INOVIQ Limited

IIQ.ASX

A research platform of MST Financial

28 June 2023

SubB2M/CA15-3 Test: Striking Study Results in Breast Cancer

NEED TO KNOW

- All stages of breast cancer (BC) detected by blood test excellent accuracy, sensitivity and specificity
- Significant outperformance vs. leading commercially available CA15-3 test
- Results support planned BC monitoring study + commercial discussions with potential partners, KOLs

Very promising results from independent clinical validation study: INOVIQ (IIQ) has released clinical data for its SubB2M/CA15-3 breast cancer test, with accuracy of 87%, sensitivity of 81%, and specificity of 93%. IIQ has stated that these results outperform a leading, approved, and commercially available CA15-3 test.

Next commercial steps – discussions with potential partners, KOLs: IIQ has indicated that it will present the data from this study alongside its development plans to potential partners and key opinion leaders, with a view to advancing commercial discussions for the SubB2M/CA15-3 test, as well as the SubB2M/CA125 and SubB2M multi-cancer tests.

Next clinical steps – breast cancer monitoring study being finalised – market-ready to follow: With the analytical and clinical validation work completed, IIQ is finalising plans for a cross-sectional monitoring study to assess the performance of the SubB2M/CA15-3 test vs. approved CA15-3 tests. The company expects the study to be completed by end-2QFY24, with the test then to be market-ready.

Investment Thesis

Diversified portfolio of versatile technology platforms and products: IIQ's portfolio is wide, with its EXO-NET and SubB2M technologies creating substantial new opportunities alongside its existing hTERT test, as well as potential future royalties from BARD1.

Collaboration with UQ to develop ovarian cancer screening test based on EXO-NET technology: This collaboration combines best-in-class exosome capture technology with University of Queensland (UQ) biomarkers for application in liquid biopsies.

SubB2M platform: strong data in ovarian, breast cancers support potential to supercharge current tests and monitor disease progression: The company expects that the SubB2M-CA15-3 breast cancer test could be market-ready for a lab partner from December 2023.

Valuation

We increase our valuation of IIQ to A$213m or A$2.31 per share (previously A$195m or A$2.11 per share), using a risk-adjusted net present value (rNPV) method to discount future cash flows through to 2043, consistent with the expiry life of patent families. The increase reflects an increase in the probability of success in the subB2M breast cancer program to 40% from 20% previously.

Risk

Key risks to our valuation include demonstrating efficacy, establishing clinical utility, and meeting regulatory requirements.

Equities Research Australia

Pharmaceuticals, Biotechnology and Life Sciences

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INOVIQ is developing and commercialising next-generation exosome solutions and precision diagnostics to improve the diagnosis and treatment of cancer and other diseases. The company has commercialised the EXO-NET pan-exosome capture tool for research purposes and the hTERT test as an adjunct to urine cytology testing for bladder cancer. Its cancer diagnostic pipeline includes blood tests in development for earlier detection and monitoring of ovarian, breast and other cancers.

https://www.inoviq.com/

Valuation	**A$2.31** (previously *A$2.11*)
Current price	**A$0.71**
Market cap	**A$65m**
Cash on hand	**A$8.8m (31 March 2023)**

Resources

Presentation

CSO Dr Gregory Rice: 'Enabling EV-based Biomarker Discovery and Diagnostics' (Preterm Birth International Collaborative Australasian Workshop, 21 March 2023, Brisbane)

Upcoming Catalysts/Newsflow

Period	
4QFY23	EXO-OC test: equivalence study data
1QFY24	EXO-NET partnering progress
1QFY24	SubB2M SPR feasibility data
1HFY24	SubB2M/CA125 OC test: analytical data
2QFY24	SubB2M/CA15-3 test: monitoring study data

Share Price (A$)

Source: FactSet, MST Access.

