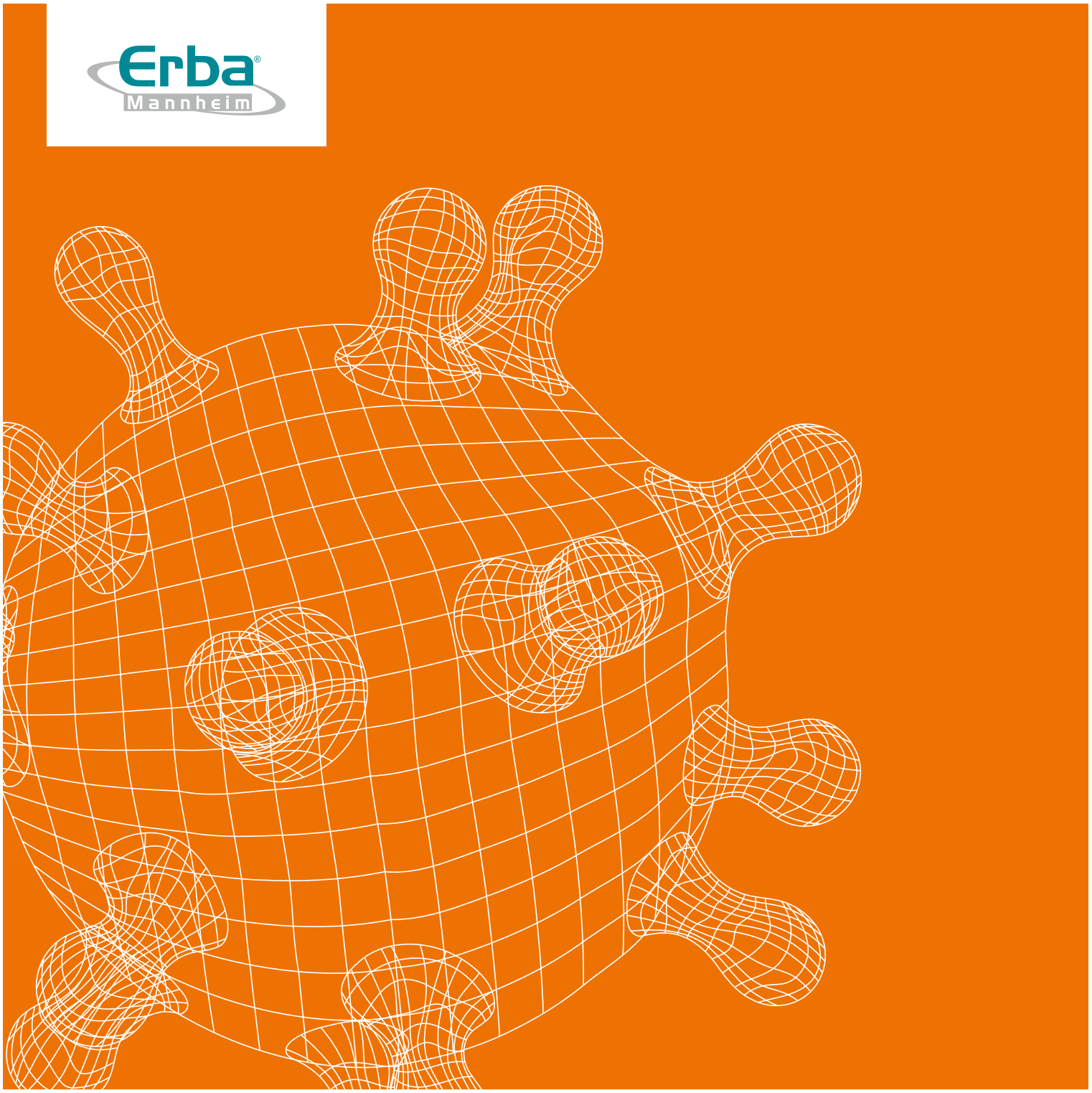


Laboratory Evidence

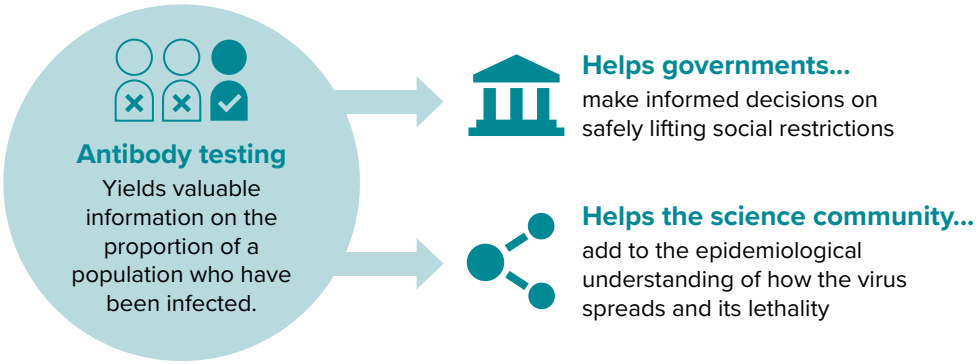
Summary of performance evaluations featuring ErbaLisa COVID-19 IgG and IgM

