Aβ42检测试纸

专业人员体外检测 | 人血清 / EDTA抗凝血浆

包装规格：1、5、10、20或25测试/盒，以盒签为准 | 样本：EDTA抗凝血浆或血清

预期用途

本品用于定性检测人EDTA抗凝血浆或血清中β-淀粉样蛋白42（Aβ42）的升高情况，作为辅助评估。检测结果应结合病史、临床表现及其他适宜检查综合判断；不得仅凭本品结果确诊或排除阿尔茨海默病。

概述

Aβ42是一种与淀粉样蛋白病理研究有关的生物标志物。结果受检测方法、样本类型及前处理等因素影响，不同方法或样本的数值不能直接等同。本品为单项定性检测，不提供精确的Aβ42浓度。

检测原理

采用胶体金免疫层析双抗体夹心法。样本中的Aβ42与胶体金标记的抗Aβ42抗体结合，沿膜迁移并由T线包被的另一株抗Aβ42抗体捕获，形成可见色带。C线为内部过程质控线；在C线有效时，C线和T线均出现表示Aβ42升高。

试剂组成与所需材料

包装规格：1、5、10、20或25测试/盒，实际配置以盒签和包装清单为准。每次检测使用检测装置、1滴样本及3滴配套缓冲液。另需计时器、样本标识用品及个人防护用品。

样本采集与处理

本品适用EDTA抗凝血浆或血清。由受训人员按规范采集静脉血：血浆使用EDTA抗凝采血管，血清按血清采集管要求分离。依据采血管说明及实验室规程分离样本，并使用分离后的血浆或血清检测。记录样本信息，防止交叉污染；样本稳定性、保存及运输条件以本品验证资料为准。不要将全血或其他抗凝剂血浆代替本品已确认的样本。

储存与有效期

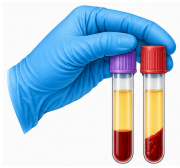
按本品标签标示的储存条件及有效期保存，保持密封、干燥并避免阳光直射。不得使用过期、受潮或包装破损产品。检测前开袋并及时使用，不混用不同批号或不同产品的试剂。

注意事项

仅供经培训人员体外检测使用。人源样本按潜在感染性材料处理，佩戴适当防护用品并防止交叉污染。检测装置和一次性耗材不得重复使用；使用配套缓冲液，不混用不同批次或不同产品的试剂。严格按照加样方法及规定时间判读，废弃物按适用规定处理。

样本采集与检测操作示意图

01 采集与分离



由受训人员采集静脉血，按采血管说明及实验室规程分离。仅使用分离后的 EDTA 血浆或血清。

02 加入样本



1 滴

将检测卡水平放置，向唯一的 S 孔加入 1 滴分离后的 EDTA 血浆或血清。

03 加入缓冲液



3 滴

向同一 S 孔加入 3 滴配套缓冲液，避免气泡，加完立即计时。

04 判读并记录



10 分钟

10 分钟判读并记录。15 分钟及以后不得判读。

Aβ42检测试纸

专业人员体外检测 | 人血清 / EDTA抗凝血浆

包装规格：1、5、10、20或25测试/盒，以盒签为准 | 样本：EDTA抗凝血浆或血清

检测步骤

1. 核对试剂包装及有效期，按产品要求准备试剂与样本。标记检测装置及样本编号，取出检测卡并水平放置。
2. 向唯一S孔先加入1滴EDTA抗凝血浆或血清，再加入3滴配套缓冲液，避免气泡；加完缓冲液后立即开始计时。
3. 加样后10分钟观察并记录结果。15分钟及以后结果无效，不得判读；无C线时使用新卡复测。

质量控制

每次有效检测必须出现C线；缺少C线时结果无效。C线用于监测层析过程，并不证明样本采集充分或Aβ42浓度正确。可依照实验室质量管理要求使用适宜外部质控品。

结果判读

C + T：提示升高



仅C：未显示升高



无C：无效



C线和T线均出现：按本品判读规则提示Aβ42升高；任何可见T线，包括浅色线，均应判读。仅C线出现、T线不出现：本次检测未显示Aβ42升高。C线不出现：无论T线是否出现均为无效，应使用新卡复测。以上结果均不能单独确诊或排除阿尔茨海默病；不得凭色带深浅报告未经验证的定量浓度。

局限性与检测建议

本品检测Aβ42升高情况，不能单独诊断或排除阿尔茨海默病，也不能单独确定脑内淀粉样蛋白病理状态。本品阳性判定的具体浓度界值尚未列明，不能据此判断是否超出临床参考范围；应结合定量检测及临床资料评估。结果可能受采样、前处理、检测方法和患者临床状态等因素影响；临床不符、无效或难以判读的结果应进一步评估。

与化学发光法的比较

共160份样本与化学发光法比较：参考阳性60份、参考阴性100份；比较方法的分组阈值尚待确认。下列统计表示所给分组下两种方法间的一致性，不代表本品对阿尔茨海默病的临床诊断灵敏度、特异性或准确性。

本品结果	化学发光法阳性	化学发光法阴性	合计
阳性	59	2	61
阴性	1	98	99
合计	60	100	160

阳性一致率：98.33%（95% CI: 91.14%-99.71%）

阴性一致率：98.00%（95% CI: 93.00%-99.45%）

总一致率：98.13%（95% CI: 94.63%-99.36%）

双侧95% Wilson置信区间；总一致率按十进制四舍五入显示。

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Reference (clinical background): FDA. FDA Clears First Blood Test Used in Diagnosing Alzheimer's Disease (2025). FDA publication. The FDA reference describes a different assay.