INOVIQ LTD IIQ

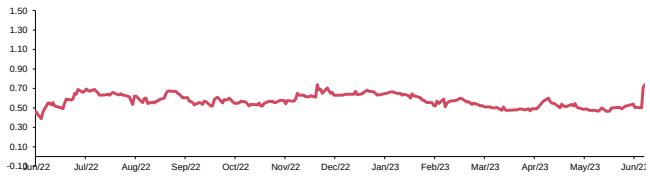
IIQ-AU

Year end 30 June, AUD unless otherwise noted

MARKET DATA

Price	**$**	**0.74**
52 week high / low	$	0.39-0.74
Valuation	**$**	**2.31**
Market capitalisation	$m	68.1
Shares on issue (basic)	**m**	92.0
Options / rights	m	9.3
Other equity	m	0.0
Shares on issue (diluted)	**m**	**101.4**

12-MONTH SHARE PRICE PERFORMANCE (A$)



INVESTMENT FUNDAMENTALS		FY21A	FY22A	FY23E	FY24E	FY25E
Reported NPAT	$m	(11.2)	(18.2)	(9.8)	(9.1)	(5.5)
Underlying NPAT	**$m**	**(11.2)**	**(18.2)**	**(9.8)**	**(9.1)**	**(5.5)**
Reported EPS (diluted)	¢	(14.4)	(20.0)	(10.7)	(9.9)	(5.0)
Underlying EPS (diluted)	**¢**	**(14.4)**	**(20.0)**	**(10.7)**	**(9.9)**	**(5.0)**
Growth	%					
Underlying PER	x	**nm**	**nm**	**nm**	**nm**	**nm**
Operating cash flow per share	¢	(5.7)	(6.6)	(7.9)	(6.9)	(3.5)
Free cash flow per share	¢	(2.5)	(7.0)	(8.2)	(7.4)	(3.5)
Price to free cash flow per share	**x**	**nm**	**nm**	**nm**	**nm**	**nm**
FCF Yield	%	nm	nm	nm	nm	nm
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	%	0.0%	0.0%	0.0%	0.0%	0.0%
Enterprise value	**$m**	**64.4**	**53.7**	**61.3**	**59.5**	**58.8**
EV/EBITDA	x	(4.9)	(3.0)	(7.3)	(7.7)	(13.8)
EV/EBIT	x	(4.6)	(2.7)	(6.2)	(6.5)	(10.6)
Price to book (NAV)	x	2.3	2.4	3.5	4.1	4.5
Price to NTA	x	23.4	4.1	7.6	7.5	7.8

KEY RATIOS		FY21A	FY22A	FY23E	FY24E	FY25E
EBITDA margin	%	nm	nm	nm	nm	nm
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	0.2	0.1	0.1	0.1
Book value per share	$	0.3	0.3	0.2	0.2	0.2
Net debt/(cash)	$m	(3.7)	(14.4)	(6.8)	(8.6)	(9.3)
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		FY21A	FY22A	FY23E	FY24E	FY25E
Net Profit Margin	%	nm	nm	nm	nm	nm
Asset Turnover	x	0.0	0.0	0.0	0.1	0.3
Return on Assets	%	nm	nm	nm	nm	nm
Leverage	x	1.2	1.1	1.1	1.1	1.1
Return on Equity	%	nm	nm	nm	nm	nm

KEY PERFORMANCE INDICATORS	FY21A	FY22A	FY23E	FY24E	FY25E
SubB2M			0.0	0.0	0.2
SubB2M			0.0	0.2	1.9
EXO-NET Research Use Only			0.1	1.1	3.9
EXO-NET DX (Clinical)			0.0	0.0	0.0
hTert	0.5	0.28	0.3	0.3	0.3

HALF YEARLY DATA		2H21	1H22	2H22	1H23	2H23
Product revenue	$m	0.3	0.1	0.2	0.2	0.1
Operating expenses	$m	(11.9)	(4.4)	(17.9)	(6.3)	(4.8)
EBITDA	$m	(9.9)	(3.3)	(14.9)	(5.6)	(4.3)
EBIT	$m	(10.8)	(3.3)	(17.0)	(5.6)	(4.3)
PBT	$m	(10.8)	(3.3)	(17.0)	(5.6)	(4.3)
Reported NPAT	$m	(7.9)	(2.7)	(15.5)	(5.6)	(4.3)

