

Biomarkers for Alzheimer testing in routine

INNOTEST® immunoassays for the quantification of β -amyloid₍₁₋₄₂₎, β -amyloid₍₁₋₄₀₎, total tau and phospho-tau_(181P) in cerebrospinal fluid

ORDERING INFORMATION

PRODUCT	PRODUCT DESCRIPTION		ARTICLE NO.
INNOTEST® β -AMYLOID ₍₁₋₄₂₎	96 tests/kit	CE-IVD	81576***
A β ₍₁₋₄₂₎ CAL-RVC pack		CE-IVD	81577***
A β ₍₁₋₄₂₎ HS Conj	96 tests/kit	RUO	81587***
INNOTEST® β -AMYLOID ₍₁₋₄₀₎	96 tests/kit	CE-IVD	80462***
A β ₍₁₋₄₀₎ CAL-RVC pack		CE-IVD	80461***
INNOTEST® hTAU Ag	96 tests/kit	CE-IVD	81572
Tau Ag CAL-RVC pack		CE-IVD	81573
INNOTEST® PHOSPHO-TAU _(181P)	96 tests/kit	CE-IVD	81574
PHOSPHO-TAU CAL-RVC pack		CE-IVD	81575

* Slaets et al., J Alzheimers Dis. 2013; 36(4): 759-767 - Tabaraud et al., Acta Neurol Scand. 2012; 125(6): 416-423 - McKhann et al., Alzheimers Dement 2011; 7(3): 263-269 - Hansson et al., Lancet Neurol 2006; 5: 228-234 - Mattsson et al., JAMA 2009; 302(4): 385-393 - Bucchave et al., Arch Gen Psychiatry 2012; 69(1): 98-106.

** Dumurgier et al., Alzheimers Res. Ther. 2015; 7 (1):30.

*** A license for the use of amyloid beta monoclonal antibodies contained in this product under patents US 6114133, US7811769, and EP 0792458 has been obtained from Eli Lilly and Company.

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The next step for INNOTEST® Alzheimer assays

- Ready-to-use calibrators
- Assay run validation
- Easier test automation
- Reduced inter- and intra-run variation
- Generic and color-coded reagents
- CE mark of INNOTEST β -AMYLOID₍₁₋₄₀₎

Single-analyte assays using ELISA technology



CLINICAL BACKGROUND

Alzheimer's disease (AD) is the most common form of dementia and is histologically characterized by the accumulation of **extracellular amyloid plaques** and **intracellular neurofibrillary tangles** throughout the brain. The major constituents of amyloid plaques are the **β -amyloid peptides consisting of 40 and 42**

amino acids, which are derived from the amyloid precursor protein. Neurofibrillary tangles are made up of paired helical filaments consisting of **hyperphosphorylated tau protein** (phospho-tau). Tau protein, present in the brain in **6 different isoforms**, is an intracellular protein that is released upon neuronal death.

INTENDED USE

The INNOTEST[®] assays described here are solid-phase enzyme immunoassays for the quantitative determination of β -amyloid₍₁₋₄₂₎, β -amyloid₍₁₋₄₀₎, total tau and phospho-tau_(181P) in human cerebrospinal fluid (CSF). The combined use of these markers allows identification of AD pathology ante-mortem.

These markers can be used in clinical routine to discriminate AD from normal aging, other neurological diseases and other types of dementia (non-AD). Interpretation of the results, however, should always be done in combination with other clinical information.

PRODUCTS

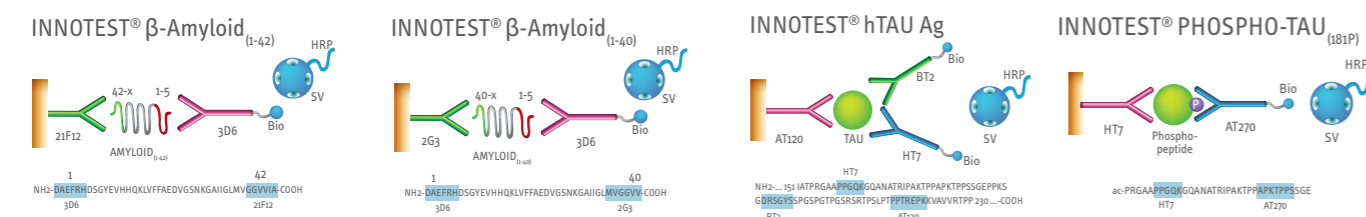
INNOTEST[®] CE
 β -AMYLOID
(1-42)

INNOTEST[®] CE
 β -AMYLOID
(1-40)

INNOTEST[®] CE
hTAU Ag

INNOTEST[®] CE
PHOSPHO-TAU
(181P)

ASSAY PRINCIPLE



FEATURES OF INNOTEST[®] PRODUCTS

Run Validation Controls (RVC)

Validation of test runs:

- general test performance
- correctness of the standard curve

Facilitates lab accreditation

Ready-to-use calibrators (RTU CAL)

Ease of use, less chance of errors

Reduction of variation:

- inter-run, intra-lab variation
- inter-lab variation

Generic and color-coded components

Interchangeable components between all INNOTEST β -amyloid and tau assays are: Sample Diluent, Wash Solution, Substrate, Substrate Buffer and Stop Solution:

- Easier test automation

Color-coded reagents: Conjugate Diluent 1 and 2:

- Easy recognition of different components

ASSAY ADVANTAGES

- Simple colorimetric immunoassays, standard technology
- Easily automated on microplate processor (generic components)
- Reference assays for CSF testing in routine, supported by many peer-reviewed scientific publications
- Less than 300 μ L of CSF necessary for determination of complete biomarker profile
- CE-mark for all INNOTEST Neuro assays: suitable for in vitro diagnostic use
- Excel macro available for consistent concentration calculation

Knowledge of a patient's AD biomarker profile increases diagnostic certainty for the clinician. Biochemically based diagnosis is probable long before the clinical symptoms of AD are fully manifest.*

In patients with a discrepancy between CSF phospho-tau_(181P) and CSF β -amyloid₍₁₋₄₂₎, the assessment of the β -amyloid₍₁₋₄₂₎/ β -amyloid₍₁₋₄₀₎ ratio leads to a 50% reduction in the number of indeterminate profiles.**

ASSAY FEATURES

	β -amyloid assays		tau assays	
	β -AMYLOID ₍₁₋₄₂₎ CE	β -AMYLOID ₍₁₋₄₀₎ CE	hTAU CE	PHOSPHO-TAU _(181P) CE
Calibrator range	62,5 - 4000 pg/mL	7,8 - 1000 pg/mL	50 - 2500 pg/mL	15,6 - 1000 pg/mL
Calibrators and Run Validation Controls (ready-to-use)	6 + 2	8 + 2 or 6 + 2 ⁽¹⁾ ⁽²⁾	6 + 2	6 + 2
Sample volume ⁽¹⁾	25 μ L	75 μ L (diluted)	25 μ L	75 μ L
Dilution	Not applicable	1:100	Not applicable	Not applicable
Assay duration	Approx. 3h (1h sample incubation)	Approx. 18h (overnight sample incubation)	Approx. 18h (overnight sample incubation)	Approx. 18h (overnight sample incubation)

⁽¹⁾duplicate testing is recommended

⁽²⁾ CAL 1 and CAL 3 can be removed from the calibration curve without impact on the concentration determination