DeanHealthPlan
A member of SSM Health

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Genetic Testing for Reproductive Carrier Screening and Prenatal Care

MP9477

Covered Service:	Yes
Prior Authorization Required:	Yes
Additional Information:	Genetic testing is covered for a Dean Health Plan member if the test results provide a direct medical benefit or guides reproductive decision-making for the Dean Health Plan member. See Genetic Testing MP9012 for additional information
Medicare Policy:	Prior authorization is dependent on the member's Medicare coverage. Prior authorization is not required for Medicare Cost (Dean Care Gold) and Medicare Supplement (Select) when this service is provided by participating providers. Prior authorization is required if a member has Medicare primary and Dean Health Plan secondary coverage. This policy is not applicable to our Medicare Replacement products.
BadgerCare Plus Policy:	Dean Health Plan covers when BadgerCare Plus also covers the benefit.

Dean Health Plan Medical Policy:

1.0 **Spinal Muscular Atrophy SMA** carrier screening by SMN1 gene dosage analysis **does not** require prior authorization and is medically necessary for the purpose of reproductive screening when testing has not been previously performed.

1.1 For individuals with a family history of SMA, pre and post genetic counseling is recommended to discuss testing strategy due to the complex inheritance of this condition. For those with abnormal or unclear results, post-test genetic counseling is recommended.

2.0 **Hemoglobinopathies Molecular Testing** for couples planning pregnancy or seeking prenatal care, testing for hemoglobinopathies and thalassemias, testing for HBB, HBA1, HBA2 and HBB **requires prior authorization** through the Health Services Division and is medically necessary when **ANY** of the following criteria are met:

2.1 Individual to be tested has a family history of a hemoglobinopathy; **OR**

2.2 Individual to be tested has an affected or carrier family member with a known mutation; **OR**

2.3 Individual to be tested is suspected to have a hemoglobinopathy based on results of a complete blood count (CBC) and hemoglobin analysis (by electrophoresis, high performance liquid chromatography [HPLC] or isoelectric focusing)

3.0 **Genetic Testing for Recurrent Pregnancy Loss** (defined as 2 or more consecutive spontaneous abortions) **does not** require prior authorization and is considered medically necessary when **ANY** of the following criteria are met:

3.1 Karyotype (cytogenetic analysis) of parents to detect balanced chromosomal anomalies; **OR**

3.2 Karyotype and/or microarray of abortus tissue when a couple with recurrent pregnancy loss experiences a subsequent spontaneous abortion; **OR**

3.3 Measurement of anti-beta2-glycoprotein I (IgG or IgM) antibodies, anti-cardiolipin (IgG or IgM) antibodies, and lupus anticoagulant, using standard assays, for diagnosis of antiphospholipid syndrome.

4.0 The following genetic tests for the evaluation of recurrent pregnancy loss are considered experimental and investigational and therefore are not medically necessary:

4.1 F2 gene

4.2 F5 gene

4.3 MTHFR gene

5.0 **Sequencing-based non-invasive prenatal testing (NIPT)** (e.g. MaterniT21) **does not** require prior authorization and is considered medically necessary as a screening tool for trisomy 21 (Down syndrome), trisomy 18 (Edwards syndrome) or trisomy 13 (Patau syndrome) for members with a singleton pregnancy equal to or greater than 10 weeks gestation.

6.0 **Sequencing-based non-invasive prenatal testing (NIPT)** is considered experimental and investigational and therefore are not medically necessary for any other indication, including but not limited to the following:

6.1 Screening for microdeletions

6.2 Screening for autosomal trisomies other than 13, 18 and 21

6.3 Prenatal cell-free DNA testing for single gene conditions

6.4 Screening for a sex-chromosome aneuploidy

6.5 Vanishing twin syndrome

6.6 Whole genome NIPT

6.7 When used to determine genetic cause of miscarriage (e.g. missed abortion, incomplete abortion)

6.8 Screening for non-medical traits (e.g. biologic sex)

7.0 **Invasive Prenatal Testing of a Fetus does not** require prior authorization and is considered medically necessary when **EITHER** of the following criteria have been met:

7.1 Testing by CVS, amniocentesis and percutaneous umbilical blood sampling (PUBS) (cordocentesis) as ordered by an OB/GYN or MFM specialist for diagnosis of fetal chromosomal abnormalities; excluding universal carrier screening panels, **OR**

7.2 Microarray (karyotype and FISH (fluorescent in-situ hybridization) for prenatal testing or testing of products of conception.

