Publication Summary

Evaluation of a New Antibody-Based NT-proBNP Assay for Acute Dyspnea in the Emergency Department [1]

Key Facts

- **Objective:** This study assessed the diagnostic and prognostic performance of the Access NT-proBNP assay in emergency department (ED) patients with suspected acute heart failure (HF)
- **Design:** Prospective, multicenter study across 17 US sites (Nov 2019–May 2022)
- **Population:** 2,384 analyzed patients (median age 59 years; 48% female; 35.7% black; 57.8% white), including 1059 with acute HF based on blinded adjudicated diagnosis
- **Assay:** Access NT-proBNP assay, a 2-site immunoenzymatic assay performed on the DxI 9000 Access Immunoassay Analyzer using novel monoclonal antibodies (reference method: Roche Elecsys proBNP II assay)

Diagnostic Performance

The Access NT-proBNP assay demonstrated robust diagnostic accuracy, with high sensitivity and negative predictive values across age groups.

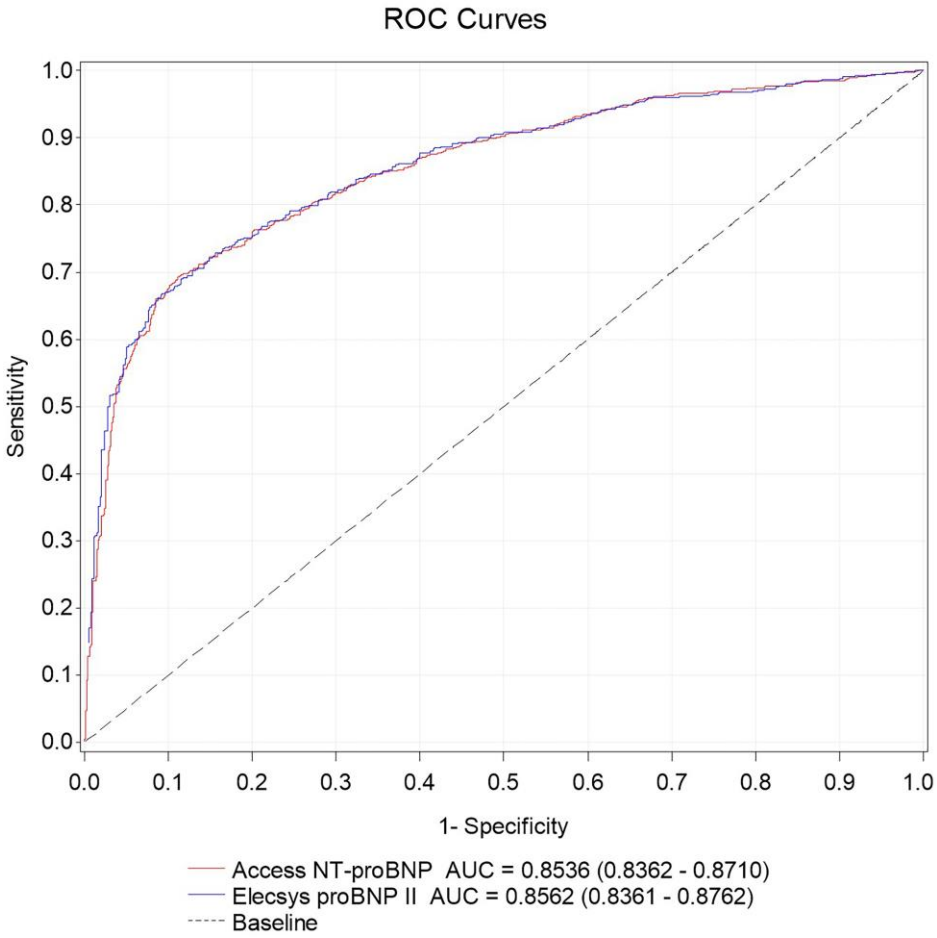
- **Diagnostic accuracy for acute HF:** area under the receiver operating characteristic curve (AUC) = 0.87 (95% CI 0.86–0.88; *P* <0.001), suggesting that the assay may provide clinically useful information to aid in ruling in or ruling out acute HF among patients suspected of having acute HF in the ED
- **Rule-out confidence:** 96% clinical sensitivity and 95% negative predictive value (NPV) at a <300 ng/L cutoff value
- **Performance relative to a reference method:** In a subset of the cohort suitable for between-method comparison, the Access NT-proBNP assay showed diagnostic performance similar to that of the Elecsys proBNP II assay (AUC 0.8536 vs 0.8562) (Figure 1).

Diagnostic performance at age-specific cutoffs

Cutoff, ng/L	Sensitivity, %	Specificity, %	PPV, %	NPV, %
<300 (rule-out; all ages)	96 (95-97)	56 (54-59)	64 (61-66)	95 (93-96)
≥ 450 (age <50 y)	90 (86-93)	78 (74-81)	69 (64-73)	93 (91-95)
≥ 900 (age 50-75 y)	85 (82-88)	78 (74-81)	78 (74-82)	85 (81-88)
≥ 1800 (age >75 y)	79 (74-83)	67 (62-72)	72 (67-76)	75 (70-80)
All ages at respective cutoffs	85 (83-87)	75 (73-78)	73 (71-76)	86 (84-88)

Data in parentheses are 95% confidence intervals. Modified from reference 1.

