BioMark DIAGNOSTICS INC

A Next Generation Company Powered by Metabolomics

www.biomarkdiagnostics.com

BioMark DIAGNOSTICS INC

Our Mission

To provide access to a new paradigm in cancer diagnostics using metabolomics

Who We Are

- Oncology-focused company with advanced near-to-market diagnostic technologies
- Multiple IPs generated in detection and quantitation of metabolites
  - collectively over 20 patents in different stages and jurisdictions in progress
- Hand-picked, proven, global enterprise team of scientists, engineers and medical professionals



ABOUT BIOMARK

Executive Team

- **Rashid Ahmed, MBA** – Founder, Chief Executive Officer
- **Dr. Thomas Malcolm, Ph.D** – Chief Scientific Advisor
- **Dr. Bram Ramjiawan, Ph.D** – Clinical Trial and Regulatory Expertise
- **Brian Cheng, MSc**– Chief Technical Officer
- **Dr. Kenneth Kohn, Ph.D** – Patent Attorney
- **Gina Huang, MBA** – CFO and Project Director



Metabolomics is Moving to the Bedside

- Number of “approved” tests arising from Metabolomics/Clinical Chem. – 334
- Number of “approved” tests arising from or using Genomics – 130
- Number of “approved” single Protein tests (ELISA) – 108
- Number of “approved” tests arising from or using Transcriptomics – 5
- Number of “approved” tests arising from or using Proteomics - 1

Value Proposition
- Physician, Patient, Payer and Pharma Impact

- Provide better early detection technologies that are reliable, non invasive and cost effective to reduce later costs of treatment – drug and hospitalization costs
- Provide better tools to assess treatment efficacy earlier so as to tailor treatment – treatment costs and quality of life measures(Reduce time / cost / challenges especially for advanced staged malignant lung cancer)
- Provide a low cost routine surveillance tool to help monitor recurrence – CEA CA 125 etc.
- Potential utility as a companion diagnostic for drug discovery

