All India Institute of Medical Sciences, Bhubaneswar
At - Sijua (Patrapada), Post - Dumuduma, Bhubaneswar (Odisha) - 751 019

To be uploaded in Website: www.aiimsbhubaneswar.edu.in (Tender)

Reference No: J-11029(045)/2020-21/S&P **Dated: 04/09/2020**

Sub: Procurement & Inclusion of anti-SARS-COV-2 antibody test kit in Rate Contract for Testing Kits of COBAS e-411 Chemiluminiscence based Fully Automated Immunoassay for Infectious Marker Testing (Make: ROCHE) installed in the Department of Transfusion Medicine & Blood Bank at AIIMS, Bhubaneswar on Reagent Rental basis - **Inviting Comments thereon.**

The Department of Transfusion Medicine & Blood Bank, AIIMS, Bhubaneswar has requested for Procurement & Inclusion of anti-SARS-COV-2 antibody test kit in Rate Contract for Testing Kits of COBAS e-411 Chemiluminiscence based Fully Automated Immunoassay for Infectious Marker Testing (Make: ROCHE) installed in their Department from **M/s Roche Diagnostics.**

The Notice is being uploaded for general information of prospective manufacturer/Authorized Distributor/Dealers to submit their objection/proposal/comments, if any, on proprietorship of the item.

In case the product of any manufacturer/Authorized distributor/Dealer conforms to the enclosed specifications, they may submit their proposal for the supply of the same along with the brochures, point by point compliance of the enclosed specifications along with all documentary evidence. One quotation of the product may also be submitted.

The objections/comments/proposal should be sent in sealed cover to the Office of Sr. Procurement Cum Stores Officer, AIIMS, Bhubaneswar (Odisha) – 751019 or through E-mail to spo@aiimsbhubaneswar.edu.in , aso.jkbiswal@aiimsbhubaneswar.edu.in and stokee_loveneet@aiimsbhubaneswar.edu.in , so as to reach on or before **date: 19 -09-2020** failing which it will be presumed that no other firm is interested to offer comments/protest/object and case will be decided on its merits.

The ref. no. – **J-11029(045)/2020-21/S&P** dt: 04 **-09-2020**, due on dated: 19 **-09-2020** should be superscripted on sealed envelope.

Enclosure:

1. Proprietary Article Certificate from Indenting Officer. **Annexure-I**
2. OEM's Proprietary-cum-Compatibility Certificate **Annexure-II**
3. OEM's subsidiaries certificate **Annexure-III**
4. Brochure & Literature of the required product **Annexure-IV**
5. Price Quotations Dated 04-08-2020 **Annexure-V**

Copy to:

1. Indenting Officer, Dept. of Transfusion Medicine & Blood Bank: for information please
2. Accounts Officer : for information please
3. IT Cell : for hoisting in the website.

Sr. Procurement-cum-Stores Officer

AIIMS, BHUBANESWAR

Proprietary Article Certificate
Valid for the Current Financial Year

File No. and Date Reference :		
1	Description of article	Elecsys Anti SARS COV2 and Anti SARS COV2 PC Elecsys
2	Forecast of quantity /annual requirement	3 PKT (600 Test)
3	Approximate estimated value for above quantity	1,00,000/- INR Approximate
4	Maker's name and address	M/s Roche Diagnostics, Switzerland
5	Name(s) of authorized dealers/ stockists	Astha Health care, Bhubaneswar
6	I approve the above purchase on PAC basis and certify that : - Note- Tick to retain only one out of (b), C-1) or (c-2) whichever is applicable and cross out others. Please do confirm (a) by ticking it - without which PAC certificate will be invalid.	
6 (a)	This is the only firm who is manufacturing / stocking this item. AND	Yes, Attached
6 (b)	A Similar article is not manufactured / sold by any other firm, which could be used in lieu OR	Yes
6 (c-1)	No other make/brand will be suitable for following tangible reasons (like OEM/ Warranty, spares.) : OR	
6 (c)	No other make/brand will be suitable for following intangible reasons (if PAC was also given in the last procurement cycle, please also bring out efforts made since then to locate more sources) : OR	
7	Reference of concurrence of finance wing to the proposal :	

History of PAC Purchase of this item for past three years may be given below : NA

Name of the Supplier: NA

Order/ Tender Reference & Date	Quantity Ordered	Basic Rate on Order (Rs.)	Adverse Performance Reported if Any

Signature of the Indenting Officer 06/08/20

Dr. Somnath Mukherjee
Associate Professor
AIIMS,Bhubaneswar-751019
Regd.No-57906(W3)

Signature of Approving Authority.....