Figure 1. Comparative ROC curve to Elecsys proBNP II assay. Modified from reference 1 (Deed - Attribution 4.0 International - Creative Commons)

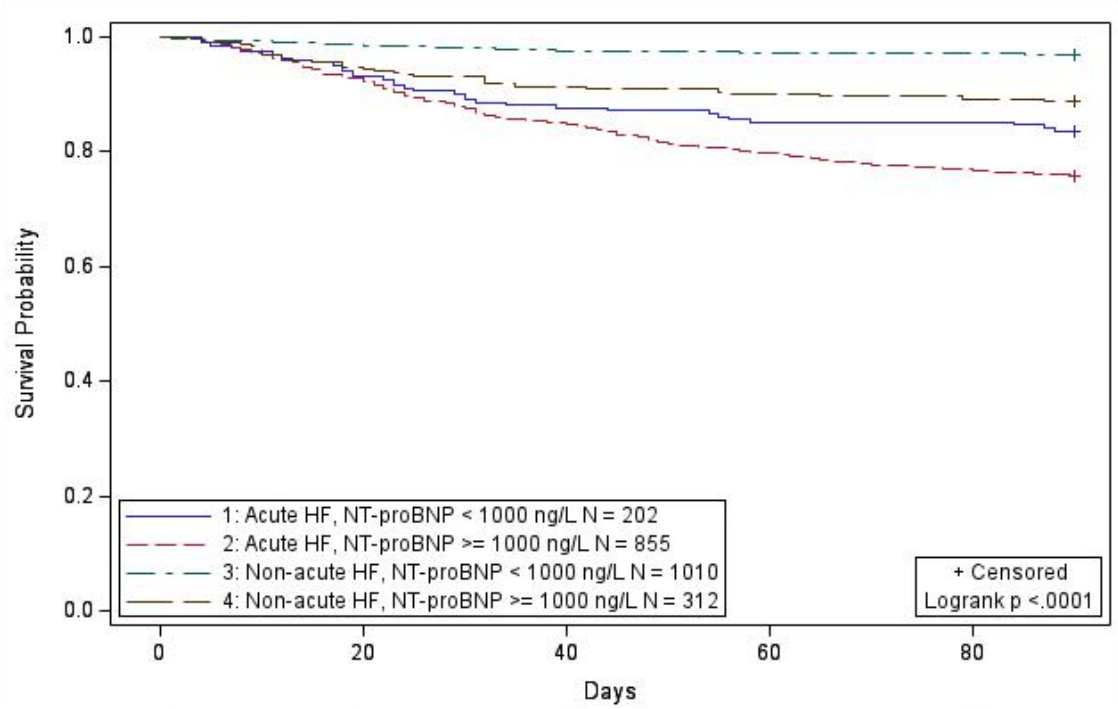


- **Rule-in performance in stage 3 CKD:** Use of age-specific cutoff values among participants with stage 3 CKD showed preserved specificity and PPV to rule in HF, relative to the overall cohort (overall specificity 75%, PPV 73%):
    - <50 years: 750 ng/L cutoff, specificity 77.5%, PPV 70.5%
    - 50-75 years: 1550 ng/L cutoff, specificity 77.3%, PPV 83.1%
    - >75 years: 1700 ng/L cutoff; specificity 66.9%, PPV 76.9%
- **Performance in Black participants:** At the <300 ng/L rule-out threshold, the Access NT-proBNP assay showed 96% sensitivity, 65% specificity, and an NPV of 94%
- **Performance in participants with elevated BMI:** For individuals with BMI ≥30, a rule-out cutoff value of 150 ng/L for acute HF yielded sensitivity (96%) and NPV (92%) comparable to those of the overall rule-out cutoff value of 300 ng/L used for the overall population

Prognostic Performance

- The assay also demonstrated strong prognostic performance: an NT-proBNP value of ≥1000 ng/L was associated with a significantly higher 90-day risk of major adverse cardiac events (MACE; Figure 2), even after adjusting for age and sex (hazard ratio = 4.29; [95% CI 3.23–5.69]).

Figure 2. MACE-free survival as a function of NT-proBNP level among ED patients evaluated for suspected acute HF; acute HF diagnosis based on blinded adjudication. Modified from reference 1 (Deed - Attribution 4.0 International - Creative Commons)



Conclusions

- The Access NT-proBNP assay provides clinically relevant diagnostic and prognostic information, aiding in the diagnosis of patients with suspected acute HF in ED settings
- Rule-out capability (96% sensitivity, 95% NPV) and diagnostic capability were demonstrated in an ED setting
- Prognostic value demonstrated by association with 90-day MACE risk (HR 4.29 for ≥1000 ng/L)
- Comparative analysis showed performance comparable to that of a reference assay in a subset of samples

Note: This material summarizes study findings and product features. The Access NT-proBNP assay is not intended to be used in isolation; results should be interpreted in conjunction with other diagnostic tests and clinical information. For complete indications, contraindications, limitations, and clinical performance, please refer to the assay's Instructions for Use (IFU).

This product may not be available in your country or region at this time. Please contact your Beckman Coulter sales representative or distributor for more information.

Reference

Allen BR, Guidi JL, Headden G, et al. Evaluation of a new antibody-based NT-proBNP assay for acute dyspnea in the emergency department. *Clin Chem*. 2026;doi:10.1093/clinchem/hvaf168.

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