8.0 **Chromosome Microarray Analysis (CMA) does not** require a prior authorization for prenatal testing of a condition associated with chromosomal imbalances including **ANY** of the following:

8.1 Abnormal fetal ultrasound findings, as indicated by **1 or more** of the following:

8.1.1 Fetal congenital anomaly plus another fetal risk factor (e.g. fetal growth retardation, fetal overgrowth, oligohydramnios, or polyhydramnios);

8.1.2 High-risk congenital anomaly (e.g. cerebellar hypoplasia, cleft lip and/or cleft palate, holoprosencephaly, hypoplastic left heart, omphalocele;

8.1.3 Multiple congenital anomalies

8.1.4 Nucal translucency of 3.5 mm or greater

8.2 Fetal demise or stillbirth

9.0 **Cystic Fibrosis (CF) Carrier Screening does not** require prior authorization.

10.0 **Cystic Fibrosis (CF) sequencing and deletion/duplication studies does not** require prior authorization and are considered medically necessary for the purpose of reproductive carrier screening when **ANY** of the following criteria are met:

10.1 The patient's reproductive partner is a carrier of a cystic fibrosis mutation; **OR**

10.2 The patient has symptoms consistent with CFTR-associated disease or atypical cystic fibrosis; **OR**

10.3 Family history of cystic fibrosis with no confirmed mutation.

11.0 **Ashkenazi Jewish carrier screening** by targeted mutation analysis for the following conditions **does not** require prior authorization and is medically necessary when an individual or their reproductive partner has Ashkenazi Jewish ancestry and of reproductive age.

11.1 Cystic fibrosis (CFTR gene)

11.2 Familial dysautonomia (Riley-Day syndrome; ELP1 gene)

11.3 Tay Sachs disease (HEXA gene)

11.4 Canavan disease (ASPA gene)

11.5 Fanconi anemia group C (FANC gene)

11.6 Niemann-Pick disease, type A and B (NPC1, NCP2, and SMPD1 genes)

11.7 Bloom syndrome (BLM gene)

11.8 Mucolipidosis type IV (MCOLN1 gene)

11.9 Gaucher disease, type I (GBA Gene)

12.0 Single gene reproductive carrier screening for familial genetic disorder **does not** require prior authorization and is medically necessary when **ANY** of the following criteria are met:

12.1 An individual's reproductive partner is a known carrier of a disease-causing mutation for a recessively inherited condition; **OR**

12.2 A diagnosis of a genetic disorder has been confirmed in an affected relative and **ONE** of the following:

12.2.1 A genetic mutation has been identified; **OR**

12.2.2 The affected relative has not had genetic testing and is unavailable for testing.

13.0 The following tests are **not** medically necessary for carrier screening in the general population:

13.1 Universal carrier screening panels

13.2 Full gene sequencing when targeted mutation testing of common variants is available

13.3 Whole exome sequencing

13.4 Additional conditions/genes not mentioned above

14.0 All other indications not listed above are considered experimental and investigational and therefore are not medically necessary.

15.0 Predictive algorithm reported as a risk score for preeclampsia (e.g. PIGF Preeclampsia Screen) is considered experimental and investigational and therefore not medically necessary.

CPT/HCPCS Codes Related to MP9477

* The list of codes (and their descriptors, if any) is provided for informational purposes only and may not be all inclusive or current. Listing of a code in this medical policy does not imply that the service described by the code is a covered or non-covered service. Benefit coverage for any service is determined by the member's policy of health coverage with Dean Health Plan. Inclusion of a code above does not imply any right to reimbursement or guarantee claim payment. Other medical policies may also apply.

