

# Frequently Asked Questions (FAQs)



## Related to Plasma Biomarker Screening in the AHEAD Study

### Questions you may have before signing screening consent:

#### Why am I taking a blood test?

- We use a quick and simple blood test as a first step in the screening process to determine if someone may be eligible to participate in the AHEAD Study.
- The blood test is helpful to show if a person is more or less likely to have amyloid build-up in the brain.
- Only people with amyloid in the brain are eligible for the AHEAD Study, so the blood test can help identify people who are not likely to qualify for the study.

#### Has this blood test been used in other studies? How many studies have been done?

- There have been about 10 studies of this blood test conducted across the full spectrum of Alzheimer's disease, from people who do not have any symptoms to people with dementia.

#### How accurate is the blood test?

- While this blood test is reasonably accurate at detecting if a person has amyloid plaques in their brain, it is used differently in the AHEAD Study.
- It is mainly used to rule out people who are not likely to qualify and should not move forward with the next step in the screening process: the amyloid PET scan, which is more definitive than the blood test.
- Some people whose blood test indicates that they are at increased likelihood of being eligible for the AHEAD Study will not show amyloid build-up on the screening amyloid PET scan.

#### When will I get results and how will the results be shared?

- It takes about 2 to 4 weeks from the time the blood sample is shipped and analyzed at a central lab before you receive your results from your study site.
- You will be notified whether or not you are eligible to move forward in the study.

#### How will this blood test be used?

- The blood test is a screening test that will indicate whether you are eligible to move to the later step in the screening process: the amyloid PET scan.
- Your blood test results will also help us learn more about how this test works in different groups of people and how this test can be used to screen and enroll people in other Alzheimer's disease research studies.

#### Will this test be shared with my primary physician and/or specialists?

- As this is part of a clinical research study and researchers are working to learn more about the blood test values in people who do not have symptoms of Alzheimer's disease, the only result that can be shared with your doctor is whether or not you are eligible to move forward in the screening process based on your blood results.

#### Will the result of this test affect my eligibility for other research studies?

- The result of your blood test will not directly affect your eligibility for other studies.
- If you are not eligible for the AHEAD Study, you may be eligible for other studies. There are many types of aging and Alzheimer's disease studies for which you may be eligible.
- Please ask your local study staff what other aging and Alzheimer's disease studies may be available to you.

#### If I'm already taking part in the APT Webstudy (or other studies), can I still do this trial?

- Yes – If you are already participating in the APT Webstudy or another registry, you can participate in the AHEAD Study.
- However, if you enroll in the AHEAD Study, you should discuss any plans to enroll in other research studies with the AHEAD Study team. A person should not enroll in two clinical trials (studies of a treatment) at one time.

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## Questions you may have if you are deemed ineligible for the AHEAD Study based on blood results:

### Does this mean I'm not going to get Alzheimer's? How much can I trust a negative result?

- This blood test **cannot** predict with certainty whether a person will or will not develop memory loss associated with Alzheimer's disease in their lifetime, regardless of the result.
- If you are not eligible based on your blood test, it is less likely that you currently have elevated brain amyloid levels. That means you may be **less likely** to develop Alzheimer's disease in the next few years, compared to someone who already has elevated brain amyloid levels.
- A person's brain amyloid levels can change with time, over many years. So a person not eligible for this study now could be eligible years from now.
- There are other things that can cause the sort of memory loss associated with Alzheimer's disease, and this blood test only examines one of the contributing factors—presence of amyloid—at one finite point in your life.
- Everyone should take precautions to lower their own risk of developing memory issues later in life by eating a healthy diet, staying physically active, getting enough sleep, and maintaining a healthy brain through socializing with friends, word games and other brain-stimulating activities.

### Does my race or ethnicity impact these blood tests?

- While we do know that people of some races or ethnicities are at greater risk for symptoms associated with Alzheimer's disease, we do not yet know if there will be racial or ethnic differences in the results of this blood test.
- That is why it is important to have people from diverse racial and ethnic backgrounds screened to participate in this and other studies. Only then will we be able to determine if there are measurable differences in blood test results among people of different racial and ethnic backgrounds.

### I'm ineligible, but can you tell anything else from the blood test results?

- At this point, the only information that can be provided based on this blood test is whether a person is eligible or not to proceed with screening for the AHEAD Study.

### Will I retest at some point?

- We do not expect differences in results within one year on either the blood test or the amyloid PET scan. You do not need to retake either the blood test or the PET scan in the short term.
- Among people invited to continue screening, the information from this and later blood tests will be used to learn more about changes over time. If you are not eligible to continue screening for the AHEAD Study, you may be invited to participate in future studies.

## Questions you may have if you are deemed eligible for the AHEAD Study based on plasma results and are invited to have an amyloid PET scan:

### Does this mean I am going to get Alzheimer's? What's my risk?

- This blood test cannot tell you whether you will develop memory loss associated with Alzheimer's disease in your lifetime.
- This blood test only tells us if you have a reasonable chance of being eligible for the AHEAD Study.
- To be fully eligible for the AHEAD Study, a person must have elevated amyloid levels measured on an amyloid PET scan, a type of brain image that measures amyloid plaque build-up.
- Some people's blood test will indicate they are eligible to have an amyloid PET scan but will not qualify for the AHEAD Study based on the results of their PET scan.
- Even for people who qualify for the AHEAD Study based on the blood test and the amyloid PET results, this does not mean that they will definitely develop memory loss or other cognitive symptoms caused by Alzheimer's disease.

### What does it mean when my blood test is eligible, but my PET scan is not? Why are they different? Should I retake one of them? Is the PET scan more reliable or the blood test?

- Amyloid PET scans are the gold standard for determining whether there is amyloid plaque build-up in the brain.
- We use this blood test to help find people who might have evidence of amyloid in their brain and then an amyloid PET scan is needed to determine if they are eligible for the AHEAD Study.
- We do not expect differences in results within 1 year on either the blood test or the amyloid PET scan. You do not need to retake either the blood test or the PET scan in the short term.

### Can I do the PET scan before the cognitive tests?

- No, you will have to do the cognitive tests before the PET scan, as we need more information to determine whether you may be eligible for this clinical trial.
- The cognitive tests are the best way for us to learn about how your brain is working and to tell if a drug is affecting brain function during the trial.
- During the cognitive tests, just do the best you can. There is no expectation for how you should do, and there is no perfect score. The tests are designed to be challenging so we may better assess your brain function.

### Can I bring a friend or family member to the test for support?

- Yes, we encourage it. Participants in this study need to have a Study Partner. Your Study Partner does not need to attend every visit, but they are welcome to attend any visit to provide you with support. You can check with your local study site to confirm who may be able to attend your visits with you.

**Please reach out to your local study site if you have any questions about how to manage the information/results once received.**