Passage Bio’s Sponsored Genetic Testing Program

General Information
- Eligibility:
  - Persons affected: Yes
  - Unaffected persons with family history: Yes; eligibility includes unaffected family members if they have a close relative (parent, sibling, adult child) with a GRN gene mutation
- Cost: $0
- Testing available outside the U.S.: No

Laboratory Information
- Lab: Prevention Genetics
- CLIA Certified: Yes
- Genes Included:
  - GRN
  - C9orf72
  - MAPT
  - Others: APP, CHCHD10, CHMP2B, CSF1R, DCTN1, FUS, ITM2B, PSEN1, PSEN2, SQSTM1, TARDBP, TBK1, TREM2, UBQLN2, VCP
- Test Limitations: C9orf72 expansion test result typically does not include exact repeat number
- Sample type: Buccal (cheek) swab; other options may be available

Genetic Counseling (GC)
- GC Provider: InformedDNA
- Counselors certified by ABGC: Yes
- Counselors with neurodegenerative disease experience licensed in all states requiring licensure: Yes
- Counselors experienced in neurodegenerative disease: Participants have the option to schedule post-testing counseling with GCs on InformedDNA’s neurology team
- Pre-testing counseling provided: Yes
- Post-testing counseling provided: Yes
- Offers in-house physician ordering: Yes, after pre-test genetic counseling

Privacy/Legal Considerations
- Validation of Patient Competence: Clinical judgment; genetic counselor will ask for power of attorney (POA) or have patient sign a healthcare surrogacy form identifying a family member to speak on their behalf.
- Data sharing: Results go to patient and physician. De-identified information goes to sponsors, no protected health information (PHI) is shared.
- Consent: Verbal consent for testing documented in visit summary; written consent in states if required. Written consent for counseling.

Links
- Passage Bio website – press release
- InformedDNA 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