

## **CRT PERFORMANCE STUDIES**

Different laboratory methods are used in the diagnosis of Covid-19 (SARS CoV-2) infection. PCR is most commonly used in throat and nasal swab samples, and antibody detection tests are applied in whole blood and serum samples. In antibody detection, quantitative tests such as ECLIA (electrochemiluminescence) and microelisa and qualitative study methods such as lateral flow technology are used.

Lateral flow technology (card-test) is a method frequently used for reasons such as fast results and easy operation technology. As in all lateral flow technologies, the CRT brand Covid-19 rapid diagnostic kit also gives qualitative results for IgG and IgM antibodies.

It was determined that the test has high sensitivity and specificity in validation studies conducted both in the Ministry of Health Reference Laboratories and in Viromed laboratory. The relevant data are specified in the kit package insert.

By evaluating of the literature information published so far, it is observed that Covid-19 IgM antibodies start to synthesize approximately from the 5th day of the infection, and the IgG antibodies from the 12th day of the infection. It was determined that IgM antibodies started to disappear from the 25th day, and IgG antibodies were detected for a longer time.

Similar results were obtained at a rate of 99% in the correlative study performed with CRT and the ECLIA method Anti SARS CoV-2 IgG / IgM total antibody kit offered to the market by Roche. IgG and IgM antibodies are detected together as combo in this test belonging to Roche company with a cut-off value of 1.0 index. Serum samples with an antibody level of lower than 1.8 (low positive) with the Roche brand kit were analyzed with our CRT brand card-test and the result was found to be positive. This result indicates that the sensitivity of our test is quite high.

### **Performance Data for each antibody**

		<b>IgM</b>	
		PCR	
		Positive	Negative
CRT	Positive	203	1
	Negative	11	304
	Total	214	305

**Sensitivity** 94,86%  
**Specificity** 99,67%  
**Accuracy** 97,69%

		<b>IgG</b>	
		PCR	
		Positive	Negative
CRT	Positive	203	2
	Negative	11	303
	Total	214	305

**Sensitivity** 94,86%  
**Specificity** 99,34%  
**Accuracy** 97,50%