Lumos Diagnostics

LDX.AX

MST Access
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Transforming Point-of-Care Medicine with Rapid Diagnostics

Equity Research Australia
Technology Hardware & Equipment

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NEED TO KNOW

- **Smart lateral flow technology**
- **Unique FebriDx® tackles unnecessary antibiotic use**
- **Contract services – end-to-end diagnostic solutions**

Smart lateral flow technology: Lumos Diagnostics (LDX) differentiates itself through its focus on developing high-quality lateral flow assays combined with advanced readers and supporting technology. This sophisticated technology offering provides a balance of speed, accuracy, and connectivity.

Flagship FebriDx® addresses critical unmet need – point-of-care bacterial vs. viral differentiation: FebriDx® addresses the need to rapidly differentiate infection types at the point of care. By simultaneously measuring MxA and CRP biomarkers, this test enables healthcare providers to quickly identify patients with viral infections (for isolation and confirmatory testing) versus those with bacterial infections (for antibiotics). This rapid differentiation improves triage efficiency, optimises resource allocation, and helps reduce unnecessary antibiotic use, supporting efforts to combat antibiotic resistance.

Contract services: LDX generated approximately 89% of FY24 revenue through its contract service offerings. These encompass a comprehensive range of end-to-end support, including product development, contract manufacturing, clinical trials, quality assurance and regulatory affairs.

Investment Thesis

Market demand for rapid point-of-care diagnostics: The global healthcare system is increasingly prioritising rapid diagnostic solutions, particularly in infectious disease management and antibiotic stewardship. LDX's proprietary technology addresses this need with point-of-care solutions that reduce the time to diagnosis and treatment. Stricter antimicrobial stewardship guidelines and government support for point-of-care testing could drive adoption.

Proprietary technology and diversified business: LDX's reader-based and reader-free diagnostics leverage advanced immunoassay technology, offering improved sensitivity and ease of use compared to traditional methods. The company's ability to develop and commercialise both proprietary and partner-based tests provides diversified revenue streams across multiple indications.

Commercialisation underway: LDX is advancing its commercialisation strategy by expanding its flagship FebriDx® test into global markets, broader clinical settings in the US and extend its labelling to paediatric populations. Strategic partnerships and regulatory approvals will be key drivers of revenue scalability and long-term profitability in the diagnostics sector.

Valuation/Risks

We value LDX at A$172m or $0.10 per fully diluted share using DCF methodology, based on 748.5m shares on issue, 157.4m options, and assuming a US$5m capital raise in 2H25, adding 256.4m new shares to the count. In the highly competitive diagnostics market, LDX's key risks are regulatory, commercialisation, reimbursement, technology and distribution.

LUMOS DIAGNOSTICS

Lumos Diagnostics is a company specializing in rapid diagnostic testing solutions, particularly in point-of-care (POC) diagnostics. They develop and manufacture custom assay solutions, reader technologies, and diagnostic platforms for various applications, including infectious disease detection, inflammatory markers, and other health conditions. Lumos also works in food and environmental testing.

https://lumosdiagnostics.com/

Valuation	**A$0.10**
Current price	**A$0.02**
Market cap	**A$18m**
Cash on hand	**US$5.5m** *(31 Dec 2024)*

Upcoming Catalysts / Next News

Period	
4Q25	Pre-submission FebriDx® paed study
4Q25	Milestone in Hologic fFN agreement
2H25	Update on FebriDx® CLIA waiver trial
2H25	Women's health diagnostic update
1H26	Completion of Hologic fFN agreement

Share Price (A$)

Source: FactSet, MST Access

Lumos Diagnostics — LDX-AU

Year end 30 June, AUD unless otherwise noted

MARKET DATA

Price	**$**	**0.02**
52 week high / low	$	0.02-0.07
Valuation	**$**	**0.10**
Market capitalisation	$m	18.0
Shares on issue (basic)	**m**	1004.9 *(includes ~256m new shares from forecast cap raise in FY25)*
Options / rights	m	157.4 *(unlisted options and performance rights)*
Other equity	m	0.0
Shares on issue (diluted)	**m**	**1162.3**

12-MONTH SHARE PRICE PERFORMANCE (A$)

INVESTMENT FUNDAMENTALS		FY23A	FY24A	FY25E	FY26E	FY27E
Reported NPAT	$m	(9.0)	(8.6)	(6.2)	(3.4)	(1.9)
Underlying NPAT	**$m**	**(9.0)**	**(8.6)**	**(6.2)**	**(3.4)**	**(1.9)**
Reported EPS (diluted)	¢	(382.0)	(185.5)	(82.9)	(46.0)	(25.1)
Underlying EPS (diluted)	**¢**	**(382.0)**	**(185.5)**	**(82.9)**	**(46.0)**	**(25.1)**
Growth	%					
Underlying PER	**x**	**nm**	**nm**	**nm**	**nm**	**nm**
Operating cash flow per share	¢	(3.1)	0.2	(0.5)	(0.1)	0.1
Free cash flow per share	¢	(1.7)	0.2	(0.5)	(0.1)	0.1
Price to free cash flow per share	**x**	**nm**	**12.5**	**nm**	**nm**	**21.1**
FCF Yield	%	nm	8.0%	nm	nm	4.7%
Dividend	**¢**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Payout	%	0.0%	0.0%	0.0%	0.0%	0.0%
Yield	**%**	**0.0%**	**0.0%**	**0.0%**	**0.0%**	**0.0%**
Franking	%	nm	nm	nm	nm	nm
Enterprise value	**$m**	**15.0**	**11.5**	**11.6**	**13.9**	**14.4**
EV/EBITDA	x	(2.8)	(3.0)	(4.3)	(290.4)	10.2
EV/EBIT	x	(1.8)	(1.5)	(2.4)	(6.4)	(23.2)
Price to book (NAV)	x	0.7	1.5	2.8	6.7	28.3
Price to NTA	x	(4.9)	(4.1)	(6.3)	(3.3)	(2.7)

KEY RATIOS		FY23A	FY24A	FY25E	FY26E	FY27E
Gross Margin	%	54.2	63.0	59.1	56.2	63.6
EBITDA margin	%	nm	nm	nm	nm	5.9
EBIT margin	%	nm	nm	nm	nm	nm
NPAT margin	%	nm	nm	nm	nm	nm
ROE	%	nm	nm	nm	nm	nm
ROA	%	nm	nm	nm	nm	nm
Net tangible assets per share	$	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)
Book value per share	$	0.0	0.0	0.0	0.0	0.0
Net debt/(cash)	$m	(3.0)	(6.5)	(6.4)	(4.1)	(3.6)
Interest cover/ (EBIT/net interest)	x	nm	nm	nm	nm	nm
Gearing (net debt/EBITDA)	x	nm	nm	nm	nm	nm
Leverage (net debt/(net debt + equity))	x	nm	nm	nm	nm	nm

DUPONT ANALYSIS		FY23A	FY24A	FY25E	FY26E	FY27E
Net Profit Margin	%	nm	nm	nm	nm	nm
Asset Turnover	x	0.4	0.4	0.5	0.8	1.0
Return on Assets	%	nm	nm	nm	nm	nm
Leverage	x	2.7	3.8	4.4	9.4	39.6
Return on Equity	%	nm	nm	nm	nm	nm

KEY PERFORMANCE INDICATORS		FY23A	FY24A	FY25E	FY26E	FY27E
Revenue						
Branded products	$m	0.3	1.2	1.4	4.3	11.4
Contract services	$m	10.2	9.9	11.2	11.7	12.3

HALF YEARLY DATA		2H22	1H23	2H23	1H24	2H24
Total Revenue	$m	6.4	5.1	5.4	2.8	8.4
Operating expenses	$m	(37.4)	(8.9)	(6.5)	(7.9)	(8.0)
EBITDA	$m	(7.9)	(4.4)	(1.0)	(4.4)	0.5
EBIT	$m	(34.2)	(6.3)	(1.8)	(5.6)	(1.9)
PBT	$m	(34.6)	(6.6)	(2.4)	(6.4)	(2.2)
Reported NPAT	$m	(45.7)	(6.6)	(2.4)	(6.4)	(2.2)

PROFIT AND LOSS		FY23A	FY24A	FY25E	FY26E	FY27E
Revenue	**$m**	**10.5**	**11.1**	**12.9**	**16.0**	**23.7**
Other income	$m	0.5	0.1	1.0	2.2	0.1
Total Revenue	**$m**	**11.0**	**11.3**	**13.9**	**18.2**	**23.7**
Gross profit	$m	6.0	7.1	8.2	10.2	15.1
Operating expenses	$m	(15.4)	(15.8)	(15.5)	(15.8)	(17.0)
EBITDA	**$m**	**(5.4)**	**(3.9)**	**(2.7)**	**(0.0)**	**1.4**
Depreciation & Amortisation	$m	(3.7)	(2.6)	(2.3)	(2.1)	(2.0)
EBIT	**$m**	**(8.2)**	**(7.5)**	**(4.9)**	**(2.2)**	**(0.6)**
Net interest	$m	(0.8)	(1.1)	(1.3)	(1.3)	(1.3)
Pretax Profit	**$m**	**(9.0)**	**(8.6)**	**(6.2)**	**(3.4)**	**(1.9)**
Tax expense	$m	0.0	0.0	0.0	0.0	0.0
Reported NPAT	**$m**	**(9.0)**	**(8.6)**	**(6.2)**	**(3.4)**	**(1.9)**
Underlying NPAT	$m	**(9.0)**	**(8.6)**	**(6.2)**	**(3.4)**	**(1.9)**
Year end shares	m	309.4	481.3	748.5	748.5	748.5

GROWTH PROFILE		FY23A	FY24A	FY25E	FY26E	FY27E
Revenue	%	(9.4)	5.7	16.0	24.2	47.5
EBITDA	%	nm	nm	nm	nm	nm
EBIT	%	nm	nm	nm	nm	nm
Reported NPAT	%	nm	nm	nm	nm	nm

BALANCE SHEET		FY23A	FY24A	FY25E	FY26E	FY27E
Cash	$m	3.0	6.5	6.4	4.1	3.6
Receivables	$m	1.5	0.7	0.8	1.0	1.4
Other	$m	1.5	2.4	2.5	2.8	3.3
Current assets	**$m**	**6.0**	**9.6**	**9.7**	**7.8**	**8.3**
PPE	$m	0.6	0.3	0.3	0.2	0.2
Intangible assets	$m	10.9	9.7	8.5	7.5	6.6
Right-of-use assets	$m	8.0	7.3	7.5	7.7	7.9
Other	$m	0.0	0.0	0.0	0.0	0.0
Non current assets	**$m**	**19.5**	**17.3**	**16.3**	**15.5**	**14.7**
Total assets	**$m**	**25.4**	**26.8**	**26.0**	**23.2**	**23.0**
Trade and other payables	$m	2.9	2.4	2.8	3.4	5.1
Borrowing and lease liabilities	$m	0.7	1.0	1.0	1.0	1.0
Other	$m	4.6	9.3	9.3	9.3	9.3
Current liabilities	**$m**	**8.2**	**12.6**	**13.0**	**13.7**	**15.3**
Borrowing and lease liabilities	$m	7.7	7.1	7.1	7.1	7.1
Other liability	$m	0.0	0.0	0.0	0.0	0.0
Non current liabilities	**$m**	**7.7**	**7.1**	**7.1**	**7.1**	**7.1**
Total liabilities	**$m**	**15.9**	**19.7**	**20.1**	**20.8**	**22.4**
Net assets	**$m**	**9.5**	**7.1**	**5.9**	**2.5**	**0.6**
Share capital	$m	92.5	98.2	103.2	103.2	103.2
Retained earnings	$m	(82.3)	(90.9)	(97.1)	(100.5)	(102.4)
Other	$m	(0.7)	(0.3)	(0.3)	(0.3)	(0.3)
Total equity	**$m**	**9.5**	**7.1**	**5.9**	**2.5**	**0.6**

CASH FLOW		FY23A	FY24A	FY25E	FY26E	FY27E
Profit/(net loss) for period	**$m**	**(9.0)**	**(8.6)**	**(6.2)**	**(3.4)**	**(1.9)**
Depreciation & Amortisation	$m	3.7	2.6	2.3	2.1	2.0
Changes in working capital	$m	(3.9)	5.4	0.1	0.3	0.6
Other	$m	(0.4)	1.5	0.0	0.0	0.0
Operating cash flow	**$m**	**(9.6)**	**0.9**	**(3.8)**	**(1.0)**	**0.8**
Payments for PPE	$m	(0.2)	(0.1)	(0.1)	(0.0)	(0.0)
Other	$m	4.5	0.0	0.0	0.0	0.0
Investing cash flow	**$m**	**4.3**	**(0.1)**	**(0.1)**	**(0.0)**	**(0.0)**
Payment of lease liabilities	$m	(1.8)	(1.3)	(1.3)	(1.3)	(1.3)
Proceeds from issued shares	$m	0.0	5.0	5.0	0.0	0.0
Dividends paid	$m	0.0	0.0	0.0	0.0	0.0
Financing cash flow	**$m**	**0.7**	**2.6**	**3.7**	**(1.3)**	**(1.3)**
Cash year end	**$m**	**3.0**	**6.5**	**6.4**	**4.1**	**3.6**
Free cash flow	**$m**	**(5.3)**	**0.8**	**(3.9)**	**(1.1)**	**0.8**

Source: Company reports, MST Access estimates

Thesis: End-to-End Point-of-Care Diagnostic Player

Lumos Diagnostics (LDX) is an Australian-based, publicly traded medical technology company which develops and commercialises rapid, point-of-care (POC) diagnostic tests. LDX aims to establish a competitive advantage by integrating high-performance lateral flow assays (LFAs) with sophisticated reader technology and a supporting suite of applications. This strategy aims to provide a balance of speed, accuracy, and connectivity at the point of care, competing with traditional laboratory testing in terms of cost, time and convenience.

Offering: rapid tests, advanced readers, custom solutions

LDX offers a range of proprietary commercially available POC tests and contract services. However, its contract services are typically not provided directly to healthcare providers. Instead, these services are contracted by third-party clients, including diagnostic and pharmaceutical companies, food and environmental testing companies, startups, and universities. LDX's expertise supports these clients as they develop, manufacture and commercialise diagnostic products.

LDX's portfolio of platforms covers several areas (readers, cassettes, app): see Figure 1 (image labels correspond with bullets below). These are provided to clients and customised to meet individual needs.

Rapid diagnostic tests (lateral flow assays and other tests) (Figure 1 – A): LDX has developed a number of proprietary LFAs, which assess a sample and determine whether a particular analyte is present, thereby diagnosing specific conditions. Its suite of tests includes flagship product FebriDx®, which can differentiate between viral and bacterial infections in patients with acute respiratory infections after 10 minutes (notably, the ex-US claim distinguishes viral from bacterial infections, whereas the US claim differentiates bacterial from non-bacterial infections). The company also develops LFAs and other diagnostic tests for its partners.

Reader platforms (Figure 1 – B): LDX's reader platforms are POC devices used to analyse, interpret and transmit the results of diagnostic tests. These include the following, which are each customisable for specific assay types and user scenarios in terms of portability, connectivity and output format:

- Single-use Disposable Reader – fully integrated with test strip in single-use, disposable system
- Multi-use Disposable Reader – facilitates easy drop-in of test strips, customisable for various needs
- Leelu Reader – research-use-only benchtop reader for assay development and quality control
- Hand-Held Camera Reader (also called 'Portable Camera Reader') – uses a high-performance camera system (also used on the Leelu Reader) to detect test strip signals and provide numerical results, with options for Bluetooth connectivity and barcode reading.

Desktop app and smartphone app (Figure 1 – C): Companion apps enhance the functionality of LDX's reader devices by integrating with cloud platforms, enabling the user-friendly capture of data.