August 2020

Introduction

As the global number of people infected by the SARS-CoV2 virus exceeded 20 million in August 2020, countries around the world continue to look to implement accurate testing strategies. Antibody tests form a vital piece of the evolving puzzle, allowing the identification of people who have already been infected in the past and recovered, and who may have some immunity to future infection.

The importance of antibody testing



The efficacy of the Erba Mannheim antibody tests

COVID-19 ELISA kits
– Reliable
– Automation-friendly
– Accurate

50 minutes
– Total incubation time
– At room temperature

Improved results
– Superior performance
– Reliable interpretation of results

With more than 1 million tests issued so far, this document collates and summarizes supporting evidence for the performance of ErbaLisa COVID-19 IgG and IgM in real world laboratories.

Overview

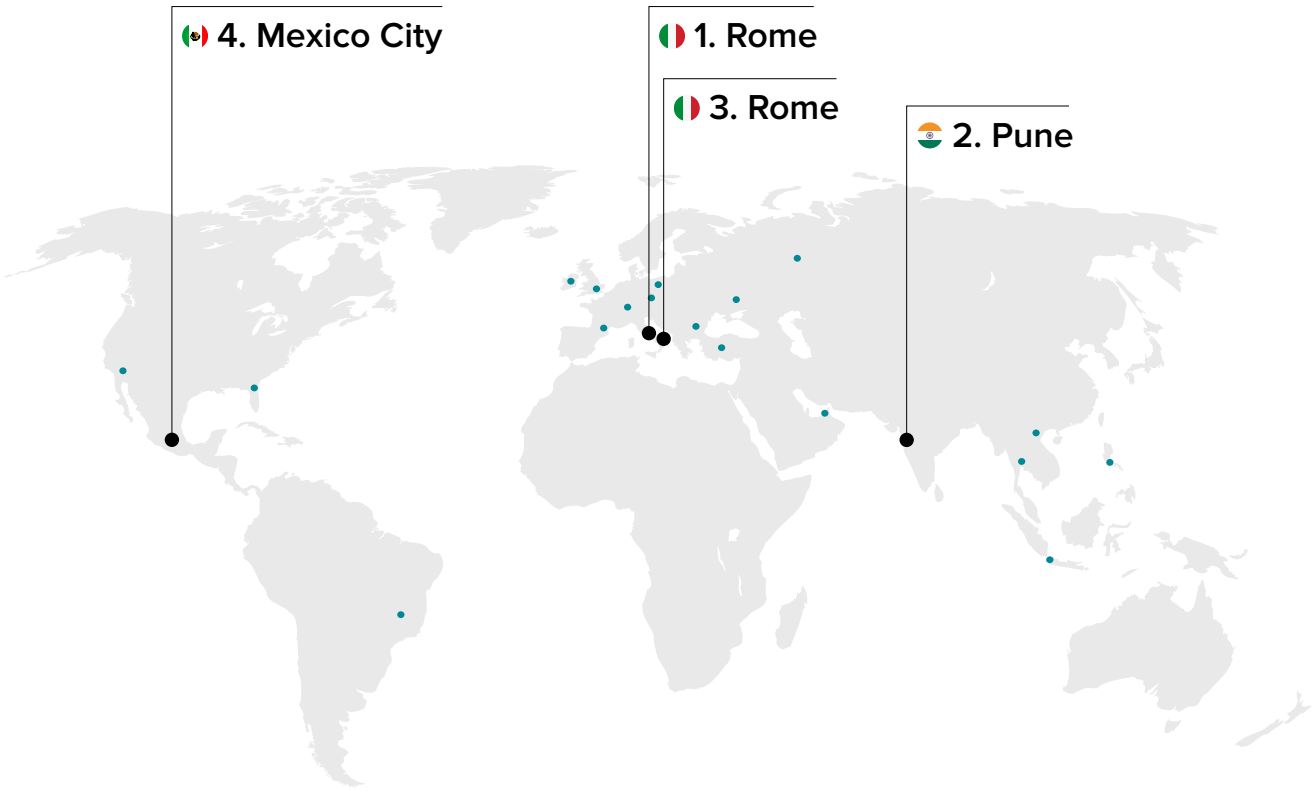
Summary of key results

Page	Country	Evaluation centre	Antibody	Key results
5	Italy	University of Rome, Clinical Microbiology Department	IgG	20 positive samples 20 negative samples from RT-PCR were tested **Sensitivity 95%** **Specificity 100%**
6	India	ICMR National Institute of Virology, Department of Health Research	IgG	100 positive samples 100 negative samples from RT-PCR were tested **Sensitivity 91%** **Specificity 97%** As per ICMR guidelines, the kit is found to be satisfactory
7	Italy	Sapienza University of Rome U.O.C. Laboratorio analisi Biochimica Clinica Diagnostica Molecolare Avanzata	IgG	30 positive samples 30 negative samples from reference method were tested **Sensitivity 100%** **Specificity 100%** Concordance coefficient p<0.0001 The use of the kit being evaluated is simple to carry out and within the reach of all laboratories
8	Mexico	Instituto Mexicano del Seguro Social (IMSS) Gobierno de México	IgG IgM	**Agreement 95%** 42 out of the 44 tests were in agreement. In one of the tests where the results disagreed, the reference method gave a positive result, and although the ErbaLisa IgG test gave a negative result, the ErbaLisa IgM test gave a positive result.

Performance evaluation details

from across the world

ErbaLisa COVID-19 antibody testing kits have been thoroughly evaluated in a variety of real world laboratory settings across the globe.



1.

UNIVERSITA' DEGLI STUDI DI ROMA "TOR VERGATA"
DIPARTIMENTO DI MEDICINA SPERIMENTALE
Cattedra di Microbiologia Clinica

Evaluation Period:

April 2020

Objective:

To evaluate the effectiveness of the ErbaLisa COVID-19 IgG Antibody Test.

Methods:

Individual serum samples from the laboratory serum library (n=40), classified on the basis of test results of an in vitro diagnostic (IVD) real-time reverse transcriptase polymerase chase reaction (RT-PCR) test, were used to test the effectiveness of the ErbaLisa IgG Antibody Test. 20 of these samples had previously tested positive for SARS-CoV2, and 20 had tested negative. The samples were tested with the ErbaLisa test, and the results compared to the RT-PCR test using the following protocol:

- 100 µl of diluted serum samples and 100 µl of control samples were incubated for 20 minutes at room temperature before being washed three times.
- 100 µl of enzyme conjugate was incubated for 20 minutes at room temperature before being washed three times.
- Enzymatic reactions with 100 µl of TMB substrate were allowed to occur for 15 minutes at room temperature before the use of 100 µl of Stop solution.

Results:

The reference method (RT-PCR) gave 20 positive and 20 negative samples. The ErbaLisa kit gave 1 false negative.

ErbaLisa COVID-19 IgG		Reference Method (RT-PCR)	
		+	-
	+	19	0
	-	1	20

Sensitivity: 95%
Specificity: 100%

Conclusion:

Diagnostic sensitivity and specificity of the ErbaLisa COVID-19 IgG kit were 95% and 100% respectively.

2.

ICMR-NATIONAL INSTITUTE OF VIROLOGY
Indian Council of Medical Research
Department of Health Research
Ministry of Health & Family Welfare, Govt. of India

Evaluation Period:

June 2020

Objective:

To evaluate the effectiveness of the ErbaLisa COVID-19 IgG Antibody Test.

Methods:

100 blood samples of patients who had tested positive for COVID-19 using the RT-PCR reference method formed the positive sample panel. 100 blood samples from patients who had tested negative for COVID-19 using the reference method formed the negative sample panel. The samples in the negative sample panel were comprised of healthy individuals whose samples were collected before the COVID-19 outbreak, and patients with confirmed influenza A, influenza B, measles, rubella or chikungunya infections.

The ErbaLisa anti-SARS-CoV-2 ELISA IgG test kit was used to test all samples in the positive sample panel and the negative sample panel using the standard testing protocol. The results were compared to the reference method, and used to calculate the sensitivity and specificity of the ErbaLisa test kit.

Results:

Sensitivity: 91%
Specificity: 97%

Conclusion:

As per ICMR guidelines of recommended sensitivity and specificity, the kit performance is found to be **Satisfactory**.

3.

SAPIENZA UNIVERSITÀ DI ROMA

U.O.C. Laboratorio analisi Biochimica Clinica Diagnostica Molecolare Avanzata

Azienda Ospedaliera Universitaria Sant'Andrea

Faculty of Medicine and Psychology
Sapienza University of Roma

Evaluation Period:

May 2020

Objective:

The purpose of this work is to verify the opportunity to use the test being evaluated for the purpose of serological screening of the population for the detection of IgG SARS - CoV2 (CoVID19) antibody positivity.

