

### Genetic Technologies – Investor Webinar

The Future: Unlocking personalised preventative medicine

4 May, 2023

Authorised by the Board of Directors of Genetic Technologies Limited

ASX: GTG NASDAQ: GENE

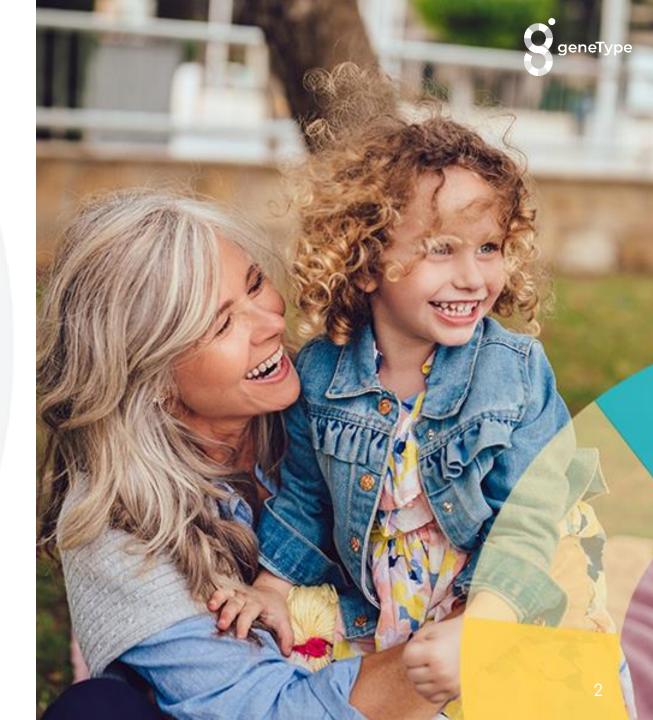
# World leading portfolio

Most comprehensive guideline driven portfolio for human and animal health.

- Patented GeneType Multi Risk Test
- Non-Invasive Prenatal Testing (NIPT)
- Carrier screen testing
- Pharmacogenomics
- Oncogenetic diseases
- Pet care

Revenues anchored by our 3 brands to seize a multi Billion-dollar opportunity.







# Comprehensive genomics-based testings

via a multi-brand strategy

Medical & Payer Business to Business (B2B)



geneType

Oncology – GTG Cardiovascular Prenatal NIPT Carrier testing Clinical & Molecular Metabolic

### Consumer initiated testing (CIT)

with medical supervision



geneType

Expanded Carrier testing & NIPT Oncology – MultiTest Cardiovascular – MultiTest Metabolic – MultiTest COVID Rick Test Pharmacogenomics

### Direct to Consumer Testing (DTC)

with no medical supervision







Ancestry Paternity Health & Wellbeing Pharmacogenetics Animal Drug testing Relationship DNA Storage



# Global Overview



14

Categories



51

Tests



Patents Granted\* (9 Pending Worldwide\*)

12

Partner Laboratories



# Snapshot and Achievements last 12 months

#### GeneType commercialization

- ✓ 9 Tests NOW commercially available in the US the geneType Multi-Risk test
- >100 medical practices on-boarded launching the foundation of geneType Hubs in Australia
- ✓ Presentations by Dr Erika Spaeth at:
  - ✓ ASCOGI Cancers Symposium Jan 2023
  - ✓ San Antonio Breast Cancer Symposium,
  - ✓ Precision Medicines leaders summit
  - ✓ Precision Medicine World Conference

#### EasyDNA & Affinity DNA

- ✓ Completed 2 Acquisitions
- ✓ NEW EasyDNA Website ready for launch
- ✓ NEW eCommerce Platform ready launch
- Launch Carrier Testing and Non-Invasive Prenatal Tests (NIPT) into Europe
- Partnering in India with stud farms extending paternity infrastructure into the equine industry
- Launch DNA storage solution in GTG NATA approved facility

#### Reimbursement activation

- ✓ Independently developed Budget Impact Model (BIM) identifies US\$1.4 billion dollars in annual saving by ALVA 10
- ✓ 11 Active payer conversations
- Progress on US Payer meetings to enable coverage across millions of lives

#### Partnerships

- Launch with A/Prof Charles Siles providing immediate access to more than 1,000 referring primary care physicians and 15,000 patients annually in Australia
- Partnerships with Australian Breast Care Centre and Dr Nicole Yap
- ✓ Launch of screening for breast cancer risk with Prof Bruce Mann at Royal Women's Hospital in Melbourne