PROFIT AND LOSS		FY21A	FY22A	FY23E	FY24E	FY25E
Product revenue	**$m**	**0.5**	**0.3**	**0.4**	**1.6**	**6.4**
income	$m	**1.0**	**1.8**	**1.0**	**0.9**	**1.2**
Operating expenses	$m	(15.5)	(22.3)	(11.2)	(11.2)	(11.3)
EBITDA	**$m**	**(13.1)**	**(18.2)**	**(8.4)**	**(7.7)**	**(4.3)**
Depreciation & Amortisation	$m	(0.9)	(2.1)	(1.4)	(1.4)	(1.3)
EBIT	**$m**	**(14.0)**	**(20.3)**	**(9.8)**	**(9.1)**	**(5.5)**
Interest expense	$m	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)
Pretax Profit	$m	(14.0)	(20.3)	(9.8)	(9.1)	(5.5)
Tax expense	$m	2.9	2.1	0.0	0.0	0.0
Reported NPAT	**$m**	**(11.2)**	**(18.2)**	**(9.8)**	**(9.1)**	**(5.5)**
Weighted average diluted shares	m	92.0	92.0	92.0	111.6	121.4

GROWTH PROFILE		FY21A	FY22A	FY23E	FY24E	FY25E
Revenue	%	nm	(40.9)	5.0	5.0	5.0
EBITDA	%	303.1	38.4	(53.5)	(8.1)	(44.9)
EBIT	%	331.1	44.4	(51.6)	(7.1)	(39.3)
Reported NPAT	%	242.7	63.2	(46.1)	(7.1)	(39.3)

BALANCE SHEET		FY21A	FY22A	FY23E	FY24E	FY25E
Cash	$m	5.0	15.4	7.8	9.6	10.3
Receivables	$m	0.2	1.7	0.2	0.2	0.2
Other	$m	0.4	0.4	0.4	0.4	0.4
Current assets	**$m**	**5.6**	**17.5**	**8.4**	**10.2**	**10.9**
PPE	$m	0.6	0.8	1.0	1.4	1.3
Intangible assets	$m	15.1	11.7	10.5	9.3	8.3
Goodwill	$m	11.0	0.0	0.0	0.0	0.0
Other	$m	1.1	0.9	1.7	1.6	1.5
Non current assets	**$m**	**27.9**	**13.3**	**13.2**	**12.3**	**11.1**
Total assets	**$m**	**33.5**	**30.8**	**21.6**	**22.5**	**22.0**
Trade and other payables	$m	0.8	1.0	0.8	0.8	0.8
Lease liabilities	$m	0.3	0.4	0.4	0.4	0.4
Other	$m	0.4	0.4	0.4	0.4	0.4
Current liabilities	**$m**	**1.5**	**1.8**	**1.5**	**1.5**	**1.5**
Lease liabilities	$m	0.9	0.6	0.6	0.6	0.6
Other liability	$m	2.1	0.0	0.0	0.0	0.0
Non current liabilities	**$m**	**3.0**	**0.7**	**0.7**	**0.7**	**0.7**
Total liabilities	**$m**	**4.5**	**2.5**	**2.2**	**2.2**	**2.2**
Net assets	**$m**	**29.1**	**28.3**	**19.4**	**20.3**	**19.8**
Share capital	$m	51.8	69.1	70.3	80.3	85.3
Retained earnings	$m	(24.0)	(41.9)	(52.0)	(61.1)	(66.6)
Other	$m	1.2	1.1	1.1	1.1	1.1
Total equity	**$m**	**29.1**	**28.3**	**19.4**	**20.3**	**19.8**

CASH FLOW		FY21A	FY22A	FY23E	FY24E	FY25E
Net loss for period	**$m**	**(11.2)**	**(18.2)**	**(9.8)**	**(9.1)**	**(5.5)**
Depreciation & Amortisation	$m	(0.9)	(2.1)	(1.4)	(1.4)	(1.3)
Changes in working capital	$m	(0.4)	(1.1)	1.2	0.0	0.0
Other	$m	7.2	15.3	2.7	2.7	2.5
Operating cash flow	**$m**	**(5.3)**	**(6.1)**	**(7.3)**	**(7.7)**	**(4.3)**
Payments for PPE	$m	(0.8)	(0.4)	(0.3)	(0.5)	0.0
Other	$m	3.8	0.0	0.0	0.0	0.0
Investing cash flow	**$m**	**3.0**	**(0.4)**	**(0.3)**	**(0.5)**	**0.0**
Equity	$m	0.3	18.5	0.0	10.0	5.0
Lease liability payments	$m	(0.3)	(0.3)	0.0	0.0	0.0
Other	$m	0.0	(1.2)	0.0	0.0	0.0
Financing cash flow	**$m**	**(0.0)**	**16.9**	**0.0**	**10.0**	**5.0**
Cash year end	**$m**	**5.0**	**15.4**	**7.8**	**9.6**	**10.3**
Free cash flow	**$m**	**(2.3)**	**(6.5)**	**(7.6)**	**(8.2)**	**(4.3)**