Aβ42 Rapid Test

For professional in vitro use | Human serum / EDTA plasma

Pack sizes: 1, 5, 10, 20 or 25 tests/box; see box label | Specimens: EDTA plasma or serum

Intended Use

For qualitative detection of elevated amyloid-beta 42 (Aβ42) in human EDTA-anticoagulated plasma or serum as an aid to assessment. Interpret the result with the medical history, clinical findings and other appropriate tests. This test alone cannot diagnose or exclude Alzheimer's disease.

Summary

Aβ42 is a biomarker associated with amyloid pathology research. Results depend on the analytical method, specimen type and pre-analytical handling; values from different methods or matrices are not automatically interchangeable. This single-analyte test is qualitative and does not provide an exact Aβ42 concentration.

Test Principle

The test uses a colloidal gold immunochromatographic double-antibody sandwich method. Aβ42 in the specimen binds gold-labeled anti-Aβ42 antibody, migrates along the membrane and is captured by a second anti-Aβ42 antibody coated at T to form a visible band. C is an internal procedural control. With a valid C line, C and T together indicate elevated Aβ42.

Reagents and Materials

Pack sizes: 1, 5, 10, 20 or 25 tests/box; see the box label and packing list for the actual configuration. Each test uses a test device, 1 drop of specimen and 3 drops of matching buffer. Also required: timer, specimen labels and personal protective equipment.

Specimen Collection and Handling

Use EDTA-anticoagulated plasma or serum. Trained personnel should collect venous blood using standard procedures: use an EDTA collection tube for plasma and a serum tube for serum. Separate specimens according to the tube manufacturer's instructions and laboratory procedures; test the separated plasma or serum. Identify each specimen and prevent cross-contamination. Follow product-validated specimen stability, storage and transport requirements. Do not substitute whole blood or plasma collected with another anticoagulant for the confirmed specimen types.

Storage and Stability

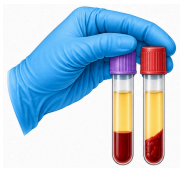
Follow the storage conditions and expiry date on the product label. Keep sealed, dry and away from direct sunlight. Do not use expired, damp or damaged products. Open immediately before use and test promptly; do not mix reagents from different lots or products.

Warnings and Precautions

For trained personnel for in vitro testing. Handle human specimens as potentially infectious, use suitable personal protective equipment and prevent cross-contamination. Do not reuse test devices or single-use materials. Use the supplied matching buffer and do not mix reagents from different lots or products. Follow the application procedure and reading time; dispose of waste according to applicable requirements.

Specimen Collection and Test Procedure

01 Collect and separate



Trained personnel collect venous blood and separate per tube and lab instructions. Use only separated EDTA plasma or serum.

02 Add specimen



1 drop

Lay the cassette flat. Add 1 drop of separated EDTA plasma or serum to the single S well.

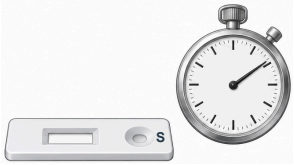
03 Add buffer



3 drops

Add 3 drops of supplied buffer to the same S well. Avoid bubbles and start timing immediately.

04 Read and record



10 min

Read and record at 10 minutes.
Do not interpret at 15 minutes or later.

Aβ42 Rapid Test

For professional in vitro use | Human serum / EDTA plasma

Pack sizes: 1, 5, 10, 20 or 25 tests/box; see box label | Specimens: EDTA plasma or serum

Test Procedure

1. Check package integrity and expiry. Prepare reagents and specimen according to product instructions, identify the device and specimen, and place the cassette level.
2. Add 1 drop of EDTA-anticoagulated plasma or serum to the only S well, followed by 3 drops of the supplied buffer. Avoid bubbles and start timing immediately after adding the buffer.
3. Observe and record the result at 10 minutes after application. Results at 15 minutes or later are invalid and must not be interpreted. If C is absent, repeat using a new cassette.

Quality Control

C must appear in every valid test; absence of C makes the result invalid. C monitors migration but does not establish adequate specimen collection or correct Aβ42 concentration. Use appropriate external controls according to laboratory quality procedures.

Interpretation of Results

C + T: elevated indicated



C only: elevated not indicated



No C: invalid



C and T present: elevated Aβ42 is indicated under this test's reading rule; read any visible T line, including a faint line. C only, with no T: elevated Aβ42 was not indicated by this test. C absent: invalid regardless of T; repeat using a new cassette. None of these results alone diagnoses or excludes Alzheimer's disease. Do not infer an unvalidated quantitative concentration from band intensity.

Limitations and Testing Recommendations

This test cannot alone diagnose or exclude Alzheimer's disease or independently establish cerebral amyloid pathology. The concentration cutoff for a positive result is not specified; a result cannot establish whether the clinical reference range is exceeded. Interpret with quantitative testing and clinical information. Results may be affected by sampling, pre-analytical handling, methods and patient clinical status; investigate discordant, invalid or difficult-to-read results.

Comparison with a Chemiluminescence Assay

A total of 160 specimens were compared with a chemiluminescence method: 60 comparator-positive and 100 comparator-negative; the comparator's classification threshold remains to be confirmed. The following figures describe agreement for the supplied groups, not diagnostic sensitivity, specificity or accuracy for Alzheimer's disease.

Test result	Comparator positive	Comparator negative	Total
Positive	59	2	61
Negative	1	98	99
Total	60	100	160

Positive percent agreement: 98.33% (95% CI 91.14%-99.71%)

Negative percent agreement: 98.00% (95% CI 93.00%-99.45%)

Overall percent agreement: 98.13% (95% CI 94.63%-99.36%)

Two-sided 95% Wilson confidence intervals; overall percent agreement rounded half-up.

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