.2.2.1 High costs of advanced testing techniques
    5.2.2.2 Lack of standardization across testing protocols
  5.2.3 OPPORTUNITIES
    5.2.3.1 Rising number of applications in novel modalities
    5.2.3.2 High growth opportunities in emerging markets
    5.2.3.3 Integration with continuous and accelerated bioprocessing
    5.2.3.4 Rising outsourcing to CROs and CDMOs
  5.2.4 CHALLENGES
    5.2.4.1 Complexity in sample preparation and assay validation
5.3 TRENDS/DISRUPTIONS IMPACTING CUSTOMER’S BUSINESS
5.4 PRICING ANALYSIS
  5.4.1 AVERAGE SELLING PRICE TREND OF RESIDUAL DNA TESTING PRODUCTS, BY KEY PLAYER, 2022–2024
  5.4.2 AVERAGE SELLING PRICE TREND OF RESIDUAL DNA TESTING PRODUCTS, BY REGION, 2022–2024
5.5 VALUE CHAIN ANALYSIS
5.6 ECOSYSTEM ANALYSIS
  5.6.1 ROLE IN ECOSYSTEM
5.7 INVESTMENT & FUNDING SCENARIO
5.8 TECHNOLOGY ANALYSIS
  5.8.1 KEY TECHNOLOGIES
    5.8.1.1 Quantitative PCR (qPCR)
    5.8.1.2 Droplet digital PCR (ddPCR)
    5.8.1.3 Next-generation sequencing (NGS)

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5.8.2 COMPLEMENTARY TECHNOLOGIES
5.8.2.1 Automated magnetic bead-based DNA extraction
5.8.2.2 Capillary electrophoresis
5.8.2.3 Nanopore sequencing
5.8.3 ADJACENT TECHNOLOGIES
5.8.3.1 High-performance liquid chromatography (HPLC)
5.8.3.2 Electron microscopy
5.8.3.3 Mass spectrometry
5.9 PATENT ANALYSIS
5.9.1 LIST OF KEY PATENTS
5.10 KEY CONFERENCES & EVENTS, 2025–2026
5.11 REGULATORY ANALYSIS
5.11.1 REGULATORY FRAMEWORK
5.11.1.1 North America
5.11.1.1.1 US
5.11.1.1.2 Canada
5.11.1.2 Europe
5.11.1.2.1 UK
5.11.1.3 Asia Pacific
5.11.1.3.1 China
5.11.1.3.2 Japan
5.11.1.3.3 India
5.11.2 REGULATORY BODIES, GOVERNMENT AGENCIES, AND OTHER ORGANIZATIONS
5.12 PORTER'S FIVE FORCES ANALYSIS
5.12.1 BARGAINING POWER OF SUPPLIERS
5.12.2 BARGAINING POWER OF BUYERS
5.12.3 THREAT OF NEW ENTRANTS
5.12.4 THREAT OF SUBSTITUTES
5.12.5 INTENSITY OF COMPETITIVE RIVALRY
5.13 KEY STAKEHOLDERS & BUYING CRITERIA
5.13.1 KEY STAKEHOLDERS IN BUYING PROCESS
5.13.2 KEY BUYING CRITERIA, BY END USER
5.14 IMPACT OF AI/GEN AI ON RESIDUAL DNA TESTING MARKET
5.14.1 MARKET POTENTIAL OF AI IN RESIDUAL DNA TESTING
5.14.2 AI USE CASES
5.14.3 KEY COMPANIES IMPLEMENTING AI/GEN AI
5.14.4 FUTURE OF AI/GEN AI IN RESIDUAL DNA TESTING MARKET
5.15 TRADE DATA ANALYSIS

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5.15.1 IMPORT DATA FOR HS CODE 9027, 2020–2024
5.15.2 EXPORT DATA FOR HS CODE 9027, 2020–2024
5.16 IMPACT OF 2025 US TARIFF ON RESIDUAL DNA TESTING MARKET
5.16.1 KEY TARIFF RATES
5.16.2 PRICE IMPACT ANALYSIS
5.16.3 IMPACT ON COUNTRIES/REGIONS
5.16.3.1 North America
5.16.3.1.1 US
5.16.3.2 Europe
5.16.3.3 Asia Pacific
5.16.3.4 Rest of the World
5.16.4 IMPACT ON END-USE INDUSTRIES
5.16.4.1 Pharmaceutical & biotechnology companies
5.16.4.2 CROs & CDMOs
5.16.4.3 Academic & research institutes

6 RESIDUAL DNA TESTING MARKET, BY OFFERING

6.1 INTRODUCTION
6.2 PRODUCTS
6.2.1 CONSUMABLES
6.2.1.1 Increasing focus on development of biologics and biosimilars to propel segment growth
6.2.2 INSTRUMENTS & SOFTWARE
6.2.2.1 Continuous advancement in analytical technologies to fuel segment growth
6.3 SERVICES
6.3.1 STRINGENT REGULATORY STANDARDS TO PROMOTE MARKET GROWTH

7 RESIDUAL DNA TESTING MARKET, BY TEST TYPE

7.1 INTRODUCTION
7.2 FINAL PRODUCT RELEASE TESTING
7.2.1 FAVORABLE REGULATORY MANDATES AND BIOLOGICS INNOVATION TO FUEL MARKET GROWTH
7.3 BULK LOT RELEASE TESTING
7.3.1 INCREASING BIOLOGIC COMPLEXITY TO FUEL MARKET GROWTH
7.4 RAW MATERIAL TESTING
7.4.1 ENHANCED FOCUS ON PRODUCT SAFETY AND REGULATORY COMPLIANCE TO AUGMENT MARKET GROWTH

+357 96 030922
info@marketpublishers.com

8 RESIDUAL DNA TESTING MARKET, BY TECHNOLOGY

8.1 INTRODUCTION
8.2 POLYMERASE CHAIN REACTION
  8.2.1 HIGH THROUGHPUT DETECTION TO SUPPORT SEGMENT DOMINANCE
8.3 THRESHOLD ASSAYS
  8.3.1 HIGH SPECIFICITY OF DNA DETECTION AT LOW CONCENTRATION TO FUEL MARKET GROWTH
8.4 DNA PROBE HYBRIDIZATION
  8.4.1 EASY-TO-USE PORTFOLIO TO BOOST ADOPTION OF DNA PROBE HYBRIDIZATION
8.5 OTHER TECHNOLOGIES

9 RESIDUAL DNA TESTING MARKET, BY APPLICATION

9.1 INTRODUCTION
9.2 MONOCLONAL ANTIBODIES
  9.2.1 EXPANSION OF BIOSIMILAR PIPELINE TO AID MARKET GROWTH
9.3 CELL & GENE THERAPY
  9.3.1 RISING POPULARITY OF VIRAL VECTOR-BASED SYSTEMS AND INCREASING REGULATORY APPROVALS TO AID MARKET GROWTH
9.4 VACCINES
  9.4.1 PREVALENCE OF INFECTIOUS DISEASES TO DRIVE MARKET
9.5 OTHER APPLICATIONS

10 RESIDUAL DNA TESTING PRODUCTS MARKET, BY END USER

10.1 INTRODUCTION
10.2 PHARMACEUTICAL & BIOTECHNOLOGY COMPANIES
  10.2.1 HIGH BIOPHARMACEUTICAL R&D SPENDING AND INCREASED REGULATORY PRESSURE TO FUEL MARKET GROWTH
10.3 CROS & CDMOS
  10.3.1 FOCUS ON BIOLOGICS DEVELOPMENT AND CDMO FACILITY EXPANSION TO BOOST MARKET GROWTH
10.4 ACADEMIC & RESEARCH INSTITUTES
  10.4.1 SURGE IN R&D ACTIVITIES FOR DEVELOPMENT OF ADVANCED THERAPIES TO DRIVE MARKET GROWTH

+357 96 030922
info@marketpublishers.com

11 RESIDUAL DNA TESTING SERVICES MARKET, BY END USER

11.1 INTRODUCTION
11.2 PHARMACEUTICAL & BIOTECHNOLOGY COMPANIES
11.2.1 SURGE IN R&D INVESTMENTS IN BIOPHARMACEUTICAL INNOVATION TO PROPEL MARKET GROWTH
11.3 ACADEMIC & RESEARCH INSTITUTES
11.3.1 SSLIMITED IN-HOUSE CAPABILITIES TO DRIVE OUTSOURCING

12 RESIDUAL DNA TESTING MARKET, BY REGION

12.1 INTRODUCTION
12.2 NORTH AMERICA
12.2.1 MACROECONOMIC OUTLOOK FOR NORTH AMERICA
12.2.2 US
12.2.2.1 US to dominate North American residual DNA testing market during study period
12.2.3 CANADA
12.2.3.1 Increasing government support for biologics manufacturing and rising research funding to propel market growth
12.3 EUROPE
12.3.1 MACROECONOMIC OUTLOOK FOR EUROPE
12.3.2 GERMANY
12.3.2.1 Increasing investments in biopharma and rising focus on developing manufacturing capabilities to drive market
12.3.3 UK
12.3.3.1 Booming life science industry and growing focus on vaccine development to aid market growth
12.3.4 FRANCE
12.3.4.1 Growing biotechnology sector and rising research funding to drive market
12.3.5 ITALY
12.3.5.1 High R&D investments in life sciences research to augment market growth
12.3.6 SPAIN
12.3.6.1 Increasing number of biotech companies to favor market growth
12.3.7 REST OF EUROPE
12.4 ASIA PACIFIC
12.4.1 MACROECONOMIC OUTLOOK FOR ASIA PACIFIC
12.4.2 CHINA
12.4.2.1 High R&D expenditure and favorable strategic alliances to propel market