Date..... Designation of Officer.....

Roche

PROPRIETARY CERTIFICATE

This is to certify, we, M/s. Roche Diagnostics GmbH, Sandhofer Str. 116, D-68305 Mannheim, Germany, are the legal manufacturer and actual manufacturer for below listed Covid-19 test parameters. These assays run on Roche cobas e411, e601, e602 & e801 analyzers.

- Elecsys Anti-SARS-CoV-2 (# 09203095190 & 09203079190)
- Preci Control Anti-SARS-CoV-2 (# 09216928190)

We hereby confirm that Roche Diagnostics India Pvt. Ltd., having its registered office in 501 B, Silver Utopia, Cardinal Gracious Road, Andheri (Est), Mumbai-400069, India, is 100% subsidiary of M/s. Roche Diagnostics GmbH, Germany, is responsible for the sales and service of the equipment including its spare parts, accessories, and distribution of associated reagents & consumable etc.

Mannheim, June 15, 2020

Roche Diagnostics GmbH

Roche Diagnostics Gmbh
Sandhofer Straße 116
D-68305 Mannheim

i.V. Stefan Grigarczik
Manager Global Regulatory Affairs

i.V. Dr. Manfred Böhm
Manager Global Regulatory Affairs

03/09/2020

Roche Diagnostics GmbH; Sandhofer Strasse 116; D-68305 Mannheim; Telefon +49 621 759 0; Telefax +49 621 759 2890

Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Claus Haberda; Andreas Schmitz - Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

Roche

TO WHOM IT MAY CONCERN

January 31, 2018

Roche Diagnostics India Pvt. Ltd. a company registered under the Indian Companies Act,1956 is a wholly owned subsidiary of Roche Pharmholding B.V., The Netherlands. Further, Roche Pharmholding B.V. is a wholly owned subsidiary of Roche Finance Ltd., Switzerland, a company incorporated under laws of Switzerland.

Roche Diagnostics India Pvt. Ltd. is directly handling all business transactions in India for the Roche Diagnostics range of products.

Sincerely,

ROCHE PHARMHOLDING B.V.

Dieter F. Heinis
Director

Roche Pharmholding B.V. Roche Corporate Seal

Sheri L. Morin
Chairwoman of the Board

03/09/2020

ROCHE PHARMHOLDING B.V. Beneluxlaan 2A, NL-3446 GR
P.O. Box 424, NL-3440 AK
Woerden/ The Netherlands

09203095500V1.0

Elecsys Anti-SARS-CoV-2

cobas®

REF		Σ	SYSTEM
			cobas e 411
09203095190	09203095500	200	**cobas e** 601
			cobas e 602

English

System information

For **cobas e** 411 analyzer: test number 3000
For **cobas e** 601 and **cobas e** 602 analyzers: Application Code Number 737

Intended use

Elecsys Anti-SARS-CoV-2 is an immunoassay for the in vitro qualitative detection of antibodies (including IgG) to Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) in human serum and plasma. The test is intended as an aid in the determination of the immune reaction to SARS-CoV-2.

The **electrochemiluminescence immunoassay** "ECLIA" is intended for use on **cobas e** immunoassay analyzers.

Summary

SARS-CoV-2 is an enveloped, single-stranded RNA virus of the family Coronaviridae, genus Betacoronaviruses. All coronaviruses share similarities in the organization and expression of their genome, which encodes 16 nonstructural proteins and the 4 structural proteins spike (S), envelope (E), membrane (M), and nucleocapsid (N). Viruses of this family are of zoonotic origin. They cause disease with symptoms ranging from those of a mild common cold to more severe ones such as the Severe Acute Respiratory Syndrome (SARS), Middle East Respiratory Syndrome (MERS) and Coronavirus Disease 2019 (COVID-19). Other coronaviruses known to infect humans include 229E, NL63, OC43 and HKU1. The latter are ubiquitous and infection typically causes common cold or flu-like symptoms.[1,2]