Figure 1: LDX Portfolio of Platforms

Source: LDX.

Figure 2: Product portfolio overview

Product division	**Division contribution: 11% of FY24 revenue; projected revenue CAGR (FY24–29): 308%**
Lateral flow assays, including:	
FebriDx®	Rapid, all-in-one point-of-care test that diagnoses acute respiratory infections and differentiates between bacterial and viral respiratory infections
ViraDx™	Rapid point-of-care test that diagnoses and distinguishes between acute viral respiratory infections caused by COVID-19, Influenza A and Influenza B
Contract Services division	**Division contribution: 89% of FY24 revenue; projected revenue CAGR (FY24–29): 7%**
Services contracted by third parties (e.g. healthcare organisations and biotechs), including:	
Assay development	Offers comprehensive services encompassing the development of diagnostic tests, from reagent sourcing to verification, validation, and design transfer
Reader development	Customises reader platforms based on client needs, including disposable and reusable readers, as well as off-the-shelf product solutions
Supporting technology and services, including:	
• App and cloud services	Develops applications and cloud-based solutions to support data management and connectivity for diagnostic devices
• Manufacturing	Conducts full-scale manufacturing of diagnostic reagents, cartridges, and test kits, with capabilities for manufacturing transfer and process validation
• Medical affairs	Supports all stages of product development and commercialisation, including clinical trials and medical communications
• Quality and regulatory affairs	Assists with quality management systems and regulatory compliance throughout the product lifecycle

Source: LDX.

Technology: proprietary platform underpins product development

LDX's technology platform uniquely positions the company to offer tailored, innovative, and efficient POC diagnostic solutions across various healthcare settings. Highlights of the platform are as follows:

- **Portfolio of proprietary tests:** LDX develops its own branded POC tests (FebriDx® and ViraDx™), targeting infectious and inflammatory diseases and focusing on rapid results. By integrating its development process, LDX benefits from synergy gains in optimising costs and maximising profit margins. Additionally, LDX is building a strong intellectual property portfolio, giving it a stronger competitive edge in the diagnostics market.
- **End-to-end development services:** LDX provides a comprehensive development process, from feasibility studies using the Leelu R&D Reader to clinical validation and design transfer for commercial-scale manufacturing. This reduces development timelines, costs, and risks.
- **Rapid development of assays:** LDX's rapid prototyping capabilities enable it to develop assays at an accelerated pace compared with competitors.
- **Versatile reader portfolio:** LDX's readers range from single-use disposables to reusable camera-based systems, and are adaptable to various assay chemistries and formats. Test strips can be seamlessly integrated with digital readers. Custom assay-specific algorithms can be uploaded to readers for qualitative or quantitative results. Readers can be branded and customised with application-specific features, alternate form factors, and connectivity options (e.g., Bluetooth).
- **Digital ecosystem (apps and cloud integration) supporting the LDX offering:** LDX offers companion mobile and desktop apps for workflow guidance and data management, analytics and visualisation. Connectivity options enable real-time reporting, integrating with laboratory information systems. Cloud platforms capture key data such as test results, device usage, and patient metrics.
- **Regulatory-compliant manufacturing:** Readers are manufactured to ISO 13485 standards, ensuring readiness for regulatory trials and compliance with international quality requirements.

Market opportunity and competitive advantages

Overall market: point-of-care diagnostics

Opportunity – growing point-of-care diagnostics market (10% CAGR): LDX operates within the POC diagnostics sector, a rapidly expanding healthcare segment. This market is projected to grow to US$65.9 bn by 2029 from US$44.24 bn in 2023 (see References: 1), a compound annual growth rate (CAGR) of ~10.2%. The COVID-19 pandemic significantly accelerated the adoption of POC diagnostics, driving demand for rapid, decentralised testing beyond traditional hospital settings.

Competitive advantages: Competitors in the POC diagnostics space include both large multinationals and innovative startups. Molecular POC testing has surged post–COVID-19, with platforms such as Abbott ID NOW and Cepheid GeneXpert gaining widespread use. AI-powered, digital POC solutions and at-home testing have become mainstream, while regulatory fast-tracking has improved market access.

LDX has meaningful advantages over its competitors in this space, including:

- **customisable LFAs,** allowing partners to tailor tests for specific biomarkers and applications
- **superior accuracy** due to integrated digital reader technology: Integrated digital readers provide quantitative and semi-quantitative results, improving accuracy over traditional visual LFAs
- **ability to assess multiple biomarkers in one test:** Some of LDX's solutions can detect multiple biomarkers in one test, improving diagnostic efficiency compared to single-marker LFAs. This allows a more detailed snapshot of a patient's condition and the capture of more information on various targets in parallel and is particularly valuable for complex diseases where multiple factors may be relevant for diagnosis or prognosis
- **less expensive and faster** than PCR and other lab tests: While less sensitive than PCR testing, LDX's solutions are lower cost and enable rapid decision-making (for example, FebriDx® provides results in ~10 minutes). These features are particularly useful in decentralised healthcare settings
- **global market access:** With regulatory approvals in multiple regions (specifically, FebriDx® has FDA clearance and CE marking), LDX has a stronger international market foothold than many competitors.

Immediate and critical market opportunity: differentiating bacterial vs. viral infections at point of care

Opportunity – combatting antibiotic overuse with flagship product, FebriDx®: LDX's immediate market opportunity rests with FebriDx®, specifically with respect to the overuse of antibiotics in the treatment of acute respiratory infections (ARIs) – a well-documented contributor to the escalating global challenge of antimicrobial resistance among bacterial pathogens.

Although ARIs are mostly caused by viruses, US healthcare providers in outpatient settings issued approximately 211 million antibiotic prescriptions for ARIs in 2021 – a rate of 636 prescriptions per 1,000 individuals. The CDC estimates that up to 28% of these prescriptions were unwarranted.

Competitive advantages: MeMed is the only real direct competitor to LDX in the host-response biomarker-based POC diagnostics space. Both tests differentiate bacterial from viral infections, positioning them uniquely in the POC market. However, we see FebriDx® as having meaningful competitive advantages over MeMed. FebriDx®:

- **is smaller (instrument-free) and thus more portable** (MeMed requires the use of an instrument)
- **is stored at room temperature** (MeMed which requires cold chain storage)
- **is less expensive**
- **requires a smaller volume of blood for the test** (fingerstick for FebriDx® vs. blood draw for MeMed)
- **provides clearer, definitive results** (in MeMed's algorithm, 30% of patients can fall into an equivocal zone).

Valuation and catalysts

We value LDX at A$172m or $0.10 per fully diluted share using DCF methodology, considering current shares, options and performance rights, and a projected US$5m capital raise in 2H25. Key catalysts for 2025 include an FDA pre-submission for FebriDx® paediatric study, Hologic agreement milestones, FebriDx® CLIA waiver trial updates, development of women's health diagnostics, and completion of the Hologic Development Agreement by December.

Risks and sensitivities

LDX creates synergies between contract development and proprietary products, leveraging its expertise to enhance its in-house pipeline and market positioning. However, the company faces significant challenges in a highly competitive diagnostics market dominated by well-established entities. LDX's success hinges on effective commercialisation, navigating complex regulatory landscapes, securing favourable reimbursement policies, and maintaining technological relevance. The company's reliance on distributors, ongoing funding needs, and the critical importance of intellectual property protection further underscore the multifaceted risks and opportunities in its growth strategy.

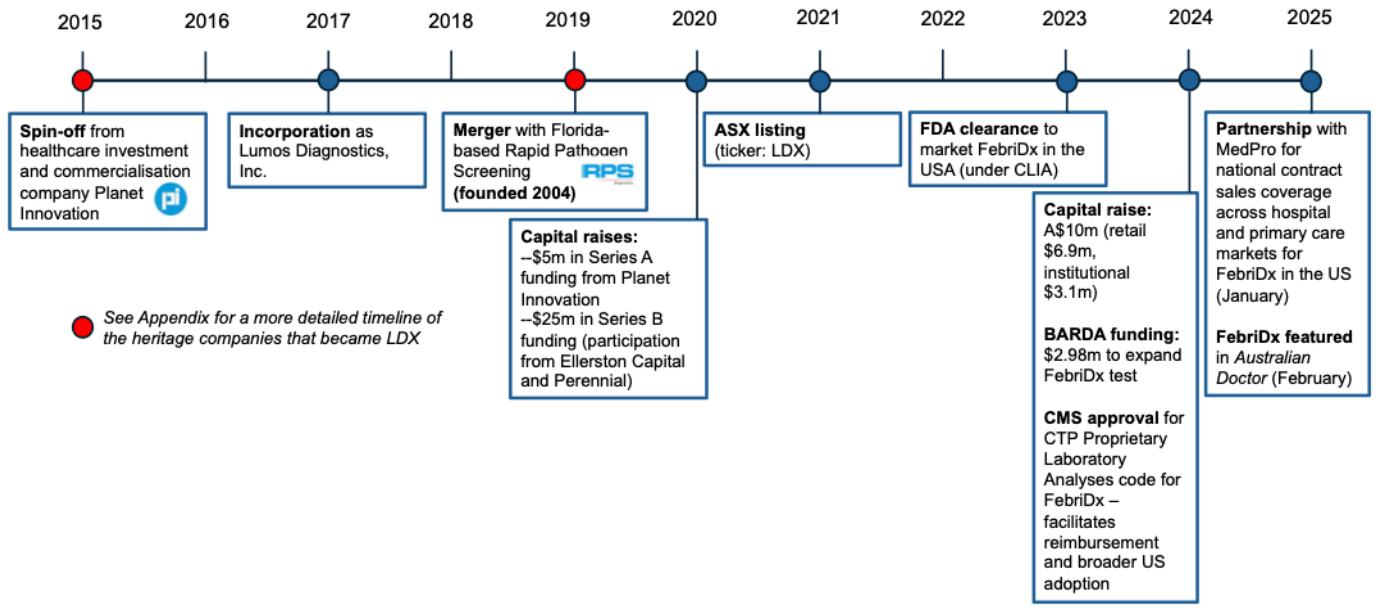
Outlook: Connected, Rapid End-to-End Diagnostics

Lumos Diagnostics (LDX) develops and manufactures point-of-care (POC) diagnostic solutions, specialising in rapid testing technologies that support healthcare decision-making. The company's core focus is on POC diagnostic tests for infectious diseases, using advanced assay technologies and digital reader systems to enhance test accuracy and usability. LDX's expertise spans the full lifecycle of POC diagnostic test development, from initial product concept to commercial-scale manufacturing.

Company history

Founded in 2015 following Planet Innovation's acquisition of Nplex Pty Ltd, LDX expanded through strategic acquisitions. These transactions included Kestrel Biosciences in 2017 and Rapid Pathogen Screening Inc. (RPS) in 2019, which provided access to proprietary tests including FebriDx®. See Figure 3 for a history of key events for LDX over the past decade. Appendix 4 provides the background of LDX before it was spun out of Planet Innovation, as well as the history of RPS before its acquisition.

Figure 3: Lumos company history



Source: LDX.

Technology suite: diagnostic technology with a focus on point-of-care

A diagnostic assay is an analytical procedure used to detect, measure, or evaluate the presence, concentration, or activity of specific biological markers or analytes in a sample. Lateral flow assays (LFAs) and immunoassays are key technologies used in the rapid, POC diagnostic solutions offered by LDX for both its key divisions (Products and Contract Services, discussed in the next section).

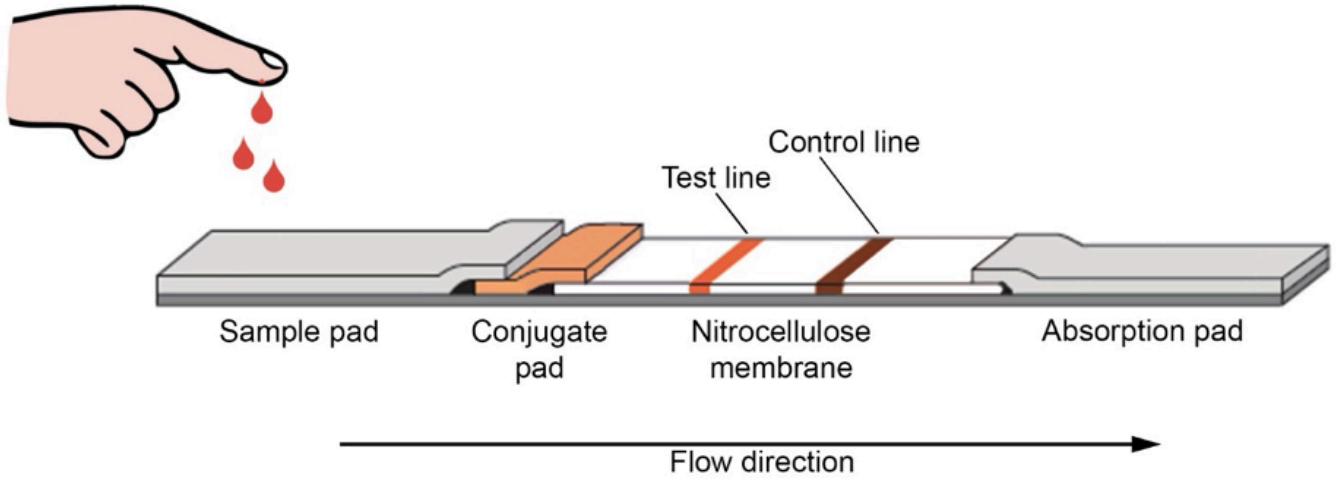
Assay types – what is the format of the test/assay?

LDX has broad experience over a wide range of assays, including LFAs, enzyme-linked immunosorbent assays (ELISA), and novel POC platforms that integrate microfluidic and sensor technologies. Some of these are multiplex assays, which can detect more than one analyte (e.g., ViraDx™ can detect COVID-19 and Influenza A and B).

Lateral flow assays (which include immunoassays): LFAs are paper-based platforms used to detect and quantify target substances or molecules in a test sample – for example, antigens produced by the COVID-19 virus in a saliva sample. These tests have become a widely familiar concept after the COVID-19 pandemic and the resulting proliferation of rapid antigen tests. LDX's LFAs use capillary action to move liquid samples through various zones on polymeric strips. Figure 4 shows the typical components of an LFA.

LDX offers customised assay development and manufacturing services for POC tests using this technology to its third-party clients, and also uses this technology in its own line of tests.

Figure 4: Basic schematic of a lateral flow assay – example shows a blood sample (although other liquid samples are used)



Source: https://lateralflows.com/lateral-flow-assays/.

Assay indicators/signals – how does the assay show its result to the user?

Colorimetric (visual) assays rely on colour changes that can be seen with the naked eye. For example, a chemical reaction might produce a noticeable colour shift, highlighting the presence of a specific substance.

Fluorescent assays use molecules that emit light when exposed to certain wavelengths. This highly sensitive technique is often used to detect very small amounts of substances or track biological processes.

Chemiluminescent assays produce light through a chemical reaction. The light indicates the presence or level of specific substances, making this method useful for medical tests and scientific research.

Assay chemistries – how does the assay actually work scientifically?

The assay chemistry refers to the specific biochemical reactions and molecular interactions used to detect or measure the analyte of interest. LDX uses a variety of assay chemistries to develop a range of types of assays. These include **immunoassays**, **enzyme-linked immunosorbent assays (ELISA)**, **enzymatic chemistry** and **DNA lateral flow methods**. An overview of the science behind each of these assay types is found in Appendix 2.

Advanced reader technology – enhancing diagnostic accuracy

LDX's technology platform includes digital readers and software applications that enhance test functionality and integration with electronic medical records.

Reader platforms with LDX's POC assays enable better decision making by healthcare professionals because they improve diagnostic accuracy. LDX's range of readers is designed to work with various diagnostic tests and can be customised to meet specific user needs.