+357 96 030922
info@marketpublishers.com

growth
12.4.3 JAPAN
12.4.3.1 Favorable government initiatives for drug development to support market growth
12.4.4 INDIA
12.4.4.1 Increasing R&D investments and funding for life science research to support market growth
12.4.5 SOUTH KOREA
12.4.5.1 Increasing strategic alliances and investments to spur market growth
12.4.6 AUSTRALIA
12.4.6.1 Booming life science sector to fuel market growth
12.4.7 REST OF ASIA PACIFIC
12.5 LATIN AMERICA
12.5.1 MACROECONOMIC OUTLOOK FOR LATIN AMERICA
12.5.2 BRAZIL
12.5.2.1 Substantial R&D investments by pharmaceutical companies to fuel market growth
12.5.3 MEXICO
12.5.3.1 Rising government support for biopharmaceutical production to drive market
12.5.4 REST OF LATIN AMERICA
12.6 MIDDLE EAST
12.6.1 MACROECONOMIC OUTLOOK FOR MIDDLE EAST
12.6.2 GCC COUNTRIES
12.6.2.1 Kingdom of Saudi Arabia
12.6.2.1.1 Increasing R&D investments in pharmaceutical industries to drive market
12.6.2.2 UAE
12.6.2.2.1 Investments in biopharma sector to offer growth opportunities
12.6.2.3 Rest of GCC Countries
12.6.3 REST OF MIDDLE EAST
12.7 AFRICA
12.7.1 RISING PREVALENCE OF CHRONIC DISEASES AND INCREASING FUNDING FOR BIOPHARMA SECTOR TO FUEL MARKET GROWTH
12.7.2 MACROECONOMIC OUTLOOK FOR AFRICA

13 COMPETITIVE LANDSCAPE

13.1 INTRODUCTION
13.2 KEY PLAYER STRATEGIES/RIGHT TO WIN
13.2.1 OVERVIEW OF STRATEGIES ADOPTED BY KEY PLAYERS IN RESIDUAL

+357 96 030922
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DNA TESTING MARKET
13.3 REVENUE ANALYSIS, 2020–2024
13.4 MARKET SHARE ANALYSIS, 2024
13.5 COMPANY EVALUATION MATRIX: KEY PLAYERS, 2024
13.5.1 STARS
13.5.2 EMERGING LEADERS
13.5.3 PERVASIVE PLAYERS
13.5.4 PARTICIPANTS
13.5.5 COMPANY FOOTPRINT: KEY PLAYERS, 2024
13.5.5.1 Company footprint
13.5.5.2 Region footprint
13.5.5.3 Offering footprint
13.5.5.4 Technology footprint
13.5.5.5 Test type footprint
13.6 COMPANY EVALUATION MATRIX: STARTUPS/SMES, 2024
13.6.1 PROGRESSIVE COMPANIES
13.6.2 RESPONSIVE COMPANIES
13.6.3 DYNAMIC COMPANIES
13.6.4 STARTING BLOCKS
13.6.5 COMPETITIVE BENCHMARKING: STARTUPS/SMES, 2024
13.6.5.1 Detailed list of key startups/SMEs
13.6.5.2 Competitive benchmarking of Key startups/SMEs
13.7 COMPANY VALUATION & FINANCIAL METRICS
13.7.1 FINANCIAL METRICS
13.7.2 COMPANY VALUATION
13.8 BRAND/PRODUCT COMPARISON
13.9 COMPETITIVE SCENARIO
13.9.1 PRODUCT LAUNCHES
13.9.2 DEALS
13.9.3 OTHER DEVELOPMENTS

14 COMPANY PROFILES

14.1 KEY PLAYERS
14.1.1 THERMO FISHER SCIENTIFIC INC.
14.1.1.1 Business overview
14.1.1.2 Products/Services offered
14.1.1.3 Recent developments
14.1.1.3.1 Expansions

+357 96 030922
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14.1.1.3.2 Other developments
14.1.1.4 MnM view
14.1.1.4.1 Key strengths
14.1.1.4.2 Strategic choices
14.1.1.4.3 Weaknesses & competitive threats
14.1.2 CHARLES RIVER LABORATORIES
14.1.2.1 Business overview
14.1.2.2 Products/Services offered
14.1.2.3 Recent developments
14.1.2.3.1 Expansions
14.1.2.4 MnM view
14.1.2.4.1 Key strengths
14.1.2.4.2 Strategic choices
14.1.2.4.3 Weaknesses & competitive threats
14.1.3 F. HOFFMANN-LA ROCHE LTD.
14.1.3.1 Business overview
14.1.3.2 Products/Services offered
14.1.3.3 Recent developments
14.1.3.3.1 Product launches
14.1.3.4 MnM view
14.1.3.4.1 Key strengths
14.1.3.4.2 Strategic choices
14.1.3.4.3 Weaknesses & competitive threats
14.1.4 MERCK KGAA
14.1.4.1 Business overview
14.1.4.2 Products/Services offered
14.1.4.3 Recent developments
14.1.4.3.1 Product launches
14.1.4.3.2 Expansions
14.1.4.4 MnM view
14.1.4.4.1 Key strengths
14.1.4.4.2 Strategic choices
14.1.4.4.3 Weaknesses & competitive threats
14.1.5 MARAVAI LIFESCIENCES
14.1.5.1 Business overview
14.1.5.2 Products/Services offered
14.1.5.3 Recent developments
14.1.5.3.1 Deals
14.1.5.4 MnM view

14.1.5.4.1 Key strengths
14.1.5.4.2 Strategic choices
14.1.5.4.3 Weaknesses & competitive threats
14.1.6 EUROFINS SCIENTIFIC
14.1.6.1 Business overview
14.1.6.2 Products/Services offered
14.1.6.3 Recent developments
14.1.6.3.1 Deals
14.1.7 BIO-RAD LABORATORIES, INC.
14.1.7.1 Business overview
14.1.7.2 Products/Services offered
14.1.7.3 Recent developments
14.1.7.3.1 Deals
14.1.8 QIAGEN
14.1.8.1 Business overview
14.1.8.2 Products/Services offered
14.1.8.3 Recent developments
14.1.8.3.1 Product launches
14.1.9 FUJIFILM CORPORATION
14.1.9.1 Business overview
14.1.9.2 Products/Services offered
14.1.10 SGS SOCI?T? G?N?RALE DE SURVEILLANCE SA.
14.1.10.1 Business overview
14.1.10.2 Products/Services offered
14.1.11 HILLGENE BIOPHARMA CO., LTD.
14.1.11.1 Business overview
14.1.11.2 Products/Services offered
14.1.12 REVVITY
14.1.12.1 Business overview
14.1.12.2 Products/Services offered
14.1.12.3 Recent developments
14.1.12.3.1 Product launches
14.1.13 INTERTEK GROUP PLC
14.1.13.1 Business overview
14.1.13.2 Products/Services offered
14.1.14 SARTORIUS AG
14.1.14.1 Business overview
14.1.14.2 Products/Services offered
14.1.15 LONZA

+357 96 030922
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14.1.15.1 Business overview
14.1.15.2 Products/Services offered
14.1.16 WUXI APPTEC
14.1.16.1 Business overview
14.1.16.2 Products/Services offered
14.2 OTHER PLAYERS
14.2.1 TRANSGEN BIOTECH CO., LTD.
14.2.2 EAGLEBIO
14.2.3 YEASEN
14.2.4 ACROBIOSYSTEMS
14.2.5 CREATIVE BIOGENE
14.2.6 MINERVA BIOLABS GMBH
14.2.7 CREATIVE PROTEOMICS
14.2.8 AVANCE BIOSCIENCES
14.2.9 GENERI BIOTECH

15 APPENDIX

15.1 DISCUSSION GUIDE
15.2 KNOWLEDGESTORE: MARKETSANDMARKETS' SUBSCRIPTION PORTAL
15.3 CUSTOMIZATION OPTIONS
15.4 RELATED REPORTS
15.5 AUTHOR DETAILS

List Of Tables

LIST OF TABLES

TABLE 1 RESIDUAL DNA TESTING MARKET: INCLUSIONS & EXCLUSIONS
TABLE 2 IMPACT ANALYSIS OF SUPPLY- AND DEMAND-SIDE FACTORS
TABLE 3 RESIDUAL DNA TESTING MARKET: RISK ANALYSIS
TABLE 4 RESIDUAL DNA TESTING MARKET: IMPACT ANALYSIS OF DRIVERS, RESTRAINTS, OPPORTUNITIES, AND CHALLENGES
TABLE 5 LIST OF FDA-APPROVED BIOSIMILAR PRODUCTS, 2022–2024
TABLE 6 KEY PRODUCT APPROVALS IN GENE THERAPY MARKET, 2022–2024
TABLE 7 AVERAGE SELLING PRICE TREND OF RESIDUAL DNA TESTING PRODUCTS, BY KEY PLAYER, 2022–2024 (USD MILLION)
TABLE 8 AVERAGE SELLING PRICE TREND OF RESIDUAL DNA QUANTIFICATION KITS, BY REGION, 2022–2024 (USD MILLION)
TABLE 9 AVERAGE SELLING PRICE TREND OF PCR INSTRUMENTS, BY REGION, 2022–2024 (USD MILLION)
TABLE 10 RESIDUAL DNA TESTING MARKET: ROLE IN ECOSYSTEM
TABLE 11 MAJOR INVESTMENT AND FUNDING ACTIVITIES IN RESIDUAL DNA TESTING MARKET, BY KEY PLAYER, 2022?2025
TABLE 12 RESIDUAL DNA TESTING MARKET: INNOVATIONS AND PATENT REGISTRATIONS, 2024
TABLE 13 RESIDUAL DNA TESTING MARKET: LIST OF KEY CONFERENCES & EVENTS, JANUARY 2025–DECEMBER 2026
TABLE 14 NORTH AMERICA: REGULATORY BODIES, GOVERNMENT AGENCIES, AND OTHER ORGANIZATIONS
TABLE 15 EUROPE: REGULATORY BODIES, GOVERNMENT AGENCIES, AND OTHER ORGANIZATIONS
TABLE 16 ASIA PACIFIC: REGULATORY BODIES, GOVERNMENT AGENCIES, AND OTHER ORGANIZATIONS
TABLE 17 REST OF THE WORLD: REGULATORY BODIES, GOVERNMENT AGENCIES, AND OTHER ORGANIZATIONS
TABLE 18 RESIDUAL DNA TESTING MARKET: PORTER'S FIVE FORCES
TABLE 19 INFLUENCE OF KEY STAKEHOLDERS ON BUYING PROCESS, BY OFFERING (%)
TABLE 20 KEY BUYING CRITERIA, BY END USER
TABLE 21 LIST OF KEY COMPANIES IMPLEMENTING AI/GEN AI IN RESIDUAL DNA TESTING MARKET
TABLE 22 RESIDUAL DNA TESTING MARKET: IMPORT DATA FOR HS CODE 9027,

