

Instructions for CSF collection for Alzheimer's biomarker testing

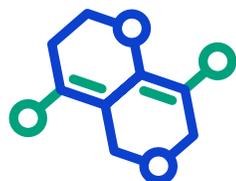
Ordering the Alzheimer's CSF biomarkers requires careful adherence to pre-analytical sample handling procedures,



which are based on recommendations from the Alzheimer's Association International guidelines.^{1,2}

Why are there specific collection and handling requirements for these tests?

Mainly due to the particularities of the Abeta42 peptides which are sticky and adsorb to the surfaces of certain types of plastic tubes. CSF exposed to polystyrene tubes leads to 20–50% reduction in Abeta42 concentration due to adherence. The Abeta42 biomarker is highly influenced by pre-analytical handling (especially by the tube type, fill volume, and transport conditions) and requires additional precautions in order to avoid Abeta42 loss.²



Adherence to the pre-analytical protocol (detailed on the back of this card) is essential for validity of results.



What are the specific instructions for collection?

1. The first 2 mL of CSF should be discarded or NOT be used for the Elecsys® CSF assay testing.
2. CSF visibly contaminated with blood should not be used for this analysis. Instead, collect additional clear (non-hemolytic) CSF in a new CSF tube.
3. The drip method is recommended for CSF collection. Avoid uses of syringes or extension tubing.
4. The CSF intended for Alzheimer's biomarker testing should be collected directly into the low-bind tube. The tube should be filled to the mark.
5. Tube type: 2.5 mL low bind false bottom tube (Sarstedt, 63.614.625). *Polystyrene collection tubes are not acceptable as exposing of CSF to polystyrene tubes may decrease Abeta42 concentrations.*
6. Do not aliquot, the analysis will be performed in the collection tube.
7. Send to the laboratory by following instructions for storage and transport.



What if I have more questions about these tests?

Please contact your laboratory for important ordering, collection, handling and transport instructions. Your lab can provide you with the assay package insert and additional guidance, and in some cases also with the appropriate collection tubes.



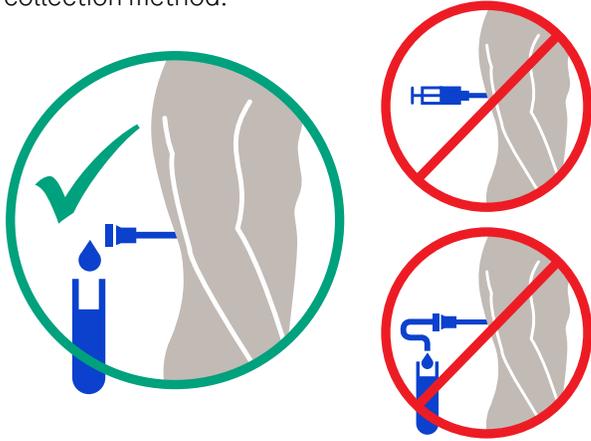
Procedure and handling

The Alzheimer's Association recommends a standardized protocol based on the drip collection method which reduces binding of Abeta42 to the syringe and instead **directly** collecting in a low bind tube.²

This protocol was the basis of the Elecsys® CSF assays protocol recommended in the package inserts.

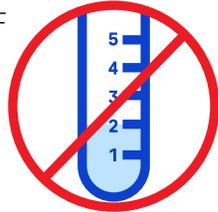
Step 1

Perform the lumbar puncture (LP) using gravity drip collection method.



Step 2

Do not use the first 2 mL of CSF for Elecsys® AD biomarker measurement.



*The tube required for CSF collection

(but not available through Roche):

Product: 2.5 mL low bind false bottom tube

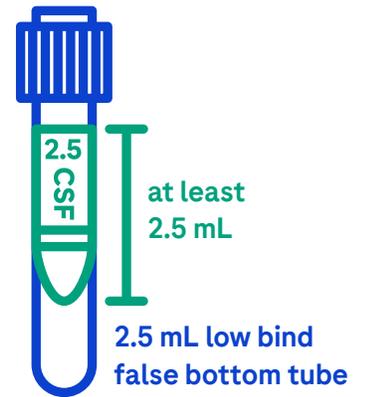
Order Number: 63.614.625

Vendor: Sarstedt



Step 3

Subsequently collect at least 2.5 mL of CSF directly into the CSF tube (2.5 mL low bind false bottom tube).



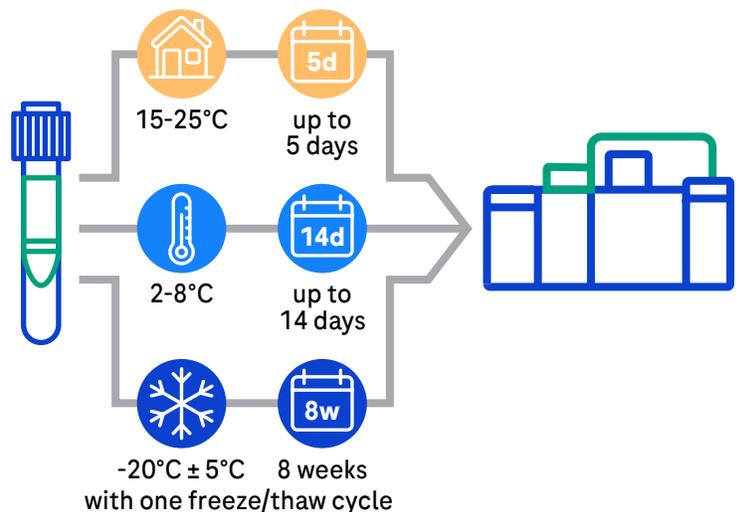
Step 4

Do not process the CSF sample before transport to the measuring site (e.g., no mixing/inverting, no tube transfers, no aliquoting, no freezing, and normally no centrifugation) until measurement.

Step 5

Transport the samples to the measuring site (laboratory), where the sample is placed directly on the **cobas e** system for measurement.¹

The CSF sample can be analyzed immediately after collection by directly placing the tube with false bottom CSF, 2.5 mL onto the analyzer. If storage and/or transport is necessary, samples can be transported/stored according to the graphic below.



1. Hansson O, et al. *Alzheimers Dement.* 2020;12:e12137
2. Elecsys® Method Sheets: ms_08821909501, ms_08821941501, ms_08846693501, ms_08846715501; https://www.accessdata.fda.gov/cdrh_docs/reviews/K231348.pdf Accessed July 14, 2023

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