SARS-CoV-2 is transmitted person-to-person primarily via respiratory droplets, but also indirect transmission through contaminated surfaces is possible.[3,4,5,6] SARS-CoV-2 can be isolated from respiratory samples obtained via naso/oropharyngeal swabs or from sputum. The virus accesses host cells via the angiotensin-converting enzyme 2 (ACE2), which is the most abundant in the lungs.[7,8]

The incubation period for COVID-19 is thought to range from 2-14 days following exposure, with most cases showing symptoms approximately 4-5 days after exposure.[3,9,10] The interval during which an individual with COVID-19 is infectious has not yet been clearly established. Transmission from symptomatic individuals, the spread of virus to new hosts shortly before symptoms appear and asymptomatic transmission have all been described; however the evidence is not conclusive.[1,11,12,13,14]

Those infected may exhibit symptoms including fever, cough, fatigue, sputum production, loss of smell and shortness of breath.[15,16,17] The spectrum of symptomatic infection ranges from mild to critical, with most cases being non-severe. Severe illness is characterized by e.g. dyspnea, hypoxia, > 50 % lung infiltrates within 24 to 48 hours and occurs predominantly in adults with advanced age or underlying medical comorbidities such as hypertension, diabetes mellitus and cardiovascular disease. Acute respiratory distress syndrome (ARDS) is a major complication in patients with severe disease. Critical cases are characterized by e.g. respiratory failure, shock and/or multiple organ dysfunction or failure. The proportion of severe or fatal infections vary greatly by location.[16,18,19]

Definite COVID-19 diagnosis entails SARS-CoV-2 detection by nucleic acid amplification technology (NAAT).[20,21,22] Although the underlying technology for NAAT is robust and shows excellent specificity, the outcome directly depends on the viral load acquired during sampling which, among others, can vary with time point of infection, individual patient, sampling method and position as well as sample preparation time.

Consequently, a non-negligible proportion of infected individuals may be missed by screenings based on symptoms and NAAT[23,24,25] and thus form an important source of continued viral spread. Serological assays can contribute to identify individuals exposed to the virus and assess the extent of exposure of a population, and might thereby help to decide on application, enforcement or relaxation of containment measures.[26]

Seroconversion has been observed as early as within 5 days after symptom onset for immunoglobulin M (IgM)[27] and within 5-7 days for IgG.[27,28] Based on still scarce data, anti-SARS-CoV-2 IgA seem to appear at around 3-6 days post-symptom onset.[25,29] Depending on the applied method, seroconversion is observed after a median of 10-13 days after symptom onset for IgM and 12-14 days for IgG.[23,30,31] Maximum seroconversion occurs at 2-3 weeks for IgM,[23,27,28,31,32] at 3-6 weeks for IgG,[23,27,28,33] and at 2 weeks for total antibodies.[31,34] Whereas IgM seems to vanish around week 6-7,[32,35] high IgG seropositivity is seen at that time.[27,32,35] Levels and chronological order of IgM and IgG antibody appearance are highly variable,[23,28,31,36] supporting detection of both antibodies simultaneously.

Neutralizing antibodies targeting spike and nucleocapsid proteins are formed as early as day 9 onwards, showing strong neutralizing response, thus seroconversion may lead to protection at a minimum for a limited time.[29,36,37,38,39] Cross-reactivity with SARS-CoV-2 induced neutralizing antibodies with SARS-CoV was observed, but not with other coronaviruses, suggesting that the vast majority of people are immunologically naive and thus susceptible to this virus.[25,29,36,37,40]

The Elecsys Anti-SARS-CoV-2 assay uses a recombinant protein representing the nucleocapsid (N) antigen for the determination of antibodies against SARS-CoV-2.

Test principle

Sandwich principle. Total duration of assay: 18 minutes.

- 1st incubation: 20 µL of sample, biotinylated SARS-CoV-2-specific recombinant antigen and SARS-CoV-2-specific recombinant antigen labeled with a ruthenium complex[a)] form a sandwich complex.
- 2nd incubation: After addition of streptavidin-coated microparticles, the complex becomes bound to the solid phase via interaction of biotin and streptavidin.
- The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with ProCell/ProCell M. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier.
- Results are determined automatically by the software by comparing the electrochemiluminescence signal obtained from the reaction product of the sample with the signal of the cutoff value previously obtained by calibration.

a) Tris(2,2'-bipyridyl)ruthenium(II)-complex ($Ru(bpy)_3^{2+}$)

Reagents - working solutions

The reagent rackpack (M, R1, R2) is labeled as ACOV2.