2020–2024 (USD THOUSAND)
TABLE 23 RESIDUAL DNA TESTING MARKET: EXPORT DATA FOR HS CODE 9027, 2020–2024 (USD THOUSAND)
TABLE 24 US ADJUSTED RECIPROCAL TARIFF RATES
TABLE 25 PRODUCT/COMPONENT-RELATED TARIFFS FOR RESIDUAL DNA TESTING PRODUCTS
TABLE 26 CRITICAL COMPONENTS EXPOSED TO TARIFF CHANGES
TABLE 27 RESIDUAL DNA TESTING MARKET, BY OFFERING, 2023–2030 (USD MILLION)
TABLE 28 RESIDUAL DNA TESTING PRODUCTS MARKET, BY REGION, 2023–2030 (USD MILLION)
TABLE 29 NORTH AMERICA: RESIDUAL DNA TESTING PRODUCTS MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 30 EUROPE: RESIDUAL DNA TESTING PRODUCTS MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 31 ASIA PACIFIC: RESIDUAL DNA TESTING PRODUCTS MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 32 LATIN AMERICA: RESIDUAL DNA TESTING PRODUCTS MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 33 MIDDLE EAST: RESIDUAL DNA TESTING PRODUCTS MARKET, BY REGION, 2023–2030 (USD MILLION)
TABLE 34 GCC COUNTRIES: RESIDUAL DNA TESTING PRODUCTS MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 35 RESIDUAL DNA TESTING PRODUCTS MARKET, BY TYPE, 2023–2030 (USD MILLION)
TABLE 36 RESIDUAL DNA TESTING CONSUMABLES MARKET, BY REGION, 2023–2030 (USD MILLION)
TABLE 37 NORTH AMERICA: RESIDUAL DNA TESTING CONSUMABLES MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 38 EUROPE: RESIDUAL DNA TESTING CONSUMABLES MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 39 ASIA PACIFIC: RESIDUAL DNA TESTING CONSUMABLES MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 40 LATIN AMERICA: RESIDUAL DNA TESTING CONSUMABLES MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 41 MIDDLE EAST: RESIDUAL DNA TESTING CONSUMABLES MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 42 GCC COUNTRIES: RESIDUAL DNA TESTING CONSUMABLES MARKET, BY COUNTRY, 2023–2030 (USD MILLION)

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TABLE 43 RESIDUAL DNA TESTING INSTRUMENTS & SOFTWARE MARKET, BY REGION, 2023–2030 (USD MILLION)
TABLE 44 NORTH AMERICA: RESIDUAL DNA TESTING INSTRUMENTS & SOFTWARE MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 45 EUROPE: RESIDUAL DNA TESTING INSTRUMENTS & SOFTWARE MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 46 ASIA PACIFIC: RESIDUAL DNA TESTING INSTRUMENTS & SOFTWARE MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 47 LATIN AMERICA: RESIDUAL DNA TESTING INSTRUMENTS & SOFTWARE MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 48 MIDDLE EAST: RESIDUAL DNA TESTING INSTRUMENTS & SOFTWARE MARKET, BY REGION, 2023–2030 (USD MILLION)
TABLE 49 GCC COUNTRIES: RESIDUAL DNA TESTING INSTRUMENTS & SOFTWARE MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 50 RESIDUAL DNA TESTING SERVICES MARKET, BY REGION, 2023–2030 (USD MILLION)
TABLE 51 NORTH AMERICA: RESIDUAL DNA TESTING SERVICES MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 52 EUROPE: RESIDUAL DNA TESTING SERVICES MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 53 ASIA PACIFIC: RESIDUAL DNA TESTING SERVICES MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 54 LATIN AMERICA: RESIDUAL DNA TESTING SERVICES MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 55 MIDDLE EAST: RESIDUAL DNA TESTING SERVICES MARKET, BY REGION, 2023–2030 (USD MILLION)
TABLE 56 GCC COUNTRIES: RESIDUAL DNA TESTING SERVICES MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 57 RESIDUAL DNA TESTING MARKET, BY TEST TYPE, 2023–2030 (USD MILLION)
TABLE 58 RESIDUAL DNA FINAL PRODUCT RELEASE TESTING MARKET, BY REGION, 2023–2030 (USD MILLION)
TABLE 59 NORTH AMERICA: RESIDUAL DNA FINAL PRODUCT RELEASE TESTING MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 60 EUROPE: RESIDUAL DNA FINAL PRODUCT RELEASE TESTING MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 61 ASIA PACIFIC: RESIDUAL DNA FINAL PRODUCT RELEASE TESTING MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 62 LATIN AMERICA: RESIDUAL DNA FINAL PRODUCT RELEASE TESTING

MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 63 MIDDLE EAST: RESIDUAL DNA FINAL PRODUCT RELEASE TESTING MARKET, BY REGION, 2023–2030 (USD MILLION)
TABLE 64 GCC COUNTRIES: RESIDUAL DNA FINAL PRODUCT RELEASE TESTING MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 65 RESIDUAL DNA BULK LOT RELEASE TESTING MARKET, BY REGION, 2023–2030 (USD MILLION)
TABLE 66 NORTH AMERICA: RESIDUAL DNA BULK LOT RELEASE TESTING MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 67 EUROPE: RESIDUAL DNA BULK LOT RELEASE TESTING MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 68 ASIA PACIFIC: RESIDUAL DNA BULK LOT RELEASE TESTING MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 69 LATIN AMERICA: RESIDUAL DNA BULK LOT RELEASE TESTING MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 70 MIDDLE EAST: RESIDUAL DNA BULK LOT RELEASE TESTING MARKET, BY REGION, 2023–2030 (USD MILLION)
TABLE 71 GCC COUNTRIES: RESIDUAL DNA BULK LOT RELEASE TESTING MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 72 RESIDUAL DNA RAW MATERIAL TESTING MARKET, BY REGION, 2023–2030 (USD MILLION)
TABLE 73 NORTH AMERICA: RESIDUAL DNA RAW MATERIAL TESTING MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 74 EUROPE: RESIDUAL DNA RAW MATERIAL TESTING MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 75 ASIA PACIFIC: RESIDUAL DNA RAW MATERIAL TESTING MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 76 LATIN AMERICA: RESIDUAL DNA RAW MATERIAL TESTING MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 77 MIDDLE EAST: RESIDUAL DNA RAW MATERIAL TESTING MARKET, BY REGION, 2023–2030 (USD MILLION)
TABLE 78 GCC COUNTRIES: RESIDUAL DNA RAW MATERIAL TESTING MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 79 RESIDUAL DNA TESTING MARKET, BY TECHNOLOGY, 2023–2030 (USD MILLION)
TABLE 80 RESIDUAL DNA TESTING MARKET FOR POLYMERASE CHAIN REACTION, BY REGION, 2023–2030 (USD MILLION)
TABLE 81 NORTH AMERICA: RESIDUAL DNA TESTING MARKET FOR POLYMERASE CHAIN REACTION, BY COUNTRY, 2023–2030 (USD MILLION)

TABLE 82 EUROPE: RESIDUAL DNA TESTING MARKET FOR POLYMERASE CHAIN REACTION, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 83 ASIA PACIFIC: RESIDUAL DNA TESTING MARKET FOR POLYMERASE CHAIN REACTION, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 84 LATIN AMERICA: RESIDUAL DNA TESTING MARKET FOR POLYMERASE CHAIN REACTION, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 85 MIDDLE EAST: RESIDUAL DNA TESTING MARKET FOR POLYMERASE CHAIN REACTION, BY REGION, 2023–2030 (USD MILLION)
TABLE 86 GCC COUNTRIES: RESIDUAL DNA TESTING MARKET FOR POLYMERASE CHAIN REACTION, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 87 RESIDUAL DNA TESTING MARKET FOR THRESHOLD ASSAYS, BY REGION, 2023–2030 (USD MILLION)
TABLE 88 NORTH AMERICA: RESIDUAL DNA TESTING MARKET FOR THRESHOLD ASSAYS, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 89 EUROPE: RESIDUAL DNA TESTING MARKET FOR THRESHOLD ASSAYS, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 90 ASIA PACIFIC: RESIDUAL DNA TESTING MARKET FOR THRESHOLD ASSAYS, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 91 LATIN AMERICA: RESIDUAL DNA TESTING MARKET FOR THRESHOLD ASSAYS, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 92 MIDDLE EAST: RESIDUAL DNA TESTING MARKET FOR THRESHOLD ASSAYS, BY REGION, 2023–2030 (USD MILLION)
TABLE 93 GCC COUNTRIES: RESIDUAL DNA TESTING MARKET FOR THRESHOLD ASSAYS, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 94 RESIDUAL DNA TESTING MARKET FOR DNA PROBE HYBRIDIZATION, BY REGION, 2023–2030 (USD MILLION)
TABLE 95 NORTH AMERICA: RESIDUAL DNA TESTING MARKET FOR DNA PROBE HYBRIDIZATION, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 96 EUROPE: RESIDUAL DNA TESTING MARKET FOR DNA PROBE HYBRIDIZATION, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 97 ASIA PACIFIC: RESIDUAL DNA TESTING MARKET FOR DNA PROBE HYBRIDIZATION, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 98 LATIN AMERICA: RESIDUAL DNA TESTING MARKET FOR DNA PROBE HYBRIDIZATION, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 99 MIDDLE EAST: RESIDUAL DNA TESTING MARKET FOR DNA PROBE HYBRIDIZATION, BY REGION, 2023–2030 (USD MILLION)
TABLE 100 GCC COUNTRIES: RESIDUAL DNA TESTING MARKET FOR DNA PROBE HYBRIDIZATION, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 101 RESIDUAL DNA TESTING MARKET FOR OTHER TECHNOLOGIES, BY