#### Clinical Validity and IP Strategy

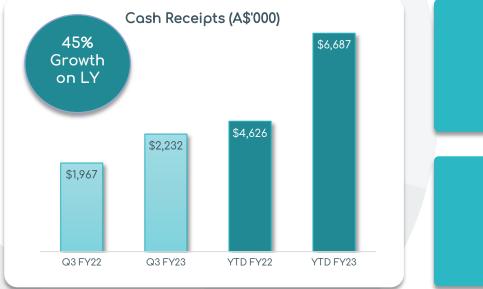
- ✓ 5 Peer reviewed publication in 6 months
- ✓ Published in PLOS ONE
- ✓ Published in Journal or Precision Medicine
- Published in European Journal of Cancer prevention
- Published in journal Breast Cancer Research and Treatment
- ✓ 25 Patents granted or pending
- ✓ 3 more papers under review

#### Laboratory Capability

- Gained NATA and CMS-CLIA accreditation and certification for 6 polygenic risk score tests
- Successful ARTG notification to TGA for company IVDs for all tests on the multirisk test



### Delivering Revenue and Growth – Q3 FY23



| Q3 CASH RECEIPTS A\$2.2m     | cash balance<br>A\$10.5m*               |
|------------------------------|---|
| gross margin <b>A\$1.13m</b> | March GROSS MARGIN<br><b>49%</b> +2ppts |

#### Strategic & Operational Highlights:

- March Quarter FY23 receipts A\$4.22 million
- Cash receipts from customers A\$2.2m +13% on last year;
- R&D Tax Incentive of A\$1.96m was received in Q3 2023
- YTD receipts from customers A\$6.69 million up 45% on prior year
- 7 consecutive qtrs. of growth on prior year

- Launched Melanoma, Pancreatic Cancer and Atrial Fibrillation in U.S.
- Back to Back peer reviewed publications demonstrating Genetype for Breast cancer identifies MORE at risk patients then the current standards
- Presentations at ASCO Gi Cancers Symposium in San Francisco







## NEW Comprehensive Breast and Ovarian Cancer test

Evaluates a woman's risk of developing Breast and/or Ovarian Cancer in women 30 years+



- The test evaluates a women's risk of developing Breast and/or Ovarian Cancer either from a hereditary genetic mutation or from the far more common familial or sporadic cancer. (<u>Announced Feb 3, 2023</u>)
- GTG's unique approach "appends" the detection of the 13 major "actionable" Breast and Ovarian cancer susceptibility genes to the GeneType test platform.
- Advances the goal of providing population-based genetic screening where up to 85% of cancers diagnosed do
  not have hereditary or family history
- Showcase at BRCA 2023 in Montreal

<sup>1</sup> <u>https://www.breastcancer.org/facts-statistics</u> Announcement - <u>Globe Newswire</u>



GeneType Multi-

# NEW – 9 Diseases now available in the US

GeneType can identify patients 'at risk' before onset and aid in the early detection and treatment.

GeneType Risk assessment test for breast cancer has demonstrated improved early stage detection 18% and saving approx. US\$1.4B per annum<sup>4</sup> for the US payer



Commercial availability in Australia and the US since Q1 CY2022

- З. Commercial availability in the US and waiting on NATA Approval for Australia
- Budget Impact Model prepared by Alva10



# NEW – 3 Peer Review Publications Released

Our Scientific team continues to achieve scientific publication milestones, with 3 publications accepted in three peer-reviewed journals during the quarter

#### Concer Prevention Research

Validation of an abridged breast cancer risk prediction model for the general population<sup>1</sup>. Spaeth EL, Dite GS, Hopper JL, Allman R.

#### European Journal of Cancer Prevention

A combined clinical and genetic model for predicting risk of OVARIAN CANCER<sup>2</sup> Dite GS, Spaeth E, Murphy NM, Allman R.

#### Breast Concer Research and Treatment

Validation of a breast cancer risk prediction model based on the key risk factors: family history, mammographic density and polygenic risk<sup>3</sup> Allman R, Mu Y, Dite GS, Spaeth E, Hopper JL, Rosner BA.

