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Area	Laboratory
Applicability	TMH+NH+RIH/ HCH

Alinity Nt-Probnp Sop

Alere NT-proBNP for Alinity i (also referred to as Alere NT-proBNP)

INTENDED 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.

SUMMARY AND EXPLANATION OF THE TEST

- Heart failure (HF) is a complex clinical syndrome that can result from structural or functional cardiac disorders causing impairment of ventricular filling or ejection of blood from the heart.*1, 2* HF is a clinical diagnosis based upon patient history and physical examination in conjunction with laboratory tests and imaging procedures.*2, 3* Symptoms of HF include dyspnea, ankle swelling, fatigue, and weakness which may be more pronounced with exertion.*4*
- The American Heart Association (AHA) / American College of Cardiology (ACC) stages of HF*3* highlight the development and progression of the disease from stage A (at risk of HF, asymptomatic) to stage B (pre-HF, asymptomatic), stage C (symptomatic HF), and stage D (advanced HF). The stages are defined by clinical signs and symptoms, presence of risk factors, and comorbid conditions. Progression from stage A through stage D is associated with increasing levels of cardiac biomarkers (including natriuretic peptides) and echocardiographic findings of structural heart disease and ventricular dysfunction, along with worsening symptoms of HF that interfere with daily life, increased rate of hospitalization, and elevated risk of mortality. For stage C and D HF, the New York Heart Association (NYHA)

classification is utilized to categorize patients based on symptoms and functional capacity.*3*

- B-type natriuretic peptide (BNP) is a natriuretic hormone synthesized and secreted into the blood stream by cardiac myocytes in response to volume overload, increased stress on ventricular walls, and ventricular hypertrophy.*5* Physiologically active BNP and biologically inert 76 amino acid peptide NT-proBNP are formed through the proteolytic cleavage of the precursor proBNP.*6* In patients presenting with dyspnea, the measurement of NT-proBNP is useful to support diagnosis or exclusion of HF.*3*
- In patients with impaired renal function, decreased glomerular filtration rate (GFR) is associated with increased NT-proBNP concentration, since NT-proBNP is cleared by the kidney. BNP/NT-proBNP levels may also be modified due to biological factors like age, sex, and body mass index.*5* Age has the strongest effect, leading to the use of age-dependent positive cutoffs.*2, 7* Elevated natriuretic peptide (BNP/NT-proBNP) levels should be interpreted in the context of other clinical information; they should not be used in isolation to diagnose HF.

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

- This 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.
- For additional information on system and assay technology, refer to the Alinity ci-series Operations Manual, Section 3.

REAGENTS

Kit Contents

Alere NT-proBNP for Alinity i Reagent Kit 04S79

Volumes (mL) listed in the following table indicate the volume per cartridge.

REF	**04S7921**
Tests per cartridge	100
Number of cartridges per kit	2
Tests per kit	200
MICROPARTICLES	6.7 mL
CONJUGATE	6.1 mL
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.
	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.

Warnings and Precautions

- IVD
- For *In Vitro* Diagnostic Use
- Rx ONLY

Safety Precautions

CAUTION: This product requires the handling of human specimens. It is recommended that all human-sourced materials and all consumables contaminated with potentially infectious materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate regional, national, and institutional biosafety practices should be used for materials that contain, are suspected of containing, or are contaminated with infectious agents.*8, 9, 10, 11*

The following warnings and precautions apply to:	
WARNING	Contains Bis-TRIS propane* and sodium azide.
H316*	Causes mild skin irritation.
EUH032	Contact with acids liberates very toxic gas.
Response	
P332+P313*	If skin irritation occurs: Get medical advice / attention.
Disposal	
P501	Dispose of contents / container in accordance with local regulations.

* Not applicable where regulation EC 1272/2008 (CLP) or OSHA Hazard Communication 29 CFR 1910.1200 (HCS) 2012 have been implemented.

Follow local chemical disposal regulations based on your location along with recommendations and content in the Safety Data Sheet to determine the safe disposal of this product.

For the most current hazard information, see the product Safety Data Sheet.

Safety Data Sheets are available at www.corelaboratory.abbott or contact your local representative.