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REGION, 2023–2030 (USD MILLION)
TABLE 102 NORTH AMERICA: RESIDUAL DNA TESTING MARKET FOR OTHER TECHNOLOGIES, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 103 EUROPE: RESIDUAL DNA TESTING MARKET FOR OTHER TECHNOLOGIES, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 104 ASIA PACIFIC: RESIDUAL DNA TESTING MARKET FOR OTHER TECHNOLOGIES, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 105 LATIN AMERICA: RESIDUAL DNA TESTING MARKET FOR OTHER TECHNOLOGIES, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 106 MIDDLE EAST: RESIDUAL DNA TESTING MARKET FOR OTHER TECHNOLOGIES, BY REGION, 2023–2030 (USD MILLION)
TABLE 107 GCC COUNTRIES: RESIDUAL DNA TESTING MARKET FOR OTHER TECHNOLOGIES, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 108 RESIDUAL DNA TESTING MARKET, BY APPLICATION, 2023–2030 (USD MILLION)
TABLE 109 RESIDUAL DNA TESTING MARKET FOR MONOCLONAL ANTIBODIES, BY REGION, 2023–2030 (USD MILLION)
TABLE 110 NORTH AMERICA: RESIDUAL DNA TESTING MARKET FOR MONOCLONAL ANTIBODIES, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 111 EUROPE: RESIDUAL DNA TESTING MARKET FOR MONOCLONAL ANTIBODIES, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 112 ASIA PACIFIC: RESIDUAL DNA TESTING MARKET FOR MONOCLONAL ANTIBODIES, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 113 LATIN AMERICA: RESIDUAL DNA TESTING MARKET FOR MONOCLONAL ANTIBODIES, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 114 MIDDLE EAST: RESIDUAL DNA TESTING MARKET FOR MONOCLONAL ANTIBODIES, BY REGION, 2023–2030 (USD MILLION)
TABLE 115 GCC COUNTRIES: RESIDUAL DNA TESTING MARKET FOR MONOCLONAL ANTIBODIES, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 116 RESIDUAL DNA TESTING MARKET FOR CELL & GENE THERAPY, BY REGION, 2023–2030 (USD MILLION)
TABLE 117 NORTH AMERICA: RESIDUAL DNA TESTING MARKET FOR CELL & GENE THERAPY, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 118 EUROPE: RESIDUAL DNA TESTING MARKET FOR CELL & GENE THERAPY, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 119 ASIA PACIFIC: RESIDUAL DNA TESTING MARKET FOR CELL & GENE THERAPY, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 120 LATIN AMERICA: RESIDUAL DNA TESTING MARKET FOR CELL & GENE THERAPY, BY COUNTRY, 2023–2030 (USD MILLION)

TABLE 121 MIDDLE EAST: RESIDUAL DNA TESTING MARKET FOR CELL & GENE THERAPY, BY REGION, 2023–2030 (USD MILLION)
TABLE 122 GCC COUNTRIES: RESIDUAL DNA TESTING MARKET FOR CELL & GENE THERAPY, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 123 RESIDUAL DNA TESTING MARKET FOR VACCINES, BY REGION, 2023–2030 (USD MILLION)
TABLE 124 NORTH AMERICA: RESIDUAL DNA TESTING MARKET FOR VACCINES, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 125 EUROPE: RESIDUAL DNA TESTING MARKET FOR VACCINES, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 126 ASIA PACIFIC: RESIDUAL DNA TESTING MARKET FOR VACCINES, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 127 LATIN AMERICA: RESIDUAL DNA TESTING MARKET FOR VACCINES, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 128 MIDDLE EAST: RESIDUAL DNA TESTING MARKET FOR VACCINES, BY REGION, 2023–2030 (USD MILLION)
TABLE 129 GCC COUNTRIES: RESIDUAL DNA TESTING MARKET FOR VACCINES, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 130 RESIDUAL DNA TESTING MARKET FOR OTHER APPLICATIONS, BY REGION, 2023–2030 (USD MILLION)
TABLE 131 NORTH AMERICA: RESIDUAL DNA TESTING MARKET FOR OTHER APPLICATIONS, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 132 EUROPE: RESIDUAL DNA TESTING MARKET FOR OTHER APPLICATIONS, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 133 ASIA PACIFIC: RESIDUAL DNA TESTING MARKET FOR OTHER APPLICATIONS, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 134 LATIN AMERICA: RESIDUAL DNA TESTING MARKET FOR OTHER APPLICATIONS, BY COUNTRY, 2023–2030 (USD MILLION)TABLE 135 MIDDLE EAST: RESIDUAL DNA TESTING MARKET FOR OTHER APPLICATIONS, BY REGION, 2023–2030 (USD MILLION)
TABLE 136 GCC COUNTRIES: RESIDUAL DNA TESTING MARKET FOR OTHER APPLICATIONS, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 137 RESIDUAL DNA TESTING PRODUCTS MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 138 RESIDUAL DNA TESTING PRODUCTS MARKET FOR PHARMACEUTICAL & BIOTECHNOLOGY COMPANIES, BY REGION, 2023–2030 (USD MILLION)
TABLE 139 NORTH AMERICA: RESIDUAL DNA TESTING PRODUCTS MARKET FOR PHARMACEUTICAL & BIOTECHNOLOGY COMPANIES, BY COUNTRY,

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2023–2030 (USD MILLION)
TABLE 140 EUROPE: RESIDUAL DNA TESTING PRODUCTS MARKET FOR PHARMACEUTICAL & BIOTECHNOLOGY COMPANIES, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 141 ASIA PACIFIC: RESIDUAL DNA TESTING PRODUCTS MARKET FOR PHARMACEUTICAL & BIOTECHNOLOGY COMPANIES, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 142 LATIN AMERICA: RESIDUAL DNA TESTING PRODUCTS MARKET FOR PHARMACEUTICAL & BIOTECHNOLOGY COMPANIES, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 143 MIDDLE EAST: RESIDUAL DNA TESTING PRODUCTS MARKET FOR PHARMACEUTICAL & BIOTECHNOLOGY COMPANIES, BY REGION, 2023–2030 (USD MILLION)
TABLE 144 GCC COUNTRIES: RESIDUAL DNA TESTING PRODUCTS MARKET FOR PHARMACEUTICAL & BIOTECHNOLOGY COMPANIES, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 145 RESIDUAL DNA TESTING PRODUCTS MARKET FOR CROS & CDMOS, BY REGION, 2023–2030 (USD MILLION)
TABLE 146 NORTH AMERICA: RESIDUAL DNA TESTING PRODUCTS MARKET FOR CROS & CDMOS, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 147 EUROPE: RESIDUAL DNA TESTING PRODUCTS MARKET FOR CROS & CDMOS, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 148 ASIA PACIFIC: RESIDUAL DNA TESTING PRODUCTS MARKET FOR CROS & CDMOS, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 149 LATIN AMERICA: RESIDUAL DNA TESTING PRODUCTS MARKET FOR CROS & CDMOS, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 150 MIDDLE EAST: RESIDUAL DNA TESTING PRODUCTS MARKET FOR CROS & CDMOS, BY REGION, 2023–2030 (USD MILLION)
TABLE 151 GCC COUNTRIES: RESIDUAL DNA TESTING PRODUCTS MARKET FOR CROS & CDMOS, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 152 RESIDUAL DNA TESTING PRODUCTS MARKET FOR ACADEMIC & RESEARCH INSTITUTES, BY REGION, 2023–2030 (USD MILLION)
TABLE 153 NORTH AMERICA: RESIDUAL DNA TESTING PRODUCTS MARKET FOR ACADEMIC & RESEARCH INSTITUTES, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 154 EUROPE: RESIDUAL DNA TESTING MARKET FOR ACADEMIC & RESEARCH INSTITUTES, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 155 ASIA PACIFIC: RESIDUAL DNA TESTING PRODUCTS MARKET FOR ACADEMIC & RESEARCH INSTITUTES, BY COUNTRY, 2023–2030 (USD MILLION)

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TABLE 156 LATIN AMERICA: RESIDUAL DNA TESTING PRODUCTS MARKET FOR ACADEMIC & RESEARCH INSTITUTES, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 157 MIDDLE EAST: RESIDUAL DNA TESTING PRODUCTS MARKET FOR ACADEMIC & RESEARCH INSTITUTES, BY REGION, 2023–2030 (USD MILLION)
TABLE 158 GCC COUNTRIES: RESIDUAL DNA TESTING PRODUCTS MARKET FOR ACADEMIC & RESEARCH INSTITUTES, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 159 RESIDUAL DNA TESTING SERVICES MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 160 RESIDUAL DNA TESTING SERVICES MARKET FOR PHARMACEUTICAL & BIOTECHNOLOGY COMPANIES, BY REGION, 2023–2030 (USD MILLION)
TABLE 161 NORTH AMERICA: RESIDUAL DNA TESTING SERVICES MARKET FOR PHARMACEUTICAL & BIOTECHNOLOGY COMPANIES, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 162 EUROPE: RESIDUAL DNA TESTING SERVICES MARKET FOR PHARMACEUTICAL & BIOTECHNOLOGY COMPANIES, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 163 ASIA PACIFIC: RESIDUAL DNA TESTING SERVICES MARKET FOR PHARMACEUTICAL & BIOTECHNOLOGY COMPANIES, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 164 LATIN AMERICA: RESIDUAL DNA TESTING SERVICES MARKET FOR PHARMACEUTICAL & BIOTECHNOLOGY COMPANIES, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 165 MIDDLE EAST: RESIDUAL DNA TESTING SERVICES MARKET FOR PHARMACEUTICAL & BIOTECHNOLOGY COMPANIES, BY REGION, 2023–2030 (USD MILLION)
TABLE 166 GCC COUNTRIES: RESIDUAL DNA TESTING SERVICES MARKET FOR PHARMACEUTICAL & BIOTECHNOLOGY COMPANIES, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 167 RESIDUAL DNA TESTING SERVICES MARKET FOR ACADEMIC & RESEARCH INSTITUTES, BY REGION, 2023–2030 (USD MILLION)
TABLE 168 NORTH AMERICA: RESIDUAL DNA TESTING SERVICES MARKET FOR ACADEMIC & RESEARCH INSTITUTES, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 169 EUROPE: RESIDUAL DNA TESTING SERVICES MARKET FOR ACADEMIC & RESEARCH INSTITUTES, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 170 ASIA PACIFIC: RESIDUAL DNA TESTING SERVICES MARKET FOR ACADEMIC & RESEARCH INSTITUTES, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 171 LATIN AMERICA: RESIDUAL DNA TESTING SERVICES MARKET FOR