- https://pubmed.ncbi.nlm.nih.gov/36862830/
- https://pubmed.ncbi.nlm.nih.gov/36503897
- https://pubmed.ncbi.nlm.nih.gov/36749458/





## NEW Strategic Alliance with Qiagen

The alliance will establish and develop a 'Centre of Excellence' facility in Australia



GTG to form Strategic Alliance with Global Leader QIAGEN

Genetic

⊕ genetype.com 🗗 GeneTypeglobal 🎔 @Gene\_type



Announcement – <u>Globe Newswire Feb 1 2023</u>

QIAGEN will support the enhancement of GTG capabilities through software, hardware, consumable and technical solutions, including:

- Reagents and QIAGEN's proprietary QCII software to complete Next Generation Sequencing (NGS) validation in house.
- The rollout will include QIAGEN's QIAseq targeted DNA Pro Sample to Insight solutions for NGS Oncology and customized inhouse data analysis tools to provide sample to result service for GTG customers



# GeneType Priority Pathway to Market

### Medical & Payer Business to Business (B2B)

| Revenue<br>Drivers | Health Economic modeling completed by ALVA10*  |  |
|--------------------|--|--|
|                    | Certifying reimbursable testing platform:<br>BRCA test & LYNCH Syndrome test   |  |
| Partners           | A plan curated for: Payers / Insurers*<br>Primary Care Physicians, Specialists,<br>Surgeons, Concierge Medicine Groups |  |
| Products           | geneType Multi-test  |  |
|                    | NGS platforms with Germline, Carrier<br>Screening and NIPT   |  |
|                    | BRCA test & LYNCH Syndrome test  |  |
|                    | geneType   |  |

Payer coverage is the key driver of revenues for geneType

Coverage from payers in the US will accelerate adoption of geneType Risk Assessment Tests more widely

Budget Impact Model (BIM) demonstrates significant health & economic benefits of implementing the geneType Breast Cancer Risk Assessment Test

11 Active conversations with payer groups in the US

US Payers include:

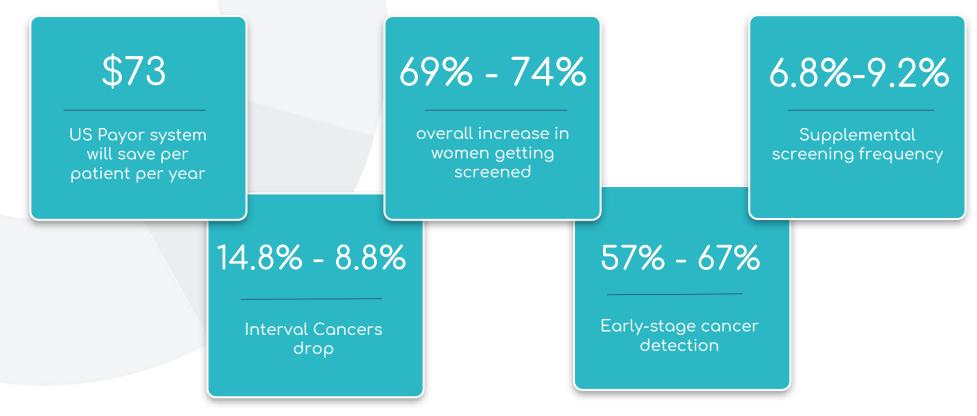
- Humana 17 million lives covered
- Aetna 22.1 million live covered
- Independence Blue Cross 3 million lives covered

Smaller payers such as employer groups have potential to move quickly

BIM validates the benefits of implementing geneType



### Economic Modeling in the US Payer System<sup>1</sup> The economic benefit to the payers in the US is US\$1.4B per annum