M	Streptavidin-coated microparticles (transparent cap), 1 bottle, 12 mL: Streptavidin-coated microparticles 0.72 mg/mL; preservative.
R1	SARS-CoV-2-Ag~biotin (gray cap), 1 bottle, 16 mL: Biotinylated SARS-CoV-2-specific recombinant antigen (E. coli); preservative.
R2	SARS-CoV-2-Ag ~$Ru(bpy)_3^{2+}$ (black cap), 1 bottle, 16 mL: SARS-CoV-2-specific recombinant antigen labeled with ruthenium complex, preservative.

ACOV2 Cal1	Negative calibrator 1 (white cap), 1 bottle of 0.67 mL: Human serum, non-reactive for anti-SARS-CoV-2 antibodies; buffer; preservative.
ACOV2 Cal2	Positive calibrator 2 (black cap), 1 bottle of 0.67 mL: Human serum, reactive for anti-SARS-CoV-2 antibodies; buffer; preservative.

Precautions and warnings

For in vitro diagnostic use.
Exercise the normal precautions required for handling all laboratory

Elecsys Anti-SARS-CoV-2

cobas®

reagents.
Disposal of all waste material should be in accordance with local guidelines. Safety data sheet available for professional user on request.

This kit contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:

Warning

H317	May cause an allergic skin reaction.

Prevention:

P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves.

Response:

P333 + P313	If skin irritation or rash occurs: Get medical advice/attention.
P362 + P364	Take off contaminated clothing and wash it before reuse.

Disposal:

P501	Dispose of contents/container to an approved waste disposal plant.

Product safety labeling follows EU GHS guidance.

Contact phone: all countries: +49-621-7590

All human material should be considered potentially infectious. All products derived from human blood are prepared exclusively from the blood of donors tested individually and shown to be free from HBsAg and antibodies to HCV and HIV. The testing methods used assays approved by the FDA or cleared in compliance with the European Directive 98/79/EC, Annex II, List A.

The serum containing anti-SARS-CoV-2 (ACOV2 Cal2) was heat-inactivated for 30 minutes at 56 °C.

However, as no inactivation or testing method can rule out the potential risk of infection with absolute certainty, the material should be handled with the same level of care as a patient specimen. In the event of exposure, the directives of the responsible health authorities should be followed.[41,42]

Avoid foam formation in all reagents and sample types (specimens, calibrators and controls).

Reagent handling

For professional use.

The reagents in the kit are ready-for-use and are supplied in bottles compatible with the system.

cobas e 411 analyzer: The calibrators should only be left on the analyzer during calibration at 20-25 °C. After use, close the bottles as soon as possible and store upright at 2-8 °C.

Due to possible evaporation effects, not more than 4 calibration procedures per calibrator bottle set should be performed.

cobas e 601 and **cobas e** 602 analyzers: Perform only one calibration procedure per bottle.

All information required for correct operation is read in from the respective reagent barcodes.

Please note: Both the vial labels contain 2 different barcodes. The barcode between the yellow markers is for **cobas** 8000 systems only. If using a **cobas** 8000 system, please turn the vial cap 180° into the correct position so that the barcode between the yellow markers can be read by the system. Place the vial on the analyzer as usual.

Storage and stability

Store at 2-8 °C.

Do not freeze.

Store the Elecsys reagent kit **upright** in order to ensure complete availability of the microparticles during automatic mixing prior to use.

Stability of the reagent rackpack	
unopened at 2-8 °C	up to the stated expiration date
after opening at 2-8 °C	72 hours
on the analyzers	72 hours

Stability of the calibrators	
unopened at 2-8 °C	up to the stated expiration date
or after opening at 2-8 °C	72 hours
on **cobas e** 411 at 20-25 °C	up to 3 hours
on **cobas e** 601 and **cobas e** 602 at 20-25 °C	use only once

Store calibrators **upright** in order to prevent the calibrator solution from adhering to the snap-cap.

Specimen collection and preparation

Only the specimens listed below were tested and found acceptable.

Serum collected using standard sampling tubes.

Li-heparin, K_2-EDTA and K_3-EDTA plasma.

Criterion: Absolute deviation of negative samples ± 0.3 COI (cutoff index) from serum value; reactive samples: recovery within 70-130 % of serum value.

Stable for 3 days at 15-25 °C, 7 days at 2-8 °C, 28 days at -20 °C (± 5 °C). The samples may be frozen twice.