For a detailed discussion of safety precautions during system operation, refer to the Alinity ci-series Operations Manual, Section 8.

Reagent Handling

- Reagents are shipped on cold packs / wet ice.

- Upon receipt, gently invert the unopened reagent kit by rotating it over and back for a full 180 degrees, 5 times with green label stripe facing up and then 5 times with green label stripe facing down. This ensures that liquid covers all sides of the bottles within the cartridges. During reagent shipment, microparticles can settle on the reagent septum.
- Place a check in the square on the reagent kit to indicate to others that the inversions have been completed.
- After mixing, place reagent cartridges in an upright position for 1 hour before use to allow bubbles that may have formed to dissipate.
- If a reagent cartridge is dropped, place in an upright position for 1 hour before use to allow bubbles that may have formed to dissipate.
- **Reagent cartridges cannot be inverted after the septum has been pierced by the system.**
- Reagents are susceptible to the formation of foam and bubbles. Bubbles may interfere with the detection of the reagent level in the cartridge and cause insufficient reagent aspiration that may adversely affect results.

For a detailed discussion of reagent handling precautions during system operation, refer to the Alinity ci-series Operations Manual, Section 7.

Reagent Storage

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened	2 to 8°C	Until expiration date	Store in upright position. If cartridge does not remain upright, gently invert the cartridge 10 times and place in an upright position for 1 hour before use.
Onboard	System Temperature	30 days	
Opened	2 to 8°C	Until expiration date	Store in upright position. If cartridge does not remain upright during storage off the system, discard the cartridge. Do not reuse original reagent caps or replacement caps due to the risk of contamination and the potential to compromise reagent performance.

- Reagents may be stored on or off the system. If removed from the system, store reagents with new replacement caps in an upright position at 2 to 8°C. For reagents stored off the system, it is recommended that they be stored in their original trays or boxes to ensure they remain upright.
- For information on unloading reagents, refer to the Alinity ci-series Operations Manual, Section 5.

Indications of Reagent Deterioration

Deterioration of the reagents may be indicated when a calibration error occurs or a control value is

out of the specified range. Associated test results are invalid, and samples must be retested. Assay recalibration may be necessary.

For troubleshooting information, refer to the Alinity ci-series Operations Manual, Section 10.

INSTRUMENT PROCEDURE

- The Alere NT-proBNP for Alinity i assay file must be installed on the Alinity i system prior to performing the assay.
- The Alinity ci-series system software version 3.3.0 or higher must be installed on the Alinity i system prior to performing the assay.
- For detailed information on assay file installation and viewing and editing assay parameters, refer to the Alinity ci-series Operations Manual, Section 2.
- For information on printing assay parameters, refer to the Alinity ci-series Operations Manual, Section 5.
- For a detailed description of system procedures, refer to the Alinity ci-series Operations Manual.

Alternate Result Units

- Edit assay parameter "Result Units" to select an alternate unit.Conversion formula:(Concentration in Default result unit) x (Conversion factor) = (Concentration in Alternate result unit)

Default Result Unit	Conversion Factor	Alternate Result Unit
pg/mL	0.118	pmol/L

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types

- The specimen types listed below were verified for use with this assay.Other specimen types and collection tube types have not been verified with this assay.

Specimen Types	Collection Tubes
Serum	Serum Serum separator
Plasma	Dipotassium EDTA Tripotassium EDTA Lithium heparin Lithium heparin separator

- The instrument does not provide the capability to verify specimen types. It is the responsibility of the operator to verify that the correct specimen types are used in the assay.