Features that improve the performance of the assays during use include:

- High-performance optical systems: For example, the Hand-Held Camera Reader detects LFA strip signals at levels 10x lower than those visible to the naked eye, and enables quantitative results for biomarker tracking. This sensitivity is critical for early disease detection and monitoring.
- Digital quantification: Proprietary readers convert colorimetric or fluorescent signals into numerical results via Bluetooth-connected devices, reducing subjective interpretation errors.
- LDX also uses its proprietary reader platform technology in developing its assays. This technology enhances assay sensitivity through advanced optical detection systems and digital integration, enabling precise quantification of biomarkers at lower concentrations. These features collectively enable assays such as FebriDx® to achieve high sensitivity (up to 95%) for detecting bacterial infections and 99% negative predictive value (NPV) for ruling out bacterial infections, directly improving clinical outcomes.

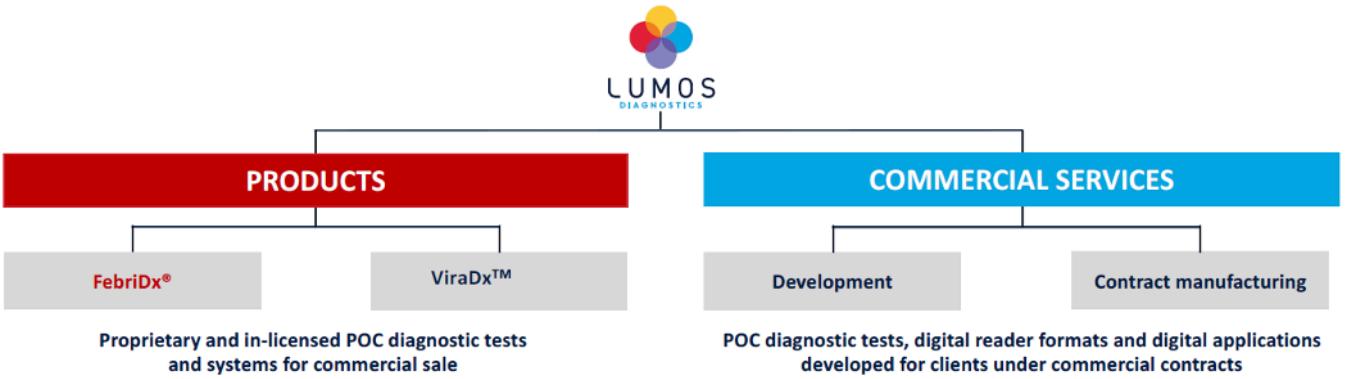
Features that improve the development of the assays include:

- Standardised optical configurations: The Leelu Reader allows partners to utilise the same optical configuration during development as the final customised reader product, ensuring consistent assay performance.
- Assay chemistry integration: The LDX system effectively combines gold-standard assay methods with advanced digital readers to enhance sensitivity while reducing development risks. By integrating assay development with the capabilities of its digital readers, the LDX system optimises overall performance and further minimises development risks. This integrated approach ensures that the system delivers accurate results with improved reliability and efficiency.

Product and Services Suite: End-to-End Solutions Across Two Key Divisions

LDX operates through two primary business divisions: Products and Contract Services.

Figure 5: LDX business divisions – two key areas, Products and Contract Services



Source: LDX.

Products division (11% of FY24 revenue)

The Products division develops and commercialises proprietary and in-licensed POC diagnostic tests (LFAs, including immunoassays): currently, flagship product FebriDx®, a test that differentiates bacterial from viral infections, and ViraDx™, a combination test for Influenza A and B and COVID-19.

Here, we outline some key information about FebriDx® and ViraDx™.

FebriDx® (flagship product, discussed in detail in next chapter)

FebriDx® is a rapid POC test that uses a small finger-prick blood sample to measure two biomarkers: C–reactive protein (CRP) and myxovirus resistance protein A (MxA). Elevated CRP indicates bacterial infection, while MxA is specific to viral infections. By detecting these biomarkers simultaneously, FebriDx® differentiates between bacterial and viral acute respiratory infections in just 10 minutes, aiding clinicians in accurate diagnosis and reducing unnecessary antibiotic use.

ViraDx™

ViraDx is a rapid POC antigen test developed by LDX to simultaneously detect and differentiate SARS-CoV-2 (COVID-19), Influenza A, and Influenza B infections. Using a single nasal or nasopharyngeal swab sample, the test delivers results within 15 minutes. Designed for use within the first 5 days of symptom onset, ViraDx provides fast, accurate differentiation of respiratory infections with similar symptoms, aiding clinicians in timely and effective patient management.

Contract Services division (89% of FY24 revenue)

LDX operates primarily through a contract service business model. This involves collaborating with companies (biotechs, pharmaceutical firms and startups) developing end-to-end solutions for healthcare professionals in hospitals, GP clinics, and urgent care facilities, as well as for molecular diagnostics, food and environmental testing and animal health applications. The company differentiates itself by offering a comprehensive service package, positioning itself as a one-stop partner for clients seeking rapid, cost-effective solutions. Its offering encompasses:

- **customised assay development:** designing and manufacturing test cartridges, including the integration of necessary chemistry
- **reader technology:** development and application of reader technology for various testing cartridges
- **software solutions** to complement hardware offering by way of companion apps and cloud connectivity
- **clinical, quality and regulatory support:** clinical trials, validation and assistance with regulatory submissions (FDA, CLIA) and quality system implementation.

Customised assay development and production

LDX designs and optimises diagnostic test assays tailored to client needs, leveraging its proprietary digital reader platforms and optical technologies. The company manages the full development cycle from concept to commercialisation, including integrating hardware, software and cloud connectivity.

LDX has established a high-throughput manufacturing facility in Carlsbad, California, with the capacity to produce up to 10 million tests per month using regulatory-compliant processes. By leveraging its proprietary technology platform, LDX supports clients in a variety of sectors, including human diagnostics, food safety, animal health, and pharmaceuticals. The company's phased development approach (see Figure 6) reduces timelines and risks, leveraging existing optical platforms and data solutions.

LDX does primarily produce LFAs, including its proprietary product FebriDx®. However, the company's customised assay development offering can develop new POC diagnostic test products, which may include different technologies beyond lateral flow.

Figure 6: Formal staged development process for regulated products (assays) – LDX

	Phase 0 Conceptual Development	Phase 1 Design Inputs	Phase 2 Design Outputs	Design Freeze Phase 3 Design Verification	Regulatory Clearance Phase 4 Design Validation & Transfer to Manufacturing
LATERAL FLOW ASSAY DEVELOPMENT	• Identify if suitable commercially available antibodies and antigen are available or do they need to be generated	• Source/generate antibodies and antigens • Conjugate detector particle to antibodies • Screen antibodies and antigens in simple lateral flow system against desired performance specifications. • Initial sample matrix testing • Lumos Leelu reader to measure and compare test signal • Identify the best configurations to progress into Phase 2	• Mature candidate assays and narrow in on one formulation • Optimise for patient samples and to required performance metrics • For multiplex tests, combine assays into one test strip or evaluate if multi-strip is required • Prepare multiple builds to confirm reproducibility • Initiate a stability (shelf-life) assessment	• Start Design Transfer - Approve manufacturing work instructions and quality control documentation • Conduct 3x pilot builds with gradual hand over from R&D into manufacturing • Conduct formal verification studies to demonstrate performance to requirements • Begin long-term stability study (real time and accelerated)	• Design Validation (clinical) studies to Customer Needs • Clinical Validation Reports • Complete Design Transfer - Finalise manufacturing work instructions and quality control documentation • Perform Manufacturing Process Validation and finalize test reports
SAMPLE PREPARATION & CASSETTE	• Identify sample preparation needs/steps and any associated reagents and/or consumables • Select appropriate Lumos cassettes for sample type and number of test strips	• Source off-the-shelf consumable options and/or begin custom design • Generate initial prototypes for evaluation with samples • Begin cassette customization design and prototypes (if required)	• Evaluate custom cassette prototypes with assay test strip • Conduct small-scale user workflow assessment with consumables • Tooling for customized cassette and other consumables (if required)	• Incorporate consumables in assay build and verification activities	• Customized consumables Manufacturing Process Validation
READER CUSTOMIZATION	• Determine most appropriate Lumos reader for end user needs • Explore customization needs (if required)	• Begin reader customization design (if required)	• Transition reader testing to selected Lumos model • Finalise algorithm for qualitative or quantitative output • Complete reader design customization (if required)	• Customized reader beta build • Conduct formal verification studies to demonstrate performance to requirements	• Customized reader Design Transfer into manufacturing • Customized reader Pilot Production and Manufacturing Process Validation
APP CUSTOMIZATION	• Map out high-level user work flow from patient presentation through to results	• Begin detailed journey mapping of app interface and workflow	• Initiate app development, including graphic design, workflows and instructions, data presentation and management, and multi-language support • Cloud integration and customisation (if required)	• Finalize app release • Conduct app verification	
CLINICAL & REGUATORY AFFAIRS	• Start map of high-level regulatory requirements according to commercialization plan	• Start Regulatory Strategy for commercial markets within scope of project • For particularly novel products, consider filing informational pre-submission for a meeting with FDA	• Formalize Regulatory Strategy and project plan for regulatory submissions • Meet with FDA (file marketing application pre-submission) to introduce device and discuss testing strategy	• Draft regulatory applications according to feedback, project plan, and regulatory strategy.	• Clinical Studies (protocol development, site selection, ethics approval, study execution, data management, data analysis, report preparation for regulatory submission) • Complete and submit applications to Regulatory Authorities for product registration (e.g., clearance, approval).

Source: LDX.

Reader platforms

LDX offers advanced reader platforms that integrate sophisticated optical technologies, providing a foundation for developing digital diagnostic products and enhancing test functionality.

Advanced features and capabilities of the LDX reader offering

- **Objectivity:** The LDX reader suite eliminates human variability in test interpretation and generates quantitative outputs. The reader technology is utilised in partnership with other companies seeking to bring products to market. An example of such a product is the Hologics test, under development, which uses a biomarker to detect preterm labour risk.

- **Customisation:** These platforms can be customised to include partner branding, application-specific features, and alternative form factors. Starting with a mature reader platform minimises the risk if problems that can occur when optical platforms and assays are developed in parallel (for example, technical incompatibilities, market misalignment, regulatory hurdles, delays, and cost overruns).
- **Versatility and usability:** The reader platform accommodates both lateral flow and non-lateral-flow cartridges. The offering balances performance with cost reduction by simplifying unnecessarily complex electronics.
- **Technology:** The reader platforms are supported by strong technology infrastructure. The devices can be designed with Bluetooth connectivity and integrated with companion apps for smartphones, tablets, and PCs, as well as with medical cloud platforms to facilitate comprehensive product ecosystems and data visualisation capabilities.
- **Data management and connectivity** is a key element of the reader product suite, with options for secure data storage, management, and integration with electronic medical records or information systems. The readers are designed to meet the latest standards in cybersecurity and patient privacy, complying with regulations such as HIPAA, HITECH, and GDPR.

The reader platforms fall into two categories: digital reader platforms and optical readers.

- **Digital reader platforms:** LDX develops proprietary digital reader platforms that can be used with various types of POC tests, including but not limited to LFAs, and typically feature custom assay-specific algorithms.
- **Optical readers:** LDX has developed optical readers such as the Leelu Reader, which can be used for various assay types and chemistries, indicating a broader scope than just LFAs. These readers use dual-lit optics, which offer enhanced performance compared with other readers.

Disposable readers

LDX offers 2 disposable reader formats:

- Single-use Disposable Reader: This format fully integrates the test strip with the reader in a single-use, disposable system.
- Multi-use Disposable Reader: Supplied in kit form with 20–50 disposable tests, this reader provides ultimate portability for digitising LFA strips.

These disposable readers can be customised with various features, including optional colorimetric or fluorescent labels; on-device LED indicator or LCD numerical results output; qualitative and quantitative options; and Bluetooth connectivity for reporting results via smartphone or tablet.

Hand-Held Camera Reader (also called Reusable Hand Held)

LDX's handheld reader format is versatile and can be used to read multiple different POC diagnostic tests using a single device. Key features include:

- high-precision camera optics for analysing entire test strips
- suitability for both qualitative and quantitative applications
- ability to be customised to serve a wide range of applications.

Leelu Reader

The Leelu Reader is a highly flexible lateral flow reader designed for research and quality control purposes. The Leelu Reader:

- supports assay development partners
- assists in quality control for LFA manufacturing
- allows partners to use the same optical configuration during development as the final customised reader product
- is suitable for various assay types and chemistries
- enables detailed examination of product quality during manufacturing.

The Leelu Reader is available for assay feasibility studies and the generation of assay-specific algorithms, facilitating a smooth transition to disposable or handheld readers. LDX's reusable reader platform employs high-precision camera optics to image entire test strips without moving parts, reducing cost and complexity. This platform supports both qualitative and quantitative applications across various assay detector chemistries, including visual, fluorescent, and luminescent.

Figure 7: Reader portfolio (disposables and reusable camera reader)

Source: LDX.

Figure 8: Leelu Reader

Source: LDX.

Figure 9: Leelu Reader features

- Different strip and cartridge formats
- Visible or fluorescent detection chemistries
- Assay specific optical configuration
- Large read window with viewable image of test strip
- Access to raw data
- Proprietary analysis software and tools

Core technology and settings optimised using the Lumos Leelu Reader can be easily transferred into a tailored reader with customised feature set.

Source: LDX (NB: Luminescent detection chemistry same as fluorescent detection chemistry).

Supporting technology – cloud and companion app services

Companion apps: LDX develops customised apps for Android, iOS, and Windows platforms that interface with its diagnostic readers. These apps guide users through test procedures, display results, and connect to cloud systems or laboratory information systems for seamless data transfer.

Cloud technology: LDX integrates its smartphone/tablet apps into cloud platforms to capture and store crucial data, such as device locations, test usage, results, and patient metrics. This enables real-time data aggregation, visualisation, and integration with electronic medical records while adhering to cybersecurity standards such as HIPAA and GDPR.

Figure 10: Supporting technology – applications and cloud

	Desktop application	Smartphone/tablet application	Cloud (various providers: commercial, client cloud)
Functionality	• Visualisation of test strips • Comprehensive raw data • Detailed analysis of lateral flow tests • Time lapse analysis	• Data entry of user and patient information • Guide user through test workflow • Analysis of lateral flow test strips • Report results to end user • Communicate test information to cloud	• Central repository of test information • Communicate test information to patient medical record
Reader	• Leelu Reader • Hand-Held Camera Reader	• Hand-Held Camera Reader • Multi-use Disposable Reader	• Hand-Held Camera Reader • Multi-use Disposable Reader
Targeted end use	• In laboratory • In field	• In home/in field • In clinic	• In home/in field • In clinic

Source: LDX.

Revenue streams from the Contract Services division

Revenue streams include:

- **fee-based contracts:** R&D and manufacturing services for third-party clients, including multinational healthcare companies
- **long-term partnerships:** multi-year manufacturing agreements due to stringent regulatory requirements for changing suppliers
- **Intellectual property (IP) license agreements (such as Hologic):** Under this licensing model, LDX monetises its IP without incurring ongoing costs, as the agreement primarily involves granting access to existing patents and technologies.

Key R&D programs and partnerships

Hologic partnership

LDX entered into a significant partnership with Hologic for the co-development of an advanced version of Hologic's fetal Fibronectin (fFN) test in January 2024. The new fFN test aims to enhance the clinical utility of the existing test in predicting preterm birth, potentially leading to better management of at-risk pregnancies and reduced unnecessary interventions.