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ACADEMIC & RESEARCH INSTITUTES, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 172 MIDDLE EAST: RESIDUAL DNA TESTING SERVICES MARKET FOR ACADEMIC & RESEARCH INSTITUTES, BY REGION, 2023–2030 (USD MILLION)
TABLE 173 GCC COUNTRIES: RESIDUAL DNA TESTING SERVICES MARKET FOR ACADEMIC & RESEARCH INSTITUTES, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 174 RESIDUAL DNA TESTING MARKET, BY REGION, 2023–2030 (USD MILLION)
TABLE 175 RESIDUAL DNA TESTING PRODUCTS MARKET, BY REGION, 2023–2030 (USD MILLION)
TABLE 176 RESIDUAL DNA TESTING SERVICES MARKET, BY REGION, 2023–2030 (USD MILLION)
TABLE 177 NORTH AMERICA: RESIDUAL DNA TESTING MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 178 NORTH AMERICA: RESIDUAL DNA TESTING PRODUCTS MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 179 NORTH AMERICA: RESIDUAL DNA TESTING SERVICES MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 180 NORTH AMERICA: RESIDUAL DNA TESTING MARKET, BY OFFERING, 2023–2030 (USD MILLION)
TABLE 181 NORTH AMERICA: RESIDUAL DNA TESTING PRODUCTS MARKET, BY TYPE, 2023–2030 (USD MILLION)
TABLE 182 NORTH AMERICA: RESIDUAL DNA TESTING MARKET, BY TECHNOLOGY, 2023–2030 (USD MILLION)
TABLE 183 NORTH AMERICA: RESIDUAL DNA TESTING MARKET, BY TEST TYPE, 2023–2030 (USD MILLION)
TABLE 184 NORTH AMERICA: RESIDUAL DNA TESTING MARKET, BY APPLICATION, 2023–2030 (USD MILLION)
TABLE 185 NORTH AMERICA: RESIDUAL DNA TESTING PRODUCTS MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 186 NORTH AMERICA: RESIDUAL DNA TESTING SERVICES MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 187 US: RESIDUAL DNA TESTING MARKET, BY OFFERING, 2023–2030 (USD MILLION)
TABLE 188 US: RESIDUAL DNA TESTING PRODUCTS MARKET, BY TYPE, 2023–2030 (USD MILLION)
TABLE 189 US: RESIDUAL DNA TESTING MARKET, BY TECHNOLOGY, 2023–2030 (USD MILLION)
TABLE 190 US: RESIDUAL DNA TESTING MARKET, BY TEST TYPE, 2023–2030 (USD MILLION)

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TABLE 191 US: RESIDUAL DNA TESTING MARKET, BY APPLICATION, 2023–2030 (USD MILLION)
TABLE 192 US: RESIDUAL DNA TESTING PRODUCTS MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 193 US: RESIDUAL DNA TESTING SERVICES MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 194 CANADA: RESIDUAL DNA TESTING MARKET, BY OFFERING, 2023–2030 (USD MILLION)
TABLE 195 CANADA: RESIDUAL DNA TESTING PRODUCTS MARKET, BY TYPE, 2023–2030 (USD MILLION)
TABLE 196 CANADA: RESIDUAL DNA TESTING MARKET, BY TECHNOLOGY, 2023–2030 (USD MILLION)
TABLE 197 CANADA: RESIDUAL DNA TESTING MARKET, BY TEST TYPE, 2023–2030 (USD MILLION)
TABLE 198 CANADA: RESIDUAL DNA TESTING MARKET, BY APPLICATION, 2023–2030 (USD MILLION)
TABLE 199 CANADA: RESIDUAL DNA TESTING PRODUCTS MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 200 CANADA: RESIDUAL DNA TESTING SERVICES MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 201 EUROPE: RESIDUAL DNA TESTING MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 202 EUROPE: RESIDUAL DNA TESTING PRODUCTS MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 203 EUROPE: RESIDUAL DNA TESTING SERVICES MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 204 EUROPE: RESIDUAL DNA TESTING MARKET, BY OFFERING, 2023–2030 (USD MILLION)
TABLE 205 EUROPE: RESIDUAL DNA TESTING PRODUCTS MARKET, BY TYPE, 2023–2030 (USD MILLION)
TABLE 206 EUROPE: RESIDUAL DNA TESTING MARKET, BY TECHNOLOGY, 2023–2030 (USD MILLION)
TABLE 207 EUROPE: RESIDUAL DNA TESTING MARKET, BY TEST TYPE, 2023–2030 (USD MILLION)
TABLE 208 EUROPE: RESIDUAL DNA TESTING MARKET, BY APPLICATION, 2023–2030 (USD MILLION)
TABLE 209 EUROPE: RESIDUAL DNA TESTING PRODUCTS MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 210 EUROPE: RESIDUAL DNA TESTING SERVICES MARKET, BY END

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USER, 2023–2030 (USD MILLION)
TABLE 211 GERMANY: RESIDUAL DNA TESTING MARKET, BY OFFERING, 2023–2030 (USD MILLION)
TABLE 212 GERMANY: RESIDUAL DNA TESTING PRODUCTS MARKET, BY TYPE, 2023–2030 (USD MILLION)
TABLE 213 GERMANY: RESIDUAL DNA TESTING MARKET, BY TECHNOLOGY, 2023–2030 (USD MILLION)
TABLE 214 GERMANY: RESIDUAL DNA TESTING MARKET, BY TEST TYPE, 2023–2030 (USD MILLION)
TABLE 215 GERMANY: RESIDUAL DNA TESTING MARKET, BY APPLICATION, 2023–2030 (USD MILLION)
TABLE 216 GERMANY: RESIDUAL DNA TESTING PRODUCTS MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 217 GERMANY: RESIDUAL DNA TESTING SERVICES MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 218 UK: RESIDUAL DNA TESTING MARKET, BY OFFERING, 2023–2030 (USD MILLION)
TABLE 219 UK: RESIDUAL DNA TESTING PRODUCTS MARKET, BY TYPE, 2023–2030 (USD MILLION)
TABLE 220 UK: RESIDUAL DNA TESTING MARKET, BY TECHNOLOGY, 2023–2030 (USD MILLION)
TABLE 221 UK: RESIDUAL DNA TESTING MARKET, BY TEST TYPE, 2023–2030 (USD MILLION)
TABLE 222 UK: RESIDUAL DNA TESTING MARKET, BY APPLICATION, 2023–2030 (USD MILLION)
TABLE 223 UK: RESIDUAL DNA TESTING PRODUCTS MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 224 UK: RESIDUAL DNA TESTING SERVICES MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 225 FRANCE: RESIDUAL DNA TESTING MARKET, BY OFFERING, 2023–2030 (USD MILLION)
TABLE 226 FRANCE: RESIDUAL DNA TESTING PRODUCTS MARKET, BY TYPE, 2023–2030 (USD MILLION)
TABLE 227 FRANCE: RESIDUAL DNA TESTING MARKET, BY TECHNOLOGY, 2023–2030 (USD MILLION)
TABLE 228 FRANCE: RESIDUAL DNA TESTING MARKET, BY TEST TYPE, 2023–2030 (USD MILLION)
TABLE 229 FRANCE: RESIDUAL DNA TESTING MARKET, BY APPLICATION, 2023–2030 (USD MILLION)

TABLE 230 FRANCE: RESIDUAL DNA TESTING PRODUCTS MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 231 FRANCE: RESIDUAL DNA TESTING SERVICES MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 232 ITALY: RESIDUAL DNA TESTING MARKET, BY OFFERING, 2023–2030 (USD MILLION)
TABLE 233 ITALY: RESIDUAL DNA TESTING PRODUCTS MARKET, BY TYPE, 2023–2030 (USD MILLION)
TABLE 234 ITALY: RESIDUAL DNA TESTING MARKET, BY TECHNOLOGY, 2023–2030 (USD MILLION)
TABLE 235 ITALY: RESIDUAL DNA TESTING MARKET, BY TEST TYPE, 2023–2030 (USD MILLION)
TABLE 236 ITALY: RESIDUAL DNA TESTING MARKET, BY APPLICATION, 2023–2030 (USD MILLION)
TABLE 237 ITALY: RESIDUAL DNA TESTING PRODUCTS MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 238 ITALY: RESIDUAL DNA TESTING SERVICES MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 239 SPAIN: RESIDUAL DNA TESTING MARKET, BY OFFERING, 2023–2030 (USD MILLION)
TABLE 240 SPAIN: RESIDUAL DNA TESTING PRODUCTS MARKET, BY TYPE, 2023–2030 (USD MILLION)
TABLE 241 SPAIN: RESIDUAL DNA TESTING MARKET, BY TECHNOLOGY, 2023–2030 (USD MILLION)
TABLE 242 SPAIN: RESIDUAL DNA TESTING MARKET, BY TEST TYPE, 2023–2030 (USD MILLION)
TABLE 243 SPAIN: RESIDUAL DNA TESTING MARKET, BY APPLICATION, 2023–2030 (USD MILLION)
TABLE 244 SPAIN: RESIDUAL DNA TESTING PRODUCTS MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 245 SPAIN: RESIDUAL DNA TESTING SERVICES MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 246 REST OF EUROPE: RESIDUAL DNA TESTING MARKET, BY OFFERING, 2023–2030 (USD MILLION)
TABLE 247 REST OF EUROPE: RESIDUAL DNA TESTING PRODUCTS MARKET, BY TYPE, 2023–2030 (USD MILLION)
TABLE 248 REST OF EUROPE: RESIDUAL DNA TESTING MARKET, BY TECHNOLOGY, 2023–2030 (USD MILLION)
TABLE 249 REST OF EUROPE: RESIDUAL DNA TESTING MARKET, BY TEST

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TYPE, 2023–2030 (USD MILLION)
TABLE 250 REST OF EUROPE: RESIDUAL DNA TESTING MARKET, BY APPLICATION, 2023–2030 (USD MILLION)
TABLE 251 REST OF EUROPE: RESIDUAL DNA TESTING PRODUCTS MARKET, BY END USER,2023–2030 (USD MILLION)
TABLE 252 REST OF EUROPE: RESIDUAL DNA TESTING SERVICES MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 253 ASIA PACIFIC: RESIDUAL DNA TESTING MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 254 ASIA PACIFIC: RESIDUAL DNA TESTING PRODUCTS MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 255 ASIA PACIFIC: RESIDUAL DNA TESTING SERVICES MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 256 ASIA PACIFIC: RESIDUAL DNA TESTING MARKET, BY OFFERING, 2023–2030 (USD MILLION)
TABLE 257 ASIA PACIFIC: RESIDUAL DNA TESTING PRODUCTS MARKET, BY TYPE, 2023–2030 (USD MILLION)
TABLE 258 ASIA PACIFIC: RESIDUAL DNA TESTING MARKET, BY TECHNOLOGY, 2023–2030 (USD MILLION)
TABLE 259 ASIA PACIFIC: RESIDUAL DNA TESTING MARKET, BY TEST TYPE, 2023–2030 (USD MILLION)
TABLE 260 ASIA PACIFIC: RESIDUAL DNA TESTING MARKET, BY APPLICATION, 2023–2030 (USD MILLION)
TABLE 261 ASIA PACIFIC: RESIDUAL DNA TESTING PRODUCTS MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 262 ASIA PACIFIC: RESIDUAL DNA TESTING SERVICES MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 263 CHINA: RESIDUAL DNA TESTING MARKET, BY OFFERING, 2023–2030 (USD MILLION)
TABLE 264 CHINA: RESIDUAL DNA TESTING PRODUCTS MARKET, BY TYPE, 2023–2030 (USD MILLION)
TABLE 265 CHINA: RESIDUAL DNA TESTING MARKET, BY TECHNOLOGY, 2023–2030 (USD MILLION)
TABLE 266 CHINA: RESIDUAL DNA TESTING MARKET, BY TEST TYPE, 2023–2030 (USD MILLION)
TABLE 267 CHINA: RESIDUAL DNA TESTING MARKET, BY APPLICATION, 2023–2030 (USD MILLION)
TABLE 268 CHINA: RESIDUAL DNA TESTING PRODUCTS MARKET, BY END USER, 2023–2030 (USD MILLION)