Specimen Conditions

- Do not use:
- heat-inactivated specimens
- pooled specimens
- grossly hemolyzed specimens
- specimens with obvious microbial contamination
- specimens with fungal growth
- For accurate results, serum and plasma specimens should be free of fibrin, red blood cells, and other particulate matter. Serum specimens from patients receiving anticoagulant or thrombolytic therapy may contain fibrin due to incomplete clot formation.
- To prevent cross contamination, use of disposable pipettes or pipette tips is recommended.
Preparation for Analysis
- Follow the tube manufacturer's processing instructions for collection tubes. Gravity separation is not sufficient for specimen preparation.
- Specimens should be free of bubbles. Remove bubbles with an applicator stick before analysis. Use a new applicator stick for each specimen to prevent cross contamination.
To ensure consistency in results, recentrifuge specimens prior to testing if
- they contain fibrin, red blood cells, or other particulate matter.
NOTE: If fibrin, red blood cells, or other particulate matter are observed, mix by low-speed vortex or by inverting 10 times prior to recentrifugation.
Prepare frozen specimens as follows:
- Frozen specimens must be completely thawed before mixing.
- Mix thawed specimens thoroughly by low-speed vortex or by inverting 10 times.
- Visually inspect the specimens. If layering or stratification is observed, mix until specimens are visibly homogeneous.
- If specimens are not mixed thoroughly, inconsistent results may be obtained.
- Recentrifuge specimens.
Recentrifugation of Specimens
- Transfer specimens to a centrifuge tube and centrifuge at a minimum of 50 000 g-minutes.
- Example of an acceptable time and force range that meets this criterion is listed in the following table.
- Centrifugation time using alternate RCF values can be calculated using the following formula:

Minimum Centrifugation time (minutes) =	50 000 g-minutes
	RCF

Recentrifugation Time (Minutes)	**RCF (x g)**	**g-Minutes**
5	10 000	50 000

- Transfer clarified specimen to a sample cup or secondary tube for testing. For centrifuged

specimens with a lipid layer, transfer only the clarified specimen and not the lipemic material.

Specimen Storage

Specimen storage times were validated with serum separator and dipotassium EDTA tube types.

Specimen Type	Temperature	Maximum Storage Time	Special Instructions
Serum/ Plasma	Room temperature (20 to 25°C)	48 hours	Remove serum or plasma from the clot, red blood cells, or separator gel if testing will be delayed more than 24 hours.
	2 to 8°C	3 days	Remove serum or plasma from the clot, red blood cells, or separator gel if testing will be delayed more than 24 hours.
	-20°C or colder	30 days	Remove serum or plasma from the clot, red blood cells, or separator gel.

Avoid more than 3 freeze/thaw cycles.

PROCEDURE

Materials Provided

04S79 Alere NT-proBNP for Alinity i Reagent Kit

Materials Required but not Provided

- Alere NT-proBNP for Alinity i assay file
- 04S7902 Alere NT-proBNP for Alinity i Calibrators
- 04S7911 Alere NT-proBNP for Alinity i Controls or other control material containing NT-proBNP
- Alinity Pre-Trigger Solution
- Alinity Trigger Solution
- Alinity i-series Concentrated Wash Buffer
- 09P1540 Alinity i Multi-Assay Manual Diluent
  For information on materials required for operation of the instrument, refer to the Alinity ci-series Operations Manual, Section 1.
  For information on materials required for maintenance procedures, refer to the Alinity ci-series Operations Manual, Section 9.

Assay Procedure

For a detailed description of how to run an assay, refer to the Alinity ci-series Operations Manual, Section 5.

- If using primary or aliquot tubes, refer to the Alinity ci-series Operations Manual, Section 4 to ensure sufficient specimen is present.
- Minimum sample cup volume is calculated by the system and printed on the Order List report. To minimize the effects of evaporation, verify adequate sample cup volume is present prior to running the test.
- Maximum number of replicates sampled from the same sample cup: 10
- Priority:
- Sample volume for first test: 100 µL
- Sample volume for each additional test from same sample cup: 50 µL
- ≤ 3 hours on the reagent and sample manager:
- Sample volume for first test: 150 µL
- Sample volume for each additional test from same sample cup: 50 µL
- > 3 hours on the reagent and sample manager:
- Replace with a fresh aliquot of sample.
- Refer to the Alere NT-proBNP for Alinity i calibrator package insert 04S7902 and/or Alere NT-proBNP for Alinity i control package insert 04S7911 for preparation and usage.
- For general operating procedures, refer to the Alinity ci-series Operations Manual, Section 5.
- For optimal performance, it is important to perform routine maintenance as described in the Alinity ci-series Operations Manual, Section 9. Perform maintenance more frequently when required by laboratory procedures.

