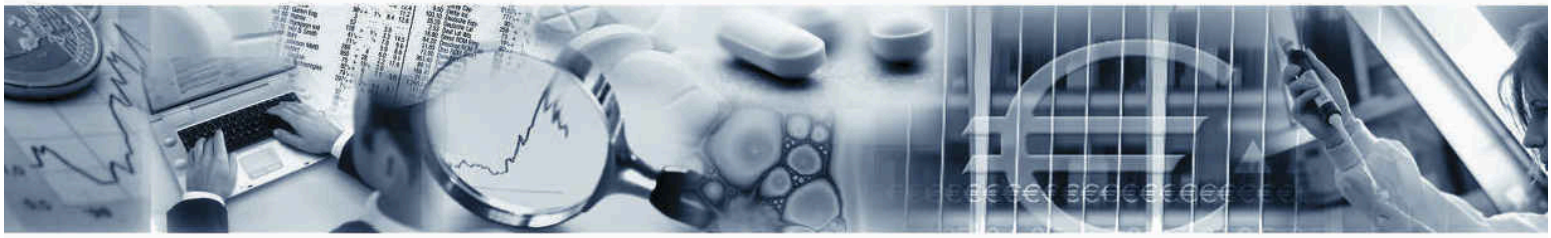

Research Note

MDxHealth

Official Launch AssureMDx for Bladder Cancer

Chief Research Analyst

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Name:	**MDxHealth SA**
Country:	**Belgium**
Price:	**EUR 4.64**
ISIN Code:	**BE0003844611**
Reuters Code:	**MDXH.BR**
Market Cap (EUR m):	**232.0**
EV (EUR m):	**201.2**
Cash & cash eq. (EUR m):	**30.8**
Shares outstanding (m):	**49.8**
Volume:	**163,798**
Free float:	**73%**
52-week Range:	**3.20-5.78**

	2015A	2016A	2017E
Total Revenues	17.640	29.970	52.000
Net (Loss)/Profit	(14.473)	(13.147)	(11.800)
Net loss per share (cents)	(0.32)	(0.26)	(0.24)
R&D costs	3.257	1.977	2.000
Cash increase/(decrease)	12.783	(0.880)	(15.000)
Cash and marketable sec.	31.680	30.800	15.800

Official Launch Liquid Biopsy test AssureMDx for Bladder Cancer

MDxHealth today announced the commercial launch of its liquid biopsy test AssureMDx for Bladder Cancer in the US. Comparable with the company's liquid biopsy test SelectMDx™ for Prostate Cancer, the AssureMDx test for Bladder Cancer is being developed for the US market as a laboratory-developed test (LDT). LDTs are a class of in vitro diagnostic test manufactured, developed and validated for use in a single laboratory. AssureMDx is a non-invasive, urine-based test, combining methylation and mutation biomarkers, to assess the risk of bladder cancer for patients diagnosed with hematuria (blood in the urine).

In 2016, the authoritative Journal of Urology published data demonstrating the clinical potential of its urine-based epigenetic bladder cancer test AssureMDx to aid urologists in the management of patients presenting with haematuria The AssureMDx for Bladder Cancer test, which analyses DNA methylation of three genes (*TWIST1*, *ONECUT2* and *OTX1)* in combination with mutation analyses of three others, was used to create an epigenetic profile of 154 urine samples from haematuria patients without (n=80) and with (n=74) bladder cancer. The study demonstrated the test's high negative predictive value (99.2%) for the detection of bladder cancer in this cohort of haematuria patients.[1]

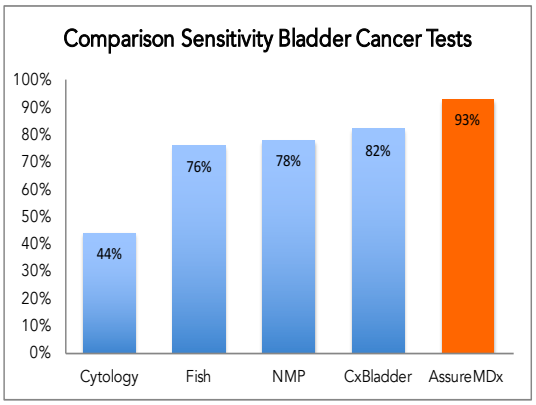
AssureMDx compares favourably with other bladder cancer tests

Van Leeuwenhoeck's analysis shows AssureMDx comparing favourably against Abbott's Urovysion in separate large-scale clinical trials, each with over 400 patients as well as to Pacific Edge's CxBladder. Urovysion was launched 2001 as an aid in monitoring bladder cancer and in 2005 to aid diagnosis. The test uses Abbott's FISH fluorescence technology to detect

