EsoGuard

esophageal DNA test

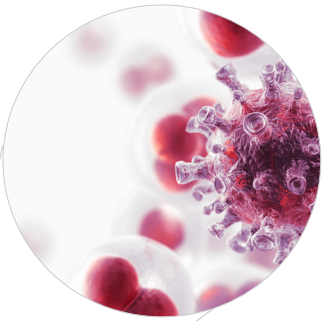
EsoGuard is a laboratory developed test that has demonstrated over 90% specificity and 90% sensitivity in diagnosing Barrett's Esophagus.[1]

The assay uses next generation sequencing (NGS) to examine individual DNA molecules for the presence or absence of cytosine methylation at 31 different genomic locations.

Barrett's Esophagus (BE) is an abnormal change in the cellular composition of the esophagus whereby the normal squamous lining changes under the influence of gastric reflux to a glandular intestinal metaplastic mucosa. This change increases the risk of affected individuals developing esophageal adenocarcinoma (EAC). BE is the only established precursor lesion of EAC. The incidence of EAC is growing faster than any other cancer in the US – with a dismal five-year survival rate of <20%. Most individuals with BE are unaware that they have BE and thus are unaware of their risk of developing EAC.

"EsoGuard's methylated DNA biomarkers have been shown to be highly accurate in detecting Barrett's Esophagus"[1]

EsoGuard uses next generation sequencing of bisulfate converted DNA to detect the presence of Vimentin and CyclinA1 methylation signatures [mVIM and mCCNA1] at 31 sites within those genes, reliably identifying individuals with Barrett's Esophagus (BE).



In a recent landmark Science Translational Medicine publication, Moinova et al compared esophageal brushings tested with EsoGuard, with esophageal tissue biopsies, evaluated with conventional histopathology in 322 patients with and without BE. EsoGuard was shown to have greater than 90% specificity and sensitivity at detecting non-dysplatic BE in these patients.

Assay: DNA methylation is an important pathological process related to BE and EAC formation. DNA methylation is the result of a chemical reaction which occurs at specific sites known as CpG sites. These CpG sites commonly cluster in large groups – some of which are known as CpG islands.

Custom proprietary software, incorporating advanced genetic informatics, uses an advanced algorithm to convert the DNA sequence at the target cytes into a binary clinical result.

EsoGuard assesses the presence of methylation in targeted regions of the Vimentin and CCNA1 genes after the samples have undergone bisulfite conversion – a chemical step which allows characterization of DNA methylation at CpG sites.

EsoGuard is used to detect non-dysplastic BE including short segment and long segment, dysplastic BE, including both low and high grade forms, adenocarcinoma of the esophagus including intramucosal disease, and adenocarcinoma of the gastroesophageal junction.

Assay Process

Process Esophagus Derived Samples

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Genomic DNA Extraction

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Bisulfite Conversion of Genomic DNA

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PCR Amplification

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Verification of PCR Products

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Clean up of PCR Product

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Next Generation Sequencing

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Pipeline Analysis of Sequencing Result

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Clinical Analysis using advanced genetic informatics

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Reporting of Binary Clinical Result

REFERENCES

1. https://stm.sciencemag.org/content/10/424/eaao5848.editor-summary
2. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4885788/

Lucid diagnostics

AD 0127 Rev A

LucidDX.com