ENGLISH

LumiraDx NT-proBNP

For Professional Use Only
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IVD

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LumiraDx NT-proBNP:

The LumiraDx NT-proBNP Test Strips (hereafter referred to as Test Strips) are to be used with the LumiraDx Platform. The LumiraDx Platform is a point of care system for professional use which is used for *in vitro* diagnostic tests. It comprises a portable LumiraDx Instrument and a LumiraDx Test Strip for the required test. This test is for **HEALTHCARE PROFESSIONAL USE ONLY** and allows users to perform tests and to view results quickly on the Instrument touch-screen.

Intended use:

The LumiraDx NT-proBNP test is an *in vitro* diagnostic test for the quantitative determination of N-terminal pro-Brain Natriuretic Peptide (NT-proBNP) in human capillary and venous whole blood and plasma samples (Lithium Heparin).

The LumiraDx NT-proBNP Test Strips are intended for use with the LumiraDx Instrument. It is an automated *in vitro* diagnostic test for near-patient testing. The NT-proBNP test is intended to be used as an aid in the diagnosis of individuals suspected of having congestive heart failure (also referred to as heart failure). The LumiraDx NT-proBNP test is for Professional Use Only. For patients ≥18 years of age.

Caution: For *in vitro* diagnostic use.

Before you start testing, if you are new to the LumiraDx Instrument and LumiraDx Platform, you must read the LumiraDx Platform User Manual, the LumiraDx NT-proBNP Quick Reference Instructions and this entire product insert. In addition, please watch the LumiraDx Platform Training Video available at lumiradx.com.

Summary and explanation of the test:

Heart failure (HF) is a clinical syndrome with symptoms and/or signs caused by a structural and/or functional cardiac abnormality and corroborated by elevated natriuretic peptide levels and/or objective evidence of pulmonary or systemic congestion.[1]

Natriuretic peptides such as N-terminal pro-Brain Natriuretic Peptide (NT-proBNP) is elevated in most forms of HF and are an integral component of making a diagnosis of HF in many clinical settings.[1]

The use of NT-proBNP has the highest class of recommendation to support a diagnosis or exclusion of heart failure in contemporary practice guidelines.[2]

Principle of the assay:

The LumiraDx NT-proBNP test is a rapid microfluidic immunofluorescence assay for use with the LumiraDx Instrument for the quantitative measurement of NT-proBNP in human whole blood (direct fingerstick or Lithium Heparin-venous) and Lithium Heparin plasma specimens.

The test procedure involves the addition of fingerstick, venous whole blood or plasma sample to the sample application area of the Test Strip inserted in the Instrument.

The Instrument is programmed to perform the analysis when the sample has reacted with the reagents. The analysis is based on the amount of fluorescence the Instrument detects within the measurement area of the Test Strip. The concentration of the analyte in the sample is proportional to the fluorescence detected. The results are displayed on the Instrument touch-screen in 12 minutes from the addition of sample.

Materials provided:

- Lumiradx NT-proBNP Test Strips packed individually in sealed desiccant foil pouches
- LumiraDx NT-proBNP Product Insert
- RFID (Radio frequency ID) Tag held inside the Test Strip carton
- Quality Control Ranges Pack Insert

Materials required but not provided with the Test Strip carton:

- LumiraDx Instrument
- LumiraDx NT-proBNP Quality Controls (as required to meet local and organisational compliance)
- Standard blood collection equipment (high flow lancets if using fingerstick whole blood sample, blood collection tube (Lithium Heparin) if using venous whole blood or plasma sample, Lithium Heparin transfer tubes of 20μl or 25μl size, appropriate biowaste disposal)
- LumiraDx Connect if connectivity required (refer to LumiraDx Connect User Manual)

Reagents:

The Test Strip contains reagents designed to detect the presence of NT-proBNP in the applied sample and to generate an optical signal that can be used to measure the concentration of NT-proBNP. The key components of these reagents are mouse monoclonal anti-NT-proBNP antibodies, recombinant NT-proBNP monoclonal antibody, fluorescent microparticles and magnetic microparticles.

