



LUNGClear™

CLARITY IN ONE BLOOD DRAW

LUNGClear™ is a simple and convenient blood test powered by microRNA technology for early detection of lung cancer.

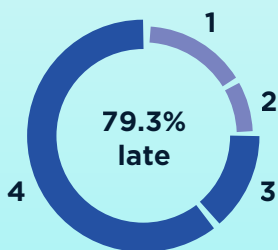


Early
Screening
Saves Lives

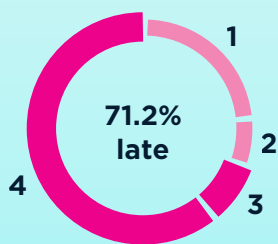
Lung Cancer in Singapore¹

High proportion of late diagnosis.

Cancer stage at diagnosis in Singapore.



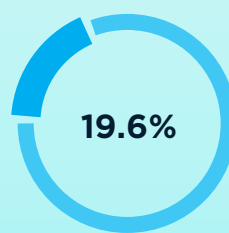
Male



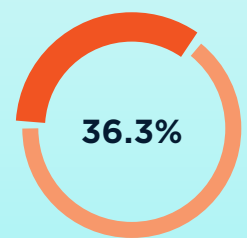
Female

Relatively low survival rate due to late diagnosis.

Five-year survival rate in Singapore.





Male



Female

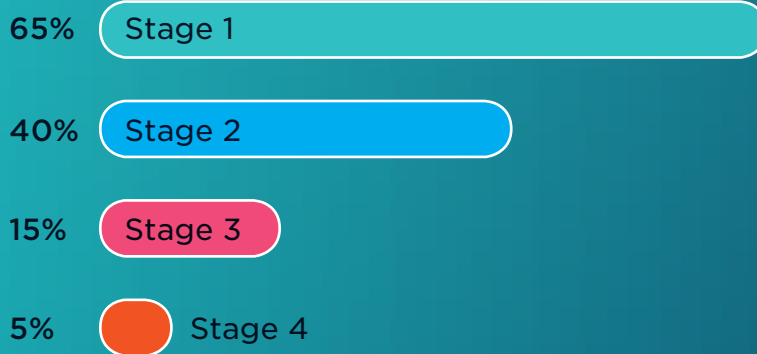
In Singapore, lung cancer is the cancer with the third-highest incidence in both males and females. It is also the cancer with the highest mortality in males, and third-highest mortality in females.¹

Current Screening Methods

	Advantages	Disadvantages
 Low-dose CT	<ul style="list-style-type: none">• Recognised in many screening guidelines for high risk groups²	<ul style="list-style-type: none">• Narrow definition of high risk group (e.g. smoked ≥ 30 pack years)• Radiation exposure• Inconvenient
 Chest X-ray	<ul style="list-style-type: none">• Accessible• Low cost	<ul style="list-style-type: none">• Not recommended in some screening guidelines²• Poor accuracy

Early Detection Saves Lives

Five-year survival rates of lung cancer by stage of diagnosis³

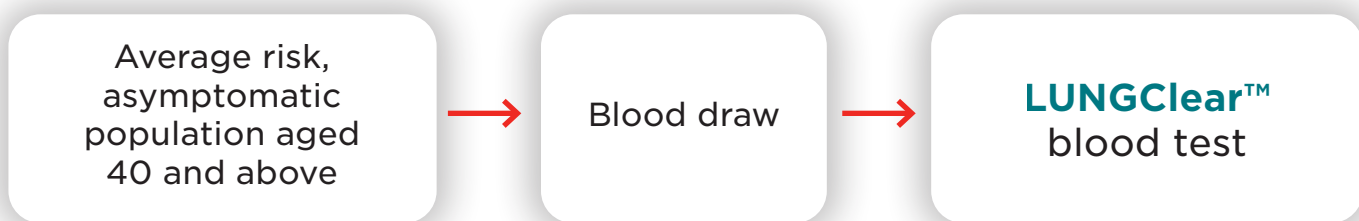





A Solution for Early Lung Cancer Detection



How does it work?

The LUNGClear test uses an algorithm that takes into account miRNA and CEA levels to provide a lung cancer risk score.



	Risk score ≥ 51.9	High Risk	The likelihood of lung cancer being present is elevated. Further medical evaluation is advised.
	Risk score 37.1–51.8	Intermediate Risk	The likelihood of lung cancer being present is slightly elevated. Further medical evaluation may be appropriate.
	Risk score ≤ 37.0	Low Risk	The likelihood of lung cancer being present is not elevated.

*Further medical evaluation may include LDCT (low-dose CT scan) or other investigation(s) as advised by a medical professional .