Source: Company reports, MST Access estimates

SubB2M/CA15-3 Breast Cancer Test: Clinical Validation Results and Next Steps

Key points from IIQ's announcement on the clinical validation results

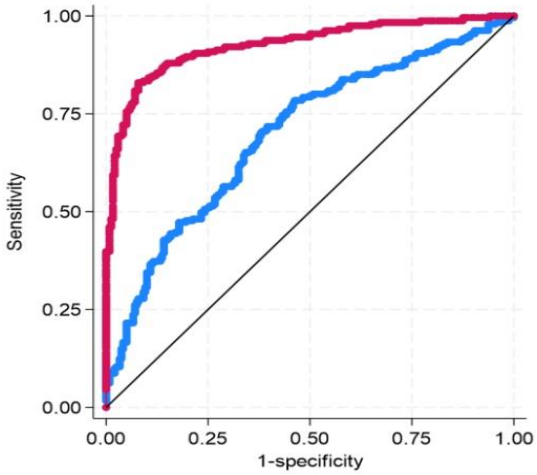
US-based contract research organisation (CRO) ResearchDx has been working on the assay development and validation of IIQ's SubB2M tests. The CRO built on previous positive results (reported in February) to further optimise the SubB2M/CA15-3 test and improve its sensitivity and specificity further in the leadup to clinical validation.

Figure 1: SubB2M/CA15-3 test vs. comparator test – key performance metrics

Breast Cancer All Stages	SubB2M	Comparator
AUC	0.93	0.70
sensitivity	81%	37%
specificity	93%	88%
false negative rate	19%	63%
false positive rate	7%	12%
positive predictive value	92%	75%
negative predictive value	83%	58%
overall accuracy	87%	63%

Source: INOVIQ.

Figure 2: ROC curves for IIQ's (red) and comparator's (blue) tests: More distant from black reference line = more accurate



Test	AUC ± SE	n
SubB2M/CA15-3	0.926 ± 0.01	481
Comparator – CA15-3	0.698 ± 0.02	481

Source: INOVIQ.
Note: Receiver Operating Characteristic (ROC) curves measure the diagnostic performance of a test. The Area Under the Curve (AUC) summarises the test's overall performance, with AUC = 1.0 being completely accurate.

Next steps in the path to market for SubB2M/CA15-3

IIQ has released its planned timeline for the path to market for this test, with market readiness to follow its final planned study – a cross-sectional monitoring study to assess the performance of the IIQ test vs. commercially available tests.

Figure 3: Key milestones in the path to market for SubB2M/CA15-3 test

Source: INOVIQ.

Other SubB2M Tests: Next Steps

IIQ indicated that it is progressing plans for two other SubB2M tests.

SubB2M/CA125 ovarian cancer test

IIQ is progressing development plans for this test, for which samples have been sourced, and has indicated the following timeline:

- 1HFY24: Assay development and analytical development studies to commence (completion within 6 months)
- 2HFY24: Clinical validation to be completed

