

STANDARD F

NT-proBNP FIA SD BIOSENSOR

STANDARD F NT-proBNP FIA is a fluorescent immunoassay for the quantitative measurement of N-terminal B-type Natriuretic Peptide (NT-proBNP) level in human serum and whole blood (EDTA). This test is to help diagnose congestive heart failure.

- Early diagnosis of acute heart failure
- Risk stratification of heart failure
- Useful tool to guide referral of chronic heart failure
- Significant cost savings due to shorter stays in the ED

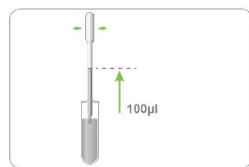


Specifications	
Introduction	Quantitative measurement of the NT-proBNP for diagnosis of heart failure
Sample Type	Whole blood(EDTA) and Serum
Sample Volume	100µl
Measurement Range	50 – 25,000 pg/mL
Measurement Time	15mins (S/P), 20mins (WB)
Reference Range	<ul style="list-style-type: none"> • Acute HF Rule-out : <300 pg/mL • Symptomatic chronic HF Rule-out : <125 pg/mL (<75 yrs) <450 pg/mL (≥75 yrs)
Storage Condition	Storage Condition

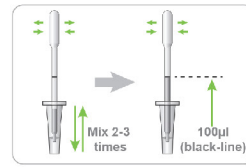
TEST PROCEDURE



1 Insert test device into the STANDARD F Analyzer.



2 Collect 100µl of sample to the black-line of the disposable dropper.



3 Mix sample and buffer 2-3 times, and collect 100µl of sample mixture to the black-line.



4 Apply the sample mixture into the sample well, and immediately press the START button.

RESULT INTERPRETATION

- In Emergency room, NT-proBNP is useful for the triage of patients with acute dyspnea and suspected acute heart failure.

Rule-out	Gray zone	Age-adjusted cut-off	Confirmation						
<300 pg/ml		<table border="1"> <tr> <td><5 yrs</td> <td>>450</td> </tr> <tr> <td>50-75 yrs</td> <td>>900</td> </tr> <tr> <td><5 yrs</td> <td>>1,800</td> </tr> </table>	<5 yrs	>450	50-75 yrs	>900	<5 yrs	>1,800	<10,000 pg/ml
<5 yrs	>450								
50-75 yrs	>900								
<5 yrs	>1,800								
HF unlikely	HF Possible	HF unlikely	HF very likely and severe						

- In primary care, NT-proBNP is useful to monitor the patients with chronic heart failure because it excludes suspected left ventricular systolic dysfunction.

Age	NT-proBNP (pg/mL)	Interpretation
<ul style="list-style-type: none"> • <75 yrs • ≥75 yrs 	<ul style="list-style-type: none"> • <125 • <450 	Heart Failure Unlikely
<ul style="list-style-type: none"> • <75 yrs • ≥75 yrs 	<ul style="list-style-type: none"> • ≥125 • ≥450 	Left ventricular dysfunction possible

METHOD COMPARISON

Reference method vs STANDARD F NT-proBNP FIA	
Correlation with Roche Cobas	$y=0.9842x + 11.036, R^2=0.9694, n=180$
CV%	QCL=11.3% / QCM=11.2% / QCH=11.3%
Differ (%)	Within 15%

ORDERING INFORMATION

Category	Product	Pack Size
Cardiovascular Disease	STANDARD F NT-proBNP FIA	20 Test
	STANDARD F NT-proBNP Control	Lv1 x 10 / Lv2 x 10