LUNGClear™ Clinical Studies⁴



Discovery Phase

Multi-centre Chinese and Causasian Cohort (N= 3134)
1449 Lung Cancers and 1685 Matched Healthy Controls



Verification Phase

Japan Cohort (N= 233)
101 Lung Cancers and 132 Matched Healthy Controls



Validation Phase

Japan Cohort (N= 292)
160 Lung Cancers and 132 Matched Healthy Controls

Lung Cancer Risk Stratification Using Risk Scores

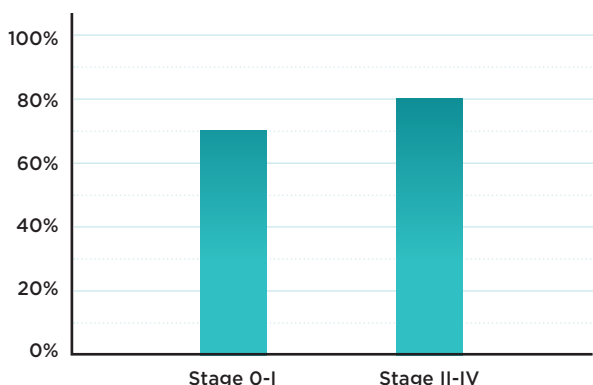
With up to 74% sensitivity and 97% specificity, the risk-stratification provided by LUNGClear empowers clinicians to appropriately counsel patients regarding their lung cancer risk and whether further evaluation is advised.

The LUNGClear test reports a risk score, indicating whether a person is at low, intermediate or high risk of having lung cancer. LUNGClear has 74% sensitivity and 78% specificity when intermediate and high risk results are deemed positive. It has 34% sensitivity and 97% specificity when only high risk results are deemed positive. This allows clinicians to appropriately counsel patients and advise on whether further evaluation is recommended based on factors such as clinical history, presentation and patient preference.