Warnings and precautions:

- For *in vitro* diagnostic use only.
- Do not open the Test Strip until ready for immediate use.
- Discard and do not use any damaged or dropped Test Strips or other materials.
- Inadequate or inappropriate sample collection, storage, and transport can result in incorrect results.
- The test cannot be visually interpreted; the LumiraDx Instrument must be used to generate results.
- Do not use the kit components beyond the expiration date.
- Do not reuse any kit components.
- Samples must be processed as indicated in the Performing a Test section of this Product Insert. Failure to follow the instructions for use can result in inaccurate results.
- All components of this kit should be discarded as Biohazard waste according to local regulations and procedures.
- Refer to the product safety data sheet for risk and safety phrases and disposal information. The product safety data sheet is available via our website lumiradx.com.
- Exercise the normal precautions required for handling all laboratory reagents. Wear protective clothing such as laboratory coats, disposable gloves, and eye protection when samples are collected and evaluated.
- Proper laboratory safety techniques should be followed at all times when working with patient samples. Patient samples, used Test Strips and used blood collection equipment may be potentially infectious. Proper handling and disposal methods should be established by the laboratory in accordance with local regulations and procedures.

Storing the Test Strips:

Store the Test Strips in their original carton. You can store the Test Strips at a temperature between 2°C and 30°C (36°F and 86°F). Avoid freezing or storing in any area that could exceed 30°C. When stored properly, the Test Strips can be used until the expiration date printed on the Test Strip foil pouch and the Test Strip carton. Discard the Test Strips if they are past the expiration date.

Handling the Test Strips:

When you are ready to perform a test, open the Test Strip carton, take out a Test Strip, and remove it from the foil pouch. Hold the Test Strip by gripping the blue label end with the label facing upwards. Do not touch the Test Strip Sample Application Area. Do not bend or fold the Test Strip. Do not touch the Test Strip contacts. After removing the Test Strip from the foil pouch, it should be used immediately. Do not use the Test Strip if there are any visible signs of damage to the foil pouch such as tears or holes.

Sample material:

The following samples can be used with the LumiraDx NT-proBNP Test Strip:

- Whole blood – Capillary fingerstick sample (direct – non-anticoagulated) or using
- Transfer tube – (Lithium Heparin anticoagulated)
- Anticoagulated venous whole blood (Lithium Heparin)
- Plasma (Lithium Heparin)
- LumiraDx NT-proBNP Quality Controls

The test device contains:

- Mouse monoclonal antibodies
- Recombinant NT-proBNP monoclonal antibody
- Magnetic particles
- Fluorescent Latex particles
- Buffer and Stabilising Agents
- Lectins in buffer solution

Sample collection and preparation for analysis:

When collecting any type of sample, follow universal blood collection precautions and guidelines according to your organization. For sample collection of venous whole blood or plasma, follow the sample tube manufacturer's recommended procedure.

The steps that follow apply to collecting a capillary blood sample from a fingerstick. Optionally, you may use a Lithium Heparin anticoagulated transfer tube to collect the fingerstick blood sample. Details of recommended transfer tubes are available at lumiradx.com. Only auto-disabling, high flow single use lancing devices may be used to collect capillary blood.

When testing from venous whole blood or plasma sample use Lithium Heparin as the anticoagulant with this product.

- Capillary blood samples cannot be stored and must be tested immediately.
- Venous blood samples should be tested within 24 hours of sample collection or refrigerated and tested within 6 days. Do not freeze.
- Plasma samples should be tested within 24 hours of sample collection or refrigerated and tested within 6 days. Do not freeze.

Preparing the Instrument to perform a test:

Power on the Instrument by pressing the power button at the rear of the Instrument. You will hear the Instrument powering on, and the display will be a blank black screen for several seconds before starting up. If the screen is just dimmed tap the touch-screen to wake up the Instrument.

Refer to the section on Performing a Test in this Product Insert for information on how to test a Patient sample. The LumiraDx Quick Reference Instructions (QRI) provide an illustrated step-by-step procedure on how to run a Test. Operate the LumiraDx Platform with the NT-proBNP test at room temperature between 15°C and 30°C (59°F and 86°F) and 10% - 90% relative humidity.

