February 18, 2026

Axis-Shield Diagnostics Limited
Claire Dora
Quality Director
17 Luna Place, The Technology Park
Dundee, Scotland DD2 1XA
United Kingdom

Re: K253539
Trade/Device Name: Alere NT-proBNP for Alinity i
Regulation Number: 21 CFR 862.1117
Regulation Name: B-type natriuretic peptide test system
Regulatory Class: Class II
Product Code: NBC
Dated: November 13, 2025
Received: November 13, 2025

Dear Claire Dora:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

PAULA V. CAPOSINO -S

Paula Caposino, Ph.D.
Deputy Director
Division of Chemistry and
Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253539

Device Name
Alere NT-proBNP for Alinity i

Indications for Use *(Describe)*
The Alere NT-proBNP for Alinity i assay is a chemiluminescent microparticle immunoassay (CMIA) used for the in vitro quantitative determination of N-terminal pro B-type natriuretic peptide (NT-proBNP) in human serum and plasma on the Alinity i system.

In the emergency department, measurements of NT-proBNP are used as an aid in the diagnosis of heart failure (HF) in patients with clinical suspicion of new onset or worsening HF.

The Alere NT-proBNP for Alinity i assay can also be used as an aid in 12-month risk stratification for prognosis of all-cause mortality, cardiac-related mortality, and heart-related hospitalization in patients presenting to the emergency department, diagnosed with new onset or worsening HF.

The assay may further be used in the risk stratification of patients with acute coronary syndrome (ACS).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Administrative Documentation – 510(k) Summary

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

I. 510(k) Number

K253539

II. Applicant Name

Axis-Shield Diagnostics Limited
Luna Place, The Technology Park,
Dundee DD2 1XA
United Kingdom

Primary contact:

Claire Dora, Quality Director
Axis-Shield Diagnostics Ltd
Phone: +44(0)790994098
Email: claire.dora@abbott.com

Date summary prepared: February 18, 2026

III. Device Name

Trade Name: Alere NT-proBNP for Alinity i

Alere NT-proBNP for Alinity i
Device Classification: Class II
Classification Name: BNP Test System
Governing Regulation: 21 CFR Part 862.1117
Code: NBC

IV. Predicate Device

Roche Elecsys proBNP II (K092649)

V. Description of Device

A. Reagents

The various configurations of the Alere NT-proBNP for Alinity i reagent kits are described below.

	List Number	
	04S7921	**04S7931**
Tests per cartridge	100	500
Number of cartridges per kit	2	2
Tests per kit	200	1000
Microparticle volume	6.7 mL	27.0 mL
Conjugate volume	6.1 mL	26.5 mL

Microparticles: Anti-NT-proBNP (sheep, monoclonal) coated microparticles in Bis-TRIS buffer with protein (bovine) stabilizer, non-specific binding blocking agents, and surfactant. Minimum concentration: 0.05% solids. Preservative: sodium azide.

Conjugate: Anti-NT-proBNP (mouse, monoclonal) acridinium-labeled conjugate in MES buffer with protein (bovine) stabilizer and surfactant. Minimum concentration: 0.12 µg/mL. Preservatives: antimicrobial agents.

B. Biological Principles of the Procedure

The Alere NT-proBNP for Alinity i assay is an automated, two-step immunoassay for the *in vitro* quantitative determination of NT-proBNP in human serum and plasma using chemiluminescent microparticle immunoassay (CMIA) technology.

Sample and anti-NT-proBNP coated paramagnetic microparticles are combined and incubated. The NT-proBNP present in the sample binds to the anti-NT-proBNP coated microparticles. The mixture is washed. Anti-NT-proBNP acridinium-labeled conjugate is added to create a reaction mixture and incubated. Following a wash cycle, Pre-Trigger and Trigger Solutions are added.

The resulting chemiluminescent reaction is measured as a relative light unit (RLU). There is a direct relationship between the amount of NT-proBNP in the sample and the RLU detected by the system optics.