Sample Dilution Procedures

- Samples with a NT-proBNP value exceeding 35 000.0 pg/mL (4130.0 pmol/L) are flagged with the code "> 35 000.0 pg/mL" ("> 4130.0 pmol/L") and may be diluted with either the Automated Dilution Protocol or the Manual Dilution Procedure.

Automated Dilution Protocol

- The system performs a 1:2 dilution of the sample and automatically calculates the concentration by multiplying the result by the dilution factor.
- For details on configuring automated dilutions, refer to the Alinity ci-series Operations Manual, Section 2.

Manual Dilution Procedure

- Suggested dilution: 1:10
  It is recommended that dilutions not exceed 1:10.
  Add 50 µL of the sample to 450 µL of Alinity i Multi-Assay Manual Diluent.
  The operator must enter the manual dilution factor in the Specimen or Control tab of the Create Order screen. The system will use this dilution factor to automatically calculate the

concentration of the sample and report the result.
The result should be > 35 000.0 pg/mL (> 4130.0 pmol/L) before the manual dilution factor is applied.
If the operator does not enter the manual dilution factor, the result must be manually multiplied by the appropriate manual dilution factor before reporting the result. If a diluted sample result is less than 15.8 pg/mL (1.9 pmol/L), do not report the result. Rerun using an appropriate dilution.
For detailed information on ordering dilutions, refer to the Alinity ci-series Operations Manual, Section 5.

Calibration

- For instructions on performing a calibration, refer to the Alinity ci-series Operations Manual, Section 5.
- Each assay control must be tested to evaluate the assay calibration.
- Once a calibration is accepted and stored, all subsequent samples may be tested without further calibration unless:
- A reagent kit with a new lot number is used.

Quality Controls

- Daily quality control results are outside of quality control limits used to monitor and control system performance, as described in the Quality Control Procedures section of this package insert.
This assay may require recalibration after maintenance to critical parts or subsystems or after service procedures have been performed.

Quality Control Procedures

- The recommended control requirement for the Alere NT-proBNP for Alinity i assay is that a single sample of each control level be tested once every 24 hours each day of use.
- Controls should be tested in accordance with local, state, and/or federal regulations or accreditation requirements and your laboratory's quality control policy.
Refer to published guidelines for information or general control recommendation, for example Clinical and Laboratory Standards Institute (CLSI) or other published guidelines, for general quality control recommendations.
- If more frequent control monitoring is required, follow the established quality control procedures for your laboratory.
- If quality control results do not meet the acceptance criteria defined by your laboratory, sample results may be suspect. Follow the established quality control procedures for your laboratory. Recalibration may be necessary. For troubleshooting information, refer to the Alinity ci-series Operations Manual, Section 10.
- Review quality control results and acceptance criteria following a change of reagent or calibrator lot.
Controls should be used according to the guidelines and recommendations of the control manufacturer. Concentration ranges provided in the control package insert should be used

only for guidance.
For any control material in use, the laboratory should ensure that the matrix of the control material is suitable for use in the assay per the assay package insert.

Verification of Assay Claims

For protocols to verify package insert claims, refer to Verification of Assay Claims in the Alinity ci-series Operations Manual.

RESULTS

- **Calculation**

  The Alere NT-proBNP for Alinity i assay utilizes a 4 Parameter Logistic Curve fit data reduction method (4PLC, Y-weighted) to generate a calibration and results.

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.
  Clinical guidelines*3* recommend using natriuretic peptides in emergency department (ED) for diagnosis or exclusion of HF. The performance of the Alere NT-proBNP for Alinity i assay was evaluated in an ED setting using published age-independent rule-out and age-dependent rule-in cutoffs.*7, 12*

  Emergency Department

  For patients presenting to the ED with clinical suspicion of HF, the results should be interpreted as indicated in the table below.