SubB2M multi-cancer test

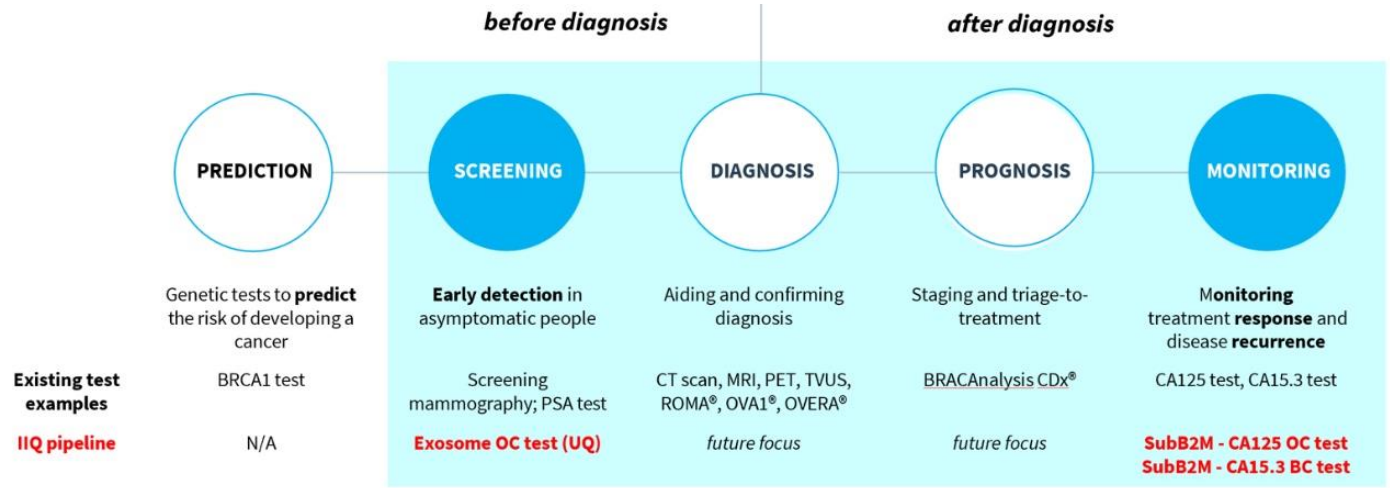
This test on the Nicoya ALTO™ SPR instrument is being evaluated further. IIQ expects that data will be reported in 1QFY24.

The company is also evaluating other opportunities for a potential SubB2M multi-cancer test for point-of-care testing with potential partners.

IIQ's Portfolio and the Potential for SubB2M: A Refresher

IIQ is a development-stage precision diagnostic company developing and commercialising a broad portfolio of diagnostics and exosome-based solutions to diagnose cancer and other diseases, with a portfolio of products that span the diagnostic continuum, from screening to monitoring.

Figure 4: IIQ's pipeline of products is targeting multiple positions along the diagnostic continuum



Source: INOVIQ.

SubB2M platform for ovarian and breast cancer

The SubB2M technology platform uses SubB2M, an engineered, highly selective ligand (recombinant protein), to binds the pan-cancer biomarker Neu5Gc that decorates cancer antigens such as CA125 and CA15.3, a novel cancer biomarker that is elevated at all stages of ovarian and breast cancers and found at elevated levels in humans on tumour cells and tumour-associated molecules. IIQ has engaged US-based CRO ResearchDx to advance IIQ's two lead products, the SubB2M-CA125 assay (for monitoring ovarian cancers) and SubB2M- CA15.3 assay (for monitoring breast cancers).

Combining SubB2M with next-gen SPR for pan-cancer test

Feasibility studies to date in the SubB2M program have used Surface Plasmon Resonance (SPR)–based tests, considered the gold standard in direct biomolecular interaction sensing, to directly measure the levels of the pan-cancer biomarker Neu5Gc. SPR is an optical biosensor technology that uses changes in refraction of light shone onto a metallic surface to detect interactions at the molecular level. The SPR technique allows molecular interactions in a target of interest to be measured ('characterised'). SubB2M-based SPR tests have generated encouraging data; POC results vs healthy controls show SubB2M detects all cancer stages with >95%/100% sensitivity and 100%/100% specificity in breast/ovarian cancers, respectively.

SPR-based platforms that process a patient sample to detect and quantify biomarkers using liquid biopsies for cancer patients represent a new alternative to conventional approaches, such as cell culture methods (histopathology/cytology), enzyme-linked immunosorbent assays (ELISA), next-generation sequencing (NGS), and polymerase chain reaction (PCR)–based platforms), currently in use in commercial laboratories and considered highly efficient for processing relatively large numbers of samples[1]. Notably, the use of an SPR platform enables the measurement of multiple glycoproteins with aberrant Neu5Gc leading to improved sensitivity and specificity for cancer.