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TABLE 269 CHINA: RESIDUAL DNA TESTING SERVICES MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 270 JAPAN: RESIDUAL DNA TESTING MARKET, BY OFFERING, 2023–2030 (USD MILLION)
TABLE 271 JAPAN: RESIDUAL DNA TESTING PRODUCTS MARKET, BY TYPE, 2023–2030 (USD MILLION)
TABLE 272 JAPAN: RESIDUAL DNA TESTING MARKET, BY TECHNOLOGY, 2023–2030 (USD MILLION)
TABLE 273 JAPAN: RESIDUAL DNA TESTING MARKET, BY TEST TYPE, 2023–2030 (USD MILLION)
TABLE 274 JAPAN: RESIDUAL DNA TESTING MARKET, BY APPLICATION, 2023–2030 (USD MILLION)
TABLE 275 JAPAN: RESIDUAL DNA TESTING PRODUCTS MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 276 JAPAN: RESIDUAL DNA TESTING SERVICES MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 277 INDIA: RESIDUAL DNA TESTING MARKET, BY OFFERING, 2023–2030 (USD MILLION)
TABLE 278 INDIA: RESIDUAL DNA TESTING PRODUCTS MARKET, BY TYPE, 2023–2030 (USD MILLION)
TABLE 279 INDIA: RESIDUAL DNA TESTING MARKET, BY TECHNOLOGY, 2023–2030 (USD MILLION)
TABLE 280 INDIA: RESIDUAL DNA TESTING MARKET, BY TEST TYPE, 2023–2030 (USD MILLION)
TABLE 281 INDIA: RESIDUAL DNA TESTING MARKET, BY APPLICATION, 2023–2030 (USD MILLION)
TABLE 282 INDIA: RESIDUAL DNA TESTING PRODUCTS MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 283 INDIA: RESIDUAL DNA TESTING SERVICES MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 284 SOUTH KOREA: RESIDUAL DNA TESTING MARKET, BY OFFERING, 2023–2030 (USD MILLION)
TABLE 285 SOUTH KOREA: RESIDUAL DNA TESTING PRODUCTS MARKET, BY TYPE, 2023–2030 (USD MILLION)
TABLE 286 SOUTH KOREA: RESIDUAL DNA TESTING MARKET, BY TECHNOLOGY, 2023–2030 (USD MILLION)
TABLE 287 SOUTH KOREA: RESIDUAL DNA TESTING MARKET, BY TEST TYPE, 2023–2030 (USD MILLION)
TABLE 288 SOUTH KOREA: RESIDUAL DNA TESTING MARKET, BY APPLICATION,

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2023–2030 (USD MILLION)
TABLE 289 SOUTH KOREA: RESIDUAL DNA TESTING PRODUCTS MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 290 SOUTH KOREA: RESIDUAL DNA TESTING SERVICES MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 291 AUSTRALIA: RESIDUAL DNA TESTING MARKET, BY OFFERING, 2023–2030 (USD MILLION)
TABLE 292 AUSTRALIA: RESIDUAL DNA TESTING PRODUCTS MARKET, BY TYPE, 2023–2030 (USD MILLION)
TABLE 293 AUSTRALIA: RESIDUAL DNA TESTING MARKET, BY TECHNOLOGY, 2023–2030 (USD MILLION)
TABLE 294 AUSTRALIA: RESIDUAL DNA TESTING MARKET, BY TEST TYPE, 2023–2030 (USD MILLION)
TABLE 295 AUSTRALIA: RESIDUAL DNA TESTING MARKET, BY APPLICATION, 2023–2030 (USD MILLION)
TABLE 296 AUSTRALIA: RESIDUAL DNA TESTING PRODUCTS MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 297 AUSTRALIA: RESIDUAL DNA TESTING SERVICES MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 298 REST OF ASIA PACIFIC: RESIDUAL DNA TESTING MARKET, BY OFFERING, 2023–2030 (USD MILLION)
TABLE 299 REST OF ASIA PACIFIC: RESIDUAL DNA TESTING PRODUCTS MARKET, BY TYPE, 2023–2030 (USD MILLION)
TABLE 300 REST OF ASIA PACIFIC: RESIDUAL DNA TESTING MARKET, BY TECHNOLOGY, 2023–2030 (USD MILLION)
TABLE 301 REST OF ASIA PACIFIC: RESIDUAL DNA TESTING MARKET, BY TEST TYPE, 2023–2030 (USD MILLION)
TABLE 302 REST OF ASIA PACIFIC: RESIDUAL DNA TESTING MARKET, BY APPLICATION, 2023–2030 (USD MILLION)
TABLE 303 REST OF ASIA PACIFIC: RESIDUAL DNA TESTING PRODUCTS MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 304 REST OF ASIA PACIFIC: RESIDUAL DNA TESTING SERVICES MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 305 LATIN AMERICA: RESIDUAL DNA TESTING MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 306 LATIN AMERICA: RESIDUAL DNA TESTING PRODUCTS MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 307 LATIN AMERICA: RESIDUAL DNA TESTING SERVICES MARKET, BY COUNTRY, 2023–2030 (USD MILLION)

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TABLE 308 LATIN AMERICA: RESIDUAL DNA TESTING MARKET, BY OFFERING, 2023–2030 (USD MILLION)
TABLE 309 LATIN AMERICA: RESIDUAL DNA TESTING PRODUCTS MARKET, BY TYPE, 2023–2030 (USD MILLION)
TABLE 310 LATIN AMERICA: RESIDUAL DNA TESTING MARKET, BY TECHNOLOGY, 2023–2030 (USD MILLION)
TABLE 311 LATIN AMERICA: RESIDUAL DNA TESTING MARKET, BY TEST TYPE, 2023–2030 (USD MILLION)
TABLE 312 LATIN AMERICA: RESIDUAL DNA TESTING MARKET, BY APPLICATION, 2023–2030 (USD MILLION)
TABLE 313 LATIN AMERICA: RESIDUAL DNA TESTING PRODUCTS MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 314 LATIN AMERICA: RESIDUAL DNA TESTING SERVICES MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 315 BRAZIL: RESIDUAL DNA TESTING MARKET, BY OFFERING, 2023–2030 (USD MILLION)
TABLE 316 BRAZIL: RESIDUAL DNA TESTING PRODUCTS MARKET, BY TYPE, 2023–2030 (USD MILLION)
TABLE 317 BRAZIL: RESIDUAL DNA TESTING MARKET, BY TECHNOLOGY, 2023–2030 (USD MILLION)
TABLE 318 BRAZIL: RESIDUAL DNA TESTING MARKET, BY TEST TYPE, 2023–2030 (USD MILLION)
TABLE 319 BRAZIL: RESIDUAL DNA TESTING MARKET, BY APPLICATION, 2023–2030 (USD MILLION)
TABLE 320 BRAZIL: RESIDUAL DNA TESTING PRODUCTS MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 321 BRAZIL: RESIDUAL DNA TESTING SERVICES MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 322 MEXICO: RESIDUAL DNA TESTING MARKET, BY OFFERING, 2023–2030 (USD MILLION)
TABLE 323 MEXICO: RESIDUAL DNA TESTING PRODUCTS MARKET, BY TYPE, 2023–2030 (USD MILLION)
TABLE 324 MEXICO: RESIDUAL DNA TESTING MARKET, BY TECHNOLOGY, 2023–2030 (USD MILLION)
TABLE 325 MEXICO: RESIDUAL DNA TESTING MARKET, BY TEST TYPE, 2023–2030 (USD MILLION)
TABLE 326 MEXICO: RESIDUAL DNA TESTING MARKET, BY APPLICATION, 2023–2030 (USD MILLION)
TABLE 327 MEXICO: RESIDUAL DNA TESTING PRODUCTS MARKET, BY END

USER, 2023–2030 (USD MILLION)
TABLE 328 MEXICO: RESIDUAL DNA TESTING SERVICES MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 329 REST OF LATIN AMERICA: RESIDUAL DNA TESTING MARKET, BY OFFERING, 2023–2030 (USD MILLION)
TABLE 330 REST OF LATIN AMERICA: RESIDUAL DNA TESTING PRODUCTS MARKET, BY TYPE, 2023–2030 (USD MILLION)
TABLE 331 REST OF LATIN AMERICA: RESIDUAL DNA TESTING MARKET, BY TECHNOLOGY, 2023–2030 (USD MILLION)
TABLE 332 REST OF LATIN AMERICA: RESIDUAL DNA TESTING MARKET, BY TEST TYPE, 2023–2030 (USD MILLION)
TABLE 333 REST OF LATIN AMERICA: RESIDUAL DNA TESTING MARKET, BY APPLICATION, 2023–2030 (USD MILLION)
TABLE 334 REST OF LATIN AMERICA: RESIDUAL DNA TESTING PRODUCTS MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 335 REST OF LATIN AMERICA: RESIDUAL DNA TESTING SERVICES MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 336 MIDDLE EAST: RESIDUAL DNA TESTING MARKET, BY REGION, 2023–2030 (USD MILLION)
TABLE 337 MIDDLE EAST: RESIDUAL DNA TESTING PRODUCTS MARKET, BY REGION, 2023–2030 (USD MILLION)
TABLE 338 MIDDLE EAST: RESIDUAL DNA TESTING SERVICES MARKET, BY REGION, 2023–2030 (USD MILLION)
TABLE 339 MIDDLE EAST: RESIDUAL DNA TESTING MARKET, BY OFFERING, 2023–2030 (USD MILLION)
TABLE 340 MIDDLE EAST: RESIDUAL DNA TESTING PRODUCTS MARKET, BY TYPE, 2023–2030 (USD MILLION)
TABLE 341 MIDDLE EAST: RESIDUAL DNA TESTING MARKET, BY TECHNOLOGY, 2023–2030 (USD MILLION)
TABLE 342 MIDDLE EAST: RESIDUAL DNA TESTING MARKET, BY TEST TYPE, 2023–2030 (USD MILLION)
TABLE 343 MIDDLE EAST: RESIDUAL DNA TESTING MARKET, BY APPLICATION, 2023–2030 (USD MILLION)
TABLE 344 MIDDLE EAST: RESIDUAL DNA TESTING PRODUCTS MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 345 MIDDLE EAST: RESIDUAL DNA TESTING SERVICES MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 346 GCC COUNTRIES: RESIDUAL DNA TESTING MARKET, BY COUNTRY, 2023–2030 (USD MILLION)

