



CRP Test Strip Product Insert

For Professional Use Only

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LumiraDx CRP Test

The LumiraDx C-Reactive Protein (CRP) 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 using small sample volumes and to view results quickly on the instrument touch-screen.

Intended Use:

The LumiraDx CRP Test Strips are intended for use with the LumiraDx Instrument. It is an automated *in vitro* diagnostic test for near-patient testing, for use by healthcare professionals, for the quantitative determination of C-reactive Protein in human whole blood (capillary fingerstick and venous) and plasma samples. The measurement of CRP provides information for the detection and evaluation of infection, tissue injury, inflammation disorders, and associated disease. It is intended for use in patients 2 years of age or older.

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 Multi Quality Control Pack Insert, and this entire product insert. In addition, please watch the LumiraDx Platform Training Video available at lumiradx.com.

Summary and Explanation of the Test:

CRP is one of the most prominent acute phase proteins (APP), a protein whose serum concentration increases or decreases during acute or chronic inflammatory conditions. As such it has become a universal biomarker of infection and inflammation for a number of diseases and pathophysiological conditions. Like many acute phase proteins, CRP is normally present at trace levels in serum, but increases rapidly and dramatically in response to a variety of infectious or inflammatory stimuli.

Principle of the Assay:

The LumiraDx CRP Test is a single use fluorescence immunoassay device designed to determine the concentration of CRP 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 within the Test Strip. 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 4 minutes from the addition of sample.

Carton Contents:

- Test Strips packed separately in desiccant foil pouches (24 or 48)
- Product Insert (1)
- RFID (Radio frequency ID) Tag held inside the Test Strip carton (1)

Materials Required but not provided with the Test Strip Carton:

- LumiraDx Instrument
- LumiraDx Multi 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 blow/discard disposal)
- LumiraDx Connect if connectivity required (refer to LumiraDx Connect User Manual)
- More information available at lumiradx.com.

Reagents:

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

Reagents: Warnings and Precautions

- 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, state and federal regulations.
- Reagents encapsulated within the Test Strip, are present in extremely small amounts and, where any component is of animal origin. The source is certified as free from infectious or contagious material - however, should any reagent become exposed it should be treated as potentially infectious.

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 1 Test Strip, and remove it from the foil pouch. 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 CRP 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 Multi Quality Controls

The Test Device Contains:

- Mouse monoclonal antibodies
- Recombinant monoclonal antibodies
- Fluorescent dye
- Magnetic particles
- Latex particles
- Buffer and Stabilising Agents

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 cut/disinfecting, high flow single use lancet 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 should be tested within 24 hours of sample collection or refrigerated and tested within 5 days.
- Plasma should be tested within 24 hours of sample collection or refrigerated and tested within 7 days or frozen at -80°C for long term storage of sample.

Procedure/performing a test:

Refer to the LumiraDx Platform User Manual for instructions on how to analyse a patient or Quality Control sample. The LumiraDx Platform Quick Reference Guide also provides an illustrated step by step procedure. Before running a LumiraDx CRP Test Strip you must transfer the LumiraDx Lot Calibration File into the instrument from the RFID Tag in the Test Strip Carton. This is explained in the LumiraDx Platform User Manual. When indicated by the touch-screen, open the foil pouch just before use and insert the LumiraDx Test Strip into the LumiraDx Instrument. The instrument will indicate when ready for the sample to be applied.

The LumiraDx CRP Test results should be evaluated in the context of all the clinical and laboratory data available by a Healthcare Professional. It is recommended that each laboratory establish its own reference values based on the population that it serves.

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 (as is recommended) 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 4 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 repeat, 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.



Sample application using a transfer tube



Sample covering Sample Application Area

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.

Testing Patient Samples Procedural Notes:

- Plasma samples can be tested post freezing. If not testing plasma immediately, it should be stored and transported in a frozen state (-80°C). No more than a single freeze/thaw cycle is recommended.
- Frozen or refrigerated whole blood or plasma samples must be allowed to reach room temperature and be mixed thoroughly before testing.
 - Before use, mix whole blood venous samples by gently inverting the tube several times
 - Before use, mix plasma samples by vortexing or inverting the tube several times

Built-in Controls:

The LumiraDx Instrument and LumiraDx CRP Test Strips have several quality control functions integrated to ensure validity of each test run. These checks ensure that the behaviour of the sample moving into the reaction area of the Test Strip is as expected. The checks also ensure that the Test Strip has not been previously used and that whole blood samples outside the accepted hematocrit range are identified. When these checks are not successful, the test run will be rejected, and an error message presented on the instrument touch-screen. For more information about the built-in quality control functions, see the LumiraDx Platform User Manual.