The sample types listed were tested with a selection of sample collection tubes that were commercially available at the time of testing, i.e. not all available tubes of all manufacturers were tested. Sample collection systems from various manufacturers may contain differing materials which could affect the test results in some cases. When processing samples in primary tubes (sample collection systems), follow the instructions of the tube manufacturer.

Specimens should not be subsequently altered with additives (e.g. biocides, anti-oxidants or substances that could possibly change the pH or ionic strength of the sample) in order to avoid erroneous findings.

Pooled samples and other artificial material may have different effects on different assays and thus may lead to discrepant findings.

Centrifuge samples containing precipitates before performing the assay.

Do not use heat-inactivated samples.

Do not use samples and controls stabilized with azide.

Ensure the samples, calibrators and controls are at 20-25 °C prior to measurement.

Due to possible evaporation effects, samples and calibrators on the analyzers should be analyzed/measured within 2 hours.

The performance of the Elecsys Anti-SARS-CoV-2 assay has not been established with cadaveric samples or body fluids other than serum and plasma.

Materials provided

See "Reagents – working solutions" section for reagents.

Materials required (but not provided)

- REF 03609987190, Diluent MultiAssay, 2 x 16 mL sample diluent
- General laboratory equipment
- **cobas e** analyzer

Additional materials for the **cobas e** 411 analyzer:

- REF 11662988122, ProCell, 6 x 380 mL system buffer
- REF 11662970122, CleanCell, 6 x 380 mL measuring cell cleaning solution
- REF 11930346122, Elecsys SysWash, 1 x 500 mL washwater additive
- REF 11933159001, Adapter for SysClean
- REF 11706802001, AssayCup, 60 x 60 reaction cups

Elecsys Anti-SARS-CoV-2

cobas®

- REF 11706799001, AssayTip, 30 x 120 pipette tips
- REF 11800507001, Clean-Liner

Additional materials for **cobas e** 601 and **cobas e** 602 analyzers:

- REF 04880340190, ProCell M, 2 x 2 L system buffer
- REF 04880293190, CleanCell M, 2 x 2 L measuring cell cleaning solution
- REF 03023141001, PC/CC-Cups, 12 cups to prewarm ProCell M and CleanCell M before use
- REF 03005712190, ProbeWash M, 12 x 70 mL cleaning solution for run finalization and rinsing during reagent change
- REF 12102137001, AssayTip/AssayCup, 48 magazines x 84 reaction cups or pipette tips, waste bags
- REF 03023150001, WasteLiner, waste bags
- REF 03027651001, SysClean Adapter M

Additional materials for all analyzers:

- REF 11298500316, ISE Cleaning Solution/Elecsys SysClean, 5 x 100 mL system cleaning solution

Assay

For optimum performance of the assay follow the directions given in this document for the analyzer concerned. Refer to the appropriate operator's manual for analyzer-specific assay instructions.

Resuspension of the microparticles takes place automatically prior to use. Read in the test-specific parameters via the reagent barcode. If in exceptional cases the barcode cannot be read, enter the 15-digit sequence of numbers.

Bring the cooled reagents to approximately 20 °C and place on the reagent disk (20 °C) of the analyzer. Avoid foam formation. The system automatically regulates the temperature of the reagents and the opening/closing of the bottles.

Calibrators:

Place the calibrators in the sample zone.

All the information necessary for calibrating the assay is automatically read into the analyzer.

After calibration has been performed, store the calibrators at 2-8 °C or discard (**cobas e** 601 and **cobas e** 602 analyzers).

Calibration

No international standard is available for Anti-SARS-CoV-2.

Calibration frequency: Calibration must be performed once per reagent lot using ACOV2 Cal1, ACOV2 Cal2 and fresh reagent (i.e. not more than 24 hours since the reagent kit was registered on the analyzer).

Calibration interval may be extended based on acceptable verification of calibration by the laboratory.

Renewed calibration is recommended as follows:

- after 3 days when using the same reagent lot
- after 3 days when using the same reagent kit on the analyzer
- as required: e.g. quality control findings outside the defined limits

Quality control

For quality control, use controls prepared as follows:

Negative control: Determine the COI of ACOV2 Cal1 by measuring it as a routine sample. Pool serum samples with a COI result of ≤ 150 % compared to the COI result of ACOV2 Cal1 (pooling of ≥ 5 non-reactive samples in this range is recommended). Mix carefully, avoiding foam formation. Prepare aliquots of at least 250 µl from this sample pool and store frozen at -20 °C (± 5 °C) or colder. Use these aliquots to perform regular quality control.