Project objectives

The project aims to improve upon the existing test in several ways including:

- Quantitative results: The new test is designed to provide quantitative fFN measurements, as opposed to the current qualitative (positive/negative) results. This quantitative approach may offer more precise risk assessment for preterm birth.
- Improved connectivity: The new version will utilise LDX's proprietary reader platform, which is expected to provide enhanced connectivity options. This could facilitate better data management and integration with healthcare systems.
- Enhanced accuracy: While the existing fFN test already has high specificity (91.1%) and negative predictive value (79.1%), the quantitative approach of the new test may further improve its predictive capabilities.
- Potential for serial measurements: The quantitative nature of the new test could allow for more effective serial measurements, which may be particularly useful for high-risk groups.
- Integration with other predictive factors: The new test might be better suited for integration with other preterm birth predictors, such as cervical length measurements, potentially improving overall prediction accuracy by up to 50%

Details of the partnership and agreements

The partnership was established through two key agreements:

- An intellectual property (IP) agreement valued at US$10m
- A development agreement valued at US$4.7m

The development agreement focuses on adapting Hologic's existing fFN diagnostic product for pre-term birth to use LDXs' proprietary reader platform and provide improved connectivity options. The project is structured in three phases:

- Phase 1: Product definition and planning (completed in May 2024, US$0.4m milestone payment received).
- Phase 2: Assay feasibility to demonstrate biomarker detection (ongoing; expected completion by April 2025, triggering a US$0.3m milestone payment).
- Phase 3: Delivery of a working system prototype, now expanded to include additional hardware features, increasing the scope's value to US$4.3–4.5m. Completion expected by December 2025.

As of March 2025, LDX and Hologic have agreed to expand the scope of work for Phase 3, which will now include additional hardware features in the proprietary reader technology. This expansion is estimated to generate additional revenue of US$600,000–800,000 for LDX, bringing the total value of the development agreement to approximately US$5.3–5.5m.

The partnership with Hologic stands out as LDX's most significant and transformative strategic collaboration to date, expanding its partnership with a leading women's health company and advancing ots proprietary reader technology in a long-term project, potentially opening doors for future collaborations and market opportunities.

Figure 11: Hologic - fFN product development overview

Source: LDX

Burnet Diagnostics initiative

LDX and the Burnet Diagnostics Initiative (BDI) established a partnership in July 2023 to undertake an initial feasibility project with BDI on a novel companion diagnostic biomarker with utility across a range of human health applications.

In August 2024, LDX extended its collaboration with the BDI to manufacture a lateral flow test and develop customised readers for monitoring liver function. Specifically, they are developing tests to measure Alanine Transaminase (ALT) levels, which can indicate liver injury when elevated. The extended agreement includes producing ALT lateral flow tests, customised LDX readers, and a mobile phone application for use in an upcoming US-based clinical trial. LDX will provide development, regulatory, and manufacturing services to BDI over 9–12 months, generating fees of US$0.7–1.0m.

FebriDx® development (more details in next chapter)

The flagship proprietary product, FebriDx®, a POC test distinguishing between viral and bacterial infections, continues to progress.

Recent development include:

- In October 2024, LDX secured US$8.3m in BARDA funding for CLIA waiver and paediatric studies
- CLIA waiver study commenced in December 2024, testing ~300 patients so far. Notably, achieving a CLIA waiver will allow FebriDx® to be used in approximately 270,000 CLIA-waived sites across the U.S., such as physician offices, urgent care centres, and outpatient clinics
- Paediatric study pre-submission planned for April 2025.

New product development – 'Product One' program in women's sexual health

LDX is also currently in the process of developing 'Product One' (a working name during product development). Product One is a novel diagnostic tool aimed at addressing critical needs in women's sexual health. According to management, this product is part of LDXs' strategic initiative to establish a leadership position in point-of-care (POC) testing for women's health and sexual health.

At this stage, the actual product name or precise indication has not been disclosed. The development timeline for Product One is projected to span approximately 3 years, encompassing several crucial stages: feasibility assessment, development, verification, clinical sample acquisition, pilot study execution, clinical trial implementation, and FDA review.

The company has described Product One as a visual read product, suggesting that it may not require specialised reader devices, which could enhance its accessibility and ease of use in various POC clinical settings.

Notably, the women's sexual health market indication, which Product One is targeting, affects 30-40% of women and accounts for over 10 million healthcare visits annually in the United States. This substantial market size indicates not only the potential economic impact of the product to LDX but also its possible significance in addressing unmet medical needs. The global women's health diagnostics market is projected to reach $36.3 billion by 2030, growing at a CAGR of 6.9% (2021–2030).

Broader R&D service programs

LDX actively works with clients in the POC diagnostics industry and currently has 11 active R&D programs which range from early feasibility studies to advanced development and manufacturing transfer, specifically:

- 4 programs in feasibility/early development
- 5 programs in advanced development or verification
- 2 programs successfully transferred to manufacturing.

Flagship Product FebriDx®: Major Strategic Opportunity at Critical Moment

Key product offering: rapidly differentiating viral and bacterial infections

LDX's flagship product is FebriDx®, a point-of-care (POC) fingerstick blood test designed to rapidly differentiate viral from bacterial acute respiratory infections (see Figure 12 for an overview of the simple fingerstick procedure).

The problem of over- and under-prescription of antibiotics

Medical practitioners often face challenges in distinguishing between viral and bacterial acute respiratory infections (ARIs), as both can present with similar symptoms such as sore throat, cough, and shortness of breath. This uncertainty makes it difficult for clinicians to know when antibiotics are appropriate.

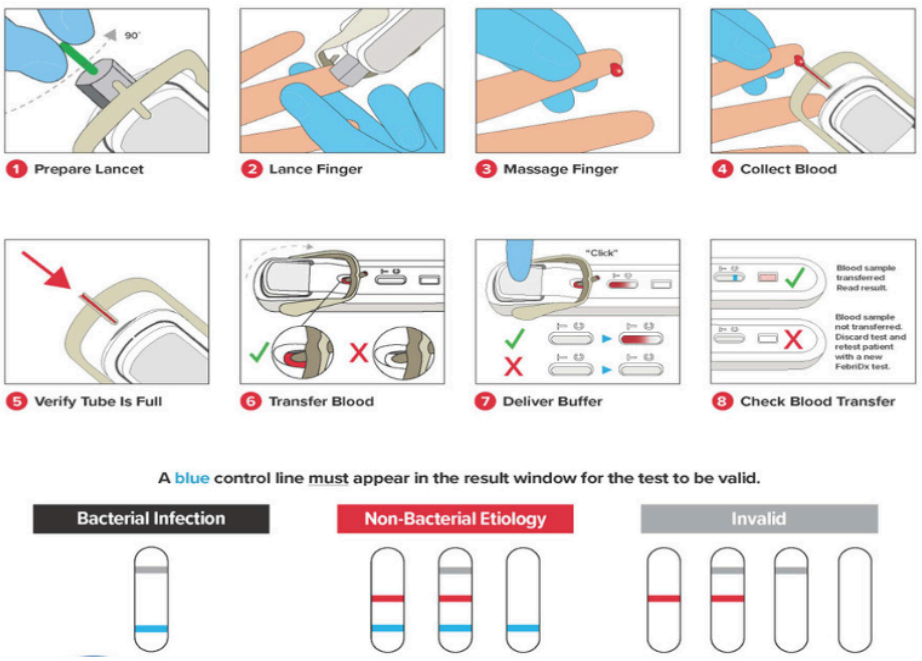
While antibiotics are only effective against bacterial infections, these medicines are routinely over-prescribed, often being provided to patients who in fact have viral infections. Over-prescription is creating an increasing problem of antimicrobial resistance, leading antibiotics to lose their efficacy across the population. However, when antibiotics are under-prescribed (not provided to patients who do in fact have bacterial ARIs), patients miss out on the medication that would be most effective for their illness. FebriDx® helps address both over-prescription and under-prescription by accurately distinguishing between viral and bacterial ARIs.

A simple, point-of-care solution

In this context, FebriDx® has emerged as a valuable tool for diagnosing ARIs. Its rapid and accurate differentiation between viral and bacterial infections supports timely clinical decisions, enhances patient management, and contributes to global efforts in combating antibiotic resistance.

FebriDx® is currently approved for patients aged 12–64 presenting with recent-onset ARI symptoms in urgent or emergency care settings. Outside of the US, the FebriDx® age limit is 1 year and above. The test, which provides results after 10 minutes, is not intended to identify specific pathogens or infection severity. However, the assay serves as a valuable adjunct to clinical judgment and other diagnostic findings. By facilitating more informed decision-making regarding antibiotic prescriptions, FebriDx® has the potential to enhance antimicrobial stewardship, addressing a critical need in contemporary healthcare practice and potentially contributing to the mitigation of the global antimicrobial resistance crisis.

Figure 12: The FebriDx® test procedure: simple and instrument-free



Source: LDX.

Key characteristics of the FebriDx® test

The FebriDx® test offers a fast, accurate result at the point of care, with a procedure that is easy for both the clinician and the patient. Key characteristics of the test include:

- **Dual biomarker detection:** FebriDx® simultaneously measures elevated levels of C-reactive protein (CRP) and myxovirus resistance protein A (MxA), providing a more comprehensive assessment of infection type compared to single-biomarker tests. The MxA biomarker in FebriDx® acts as a 'pan-viral' test, identifying the presence of active pathologies from common acute respiratory viral causes.
- **Rapid results:** The test provides actionable results in approximately 10 minutes, allowing for quick decision-making in clinical settings.
- **High diagnostic accuracy:** Studies have demonstrated high sensitivity and specificity in identifying clinically significant bacterial and viral ARIs.
- **Ease of use:** The all-in-one, single-use, disposable test device requires no additional equipment, making it simple to administer in various healthcare settings.
- **Potential for antibiotic stewardship:** The test has shown potential to improve antibiotic-prescribing decisions, supporting efforts to combat antimicrobial resistance.
- **Versatility:** FebriDx® has been evaluated for use in various settings, including emergency departments, primary care, and as a triage tool for COVID-19.

Commercially attractive to physicians: FebriDx® offers GPs a commercially viable opportunity by enhancing clinical workflow while also generating revenue. They can profit from test purchases, patient charges, and the $41.38 PLA code reimbursement, a key incentive in the US market.

A superior offering compared with MeMed BV – the closest competitor

Cost-effectiveness: An economic evaluation found that implementation of FebriDx® reduced costs related to ARIs by approximately 27% compared to standard care (References: 2).

MeMed BV and FebriDx® are both rapid diagnostic tests designed to differentiate bacterial from viral infections. MeMed BV uses host-response technology, analysing 3 biomarkers (TRAIL, IP-10, and CRP) with machine learning to deliver results in 15 minutes. FebriDx® employs dual biomarker technology (CRP and MxA) via a fingerstick blood sample. In our view, FebriDx®'s simpler and quicker testing process, with less invasive sample collection, positions it as the more practical and cost-effective option in POC diagnostics.

User-experience a key point of differentiation: speed, convenience, and ease of use

The user experience of MeMed BV and FebriDx® differs in several key aspects:

- **Sample collection:** FebriDx® uses a simple fingerstick blood sample, making it minimally invasive and easy to administer in outpatient settings. MeMed BV, on the other hand, requires a serum sample obtained through venipuncture, which may be less convenient for patients and dissuade some patients who dislike the blood draw procedure.
- **Test duration:** FebriDx® provides results within 10 minutes, offering faster turnaround at the point of care. MeMed BV takes approximately 15 minutes but offers a more detailed analysis.
- **Ease of use:** FebriDx® functions as a fully self-contained diagnostic test, requiring no additional equipment beyond the test kit itself. In contrast, MeMed BV relies on the MeMed Key analyzer, which utilises computational algorithms for result interpretation. Furthermore, MeMed exhibits a relatively large range of indeterminate results, whereas FebriDx® delivers a clear binary outcome – either positive or negative – enhancing its clinical utility and simplifying result interpretation.

Figure 13: Comparing FebriDx® to MeMed (shaded metrics show where FebriDx® has a meaningful advantage)

	FebriDx®	MeMed
Regulatory and CLIA status	510(k); moderately complex	510(k); moderately complex
Setting	Emergency care / urgent care	ED or urgent care
Performance	99% NPV for bacterial	99% NPV for bacterial
Interpretation	Bacterial or non-bacterial – no indeterminate results	Score 0–100 (high/mod probability of bacterial or viral infection) – 30% indeterminate results
Instrument required?	No	Yes (creating throughput issues, capital cost and logistical issues)
Storage	4–25 C	2–8 C
Sample type	Fingerstick blood	Serum and whole blood
Turnaround time	10 minutes	15 minutes
Price point	~$25/test	~$100/test
Technology	Immunochromatographic lateral flow	Chemiluminescence

Source: LDX, MST Access.

Scientific overview: how FebriDx® works

Two biomarkers used together – a novel approach for strong results

The FebriDx® assay represents a significant advancement in rapid diagnostics for ARIs. This qualitative immunoassay simultaneously detects 2 markers from a fingerstick blood sample:

- **Myxovirus resistance protein A (MxA),** which is elevated in viral infections – this biomarker is both a sensitive and specific marker for viral ARIs, and is not elevated in the case of bacterial ARIs.
- **C-reactive protein (CRP),** a marker of acute inflammation that is elevated in both viral and bacterial ARIs. At low levels, CRP is sensitive (but not specific) for bacterial infection.

The important step is the combination of these biomarkers, neither of which is sufficiently sensitive nor specific on its own to differentiate between viral and bacterial ARIs. Using them in tandem, however, demonstrates high sensitivity (93.2%) and negative predictive value (98.7%) for bacterial infections, with an area under the curve of 0.8713 when combining MxA and CRP.

Clinical validation

Clinical testing – prospective clinical assessment (2020)

In 2020, Kettering General Hospital National Health Service (NHS) Foundation Trust in the UK conducted a prospective clinical assessment of FebriDx® which was completed in April 2020. The study aimed to evaluate the utility of FebriDx® as part of a triage strategy for identifying symptomatic cases that could potentially be linked to COVID-19. The findings suggested that FebriDx® could be effectively integrated into clinical workflows during the pandemic to facilitate timely patient management and infection control.

The study concluded that FebriDx® could be deployed as a reliable adjunct for clinical decision-making, aiding in the isolation of COVID-19 cases while also considering alternative diagnoses, especially in the context of the particular challenges associated with diagnosing infectious diseases during a viral pandemic. FebriDx® was found to offer a valuable addition to clinical decision-making with respect to confirmatory testing, patient isolation and antibiotic prescriptions, both preventing the unnecessary use of antibiotics and guiding appropriate infection control measures in the context of hospital settings experiencing high patient volumes. As well as helping to identify COVID-19 cases, using FebriDx® helped clinicians to detect alternative infectious causes that might otherwise have been overlooked during a viral outbreak.

Dr Robert Sambursky, President and CEO of LDX in 2020, highlighted the significance of FebriDx® as an effective triage tool for suspected COVID-19 cases and emphasised its potential for rapid deployment in future pandemics.

FebriDx® DISRUPT clinical trial (2021)

The FebriDx® DISRUPT clinical trial was a significant study evaluating the performance of the FebriDx® test in detecting and differentiating between bacterial and viral ARIs in 520 patients. The multi-centre clinical study was conducted by LDX to support its 510(k) submission for FDA clearance of FebriDx® in the United States. This was a key milestone for LDX, as detailed in its FY21 Annual Report and other related documents.

The DISRUPT trial evaluated the use of FebriDx® in the context of ARIs. It included 520 participants, with 24 excluded due to issues with sample handling. The expert panel agreed with the algorithm classification in 93.3% of the adjudicated cases, further validating the test's accuracy.