Standardisation:

The calibration of the LumiraDx CRP Test is traceable to ERM® -DA474/IFCC.

Hematocrit (Hct) Range:

The Hct level is determined by the Instrument for each blood sample applied to the test. The LumiraDx CRP Test can be used with blood samples with Hct levels of 15-65%. Hct Samples with Hct levels outside this range are shown as 'Hct Out of Range' on the instrument touch-screen. No CRP value is reported in samples with Hct 'Out of Range'.

External Quality Controls:

External Liquid Quality Controls for LumiraDx CRP 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 CRP. Refer to the LumiraDx Multi Quality Controls Insert available at lumiradx.com for detailed instructions. LumiraDx Multi Quality Controls are purchased separately.

If the LumiraDx Multi 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 biohazardous 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 for 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 www.lumiradx.com.

Limitations of the Procedure:

- The LumiraDx CRP 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 minimise 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 may cause erroneous results.
- Hematocrit values between 15-65% do not significantly affect test results. Hematocrit values outside the range 15-65% will generate an error message showing 'Hct Out of Range' and no CRP result will be reported.
- Any unusual result must always be followed up to identify the potential cause.
- LumiraDx CRP is not intended for measuring CRP as a risk marker of coronary heart disease. For this purpose, a high sensitivity CRP test has to be used.
- 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 2 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 CRP Test measures CRP 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 CRP concentration. The optical signal is then converted to CRP concentration via use of a calibration curve, which is established per lot of Test Strips during the calibration process.

Specific Performance Characteristics

Measuring Range

The LumiraDx CRP Test used with the LumiraDx Instrument has a reportable range of 5 – 250 mg/L. CRP <5 mg/L is displayed if the CRP concentration is less than 5 mg/L. CRP > 250 mg/L is displayed if the CRP concentration is more than 250 mg/L.

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.

Linearity:

Linearity was established according to a protocol based on CLSI EP06-A² in heparinised venous blood and plasma. High CRP concentration samples were prepared by spiking each sample type with a commercially available CRP antigen. Linearity series were then prepared by mixing the high concentration samples with blood or plasma depleted of analyte. The results obtained, confirm linearity across the measuring range of 5.0 to 271 mg/L.

Detection Capability:

Detection Capability studies were performed according to a protocol that was based on the CLSI EP17-A2³ guideline. The studies were carried out in venous blood and plasma with 2 lots of Test Strips. Limit of blank (LoB) was calculated non-parametrically using 4 samples depleted of CRP on 15 instruments over 2 days. Limit of Detection (LoD) was determined non-parametrically using 4 low concentration CRP samples, on 15 instruments over 2 days. The Limit of Quantitation (LoQ) was determined by testing 4 low concentration CRP samples, on 15 instruments over 2 days.

Detection Limit	CRP Concentration (mg/L)	N
LoB	1.3	60
LoD	5.0	60
LoQ	5.0	60

Hook Effect:

No hook effect is observed with the LumiraDx CRP Test at CRP concentrations up to 1044 mg/L.

Precision:

A precision study was carried out in heparinised venous plasma on a protocol based on CLSI EP5-A3⁴. The study was carried out at 3 concentrations of CRP 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:

CRP Concentration (mg/L)	Within Day Precision (%CV)	Between Day Precision (%CV)	Between Site Precision (%CV)	Total Precision (%CV)	n
11.6	4.8	0.5	5.6	7.4	75
20.2	4.8	0.0	3.7	6.0	75
148.3	4.5	1.4	3.2	5.6	75

Blood precision was also determined using duplicate samples from patients tested on 1 Test Strip lots at multiple sites across a CRP range of 19.9-185.4 mg/L. The following results represent the mean paired rep %CV for each sample type tested:

Sample Type	n	Mean% CV
Capillary Blood - Direct Application	23	6.6
Capillary Blood - Transfer Tube	29	7.6
Venous Blood (Lithium Heparin)	31	8.1
Plasma	32	6.4

Method Comparison:

The method comparison was performed using 2 Test Strip lots with plasma samples (Lithium Heparin) sourced from patients presenting with symptoms of respiratory illness, inflammation or injury, at hospital Emergency Departments (ED), acute medical units or out-patient clinics.