Assay Standardization

There is currently no international recognized reference method or reference material for standardization. The Alere NT-proBNP for Alinity i Calibrators are traceable to internal reference standards at every concentration level that were value assigned on and made traceable to the predicate device by transference, as described by Clinical and Laboratory Standards Institute (CLSI) Document EP32-R.*

C. Interpretation of Results

As with all analyte determinations, the NT-proBNP value should be used in conjunction with information available from clinical evaluation and other diagnostic procedures.

Risk of Adverse Events in Patients Diagnosed with New Onset or Worsening HF Presenting to the ED

Elevated NT-proBNP levels are associated with an increased risk of adverse events (all-cause mortality, cardiac-related mortality, and heart-related hospitalization). The observed hazard ratios and absolute risk for each NT-proBNP quartile from the clinical study are provided in the Clinical Performance section of this 510(k) Summary.

* Clinical and Laboratory Standards Institute (CLSI). *Metrological Traceability and Its Implementation–First Edition.* CLSI document EP32-R. Wayne, PA: CLSI; 2006.

VI. Intended Use of the Device

The Alere NT-proBNP for Alinity i assay is a chemiluminescent microparticle immunoassay (CMIA) used for the *in vitro* quantitative determination of N-terminal pro B-type natriuretic peptide (NT-proBNP) in human serum and plasma on the Alinity i system.

In the emergency department (ED), measurements of NT-proBNP are used as an aid in the diagnosis of heart failure (HF) in patients with clinical suspicion of new onset or worsening HF.

The Alere NT-proBNP for Alinity i assay can also be used as an aid in 12-month risk stratification for prognosis of all-cause mortality, cardiac-related mortality, and heart-related hospitalization in patients presenting to the emergency department, diagnosed with new onset or worsening HF.

The assay may further be used in the risk stratification of patients with acute coronary syndrome (ACS).

VII. Comparison with the Predicate Device

The similarities and differences between the subject device and the predicate device are presented in the table below.

	Subject Device: Alere NT-proBNP for Alinity i	Predicate Device: Roche Elecsys proBNP II (K092649)
General Device Characteristic Similarities		
Intended Use/Indications for Use	The Alere NT-proBNP for Alinity i assay is a chemiluminescent microparticle immunoassay (CMIA) used for the *in vitro* quantitative determination of N-terminal pro B-type natriuretic peptide (NT-proBNP) in human serum and plasma on the Alinity i system. In the emergency department, measurements of NT-proBNP are used as an aid in the diagnosis of heart failure (HF) in patients with clinical suspicion of new onset or worsening HF. The Alere NT-proBNP for Alinity i assay can also be used as an aid in 12-month risk stratification for prognosis of all-cause mortality, cardiac-related mortality, and heart-related hospitalization in patients presenting to the emergency department, diagnosed with new onset or worsening HF. The assay may further be used in the risk stratification of patients with acute coronary syndrome (ACS).	Immunoassay for the *in vitro* quantitative determination of N-terminal pro-Brain natriuretic peptide in human serum and plasma. This assay is used as an aid in the diagnosis of individuals suspected of having congestive heart failure. The test is further indicated for the risk stratification of patients with acute coronary syndrome and congestive heart failure. The test may also serve as an aid in the assessment of increased risk of cardiovascular events and mortality in patients at risk for heart failure who have stable coronary artery disease.
Specimen Type	Human serum and plasma	Same
Test Principle	Sandwich immunoassay	Same
Measurement Type	Quantitative	Same
Analyte	NT-proBNP	Same
Antibody	Monoclonal anti-NT-proBNP	Same
Detection Technology	Chemiluminescence	Same
Risk Stratification of Patients With ACS	Based on findings from peer-reviewed literature publications and clinical guidelines.	Based on findings from peer-reviewed literature publications.
General Device Characteristic Differences		
Principle of Operation	CMIA	Electro chemiluminescent microparticle immunoassay (ECLIA)
Measuring Interval	Analytical Measuring Interval (AMI): 15.8 to 35,000.0 pg/mL (1.9 to 4130.0 pmoL/L)	5 to 35,000 pg/mL

	Subject Device: Alere NT-proBNP for Alinity i	Predicate Device: Roche Elecsys proBNP II (K092649)
Hook Effect	No hook effect up to 372,620 pg/mL	No hook effect up to 300,000 pg/mL
Assessment of Risk in Patients With HF	Clinical performance study of 840 subjects with adjudicated HF diagnosis prospectively followed for 12 months.	Based on findings from peer-reviewed literature study.

