



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: **male**, Your ref.: **xxx**

Additional report recipient(s): xxx

Test(s) requested: CentoXome®

CLINICAL INFORMATION

Abnormality of the urinary system; Autism; Delayed speech and language development; Global developmental delay; Intellectual disability; Nephrotic syndrome
(Clinical information indicated above follows HPO nomenclature.)

Family history: Unknown.

Siblings unaffected.

Consanguineous parents: Yes.



POSITIVE RESULT

Likely pathogenic variant identified

INTERPRETATION

A heterozygous likely pathogenic variant was identified in the SETD5 gene.

The result is consistent with a genetic diagnosis of autosomal dominant mental retardation type 23.

RECOMMENDATIONS

- We recommend parental carrier testing and genetic counseling.

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RESULT SUMMARY

GENE	VARIANT COORDINATES	AMINO ACID CHANGE	SNP IDENTIFIER	ZYGOSITY	IN SILICO PARAMETERS*	ALLELE FREQUENCIES**	TYPE AND CLASSIFICATION***
SETD5	NM_001080517.1:c.700G>T	p.(Glu234*)	N/A	heterozygous	PolyPhen: N/A Align-GVGD: N/A SIFT: N/A MutationTaster: Disease causing Conservation_nt: moderate Conservation_aa:	gnomAD: - ESP: - 1000 G: - CentoMD: -	Nonsense Likely Pathogenic (class 2)

Variant description based on OTFA (using VEP v93). * AlignGVD: C0: least likely to interfere with function, C65: most likely to interfere with function; splicing predictions: Ada and RF scores. ** Genome Aggregation Database (gnomAD), Exome Sequencing Project (ESP), 1000Genome project (1000G) and CentoMD® (latest database available). *** based on ACMG recommendations.

VARIANT INTERPRETATION

SETD5, c.700G>T p.(Glu234*)

The SETD5 variant c.700G>T p.(Glu234*) creates a premature stop codon. It is classified as likely pathogenic (class 2) according to the recommendations of Centogene and ACMG (please, see additional information below).

Pathogenic variants in the SETD5 gene have been associated with autosomal dominant mental retardation type 23, also known as intellectual disability-facial dysmorphism syndrome. The majority of affected patients have developmental delay, behavioral/psychiatric issues such as autism, and variable hand and skeletal abnormalities. So far patients with 3p25.3 deletions and few individuals with de novo sequence alterations have been described. Furthermore, apparently unaffected carrier mothers have been described, suggesting that the phenotype of SETD5 is more complex and variable than previously presented (OMIM®: 615761, PMID: 28881385).

INCIDENTAL FINDINGS

We did not detect any class 1 or 2 variants in the genes for which incidental findings are reported based on the ACMG guidelines.

TABULAR LIST OF ADDITIONAL PATHOGENIC AND LIKELY PATHOGENIC VARIANTS

To provide the most comprehensive and relevant genetic information, we below list selected variants found in severe and early onset disease genes of your patient. We consider these at the time of reporting as "pathogenic" and "likely pathogenic" (see our mutation database CentoMD® for further information). Variants not included and classified in the current release of CentoMD®, and low quality variants which usually represent technical artifacts, are not included. In our review, we follow an internally expert-curated list of more than 1.700 genes currently, as attached hereto.

The listed variants may not directly answer the diagnostic request, at least not with the clinical information provided to CENTOGENE or current scientific understanding of relevant genetic disease mechanisms. However, these variants may help to close a potential diagnostic gap with regard to the current disease and are therefore provided here for a full diagnostic overview.

Variants in genes related to late-onset diseases with unclear (considerably reduced) penetrance and/or cancer related genes with typically onset in adulthood only are not included in this list. This is therefore not a complete list of potentially relevant genetic variants in the patient and the classification of these variants may also change over time. CENTOGENE is not liable for any missing variant in this list and/or any provided classification of the variants at a certain point of time.

Insofar, as the identified variants may indicate (additional) genetic risks or diagnoses in the patient and/or his family and/or inform about reproductive risks, we strongly recommend to follow applicable local guidelines with regard to informing the patient about such findings. Particularly, if the patient decided not to be informed about "incidental findings" (to avoid any misunderstanding the list given here is not covering "incidental findings")

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according to ACMG), such are not reported in this variant list either, and you should carefully inform and check with the patient whether he/she wants to be informed about these additional variants.

