xxx

Order no.: xxx
Order received: xxx
Sample type: blood, filter card
Sample collection date: xxx
Report date: xxx
Report type: Final Report

Patient no.: **xxx**, First Name: **xxx**, Last Name: **xxx**
DOB: **xxx**, Sex: **female**, Your ref.: **xxx**

Test(s) requested: CentoCancer® panel (sequencing)

CLINICAL INFORMATION

The patient with breast cancer (triple negative invasive ductal carcinoma), and biliary liver cirrhosis. She has also history of colon cancer (in 2005).

NEGATIVE RESULT

INTERPRETATION

No clinically relevant variant has been detected.

RECOMMENDATIONS

- Full gene coverage sequencing and deletion/duplication analysis of the relevant genes in the panel, specifically the BRCA1 and BRCA2 genes are recommended.
- Genetic counselling is recommended.

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ANALYSIS STATISTICS

Please be aware that NGS panels do not give full coverage for all genes. An overall coverage of 99.91% was achieved, with 142 missing base pairs (coding region including +/- 10bp). At your request, it is possible to test for every fragment with missing bases.

METHODS

Genomic DNA is enzymatically fragmented and regions of interest are selectively enriched using capture probes targeted against coding regions of panel genes. Libraries are generated with Illumina compatible adaptors and sequenced on an Illumina platform.
For the CentoCancer panel, the entire coding region of the APC, ATM, BARD1, BLM, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDK4, CDKN2A, CHEK2, EPCAM, FH, FLCN, HNF1A, HNF1B, HOXB13, MC1R, MEN1, MET, MITF, MLH1, MRE11A, MSH2, MSH6, MUTYH, NBN, NTHL1, PALB2, PMS1, PMS2, POLD1, POLE, POT1, PRSS1, PTCH1, PTEN, RAD50, RAD51C, RAD51D, RET, SDHA, SDHAF2, SDHB, SDHC, SDHD, SMAD4, STK11, TP53, TSC1, TSC2, VHL, WT1, XRCC2, XRCC3 genes including 10 bp of flanking intronic sequences are targeted. Due to limitations of the NGS analysis alone, the targeted region within the requested panel may not reach 100% coverage. Raw sequence data analysis, including base calling, demultiplexing, alignment to the hg19 human reference genome (Genome Reference Consortium GRCh37) and variant calling is performed using validated in-house software. All identified variants are evaluated with respect to their pathogenicity and causality, and these are categorized into classes 1 - 5. All variants related to the phenotype of the patient, except benign or likely benign variants, are reported.

ADDITIONAL INFORMATION

This test was developed and its performance validated by CENTOGENE AG. The US Food and Drug Administration (FDA) has determined that clearance or approval of this method is not necessary and thus neither have been obtained. This test has been developed for clinical purposes. All test results are reviewed, interpreted and reported by our scientific and medical experts.

To also exclude mistaken identity in your clinic, several guidelines recommend testing a second sample that is independently obtained from the proband. Please note that any further analysis will result in additional costs.

The classification of variants can change over the time. Please feel free to contact CENTOGENE (customer.customer.support@centogene.com) in the future to determine if there have been any changes in classification of any reported variants.

DISCLAIMER

Any preparation and processing of a sample from patient material provided to CENTOGENE by a physician, clinical institute or a laboratory (by a "Partner") and the requested genetic and/or biochemical testing itself is based on the highest and most current scientific and analytical standards. However, in very few cases genetic or biochemical tests may not show the correct result, e.g. because of the quality of the material provided by a Partner to CENTOGENE or in cases where any test provided by CENTOGENE fails for unforeseeable or unknown reasons that cannot be influenced by CENTOGENE in advance. In such cases, CENTOGENE shall not be responsible and/or liable for the incomplete, potentially misleading or even wrong result of any testing if such issue could not be recognized by CENTOGENE in advance.

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