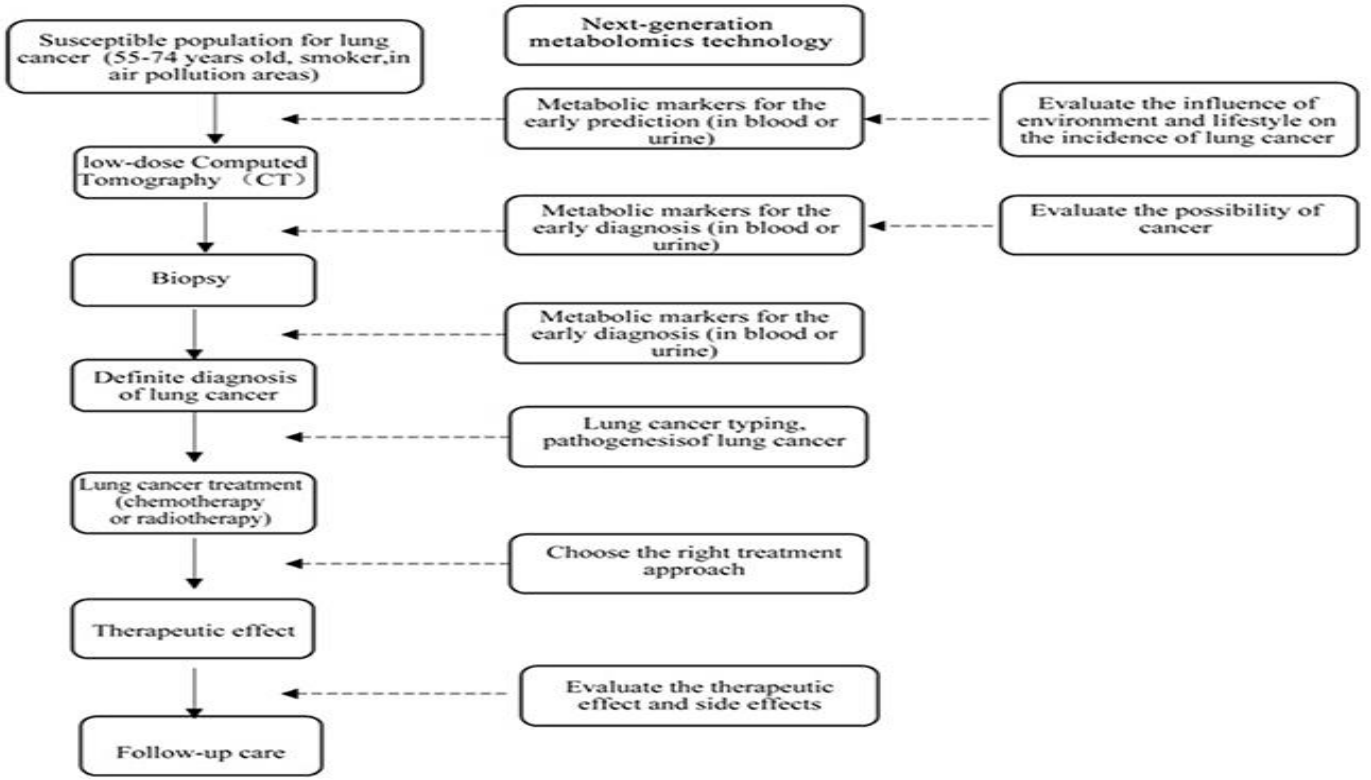


Our position in the competitive Metabolomics Space

- BioMark has/is been working with the world renowned scientist and The Metabolomics Innovation Centre started by Dr. Wishart
- Dr. Wishart led the Human Metabolome Project (HMP), a multi-university, multi-investigator project that catalogued all of the known metabolites in human tissues and biofluids.
- Using advanced methods in NMR spectroscopy, mass spectrometry, multi-dimensional chromatography and machine learning Dr. Wishart and his colleagues identified more than 8000 endogenous metabolites. The methods and ideas developed for the HMP have helped lay the foundation for a number of other metabolomic databases (DrugBank, FooDB) and metabolomic software tools (MSEA, MetaboAnalyst, MetPA, MetaboMiner).
- They have also led to the development of a number of interesting clinical metabolomics projects and collaborations.



Clinical Applications





Discovery and Development of Metabolomic Assays

Completed development and validation of 2 principle assays – Platform Play

a). Acetyl Amantadine Assay

- Based on key discovery by Dr. Sitar UoM – Amantadine and SSAT1 (Linked to Polyamine pathway)
- Recently completed a clinical trail based on a total of 450 patients after gaining CTA for phase III with focus on lung and breast and cancers
- Obtained ITA (Health Canada) on internal standards for quantification using LC- MS
- Encouraging results and in process to submit application to Health Canada

b). New lung cancer fingerprints – high performance biomarkers

- Revalidated and reproduced custom assay
- Strong ROC (Receiver Operating Curves)