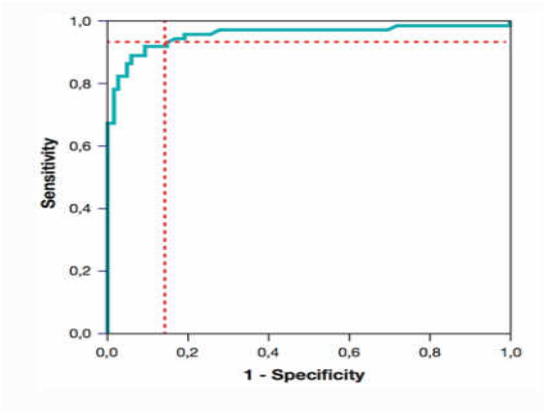
[1] Van Kessel et al; Evaluation of an Epigenetic Profile for the Detection of Bladder Cancer in Patients with Hematuria. The Journal of Urology

chromosomal abnormalities. In a trial conducted by Abbott, Urovysion showed an overall sensitivity of 68.6% and specificity of 77.7% in the detection of bladder cancer in 479 patients presenting with hematuria. CxBladder showed an overall sensitivity of 82% and specificity of 85%. This compared with a sensitivity of 93% and specificity of 85% AssureMDx™. We note some caution must be used with the comparisons, given tests were not compared head to head.

AssureMDx Clinical Performance



Source: Van Leeuwenhoeck Inc



Source: MDX Health

There are a number of commercially available in-vitro diagnostic (IVD) tests to detect bladder cancer in haematuria patients, although the specificity and sensitivity of such tests is variable. NMP22 has been widely adopted as an adjunct to cytology. However, no other test is being used as standard, as none has been shown to be more accurate than the existing benchmark.

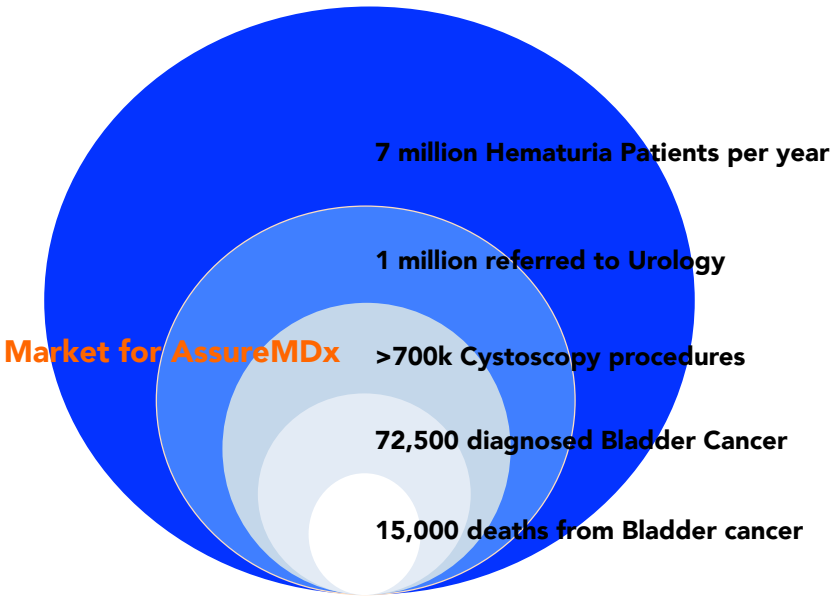
Test/distributor	Methodology	Advantages	Limitations
UroVysion/Abbott	FISH fluorescence in situ hybridisation assay; detects chromosomal abnormalities	Higher sensitivity than cytology across all stages and grades	Requires a large specimen sample. Poor positive predictive value
NMP22 ELISA	Measures levels of protein NMP22, which is elevated in bladder cancer patients	Higher sensitivity than cytology for grade I/II	Low specificity; interference from benign urinary tract conditions
NMP22 BladderChek	Point of care test with 30 minute turnaround.	Improves detection vs cytology in cases of recurrent cancer.	Relatively high rate of false positives
BTA Stat/Polymedco	POC, detects human complement factor H related protein	Immediate result	High rate of false positive results in cases of co-existing genitourinary conditions
BTA Trak/Polymedco	Lab based immunoassay	Higher sensitivity than cytology for low grade tumors	High rate of false positive results in cases of genitourinary conditions
ImmunoCyt	Lab based immunofluorescence assay	Relatively high sensitivity in some patient groups	High rate of false positive results in cases of genitourinary conditions
UBC/IDL Biotech	Measures soluble fragments of cytokeratins 8 and 18. Cytokeratins are characteristic of epithelial cells	More accurate at detecting CIS than cytology	Overall performance not superior to cytology. Ongoing testing