CPT Code	Description
0012U	Germline disorders, gene rearrangement detection by whole genome next-generation sequencing, DNA, whole blood, report of specific gene rearrangement(s)
0060U	Twin zygosity, genomic targeted sequence analysis of chromosome 2, using circulating cell-free fetal DNA in maternal blood
0062U	Autoimmune (systemic lupus erythematosus), IgG and IgM analysis of 80 biomarkers, utilizing serum, algorithm reported with a risk score (e.g. SLE-key Rule Out)
0094U	Genome (eg, unexplained constitutional or heritable disorder or syndrome), rapid sequence analysis
0234U	MECP2 (methyl CpG binding protein 2) (eg, Rett syndrome), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions
0236U	SMN1 (survival of motor neuron 1, telomeric) and SMN2 (survival of motor neuron 2, centromeric) (eg, spinal muscular atrophy) full gene analysis, including small sequence changes in exonic and intronic regions, duplications and deletions, and mobile element insertions
0243U	Obstetrics (preeclampsia), biochemical assay of placental-growth factor, time-resolved fluorescence immunoassay, maternal serum, predictive algorithm reported as a risk score for preeclampsia (e.g. PIGF Preeclampsia Screen)

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CPT Code	Description
0252U	Fetal aneuploidy short tandem-repeat comparative analysis, fetal DNA from products of conception, reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplications, mosaicism, and segmental aneuploidy (e.g. POC (Products of Conception), Igenomix)
0253U	Reproductive medicine (endometrial receptivity analysis), RNA gene expression profile, 238 genes by next-generation sequencing, endometrial tissue, predictive algorithm reported as endometrial window of implantation (eg, pre-receptive, receptive, post-receptive) (e.g. ERA® (Endometrial Receptivity Analysis), Igenomix)
0254U	Reproductive medicine (preimplantation genetic assessment), analysis of 24 chromosomes using embryonic DNA genomic sequence analysis for aneuploidy, and a mitochondrial DNA score in euploid embryos, results reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplications, mosaicism, and segmental aneuploidy, per embryo tested (e.g. ERA® (Endometrial Receptivity Analysis), Igenomix)
81161	DMD (dystrophin) (eg, Duchenne/Becker muscular dystrophy) deletion analysis, and duplication analysis, if performed
81187	CNBP (CCHC-type zinc finger nucleic acid binding protein) (eg, myotonic dystrophy type 2) gene analysis, evaluation to detect abnormal (eg, expanded) alleles
81200	ASPA (aspartoacylase) (e.g., Canavan disease) gene analysis, common variants (e.g., E285A, Y231X)
81205	BCKDHB (branched-chain keto acid dehydrogenase E1, beta polypeptide) (e.g., maple syrup urine disease) gene analysis, common variants (e.g., R183P, G278S, E422X)
81209	BLM (Bloom syndrome, RecQ helicase-like) (e.g., Bloom syndrome) gene analysis, 2281del6ins7 variant
81220	CFTR (cystic fibrosis transmembrane conductance regulator) (e.g., cystic fibrosis) gene analysis; common variants (e.g., ACMG/ACOG guidelines)
81221	CFTR (cystic fibrosis transmembrane conductance regulator) (e.g., cystic fibrosis) gene analysis; known familial variants
81222	CFTR (cystic fibrosis transmembrane conductance regulator) (e.g., cystic fibrosis) gene analysis; duplication/deletion variants
81223	CFTR (cystic fibrosis transmembrane conductance regulator) (e.g., cystic fibrosis) gene analysis; full gene sequence