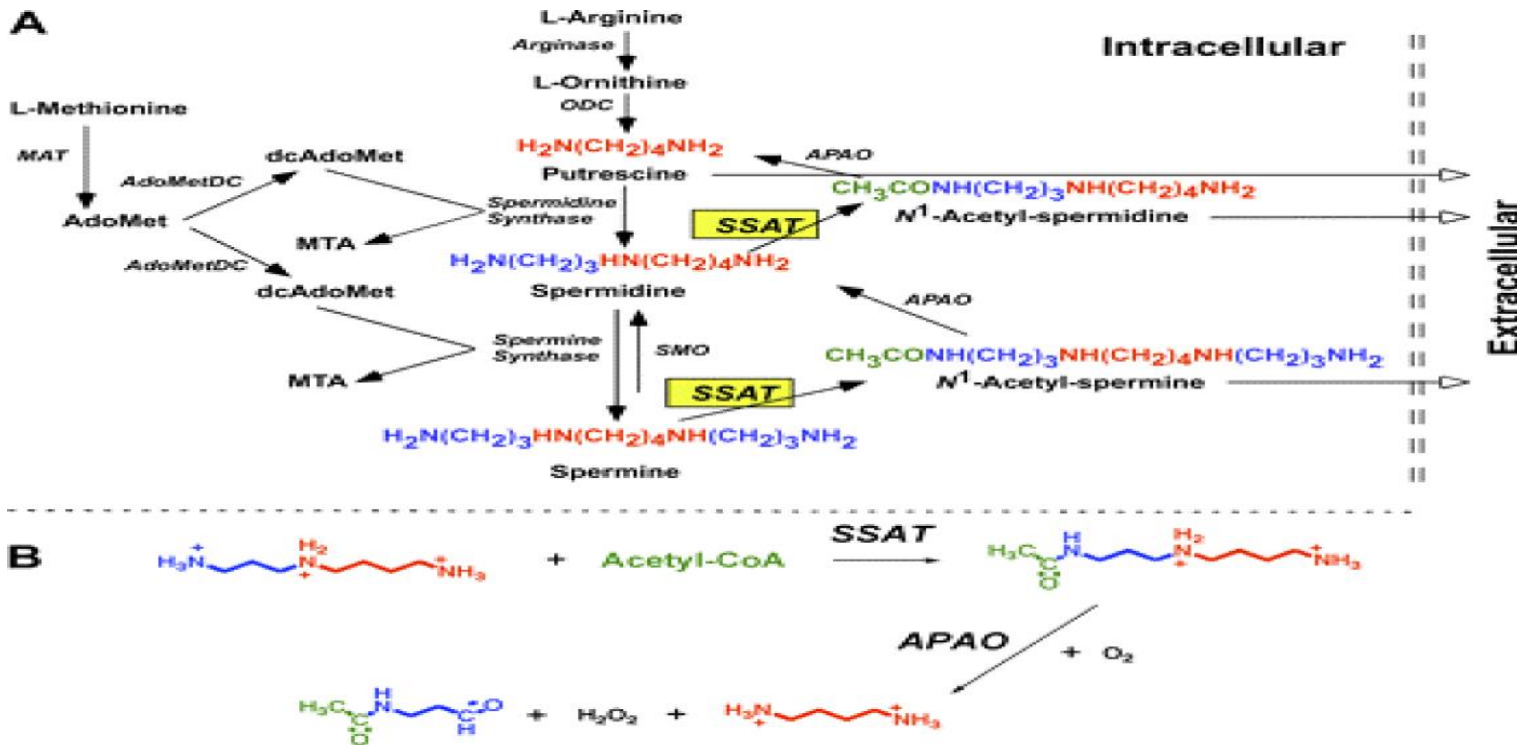
Both discoveries supported by multiple patents



