



भारतीय आयुर्विज्ञान अनुसंधान परिषद
स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार
कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

Date: 26.08.2020

The **IgG ELISA** and **CLIA** tests are recommended only for the following purpose:

- Serosurveys to understand the proportion of population exposed to infection including asymptomatic individuals. Depending upon the level of seroprevalence of infection, matching public health interventions can be implemented for prevention and control of the disease.
- Survey in high risk or vulnerable populations (health care workers, frontline workers, immunocompromised individuals, individuals in containment zones etc) to know who has been infected in the past and has now recovered.

Please Note:

- The ELISA tests have been validated in the laboratory. However, the performance of the test may be subject to variation under field conditions.
- The below listed ELISA tests are validated with the mentioned batch number only. Responsibility for batch to batch consistency lies with the manufacturer.
- IgG ELISA / CLIA tests which are US-FDA approved** can be used directly after due marketing approval from DCGI.

**LIST OF SATISFACTORY IgG ELISA/CLIA KITS FOR COVID-19 VALIDATED
BY ICMR IDENTIFIED VALIDATION CENTRES**

Sl. No	Name of Company	Name of the Kit	*Batch Number
1.	Zydus Cadila Healthcare Ltd., Ahmedabad (Gujarat), India	COVID Kavach IgG ELISA	CoV2HI GG96-001 CoV2HI GG96-002 CoV2HI GG96-003
2.	Euroimmun US Inc., USA	Euroimmun Anti- SARS-COV-2 IgG ELISA	E200420AW
3	YHLO iFlash, China	SARS-CoV-2 IgG CLIA	C86095G-20200206 C86095G-20200210
4.	Karwa Enterprises Pvt. Ltd, Delhi, India	KAVACH Karwa SARS-COV 2 IgG ELISA	A06201 A06202 A06203
5.	Voxtur Bio Ltd., Mumbai (Maharashtra) India	VOXEL Anti-SARS COV-2 IgG Antibody detection kit COVID KAVACH	ECCV200601S ECCV200602S ECCV200603S
6.	Lab-Care Diagnostics (India) Pvt. Ltd., Valsad (Gujarat), India	Novel Coronavirus COVID-19 IgG ELISA	CVEG200601 CVEG200602 CVEG200603
7.	Transasia Bio-Medicals Ltd., Mumbai (Maharashtra), India	ErbaLisa COVID-19 IgG ELISA	TCOG2001 TCOG2002 TCOG2003
8.	Meril Diagnostics Pvt. Ltd., Vapi (Gujarat), India	Anti-SARS CoV-2 Human IgG ELISA	MRD-113 MRD-114 MRD-115



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9.	J. Mitra & Co. Pvt. Ltd., Delhi, India	COVID Kawach IgG MICROLISA	EKG010620 EKG020720 EKG030720
10.	Aspen Laboratories Pvt. Ltd., Hyderabad (Telangana), India	ASPEN SARS CoV-2 IgG ELISA Kit	COV2006 COV2007 COV2008
11.	Promea Therapeutics Pvt. Ltd., Hyderabad (Telangana), India	PROLISA Covid-19 IgG ELISA	TEGGCV-2001 TEGGCV-2002 TEGGCV-2003
12.	Trivitron Healthcare Pvt. Ltd., Mumbai (Maharashtra), India	COVID KAVACH Anti-SARS CoV-2 Human IgG ELISA kit	COVK-004 COVK-005 COVK-006
13	DIA.PRO Diagnostic Bioprobes Srl, Italy	COVID-19 IgG ELISA	0420/3AA 0420/5AA 0420/6FB
#14.	Calbiotech Inc., USA	Erbalisa COVID-19 IgG ELISA	CVG6087

IgG ELISA kits manufactured by **Calbiotech Inc., USA** and supplied by **M/s Transasia Bio Medicals Ltd., Mumbai** of the specified batch were evaluated by ICMR earlier. However, the marketing license of the distributor of the above company has been **suspended** by the Central Drugs Standard Control Organization (CDSCO) after removal of the COVID-19 serology test kits from the notification list by USFDA.