Source: Van Leeuwenhoeck Inc

Growing need for accurate testing in urologic cancers

Bladder cancer is the sixth most common cancer worldwide and has the highest per patient medical costs of any cancer. There will be an estimated 77,000 new cases diagnosed in the US and over 300,000 worldwide at an incidence rate of approximately 3%. Over 90% of bladder cancers are transitional cell carcinomas. Hematuria can be continuous or intermittent and either

visible (gross) or microscopic. Screening studies have shown that in up to 20% of cases of gross hematuria, patients go on to be diagnosed with Urothelial Cancers (UC), while only 5% of cases of microscopic hematuria turn out to be UCs such that the 2001 American Urological Association (AUA) Best Practice Policy on Asymptomatic Microscopic Hematuria recommends that all patients presenting with gross hematuria, particularly those without evidence of infections, should undergo full urologic work-up. This procedure includes provision of a urine sample for testing with cytology (manual examination under a microscope) in conjunction with cystoscopy (insertion of a flexible scope into the urinary tract). Some patients are also examined by means of upper tract imaging, typically with a CT scan or ultrasound imaging. Cytology tends to have low sensitivity (true positives), particularly at the earlier stages of cancer, and is subject to user variability. Importantly, bladder cancer is one of the most expensive cancers to treat, given more than half of all early stage bladder cancer patients will recur in the three years following treatment.



Drivers of healthcare decisions by clinicians in the US include the avoidance of malpractice suits on missed tumours, the clinical utility of the product and minimising co-payments to the patients, thereby boosting patient retention rates. Assure directly covers the first two and, more indirectly, the third.

The market for hematuria testing and monitoring represents a noteworthy commercial opportunity. Each year in the United States, it is estimated that nearly 11 million patients are referred to a urologist for clinical evaluation due to hematuria. For patients treated for early stage bladder cancer, a high recurrence rate means continual monitoring at an estimated extra cost of USD 1-2 billion for those requiring regular follow-on testing.

MDxHealth remains undervalued: Estimated value EUR 500 million

Based on NPV based valuation, we believe that MDxHealth is substantially undervalued at the current share price of EUR 4.54. Using our valuation model and taking into account the increased outlook for the future revenues of ConfirmMDx®, SelectMDx™ and AssureMDx™, we estimate MDX Health's current value at EUR 500 million or EUR 10.00 per share. This represents a substantial upside from the current share price.

Sales forecast and valuation AssureMDx

Year	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026
Price	500	500	500	500	500	500	500	500	500	500
Number of tests	6000	14566	20800	26520	34006	43357	53069	65613	75291	85330
Market share	0.8%	2.0%	2.8%	3.5%	4.4%	5.5%	6.6%	8.0%	9.0%	10.0%
Tests US (million)	0.714	0.728	0.743	0.758	0.773	0.788	0.804	0.820	0.837	1.000
Revenues (million)	3.00	7.28	10.40	13.26	17.00	21.68	26.53	32.81	37.65	42.66
Net Margin 50%	1.50	3.64	5.20	6.63	8.50	10.84	13.27	16.40	18.82	21.33
WACC 10%	0.91	0.83	0.75	0.68	0.62	0.56	0.51	0.47	0.42	0.39
NPV (million)	1.36	3.01	3.91	4.53	5.28	6.12	6.81	7.65	7.98	8.22
Total NPV (million)										**63.3**
Value per share										**1.27**

Source: Van Leeuwenhoeck Inc

Analyst: Marcel Wijma MSc

Marcel Wijma, Chief Research Officer and managing partner, has a longstanding history in financial biotech research. After selling Van Leeuwenhoeck Research (VLR) to SNS Securities in 2006, he established an award winning analyst team in biotech/life sciences at SNS Securities. In 2009, Marcel was awarded by Financial Times/Starmine as being one of the Top-3 biotech analysts in Europe. Later that year, Marcel purchased VLR from SNS Securities after which the company was reconstituted. At VLR, he leads the professional VLR research organisation, which is augmented by selected external financial researchers with a specialisation in Life Sciences. Mr. Wijma has a Masters degree in Financial Economics from Erasmus University in Rotterdam.