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TABLE 347 GCC COUNTRIES: RESIDUAL DNA TESTING PRODUCTS MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 348 GCC COUNTRIES: RESIDUAL DNA TESTING SERVICES MARKET, BY COUNTRY, 2023–2030 (USD MILLION)
TABLE 349 GCC COUNTRIES: RESIDUAL DNA TESTING MARKET, BY OFFERING, 2023–2030 (USD MILLION)
TABLE 350 GCC COUNTRIES: RESIDUAL DNA TESTING PRODUCTS MARKET, BY TYPE, 2023–2030 (USD MILLION)
TABLE 351 GCC COUNTRIES: RESIDUAL DNA TESTING MARKET, BY TECHNOLOGY, 2023–2030 (USD MILLION)
TABLE 352 GCC COUNTRIES: RESIDUAL DNA TESTING MARKET, BY TEST TYPE, 2023–2030 (USD MILLION)
TABLE 353 GCC COUNTRIES: RESIDUAL DNA TESTING MARKET, BY APPLICATION, 2023–2030 (USD MILLION)
TABLE 354 GCC COUNTRIES: RESIDUAL DNA TESTING PRODUCTS MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 355 GCC COUNTRIES: RESIDUAL DNA TESTING SERVICES MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 356 KINGDOM OF SAUDI ARABIA: RESIDUAL DNA TESTING MARKET, BY OFFERING, 2023–2030 (USD MILLION)
TABLE 357 KINGDOM OF SAUDI ARABIA: RESIDUAL DNA TESTING PRODUCTS MARKET, BY TYPE, 2023–2030 (USD MILLION)
TABLE 358 KINGDOM OF SAUDI ARABIA: RESIDUAL DNA TESTING MARKET, BY TECHNOLOGY, 2023–2030 (USD MILLION)
TABLE 359 KINGDOM OF SAUDI ARABIA: RESIDUAL DNA TESTING MARKET, BY TEST TYPE, 2023–2030 (USD MILLION)
TABLE 360 KINGDOM OF SAUDI ARABIA: RESIDUAL DNA TESTING MARKET, BY APPLICATION, 2023–2030 (USD MILLION)
TABLE 361 KINGDOM OF SAUDI ARABIA: RESIDUAL DNA TESTING PRODUCTS MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 362 KINGDOM OF SAUDI ARABIA: RESIDUAL DNA TESTING SERVICES MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 363 UAE: RESIDUAL DNA TESTING MARKET, BY OFFERING, 2023–2030 (USD MILLION)
TABLE 364 UAE: RESIDUAL DNA TESTING PRODUCTS MARKET, BY TYPE, 2023–2030 (USD MILLION)
TABLE 365 UAE: RESIDUAL DNA TESTING MARKET, BY TECHNOLOGY, 2023–2030 (USD MILLION)
TABLE 366 UAE: RESIDUAL DNA TESTING MARKET, BY TEST TYPE, 2023–2030

(USD MILLION)
TABLE 367 UAE: RESIDUAL DNA TESTING MARKET, BY APPLICATION, 2023–2030 (USD MILLION)
TABLE 368 UAE: RESIDUAL DNA TESTING PRODUCTS MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 369 UAE: RESIDUAL DNA TESTING SERVICES MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 370 REST OF GCC COUNTRIES: RESIDUAL DNA TESTING MARKET, BY OFFERING, 2023–2030 (USD MILLION)
TABLE 371 REST OF GCC COUNTRIES: RESIDUAL DNA TESTING PRODUCTS MARKET, BY TYPE, 2023–2030 (USD MILLION)
TABLE 372 REST OF GCC COUNTRIES: RESIDUAL DNA TESTING MARKET, BY TECHNOLOGY, 2023–2030 (USD MILLION)
TABLE 373 REST OF GCC COUNTRIES: RESIDUAL DNA TESTING MARKET, BY TEST TYPE, 2023–2030 (USD MILLION)
TABLE 374 REST OF GCC COUNTRIES: RESIDUAL DNA TESTING MARKET, BY APPLICATION, 2023–2030 (USD MILLION)
TABLE 375 REST OF GCC COUNTRIES: RESIDUAL DNA TESTING PRODUCTS MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 376 REST OF GCC COUNTRIES: RESIDUAL DNA TESTING SERVICES MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 377 REST OF MIDDLE EAST: RESIDUAL DNA TESTING MARKET, BY OFFERING, 2023–2030 (USD MILLION)
TABLE 378 REST OF MIDDLE EAST: RESIDUAL DNA TESTING PRODUCTS MARKET, BY TYPE, 2023–2030 (USD MILLION)
TABLE 379 REST OF MIDDLE EAST: RESIDUAL DNA TESTING MARKET, BY TECHNOLOGY, 2023–2030 (USD MILLION)
TABLE 380 REST OF MIDDLE EAST: RESIDUAL DNA TESTING MARKET, BY TEST TYPE, 2023–2030 (USD MILLION)
TABLE 381 REST OF MIDDLE EAST: RESIDUAL DNA TESTING MARKET, BY APPLICATION, 2023–2030 (USD MILLION)
TABLE 382 REST OF MIDDLE EAST: RESIDUAL DNA TESTING PRODUCTS MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 383 REST OF MIDDLE EAST: RESIDUAL DNA TESTING SERVICES MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 384 AFRICA: RESIDUAL DNA TESTING MARKET, BY OFFERING, 2023–2030 (USD MILLION)
TABLE 385 AFRICA: RESIDUAL DNA TESTING PRODUCTS MARKET, BY TYPE, 2023–2030 (USD MILLION)

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TABLE 386 AFRICA: RESIDUAL DNA TESTING MARKET, BY TECHNOLOGY, 2023–2030 (USD MILLION)
TABLE 387 AFRICA: RESIDUAL DNA TESTING MARKET, BY TEST TYPE, 2023–2030 (USD MILLION)
TABLE 388 AFRICA: RESIDUAL DNA TESTING MARKET, BY APPLICATION, 2023–2030 (USD MILLION)
TABLE 389 AFRICA: RESIDUAL DNA TESTING PRODUCTS MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 390 AFRICA: RESIDUAL DNA TESTING SERVICES MARKET, BY END USER, 2023–2030 (USD MILLION)
TABLE 391 OVERVIEW OF STRATEGIES DEPLOYED BY KEY PLAYERS IN RESIDUAL DNA TESTING MARKET
TABLE 392 RESIDUAL DNA TESTING MARKET: DEGREE OF COMPETITION
TABLE 393 RESIDUAL DNA TESTING MARKET: REGION FOOTPRINT
TABLE 394 RESIDUAL DNA TESTING MARKET: OFFERING FOOTPRINT
TABLE 395 RESIDUAL DNA TESTING MARKET: TECHNOLOGY FOOTPRINT
TABLE 396 RESIDUAL DNA TESTING MARKET: TEST TYPE FOOTPRINT
TABLE 397 RESIDUAL DNA TESTING MARKET: DETAILED LIST OF KEY STARTUPS/SMES
TABLE 398 RESIDUAL DNA TESTING MARKET: COMPETITIVE BENCHMARKING OF KEY STARTUPS/SME PLAYERS
TABLE 399 RESIDUAL DNA TESTING MARKET: PRODUCT LAUNCHES, JANUARY 2021–MAY 2025
TABLE 400 RESIDUAL DNA TESTING MARKET: DEALS, JANUARY 2021–MAY 2025
TABLE 401 RESIDUAL DNA TESTING MARKET: OTHER DEVELOPMENTS, JANUARY 2021–MAY 2025
TABLE 402 THERMO FISHER SCIENTIFIC INC.: COMPANY OVERVIEW
TABLE 403 THERMO FISHER SCIENTIFIC INC.: PRODUCTS/SERVICES OFFERED
TABLE 404 THERMO FISHER SCIENTIFIC INC.: EXPANSIONS, JANUARY 2022–MAY 2025
TABLE 405 THERMO FISHER SCIENTIFIC INC.: OTHER DEVELOPMENTS, JANUARY 2022–MAY 2025
TABLE 406 CHARLES RIVER LABORATORIES: COMPANY OVERVIEW
TABLE 407 CHARLES RIVER LABORATORIES: PRODUCTS/SERVICES OFFERED
TABLE 408 CHARLES RIVER LABORATORIES: EXPANSIONS, JANUARY 2022–MAY 2025
TABLE 409 F. HOFFMANN-LA ROCHE LTD.: COMPANY OVERVIEW
TABLE 410 F. HOFFMANN-LA ROCHE LTD.: PRODUCTS/SERVICES OFFERED
TABLE 411 F. HOFFMANN-LA ROCHE LTD.: PRODUCT LAUNCHES, JANUARY

