

Prevail Therapeutics' Sponsored Genetic Testing Program

General Information

- Eligibility:
 - Persons affected: Yes; program includes testing for patients diagnosed with amyotrophic lateral sclerosis (ALS), Parkinson's disease (PD), frontotemporal degeneration (FTD), Alzheimer's disease with onset before 65 years of age, hereditary prion disease, or unaffected individuals with a family history of any of these conditions diagnosed in a relative under the age of 65.
 - Unaffected persons with family history: Yes
- Cost: \$0 (optional pre-test counseling is \$125)
- Testing available outside the U.S.: Yes, Australia, Brazil, Canada
- Primary Program Limitations: Exclusion of *C9orf72* gene; cost to patient for pre-test counseling

Laboratory Information

- Lab: Invitae
- CLIA Certified: Yes
- Genes Included:
 - *GRN*
 - *MAPT*
 - Others: *ALS2, ANG, ANXA11, APP, CHCHD10, CHMP2B, DCTN1, ERBB4, FUS, HEXA, HNRNPA2B1, ITM2B, KIF5A, OPTN, PFN1, PRNP, PSEN1, PSEN2, SETX, SNCA, SOD1, SORL1, SPG11, SQSTM1, TARDBP, TBK1, TFG, TREM2, UBQLN2, VAPB, VCP, ATP13A2, DDHD1, ERLIN1, FIG4, LRRK2, MATR3, NEFH, SIGMAR1, TIA1*
- Test Limitations: Excludes *C9orf72*
- Sample type: Saliva; other options may be available

Genetic Counseling (GC)

- GC Provider: Genome Medical
- Counselors certified by ABGC: Yes
- Counselors with neurodegenerative disease experience licensed in all states requiring licensure: Yes
- Counselors experienced in neurodegenerative disease: Patients are only scheduled with genetic counselors on Genome Medical's neurology team
- Pre-testing counseling provided: No, available for \$125
- Post-testing counseling provided: Yes
- Offers in-house physician ordering: Yes, after pre-test counseling

Privacy/Legal Considerations

- Validation of Patient Competence: Clinical judgment; genetic counselor will defer testing and ask for a power of attorney (POA) if needed.
- Data sharing: Results go to patient and physician. De-identified information goes to sponsors, no protected health information (PHI) is shared. Sponsors may receive contact information for healthcare providers (HCP) who use the program.
- Consent: Verbal consent for testing documented in visit summary. Written consent for counseling.

Links

- [Prevail Therapeutics sponsorship statement](#)
- [Invitae website for program](#)

KEY

ABGC = American Board of Genetic Counseling
ACMG = American College of Medical Genetics and Genomics
CLIA = Clinical Laboratory Improvement Amendment
GC = genetic counseling, genetic counselor
HCP = healthcare provider
PHI = personal health information, protected health information
POA = power of attorney