GENE	VARIANT COORDINATES	AMINO ACID CHANGE	SNP IDENTIFIER	ZYGOSITY	IN SILICO PARAMETERS*	ALLELE FREQUENCIES**	TYPE AND CLASSIFICATION***
AAAS	NM_015665.5:c.1432C>T	p.(Arg478*)	rs121918548	heterozygous	PolyPhen: N/A Align-GVGD: N/A SIFT: N/A MutationTaster: Disease causing Conservation_nt: weak Conservation_aa:	gnomAD: 0.000043 ESP: - 1000 G: 0.000037 CentoMD: 0.00011	Nonsense Pathogenic (class 1)
GBE1	NM_000158.3:c.986A>G	p.(Tyr329Cys)	rs80338671	heterozygous	PolyPhen: - Align-GVGD: C65 SIFT: Deleterious MutationTaster: Disease causing Conservation_nt: high Conservation_aa: high	gnomAD: 0.00043 ESP: 0.00049 1000 G: 0.00020 CentoMD: 0.0069	Missense Pathogenic (class 1)

Variant description based on OTFA (using VEP v93). * AlignGVGD: C0: least likely to interfere with function, C65: most likely to interfere with function; splicing predictions: Ada and RF scores. ** Genome Aggregation Database (gnomAD), Exome Sequencing Project (ESP), 1000Genome project (1000G) and CentoMD® (latest database available). *** based on ACMG recommendations.

ANALYSIS STATISTICS WES

% TARGET NUCLEOTIDES COVERED			
0X	≥ 10X	≥ 20X	≥ 50X
0.03	99.77	99.32	87.44

CENTOGENE VARIANT CLASSIFICATION (BASED ON ACMG RECOMMENDATIONS)

Class 1 – Pathogenic

Class 2 – Likely pathogenic

Class 3 – Variant of uncertain significance (VUS)

Class 4 – Likely benign

Class 5 – Benign

Additionally, other types of clinical relevant variants can be identified (e.g. risk factors, modifiers).

METHODS

Double stranded DNA capture baits against approximately 36.5 Mb of the human coding exome (targeting >98% of the coding RefSeq and Gencode v28 regions, which was obtained from the human genome build GRCh37/hg19 on May 2018) were used to enrich target regions from fragmented genomic DNA with the Twist Human Core Exome Plus kit. The generated library is sequenced on an Illumina platform to obtain at least 20x coverage depth for >98% of the targeted bases. An in-house bioinformatics pipeline, including read alignment to GRCh37/hg19 genome assembly, variant calling and annotation, and comprehensive variant filtering is applied. All disease-causing variants reported in HGMD®, in ClinVar and in CentoMD® as well as all variants with minor allele frequency (MAF) below 1% in gnomAD database are considered. The investigation for relevant variants is focused on coding exons and flanking +/-20 intronic bases. All potential modes of inheritance patterns are considered. In addition, provided family history and clinical information are used to evaluate identified variants with respect to their pathogenicity and causality, and are categorized into classes 1 - 5 (see above). All variants related to the phenotype of the patient, except benign or likely benign variants, are reported.

Centogene has established stringent quality criteria and validation processes for variants detected by NGS. Low quality single nucleotide variants and all relevant deletion/insertion variants are confirmed by Sanger sequencing. Consequently, we warrant a specificity of >99.9% for all reported variants.

LIMITATIONS

The genetic results are interpreted in the context of the provided clinical findings, family history, and other laboratory data. Only variants in genes potentially related to the proband's medical condition are reported. Misinterpretation of results may occur if the provided information is

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inaccurate and/or incomplete. If the obtained genetic results do not concur with the clinical findings, additional testing should be considered.

Complex genetic events such as copy number variants, inversions, translocations and repeat expansions, may not be reliably detected with Exome Sequencing. In addition, due to technology limitations, certain regions may be either not or poorly covered. In these regions variants cannot be confidently detected. Extremely low coverage calls (homo/hemizygous or heterozygous calls with less than three or four reads, respectively) are expected to be artifacts based on our extensive validations and consequently are not considered during the analysis.

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.