The FebriDx® DISRUPT clinical trial, completed in 2021, provided crucial data for FDA approval (see next section), demonstrating high performance in differentiating between viral and bacterial infections. Notably, the test's high negative predictive value of 98.7% indicated its reliability in ruling out bacterial infections. These findings, along with the test's ability to provide results within 10 minutes, supported the FDA's decision to clear FebriDx® for marketing in the US.

Two recent studies

Recent studies in UK primary care and Barcelona paediatric settings demonstrate the potential of FebriDx® to reduce inappropriate antibiotic prescribing.

UK Primary Care study (2024) (References: 3)

A UK Independent study by the National Institute for Health and Care Research (NIHR) assessed the impact of FebriDx®, a point-of-care diagnostic tool, on antibiotic prescribing for lower respiratory tract infections (LRTIs) in primary care. The study involved 155 paediatric and adult patients across nine GP practices, all of whom were considered likely to receive antibiotics. FebriDx® testing influenced clinical decision-making significantly, with clinicians reporting increased confidence in their prescribing choices. After testing, 51% of clinicians were more certain that antibiotics were unnecessary, while 31% felt more confident that antibiotics were required.

Importantly, antibiotic prescriptions were primarily limited to patients with bacterial-positive FebriDx® results, leading to a 40% reduction in overall antibiotic prescribing. Patient outcomes remained positive, with no evidence of increased re-consultation rates or adverse events among those who did not receive antibiotics. Both patients and clinicians provided favourable feedback, highlighting the test's speed, efficiency, and potential cost savings. These findings suggest that FebriDx® could be a valuable tool in primary care. Its ability to provide rapid and accurate results supports global efforts to combat antimicrobial resistance while maintaining high standards of patient care.

Barcelona paediatric study (2024) (References: 4)

A recent paediatric study conducted at Sant Joan De Deu hospital in Barcelona, Spain, evaluated the impact of FebriDx® on antibiotic prescribing and diagnostic testing in children with acute respiratory infections (ARIs). The study found that FebriDx® significantly reduced inappropriate antibiotic prescribing by 40% and eliminated unnecessary chest X-rays.

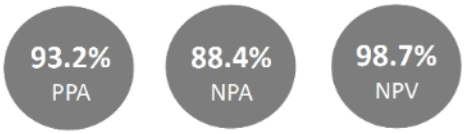
FebriDx® demonstrated particular efficacy in cases of suspected bacterial ARI, altering the etiological decision in nearly 75% of these patients. This led to a 40% reduction in inappropriate antibiotic prescriptions. The test showed the most substantial impact in patients with pneumonia, where it resulted in antibiotics not being prescribed in 34.5% of cases.

Researchers concluded that FebriDx® is a valuable tool for managing paediatric patients with febrile ARIs, optimising antibiotic prescriptions, and reducing unnecessary diagnostic procedures such as chest X-rays. These findings align with other recent studies that have demonstrated FebriDx®'s utility in guiding antibiotic therapy and improving clinical management decisions in primary care settings.

Figure 14: FebriDx® clinical performance

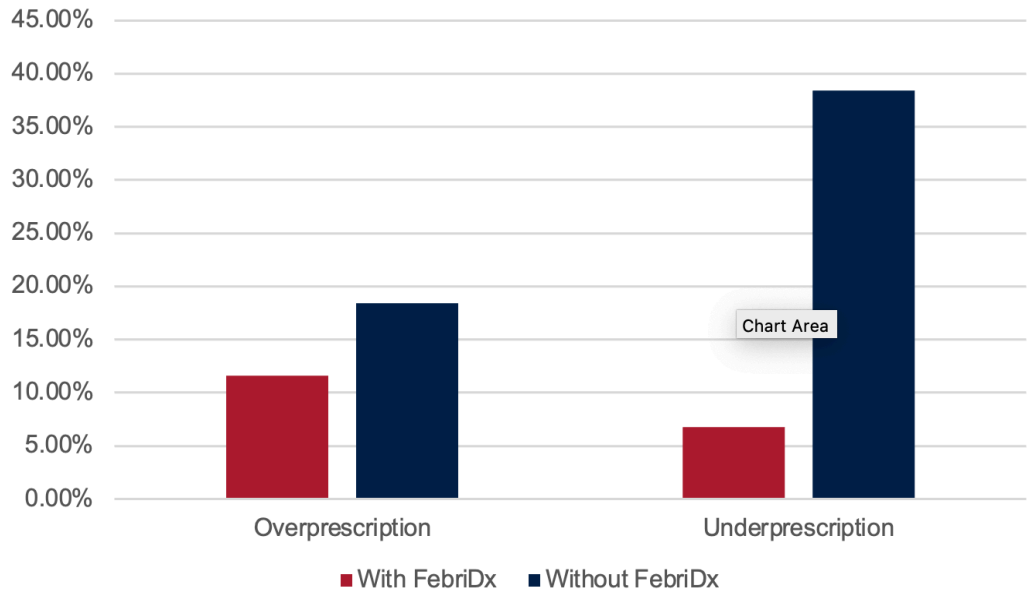
- Multi-center prospective clinical trials 20 POC sites.
- FebriDx compared to a composite Clinical Reference Algorithm including bacterial culture, multiplex PCR and measures of host immune response.
- FebriDx showed high sensitivity and specificity to differentiate bacterial from non-bacterial ARI.
- FebriDx has a 99% NPV to rule out a bacterial infection.[9]

Bacterial Infection[8]:



Source: LDX. 8 Acute respiratory infection: 9. Shapiro NI, Filbin MR, Hou PC, Kurz MC, Han JH, Aufderheide TP, Ward MA, Pulia MS, Birkhahn RH, Diaz JL, Hughes TL, Harsch MR, Bell A, Suarez-Cuervo C, Sambursky R. Diagnostic Accuracy of a Bacterial and Viral Biomarker Point-of-Care Test in the Outpatient Setting. JAMA Netw Open. 2022 Oct 3;5(10):e2234588.doi:10.1001/jamanetworkopen.2022.34588. PMID: 36255727; PMCID: PMC9579916.

Figure 15: Significant improvements to diagnostic decision-making using FebriDx®



Source: Shapiro et al 2022, 'Diagnostic Accuracy of a Bacterial and Viral Biomarker Point-of-Care Test in the Outpatient Setting', JAMA Network Open 5(10), doi:10.1001/jamanetworkopen.2022.34588.

FDA 510(k) clearance (July 2023)

In July 2023, the FDA granted clearance for FebriDx®, authorising its use by healthcare professionals to aid in diagnosing bacterial ARIs and distinguishing them from non-bacterial causes in urgent and emergency care environments.

More encouraging data from subsequent studies and BARDA partnership

Recent studies have reinforced the diagnostic accuracy and utility of FebriDx® in various clinical settings. A notable study published in the *Journal of Clinical Medicine* in 2024 (see References: 5) evaluated FebriDx®'s performance in an emergency department cohort. The study reported a sensitivity of 87% and a negative predictive value of 91% for detecting bacterial infections, underscoring FebriDx®'s reliability in acute care scenarios.

Additionally, a study published in *JAC-Antimicrobial Resistance* in 2024 (see References: 6) demonstrated that implementing FebriDx® in primary care settings could reduce unnecessary antibiotic prescriptions for lower respiratory tract infections. The study suggested that the test provided clinicians with rapid, reliable data, facilitating informed decision-making and promoting appropriate antibiotic use.

Regulatory status

FDA clearance as Class II medical device (July 2023)

FebriDx® received FDA marketing clearance in July 2023 as a POC test to aid in diagnosing bacterial ARIs and distinguishing them from non-bacterial etiologies. The test is classified as a Class II medical device.

The clearance allows FebriDx® to be used in the United States by healthcare professionals in urgent care and emergency care settings for patients aged 12–64 presenting with ARI symptoms. As such, the current market potential is limited to these settings, which total around 18,000 sites.

CMS reimbursement approval (January 2025)

On 1 January 2025, The Centers for Medicare and Medicaid Services (CMS) Panel approved the FebriDx® PLA (Proprietary Laboratory Analyses) code to be reimbursed at a rate of US$41.38 per test. This allows for reimbursement from both government and private insurers, which we expect will facilitate broader adoption of the test across medical networks over time.

CLIA waiver study (ongoing)

The Clinical Laboratory Improvement Amendments (CLIA) establish comprehensive regulations for laboratory testing in the US. Key provisions include quality standards for all tests, mandatory certification for facilities performing human specimen examinations, and categorisation of tests into waived, moderate, and high complexity levels. CLIA specifies personnel qualifications, proficiency testing requirements, and quality management systems. It mandates regular inspections and outlines sanctions for non-compliance. The regulations cover facility administration, record-keeping, and reporting requirements. By setting these standards, CLIA aims to ensure accurate, reliable, and timely laboratory test results, ultimately enhancing patient care and safety across the healthcare system.

LDX has recently initiated a CLIA waiver study for FebriDx®. The study evaluates the test's accuracy, ease of use, and performance in non-laboratory settings to support an FDA CLIA waiver application. If granted, this waiver would enable FebriDx® to be more broadly adopted in decentralised healthcare settings, enhancing diagnostic accessibility and antimicrobial stewardship efforts. If successful, the CLIA waiver would significantly expand FebriDx®'s market potential by allowing its use in physician offices, urgent care clinics, and other outpatient settings. Such a waiver could expand the market for FebriDx® in the US by more than 15 times, increasing the number of potential customer sites from 18,000 to 270,000.

The CLIA waiver study commenced in December 2024, with the first patient successfully tested. The study is expected to enrol 500–800 patients across at least 6 sites to achieve the required 120 positive bacterial cases. Completion of the study is expected by the spring of 2025. The company expects the CLIA waiver study to read out in the middle of 2025, with a potential submission to the FDA in August/September 2025.

BARDA

In October 2024, LDX received a non-dilutive funding award of US$2,984,571 from the Biomedical Advanced Research and Development Authority (BARDA) to support the CLIA waiver study and FDA application for FebriDx®. This partnership aims to expand authorised testing to CLIA-waived POC settings, including physician offices, urgent care clinics, and other outpatient clinics where empiric (based on clinical judgment rather than waiting for lab results) antibiotic prescription is common practice. BARDA's support includes comparing test usage among untrained users in CLIA-waived settings to trained users, as well as providing regulatory expertise for the FDA CLIA-waiver application.

The initiation of the study and the first patient tested triggered the first two milestone payments under the BARDA partnership, totalling US$0.90m. These were received in January 2025. An additional option in the BARDA agreement, if exercised, would support a paediatric study for the authorised use of FebriDx® in children under 12 years of age in the US, potentially increasing the total awarded contract value to US$8,258,774.

Regulatory approval process and timelines – what's next?

Patient enrichment strategy modifications

The FebriDx® CLIA waiver trial has implemented protocol updates to accelerate study completion and meet regulatory requirements. This strategy aims to increase clinically relevant bacterial-positive cases in the study cohort, addressing previous recruitment challenges.

The key elements of the bacterial positive enrichment strategy for the FebriDx® CLIA waiver trial are:

- **Targeted enrolment of specific populations:** The trial will focus on subjects that were prescribed antibiotics or those with a Rapid Strep A positive test to increase the representation of bacterial-positive cases in the study cohort.
- **Multi-operator testing:** Sites with multiple untrained operators are instructed to conduct a second fingerstick test on FebriDx®-positive subjects to validate reproducibility and accuracy across different operators.

The implementation of the patient enrichment strategy necessitates approvals from both BARDA and the FDA, as well as an Institutional Review Board (IRB). The process involves the following steps:

1. **BARDA approval:**Securing agreement from BARDA regarding the protocol modification.
2. **FDA communication:**Communicating the revised protocol to the FDA and obtaining its feedback.
3. **IRB approval:**Submitting the revised protocol to the IRB for ethical review and approval. This process is estimated to take approximately 3 weeks.
4. **Site retraining:**Once IRB approval is granted, the Contract Research Organization (CRO) will retrain clinical trial sites on the modified enrolment criteria.

LDX expects implementation of the revised protocol to commence by the end of March 2025. The impact of the enrichment strategy on the overall trial timeline remains uncertain, although LDX expects that it will expedite the trial compared to continuing with the original protocol.

Paediatric labelling and future studies

LDX is also seeking to expand and obtain paediatric labelling for FebriDx®. A separate protocol for a paediatric study has been submitted to the FDA under a pre-submission process. A meeting with the FDA is scheduled for 16 April to discuss the FDA's feedback on the proposed protocol. BARDA will also be in attendance. Previous challenges in obtaining paediatric labelling by the FDA were attributed to an insufficient number of paediatric patients in the initial DISRUPT study cohort.

Commercialisation strategy – distribution partners

LDX has established distribution partnerships with Henry Schein, Thermo Fisher and MediGroup, expanding access to these essential diagnostics in the US, Australia, New Zealand and several European markets.

- **Henry Schein partnership:** LDX began its partnership with Henry Schein (UK) on in December 2018. The agreement expanded to include Spain and Portugal in July 2023, and Belgium in July 2024. FebriDx® is also distributed in the Netherlands, UK, and US, with Australia and New Zealand covered through Regional Health Care Group. This partnership has contributed to LDX's global distribution network.
- **Thermo Fisher partnership:** In 1QFY25, Thermo Fisher became a distributor for LDX in the US. The partnership aims to leverage Thermo Fisher's network to expand access to LDX's diagnostics. While specific details are limited, this collaboration is part of LDX’s broader distribution strategy.
- **MediGroup partnership:** On 25 September 2024, LDX secured a national contract with MediGroup for FebriDx® distribution in the US. This agreement makes FebriDx® available to MediGroup's members nationwide. The partnership is part of LDX’s efforts to expand its distribution channels in the US healthcare market.

FebriDx® – outside of the United States

The US launch of FebriDx® commenced after receiving FDA clearance in July 2023 for use in moderate/high complexity labs, urgent care, and emergency care settings. This market remains the most commercially attractive opportunity for FebriDx® with significant potential to expand. Subject to the successful completion of the ongoing FebriDx® CLIA waiver trial, its US addressable market could expand by up to 15 times from 18,000 to 270,000 potential customer sites, representing more than US$1bn.

Nonetheless, FebriDx® was initially launched in 2018 after obtaining CE mark and securing regulatory registrations in multiple countries before entering the US market, including the UK, Europe, Canada, UAE, Australia, Malaysia, Singapore, Pakistan, Turkey, and Brazil.

LDX continues to grow its international FebriDx® business with a 170% increase in sales from the UK and European countries over the previous year, albeit from a low base. Additionally, the company continues to grow its footprint in the international market with ongoing registrations in the Middle East.

The performance of FebriDx® since launching outside the US highlight its varied adoption and use across different healthcare systems, with the UK showing the most extensive implementation and reported outcomes.

United Kingdom

In the UK, FebriDx® is used in primary care, urgent care, emergency departments, and acute respiratory infection hubs. It reduces inappropriate prescribing by 40% and improves patient and clinician satisfaction. Its potential for national triage solutions in future pandemics has been noted. Adoption is strong, with over 100 pharmacies in Liverpool launching FebriDx® services in January 2022.

Spain

In Spain, FebriDx® is implemented in paediatric emergency departments, where it reduces inappropriate antibiotic use by 40% and decreases the need for chest X-rays. This implementation has been successful in key paediatric hospitals, demonstrating the effectiveness of FebriDx® in reducing unnecessary medical interventions.

Greece

In emergency departments in Greece, the use of FebriDx® has been shown to reduce patient waiting times whilst providing a lower-cost solution to the laboratory, overcoming discomfort for patients and inefficiencies in ED operations. As a result, Greece plans to expand FebriDx® into adult emergency departments. While specific outcomes are not yet reported, this expansion marks an early stage in integrating FebriDx® into the Greek healthcare system.

Australia

In Australia, although detailed outcomes are not yet available, the ongoing implementation of FebriDx® is focused on urgent care centres.