Another purpose of this work is to detect the correlation index with an IgG Maglumi test.

Methods:

Single serum samples from the laboratory library (n = 60), classified on the basis of the results of an in vitro diagnostic test (IVD) 2019-nCoV IgG – Maglumi were used to test the effectiveness of the ErbaLisa IgG Antibody Test. 30 of these samples had previously tested positive for SARS-CoV2, and 30 had tested negative. The samples were tested with the ErbaLisa test, and the results compared to the Maglumi test using the following protocol:

- 100 µl of Controls and sample of diluted serum (1:21) were incubated for 20 minutes at room temperature before being washed three times
- 100 µl of Conjugate was incubated for 20 minutes at room temperature before being washed three times
- Enzymatic reactions with 100 µl of TMB substrate were allowed to occur for 15 minutes at room temperature before the use of 100 µl of Stop solution

Results:

The reference method provided 30 positive and 30 negative samples.

ErbaLisa COVID-19 IgG		Reference Method (2019-nCoV IgG – Maglumi)	
		+	-
	+	30	0
	-	0	30

The sensitivity and diagnostic specificity of the ErbaLisa COVID-19 IgG kit were 100% and 100% respectively with a concordance coefficient p <0.0001.

Conclusion:

With regard to the technical and practical aspects, the use of the kit being evaluated is simple to carry out and within the reach of all laboratories.

As far as clinical validity is concerned, it has specific diagnostic sensitivity and specificity for the purpose for which it was developed.

4.

GOBIERNO DE MÉXICO | IMSS | 2020 LEONA VICARIO

Directorate of Medical Care Unit of Education, Research and
Health Sciences Coordination of Research into Health Research Development
Division Medical Research into Immunochemistry Unit

Evaluation Period:

May 2020

Objective:

To assess the performance of the ErbaLisa COVID-19 IgG and IgM Antibody tests.

Methods:

The ErbaLisa IgG and IgM test kits were validated in a quality control procedure before the assessment began, no issues were found.

Serum samples from 44 patients was used to assess the effectiveness of the ErbaLisa IgG Antibody test. The serum had been taken from patients diagnosed with COVID-19 (confirmed by PCR during hospital admission), contacts of confirmed COVID-19 cases, and pre-pandemic samples.

Each sample was tested using the ErbaLisa IgG antibody test and the ErbaLisa IgM antibody test, and these results were compared to a specific ELISA test for SARS-CoV-2 IgG antibody developed by a national research laboratory. No IgM reference method was used.

Results:

The reference method gave 20 positive samples and 24 negative samples.

ErbaLisa COVID-19 IgG		Reference Method (ELISA IgG)	
		+	-
	+	19	1
	-	1	23

Agreement: 95%

42 out of the 44 tests were in agreement. In one of the tests where the results disagreed, the reference method gave a positive result, and although the ErbaLisa IgG test gave a negative result, the ErbaLisa IgM test gave a positive result. The lack of agreement in this case may be due to the dynamics of IgM and IgG antibodies, and the different cut-offs used in each test.

In the other case, the reference method gave a negative result, but both the ErbaLisa IgG and IgM tests gave a positive result, suggesting that the reference method may have been a false negative.

Conclusion:

Consistency was observed between the quality control values declared by the manufacturer and those obtained experimentally with the ELISA for IgG which detects S1, developed in the national research laboratory.
Consistency in inter-test repeatability was observed using duplicates of the samples.
The test duration time is short.
The plate and the controls supplied by the manufacturer are ready for use.

Product details

Product name	Catalogue number	Format
ErbaLisa COVID-19 IgG	IME00136	96-well ELISA
ErbaLisa COVID-19 IgM	IME00137	96-well ELISA

Calling all researchers

ErbaLisa ELISA kits continue to be used worldwide for a broad range of research applications. Universities, contract research organisations, government laboratories, and research hospitals all rely on our kits to provide accurate and reliable results.

At Erba we believe that only through good, thorough research can we succeed in finding the answers we need to address the challenges presented by the SARS-CoV-2 pandemic.

For this reason, we are committed to providing our ELISA kits for worthwhile research projects across the world and being a partner in your scientific endeavours.

Send us your ideas for academic or epidemiological studies to
covid19@erbamannheim.com

You provide the idea, we provide the immunoassays!

For more information:

E covid19@erbamannheim.com
W https://erbalisacovid19.erbamannheim.com