Age Group (Years)	NT-proBNP		Interpretation
	(pg/mL)	(pmol/L)	
All	< 300.0	< 35.4	Negative: HF unlikely
18 to < 50	≥ 300.0 to < 450.0	≥ 35.4 to < 53.1	Grayzone: Indeterminate Consider other causes of NT-proBNP elevation.
50 to 75	≥ 300.0 to < 900.0	≥ 35.4 to < 106.2	
> 75	≥ 300.0 to < 1800.0	≥ 35.4 to < 212.4	
18 to < 50	≥ 450.0	≥ 53.1	Positive: HF likely
50 to 75	≥ 900.0	≥ 106.2	
> 75	≥ 1800.0	≥ 212.4	

Flags

Some results may contain information in the Flags field. For a description of the flags that may

appear in this field, refer to the Alinity ci-series Operations Manual, Section 5.

Reportable Interval

Based on representative data for the limit of quantitation (LoQ), the ranges over which results can be reported are provided below.

	pg/mL	pmol/L
Analytical Measuring Interval (AMI)[a]	15.8 - 35 000.0	1.9 - 4130.0
Extended Measuring Interval (EMI)[b]	35 000.0 - 350 000.0	4130.0 - 41 300.0
Reportable Interval[c]	15.8 - 350 000.0	1.9 - 41 300.0

[a] AMI: The AMI extends from the LoQ to the upper limit of quantitation (ULoQ). This is determined by the range of values in pg/mL (pmol/L) that demonstrated acceptable performance for linearity, imprecision, and bias.

[b] EMI: The EMI extends from the ULoQ to the ULoQ × dilution factor. The value reflects a 1:10 dilution factor.

[c] The reportable interval extends from the LoQ to the upper limit of the EMI.

NOTE: The default Low Linearity value of the assay file corresponds to the lower limit of the reportable interval.

LIMITATIONS OF THE PROCEDURE

- Elevated NT-proBNP concentrations may be associated with impaired renal function (estimated glomerular filtration rate [eGFR] < 60 mL/min/1.73 m^2), history of HF and other conditions such as acute coronary syndrome, atrial fibrillation, pulmonary embolism, valvular heart disease, myocarditis, pulmonary hypertension, stroke, and sepsis, which may lead to false positive results. Obesity (body mass index [BMI] ≥ 30 kg/m^2)*3* and other conditions such as flash pulmonary edema, pericarditis, and cardiac tamponade may lower NT-proBNP concentrations, which may lead to false negative results.
- Results should be used in conjunction with other data; e.g., symptoms, results of other tests, and clinical impressions.
- If the NT-proBNP results are inconsistent with clinical evidence, additional testing is recommended.
- Substances that demonstrated interference with the Alere NT-proBNP for Alinity i assay are listed in the SPECIFIC PERFORMANCE CHARACTERISTICS, Analytical Specificity, Interference section of this package insert.
- Potential interference has not been evaluated for substances other than those described in the SPECIFIC PERFORMANCE CHARACTERISTICS, Analytical Specificity, Interference section of this package insert.
- The Alere NT-proBNP for Alinity i assay is susceptible to interference effects from total protein > 12.6 g/dL. Total protein at 15.2 g/dL decreased NT-proBNP values at 125 pg/mL by -12.7%.

- Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA). Such specimens may show either falsely elevated or depressed values when tested with assay kits such as Alere NT-proBNP for Alinity i that employ mouse monoclonal antibodies. Additional information may be required for diagnosis.*13, 14*
- Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with *in vitro* immunoassays. Patients routinely exposed to animals or to animal serum products can be prone to this interference, and anomalous values may be observed. Additional information may be required for diagnosis.*15*
- Rheumatoid factor (RF) in human serum can react with reagent immunoglobulins, interfering with *in vitro* immunoassays.*15*

EXPECTED VALUES

- Refer to LabAdm1.8 policy for all Reference Ranges and Critical values

SPECIFIC PERFORMANCE CHARACTERISTICS

- Representative performance data are provided in the attached package inset.. Results obtained in individual laboratories may vary
  Precision,Within-Laboratory Precision,Reproducibility andLower Limits of Measurement are a**ll** located in attached package insert
- **Linearity**
  A study was performed based on guidance from CLSI EP06, 2nd ed.*19*
  This assay is linear across the analytical measuring interval of 15.8 to 35 000.0 pg/mL (1.9 to 4130.0 pmol/L).