VIII. Summary of Nonclinical Performance

The following nonclinical performance characteristics of the Alere NT-proBNP for Alinity i assay are provided in K241176:

- Reportable Interval
- Within-Laboratory Precision (20-Day)
- Linearity
- Lower Limits of Measurement
- Analytical Specificity (Potentially Interfering Endogenous Substances, Potentially Interfering Drugs, and Cross-Reactants)
- High Dose Hook
- Expected Values (Reference Interval)

IX. Summary of Clinical Performance

A. Reproducibility

Reproducibility of the Alere NT-proBNP for Alinity i assay is provided in K241176.

B. Clinical Performance

1. Aid in the Diagnosis of HF

Study results for patients with clinical suspicion of new onset or worsening HF in ED are presented in K241176.

2. Risk of Adverse Events in Patients Diagnosed with New Onset or Worsening HF Presenting to the ED

Of the 880 subjects with an adjudicated diagnosis of HF, 861 subjects were included in a prospective 12-month follow-up study. (The remaining 19 subjects did not have a follow-up evaluation). The study included 495 (57.5%) male subjects and 366

(42.5%) female subjects, with an overall mean age of 62.0 years. Specimens were collected at admission to the ED and tested with the Alere NT-proBNP for Alinity i assay. Study population quartiles for NT-proBNP were calculated in pg/mL from the included population (n = 861):

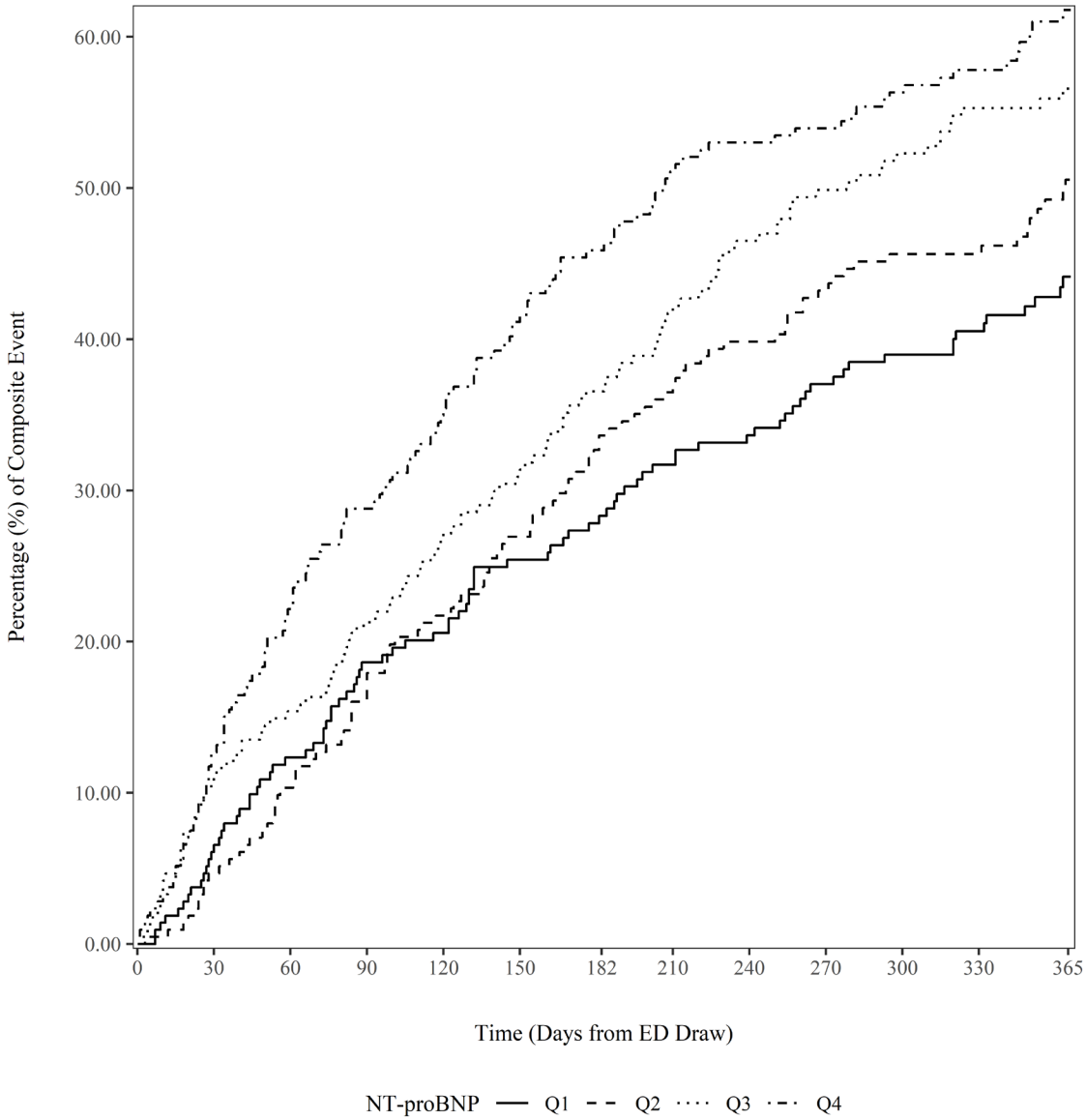
First Quartile (Q1)	Second Quartile (Q2)	Third Quartile (Q3)	Fourth Quartile (Q4)
≤ 1214.7	> 1214.7 to 3261.3	> 3261.3 to 7031.3	> 7031.3