This negative control has a target value range of COI < 0.8 (qualitative assay result "non-reactive")

Positive control: Determine the COI of ACOV2 Cal2 by measuring it as a routine sample. Pool serum samples with a COI result that is higher than the COI result of ACOV2 Cal2 (pooling of ≥ 3 reactive samples in this range is recommended). Dilute the sample pool by adding pooled negative serum (pooling criterion see negative control) or Diluent MultiAssay to obtain a COI between 3 and 15. Mix carefully, avoiding foam formation. It is recommend to confirm calculated reactivity after dilution by a measurement.

Prepare aliquots of at least 250 µl from this sample pool and store frozen at -20 °C (± 5 °C) or colder. Use these aliquots to perform regular quality control. Upon first use of this control, determine the COI of the control by measurement of the control in triplicate and using a freshly opened reagent rack pack.

The obtained median of these measurements serves as target value for this positive control. Subsequent measurements of all aliquots of this control material must match this target value ± 45 % (3SD = 45 %, 1SD = 15 %; qualitative assay result "reactive"). In case the quality control fails, thaw a new aliquot and re-assess the performance of the assay.

The target value of the positive control is lot specific and target value assessment as described above has to be performed for every assay lot.

After measurement, discard aliquots with a remaining volume of 250 µl or less. Aliquots with a remaining volume of more than 250 µl can be re-used if sealed tightly and stored immediately at 2-8 °C for max. 3 days.

In case quality control fails for any reason, thaw a new control aliquot and re-assess the performance of the assay.

Also pools of plasma samples with similar reactivity can be used, however re-clotting frequently occurs with plasma after thawing. If this occurs, either discard or centrifuge the aliquot before use. Do not mix serum samples and plasma samples to prepare a sample pool.

The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

Controls for the various concentration ranges should be run individually at least once every 24 hours when the test is in use, once per reagent kit, and following each calibration.

If necessary, repeat the measurement of the samples concerned.

Follow the applicable government regulations and local guidelines for quality control.

Note: The controls should be run like external controls. All values and ranges have to be entered manually. Please refer to the section "QC" in the operator's manual or to the online help of the instrument software. Only one target value and range for each control level can be entered in the analyzer. The reagent lot-specific target values have to be re-entered each time a specific reagent lot with different control target values and ranges is used. Two reagent lots with different control target values and ranges cannot be used in parallel in the same run.

Calculation

The analyzer automatically calculates the cutoff based on the measurement of ACOV2 Cal1 and ACOV2 Cal2.

The result of a sample is given either as reactive or non-reactive as well as in the form of a cutoff index (COI; signal sample/cutoff).

Interpretation of the results

Results obtained with the Elecsys Anti-SARS-CoV-2 assay can be interpreted as follows:

Numeric result	Result message	Interpretation
COI < 1.0	Non-reactive	Negative for anti-SARS-CoV-2 antibodies
COI ≥ 1.0	Reactive	Positive for anti-SARS-CoV-2 antibodies

The magnitude of the measured result above the cutoff is not indicative of the total amount of antibody present in the sample.
The individual immune response following SARS-CoV-2 infection varies considerably and might give different results with assays from different manufacturers. Results of assays from different manufacturers should not be used interchangeably.

Limitations - interference

The effect of the following pharmaceutical compound on assay performance was tested. Interference was tested up to the listed concentration and no impact on results was observed.

15 U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. Symptoms of Coronavirus. https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html. Published March 20, 2020. Accessed April 15, 2020.

16 Wang D, Hu B, Hu C, et al. Clinical characteristics of 138 hospitalized patients with 2019 novel coronavirus–infected pneumonia in Wuhan, China. JAMA. 2020. 10.1001/jama.2020.1585.

17 Huang C, Wang Y, Li X, et al. Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. Lancet. 2020. 10.1016/S0140-6736(20)30183-5.

18 Arentz M, Yim E, Klaff L. Characteristics and outcomes of 21 critically Ill patients with COVID-19 in Washington state. JAMA. 2020 Mar 19: e204326. doi: 10.1001/jama.2020.4326.