Assay I

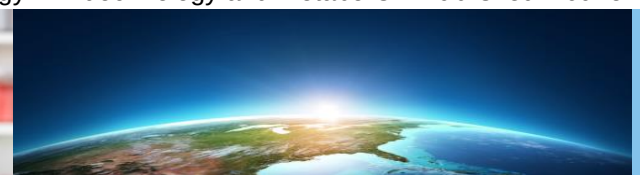
BioMark SSAT1 Assay

SSAT Biochemistry – Polyamine Pathway

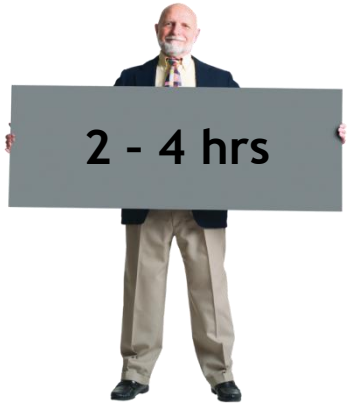


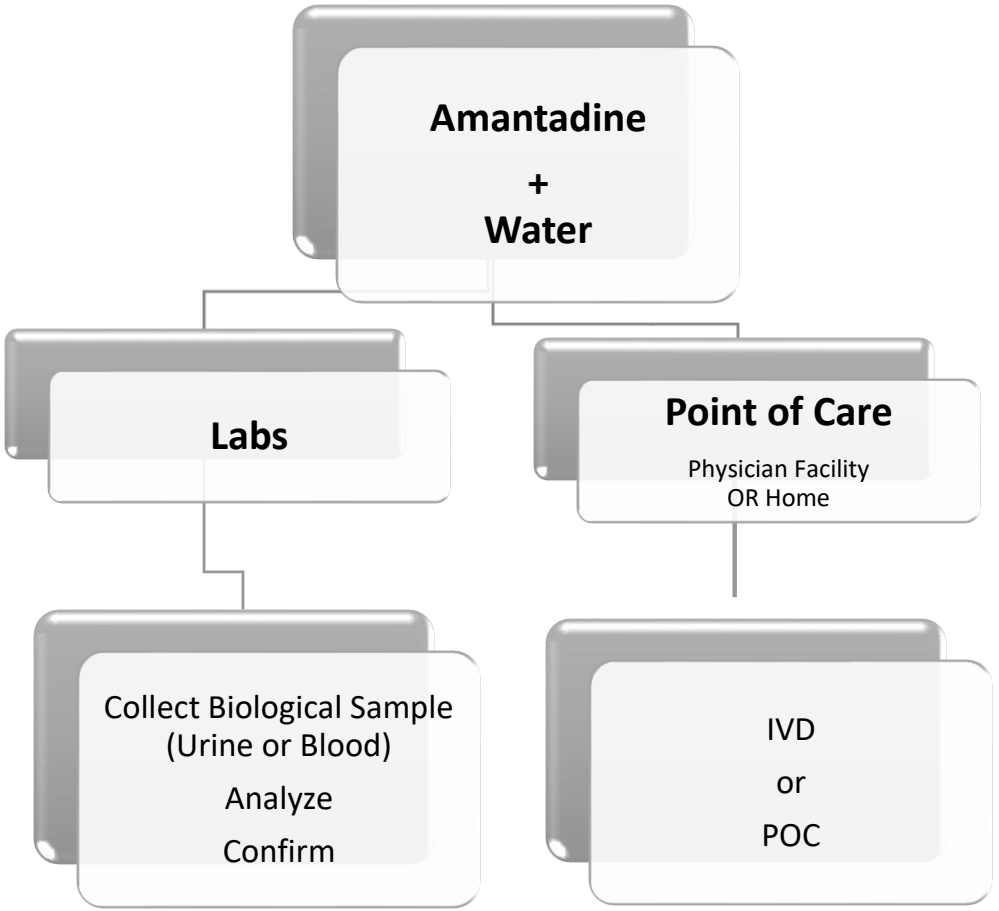
Source: American Journal of Physiology - Endocrinology and Metabolism Published 4 June 2008 Vol. 294 no. 6





How We Conduct Our Test (SSAT1 Assay) - Convenient & Non Invasive





Activities undertaken in Discovery and Development Phase of SSAT1 Assay

Validation of SSAT1 platform / Expansion to other metabolites

- Confirmation at genomic level using PCR and cell line studies at BRI (2011-003)
- Proteomic level – western blot Manitoba Tumour Bank and University of British Columbia
- Selection of cancers with highest gene expression for SSAT1 – Lung, Breast, Prostate and GBM
- Correlate SSAT1 Expression Signatures
- Identification of other new polyamine and select metabolites using LCMS
- Increase specificity and selectivity using new partnerships at TMIC



BioMark SSAT1 Assay - Measurement Technologies

LC/MS - Gold Standard

- Highly sensitive detection from urine and blood
- Secured Investigational and Testing Authorization from Health Canada 2014

Modified MS – Positioned to reduce quantification costs

Point Of Care (ELISA Kit) - Prototype can be made in 6 months

- Generated monoclonal antibodies against small molecule
- Completed validation of these highly specific monoclonal antibodies
- Test to be completed on biological samples



Current SSAT1 Assay Activities and Clinical Applications

- **Phase III Clinical Trial** – Urinary Excretion of Acetylamantadine by Cancer Patients
  - Health Canada & Ethics Approval, in Canada & Bangladesh;
  - Completed clinical trial follow-up on outliers and incorporating findings for Health Canada filing submission

- **Clinical Trial – Response to Chemo Therapy for Lung Cancer** - Cancer Care Manitoba
  - Health Canada & Ethics Approval; Started patient recruitment. Several patients already completed studies

- **Clinical Trial – Response to Lung Cancer Resection** – Surrey Memorial Hospital
  - Completed comprehensive protocol and selected a site and team to conduct trial

- **Use of SSAT1 for GBM –** the use of an SSAT1 based biomarker to assess surgical resection and determine potential physiological and anatomical correlation as a guide and complimentary tool to existing procedure



Assay II

Targeted BioMarker Panel for Lung Cancer



Recently Completed Initiative
- Discovery and validation on prospective studies

Goal: Discover and validate putative lung cancer biomarkers on N. American cohort markers that :