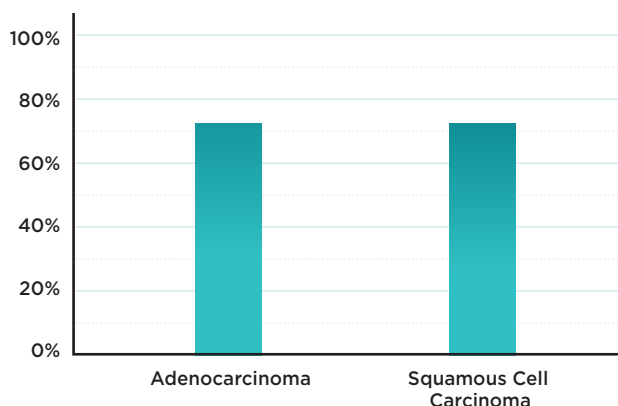
LUNGClear™ Clinical Performance⁴

Performance of LUNGClear by clinical stages and subtypes in Japanese cohort

Sensitivity of LUNGClear in detecting NSCLC stages

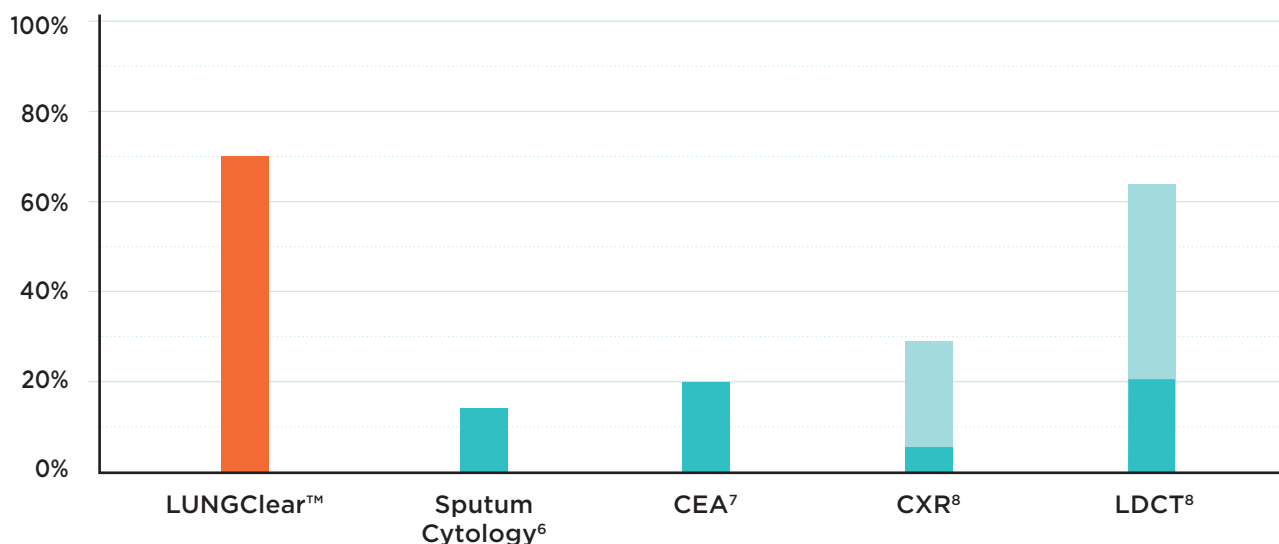


Sensitivity of LUNGClear in detecting subtypes of NSCLC by histology



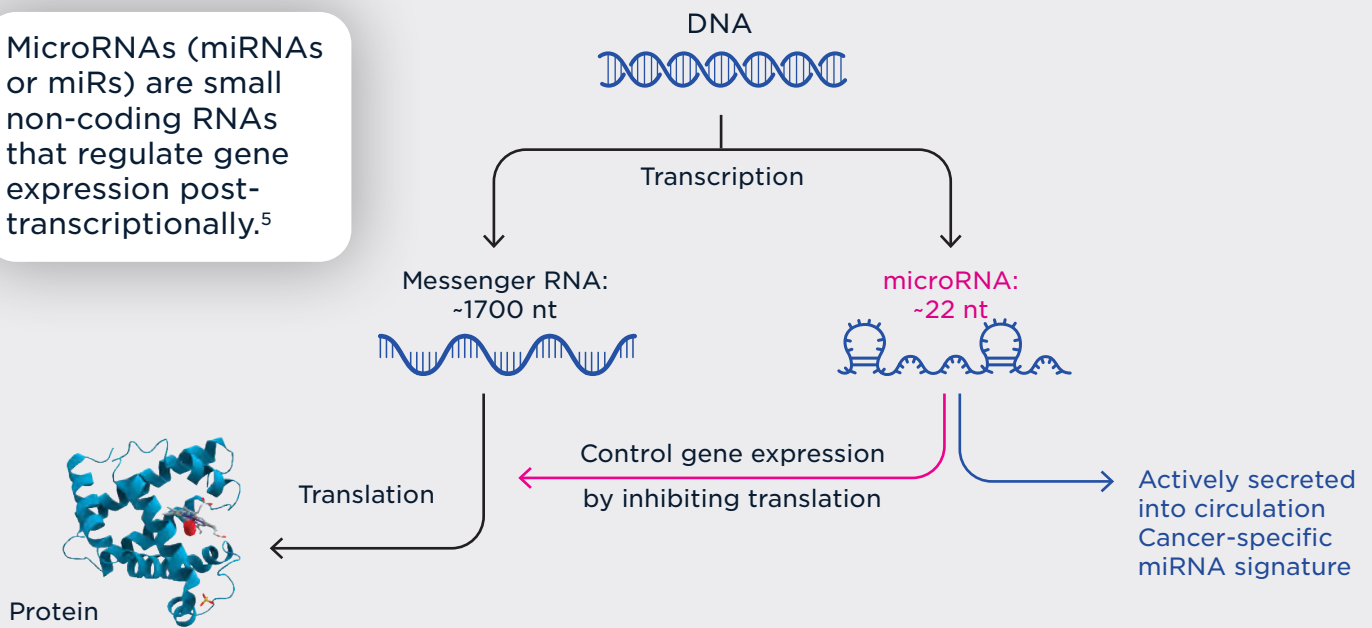
Comparison with Other Tests

Sensitivity of Stage I Lung Cancer Detection



What is microRNA?

MicroRNAs (miRNAs or miRs) are small non-coding RNAs that regulate gene expression post-transcriptionally.⁵



Comparison with other Blood Biomarkers

	Advantages	Disadvantages
Circulating miRNA	<ul style="list-style-type: none"> Changes in miRNA signatures are specific to each cancer, and can be detected in early stages Balanced sensitivity and specificity 	<ul style="list-style-type: none"> Higher cost than protein biomarkers
Circulating tumour DNA (ctDNA) or tumour cells (CTC)	<ul style="list-style-type: none"> Highly specific to each cancer depending on marker detected 	<ul style="list-style-type: none"> Low sensitivity for early stage cancer High cost
Protein biomarkers	<ul style="list-style-type: none"> Low cost Reasonable specificity 	<ul style="list-style-type: none"> Low sensitivity for early stage cancer

Risk Factors for Lung Cancer^{9,10}

- **Cigarette smoking** is the most common risk factor for lung cancer
- **Passive smoking** increases the risk of non-smokers developing lung cancer by 20-30%
- **Exposure to certain industrial hazards**, including asbestos, coal gas, chromates, nickel, arsenic, and vinyl chloride
- **Family or personal history**; having an immediate relative with lung cancer increases lung cancer risk. Lung cancer survivors are at increased risk of developing another form of lung cancer

While smoking is strongly associated with developing lung cancer, one-third of cases in East Asia occur in never smokers.^{11,12} A National Cancer Centre Singapore (NCCS) study conducted in 2018 showed that 48% of non-small cell lung cancer (NSCLC) patients were never smokers.^{12,13} Research is being conducted to examine extending screening to both smokers and non-smokers in Singapore.¹³

The Mirxes LUNGClear™ Test is offered through M Diagnostics, powered by the technology of Mirxes.

References:

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LUNGClear™
Powered by the technology of

mirxes

TO KNOW. TO ACT.