DNAvi Liquid Biopsy Report

based on ELBS recommendations, 2025

Created on: 2025-10-29 19:00:36

Disclaimer

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No warranty, express or implied, is given as to the accuracy or completeness of this report, and no liability will be accepted for any reliance placed upon its contents.

References

1. Jager, V. D. de et al. Reporting of molecular test results from cell-free DNA analyses: expert consensus recommendations from the 2023 European Liquid Biopsy Society ctDNA Workshop. eBioMedicine 114, (2025).

Section 1 - Intention of the test and patient Information

ID	Item	action	show
1.0	My patient(s) were informed about the potential consequences of unexpected or incidental findings	bool	True
2.0	Opt-out: My patient(s) do NOT wish to be informed about unexpected and/or incidental findings	opt	True
3.0	Test purpose (Why is this test performed):	info	True
4.0	Disease specifics	info	False
4.1	Pathological diagnosis	info	True
4.2	Disease stage	info	True
4.3	Burden of disease	info	True
4.4	Disease status	info	True
4.5	Previous and current oncological treatment	info	True
4.6	Previously diagnosed malignancies	info	True
4.7	Confirmed tumor predisposition	info	True
4.8	Mutations from previous tissue or liquid profiling	info	True
4.9	Previously identified CH (clonal hematopoiesis)-related variants	info	True
5.0	Other relevant available clinical information	info	True

Section 2 - Technical aspects – cfDNA sample

ID	Item	action	show
6.0	Sample QC	info	False
6.1	Macroscopic abnormalities (e.g. hemolysis)	info	True
6.2	Cell-free DNA isolation method	info	True
6.3	DNA input (low?)	info	True
6.3	Contamination with high molecular weight DNA	info	True
6.4	Any sample QC not meeting criteria?	flag	True

Section 3 - Technical aspects – downstream test

ID	Item	action	show
7.0	Downstream Test QC	info	False
7.1	Type of planned downstream assay	info	True
7.2	LOD (limit of detection)	info	True
7.3	LOB (limit of blank)	info	True
7.4	LOQ (limit of quantification)	info	True
7.5	analytical sensitivity	info	True
7.6	analytical specificity	info	True
7.7	Sequencing: percentage of target region covered with the minimum required depth	info	True
7.8	Sequencing: average sequencing depth	info	True
7.9	Any downstream QC not meeting criteria?	bool	True
8.0	Variant QC	info	False
8.1	Confirm: this report excludes variants with variant allele fraction (VAF) below or equal to the LOB.	confirm	True
8.2	Confirm: variants with VAF between LOB and LOD will be labeled ‘equivocal’ – their presence is uncertain	confirm	True
8.3	Recommendation for equivocal variants: (option corresponding tissue testing and/or liquid re-biopsy)	action	True

Section 4 - Downstream test results

ID	Item	action	show
9.0	Variant Report Option	info	False
9.1	Pathogenic and likely pathogenic variants (incl. number of supporting reads, sequencing depth, VAF, number of mutated molecules, confidence level)	info	True
9.2	Variants in cancer susceptibility genes with VAF indicating germline origin (incl. number of supporting reads, sequencing depth, VAF, number of mutated molecules, confidence level)	info	True
9.3	Potential CH-related variants (incl. number of supporting reads, sequencing depth, VAF, number of mutated molecules, confidence level)	info	True
9.4	Recommendation for putative germline variants: (option genetic counselling and/or germline testing)	action	True
9.5	SCNA & fusions (LOD for SCNA and fusions may be lower compared to SNVs/indels; detection requires a higher tumor fraction)	flag	True
9.6	SCNA (estimated copy number or log2 ratio, confidence level, potentially co-amplified genes and estimated size of the amplified/ deleted segment)	info	True
9.7	Negative results (Tumor fraction – Not detected or Requested mutation is not detected)	flag	True
9.8	Disclaimer – the presence of mutations below the LOD cannot be excluded.	confirm	True

Section 5 - Unexpected findings

ID	Item	action	show
10.0	Unexpected findings	flag	False
10.1	Explanation why the findings were unexpected	info	True
10.2	Recommendation for referral to a Molecular Tumor Board for discussion.	confirm	True

Section 6 - Actionability

ID	Item	action	show
11.0	Clinically actionable results and evidence-based associations with response to specific drugs	info	True
11.1	Disclaimer:The actual clinical annotation for matching a treatment to a specific variant for each individual patients should only be done by the treating physician or a Molecular Tumor Board (MTB).	confirm	True