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81224	CFTR (cystic fibrosis transmembrane conductance regulator) (e.g., cystic fibrosis) gene analysis; intron 8 poly-T analysis (e.g., male infertility)
81228	Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number variants (e.g., bacterial artificial chromosome [BAC] or oligo-based comparative genomic hybridization [CGH] microarray analysis)
81229	Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities
81234	DMPK (DM1 protein kinase) (eg, myotonic dystrophy type 1) gene analysis; evaluation to detect abnormal (expanded) alleles
81239	DMPK (DM1 protein kinase) (eg, myotonic dystrophy type 1) gene analysis; characterization of alleles (eg, expanded size)
81240	F2 (prothrombin, coagulation factor II) (e.g., hereditary hypercoagulability) gene analysis, 20210G>A variant
81241	F5 (coagulation factor V) (e.g., hereditary hypercoagulability) gene analysis, Leiden variant
81242	FANCC (Fanconi anemia, complementation group C) (e.g., Fanconi anemia, type C) gene analysis, common variant (e.g., IVS4+4A>T)
81243	FMR1 (fragile X mental retardation 1) (eg, fragile X mental retardation) gene analysis; evaluation to detect abnormal (eg, expanded) alleles
81244	FMR1 (fragile X mental retardation 1) (eg, fragile X mental retardation) gene analysis; characterization of alleles (eg, expanded size and promoter methylation status)
81250	G6PC (glucose-6-phosphatase, catalytic subunit) (e.g., Glycogen storage disease, type 1a, von Gierke disease) gene analysis, common variants (e.g., R83C, Q347X)
81251	GBA (glucosidase, beta, acid) (e.g., Gaucher disease) gene analysis, common variants (e.g., N370S, 84GG, L444P, IVS2+1G>A)
81252	GJB2 (gap junction protein, beta 2, 26kDa, connexin 26) (eg, nonsyndromic hearing loss) gene analysis; full gene sequence

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CPT Code	Description
81253	GJB2 (gap junction protein, beta 2, 26kDa, connexin 26) (eg, nonsyndromic hearing loss) gene analysis; known familial variants
81254	GJB6 (gap junction protein, beta 6, 30kDa, connexin 30) (eg, nonsyndromic hearing loss) gene analysis, common variants (eg, 309kb [del(GJB6-D13S1830)] and 232kb [del(GJB6-D13S1854)])
81255	HEXA (hexosaminidase A [alpha polypeptide]) (e.g., Tay-Sachs disease) gene analysis, common variants (e.g., 1278insTATC, 1421+1G>C, G269S)
81257	HBA1/HBA2 (alpha globin 1 and alpha globin 2) (e.g., alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis, for common deletions or variant (e.g., Southeast Asian, Thai, Filipino, Mediterranean, alpha3.7, alpha4.2, alpha20.5, and Constant Spring)
81258	HBA1/HBA2 (alpha globin 1 and alpha globin 2) (eg, alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis; known familial variant
81259	HBA1/HBA2 (alpha globin 1 and alpha globin 2) (eg, alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis; full gene sequence
81260	IKBKAP (inhibitor of kappa light polypeptide gene enhancer in B-cells, kinase complex-associated protein)
81265	Comparative analysis using Short Tandem Repeat (STR) markers; patient and comparative specimen (eg, pre-transplant recipient and donor germline testing, post-transplant non-hematopoietic recipient germline [eg, buccal swab or other germline tissue sample] and donor testing, twin zygosity testing, or maternal cell contamination of fetal cells)
81266	Comparative analysis using Short Tandem Repeat (STR) markers; each additional specimen (eg, additional cord blood donor, additional fetal samples from different cultures, or additional zygosity in multiple birth pregnancies) (List separately in addition to code for primary procedure)
81269	HBA1/HBA2 (alpha globin 1 and alpha globin 2) (eg, alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis; duplication/deletion variants