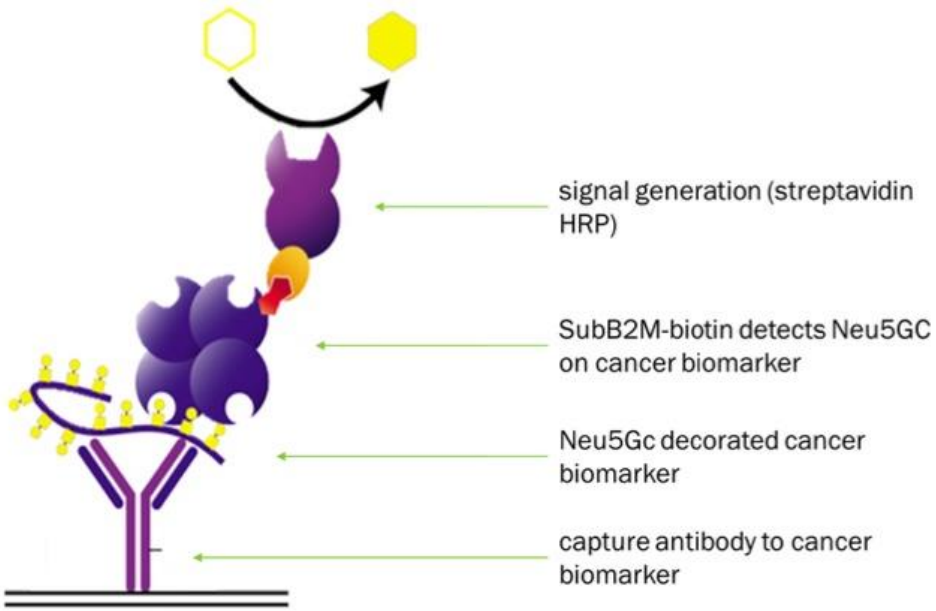
Next-generation SPR instruments with a smaller footprint (scaled-down benchtop) for use in diagnostic/pathology labs could be positive for IIQ considering compelling data rendered to date. An SPR test could be a general indicator for cancer, and potentially be developed as a multi-cancer test.

How it works: leveraging novel, highly specific ligand to detect Neu5Gc

The SubB2M platform utilises a highly specific probe (a genetically engineered lectin, or carbohydrate-binding protein) developed to bind with Neu5Gc, a pan-cancer marker found in multiple human cancers. SubB2M technology was in-licensed from University of Adelaide and Griffith University in April 2020. As such, IIQ holds the exclusive worldwide rights to the SubB2M intellectual property for diagnostic applications.

Neu5Gc occurs as cells transform to malignancy resulting from aberrant glycosylation caused by abnormal expression of certain enzymes involved in modifying of proteins and the regulation of cell growth and differentiation, cell adhesion, cell-to-cell communication, and immune recognition. IIQ is currently developing SubB2M-based immunoassays (ELISA) for multiple cancers, with an initial focus on the monitoring of breast and ovarian cancer.

Figure 5: SubB2M immuoassay



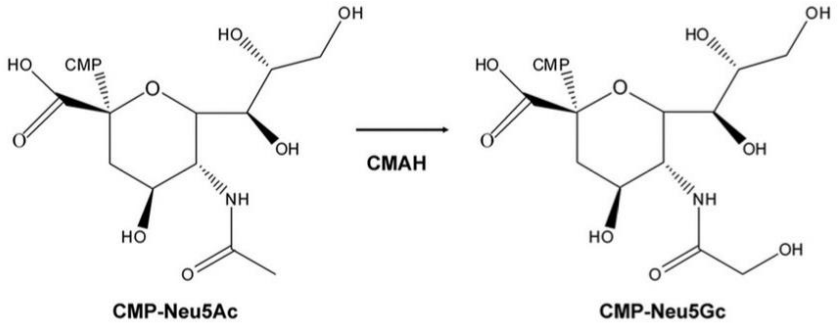
Source: INOVIQ.

[1] Surface Plasmon Resonance for Biomarker Detection: Advances in Non-invasive Cancer Diagnosis: Bellassai et al (2019)

The science of Neu5Gc – a novel pan-cancer biomarker

N-Glycolylneuraminic acid (Neu5Gc) is a sialic acid molecule not typically found in humans. This is due to the absence of the CMAH (CMP-Neu5Ac hydroxylase) enzyme responsible for converting the precursor to Neu5Gc in humans owing to an irreversible genetic mutation millions of years ago. Neu5Gc has been consistently found in various human epithelial cancers including breast, colon, lung, prostate, and ovarian, and as such, is a novel cancer biomarker.

Figure 6: Humans cannot synthesise Neu5Gc due to inactive CMP-Neu5Ac hydroxylase (CMAH) gene



Source: N-Glycolylneuraminic Acid on Human Epithelial Cells Prevents Entry of Influenza A Viruses That Possess N-Glycolylneuraminic Acid Binding Ability - Tadanobu Takahashi et al (2014).

Methodology & Disclosures

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