LumiraDx™

# CRP Test Specifications

For *in vitro* diagnostic use.

## Intended use

The LumiraDx CRP test is intended for use with the LumiraDx Platform. 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 finger stick 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.

## Test description

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.[1] As such it has become a universal biomarker of infection and inflammation for a number of diseases and pathophysiological conditions.

The LumiraDx CRP test is an easy to use, fast microfluidic immunoassay designed to rapidly quantify CRP levels in whole blood and plasma.

The test delivers rapid, quantitative results from a single direct fingerstick in 4 minutes at the point of care.

The CRP test is traceable to the ERM® - DA474/IFCC certified global reference materials.

## Built-in quality controls

The LumiraDx Platform is integrated with several built-in quality control checks to ensure that the Instrument and Test Strips are functioning correctly for every test run. These checks include:

- Electrical component operation, heater operation, battery charge state, mechanical actuators, sensors and optical system performance
- Test Strip positioning
- Test Strip expiry
- Monitoring of Test Strip performance and microfluidics controls during test runtime
- The CRP test contains an Onboard Quality Control (OBC) assay
- Sufficient sample volume
- Hematocrit determination on the Test Strip

## CRP quality controls

LumiraDx Multi Quality Controls come in two levels and are available from LumiraDx to complete Quality Control assessment of the Instrument and CRP Test Strips.

## 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. A comparison of 205 CRP measurements with the LumiraDx CRP test to the RCRP Flex® assay on the Siemens Dimension® Xpand® Plus Integrated Chemistry System analysed by Passing Bablok regression yielded the following statistics: Slope = 1.00, Intercept = -0.48, r=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 and data was analysed by Passing Bablok regression. The results showed equivalency across all matrix types.

## Precision

A precision study was carried out in heparinised venous plasma on a protocol based on CLSI EP5-A3. 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 in the below table:

| 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 |

## CRP test specifications

| | |
|---|---|
| **Displayed results** | CRP (mg/L to 1decimal place) |
| **Storage temperature** | 2–30°C (36–86°F) |
| **Operating temperature** | 15–30°C (59–86°F) |
| **Measuring range** | 5.0 - 250.0 mg/L |
| **Reference range** | CRP < 5 mg/L[2,3,4]* |
| **Hook effect** | No hook effect is observed with the LumiraDx CRP Test at CRP concentrations up to 1044 mg/L. |
| **Minimum sample size** | 20 µL |
| **Sample type** | • Direct fingerstick<br>• Venous Whole Blood (Lithium Heparin)<br>• Plasma (Lithium Heparin) |
| **Time to result** | 4 minutes |

*Each laboratory should determine a reference range that is representative of the patient population to be evaluated.


**References**

1. Clyne, B Olshaker JS. The C-reactive protein. J Emerg Med 1999;17:1019–25.
2. Claus DR, Osmand AP, Gewurz H. . J Lab Clin Med 1976; 87:120-8.
3. Dati F, Schumann G et al. Eur J Clin Chem Clin Biochem 1996; 34(6):517-20.
4. Dati F, Johnson AM, Whicher JT. Clin Chem Lab Med 2001; 39(11):1134-6.


**For more information visit lumiradx.com or contact the LumiraDx Customer Services by email: customerservices@lumiradx.com or Phone: 0080058647239**



**Product is not available in all countries and regions. Please check with your local LumiraDx sales representative or distributor for availability in specific markets.**


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