- Distinguish normal vs lung cancer groups with emphasis on early stage 1 and 2 lung cancer.
- Separate the sub-types (adeno and squamous)
- Incorporate other clinical variables to assess impact on assay performance



Larger cohort Lung cancer trials for re-validation

In progress - larger cohort (>1000 samples) studies based on power calculation

Multiple Clinical Applications of Lung Cancer Panel

- Target the high-risk smokers on the LDCT screening program in the US
  - Smokers over 55 in age with defined smoking parameters
  - Using 3 to 4 key metabolites plus smoking variable should be sufficient to replace or complement the existing program
  - Position (imaging) LDCT to help enable location and size of tumour
- Early detection of lung cancer - staging difference between early stage(asymptomatic) and late stage
- CDx



Lung Cancer Screening Market in US

Results: Screening Sites and Performed LDCTs

U.S. Census Region	Estimated Eligible Smokers	2016			2017		
		Facilities	LDCTs	Rate	Facilities	LDCTs	Rate
Northeast	1,152,141	404	40,105	3.5	487	68,792	6.0
Midwest	2,020,045	497	38,931	1.9	672	73,490	3.6
South	3,072,095	663	47,966	1.6	905	88,649	2.9
West	1,368,694	232	14,080	1.0	293	24,912	1.8
Total	**7,612,975**	**1796**	**141,260**	**1.9**	**2357**	**256,088**	**3.4**



Commercialization Roadmap
Market Focus - Lung Cancer

- Lung Cancer Screening in US for high risk groups to complement LDCT Scan
- Estimated Population Size : 8 million
- Current Uptake 3%; 18% cancers detected are indolent; over diagnosis

Imaging is used for Screening – Low Dose CT Scan (Helical CT) – reduces mortality in high risk groups by 15-20%;

➢Challenges – very high false positives rates; Diagnostic dilemma for physicians

Solution

- Use BioMark's assay that is cost effective and can potentially reduce false positive associated with LDCT Scans. (reduce and manage diagnostic dilemma)

- Follow patients with abnormalities that are too small or non-diagnostic on CT scans



Commercialization Roadmap
Market Focus – Response To Treatment For Lung Cancer

Use BioMark's assay to predict response and outcome of systemic therapy for patients on chemotherapy and radiotherapy treatment

Outcome:

- Modify / Personalize treatment for patients earlier
- Reduce costs associated with expensive therapies with an annual cost estimated at about $100K / patient
- Positively impact quality of life for patients

Potential Revenue Streams

- **Sales** of products / supplies
- **Royalty on** lab analysis (per test)
- **Licensing** – Territorial and distribution licensing
- **Services**
  - Monitoring
  - CDx for drug companies （Surrogate BioMarker）



Technology Development Pipeline

Planning	Development	Validation	Health Canada Approval	Market

SSAT-Amantadine Assay using LC/MS

Internal Standards developed and data points collected and to be validated. Transferable to FDA

SSAT-Amantadine Assay using ELISA Kit

Collaboration with an IVD kit manufacturer begin validation post trial results

Polyamine and other Pathways

Lung Cancer Metabolic Fingerprint Assay

Customize assay; Collect more data collection - all lung cancer stages and subtypes

Other Cancer Fingerprints

Breast, GBM, Thyroid and Gastric in architecture



Activities and timing for large lung cancer cohort studies

- Initiated request for additional clinical samples for lung cancer study (1200 -1500) from recognized and approved biobanks with all the relevant patient information. Ethics amendment for additional samples have been completed and MTAs signed. To date 200 samples have been received
- Working with TMIC (The Metabolomics Innovation Centre) to set time to analyze all the samples and generate data and report - Plan is to complete this portion as soon as all samples are analyzed - Late summer 2019
- Revalidate the results at an accredited lab - in discussion with lab
- Optimize the assay and develop kits. Established link for kit development
- New patents to be filed
- Regulatory preparations

2019- Other activities slated for 2019

- Integrate Total *Omics* approach
- Commence key trials in US
- Partner with key PIs and seek non-dilutive grants
- Hiring and retaining key staff and scientific advisors
- Results of multiple trials
- Health Canada submission result
- Capital raise
- Market and revenue development – Licensing and introduction of tests in select countries



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