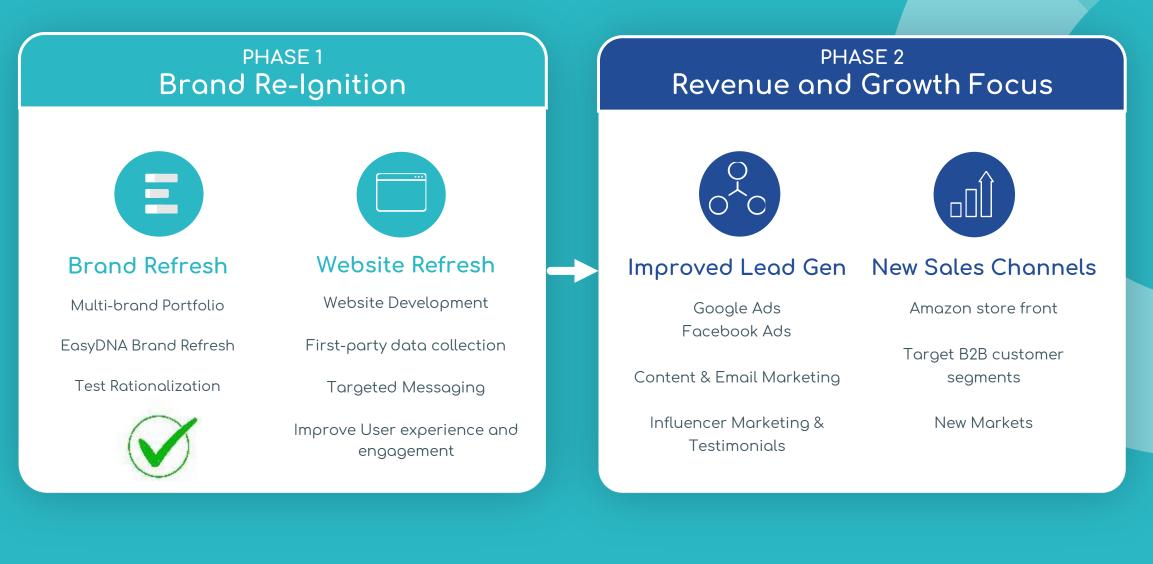


# <u>3.6% in annual savings to</u> a payer system in the screening and treatment of breast cancer.

1 Corporates and Insurance market entry assessment - Health Economic Model completed by ALVA10 May 2022.

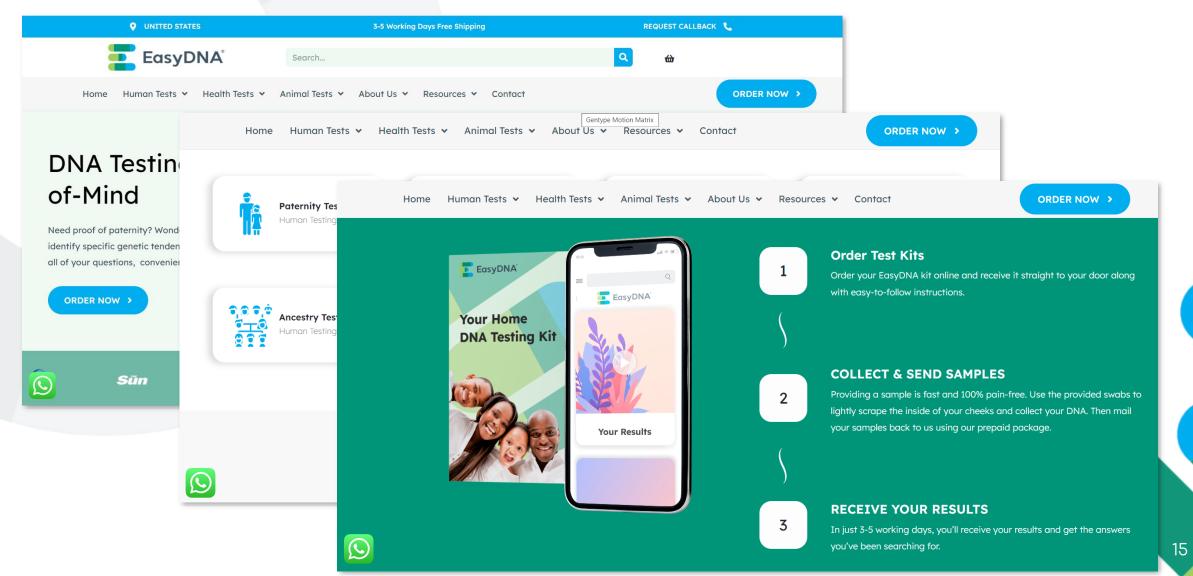


# DTC - Growth strategy for EasyDNA





# eCommerce Growth strategy for EasyDNA





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www.linkedin.com/company/genetype-limited