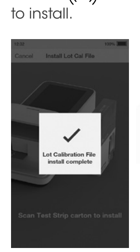
The Instrument will prompt to install the Lot Calibration File when inserting a new Test Strip Lot. Once installed, the Instrument will have all the information required to process the test, and any future tests from the same Lot of Test Strips.

Lot Calibration File installation:

Lot Calibration Files are required to provide the Instrument with the information needed to perform diagnostic tests. This only needs to be completed once for each Test Strip Lot. The Instrument will prompt to install the Lot Calibration File when inserting a new Test Strip Lot.

RFID strip code reader
Locate ((•)) symbol on Instrument.

Installation
Touch back of Test Strip Carton ((•)) symbol to install.



The Instrument will sound and a confirmation message will be displayed.

When indicated by the touchscreen, open the foil pouch just before use and insert the LumiraDx Test Strip into the LumiraDx Instrument. The Instrument will indicate when it is ready for the sample to be applied.

The LumiraDx NT-proBNP test results should be evaluated by a Healthcare Professional in the context of all available clinical and laboratory data.

Testing from a fresh capillary fingerstick sample:

1. **Collecting a capillary blood sample from a fingerstick:** Ensure the patient thoroughly washes and dries their hands with warm soapy water prior to sample collection. Note: the hands must be completely clean of all hand oils, lotions, gels, sanitizers and/or any foreign matter prior to sample collection, which may otherwise cause unreliable results. If isopropyl alcohol (IPA) wipes are used, wipe the fingerstick site with a gauze pad and make sure the site is completely dry. If any alcohol remains (or is reintroduced) on the finger, it may cause unreliable results. Increasing the blood flow in the finger will help to get a good drop of blood. Before lancing the finger, the following techniques can be used until the fingertip has increased colour:
   - Ask the patient to rinse their hands with warm water.
   - Ask the patient to hold his or her arm straight down at their side.
   - Massage the finger from its base, and if required, immediately after lancing, very gently squeeze the finger from its base to encourage blood flow.
2. **Use a high flow lancet** on the selected finger to obtain a blood sample.
3. **Immediately apply the sample** by holding the finger and the hanging blood drop over the Sample Application Area of the inserted Test Strip. Allow the blood drop to touch the Sample Application Area of the Test Strip. Blood will then be drawn by capillary action into the Test Strip. When the sample is detected, the Instrument will sound (if sounds are enabled) and a confirmation message will be displayed. The touch-screen of the LumiraDx Instrument will request the user to close the door.
4. **Do not add more blood.** Do not open the door while the test is in progress. The touch-screen will indicate test progress.
5. **The result** will appear on the Instrument touch-screen within 12 minutes of applying the sample and starting the test.
6. **Dispose** of the lancet and Test Strip in the appropriate clinical waste.
7. **Clean** the patient's finger with a clean tissue and apply slight pressure.
8. If you need to retest, use a new Test Strip and lancet, and a different finger.

Using a transfer tube from a capillary fingerstick sample:

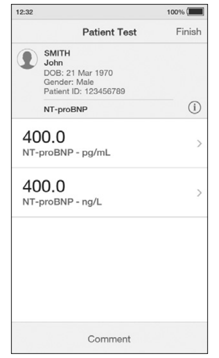
You must use a Lithium Heparin anticoagulated transfer tube to transfer the capillary sample from the fingerstick to the Sample Application Area of the Test Strip. To do this follow the procedure above for collecting a capillary blood sample from a fingerstick. Use the transfer tube by placing it into the blood droplet on the finger, and the blood should quickly move into the tube. Then hold the transfer tube over the Sample Application Area of the Test Strip and dispense the sample. This should be enough just to fill the Sample Application Area. Take care not to introduce air bubbles into the sample. When the sample is detected, the Instrument will sound (if sounds are enabled) and a confirmation message will be displayed. The touch-screen of the LumiraDx Instrument will request the user to close the door. Dispose of the transfer tube in the appropriate clinical waste. Follow instructions from step 4.