The primary outcome was a composite outcome, defined as the first occurrence of all-cause mortality, cardiac-related mortality, or heart-related hospitalization. The secondary outcomes included the individual components of the composite outcome. The prognostic value of NT-proBNP quartiles was assessed via Kaplan-Meier survival analysis, Cox proportional hazards regression, and absolute risk analysis for the primary and secondary outcomes.

Kaplan-Meier Survival Analysis

The Kaplan-Meier curves below demonstrate that the absolute risk (cumulative incidence) of the composite outcome within 12 months is elevated for higher NTproBNP population quartiles.

Alere NT-proBNP for Alinity i Design Validation Study
Kaplan-Meier Failure Curve
Analysis Variable: NT-proBNP as Study Population Quartiles
12-Month Composite Event



	Number of Subjects at Risk by Time												
Time (Days)	**0**	**30**	**60**	**90**	**120**	**150**	**182**	**210**	**240**	**270**	**300**	**330**	**365**
Q1	216	199	181	168	164	154	148	141	137	130	126	111	80
Q2	215	204	189	177	165	153	139	133	125	118	112	97	74
Q3	215	191	180	168	156	147	135	122	112	104	99	81	66
Q4	215	186	164	150	137	124	114	103	99	97	92	74	47

Absolute Risk

Absolute risk of each outcome at 12 months was estimated using univariable Cox proportional hazards models. All evaluated outcomes (all-cause mortality, cardiac-related mortality, heart-related hospitalization, and the composite) demonstrate an increasing trend across NT-proBNP quartiles. The results are summarized in the following table.

Outcome	Absolute Risk (%) (95% CI)			
	Q1	**Q2**	**Q3**	**Q4**
Composite Outcome	44.03 (36.86, 50.39)	49.40 (42.25, 55.66)	56.49 (49.37, 62.60)	63.08 (55.99, 69.02)
All-Cause Mortality	10.21 (5.97, 14.25)	11.45 (7.03, 15.66)	18.94 (13.41, 24.12)	25.50 (19.33, 31.19)
Cardiac-Related Mortality	2.03 (0.04, 3.97)	6.84 (3.31, 10.24)	7.24 (3.51, 10.83)	15.78 (10.50, 20.75)
Heart-Related Hospitalization	39.69 (32.44, 46.16)	46.74 (39.43, 53.17)	47.89 (40.34, 54.49)	53.41 (45.55, 60.13)

Cox Proportional Hazards Regression

The Cox proportional hazards regression demonstrated that NT-proBNP is a statistically significant predictor of the composite outcome at 12 months. Univariable (unadjusted) results and multivariable results (adjusted for age, sex, BMI, smoking, diabetes mellitus, hypertension, eGFR, and NYHA class) are summarized for the composite outcome and each individual outcome in the table below.

