



Clinical Samples Study Report

COVID-19 IgG/IgM Rapid Test Cassette (Whole blood/Serum/Plasma)

Purpose

Evaluate the performance of Dialab COVID-19 IgG/IgM Rapid Test Cassette (Whole blood/Serum/Plasma) for testing clinical samples.

Material

Dialab device: COVID-19 IgG/IgM Rapid Test Cassette (Whole blood/Serum/Plasma)

Lot: 20200203; Exp: 01-2022

Clinical samples information

113 blood samples were collected from patients exhibiting pneumonia or respiratory symptoms.

Method

The Dialab COVID-19 IgG/IgM Rapid Test has been evaluated with the 113 blood samples obtained from patient exhibiting pneumonia or respiratory symptoms. All samples have been tested in single with Dialab device and the results were compared to RT-PCR or clinical diagnosis (including chest Computed Tomography and clinical signs etc.) of „Diagnosis and treatment of novel coronavirus pneumonia“.

Results

Summary data of COVID-19 IgG/IgM Rapid Test as below.

Regarding the IgM test, the result comparison to RT-PCR.

| Method | | RT-PCR | | Total |
|-------------------|----------|----------|----------|-------|
| COVID-19 IgM test | Results | Positive | Negative | |
| | Positive | 87 | 0 | 87 |
| | Negative | 12 | 14 | 26 |
| Total | | 99 | 14 | 113 |

Regarding the IgG test the positive rate of the 36 of 113 patients during the convalescence period were counted.

| Method | | Number of patients during the convalescence period | Total |
|-------------------|----------|--|-------|
| COVID-19 IgG test | Positive | 35 | 35 |
| | Negative | 1 | 1 |
| Total | | 36 | 36 |

Conclusion

The above results showed that:

The sensitivity of IgM test is 87.9% (87/99) and specificity is 100% (14/14) comparison to RT-PCR. The sensitivity of IgG test is 97.2% (35/36) during the convalescence period.

Discussion

If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. Like with all diagnostic tests, a confirmed diagnosis should only be made by physician after all clinical and laboratory findings have been evaluated.