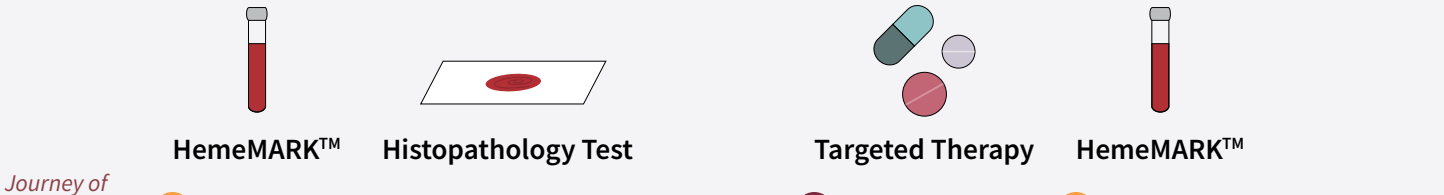
HemeMARK™

LUCENCE

A 44-gene, ultra-deep sequencing profiling assay that covers hematological malignancies including myeloid and lymphoid neoplasms.

How HemeMARK™ Helps



1. Provides additional insights into disease diagnosis
2. Predicts disease prognosis
3. Identifies mutations useful for treatment selection

1. Monitors treatment response
2. Tracks resistance mutations
3. Maps clonal evolution in disease progression

Clinical Significance & Actionability [1,2]

TARGETS	MALIGNANCY		PROGNOSTIC	ACTIONABLE
Single Nucleotide Variants (SNVs) and Short Insertions and Deletions (Indels)*				
ABL1	M			●
ASXL1	M		●	●
ATM		L	●	●
BRAF	M	L		●
BTK		L		●
CALR	M		●	●
CBL	M		●	●
CCND1		L	●	
CCND3		L		
CD79B		L		●
CDKN2A		L		
CDKN2B		L		
CEBPA	M		●	
CREBBP		L		
CSF3R	M		●	●
DNMT3A	M	L	●	●
EZH2	M	L		●
FBXW7		L		
FGFR3		L		
FLT3	M		●	✓ FDA-APPROVED
HRAS	M	L		
ID3		L		
IDH1	M	L	●	✓ FDA-APPROVED
IDH2	M	L	●	✓ FDA-APPROVED
IKZF1		L		

TARGETS	MALIGNANCY		PROGNOSTIC	ACTIONABLE
JAK2	M		●	
JAK3	M	L		
KIT	M		●	●
KRAS	M	L	●	●
MPL	M		●	●
MYC		L	●	
MYD88		L		●
NOTCH1		L		●
NPM1	M		●	●
NRAS	M	L	●	●
RUNX1	M		●	●
SETBP1	M		●	
SF3B1	M	L	●	
SRSF2	M		●	
TCF3		L		
TET2	M		●	●
TP53	M	L	●	●
U2AF1	M		●	
Fusion				
BCR/ABL1#	M	L	●	✓ FDA-APPROVED
Microsatellite Instability (MSI)				
BAT25 **BAT26** **NR21** **NR24** **NR27** **MONO27**	M	L		●

● Proven Indication ● Potential off-label use/ clinical trials available

* Targeted regions are selected for sequencing to maximise detections of known hotspot mutations List available on request.
# Detecting up to 85% of BCR/ABL1 fusions.

Technical Specifications

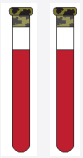
Methodology	Amplicon-based ultra-deep next-generation sequencing
Analytical Limit of Detection	1% for single nucleotide variants and insertions/deletions, 10% for *BCR/ABL1* fusion
Turnaround Time	2 Calendar Weeks
Reporting	All genomic findings are listed with FDA approved targeted therapies in patient's cancer type, other cancer types and clinical trials.

Mutation Class	**Single Nucleotide Variants (SNVs) and Insertions/ Deletions (Indels)**	**Fusion**
Mutant Allele Frequency	>1%	>10%
Sensitivity	>99%	>90%
Specificity	>99%	>99%

- Results tested at the stated mutant allele frequencies of Horizon Discovery™ Myeloid DNA reference standard.
- Sensitivity reported for true variants in the Horizon Discovery™ Myeloid DNA reference standard.
- Specificity reported is the per-base specificity across the HemeMARK™ panel (detection of true negatives).

Sample Requirements

Sample Types



2 x 9 mL Streck Tubes of Peripheral Whole Blood

AND/OR

1 x 3mL EDTA Tube of Bone Marrow Aspirate

- To ensure optimal test sensitivity, a level of 20% neoplastic lesional cell constitution or higher is recommended.
- Specimen to be kept and delivered at ambient temperature.

Shipping

- Peripheral whole blood and bone marrow aspirate must be shipped within the day of specimen extraction
- Samples are accepted from Monday to Friday, except weekends and Public Holidays. Please contact us in advance for Saturday specimen delivery.
- Detection sensitivity may be affected if sample receipt is delayed.

Sample Rejection

Specimen will be rejected if it exhibits any of the following:

- Specimen reaches Lucence lab after 24 hours after sample collection
- Specimen clotted upon sample receipt
- Wrong type of specimen
- Insufficient volume of specimen
- Leakage of tube(s) observed
- Wrong / Unsuitable type of tube (e.g. tube expired)
- Mislabelled/ unlabelled specimen tubes
- Improper labelling (e.g. illegible handwriting or wrong patient information)
- Incomplete or unsigned test order forms

Call us at: **+65 6592 5102** or email: **sales.asean@lucence.com**

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References: [1] mycancergenome.org [2] https://www.fda.gov/drugs/development-approval-process-drugs/drug-approvals-and-databases

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