2022–MAY 2025
TABLE 412 MERCK KGAA: COMPANY OVERVIEW
TABLE 413 MERCK KGAA: PRODUCTS/SERVICES OFFERED
TABLE 414 MERCK KGAA: PRODUCT LAUNCHES, JANUARY 2022–MAY 2025
TABLE 415 MERCK KGAA: EXPANSIONS, JANUARY 2022–MAY 2025
TABLE 416 MARAVAI LIFESCIENCES: COMPANY OVERVIEW
TABLE 417 MARAVAI LIFESCIENCES: PRODUCTS/SERVICES OFFERED
TABLE 418 MARAVAI LIFESCIENCES: DEALS, JANUARY 2022–MAY 2025
TABLE 419 EUROFINS SCIENTIFIC: COMPANY OVERVIEW
TABLE 420 EUROFINS SCIENTIFIC: PRODUCTS/SERVICES OFFERED
TABLE 421 EUROFINS SCIENTIFIC: DEALS, JANUARY 2022–MAY 2025
TABLE 422 BIO-RAD LABORATORIES, INC.: COMPANY OVERVIEW
TABLE 423 BIO-RAD LABORATORIES, INC.: PRODUCTS/SERVICES OFFERED
TABLE 424 BIO-RAD LABORATORIES, INC.: DEALS, JANUARY 2022–MAY 2025
TABLE 425 QIAGEN: COMPANY OVERVIEW
TABLE 426 QIAGEN: PRODUCTS/SERVICES OFFERED
TABLE 427 QIAGEN: PRODUCT LAUNCHES, JANUARY 2022–MAY 2025
TABLE 428 FUJIFILM CORPORATION: COMPANY OVERVIEW
TABLE 429 FUJIFILM CORPORATION: PRODUCTS/SERVICES OFFERED
TABLE 430 SGS SOCI?T? G?N?RALE DE SURVEILLANCE SA.: COMPANY OVERVIEW
TABLE 431 SGS SOCI?T? G?N?RALE DE SURVEILLANCE SA.: PRODUCTS/SERVICES OFFERED
TABLE 432 HILLGENE BIOPHARMA CO., LTD.: COMPANY OVERVIEW
TABLE 433 HILLGENE BIOPHARMA CO., LTD.: PRODUCTS/SERVICES OFFERED
TABLE 434 REVVITY: COMPANY OVERVIEW
TABLE 435 REVVITY: PRODUCTS/SERVICES OFFERED
TABLE 436 REVVITY: PRODUCT LAUNCHES, JANUARY 2022–MAY 2025
TABLE 437 INTERTEK GROUP PLC: COMPANY OVERVIEW
TABLE 438 INTERTEK GROUP PLC: PRODUCTS/SERVICES OFFERED
TABLE 439 SARTORIUS AG: COMPANY OVERVIEW
TABLE 440 SARTORIUS AG: PRODUCTS/SERVICES OFFERED
TABLE 441 LONZA: COMPANY OVERVIEW
TABLE 442 LONZA: PRODUCTS/SERVICES OFFERED
TABLE 443 WUXI APPTEC: COMPANY OVERVIEW
TABLE 444 WUXI APPTEC: PRODUCTS/SERVICES OFFERED
TABLE 445 TRANSGEN BIOTECH CO., LTD.: COMPANY OVERVIEW
TABLE 446 EAGLEBIO: COMPANY OVERVIEW
TABLE 447 YEASEN: COMPANY OVERVIEW

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TABLE 448 ACROBIOSYSTEMS: COMPANY OVERVIEW
TABLE 449 CREATIVE BIOGENE: COMPANY OVERVIEW
TABLE 450 MINERVA BIOLABS GMBH: COMPANY OVERVIEW
TABLE 451 CREATIVE PROTEOMICS: COMPANY OVERVIEW
TABLE 452 AVANCE BIOSCIENCES: COMPANY OVERVIEW
TABLE 453 GENERI BIOTECH: COMPANY OVERVIEW

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List Of Figures

LIST OF FIGURES

FIGURE 1 RESIDUAL DNA TESTING MARKET SEGMENTATION & REGIONAL SCOPE
FIGURE 2 RESIDUAL DNA TESTING MARKET: YEARS CONSIDERED
FIGURE 3 RESIDUAL DNA TESTING MARKET: RESEARCH DESIGN
FIGURE 4 RESIDUAL DNA TESTING MARKET: BREAKDOWN OF PRIMARIES (SUPPLY- AND DEMAND-SIDE PARTICIPANTS)
FIGURE 5 RESIDUAL DNA TESTING MARKET SIZE ESTIMATION (SUPPLY-SIDE ANALYSIS), 2024
FIGURE 6 RESIDUAL DNA TESTING MARKET: COMPANY REVENUE ANALYSIS-BASED ESTIMATION (BOTTOM-UP APPROACH) (2024)
FIGURE 7 ILLUSTRATIVE EXAMPLE OF THERMO FISHER SCIENTIFIC INC.: REVENUE SHARE ANALYSIS (2024)
FIGURE 8 RESIDUAL DNA TESTING MARKET: INSIGHTS FROM PRIMARIES
FIGURE 9 RESIDUAL DNA TESTING MARKET: TOP-DOWN APPROACH
FIGURE 10 RESIDUAL DNA TESTING MARKET: CAGR PROJECTIONS
FIGURE 11 RESIDUAL DNA TESTING MARKET: DATA TRIANGULATION
FIGURE 12 RESIDUAL DNA TESTING MARKET, BY OFFERING, 2025 VS. 2030 (USD MILLION)
FIGURE 13 RESIDUAL DNA TESTING MARKET, BY TEST TYPE, 2025 VS. 2030 (USD MILLION)
FIGURE 14 RESIDUAL DNA TESTING MARKET, BY TECHNOLOGY, 2025 VS. 2030 (USD MILLION)
FIGURE 15 RESIDUAL DNA TESTING MARKET, BY APPLICATION, 2025 VS. 2030 (USD MILLION)
FIGURE 16 RESIDUAL DNA TESTING PRODUCTS MARKET, BY END USER, 2025 VS. 2030 (USD MILLION)
FIGURE 17 RESIDUAL DNA TESTING SERVICES MARKET, BY END USER, 2025 VS. 2030 (USD MILLION)
FIGURE 18 REGIONAL ANALYSIS OF RESIDUAL DNA TESTING MARKET
FIGURE 19 INCREASE IN NUMBER OF BIOLOGICS AND BIOSIMILAR APPROVALS TO DRIVE MARKET
FIGURE 20 US AND FINAL PRODUCT RELEASE TESTING ACCOUNTED FOR LARGEST NORTH AMERICAN MARKET SHARE IN 2024
FIGURE 21 PHARMACEUTICAL & BIOTECHNOLOGY COMPANIES COMMANDED LARGEST MARKET SHARE IN 2024

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FIGURE 22 CHINA TO WITNESS HIGHEST CAGR DURING STUDY PERIOD
FIGURE 23 RESIDUAL DNA TESTING MARKET: DRIVERS, RESTRAINTS, OPPORTUNITIES, AND CHALLENGES
FIGURE 24 GLOBAL TOTAL PHARMACEUTICAL R&D SPEND, 2016–2030
FIGURE 25 RESIDUAL DNA TESTING MARKET: TRENDS/DISRUPTIONS IMPACTING CUSTOMER’S BUSINESS
FIGURE 26 AVERAGE SELLING PRICE OF DNA QUANTIFICATION KITS, BY KEY PLAYER, 2024 (USD)
FIGURE 27 AVERAGE SELLING PRICE TREND OF PCR SYSTEMS, BY KEY PLAYER, 2022–2024 (USD)
FIGURE 28 AVERAGE SELLING PRICE OF RESIDUAL DNA TESTING PRODUCTS, BY REGION, 2024 (USD)
FIGURE 29 RESIDUAL DNA TESTING MARKET: VALUE CHAIN ANALYSIS
FIGURE 30 RESIDUAL DNA TESTING MARKET: ECOSYSTEM ANALYSIS
FIGURE 31 FUNDING AND NUMBER OF DEALS IN RESIDUAL DNA TESTING MARKET, 2021–2024
FIGURE 32 TOP APPLICANTS OF RESIDUAL DNA TESTING PATENTS, 2014–2024
FIGURE 33 RESIDUAL DNA TESTING MARKET: PORTER’S FIVE FORCES ANALYSIS
FIGURE 34 INFLUENCE OF KEY STAKEHOLDERS ON BUYING PROCESS, BY OFFERING
FIGURE 35 KEY BUYING CRITERIA, BY END USER
FIGURE 36 RESIDUAL DNA TESTING MARKET: KEY AI USE CASES
FIGURE 37 NORTH AMERICA: RESIDUAL DNA TESTING MARKET SNAPSHOT
FIGURE 38 ASIA PACIFIC: RESIDUAL DNA TESTING MARKET SNAPSHOT
FIGURE 39 REVENUE ANALYSIS OF KEY PLAYERS IN RESIDUAL DNA TESTING MARKET, 2020–2024 (USD MILLION)
FIGURE 40 MARKET SHARE ANALYSIS OF KEY PLAYERS IN RESIDUAL DNA TESTING MARKET (2024)
FIGURE 41 RESIDUAL DNA TESTING MARKET: COMPANY EVALUATION MATRIX (KEY PLAYERS), 2024
FIGURE 42 RESIDUAL DNA TESTING MARKET: COMPANY FOOTPRINT
FIGURE 43 RESIDUAL DNA TESTING MARKET: COMPANY EVALUATION MATRIX (STARTUPS/SMES), 2024
FIGURE 44 WEV/EBITDA OF KEY VENDORS
FIGURE 45 YEAR-TO-DATE (YTD) PRICE TOTAL RETURN AND 5-YEAR STOCK BETA OF KEY VENDORS
FIGURE 46 RESIDUAL DNA TESTING MARKET: BRAND/PRODUCT COMPARATIVE ANALYSIS

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FIGURE 47 THERMO FISHER SCIENTIFIC INC.: COMPANY SNAPSHOT
FIGURE 48 CHARLES RIVER LABORATORIES: COMPANY SNAPSHOT
FIGURE 49 F. HOFFMANN-LA ROCHE LTD.: COMPANY SNAPSHOT
FIGURE 50 MERCK KGAA: COMPANY SNAPSHOT
FIGURE 51 MARAVAI LIFESCIENCES: COMPANY SNAPSHOT
FIGURE 52 EUROFINS SCIENTIFIC: COMPANY SNAPSHOT
FIGURE 53 BIO-RAD LABORATORIES, INC.: COMPANY SNAPSHOT
FIGURE 54 QIAGEN: COMPANY SNAPSHOT
FIGURE 55 FUJIFILM CORPORATION: COMPANY SNAPSHOT
FIGURE 56 SGS SOCI?T? G?N?RALE DE SURVEILLANCE SA.: COMPANY SNAPSHOT
FIGURE 57 HILLGENE BIOPHARMA CO., LTD.: COMPANY SNAPSHOT
FIGURE 58 REVVITY: COMPANY SNAPSHOT
FIGURE 59 INTERTEK GROUP PLC: COMPANY SNAPSHOT
FIGURE 60 SARTORIUS AG: COMPANY SNAPSHOT
FIGURE 61 LONZA: COMPANY SNAPSHOT
FIGURE 62 WUXI APPTEC: COMPANY SNAPSHOT

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