Evaluate Vantage

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Grail launches pan-cancer screen – for those who can pay out of pocket

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Grail's liquid biopsy today became the third pan-cancer blood test to be launched in the US. But it is being sold for a slightly different use versus the two approved tests. Galleri, which is not approved by the FDA but sold under a Clia waiver, is on sale as a screen, and can be used to test people aged over 50 at elevated risk of cancer. The other two tumour-agnostic liquid biopsies are used in patients who already have a confirmed cancer diagnosis, as a way to assess the mutations a tumour carries and therefore help assign targeted drugs. Grail is pitching its Galleri test at $949, quite a bit cheaper than both its rivals: Roche's FoundationOne Liquid CDx sells at $5,800 and Guardant's Guardant360 around $1,000 more than that. But the latter two have formal FDA approval, granted last August, making reimbursement easier – no reimbursement is yet in place for Galleri. Meanwhile Illumina's $8bn bid to acquire Grail is no nearer closing. The FTC recently withdrew a lawsuit seeking to block the acquisition, which sounds like good news, but is in fact the opposite. The suit will likely be refiled later, delaying the deal's close further.

Selected pan-cancer liquid biopsies – progress update

Company	Liquid biopsy	Use	Status in US	Company notes
Guardant Health	Guardant360	Helps assign targeted therapy	Approved Aug 7, 2020, price approx $6,800	$550m VC funding; floated in 2018
Foundation Medicine (Roche)	FoundationOne Liquid CDx	Helps assign targeted therapy	Approved Aug 27, 2020, price $5,800	$115m VC funding; bought by Roche for $2.5bn in 2015
Grail	Galleri	Screening for early detection and identification of tumour origin	Launched as LDT Jun 4, 2021, price $949	$2.1bn VC funding; bought by Illumina for $8bn in 2020
	Unnamed	Postsurgical, detects disease recurrence	In development	
Thrive Earlier Detection (Exact Sciences)	CancerSeek	Early detection	FDA breakthrough device status	$367m VC funding; bought by Exact Sciences in 2020 for $1.7bn
Natera	Signatera	Postsurgical, detects disease recurrence	FDA breakthrough device status	$152m in VC funding; floated in 2015
Archer DX (Invitae)	Stratafide	Helps assign targeted therapy	FDA breakthrough device status	$150m VC funding; bought by Invitae in 2020 for $1.4bn

LDT = lab-developed test. Source: EvaluateMedTech & company websites.