PIHAK BERKUASA PERANTI PERUBATAN
Medical Device Authority
KEMENTERIAN KESIHATAN MALAYSIA
Ministry of Health Malaysia
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Ref : (6) MDA.600.3/1/22 Jld 63
Date : 16 March 2021

Best Contact (M) Sdn Bhd,
No.13-12, Jalan Jalil Perkasa 13, Arked
Esplanad, Bukit Jalil, 57000, Kuala Lumpur.

Dear Sir/Madam,

IVD TEST ASSAY EVALUATION (COVID-19 TEST ASSAY) WITH TESTING FACILITY

Please be informed that the testing facility should evaluate the IVD Test Assay. Information regarding the test kit selected for evaluation is provided as shown in the following list:

Product name	:	BC Medicare SARS-CoV-2 Antigen Rapid Test Kit(Colloidal Gold)
Batch mp./Identifier	:	COV-AG-20/G10313
Product description	:	BC MEDICARE SARS-CoV-2 Antigen Rapid Test Kit uses an immunocapture method, it is designed to detect the presence or absence of SARS-CoV-2 nucleocapsid proteins in respiratory samples from patients with signs and symptoms of infection who are suspected of COVID-19. Key components: the anti-nucleocapsid protein antibody and chicken IgY labeled by colloidal gold, the nitrocellulose membrane coated with anti-nucleocapsid protein antibody, and goat anti-chicken IgY antibody. When specimens are processed and added to the test device, SARS-CoV-2 antigens present in the specimen bind to antibodies conjugated to colloidal gold in the test strip. The antigen conjugate complexes migrate across the test strip to the reaction area and are captured by a line of antibodies bound on the membrane. A color band will show up when antigen-conjugate is deposited at the Test "T" position and the Control "C" position on the device.
Intended Use	:	For in vitro qualitative detection of SARS-CoV-2 nucleocapsid antigen in nasal (NS) swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the first five days after onset of symptoms. This test is only provided for use by clinical laboratories or to healthcare workers for point-of-care testing, not for at-home testing.
Manufacturer of the test kit	:	BC Medicare Sdn Bhd Level 3, Tower 11, Avenue 5, No 8 Jalan Kerinchi, Bangsar South 59200 Kuala Lumpur.

Contact person details :

Name	:	Chong Wai Mun
Address	:	No.13-12, Jalan Jalil Perkasa 13, Arked Esplanad, Bukit Jalil, 57000, Kuala Lumpur.
Email	:	chongwm@bestcontact.com.my
Tel.no	:	03-89939139

Testing Facility : Makmal Kesihatan Awam,
Lot 1853, Kg. Melayu,
47000 Sungai Buloh,
Selangor.

A total of 150-200 tests shall be provided to the evaluation lab. (for kit evaluation)

2. To commence evaluation, you may import a total of 150-200 tests shall be provided to the evaluation lab (for kit evaluation) and this letter shall be sent to the testing facility. Evaluation in any test assays should not be conducted without a letter from Medical Device Authority (MDA). For more updates or inquiries, please contact the MDA evaluation team at evaluation.covid19@mda.gov.my.

3. Testing Facility is to sign and endorse the final evaluation report. A copy of the report should be sent to Evaluation Team via email: evaluation.covid19@mda.gov.my.

Thank you.

(AHMAD SHARIFF BIN HAMBALI)
Chief Executive
Medical Device Authority,
Ministry of Health, Malaysia