Testing from venous blood and plasma sample:

Mix the sample well before testing. You may use Lithium Heparin venous blood or plasma samples for testing. Use a pipette to remove 20μl of sample from the tube. Hold the pipette over the Sample Application Area of the Test Strip and dispense the sample. This should be enough just to fill the Sample Application Area. Take care not to introduce air bubbles into the sample. When the sample is detected, the Instrument will sound (if sounds are enabled) and a confirmation message will be displayed. The touch-screen of the LumiraDx Instrument will request the user to close the door. Dispose of the pipette in the appropriate clinical waste. Follow instructions from steps 4 and 5.

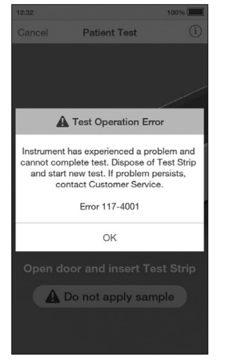
Results interpretation:

The results will be displayed on the Instrument screen (1 pg/mL = 1 ng/L) – **example of results screen display:**



Invalid test results:

If an issue occurs, a message will be displayed on the Instrument touch-screen. Alert messages include useful information and are highlighted by an orange banner. Error messages also include a ⚠ symbol. All messages will contain a description of the Instrument status or error and an instruction. Error messages contain an identifying code that may be used for further troubleshooting purposes. Refer to the LumiraDx Platform User Manual if an error message is displayed on the LumiraDx Instrument touch-screen and contact LumiraDx Customer Services.


12:32
100%
Cancel
Patient Test
Test Operation Error
Instrument has experienced a problem and cannot complete test. Dispose of Test Strip and start new test. If problem persists, contact Customer Service.
Error 117-4001
OK
Open door and insert Test Strip
Do not apply sample

Example of an error screen:

If the On Board Control (OBC) fails, an error message will be shown and no test result will be returned. Follow the on screen instructions to dispose of the Test Strip and start a new test. If the problem persists, contact Customer Services.

Testing patient samples procedural notes:

- Capillary blood samples cannot be stored and must be tested immediately.
- Venous blood samples should be tested within 24 hours of sample collection or refrigerated and tested within 6 days. Do not freeze.
- Plasma samples should be tested within 24 hours of sample collection or refrigerated and tested within 6 days. Do not freeze.
- Refrigerated plasma samples must be allowed to reach room temperature and be mixed thoroughly before testing.
  - Before use, mix plasma samples by vortexing or inverting the tube several times

Built-in controls:

The Instrument reads the 2D barcode on each Test Strip and can identify if the Test Strip has exceeded the expiry date for use, and if the Test Strip Lot Calibration file has not yet been loaded at which point it will request it.

The LumiraDx Instrument and LumiraDx NT-proBNP Test Strips have several quality control functions integrated to ensure validity of each test run. These checks ensure that the volume of sample added is sufficient and the assay sequence of the Test Strip is as expected. The checks also ensure that the Test Strip has not been damaged or used previously. If these checks are not verified, the test run will be rejected and an error message displayed on the Instrument touchscreen.

The LumiraDx Instrument ensures the quality of test results obtained through the following features:

- Automated checks of the correct functioning of the Instrument at power on and during operation. This includes electrical component operation, heater operation, battery charge state, mechanical actuators and sensors and optical system performance.
- Monitoring of Test Strip performance and controls during test runtime.
- Ability to perform Quality Control Tests using LumiraDx Quality Control solutions to meet regulatory compliance requirements.

Traceability:

The LumiraDx NT-proBNP Test is calibrated against internal panels of both clinical plasma and clinical whole blood, the concentrations of which are traceable to the Roche cobas Elecsys® proBNP II assay.

Hematocrit (Hct) range:

The Hct level is determined by the Instrument for each blood sample applied to the test. The LumiraDx NT-proBNP Test can be used with blood samples with Hct levels of 15-55% Hct. Samples with Hct levels outside this range are shown as 'Hct Out of Range' on the Instrument touch-screen. No NT-proBNP value is reported in samples with 'Hct Out of Range'.