19 Wu Z, McGoogan JM. Characteristics of and important lessons from the coronavirus disease 2019 (COVID-19) outbreak in China: summary of a report of 72 314 cases from the Chinese center for disease Control and prevention [published online ahead of print, 2020 Feb 24]. JAMA. doi: 10.1001/jama.2020.2648.

20 World Health Organization. Laboratory testing for coronavirus disease (COVID-19) in suspected human cases. https://apps.who.int/iris/bitstream/handle/10665/331501/WHO-COVID-19-laboratory-2020.5-eng.pdf. Published March 19, 2020. Accessed April 15, 2020.

21 U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. Interim Guidance: Healthcare Professionals 2019-nCoV. https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-criteria.html. Published March 14, 2020. Accessed April 15, 2020.

22 An overview of the rapid test situation for COVID-19 diagnosis in the EU/EEA. European Centre for Disease Prevention and Control. https://www.ecdc.europa.eu/sites/default/files/documents/Overview-rapid-test-situation-for-COVID-19-diagnosis-EU-EEA.pdf. Published April 1, 2020. Accessed April 15, 2020.

23 Long Q, Deng H, Chen J, et al. Antibody responses to SARS-CoV-2 in COVID-19 patients: the perspective application of serological tests in clinical practice. medRxiv. 2020. doi: https://doi.org/10.1101/2020.03.18.20038018.

24 Kissler S, Tedijanto C, Lipsitch M, et al. Social distancing strategies for curbing the COVID-19 epidemic. medRxiv. 2020. doi: https://doi.org/10.1101/2020.03.22.20041079.

25 Guo L, Ren L, Yang S, et al. Profiling Early Humoral Response to Diagnose Novel Coronavirus Disease (COVID-19) [published online ahead of print, 2020 Mar 21]. Clin Infect Dis. 2020. doi: 10.1093/cid/ciaa310.

26 World Health Organization. Coronavirus disease (COVID-2019) R&D.https://www.who.int/blueprint/priority-diseases/key-action/novel-coronavirus/en/. Published April 11, 2020. Accessed April 15, 2020.

27 Liu W, Liu L, Kou G, et al. Evaluation of Nucleocapsid and Spike Protein-based ELISAs for detecting antibodies against SARS-CoV-2 [published online ahead of print, 2020 Mar 30]. J Clin Microbiol 2020 pii: JCM.00461-20. doi: 10.1128/JCM.00461-20.

28 To K, Tsang O, Leung W, et al. Temporal profiles of viral load in posterior oropharyngeal saliva samples and serum antibody responses during infection by SARS-CoV-2: an observational cohort study [published online ahead of print, 2020 Mar 23]. Lancet Infect Dis. 2020. pii: S1473-3099(20)30196-1. doi:10.1016/S1473-3099(20)30196-1.

29 Amanat F, Nguyen T, Chromikova V, et al. A serological assay to detect SARS-CoV-2 seroconversion in humans. medRxiv. 2020. doi:10.1101/2020.03.17.20037713.

30 Lou B, Li TD, Zheng SF, et al. Serology characteristics of SARS-CoV-2 infection since the exposure and post symptoms onset. medRxiv. 2020. preprint doi: https://doi.org/10.1101/2020.03.23.20041707.

31 Zhao J, Yuan Q, Wang H, et al.. Antibody responses to SARS-CoV-2 in patients of novel coronavirus disease 2019 [published online ahead of print, 2020 Mar 28]. Clin Infect Dis 2020. pii: ciaa344. doi: 10.1093/cid/ciaa344.

32 Xiao DAT, Gao DC, Zhang DS. Profile of Specific Antibodies to SARS-CoV-2: The First Report [published online ahead of print, 2020 Mar 21]. J Infect 2020;S0163-4453(20)30138-9. doi:10.1016/j.jinf.2020.03.012.

33 Zhang B, Zhou X, Zhu C, et al. Immune phenotyping based on neutrophil-to-lymphocyte ratio and IgG predicts disease severity and outcome for patients with COVID-19. medRxiv. 2020. doi: https://doi.org/10.1101/2020.03.12.20035048.

34 Wölfel R, Corman VM, Guggemos W, et al. Virological assessment of hospitalized patients with COVID-2019. Nature 2020 Apr 1. doi: 10.1038/s41586-020-2196-x.