Competitive Landscape – In Growing POC Diagnostics Market, LDX Has an Edge

Key players in the global market

The global POC diagnostics market is experiencing significant growth, driven by increased demand following the COVID-19 pandemic, the increasing prevalence of chronic diseases and the demand for rapid diagnostic solutions. Estimates project the market to grow from $31.57 billion in 2024 to $51.19 billion by 2032, at a compound annual growth rate (CAGR) of 6.2% (References: 7).

LDX operates in a competitive environment alongside major players such as Abbott, BD, Siemens Healthineers AG, QIAGEN, Quidel Corporation, and Quest Diagnostics. These companies offer a range of POC diagnostic products and services, leveraging their extensive research and development capabilities to maintain market positions (References: 8).

Why Lumos stands out

LDX differentiates itself by providing integrated POC diagnostics solutions that combine assay development, reader development, cloud and data solutions, and manufacturing. This comprehensive approach allows LDX to tailor its offerings to specific client needs, enhancing its competitiveness.

Figure 16 categorises key players based on technology, applications, and competitive differentiation, highlighting where LDX and MeMed compete within the POC diagnostics space.

Figure 16: Key players in the POC diagnostics space

Company	Key applications	Primary Focus	Technology platform	Competitive edge
Abbott Laboratories	Infectious diseases, cardiac, blood gases	Rapid molecular & immunoassay POC testing	i-STAT (blood), ID NOW (molecular)	Broadest test portfolio, high market penetration
Roche Diagnostics	Diabetes, infectious diseases	POC blood & molecular testing	Accu-Chek (glucose), Cobas Liat (PCR)	Strong hospital & lab integration
Siemens Healthineers	Cardiac markers, coagulation, blood gases	Blood testing at POC	Various platforms	Advanced automation & connectivity
Danaher (Cepheid, Beckman Coulter)	Infectious diseases, oncology	Molecular POC diagnostics	GeneXpert PCR	High sensitivity, multiplex capabilities
QuidelOrtho	Respiratory infections, pregnancy tests	Rapid antigen & immunoassays	Sofia (flu, RSV), QuickVue	Fast turnaround, pharmacy adoption
BD (Becton Dickinson)	Infectious diseases, COVID-19, flu	Rapid antigen & molecular diagnostics	Veritor (antigen), BD MAX (PCR)	Strong in hospitals & clinics
BioMérieux	Sepsis, respiratory, GI infections	Molecular multiplex diagnostics	BioFire (PCR)	Syndromic testing approach
Lumos Diagnostics	Bacterial vs. viral differentiation	Host-response lateral flow diagnostics	FebriDx (CRP & MxA)	Simple, rapid test for AMR stewardship
MeMed	Bacterial vs. viral differentiation	Host-response biomarker diagnostics	MeMed BV (TRAIL, IP-10, CRP)	High-complexity hospital use, deeper immune profiling
LumiraDx	Coagulation, COVID-19, CRP	High-sensitivity microfluidics POC testing	LumiraDx Platform	Lab-quality results in minutes
Cue Health	Respiratory infections	At-home molecular diagnostics	Cue COVID-19 & flu (NAAT)	FDA-approved home molecular testing

Source: Biospace.com, globalgrowthinsights.com.

Lumos – uniquely positioned as an end-to-end solution provider

The direct competitor landscape is fragmented, with companies striving to innovate and capture market share in the rapidly growing POC diagnostics sector. Success in this space relies on technological innovation, strategic partnerships, and the ability to navigate regulatory challenges while meeting the increasing demand for rapid, accurate diagnostic solutions.

Companies in this landscape differentiate themselves through:

- rapid diagnostic solutions providing faster results than traditional methods
- specialised focus on specific areas (e.g., LDX's emphasis on infectious and inflammatory diseases)
- comprehensive service offerings, from assay development to contract manufacturing.

LDX offers a broad range of reagents and instrument platforms, manufacturing and associated capabilities to cater to a broad variety of customer needs.

The following companies specialise in point-of-care (POC) diagnostic technologies and rapid testing solutions. These companies operate in the in-vitro diagnostics sector, focusing on developing and manufacturing diagnostic tests for various applications.

Figure 17: Lumos services – competitor landscape

	Services Competitor Landscape					
	Assay Development	Readers	App & Cloud	Manufacturing	Medical Affairs	Quality & Regulatory Affairs
Lumos Diagnostics	★★★★★	★★★★★	★★★★★	★★★★★	★★★★★	★★★★★
DCN Diagnostics	★★★★★	★★	-	★★★★	★★★★	★★★
Abbingdon Health	★★★★★	-	-	★★★	-	★★★
BBI Solutions	★★★★★	-	-	★★★	-	-
Lateral Dx	★★★★★	-	-	★★★	-	-
Fortis Life Sciences	★★★★★	-	-	★	-	-

Source: LDX. Green stars represent areas with a high level of service offerings.

Intellectual Property

LDX has developed a substantial patent portfolio in the field of POC diagnostics technologies. The company's intellectual property (IP) portfolio includes patents related to various aspects of its diagnostic devices and systems. The company has 88 patents (issued or pending) that cover the categories and countries outlined in Figure 18.

Figure 18: Patent portfolio

Category	Patent Family		
	Patent Title	Regions	Priority Date
Lateral Flow	Method to Increase Specificity and/or Accuracy of Lateral Flow Immunoassays	USA	29/09/2009
FebriDx	Methods and Devices for Using Mucolytic Agents Including N-Acetyl Cysteine (NAC)	USA	14/07/2009
Lateral Flow	Combined visual/fluorescence analyte detection test	USA	10/06/2009
FebriDx	Method and Device for Combined Detection of Viral and Bacterial Infections	USA, Canada, EU, Japan, Korea, Australia	8/03/2013
Lateral Flow	Lateral Flow Assays	USA	8/03/2013
FebriDx	Improved Methods and Devices for Accurate Diagnosis of Infections	USA, Canada, EU, Japan, Korea, Australia	2/02/2016
FebriDx	Lateral flow assay devices and method of use	Application	27/07/2018
FebriDx	Selective white blood cell lysis for immunoassay systems	Application	18/12/2020
Reader	Device for reading an IVD assay	USA, Canada, EU, UK, Japan, Australia, China, Hong Kong	15/10/2015
Reader	A portable in-vitro diagnostic detector and apparatus	USA, UK, EU	13/11/2015
Reader	Lateral flow assay devices and method of use	Application	27/07/2018

Source: LDX (NB: Priority date of a patent is the earliest filing date that establishes when an invention was first disclosed in a patent application).

1H25 Financial Overview – Strong Revenue Growth and Margin Expansion

Income statement

Revenue

Total revenue reached US$6.3m, a substantial increase of 128.0% compared to US$2.8m in the previous corresponding period (pcp). Services income accounted for US$5.5m, reflecting a 118.0% increase from US$2.5m. The sale of goods contributed US$0.8m to the revenue, marking a significant rise of 227.0% from US$0.3m. This surge in revenue was primarily driven by increased contract development and manufacturing services and higher sales of LDX's POC diagnostic test products.

Gross profit

Gross profit totalled US$4.2m, representing a sizeable increase of 178.0% from US$1.5m in the pcp and driven by higher revenues and improved cost of sales. As a result, gross margin improved from 55.0% to 67.0%.

Other income

Other income saw a significant boost, reaching US$1.0m compared to virtually no other income in the pcp.

Operating expenses

General and administration expenses totalled US$1.9m, up 17.0%. Employee expenses were US$3.9m, up 3.0%. Marketing & sales expenses increased to US$0.2m, a 17.0% rise. Research & development expenses amounted to US$0.1m, growing 30.0%. The increase in operating expenses was mainly attributable to increases in general and administration, marketing and sales, and research and development expenses, reflecting investments in commercial production and strategic partnerships.

EBITDA loss

The adjusted EBITDA loss was US$0.9m, which is a 77.0% improvement from the previous loss of US$4.2m. The reduction in the EBITDA loss was driven by significant revenue growth and improved gross margins, offsetting increased operating expenses.

Cash flow statement

Cash burn totalled US$6.8m for the half-year, an increase from US$5.5m in the pcp, comprising cash flows from operating activities, investing activities, and lease payments. Key drivers of this increased cash burn included expenses related to the FebriDx® CLIA waiver trial, for which costs are subject to reimbursement in arrears by BARDA, and strategic investments in augmenting inventory levels to support product sales growth.

Net cash used in operating activities was US$6.3m, a 30.0% increase from US$4.8m. Net cash from financing activities amounted to US$5.8m, representing an 80.0% increase from US$3.2m.

Balance sheet

In 1H25, LDX strengthened its balance sheet by approximately A$10.0m through an equity capital raising. The retail component of this raising contributed approximately A$6.9m, while approximately A$3.1m was raised from institutional and sophisticated investors.

The company ended 1H25 with cash of US$5.5m as at 31 December 2024. On a pro-forma basis this increased to US$6.4m, after including payments from BARDA in January 2025 of US$925k, representing the first two milestone payments triggered by the official study commencement and first patient tested in the pivotal FebriDx® CLIA waiver trial.

Management anticipates further payments from BARDA contingent on achieving agreed milestones in the FebriDx® CLIA waiver trial, and development milestone 2 from Phase 2 and Phase 3 payments on the Hologic fFN development contract in calendar 2025. Separately, LDX signed an additional hardware scope of works agreement with Hologic for about US$0.7m, which will be received in the remainder of CY2025. In aggregate LDX is expecting to receive around US$6.5m in cash by the end of CY2025.

Nonetheless, given the timing of these payments as most likely in 2HCY25, we have assumed a proactive equity capital raise of US$5m in 2HFY25 in our forecasts.

Valuation

We value LDX at A$172m, or $0.10 per share (fully diluted), using discount cash flow (DCF) methodology on free cash flow and based on 748.5m shares on issue, and 157.4m options and performance rights (unlisted). Additionally, we have assumed a US$5m capital raise in 2H25 representing new shares on issue of 256.4m which we add to our basic share count.

Key inputs

- WACC of 12.5% using beta of 1.25 (FactSet)
- Long-term gross margin of around 64%
- Terminal growth rate beyond 2034 of 2%
- Net cash position of $6.4m as at 31 December 2024 (Proforma basis includes BARDA payment)
- Probability of success (POS) in FebriDx® CLIA waiver trial of 80% with clearance in 2HFY26
- FebriDx® unit sale price of US$11 in the United States
- ViraDx™ unit sale price of US$6
- Commercial services business revenue growth of around 5%

Figure 19: DCF valuation and key metrics

		Jun-24 2024	Jun-25 2025	Jun-26 2026	Jun-27 2027	Jun-28 2028	Jun-29 2029	Jun-30 2030	Jun-31 2031	Jun-32 2032	Jun-33 2033	Jun-34 2034
EBIT	US$m	(8.6)	(6.2)	(3.4)	(1.9)	2.0	5.9	9.8	13.8	18.2	23.2	28.3
Tax at standard rate		0	0	0	0	0	0	0	0	0	0	0
Post-tax EBIT	US$m	**(8.6)**	**(6.2)**	**(3.4)**	**(1.9)**	**2.0**	**5.9**	**9.8**	**13.8**	**18.2**	**23.2**	**28.3**
Depreciation & Amortization	US$m	(2.6)	(2.3)	(2.1)	(2.0)	(1.9)	(1.9)	(1.8)	(1.7)	(1.7)	(1.6)	(1.6)
Post-tax cash flow	US$m	**(11.2)**	**(8.5)**	**(5.6)**	**(3.9)**	**0.1**	**4.0**	**8.1**	**12.1**	**16.6**	**21.6**	**26.8**
Less capex	US$m	(0.1)	(0.1)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)
Less change in working capital	US$m	5.4	0.1	0.3	0.6	0.6	0.6	0.6	0.6	0.7	0.7	0.7
Free cash flow	US$m	**(5.9)**	**(8.4)**	**(5.3)**	**(3.3)**	**0.7**	**4.7**	**8.7**	**12.7**	**17.2**	**22.2**	**27.4**
Discount coefficient		0	1	2	3	4	5	6	7	8	9	10
Discounted cash flow	US$m		**(7.4)**	**(4.2)**	**(2.3)**	**0.4**	**2.6**	**4.3**	**5.6**	**6.7**	**7.7**	**8.4**
Sum of discount streams	US$m	21.8										
Terminal growth	%	2.0%										
Future value into perpetuity	US$m	266.4										
NPV of terminal value	US$m	83.7										
PV of cash flows	US$m	105.5										
PLUS: Value of investments	US$m	-										
LESS: Net debt	US$m	(6.4)		*(Proforma basis includes BARDA payment of US$925k received in January 2025 and using cash at 31 December 2024)*								
Equity value	US$m	**111.9**										
Equity value	**A$m**	**172.2**	***0.65***	***AUD:USD***								
Ordinary shares	m	1,004.9		*(includes ~256m new shares from forecast cap raise in FY25)*								
Options	m	157.4		*(includes 13.7m of performance rights)*								
Value per share (fully diluted)	**A$**	**0.10**										

Source: MST Access.

Near-term catalysts

- 4Q25: FDA pre-submission for the FebriDx® paediatric study.
- 4Q25: Achievement of Milestone 2 under Phase 2 of the Hologic fetal fibronectin (fFN) development agreement.
- 2H25: Update on FebriDx® CLIA waiver trial, increased product awareness, and sales growth in US urgent care centers.
- 2H25: Progress to formal product development of the first LDX-branded women's health diagnostics test.
- December 2025: Completion of the Hologic Development Agreement, including delivery of system prototype milestones.

Sensitivity analysis

Our base-case valuation of A$0.10 per share (fully diluted) is based on a discount rate of 12.5% and a terminal growth rate of 2%. To account for the sensitivity of our valuation to these assumptions, we provide a sensitivity matrix illustrating the potential effects of variations in these key parameters (see Figure 20).

Figure 20: Sensitivity analysis

Terminal growth rate \ Discount rate	**0.10**	11.5%	12.0%	12.5%	13.0%	13.5%
0.0%		0.10	0.09	0.08	0.08	0.07
1.0%		0.10	0.10	0.09	0.08	0.08
2.0%		0.11	0.10	**0.10**	0.09	0.08
3.0%		0.13	0.11	0.11	0.10	0.09
4.0%		0.14	0.13	0.12	0.11	0.10

Source: MST Access

Sensitivities and Risks

Synergies

Notwithstanding operational risk related to coordination, LDXs business model creates synergies between its contract development and proprietary diagnostic products. LDX's assay development expertise enhances its in-house pipeline, optimising design, regulatory pathways, and commercialisation. This integration accelerates expansion beyond FebriDx®, de-risking product development while strengthening market positioning and revenue growth in the diagnostics sector.

Competition

LDX operates within a highly competitive and dynamic market for diagnostic technologies. This sector is characterised by continuous disruption through emerging technologies and novel product offerings. The competitive landscape is dominated by well-established entities possessing substantially greater resources and market penetration compared to LDX.

Commercialisation and reliance on distributors

LDX's strategic focus going forward on branded products, such as FebriDx®, relies on consistently identifying, developing, and commercialising unique products. Market adoption of new diagnostic tests, particularly in the US, also depends on securing favourable reimbursement policies, gaining acceptance from healthcare providers, and increasing patient awareness The company also currently relies on distributors' marketing efforts to promote products in various geographies. Inadequate promotion or regulatory non-compliance could negatively impact LDX's operational and financial results.

Regulatory

Regulatory approval involves obtaining clearances, maintaining registrations, and complying with ongoing requirements in each target market. Failure to meet these obligations could result in severe consequences, including product recalls, fines, production suspensions, approval denials or withdrawals, and even criminal penalties. Such outcomes, potentially enforced by authorities such as the FDA or EU regulators, could significantly impair LDX's ability to produce, sell, or market its products. Delay or failures in obtaining approvals in new geographies or for new products could significantly impact the company's timeline and financial projections.