Outcome	NT-proBNP Quartile[a]	Unadjusted Hazard Ratio (95% CI)	Adjusted Hazard Ratio (95% CI)[b]
Composite	Q2	1.17 (0.89, 1.56)	1.16 (0.86, 1.56)
	Q3	1.43 (1.09, 1.89)	1.44 (1.08, 1.93)
	Q4	1.72 (1.31, 2.25)	1.56 (1.14, 2.12)
All-Cause Mortality	Q2	1.13 (0.63, 2.03)	1.15 (0.63, 2.10)
	Q3	1.95 (1.15, 3.32)	1.89 (1.08, 3.30)
	Q4	2.73 (1.65, 4.53)	2.13 (1.19, 3.80)
Cardiac-Related Mortality	Q2	3.46 (1.14, 10.52)	3.69 (1.19, 11.42)
	Q3	3.67 (1.21, 11.15)	3.84 (1.22, 12.04)
	Q4	8.39 (2.96, 23.77)	8.24 (2.66, 25.50)
Heart-Related Hospitalization	Q2	1.25 (0.92, 1.68)	1.23 (0.89, 1.69)
	Q3	1.29 (0.95, 1.75)	1.30 (0.94, 1.80)
	Q4	1.51 (1.12, 2.04)	1.44 (1.02, 2.03)

[a] NT-proBNP Q1 is the reference category for the hazard ratios presented for Q2, Q3, and Q4.

[b] The multivariable model was adjusted for age, sex, BMI, smoking, diabetes mellitus, hypertension, eGFR, and NYHA class. Only subjects with complete data for all covariates (n=816) were included.

The Kaplan-Meier survival analysis, absolute risk analysis, and Cox proportional hazards regression demonstrated that the Alere NT-proBNP for Alinity i assay may be used as an aid in 12-month risk stratification for prognosis of all-cause mortality, cardiac-related mortality, and heart-related hospitalization in patients presenting to the emergency department, diagnosed with new onset or worsening HF. Elevated NT-proBNP levels, as reflected in higher quartiles, are associated with an increased risk of adverse events.

Alere NT-proBNP for Alinity i assay results should be interpreted in conjunction with the patient's medical history, clinical examination, and other findings.

3. Risk Stratification of Patients with ACS

Based on findings from the peer-reviewed publications and clinical guidelines[*†‡], the measurement of NT-proBNP is recommended as an aid in risk stratification of patients with ACS. These studies consistently demonstrate that elevated NT-proBNP concentrations are associated with increased incidence of cardiovascular events and mortality.

X. Conclusion

The information presented in this 510(k) premarket notification demonstrate that the subject device, Alere NT-proBNP for Alinity i (List Number 04S79), is substantially equivalent to the predicate device, Roche Elecsys proBNP II (K092649).

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[*] Rao SV, O'Donoghue ML, Ruel M, et al. 2025 ACC/AHA/ACEP/NAEMSP/SCAI guideline for the management of patients with acute coronary syndromes: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation* 2025;151:e771–e862. doi:10.1161/CIR.0000000000001309

[†] James SK, Lindahl B, Siegbahn A, et al. N-terminal pro-brain natriuretic peptide and other risk markers for the separate prediction of mortality and subsequent myocardial infarction in patients with unstable coronary artery disease; a Global Utilization of Strategies To Open occluded arteries (GUSTO)-IV substudy. *Circulation* 2003;108(3): 275-281. doi:10.1161/01.CIR.0000079170.10579.DC

[‡] Jernberg T, Stridsberg M, Venge P, et al. N-terminal pro brain natriuretic peptide on admission for early risk stratification of patients with chest pain and no ST-segment elevation. *J Am Coll Cardiol* 2002;40(3):437-445.