35 Tan W, Lu Y, Zhang J, et al. Viral Kinetics and Antibody Responses in Patients with COVID-19. Tan et al. 2020. medRxiv. 2020. preprint doi: https://doi.org/10.1101/2020.03.24.20042382.

36 Okba N, Müller M, Li W, et al. SARS-CoV-2 specific antibody responses in COVID-19 patients. medRxiv. 2020. doi: https://doi.org/10.1101/2020.03.18.20038059.

37 Zhou P, Yang XL, Wang XG, et al. A pneumonia outbreak associated with a new coronavirus of probable bat origin. Nature 2020;579(7798):270-273.

38 Haveri A, Smura T, Kuivanen S, et al. Serological and molecular findings during SARS-CoV-2 infection: the first case study in Finland, January to February 2020. Euro Surveill 2020;25(11):2000266.

39 Poh C, Carissimo G, Wang B, et al. Potent neutralizing antibodies in the sera of convalescent COVID-19 patients are directed against conserved linear epitopes on the SARS-CoV-2 spike protein. bioRxiv. 2020. preprint doi: https://doi.org/10.1101/2020.03.30.015461.

40 Prompetchara E, Ketloy C, Palaga T. Immune responses in COVID-19 and potential vaccines: Lessons learned from SARS and MERS epidemic. Asian Pac J Allergy Immunol 2020;38(1):1-9.

41 Occupational Safety and Health Standards: Bloodborne pathogens. (29 CFR Part 1910.1030). Fed. Register.

42 Directive 2000/54/EC of the European Parliament and Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work.

For further information, please refer to the appropriate operator's manual for the analyzer concerned, the respective application sheets, the product information and the Method Sheets of all necessary components (if available in your country).

A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see dialog.roche.com for definition of symbols used):

CONTENT	Contents of kit
SYSTEM	Analyzers/Instruments on which reagents can be used
REAGENT	Reagent
CALIBRATOR	Calibrator
→	Volume after reconstitution or mixing
GTIN	Global Trade Item Number

CE

Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim
www.roche.com

Roche

Roche

Date: 04th Aug, 2020.

To
The Director,
All India Institute Of Medical Science,
Bhubaneswar, Odisha.

Kind Attention: Blood Bank Incharge.

Sub: Price of Roche Elecsys Anti SARS CoV 2 kits.

Dear Sir/Madam,

Thanks for your Enquiry about the Covid 19 antibody kits, for your prestigious institution.

In our earlier communication made to you on the upcoming Covid 19 antibody testing by Roche Diagnostics India Pvt. Ltd, we are glade to inform you the price of this kit is very very competitive.

Please find below the New Pricelist of Covid 19 Antibody Test (Elecsys Anti-SARS-CoV-2 immunoassay) & consumables.

Sr.No.	GMMI No.	Description	Pack Size	Price Per Kit (Rs.)	Per Test Cost.(Rs.)
1	09203095190	Elecsys Anti SARS CoV 2	200	26,800	134.00
2	09216928190	Anti SARS CoV 2 PC Elecsys.	4x1ml	4465	——

***GST will be charged extra as applicable.**

We also request you to kindly give us a tentative idea for your requirement of next 3 months, because the said amount kits will be in stock to our distributor ends for emergency purpose & we will supply as per your actual requirement only.

Assuring our best service support all time. Looking forward for your favorable decision in this regard.

Thanks and regards,
For Roche Diagnostics India Pvt. Ltd.

Subhashis Das.
Sr. Area Sales Manager – CD
Odisha.
Mobile: +91 9338997359

ROCHE DIAGNOSTICS INDIA PVT. LTD. KOLKATA

Santanu Roy Chowdhury.
Sr. Zonal Manager -CD
Kolkata.
Mobile: +91 9831045427

for ROCHE DIAGNOSTICS INDIA PVT. LTD. KOLKATA

03/09/20

ROCHE DIAGNOSTICS INDIA PVT. LTD.
CIN - U85195MH1988PTC141417

Regional Office:
Unit - 1002, Merlin Acropolis,
1858/1, Rajdanga Main Road,
East Kolkata Township,
Kolkata, West Bengal-700 107

Tel. : +91 (33) 4015 3700
Fax.: +91 (33) 4015 3701

Regd. Office:
501 B, Silver Utopia
Cardinal Gracious Road
Chakala, Andheri (East)
Mumbai - 400069

Tel.: +91 (22)
Fax: +91 (22)
www.roche-di