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CPT Code	Description
81290	MCOLN1 (mucolipin 1) (e.g., Mucolipidosis, type IV) gene analysis, common variants (e.g., IVS3-2A>G, del6.4kb)
81291	MTHFR (5,10-methylenetetrahydrofolate reductase) (e.g., hereditary hypercoagulability) gene analysis, common variants (e.g., 677T, 1298C)
81302	MECP2 (methyl CpG binding protein 2) (e.g., Rett syndrome) gene analysis; full sequence analysis
81303	MECP2 (methyl CpG binding protein 2) (eg, Rett syndrome) gene analysis; known familial variant
81304	MECP2 (methyl CpG binding protein 2) (eg, Rett syndrome) gene analysis; duplication/deletion variants
81329	SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; dosage/deletion analysis (eg, carrier testing), includes SMN2 (survival of motor neuron 2, centromeric) analysis, if performed
81330	SMPD1(sphingomyelin phosphodiesterase 1, acid lysosomal) (e.g., Niemann-Pick disease, Type A) gene analysis, common variants (e.g., R496L, L302P, fsP330)
81331	SNRPN/UBE3A (small nuclear ribonucleoprotein polypeptide N and ubiquitin protein ligase E3A) (eg, Prader-Willi syndrome and/or Angelman syndrome), methylation analysis
81336	SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; full gene sequence
81337	SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; known familial sequence variant(s)
81361	HBB (hemoglobin, subunit beta) (eg, sickle cell anemia, beta thalassemia, hemoglobinopathy); common variant(s) (eg, HbS, HbC, HbE)
81362	HBB (hemoglobin, subunit beta) (eg, sickle cell anemia, beta thalassemia, hemoglobinopathy); known familial variant(s)
81363	HBB (hemoglobin, subunit beta) (eg, sickle cell anemia, beta thalassemia, hemoglobinopathy); duplication/deletion variant(s)
81364	HBB (hemoglobin, subunit beta) (eg, sickle cell anemia, beta thalassemia, hemoglobinopathy); full gene sequence
81400	Molecular Pathology Procedure Level 1
81401	Molecular Pathology Procedure Level 2

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CPT Code	Description
81403	Molecular Pathology Procedure Level 4
81404	Molecular Pathology Procedure Level 5
81405	Molecular Pathology Procedure Level 6
81406	Molecular Pathology Procedure Level 7
81407	Molecular Pathology Procedure Level 8
81408	Molecular Pathology Procedure Level 9
81412	Ashkenazi Jewish associated disorders (eg, Bloom syndrome, Canavan disease, cystic fibrosis, familial dysautonomia, Fanconi anemia group C, Gaucher disease, Tay-Sachs disease), genomic sequence analysis panel, must include sequencing of at least 9 genes, including ASPA, BLM, CFTR, FANCC, GBA, HEXA, IKBKAP, MCOLN1, and SMPD1
81415	Exome (e.g., unexplained constitutional or heritable disorder or syndrome); sequence analysis
81416	Exome (e.g., unexplained constitutional or heritable disorder or syndrome); sequence analysis, each comparator exome (e.g., parents, siblings) (List separately in addition to code for primary procedure)
81417	Exome (e.g., unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously obtained exome sequence (e.g., updated knowledge or unrelated condition/syndrome)
81420	Fetal chromosomal aneuploidy (e.g., trisomy 21, monosomy X) genomic sequence analysis panel, circulating cell-free fetal DNA in maternal blood, must include analysis of chromosomes 13, 18, and 21
81422	Fetal chromosomal microdeletion(s) genomic sequence analysis (e.g., DiGeorge syndrome, Cri-du-chat syndrome), circulating cell-free fetal DNA in maternal blood
81425	Genome (e.g., unexplained constitutional or heritable disorder or syndrome); sequence analysis
81426	Genome (e.g., unexplained constitutional or heritable disorder or syndrome); sequence analysis, each comparator genome
81427	Genome (e.g., unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously obtained genome sequence (e.g., updated knowledge or unrelated condition/syndrome)

