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Screen time for Guardant



Guardant Health, first to market with a pan-cancer liquid biopsy, is also the first to launch a blood test to screen for colorectal cancer. The Shield assay, formerly called Lunar-2, went on sale yesterday in the US as a homebrew test to detect colorectal cancer in average-risk people aged 45 and older. Sales are unlikely to be stratospheric at first: the vast Eclipse trial, designed to support FDA approval of the test in this setting, has not yet reported – the data might come at Asco next month. Approval for Shield, should it be granted, ought to allow sales-boosting reimbursement and guideline changes, though guidelines are unlikely to be updated before 2026, according to Stifel analysts. At that point Shield would amount to a major threat to Exact Sciences' Cologuard stool test, currently the leading non-invasive colorectal screen. In advance of the Eclipse readout, Guardant released new data from a smaller study indicating that Shield's sensitivity and specificity for detecting cancer were 91% and 92% respectively – competitive with Cologuard and the Clinical-stage-second-gen-version of that test. Guardant is also investigating Shield as a screen for lung, pancreatic and bladder cancers, but for now all the attention remains on Eclipse.

Guardant's liquid biopsies				
Company	Liquid biopsy	Intended use	Tumour type	Status
Guardant Health	Guardant360	Helps assign targeted therapy	Pan- cancer	Approved in US Aug 7, 2020, price approx \$6,800
	Reveal	Postsurgical, detects disease recurrence	Colorectal	Launched as LDT Feb 16, 2021
	Shield	Screening	Colorectal	Launched as LDT May 2, 2022, price TBD; pivotal <u>Eclipse trial</u> to report mid-2022
			Lung	Pivotal Shield trial to report 2024
			Pancreatic	In development
			Bladder	In development
LDT = lab-developed test. Source: Evaluate Medtech & company website.				

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