In line with ACMG recommendations for reporting of incidental findings in clinical exome and genome sequencing (Genetics in Medicine, 2017; PMID: 27854360), we report incidental findings, i.e. pathogenic variants (class 1) and likely pathogenic variants (class 2) only in the recommended genes for the recommended phenotypes. For children (<15 years old), pathogenic and likely pathogenic variants in BRCA1/2, MLH1, MSH2, MSH6, PMS2 and MUTYH genes related to adult onset phenotypes are not reported.

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.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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Appendix - Current Gene List used for tabular list of additional pathogenic and likely pathogenic variants:

AAAS, AARS, ABAT, ABCA12, ABCB11, ABCB7, ABCC6, ABCC9, ABCD1, ABCD4, ABHD12, ABHD5, ACAD9, ACADM, ACADS, ACADVL, ACAN, ACAT1, ACE, ACO2, ACOX1, ACP5, ACSL4, ACTA1, ACTA2, ACTB, ACTG1, ACY1, ADA, ADAMTS2, ADAMTSL2, ADAR, ADGRG1, ADGRG6, ADGRV1, ADK, ADNP, ADPRHL2, ADSL, AFF2, AFG3L2, AGA, AGK, AGL, AGPS, AGRN, AGT, AGTR1, AGXT, AHDC1, AHI1, AIFM1, AIMP1, AIPL1, AIRE, AK2, AKR1D1, AKT3, ALDH18A1, ALDH1A3, ALDH3A2, ALDH4A1, ALDH5A1, ALDH7A1, ALDOA, ALDOB, ALG1, ALG11, ALG12, ALG13, ALG2, ALG3, ALG6, ALG8, ALG9, ALMS1, ALPL, ALS2, ALX3, ALX4, AMER1, AMPD1, AMPD2, AMT, ANK2, ANKH, ANKRD11, ANOS, ANTXR1, ANTXR2, AP1S2, AP3B2, AP4B1, AP4E1, AP4M1, AP4S1, APOPT1, APTX, AR, ARCN1, ARFGF2, ARG1, ARHGAP31, ARHGEF9, ARID1A, ARID1B, ARID2, ARL13B, ARL3, ARL6, ARMC4, ARMC9, ARSA, ARSB, ARSE, ARX, ASAH1, ASCC1, ASH1L, ASL, ASPA, ASPH, ASPM, ASS1, ASXL1, ASXL2, ASXL3, ATAD3A, ATIC, ATL1, ATOH7, ATP13A2, ATP1A1, ATP1A3, ATP6AP2, ATP6V0A2, ATP6V1A, ATP6V1B1, ATP6V1B2, ATP7A, ATP7B, ATP8A2, ATP8B1, ATRX, AUH, AUTS2, B3GALNT2, B3GALT6, B4GALT7, B9D1, BANF1, BBS1, BBS10, BBS12, BBS2, BBS4, BBS5, BBS7, BBS9, BCAP31, BCKDHA, BCKDHB, BCKDK, BCL11A, BCOR, BCS1L, BGN, BHLHA9, BICD2, BIN1, BLM, BMP2, BMP4, BMPER, BMPR1B, BOLA3, BPTF, BRAT1, BRD4, BRPF1, BRWD3, BSCL2, BSND, BTD, BTK, C12orf57, C12orf65, C1QBP, C2CD3, C8orf37, CA2, CA5A, CA8, CACNA1A, CACNA1C, CACNA1D, CACNA1E, CACNA1G, CAD, CAMK2A, CAMK2B, CAMTA1, CARLS2, CASK, CAV1, CBL, CBS, CC2D1A, CC2D2A, CCBE1, CCDC103, CCDC114, CCDC115, CCDC151, CCDC22, CCDC39, CCDC40, CCDC47, CCDC65, CCDC78, CCDC8, CCDC88A, CCDC88C, CCND2, CCNK, CCNO, CCNQ, CD40LG, CDC45, CDH23, CDH3, CDK10, CDK13, CDK5RAP2, CDKL5, CDKN1C, CDON, CDT1, CENPF, CENPJ, CEP104, CEP135, CEP152, CEP290, CEP41, CEP57, CEP63, CEP83, CFAP298, CFAP30, CFAP410, CFC1, CFL2, CFR, CHAMP1, CHAT, CHD2, CHD3, CHD4, CHD7, CHD8, CHM, CHMP1A, CHRDL1, CHRNA1, CHRNA2, CHRNA4, CHRN4, CHRD, CHRN2, CHRN3, CHRN4, CHST14, CHST3, CHSY1, CHUK, CIB2, CISD2, CIT, CKAP2L, CLCN1, CLCN4, CLCN7, CLCNKA, CLCNKB, CLDN1, CLDN19, CLMP, CLN3, CLN5, CLN6, CLN8, CLP1, CLPB, CLPP, CLRN1, CLTC, CNKSR2, CNPY3, CNTNAP1, CNTNAP2, COASY, COG1, COG4, COG5, COG7, COG8, COL10A1, COL11A1, COL11A2, COL11A3, COL17A1, COL18A1, COL1A1, COL1A2, COL2A1, COL4A1, COL4A2, COL4A3, COL4A3BP, COL4A4, COL4A5, COL6A1, COL6A2, COL6A3, COL7A1, COL9A1, COL9A2, COL9A3, COLEC10, COLEC11, COMP, COQ2, COQ4, COQ8A, COQ9, COX10, COX15, COX6B1, COX7B, CPLANE1, CPS1, CPT1A, CPT2, CRADD, CRB1, CRB2, CRBN, CREBBP, CRELD1, CRIPT, CRKL, CRLF1, CRTAP, CRX, CRYAA, CSNK2A1, CSSP1, CSTA, CSTB, CTC1, CTCF, CTDP1, CTNNA2, CTNNB1, CTNND1, CTNS, CTSA, CTSD, CTSK, CUL3, CUL4B, CUL7, CWC27, CYB5R3, CYC1, CYP11A1, CYP24A1, CYP27A1, CYP27B1, CYP2U1, CYP7B1, D2GH0D, DAG1, DARS, DARS2, DBT, DCAF17, DCDC2, DCHS1, DCLRE1C, DCX, DDB2, DDC, DDHD1, DDHD2, DDR2, DDH11, DDX3X, DDX59, DEAF1, DENND5A, DEPDG5, DGAT1, DGUOK, DHCR24, DHCR7, DHDDS, DHODH, DHTKD1, DHX30, DIAPH1, DIS3L2, DKC1, DLAT, DLL, DLG3, DLG4, DLL3, DLL4, DLX5, DMD, DMP1, DMPK, DNA2, DNAAF3, DNAAF4, DNAAF5, DNAH5, DNAH9, DNAJC12, DNAJC19, DNAJC3, DNMI1, DNMT3A, DNMT3B, DOCK6, DOCK7, DOCK8, DOK7, DOLK, DPAGT1, DPF2, DPM1, DPYD, DRC1, DSE, DSG1, DSP, DSTYK, DTNA, DVL1, DVL3, DYM, DYNCH1, DYNCH2, DYRK1A, EBF3, EBN, ECEL1, EDA, EDAR, EDNRB, EDNRB, EED, EEF1A2, EFEMP2, EFNB1, EFTUD2, EGR2, EHMT1, EIF2AK3, EIF2B1, EIF2B2, EIF2B3, EIF2B5, EIF2B3, EIF4A3, ELMO2, ELN, ELPV4, ELP1, ELP2, EMC1, EMD, EMG1, EMX2, ENPP1, ENTDP1, EOGT, EP65, EPHB4, EPM2A, EPRS, ERCC1, ERCC2, ERCC3, ERCC4, ERCC5, ERCC6L2, ERCC8, ERF, ERLIN2, ESCO2, ETTFA, ETFB, ETFDH, ETHE1, EVC, EVC2, EXOSC3, EXOSC9, EXPH5, EXT1, EXT2, EXTL3, EYA1, EZH2, FA2H, FAH, FAM111A, FAM126A, FAM161A, FAM20A, FAM20C, FANCA, FANCB, FANCC, FANCD2, FANCE, FANCF, FANCG, FANCI, FANCL, FANCLM, FAR1, FAR2, FASTKD2, FAT4, FBLN5, FBN1, FBX2, FBP1, FBXL4, FBXO11, FBXW4, FEZF1, FGA, FGB, FGD1, FGD4, FGF10, FGF12, FGF3, FGF8, FGF9, FGFFR1, FGG, FHL1, FIG4, FKBP14, FKRP, FKTN, FLAD1, FLNA, FLNB, FLT4, FLVCR1, FLVCR2, FMN2, FMR1, FN1, FOLR1, FOXC1, FOXC2, FOXE3, FOXF1, FOXG1, FOXL2, FOXN1, FOXP1, FOXP3, FOXRED1, FRAS1, FREM1, FREM2, FRMPD4, FRRS1L, FTCD, FTL, FTSJ1, FUCA1, FUT8, FXN, G6PC3, GAA, GABBR2, GABRA1, GABRB2, GABRB3, GABRG2, GALT, GALK1, GALS, GALT, GAMT, GAN, GASB, GATA1, GATA2, GATA3, GATA4, GATA6, GATAD2B, GATM, GBA, GBA2, GBE1, GCDH, GCH1, GDF1, GDF3, GDF5, GDF6, GDI1, GFAP, GFER, GFM1, GHR, GJA1, GJB8, GJB2, GJB3, GJC2, GK, GLA, GLB1, GLDC, GLDN, GLE1, GLI2, GLI3, GLIS3, GLMN, GLUD1, GLUL, GM2A, GMNN, GMPPA, GMPPB, GNA11, GNAI3, GNAO1, GNAQ, GNAS, GNB1, GNB5, GNPAT, GNPTAB, GNPTG, GNS, GORAB, GPPA1, GPC3, GPC6, GPHN, GPSM2, GPX4, GREB1L, GRHL2, GRHL3, GRIA3, GRIK2, GRIN1, GRIN2A, GRIN2B, GRIN2D, GRIPI1, GRM1, GSS, GTFH5, GTPBP3, GUCY2C, GUSB, GZF1, HACE1, HADH, HADHA, HADHB, HARS, HAX1, HBA1, HBB, HCCS, HCF1, HCN1, HDAC4, HDAC8, HECW2, HEXK1, HEXA, HEXB, HGSNAT, HIBCH, HINT1, HIST1H1E, HIVEP2, HLCS, HMGCL, HMGCS2, HMX1, HNF1B, HNF4A, HNRNP2H, HNRNPK, HNRNPJ, HOXA1, HOXA13, HOXC13, HOXD13, HPD, HPGD, HPRT1, HPS1, HPS2, HSD17B10, HSD17B4, HSD3B7, HSPD1, HSPG2, HUWE1, HYAL1, HYDIN, HYL5, IARS, IARS2, ICK, IDS, IDUA, IFIH1, IFITM5, IFT122, IFT140, IFT172, IFT43, IFT80, IGF1, IGF1R, IGF2, IGFBP7, IGHMBP2, IGSF1, IHH, IKBK, IL11RA, IL1RAPL1, IL2RG, IMPAD1, INPP5E, INPP5K, INPPL1, INSR, INVS, IQCBI, IQSEC2, IRF6, IRX5, ISPD, ITGA3, ITGA6, ITGA7, ITGA8, ITGB4, ITPR1, IVD, JAG1, JAHN1, JAK3, JAK3, KANK1, KANSL1, KARS, KAT6A, KAT6B, KBTBD13, KCNA2, KCNB1, KCNC1, KCNC3, KCNE1, KCNJ10, KCNJ11, KCNJ12, KCNJ6, KCNSA1, KCNQ1, KCNQ2, KCNQ3, KCNQ5, KCNT1, KCTD1, KCTD7, KDM5C, KDM6A, KIAA0586, KIAA1109, KIAA1279, KIDINS220, KIF11, KIF1A, KIF22, KIF2A, KIF5C, KIF7, KIRREL3, KIT, KLF1, KLHL14, KLHL40, KLHL7, KMT2A, KMT2C, KMT2D, KMT2E, KMT5B, KPTN, KRIT1, KR78, L1CAM, L2HFG3, NDE1, NDP, NDST1, NDUFA1, NDUFA10, NDUFA6, NDUFAF2, NDUFAF5, NDUFAF6, NDUFB8, NDUFS1, NDUFS2, NDUFS3, NDUFS4, NDUFS6, NDUFS7, NDUFS8, NDUFV1, NDUFV2, NEB, NECTIN1, NECTIN4, NEDD4L, NEK1, NEK8, NEU1, NEUROG3, NEXMIF, NF1, NFIA, 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