<u>www.genetype.com</u>

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# Appendices





# Board and Management: Sales and Scientific expertise leading GTG



**Mr. Peter Rubinstein** BEc, LLB Chairman Non – Executive Director



**Dr. Lindsay Wakefield** MBBS Non – Executive Director



**Mr Nick Burrows** B.Comm, FAICD, FCA, FGIA, FTIA, F Fin Non – Executive Director



**Simon Morriss** GAICD Chief Executive Officer



**Dr. Jerzy "George" Muchnicki** MBBS Non-Executive Director



**Erika Spaeth** PhD Director of Clinical & Scientific Affairs



**Richard Allman** BSc, PhD Scientific Advisor



**Tony Di Pietro** B. Comm, CA, AGIA, MAICD CFO & Company Secretary



**Carl Stubbings** Chief Commercial Officer



# Strong Scientific Leadership: Advisory Board



#### **Professor Jon Emery**

MBBCh MA DPhil FRACGP MRCGP Research & Education Lead, Primary Care Integration, Victorian Comprehensive Cancer Centre Herman Chair of Primary Care Cancer Research, University of Melbourne

#### Professor Finlay Macrae AO

MBBS, MD, FRACP, FRCP, AGAF MWGO is Principal Fellow and Professor, Department of Medicine, University of Melbourne, and Head of Colorectal Medicine and Genetics, The Royal Melbourne Hospital



#### Ora K. Gordon, M.D.

MD, MS, FACMG Regional Medical Director, Center for Clinical Genetics & Genomics. Clinical Director, PSJH Population Health Genomics Program. Chair, Integrated Network Cancer Program, Professor of Genetics, St John Cancer Institute



#### A.Prof Ron Dick

MBBS, FRACP, FCSANZ, Chairman of Cardiovascular Institute at Epworth Healthcare, an Honorary Cardiologist at the Alfred Hospital and Bendigo Healthcare Group.

Completed his MBBS in 1979 and became a Fellow of the Australian College of Physicians in 1986. His interventional cardiology fellowship was from the University of Michigan Medical Centre USA.



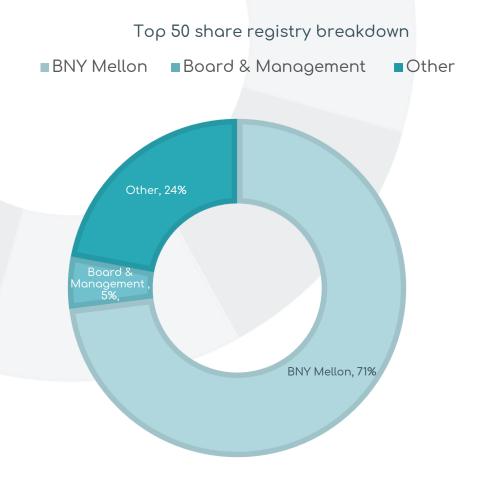
### **Financial Overview**

- Net cash outflow of A\$7.2 million for the nine months to 31 March 2023. We continue to grow EasyDNA and Affinity DNA brand sales and develop and commercialise our geneType tests
- Cash reserves will be directed to:
  - to support the commercialisation of the GeneType Multi Risk test through the B2B channels with payers, insurers and employers in the United States and expand into Europe;
  - to drive new market opportunities in reimbursable categories by leveraging our strategic relationship with QIAGEN;
  - for funding product research and development;
  - to increase our sales and marketing presences and drive of its tests via the consumer-initiated testing platforms;
  - to execute the go to market, sales and marketing to launch the Comprehensive Hereditary Breast and Ovarian Cancer Risk Test as part of our germline genetic testing division; and
  - for other working capital and general corporate purposes.

| A\$'000                 | 31-March-23 | 31-March-22 | Change |
|-------------------------|-------------|-------------|--------|
| Net operating cashflow  | (7,249)     | (6,152)     | -18%   |
| Receipts from customers | 6,687       | 4,626       | 45%    |
| Cash                    | 10,481      | 11,350      | -8%    |
|                         |             |             |        |



# **Corporate Overview**



### Dual Listed on the ASX and Nasdaq

#### Financial Information

| Share price (AUD) as at 25 April 2023  | 0.3c      |
|--|-----------|
| ADR price (USD) as at 25 February 2023 | \$1.06    |
| Ord Shares on Issue (M)                | 11,542    |
| ASX 52-week trading (AUD low/high)     | 0.2/1.3c  |
| Nasdaq 52-week trading (USD low/high)  | 0.86/1.82 |
| Market Cap (A\$M/US\$M)                | 34.6/19.0 |
| Cash at 31 March 2023                  | A\$10.5m  |
| Cash at 30 June 2022                   | A\$11.7m  |
| Debt (30 June 2022 and 31 March 2023)  | nil       |



