

One Test Premium vs Galleri for early-stage cancers

All Cancer		Lung		Liver		CRC		Pancreas						
Stage	OT-P	Galleri	Stage	OT-P	Galleri	Stage	OT-P	Galleri	Stage	OT-P	Galleri	Stage	OT-P	Galleri
All	62%	52%	All	51%	75%	All	89%	94%	All	72%	82%	All	93%	84%
I	44%	17%	I	33%	22%	I	86%		I	64%	43%	I	86%	62%
II	61%	40%	II	61%	80%	II	91%		II	80%	85%	II	96%	60%
III	77%	77%	III	53%	91%	III	100%		III	76%	88%	III	100%	86%
IV	86%	90%	IV	91%	95%	IV	100%		IV	100%	95%	IV	86%	96%
Prostate		Ovary		Breast		Gastric								
Stage	OT-P	Galleri	Stage	OT-P	Galleri	Stage	OT-P	Galleri	Stage	OT-P	Galleri	Stage	OT-P	Galleri
All	76%	11%	All	74%	83%	All	19%	31%	All	33%	67%			
I	100%		I	25%	50%	I	15%		I	27%	17%			
II	58%		II	100%	80%	II	15%		II	50%	50%			
III	89%		III	100%	87%	III	57%		III	80%	80%			
IV			IV	80%	95%	IV			IV		100%			

OneTest Premium data is provided by BioInfra. Galleri data is taken from Klein EA, Richards D, Cohn A, Tummala M, Lapham R, Cosgrove D, Chung G, Clement J, Gao J, Hunkapiller N, Jamshidi A, Kurtzman KN, Seiden MV, Swanton C, Liu MC. Clinical validation of a targeted methylation-based multi-cancer early detection test using an independent validation set. Ann Oncol. 2021 Sep;32(9):1167-1177. doi: 10.1016/j.annonc.2021.05.806. Epub 2021 Jun 24. PMID: 34176681. OneTest premium specificity is held at >98%, Galleri specificity is at 99.5%. This is case:control data for both tests.

Note on sensitivity of ctDNA

Pons-Belda, Fernandez-Uriarte, & Diamandis, “Can Circulating Tumor DNA Support a Successful Screening Test for Early Cancer Detection? The Grail Paradigm.”
Diagnostics 2021, 11, 2171

“When tumors are of this size or smaller, their MAF is about 0.01% (one tumor DNA molecule admixed with 10,000 normal DNA molecules). The use of 10 mL of blood (4 mL of plasma) will likely contain less than a complete cancer genome, thus rendering the diagnosis of cancer impossible. Grail’s new data confirm the low sensitivity for early cancer detection (<30% for Stage I–II tumors, <20% for Stage I tumors), but specificity was high at 99.5%. According to these latest data, the sensitivity of the Grail test is less than 20% in Stage I disease, casting doubt if this test could become a viable pan-cancer clinical screening tool.”