Reimbursement landscape

The importance of reimbursement for diagnostic tests, particularly in the US healthcare system, cannot be overstated. For tests like FebriDx®, current reimbursement levels within the existing code structure appear to be relatively secure, especially considering the test's high sensitivity and specificity compared to traditional methods. However, in European and other single-payer healthcare systems, the pricing and reimbursement landscape differs significantly. Changes in healthcare policies and reimbursement models can represent risks in these jurisdictions.

Technological disruption

The diagnostics field is constantly evolving driven by advances in molecular biology, artificial intelligence, miniaturisation, and automation. New technologies could emerge, rendering LDX's platform obsolete.

Funding

LDX must effectively manage its operations, scale its manufacturing, and allocate capital across both its growing branded products and commercial service divisions respectively. The company is still loss making and as such is vulnerable to volatility in cash flows and funding shortfalls.

Intellectual property

Intellectual property is critical for LDX, as it protects its proprietary reader and POC technologies, enables lucrative licensing agreements like the US$10m deal with Hologic, and underpins the value of its products and partnerships in the competitive diagnostics market. The company has 88 patents (issued or pending), and as such we consider the risk to IP as low.

Board and Management

Board of Directors

Sam Lanyon, Non-Executive Chair: Mr Lanyon has more than 25 years of experience in strategy, sales and operations with a demonstrated track record in the global commercialisation of technology-rich healthcare products.

Mr Lanyon currently serves as Executive Director and co-founder of Planet Innovation and a Non-Executive Director of Paragon Funds Management. He also serves as a Non-Executive Director of Visus Therapeutics, a clinical-stage company focused on developing innovative medicines to improve vision. He has previously held international executive roles with Leica Microsystems and ASX-listed Visions Systems Ltd.

Mr Lanyon holds an Honors degree in Mechanical Engineering from the University of Melbourne, a Post Graduate Diploma in Management from Melbourne Business School and has completed strategy training from London Business School.

Bronwyn Le Grice, Non-Executive Director: Ms Le Grice has more than 18 years of executive experience in the health technology sector spanning commercialisation, venture capital, corporate development, capital raising and industry advocacy.

Formerly an Investment Director with leading healthcare investment firm, BioScience Managers, Ms Le Grice managed over $65m of private and public equity capital raisings and was actively involved in over $30m of portfolio investments. In 2017, she founded ANDHealth, Australia's only dedicated digital health accelerator and commercialisation support organisation. She holds a number of health, technology and innovation advisory roles both in Australia and internationally.

Ms Le Grice has a Masters of Commercial Law from the University of Melbourne and a Bachelor of Commerce from the University of Western Australia.

Lawrence Mehren, Non-Executive Director: Mr Mehren served as President and Chief Executive Officer as well as a Director of Accelerate Diagnostics from 2012 to 2020. During his tenure, the company developed and launched its groundbreaking Accelerate Pheno™ instrument.

Prior to this, Mr Mehren was the Head of Global Business for Ventana Medical Systems and Roche Tissue Diagnostics, managing its four business units, and also held various global leadership positions with Ventana. Mr Mehren was also Managing Director, Partner and Head of P&M Corporate Finance's life sciences practice.

Mr Mehren holds an MBA from Northwestern University's Kellogg Graduate School of Management and a BA in Political Science from the University of Arizona.

Catherine Robson, Non-Executive Director: Ms Robson has more than 20 years of experience in management, finance and investment. She currently serves as a Non-Executive Director for ASX-listed Equity Trustees (EQT Holdings Limited), where she is the chair of the Risk Committee and chair of subsidiary entity Equity Trustees Superannuation Limited.

Ms Robson's other Board appointments include serving as a non-executive director and chair of the Audit Committee of NGM Group, one of Australia's largest customer-owned banking groups, operating the Greater Bank and Newcastle Permanent Building Society Brands. She is also a non-executive director and chair of the Audit and Risk Committee of the Australian Business Growth Fund and is chair of Korowa Anglican Girls School Council.

Ms Robson holds a Master of Laws, majoring in tax, from Melbourne University, and a Bachelor of Laws and BA in Asian Studies from the Australian National University. She has a Graduate Diploma in Applied Finance and is a graduate of the Australian Institute of Company Directors Course.

Management team

Doug Ward, Chief Executive Officer and Managing Director: Mr Ward has more than 30 years of medical device and diagnostics experience at notable global healthcare companies including Roche, GE, Siemens, Bayer, Chiron and Hologic. He was named CEO of LDX in June 2022.

During his career, Mr Ward has held executive positions where he developed and implemented novel business strategies and introduced transformational products to the practice of medicine.

Prior to joining LDX, he served as Vice President, Strategy and Business Development at Hologic, where he led a global team responsible for fostering innovation in women's healthcare to improve clinical results. Mr Ward also previously served as the CEO of Personal Genome Diagnostics (PGDx) where he led the organisation's transformation from a clinical laboratory testing service into a fully functional molecular in-vitro diagnostics (IVD) company.

Mr Ward earned his Bachelor of Arts in Pre-medicine Studies from Ohio Wesleyan University.

Sacha Dopheide, PhD, Chief Technology Officer: Dr Dopheide has more than 20 years of experience in the in-vitro diagnostic device industry, ranging from POC devices to laboratory analysers. She currently serves as the company's Chief Technology Officer and has held an executive leadership role within LDX since 2017.

Dr Dopheide has experience managing the full product development process for immunoassays and their accompanying electronic readers from proof of concept through development, verification and external validation trials. She has taken a leading role in identification and due diligence of M&A targets and integration activities. She also leads the LDX service business unit's business development activities, including directly conducting global market research, establishing partnerships and generating strategic product roadmaps for new tests.

Dr Dopheide holds a BSc (Hons) and PhD from Monash University.

Barrie Lambert, Chief Financial Officer: Mr Lambert has more than 20 years of international experience in high-growth companies from the medical device research and development services and manufacturing sector, as well as technology, retail, ecommerce, consumer goods and business services.

Prior to joining LDX, Mr Lambert was the Chief Financial Officer of Planet Innovation, one of the founding shareholders and current major shareholder of LDX. In that role, he was a member of the executive team helping to grow Planet Innovation fourfold, completing several capital raises, financing, and merger and acquisition transactions.

Mr Lambert's previous roles have included Chief Financial Officer and President & Chief Executive Officer of technology businesses with operations in Australia, United States, New Zealand and United Kingdom. He also spent more than 6 years as Chief Financial Officer, Vice President of Operations, then as the Vice President and General Manager of Sephora.com, a business unit of Louis Vuitton Moët Hennessy.

His qualifications include a BA in Accounting from the University of South Australia, Chartered Accountant from the Australian Institute of Chartered Accountants, MBA from the Graduate School of Business, University of Sydney, and a graduate of the Australian Institute of Company Directors.

Paul Kase, Senior Vice President of Commercial Operations: Mr Kase brings more than 28 years of medical sales and leadership experience in the POC diagnostic testing market to LDX.

As the Senior Vice President of Commercial Operations, he leads worldwide commercial sales efforts, while implementing marketing strategies focused on revenue growth, building strong customer partnerships, and generating end-user demand and adoption for a portfolio of products.

His experience also extends to overseeing customer and technical support divisions, commercial product launches, key opinion leader development, and the creation of distributor networks in the hospital and primary care markets.

Mr Kase earned his Bachelors in Economics and English from Bucknell University.

Appendix 1 – Glossary and Key Terminology

Figure 21: Glossary of general terms in diagnostics

Term	Definition
Analyte	A specific substance or component being measured or detected in an assay (e.g. proteins, DNA, drugs)
Assay	An analytical procedure used to detect, identify, or quantify a specific substance or activity
Cloud	A central repository for storing and sharing test information, which can be integrated with patient medical records
Desktop application	Software designed for detailed analysis of lateral flow tests, typically used in a laboratory setting
Hand-Held Camera Reader	A portable reader that uses a camera to capture and analyse lateral flow tests
Leelu Reader	A laboratory-based reader used for detailed analysis of lateral flow tests
Multi-use Disposable Reader	A portable reader designed for a limited number of tests (≤50) featuring Bluetooth connectivity
Multiplex	The ability to measure multiple analytes simultaneously in a single assay
Qualitative	Providing a yes/no answer, indicating the presence or absence of a substance
Quantitative	Providing a numerical result, indicating the amount or concentration of a substance
Reagents	Substances or mixtures used in a chemical analysis or reaction
Single-use Disposable Reader	A portable, single-use reader powered by a coin cell battery, featuring Bluetooth connectivity
Smartphone/tablet application	Mobile software used for guiding users through workflow steps, analysing lateral flow tests, reporting results, and communicating test information to the cloud
Visual	Detection method relying on the naked eye

Source: LDX, cdc.gov, MST Access

Figure 22: Key technologies in POC diagnostics (highlighted test types are offered by LDX)

Technology	Description	Applications
Lateral flow assays (LFAs)	Rapid, disposable tests using capillary action for detection	Pregnancy tests, COVID-19 antigen tests, drug screening, infectious disease detection (HIV, flu)
DNA lateral flow assays (DNA-LFAs), also known as nucleic acid lateral flow	Combines nucleic acid amplification with lateral flow strips for rapid DNA/RNA detection	Tuberculosis, COVID-19, antibiotic-resistant gene detection, genetic disease screening
Enzymatic chemistry	Uses enzymes to catalyse reactions for biomarker detection	Blood glucose monitoring (glucose oxidase), cholesterol testing, liver/kidney function tests, infectious disease testing
Immunoassays	Detects antigens, antibodies, or proteins using labelled detection methods – can use lateral flow or other technologies	Rapid tests (COVID-19, HIV, flu), ELISA, , cancer biomarker testing, cardiac markers (troponin, BNP)
ELISA (enzyme-linked immunosorbent assay)	A plate-based immunoassay that detects antigens or antibodies using enzyme-linked reactions	HIV, hepatitis, COVID-19 serology, cancer biomarkers, autoimmune disease detection, allergy testing
Multiplex POC diagnostics	Simultaneous detection of multiple analytes in a single test, improving efficiency and accuracy	Respiratory panel tests (COVID-19, flu, RSV), sepsis biomarker panels, cancer biomarker profiling, drug resistance testing
Biosensors	Sensors detecting biological molecules via electrochemical, optical, or piezoelectric signals	Glucose meters, wearable health monitors, cardiac biomarker detection, food safety testing
Chemiluminescent	Detection method based on the emission of light as a result of a chemical reaction	
CRISPR-based diagnostics	Highly specific gene-editing tool for rapid nucleic acid detection	Infectious disease detection (Zika, COVID-19), precision medicine, genetic disorder screening
Electrochemical assays	Analyses disease biomarkers with high sensitivity and specificity using electrochemical techniques. Good for multiplexed biomarker detection. Portable, low cost, user friendly	Viral infections, DNA and cancer markers, clinical diagnostics (glucose, lactate, cholesterol, urea, creatinine)
Fluorescent	Detection method utilising fluorescent labels and measurement of emitted light	
Isothermal nucleic acid amplification (loop-mediated isothermal amplification [LAMP], recombinase polymerase amplification [RPA], etc)	DNA/RNA amplification without thermal cycling for fast molecular diagnostics	Infectious disease detection (COVID-19, TB, malaria), genetic screening, cancer biomarker testing
Microfluidics and lab-on-a-chip (LoC)	Miniaturised fluid handling for rapid biochemical analysis	Blood glucose monitoring, infectious disease testing (HIV, malaria, TB), biomarker detection, cancer diagnostics
Paper-based diagnostics	Low-cost, biodegradable tests for field use and low-resource settings	Disease screening, environmental monitoring, food safety testing, veterinary diagnostics
Protein chemistry	Involves the study and manipulation of proteins for biomarker detection and disease diagnostics	Immunoassays (ELISA, lateral flow tests), protein-based biosensors, cancer biomarker testing, infectious disease screening (HIV, hepatitis, sepsis)
Smartphone-based diagnostics and AI	Uses smartphone cameras and AI for image analysis and telemedicine	AI-driven ECG interpretation, mobile urinalysis, digital pathology, remote disease screening
Wearable and implantable sensors	Continuous real-time monitoring of physiological parameters	Diabetes management (CGM), cardiac monitoring, fitness tracking, remote patient monitoring

Source: LDX, cdc.gov, various

Appendix 2 – Overview of Assay Chemistries Used in LDX Products

DNA lateral flow methods: A specialised LFA that uses nucleic acid probes to detect DNA or RNA targets, providing rapid and visual results for genetic analysis or pathogen detection. These tests can identify genetic material on test strips, enabling rapid molecular diagnostics, particularly for infectious disease testing.

Enzymatic chemistry: These systems employ enzymes to catalyse reactions with diverse substrates, useful in applications such as biofuel cells or biochemical assays.

LDX employs enzymatic reactions in some of its assays to amplify signals or detect specific biochemical markers. This approach enhances sensitivity and specificity in detecting disease-related analytes.

Enzyme-linked immunosorbent assay (ELISA): A highly sensitive and specific immunoassay technique that uses enzyme-conjugated antibodies to detect and quantify target antigens in a sample, often visualised through colorimetric or luminescent signals. These tests are performed in a lab.

LDX's assays use these same ELISA principles, detecting antigens using antibodies. However, unlike traditional ELISA tests, LDX tests obtain faster results with minimal equipment at the POC.

Immunoassay: A particular type of LFA that specifically uses antibodies to detect target analytes. These assays can be used for various applications, including measuring levels of target analytes in cell lysates and detecting interactions between proteins.

LDX's lateral flow assays (LFAs), such as FebriDx®, are immunoassays designed for rapid POC testing. These tests detect specific antigens or antibodies in liquid samples such as blood or saliva using labelled biomolecules and provide qualitative or quantitative results through digital readers.

Protein chemistry: This involves studying the structure, function, and interactions of proteins, using chemistry principles to identify and quantify disease proteins in a patient sample. Advanced techniques such as mass spectrometry are used to analyse complex samples.

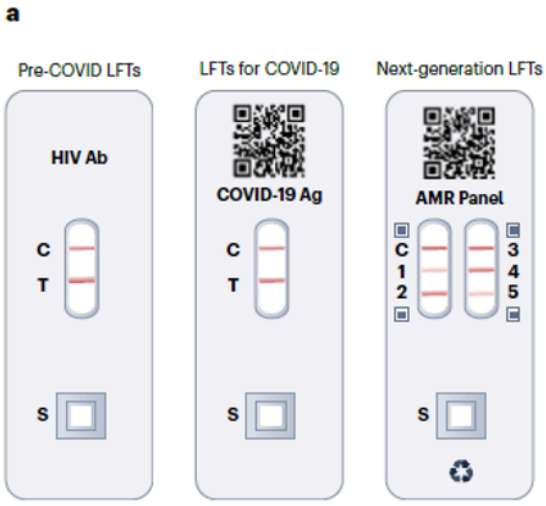
LDX integrates protein chemistry into its diagnostic platforms by detecting protein biomarkers indicative of diseases. For instance, FebriDx® differentiates bacterial from viral infections by analysing host immune responses involving CRP (C-reactive protein).

Appendix 3 – A Detailed Overview of Lateral Flow Assays (LFAs)

The history of lateral flow assays

The bioengineering principles underlying LFAs, also referred to as lateral flow tests (LFTs) or rapid diagnostic tests (RDTs), have a developmental history spanning several decades. Originating with latex agglutination and immunoassays in the 1950s, and further advanced by the refinement of solid-phase LFAs in the 1980s, these technologies culminated in the development of the first LFA pregnancy tests. LFAs were adopted at an unprecedented scale during the COVID-19 pandemic, enabling access to testing beyond healthcare settings.