Analytical Specificity interferences

- **Potentially Interfering Endogenous Substances**

A study was performed based on guidance from CLSI EP07, 3rd ed.*20* Each substance was tested at 2 levels of the analyte (approximately 125 pg/mL and 2000 pg/mL).
No significant interference (interference within ± 10.0%) was observed at the following concentrations.

No Significant Interference (Interference within ± 10.0%)	
Potentially Interfering Substance	**Interferent Level**
Bilirubin (conjugated)	60 mg/dL
Bilirubin (unconjugated)	60 mg/dL
Biotin	4250 ng/mL
Cholesterol	700 mg/dL

HAMA	1500 ng/mL
Hemoglobin	1 g/dL
IgG	6 g/dL
Intralipid	3000 mg/dL
RF	600 IU/mL
Total Protein	12.6 g/dL

Interference beyond ± 10.0% (based on 95% confidence interval [CI]) was observed at the concentrations shown below for the following substances.

Interference Beyond ± 10.0% (Based on 95% CI)			
Potentially Interfering Substance	**Interferent Level**	**Analyte Level**	**% Interference (95% CI)**
RF	1520 IU/mL	125 pg/mL	-8.9% (-10.4%, -7.5%)
	1520 IU/mL	2000 pg/mL	-11.4% (-12.4%, -10.4%)
Total Protein	15.2 g/dL	125 pg/mL	-12.7% (-14.7%, -10.7%)
	15.5 g/dL	2000 pg/mL	-9.9% (-11.4%, -8.5%)

Potentially Interfering Drugs

A study was performed based on guidance from CLSI EP07, 3rd ed.*20* Each substance was tested at 2 levels of the analyte (approximately 125 pg/mL and 2000 pg/mL).

No significant interference (interference within ± 10.0%) was observed at the following concentrations.

No Significant Interference (Interference within ± 10.0%)			
Potentially Interfering Drug	**Interferent Level**	**Potentially Interfering Drug**	**Interferent Level**
Acetaminophen	15.6 mg/dL	Lidocaine	8.0 mg/dL
Acetylsalicylic Acid	60 mg/dL	Lisinopril	1.6 mg/dL
Allopurinol	6.0 mg/dL	Lithium	4.20 mg/dL
Amikacin	15 mg/dL	Losartan potassium	5.99 mg/dL
Amiodarone	4.2 mg/dL	Lovastatin	2.0 mg/dL
Amlodipine Besylate	0.4 mg/dL	L-Thyroxine	0.06 mg/dL
Ampicillin	7.5 mg/dL	Methyldopa	2.5 mg/dL

Ascorbic acid	5.25 mg/dL	Methylprednisolone	0.75 mg/dL
Atenolol	1.0 mg/dL	Metoprolol	1.5 mg/dL
Atorvastatin	32 mg/dL	Milrinone	0.183 mg/dL
Caffeine	10.8 mg/dL	Naproxen	49.97 mg/dL
Captopril	5.0 mg/dL	Nicotine	0.1 mg/dL
Carbamazepine	4.5 mg/dL	Nicotinic acid	4.0 mg/dL
Carvedilol	3.75 mg/dL	Nifedipine	6.0 mg/dL
Chloramphenicol	7.8 mg/dL	Nitrofurantoin	4.0 mg/dL
Chlordiazepoxide	1.0 mg/dL	Nitroglycerin	0.016 mg/dL
Chlorpromazine	0.33 mg/dL	Oxazepam	1.2 mg/dL
Cimetidine	3.0 mg/dL	Oxytetracycline	10 mg/dL
Cinnarizine	3.1 mg/dL	Penicillin G	25 U/mL
Clopidogrel bisulfate	7.5 mg/dL	Pentobarbital	12.6 mg/dL
Creatinine	30 mg/dL	Phenobarbital	69 mg/dL
Cyclosporine A	0.4 mg/dL	Phenprocoumon (Marcumar)	1.53 mg/dL
Dextran 40	6000 mg/dL	Phenytoin	6.0 mg/dL
Diazepam	3.0 mg/dL	Primidone	5.7 mg/dL
Diclofenac	6.0 mg/dL	Probenecid	60 mg/dL
Digoxin	0.025 mg/dL	Procainamide	4.8 mg/dL
Diltiazem	12 mg/dL	Propafenone	30 mg/dL
Dipyridamole	8.0 mg/dL	Propanolol	0.2 mg/dL
Disopyramide	4.0 mg/dL	Propoxyphene	0.321 mg/dL
Dobutamine	10 mg/dL	Quinidine	2.0 mg/dL
Dopamine	65 mg/dL	Ramipril	0.6 mg/dL
Enalapril Maleate	1.6 mg/dL	Retaplase	3.33 mg/dL
Epinephrine	0.05 mg/dL	Simvastatin	3.2 mg/dL
Erythromycin	13.8 mg/dL	Spironolactone	7.5 mg/dL
Ethanol	600 mg/dL	Sulfamethoxazole	112 mg/dL
Ethosuximide	30 mg/dL	Theophylline	6.0 mg/dL
Fenofibrate	4.5 mg/dL	Tolbutamide	150 mg/dL
Furosemide	6.0 mg/dL	Torasemide	1.5 mg/dL
Gentamicin	12 mg/dL	Trandolapril	4.0 mg/dL
Heparin	8 U/mL	Trasylol/Aprotinin	501.8 KIE/mL
Hydralazine	2.0 mg/dL	Trimethoprim	6.4 mg/dL