External Quality Controls:

External liquid Quality Controls for LumiraDx NT-proBNP are available from LumiraDx and may be used to demonstrate that the Test is functioning properly by demonstrating the expected Quality Control results and correct test performance by the operator. External Quality Control requirements should be established in accordance with local and organizational compliance. It is recommended that external control testing be performed with each new operator and before using a new lot or shipment of the LumiraDx NT-proBNP Test Strips. Refer to the LumiraDx NT-proBNP Quality Controls pack insert available at lumiradx.com for detailed instructions. LumiraDx NT-proBNP Quality Controls are purchased separately.

If the LumiraDx NT-proBNP Quality Controls do not perform as expected, repeat the QC Test and if the problems persist, do not report patient results and contact LumiraDx Customer Services.

Cleaning and disinfection:

It is recommended to disinfect the Instrument after each patient sample, or if contamination is suspected. Excessive liquid may damage the Instrument. It is important for the protection of the Instrument that exposure to excess moisture is prevented. All disinfection cloths and/or wipes should only be slightly damp, with any excess liquid being manually removed from the cloth before use. Alcohol wipes alone are not sufficient to disinfect the Instrument for blood-based samples, due to the potential presence of bloodborne pathogens

1. Using a LumiraDx recommended disinfecting material, wipe the external surfaces of the Instrument while taking care to avoid the door hinges, Test Strip inlet, power cord, and USB port.
2. Allow the disinfectant at least 5 minutes contact time with the Instrument before testing the next sample.
3. Dispose of disinfectant materials in accordance with local biohazardous waste disposal procedures.

To clean the Instrument wipe the external surfaces with a soft, slightly damp cloth when it appears visibly dirty.

For more information, or for the full procedure on cleaning and disinfection, please refer to the Technical Bulletin Platform Disinfection Procedure at lumiradx.com.

Limitations:

- The LumiraDx NT-proBNP test uses fresh capillary whole blood, venous blood and plasma samples. The sample size must be a minimum of 20μL in volume. Low sample volume will cause an error message. Never add more sample to the Test Strip after the test has begun.
- Use the Test Strip only once and then dispose of it appropriately in clinical waste.
- There is the possibility that factors such as technical or procedural errors, as well as additional substances in blood and plasma samples that are not listed below, may interfere with the test and cause erroneous results.
- Blood sample types, draw methods or anticoagulants different from those described in this pack insert have not been evaluated.
- As with any assay employing mouse antibodies, the possibility exists for interference by human anti-mouse antibodies (HAMA) in the sample. The test has been formulated to minimize this interference; however, samples from patients who have been routinely exposed to animal serum products may contain heterophile antibodies which may cause erroneous results.
- The test has been formulated to minimise interference from Rheumatoid Factors (RF), however, due to heterogeneity of RF, specimens from patients with highly elevated RF may cause erroneous results.
- Hematocrit values between 15-55% do not significantly affect test results. Hematocrit values outside the range 15-55% will generate an error message showing 'Hct Out of Range' and no NT-proBNP result will be reported.
- Any unusual result must always be followed up to identify the potential cause.
- Results that do not match the clinical symptoms should be repeated to rule out a procedural error.
- The assay has not been validated for individuals younger than 18 years old.
- When performing a new test or repeating a patient test, always use a new lancet to obtain a fresh drop of blood from a different finger and use a new Test Strip.
- Unusual Results: If the LumiraDx Instrument displays an error message, refer to the Troubleshooting section of the LumiraDx Platform User Manual. If the LumiraDx Instrument displays an unexpected test result (other than an error message), check this Limitations section.

Results:

The LumiraDx NT-proBNP test measures NT-proBNP concentration via measurement of an optical signal generated when the fluorescent immunoassay (FIA) reagents deposited on the Test Strip are resuspended in the patient sample. The measured optical signal is proportional to the NT-proBNP concentration. The optical signal is then converted to NT-proBNP concentration via use of a calibration curve, which is established per lot of Test Strips during the calibration process.