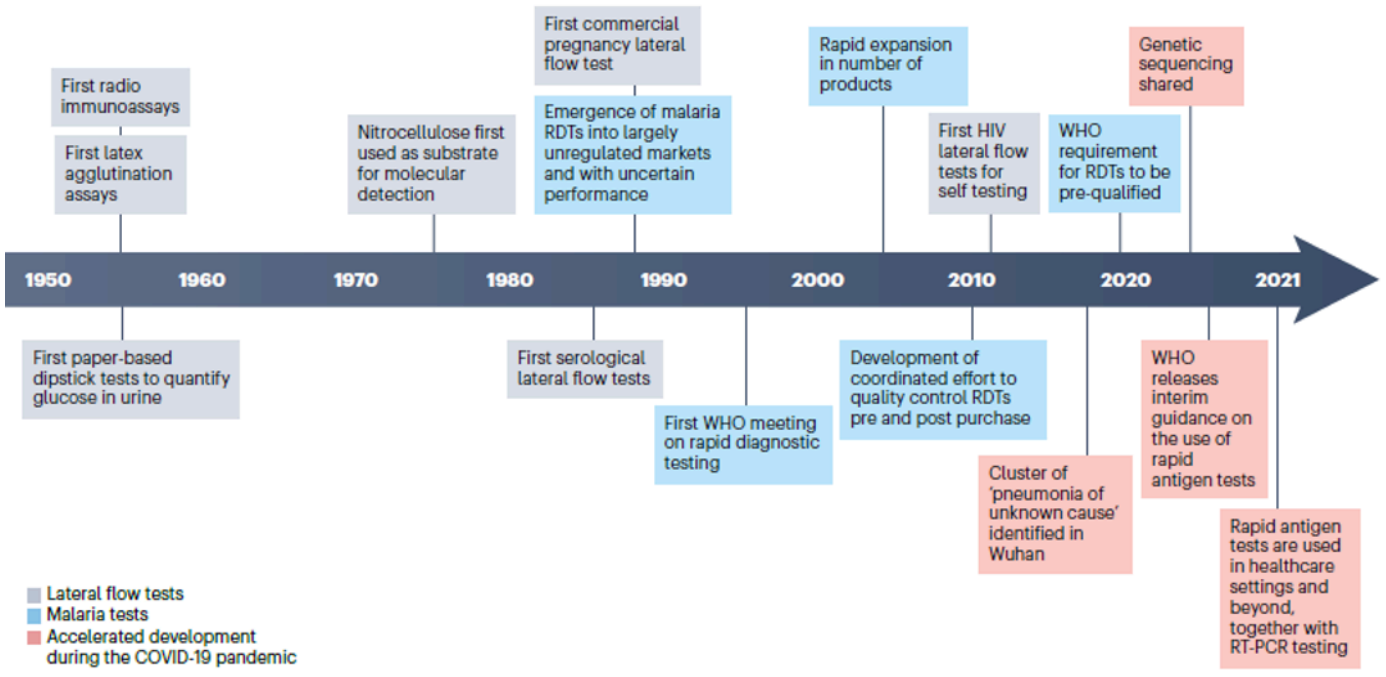
Figure 23: Examples of pre-COVID-19 LFAs (left image), LFAs deployed in the COVID-19 pandemic (middle image), and next-generation LFAs (right image), with comparison of key characteristics (table)



	Pre-COVID LFTs	LFTs for COVID-19	Next-generation LFTs
Targets	• Antibody • Antigen	• Antibody • Antigen	• Antibody • Antigen • Molecular
Use cases	• Self-testing • Clinical diagnosis • Screening	• Self-testing • Surveillance • Screening	• Self-testing • Clinical diagnosis • Screening • Surveillance • Environmental monitoring
Settings	• Homes • Clinics • Community	• Homes • Mass gatherings • Schools • Borders • Workplaces	• Homes • Mass gatherings • Schools • Borders • Workplaces • Clinics • A&E
Materials	• Gold nanoparticles • Latex beads	• Gold nanoparticles • Latex beads • Quantum dots	Ultra-sensitive materials: • Enzymatic nanoparticles • Nanodiamonds
Result capture	• Manual	• Manual	• Digital • Automatic connection to healthcare pathway

Source: Lateral flow test engineering and lessons learned from COVID-19: Budd et al (Nature Reviews 2023).

Figure 24: Timeline of key advances in lateral flow testing



Source: Lateral flow test engineering and lessons learned from COVID-19: Budd et al (Nature Reviews 2023). Note: WHO = World Health Organization. AMR = antimicrobial resistance.

Key considerations for lateral flow assay development

Sensitivity and specificity

In testing, **sensitivity** refers to how well a test finds what it's looking for, avoiding misses. **Specificity** is how well a test indicates that something isn't there, avoiding false alarms. Good tests need both. Sensitivity can be hurt by weak signals or background noise. Specificity can be affected by contamination or deterioration of samples, leading to false positive results.

Making a test more sensitive can sometimes make it less specific, and vice versa. These measures are affected by how much of the test's ingredients are used, how the test flows, its materials and its design. Complex samples might need extra steps. Better understanding and new tech can improve tests.

Negative predictive value (NPV)

Negative Predictive Value (NPV) represents the probability that individuals with a negative test result are truly disease-free. It is calculated as the proportion of true negatives (TNs) out of all negative test results (TNs + false negatives). NPV is influenced by both test sensitivity and disease prevalence, with higher values in low-prevalence settings due to a larger proportion of true negatives. Clinically, a high NPV is critical for ruling out conditions where false negatives could lead to severe consequences, such as infections or malignancies. Thus, NPV serves as a key metric in evaluating the reliability of diagnostic tests in risk-sensitive scenarios.

Sample collection and preparation

The quality of samples taken for tests affects their sensitivity and specificity.

POC tests must work with many different sample types, such as blood, saliva, or swabs. Each sample is unique, which makes designing these tests difficult. Tests must handle these differences reliably. Built-in tools, such as finger-prickers for blood, can simplify the process. However, some samples require extra preparation steps. The materials inside the test control sample flow and clean it. Fast and simple sample preparation is essential for tests used outside of labs.

Molecular tests, which analyse DNA or RNA, are sensitive to contamination. This is a challenge for tests used outside of controlled lab environments. New methods are making these tests easier to use in everyday settings. Combining these tests with simple readouts brings advanced diagnostics closer to patients. Using tiny magnetic particles to capture and concentrate the target can improve test sensitivity, especially with complex samples. The aim is to create user-friendly, fast, and reliable tests for any location.

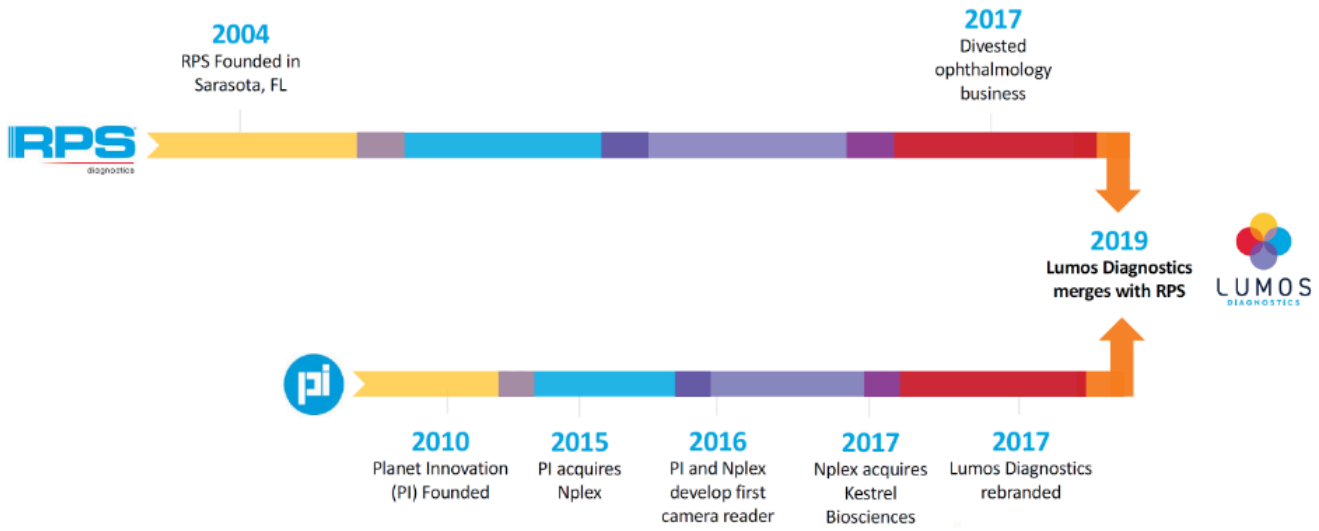
Regulatory issues

The COVID-19 pandemic significantly altered regulatory approaches to LFA approvals, including enhanced engagement and guidance for test developers. Emergency use authorisation procedures, established in the UK and USA but newly implemented by some other countries' agencies for COVID-19, facilitated more rapid review processes. The World Health Organization (WHO) used its Emergency Use Listing process to evaluate SARS-CoV-2 LFAs, enabling global procurement. Under emergency authorisation frameworks, a substantial number of COVID-19 LFAs received authorisation, with initial approvals for professional use tests in May 2020 and for self-tests in December 2020.

The regulatory pathway for LFAs is a complex, region-specific process involving classification based on risk, stringent performance evaluations (analytical and clinical), adherence to quality management systems, and post-market surveillance. While emergency use authorisations have expedited approvals during pandemics, standard pathways require manufacturers to demonstrate safety and efficacy through rigorous testing and documentation, with variations existing between regulatory bodies and statutes including the FDA, the EU's In Vitro Diagnostic Regulation, and the World Health Organization, highlighting the ongoing need for harmonisation to ensure global access to reliable diagnostics.

Appendix 4 – Corporate History of LDX Heritage Companies

Figure 25: Corporate history of RPS Diagnostics (acquired by LDX in 2019) and Planet Innovation (original brand of LDX)



Source: LDX.

Appendix 5 – LDX Test Kit Portfolio

Figure 26: LDX test kit portfolio (cartridge and readers)

	Visual Read	Single-use Disposable Reader	Multi-use Disposable Reader	Hand-Held Camera Reader	Leelu Reader
Targeted End Use	In home / In field In clinic In laboratory	In home / In field In clinic	In home / In field In clinic	In home / In field In clinic In laboratory	In laboratory
Test Read Consistency	Moderate, user subjectivity	High	High	Very High	Very High
Portability	High	High - coin cell battery (not replaceable)	High - coin cell battery (not replaceable) Bluetooth connectivity	High - internal rechargable battery Bluetooth connectivity	Low - USB powered
Assay Chemistry Type	Visual lateral flow	Visual lateral flow Other assay types*	Visual lateral flow Fluorescent lateral flow Other assay types*	Visual lateral flow Fluorescent lateral flow Other assay types*	Visual lateral flow Fluorescent lateral flow Other assay types*
Assay Number	Multiplex Multiple strips	Multiplex Single strip	Multiplex Single strip	Multiplex Multiple strips	Multiplex Multiple strips
Assay Result Type	Qualitative Yes/No result	Qualitative Yes/No result	Qualitative Yes/No result Quantitative, numerical result	Qualitative Yes/No result Quantitative, numerical result	Qualitative Yes/No result Quantitative, numerical result
Test menu expansion	N/A	N/A	N/A	Suitable	Suitable
Temperature Control	N/A	N/A	N/A	Direct - on board heating Indirect - algorithm	N/A
Barcode Reading	N/A	N/A	N/A	Yes	N/A
Size (W x L x H)	N/A	28 mm x 111 mm x 18 mm	28 mm x 111 mm x 18 mm	82 mm x 100 mm x 87 mm	80 mm x 160 mm x 120 mm
Reader Lifetime	N/A	1 test/reader	≤50 tests/reader	>10,000 tests per reader	>10,000 tests per reader

Source: LDX.

Appendix 6 – Competitive Landscape in Point-of-Care Diagnostics – Key Players

Established leaders

- Abbott Laboratories (i-STAT, ID NOW)
- Roche Diagnostics (Accu-Chek, Cobas Liat)
- Siemens Healthineers (POC blood testing)
- Danaher (Cepheid, Beckman Coulter) (GeneXpert molecular platform)
- QuidelOrtho (Sofia, QuickVue rapid tests)
- BD (Becton Dickinson) (Veritor, BD MAX)
- BioMérieux (BioFire for molecular POC)

Innovative emerging companies

- Lumos Diagnostics – Specialises in rapid, lateral flow-based diagnostic solutions, focusing on infectious diseases and inflammatory markers
- MeMed – Developing POC solutions that use host-response biomarkers to differentiate between bacterial and viral infections
- LumiraDx – Microfluidics-based compact POC platform
- Cue Health – At-home molecular testing solutions
- Scanwell Health – Smartphone-integrated POC diagnostics
- Truvian Sciences – Blood diagnostics for multiple analytes in one test

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Appendix 7 - Shareholder Registry

Figure 27: Top 20 shareholders

		Number of Fully Paid Ordinary Shares	Percentage of issued capital
1	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED	160,592,382	21.45
2	J P MORGAN NOMINEES AUSTRALIA PTY LIMITED	85,813,030	11.46
3	RYDER INVESTMENT MANAGEMENT PTY LTD	38,359,752	5.12
4	RYDER CAPITAL MANAGEMENT PTY LTD	32,021,878	4.28
5	SPICEME CAPITAL PTY LTD	30,000,000	4.01
6	PLANET INNOVATION HOLDINGS LTD	23,021,060	3.08
7	BILGOLA NOMINEES PTY LIMITED	16,807,667	2.25
8	GZ GROUP HOLDINGS PTY LTD	11,860,707	1.58
9	MR LAWRENCE WING MING HO + MRS YING HO <L&Y FAMILY SUPER FUND A/C>	11,000,000	1.47
10	CITICORP NOMINEES PTY LIMITED	7,825,689	1.05
11	MR JORDAN EDWARD DUNCAN WHICKER	7,000,000	0.94
12	CITY COMFORT PTY LTD	6,783,023	0.91
13	MR KENNETH GRAHAM MILLER	5,398,165	0.72
14	BNP PARIBAS NOMINEES PTY LTD BARCLAYS	5,011,811	0.67
15	MR ROBERT JULIAN CONSTABLE + MRS JANET MARIE CONSTABLE	4,633,000	0.62
16	BNP PARIBAS NOMINEES PTY LTD <IB AU NOMS RETAILCLIENT>	4,571,558	0.61
17	MISS JIAZHEN WANG <JW A/C>	4,397,893	0.59
18	BOWVALE INVESTMENTS PTY LIMITED <BOWVALE INVESTMENTS S/F A/C>	4,312,095	0.58
19	PARANJI SUPER FUND PTY LTD <PARANJI SUPERFUND A/C>	4,000,000	0.53
20	MR GARRY TEMPLE	3,843,517	0.51
Totals: Top 20 holders of ORDINARY FULLY PAID SHARES (Total)		**467,253,227**	**62.42**
Total Remaining Holders Balance		**281,269,795**	**37.58**

Source: LDX

Personal disclosures

Chris Kallos, CFA received assistance from the subject company or companies in preparing this research report. The company provided them with communication with senior management and information on the company and industry. As part of due diligence, they have independently and critically reviewed the assistance and information provided by the company to form the opinions expressed in this report. They have taken care to maintain honest and fair objectivity in writing this report and making the recommendation. Where MST Financial Services or its affiliates has been commissioned to prepare content and receives fees for its preparation, please note that NO part of the fee, compensation or employee remuneration paid has, or will, directly or indirectly impact the content provided in this report.

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Lumos Diagnostics (LDX.AX) | Price A$0.02 | Valuation A$0.10;

Price and valuation as at 28 March 2025 (not covered)*

Additional disclosures

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