Hydrochlorothiazide	2.0 mg/dL	Uric Acid	23.5 mg/dL
Insulin	0.16 mg/dL	Valproic Acid	50 mg/dL
Ibuprofen	50 mg/dL	Verapamil	24 mg/dL
Indomethacin	3.6 mg/dL	Warfarin	7.5 mg/dL
Isosorbide dinitrate	6.0 mg/dL		

Cross-Reactants

A study was performed based on guidance from CLSI EP07, 3rd ed.*20* Samples with NT-proBNP target concentrations of 125 pg/mL and 2000 pg/mL containing the cross-reactants at the concentration listed below were tested with the Alere NT-proBNP for Alinity i assay on the Alinity i system. For each cross-reactant, the % recovery was calculated as: (NT-proBNP concentration with cross-reactant) / (NT-proBNP concentration without cross-reactant) × 100%. The observed % recovery of NT-proBNP was within 100% ± 10% for all cross-reactants evaluated at each analyte level.

Potential Cross-Reactant	Cross-Reactant Concentration
Adrenomedullin	1000 pg/mL
Aldosterone	600 pg/mL
Angiotensin I	600 pg/mL
Angiotensin II	600 pg/mL
Angiotensin III	1000 pg /mL
ANP 28	3100 ng/mL
Arg-Vasopressin	1000 pg/mL
BNP 32	3500 ng/mL
CNP 22	2200 ng/mL
Endothelin	20 pg/mL
NT-proANP 1-30 (preproANP26-55)	3500 ng/mL
NT-proANP 31-67 (preproANP56-92)	1000 pg/mL
NT-proANP 79-98 (preproANP104-123)	1000 pg/mL
Renin	50 000 pg/mL
Urodilatin	3500 ng/mL

High Dose Hook

High dose hook effect was not observed on samples up to 372 620 pg/mL.

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Key to Symbols

For interpretation of the symbols found in this SOP, refer to the PolicyStat procedure: "Abbott Alinity Key to Symbols SOP".

- A space is used as thousands separator (example: 10 000 specimens).
- A period is used to separate the integer part from the fractional part of a number written in decimal form (example: 3.12%).

Approval Signatures

Step Description	Approver	Date
Director Approval	Adina Badea: Director of Toxicology	12/2025
Chief Approval	Dariusz Stachurski: Chief of Pathology NH	12/2025
Medical Director Approval	Li Juan Wang: Pathologist	12/2025
Chief Approval	Murray Resnick: Pathologist-in-Chief	12/2025
	Debra Smeal: Mgr Core Lab RIH	12/2025

Applicability

Newport Hospital, Rhode Island Hospital/Hasbro Children's, The Miriam Hospital