CPT Code	Description
81442	Noonan spectrum disorders (e.g., Noonan syndrome, cardio-facio-cutaneous syndrome, Costello syndrome, LEOPARD syndrome, Noonan-like syndrome), genomic sequence analysis panel, must include sequencing of at least 12 genes, including BRAF, CBL, HRAS, KRAS, MAP2K1, MAP2K2, NRAS, PTPN11, RAF1, RIT1, SHOC2, and SOS1
81443	Genetic testing for severe inherited conditions (eg, cystic fibrosis, Ashkenazi Jewish-associated disorders [eg, Bloom syndrome, Canavan disease, Fanconi anemia type C, mucolipidosis type VI, Gaucher disease, Tay-Sachs disease], beta hemoglobinopathies, phenylketonuria, galactosemia), genomic sequence analysis panel, must include sequencing of at least 15 genes (eg, ACADM, ARSA, ASPA, ATP7B, BCKDHA, BCKDHB, BLM, CFTR, DHCR7, FANCC, G6PC, GAA, GALT, GBA, GBE1, HBB, HEXA, IKBKAP, MCOLN1, PAH)
81460	Whole mitochondrial genome (eg, Leigh syndrome, mitochondrial encephalomyopathy, lactic acidosis, and stroke-like episodes [MELAS], myoclonic epilepsy with ragged-red fibers [MERFF], neuropathy, ataxia, and retinitis pigmentosa [NARP], Leber hereditary optic neuropathy [LHON]), genomic sequence, must include sequence analysis of entire mitochondrial genome with heteroplasmy detection
81465	Whole mitochondrial genome large deletion analysis panel (eg, Kearns-Sayre syndrome, chronic progressive external ophthalmoplegia), including heteroplasmy detection, if performed
81470	X-linked intellectual disability (XLID) (eg, syndromic and non-syndromic XLID); genomic sequence analysis panel, must include sequencing of at least 60 genes, including ARX, ATRX, CDKL5, FGD1, FMR1, HUWE1, IL1RAPL, KDM5C, L1CAM, MECP2, MED12, MID1, OCRL, RPS6KA3, and SLC16A2
81471	X-linked intellectual disability (XLID) (eg, syndromic and non-syndromic XLID); duplication/deletion gene analysis, must include analysis of at least 60 genes, including ARX, ATRX, CDKL5, FGD1, FMR1, HUWE1, IL1RAPL, KDM5C, L1CAM, MECP2, MED12, MID1, OCRL, RPS6KA3, and SLC16A2
81479	Unlisted molecular pathology procedure
81507	Fetal aneuploidy (trisomy 21, 18, and 13) DNA sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy

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81599	Unlisted multianalyte assay with algorithmic analysis
86146	Beta 2 Glycoprotein I antibody, each
86147	Cardiolipin (phospholipid) antibody, each Ig class
88230	Tissue culture for non-neoplastic disorders; lymphocyte
88233	Tissue culture for non-neoplastic disorders; skin or other solid tissue biopsy
88235	Tissue culture for non-neoplastic disorders; amniotic fluid or chorionic villus cells
88248	Chromosome analysis for breakage syndromes; baseline breakage, score 50-100 cells, count 20 cells, 2 karyotypes (eg, for ataxia telangiectasia, Fanconi anemia, fragile X)
88261	Chromosome analysis; count 5 cells, 1 karyotype, with banding
88262	Chromosome analysis; count 15-20 cells, 2 karyotypes, with banding
88267	Chromosome analysis, amniotic fluid or chorionic villus, count 15 cells, 1 karyotype, with banding
88269	Chromosome analysis, in situ for amniotic fluid cells, count cells from 6-12 colonies, 1 karyotype, with banding
88271	Molecular cytogenetics; DNA probe, each (e.g., FISH)
88273	Molecular cytogenetics; chromosomal in situ hybridization, analyze 10-30 cells (e.g., for microdeletions)
88274	Molecular cytogenetics; interphase in situ hybridization, analyze 25-99 cells
88275	Molecular cytogenetics; interphase in situ hybridization, analyze 100-300 cells
88280	Chromosome analysis; additional karyotypes, each study
88285	Chromosome analysis; additional cells counted, each study
S3845	Genetic testing for alpha-thalassemia
S3846	Genetic testing for hemoglobin e beta-thalassemia
S3849	Genetic testing for Niemann-pick disease
S3850	Genetic testing for sickle cell anemia
S3853	Genetic testing for myotonic muscular dystrophy

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