Each sample tested on the LumiraDx Platform was compared to plasma tested on the RCRP Flexi[®] assay on the Siemens Dimension[®] Xpand[®] plus Integrated Chemistry System. The data was analysed by Passing Bablok regression. The analyses are summarised below:

LumiraDx LOT	n	CRP range (mg/L)	Slope	Intercept	r
All Lots Venous Plasma (Lithium Heparin)	205	5.1 - 245.2	1.00	-0.48	0.99

Matrix Equivalency:

A study was carried out with 40 subjects presenting with symptoms of respiratory illness, inflammation or injury. Samples of capillary fingerstick blood (direct application and transfer tube) and paired whole blood (Lithium Heparin) and plasma (Lithium Heparin) samples were collected and tested. The data was analysed by Passing Bablok regression. The analyses are summarised below:

LumiraDx Sample Type	n	CRP range (mg/L)	Slope	Intercept	r
Capillary Blood - Direct Application vs Plasma (Lithium Heparin)	44	5.2 - 169.6	0.98	-0.29	0.97
Capillary Blood - Transfer Tube vs Plasma (Lithium Heparin)	44	5.2 - 169.6	0.93	0.90	0.98
Venous Blood (Lithium Heparin) vs Plasma (Lithium Heparin)	43	5.2 - 169.6	1.05	-0.79	0.98

Interference:

Testing was performed according to a protocol based on CLSI EP07-ED3⁵. Testing was carried out using Lithium Heparin plasma samples, where possible, at three concentrations of CRP (10, 20, & 120 mg/L) spiked with interfering substances. The following interfering substances showed no significant effect on CRP Test results (≤10% (≤100 mg/L) and ≤15% (>100mg/L) difference compared to negative control with 95% confidence).

Exogenous (Test Concentration)

Acetaminophen (15.6mg/dl), Amikacin Sulphate (14.4mg/dl), Ampicillin (7.5 mg/dl), Ascorbic Acid (5.25 mg/dl), Biotin (0.35 mg/dl), Caffeine (10.8mg/dl), Carbamazepine (4.5mg/dl), Chloramphenicol (7.8mg/dl) Chlorzoxipride (0.69mg/dl), Chlorpromazine (0.33mg/dl), Cimetidine (3mg/dl), Diazepam (3mg/dl), Digoxin (0.0039mg/dl), K2-EDTA (0.099mg/dl), Erythromycin (13.8 mg/dl), Ethanol (600mg/dl), Ethosuximide (30mg/dl), Furosemide (1.59mg/dl), Gentamicin (8mg/dl), Heparin (Lithium) (203,000 IU/L), Ibuprofen (21.9 mg/dl), Lidocaine (1.5 mg/dl), Lithium (3.2mmol/l), Nicotine (0.08mg/ml), Pentobarbital (12.6 mg/dl), Phenytoin (6mg/dl), Primidone (5.7 mg/L), Salicylic acid (2.86mg/dl), Theophylline (6mg/dl), Valproic acid (31.8mg/dl).

Endogenous (Test Concentration)

Bilirubin (unconjugated) (16 mg/dl), Cholesterol (400mg/dl), Creatinine (15mg/dl), Hemoglobin (via Hemolysis) (150 mg/dl), Human Albumin (800mg/dl), Total IgG (800mg/dL), Total Protein (3g/dl), Lipemia (triglycerides) (1500 mg/dl), Urea (120mg/dl), Uric acid (23.5 mg/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
	Importer
	Distributor
	<i>In vitro</i> diagnostic medical device
	Catalogue Number
	Lot Number
	Use-by Date – indicates the date after which the unopened IVD/Quality Control Material cannot be used
	'CE Mark'. This product fulfils the requirements of the European Directive 98/79/EC on <i>in vitro</i> diagnostic medical devices.
	UK conformity assessed under the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002)
	Refer to instructions for use

Symbol	Meaning
	Do not re-use
	Indicates the presence of the Radio Frequency Identification (RFID) reader/tag.
	Authorized Representative in the European Union
	Total number of IVD tests that can be performed with the IVD medical device.
	For near patient testing

References:

1. Clyne, B. Otsaker JS. The C-reactive protein. J Emerg Med 1999;17:1019-25.
2. CLSI EP06-A
3. CLSI EP17-A2
4. CLSI EP5-A3
5. 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.

Any adverse results experienced with the use of this product, and/or quality problems should also be reported to LumiraDx Customer Services on 0800 817 7239 or by email: customerservices@lumiradx.com or at www.lumiradx.com.

For a patient/user/third party in the European Union and in countries with identical regulatory regime (98/79/EC on *in vitro* Diagnostic Medical Devices); 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 CRP Tests 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