Each NT-proBNP result is reported on screen in any 1 of the following user-selectable options:

1. Both pg/mL and ng/L
2. pg/mL
3. ng/L

The system default unit of measurement is both pg/mL and ng/L units of measurement. Units of measurement are configurable via the Settings Menu. Please refer to the Platform User Manual for more information.

The conversion from pg/mL to ng/L is 1:1.

Performance characteristics

Expected values:

The diagnostic value of NT-proBNP, in addition to signs and symptoms and other diagnostic tests, such as an electrocardiogram (ECG/EKG), has been assessed in several studies in the non-acute, primary care setting[3-8]. The aim of these studies was to either exclude or establish a diagnosis of heart failure[9]. In these studies, the upper cut-off limit for NT-proBNP was determined to be 125 pg/mL (ng/L)[9]. For results <125 pg/mL (ng/L), the probability of having heart failure was determined to be very low based on the robustness of the studies conducted[9].

Each laboratory should establish a reference range that is representative of the patient population to be evaluated. Additionally, each laboratory should consider the current practice in the evaluation of patients experiencing symptoms at each institution.

Measuring range:

The LumiraDx NT-proBNP test used with the LumiraDx Instrument has a reportable range of 50 - 9,000 pg/mL (ng/L). 'NT-proBNP <50 pg/mL (ng/L)' is displayed if the NT-proBNP concentration is less than 50 pg/mL (ng/L). 'NT-proBNP > 9,000 pg/mL (ng/L)' is displayed if the NT-proBNP concentration is more than 9,000 pg/mL (ng/L).

Linearity:

Linearity was established according to a protocol based on CLSI EP06-ED2[11] in heparinised plasma. High NT-proBNP concentration samples were screened clinical samples and assigned a value using a reference system. Linearity series were then prepared by mixing the high concentration samples with plasma depleted of analyte. The results obtained, confirm linearity across the measuring range of 50 to 9,000 pg/mL (ng/L).

Hook effect:

No hook effect is observed with the LumiraDx NT-proBNP test at NT-proBNP concentrations up to 20,000 pg/mL (ng/L).

Precision:

A precision study was carried out in heparinised venous plasma on a protocol based on CLSI EP05-A3[12]. The study was carried out at 2 concentrations of NT-proBNP, each was tested in 1 run of 5 replicates per day, for five days across 3 sites. The results of the precision study are summarised below:

NT-proBNP Concentration (pg/mL & ng/L)	Within Day Precision (%CV)	Between Day Precision (%CV)	Between Site Precision (%CV)	Total Precision (%CV)	n
100 - 150	8.4	0.0	4.3	9.4	75
800 - 1200	10.4	0.0	6.0	12.0	75

Blood precision was also determined using duplicate samples from patients tested on 1 Test Strip lot at 1 site across a NT-proBNP range of 51 - 5514 pg/mL (ng/L). The following results represent the mean paired rep %CV for each sample type tested:

Sample Type	n	Range (pg/mL & ng/L)	Mean % CV
Capillary Blood	22	59.2 - 4559	4.1
Venous Blood (Lithium Heparin)	32	51 - 5514	4.7
Plasma (Lithium Heparin)	31	57 - 5182	5.1

Method comparison:

A method comparison study was carried out in heparinised venous plasma on a protocol based on CLSI EP09c-ED3[10]. The study was carried out using 3 Test Strip lots.

Each sample tested on the LumiraDx Platform was compared to plasma tested on the Roche cobas Elecsys® proBNP II assay. The data was analysed by Passing Bablok regression. The analyses are summarised below:

LumiraDx LOT	n	NT-proBNP range (pg/mL & ng/L)	Slope	Intercept	r
All LOTs Venous Plasma (Lithium Heparin)	659	50.5 - 8789	0.86	-4.12	0.97

Matrix equivalency:

A study was carried out on capillary fingerstick blood, paired whole blood (Lithium Heparin) and plasma (Lithium Heparin) samples. The data was analysed by Passing Bablok regression. The analyses are summarised below:

LumiraDx Sample Type	n	NT-proBNP range (pg/mL & ng/L)	Slope	Intercept	r
Capillary Blood vs Plasma (Lithium Heparin)	51	57.0 - 5182	1.07	-3.85	0.99
Venous Blood (Lithium Heparin) vs Plasma (Lithium Heparin)	62	57.0 - 5514	1.17	-11.36	0.99

Interference:

Testing was performed according to a protocol based on CLSI EP07-ED3[13]. Testing was carried out using Lithium Heparin plasma samples, where possible, at two concentrations of NT-proBNP (100-150 pg/mL (ng/L) and 800-1200 pg/mL (ng/L)) spiked with interfering substances. The following interferents showed no significant effect on NT-proBNP Test results (≤15% (≤799 pg/mL (ng/L)) and ≤20% (≥800 pg/mL (ng/L))) difference compared to negative control with 95% confidence.

Exogenous (test concentration):

Amlodipine (0.0075 mg/dL), Amoxicillin (5.4 mg/dL), Apixaban (0.0315 mg/dL), Ascorbic Acid (5.25 mg/dL), Aspirin (3 mg/dL), Atenolol (0.72 mg/dL), Atorvastatin (0.075 mg/dL), Bendroflumethiazide (0.6 mg/dL), Biotin (0.2808 mg/dL), Bisoprolol (0.0258 mg/dL), Caffeine (10.8 mg/dL), Calciferol (0.015 mg/dL), Cetirizine (0.435 mg/dL), Citalopram (0.543 mg/dL), Clarithromycin (0.72 mg/dL), Clopidogrel (18 mg/dL), Doxycycline (1.8 mg/dL), EDTA (0.099 mg/dL), Fluconazole (2.55 mg/dL), Folic acid (0.0012 mg/dL), Furosemide (1.59 mg/dL), Heparin sodium (330 U/dL), Ibuprofen (21.9 mg/dL), Levothyroxine (0.0429 mg/dL), Losartan (9 mg/dL), Metronidazole (12.3 mg/dL), Nicotine (0.0969 mg/dL), Omeprazole (0.168 mg/dL), Paracetamol (15.6 mg/dL), Prochlorperazine (0.345 mg/dL), Ramipril (0.0156 mg/dL), Sacubitril (0.915 mg/dL), Salbutamol (0.0045 mg/dL), Sertraline (0.0927 mg/dL), Simvastatin (0.168 mg/dL), Spironolactone (0.0555 mg/dL) and Warfarin (7.5 mg/dL)

Endogenous (test concentration):

Bilirubin (unconjugated) (40 mg/dL), Fibrinogen (10 mg/mL), Hemoglobin (Via hemolysis) (216 mg/dL), Lipemia (1320.5 mg/dL), and Total Protein (9.49 g/dL)

It is possible that other substances and/or factors not listed above may interfere with the test and cause inaccurate results.

Symbols glossary

Symbol	Meaning
	Temperature limitation
	Manufacturer
IVD	*In vitro* diagnostic medical device
REF	Catalogue Number
LOT	Lot Number
	Use-by Date – indicates the date after which the unopened IVD/Quality Control Material cannot be used
	Refer to instructions for use
	Do not re-use
	For near patient testing
CE	"CE Mark". This product fulfils the requirements of the European Directive 98/79/EC on *in vitro* diagnostic medical devices.
((•))	Indicates the presence of the Radio Frequency Identification (RFID) reader/tag.
Σ	Total number of IVD tests that can be performed with the IVD medical device.
UDI	Indicates a carrier that contains unique device identifier information.
	Importer
	Distributor
UK CA	UK conformity assessed under the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002)
EC REP	Authorized Representative in the European Union

References:

1. Bozkurt B., et. al. Universal definition and classification of heart failure: a report of the Heart Failure Society of America, Heart Failure Association of the European Society of Cardiology, Japanese Heart Failure Society and Writing Committee of the Universal Definition of Heart Failure: Endorsed by the Canadian Heart Failure Society, Heart Failure Association of India, Cardiac Society of Australia and New Zealand, and Chinese Heart Failure Association. Eur. J. Heart Fail. 2021.
2. Yancy, C., et. al. 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. Circulation. 2017.
3. Gohar A, et al. Mid-regional pro-atrial natriuretic peptide for the early detection of non-acute heart failure. Eur J Heart Fail. 2019.
4. Cowie MR, et. al. Value of natriuretic peptides in assessment of patients with possible new heart failure in primary care. Lancet. 1997.
5. Zaphiriou A, et. al. The diagnostic accuracy of plasma BNP and NTproBNP in patients referred from primary care with suspected heart failure: results of the UK natriuretic peptide study. Eur J Heart Fail. 2005.
6. Kelder JC, et. al. Clinical utility of three B-type natriuretic peptide assays for the initial diagnostic assessment of new slow-onset heart failure. J Card Fail. 2011.
7. Verdu JM, et. al. Rapid point-of-care NT-proBNP optimal cut-off point for heart failure diagnosis in primary care. Rev Esp Cardiol (Engl Ed). 2012.
8. Taylor CJ, et. al. Primary care REFerral for EchocaRdiogram (REFER) in heart failure: a diagnostic accuracy study. Br J Gen Pract. 2017.
9. McDonagh TA & the Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC). 2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. European Heart Journal. 2021.
10. CLSI EP09c-ED3
11. CLSI EP06-ED2
12. CLSI EP05-A3
13. CLSI EP07-ED3

Visit www.CLSI.org for information

LumiraDx customer services:

For product inquiries please contact LumiraDx Customer Services at customerservices@lumiradx.com or find telephone contact details at lumiradx.com.

If during the use of the device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority.

For return policy:

If there is a problem with the LumiraDx NT-proBNP test strips you may be asked to return them. Before returning tests please obtain a return authorization number from LumiraDx Customer Services. This return authorization number must be on the shipping carton for return. For ordinary returns following purchase, please contact LumiraDx Customer Services for terms and conditions.

Limited warranty:

LumiraDx NT-proBNP Test Strips – as per shelf life.

Unused strips must be stored according to the required storage conditions as printed in this product insert and they can be used only up to the expiry date printed on the Test Strip pouch and Test Strip box. For the applicable warranty period, LumiraDx warrants that each product shall be (i) of good quality and free of material defects, (ii) function in accordance with the material specifications referenced in the product insert, and (iii) approved by the proper governmental agencies required for the sale of products for their intended use (the "limited warranty"). If the product fails to meet the requirements of the limited warranty, then as customer's sole remedy, LumiraDx shall either repair or replace, at LumiraDx's discretion, the Test Strips. Except for the limited warranty stated in this section, LumiraDx disclaims any and all warranties, express or implied, including but not limited to, any warranty of merchantability, fitness for a particular purpose and non-infringement regarding the product. LumiraDx's maximum liability with any customer claim shall not exceed the net product price paid by the customer. Neither party shall be liable to the other party for special, incidental or consequential damages, including, without limitation, loss of business, profits, data or revenue, even if a party receives notice in advance that these kinds of damages might result. The Limited Warranty above shall not apply if the customer has subjected the LumiraDx NT-proBNP Test Strips to physical abuse, misuse, abnormal use, use inconsistent with the LumiraDx Platform User Manual or Product Insert, fraud, tampering, unusual physical stress, negligence or accidents. Any warranty claim by Customer pursuant to the Limited Warranty shall be made in writing within the applicable Limited Warranty period.

Intellectual property:

The LumiraDx Instrument, Test Strips and all provided LumiraDx documentation ('Products') are protected by law. The Intellectual Property of the LumiraDx Products remains at LumiraDx. Details of relevant Intellectual Property regarding our products can be found at lumiradx.com/IP. Test Strips contained herein include reagents provided under license right from TriLink BioTechnologies LLC.

Legal notices:

Manufacturer information:

LumiraDx UK Ltd
Dumyat Business Park, Alloa, FK10 2PB, UK.
Registration number: 09206123

EC REP LumiraDx AB, Västra Vägen 5A, 16961 Solna, Sweden

CE Mark applies to LumiraDx Instrument, Test Strips, Quality Controls, and Connect Hub only

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