# **Our Intellectual Property**

#### 4 Patents granted in the US

- Patent No: US 11,257,569, Methods of assessing risk of developing a severe response to Coronavirus infection
- Patent No: US 11,072,830, Methods for breast cancer risk assessment
- Patent No: US 10,683,549, Methods for assessing risk of developing breast cancer
- Patent No: US 10,920,279, Methods for assessing risk of developing breast cancer

### 2 Patents granted in PRC (China & HK)

- Patent No. 201080033130.5 Methods for Breast Cancer Risk Assessment
- Patent No. 201580063966.2 Methods for assessing risk of developing breast cancer

#### 9 Patent families pending

- Breast cancer risk assessment
- Methods for assessing risk of developing prostate cancer
- Methods for assessing risk of developing ovarian cancer
- Methods of assessing risk of developing a severe response to Coronavirus infection
- Methods of assessing risk of developing a disease
- Methods for assessing risk of developing breast cancer
- Improved methods for assessing risk of developing breast cancer
- Methods of assessing risk of developing breast cancer
- Methods for assessing risk of developing colorectal cancer



## Defined Terms

Common Complex Diseases (CCP) - A complex disease is caused by the interaction of multiple genes and environmental factors. Complex diseases are also called multifactorial. Examples of common complex diseases include cancer and heart disease.

Polygenic risk score - a number associated with one's disease risk based on the aggregated effects of individual risk variants through a multiplicative algorithm.

Variant - Single Nucleotide polymorphism (SNP), an alteration in DNA that may be a common or rare event.

Genomic - pertaining to function of genetics from structure to relationship between genetic events.

Genetic - pertaining to a gene.

**GWAS -** genome-wide association studies are large population level studies which enable scientists to identify genes and genetic markers involved in human disease. This method searches the genome for SNPs that occur more frequently in people with a particular disease than in people without the disease. Each study can look at hundreds or many thousands of SNPs at the same time. Researchers use data from this type of study to pinpoint genetic variations that may contribute to a person's risk of developing a certain disease.

SNP - Single nucleotide polymorphisms, frequently called SNPs (pronounced "snips"), are the most common type of genetic variation among people. Each SNP represents a difference in a single DNA building block, called a nucleotide. For example, a SNP may replace the nucleotide cytosine (C) with the nucleotide thymine (T) in a certain stretch of DNA.

Serious Disease Risk (SDR) - Risk associated with acquiring COVID-19 and requiring hospitalisation withs its associated morbidities and mortalities.

Germline Testing – Germline testing is done on cells that do not have cancer. It is done to see if a person has a gene mutation that is known to increase the risk of developing cancers and other health problems. This test uses cells (such as blood or skin cells) that do not have any cancer cells. Germline mutations can sometimes be passed down from parents.

Clinical Laboratory Improvement Amendments (CLIA) - Regulates laboratory testing and require clinical laboratories to be certified by the Center for Medicare and Medicaid Services (CMS) before they can accept human samples for diagnostic testing

National Association of Testing Authorities (NATA) - the authority responsible for the accreditation of laboratories, inspection bodies, calibration services, producers of certified reference materials and proficiency testing scheme providers throughout Australia. It is also Australia's compliance monitoring authority for the OECD Principles of GLP. NATA provides independent assurance of technical competence through a proven network of best practice industry experts for customers who require confidence in the delivery of their products and services.

Next Generation Sequencing (NGS) – Next-generation sequencing (NGS), also known as high-throughput sequencing, is the catch-all term used to describe a number of different modern sequencing technologies. These technologies allow for sequencing of DNA and RNA much more quickly and cheaply than the previously used Sanger sequencing, and as such revolutionised the study of genomics and molecular biology.

Laboratory Developed Tests (LDT) – A type of in vitro diagnostic test that is designed, manufactured and used within a single laboratory.

Consumer Initiated Tests (CIT) - laboratory testing that is initiated by the consumer without a physician order but reviewed and communicated back to the consumer via a physician.

Direct to Consumer (DTC) – laboratory testing that is initiated by the consumer without a physician order. The results are reported back directly to the consumer.

Health Care Professionals (HCP) – physician, GP, or specialist authorized to receive the patient results