



ICMR- National AIDS Research Institute, Pune

PERFORMANCE EVALUATION REPORT FOR ANTIBODY-BASED ELISA DIAGNOSTIC KIT

- Name of the kit DIPAS-VDx COVID-19 IgG Antibody
- Name of the manufacturer Vangaurd Diagnostics Private Limited
- Batch numbers EVCAB210101, EVCAB210102 & EVCAB210103
- Application IgG ELISA
- Kit components COVID-19 Ag coated Microwells ELISA plate, Sample diluent, Conjugate Diluent, Enzyme Conjugate, TMB substrate, Substrate Buffer, Positive & Negative controls, Wash Buffer and Stop solution
- Sample Panel
 - Positive samples Known anti-SARS-CoV-2 IgG positive Serum /Plasma samples collected after 14 days from the COVID-19 RT-PCR positive individuals
 - Negative samples Pre-pandemic sera (25 positive for HIV antibodies, 25 HBsAg antigen positive, 25 positive for HCV antibodies and 25 healthy controls)
- Results

Antibody based CMIA kit and RT PCR result

DIPAS-VDx COVID-19
IgG Antibody Positive
Batch No. Negative
EVCAB210101 Grey Zone
Total

Positive	Negative	Total
97	0	97
3	99	102
0	1	1
100	100	200

	Estimate (%)	95% CI
Sensitivity	97%	91.48% to 99.38%
Specificity	99%	94.55% to 99.97%

- **Conclusions:**
 - **Sensitivity: 97%, Specificity: 99%**
 - **Performance: Satisfactory**

Antibody based CMIA kit and RT PCR result

DIPAS-VDx COVID-19
IgG Antibody Positive
Batch No. Negative
EVCAB210102 Grey Zone
Total

Positive	Negative	Total
98	0	98
1	100	101
1	0	1
100	100	200

	Estimate (%)	95% CI
Sensitivity	98%	94.50% to 99.97%
Specificity	100%	96.38% to 100.00%

- **Conclusions:**



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आई सी एम आर – राष्ट्रीय एड्स अनुसंधान संस्थान
स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार
कल्याण मंत्रालय, भारत सरकार

ICMR - National AIDS Research Institute
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

- Sensitivity: 98%, Specificity: 100%
- Performance: Satisfactory

DIPAS-VDx COVID-
19 IgG Antibody
Batch No.
EVCAB210103

Positive
Negative
Grey Zone
Total

Antibody based CMIA kit and RT PCR result

Positive	Negative	Total
97	0	97
2	99	101
1	1	2
100	100	200

	Estimate (%)	95% CI
Sensitivity	97%	91.48% to 99.38%
Specificity	99%	94.55% to 99.97%

- **Conclusions:**
 - Sensitivity: 97%, Specificity: 99%
 - Performance: Satisfactory

(Sensitivity and specificity have been assessed in controlled lab setting using kits provided by the manufacturer from the batches mentioned above)

Disclaimers

1. The kits for IgM/IgG detection are not recommended for diagnosis of COVID-19.
2. ICMR's validation process does not approve / disapprove the kit design.
3. ICMR's validation process does not certify user friendliness of the kit / assay.
4. Validation of a kit by ICMR is not an assurance that the kit specifications would be included in the tendering process.

Note: This report is exclusively for Antibody Kit (Lot Nos. EVCAB210101, EVCAB210102 & EVCAB210103) manufactured by Vanguard Diagnostics Private Limited.

Evaluation completed on 21.04.2021

Signature of Nodal Officer

M. Phalakar
22/4/2021

Signature of Director/ Director-In charge

[Signature]
22.4.2021

DIPAS-VDx COVID-19 IgG Antibody

Microwell ELISA Detection Kit

Performance Characteristics : Sensitivity & Specificity

Studies on DIPAS-VDx COVID-19 IgG ELISA Kit were conducted at various sites using known positive and known negative samples. Results obtained were as under:

Testing Site	No. of Samples	True Positive	True Negative	Sensitivity	Specificity
Rajy Gandhi Hospital, Delhi	80	45	45	97.7%	100%
DIPAS, Delhi	71	20	51	100%	97%
ICMR/ARI, Pune	200	100	100	97%	99%
In-house Evaluation	562	62	500	100%	100%
Total	723	927	695	98.7%	99.8%

Extensively Validated, Approved by ICMR

100% Accuracy

A REAL Performer
Reliable, Efficient, Affordable, Local

A Synergistic Collaboration
between



Developed by
Defence Institute of Physiology & Allied Sciences
C-102, Lodi Road, New Delhi 110011 | www.dias.gov.in

Manufactured by
Vanguard Diagnostics Private Limited
C-102, Phase 1, Gurgaon, Haryana, India, Gurgaon - 122001 | www.vanguarddiagnostics.com
Email: info@vanguarddiagnostics.com




DIPAS-VDx COVID-19 IgG Antibody

Microwell ELISA
Covid-19 IgG Antibody Detection Test




A Qualitative Test that Spells Quality



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DIPAS-VDx COVID-19 IgG Antibody

Microwell ELISA
Covid-19 IgG Antibody Detection Test



A Qualitative Test that Spells Quality

High Sensitivity

High Specificity

ICMR Approved

Local

What does the DIPAS-VDx COVID-19 IgG Antibody Test Do?


It is intended for the qualitative detection of IgG antibodies in human serum or plasma, targeting SARS-CoV-2 related antigens.

Accurate and Precise Results

How is the performance of the DIPAS-VDx COVID-19 IgG Antibody Test?

- Sensitivity : 98.7%.
- Specificity : 99.8%.

Reproducible • Reliable • Responsible



Where can the DIPAS-VDx COVID-19 IgG Antibody Test be used?

- Its applications include Understanding COVID-19 epidemiology.
- Assessing an individual's previous SARS-CoV-2 exposure.
- Identifying convalescent plasma donors.

A Key Test to Monitor Infections, to Effect Contact Tracing and for Sero-Surveillance

How much time does the DIPAS-VDx COVID-19 IgG Antibody Test take?


- Only 75 Minutes.
- Half the time taken by other tests.

Saves Precious Time

How is the DIPAS-VDx COVID-19 IgG Antibody Test priced?

- Significantly lower than competitors' kits.

Affordable





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DIPAS-VDx COVID-19 IgG Antibody

Microwell ELISA

Covid-19 IgG Antibody Detection Test



A Qualitative Test that Spells Quality

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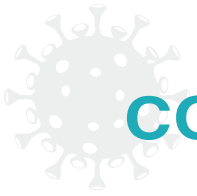
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DIPAS-VDx COVID-19 IgG Antibody

Microwell ELISA Detection Kit

Performance Characteristics : Sensitivity & Specificity

Studies on DIPAS-VDx-COVID-19 IgG ELISA Kit were conducted at various sites using known positive and known negative samples.

Results obtained were as under:

Testing Site	No. of Samples	True Positive	True Negative	Sensitivity	Specificity
Rajiv Gandhi Hospital, Delhi	90	45	45	97.7%	100%
DIPAS, Delhi	71	20	51	100%	100%
ICMR/NARI, Pune	200	100	100	97%	99%
In-house Evaluation	362	62	300	100%	100%
Total	723	227	496	98.7%	99.8%

Extensively Validated, **Approved by**



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INDIAN COUNCIL OF
MEDICAL RESEARCH
Serving the nation since 1911

100%



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Reliable, Efficient, Affordable, Local

NOW AVAILABLE
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NOW AVAILABLE



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