Biolidics Ltd

Q&A on their COVID-19 rapid test kit

SINGAPORE | HEALTHCARE | UPDATE

21 April 2020

- Biolidics has received approvals to distribute its rapid test kit for COVID-19 in the U.S., Philippines and EU.
- The rapid test can detect COVID-19 with more than 95% accuracy in 10 minutes* by the presence of antibodies. But it is not to be used for confirmatory testing or as the sole basis for diagnosis.
- We arranged for a Q & A with Biolidics on their recent development with their test kit.

Company Background

Incorporated in 2009, Biolidics is a Singapore-based medical technology company. The company has developed and commercialised the ClearCell® FX1 System, a fully automated CEIVD medical device which relies on a novel patented technology to separate and enrich cancer cells from blood. The ClearCell® FX1 System allows users to perform liquid biopsies to test for the presence of cancer cells (specifically circulating tumour cells, or CTCs) in blood samples or perform further analysis on cancer cells. The three virologists in the company are Dr Wang Qing-Yin (COO), Dr Dong Hongping and Dr Chassidy Johnson.

** based on validation data obtained in studies conducted in China involving 570 samples from 5 hospitals.*

1. How is COVID-19 being tested globally?

The causative agent of COVID-19 pandemic is a virus named SARS-CoV-2. There are generally 4 methods to identify the causative agent:

a. Antibodies test: Detection of a meaningful immune response to the virus by immunoassays (often called Serology test). The Lateral Flow Assay (LFA) used by Biolidics' rapid test kit is one of these such assays.

b. PCR: Detection of the viral genome via PCR (polymerase chain reaction) method. Reverse transcriptase-polymerase chain reaction (RT-PCR) is one such methodology.

c. Staining specimens: Identification of the virus by staining specimens and observe under a microscope (e.g. light and electron microscopy), which is a long and tedious process.

d. Isolation and identification of the virus via cell culture and fertile eggs, which is also a long and tedious process.

RT-PCR testing is generally adopted around the world to confirm cases of COVID-19 because it is very specific and sensitive. All types of testing have its limitations and here are the key issues generally associated with RT-PCR testing: (i) As it is a laboratory procedure and require specialised laboratory personnel, it is a low-throughput method; (ii) If the viral load within a COVID-19 patient diminishes and unable to be detected, the result will be negative. Hence, this test will not be suitable to tell if a patient had COVID-19 previously.

2. How does Biolidics rapid test kit work?

Biolidics rapid test kit is one of the few that combines both IgG/IgM antibody test for COVID-19. The IgM and IgG antibodies are produced by the human body in response to SARS-CoV-2 (i.e the virus which causes COVID-19) infection. Biolidics' rapid test kit serves as an added tool for detecting the presence of immune antibodies against COVID-19 during or post-infection.

NON-RATED

LAST CLOSE PRICE	SGD 0.380
FORECAST DIV	N.A
TARGET PRICE	N.A
TOTAL RETURN	N.A

COMPANY DATA

BLOOMBERG CODE:	BLD SP
O/S SHARES (MN) :	260
MARKET CAP (USD mn / SGD mn) :	69 / 98
52 - WK HI/LO (SGD) :	0.39 / 0.18
3M Average Daily T/O (mn) :	3.17

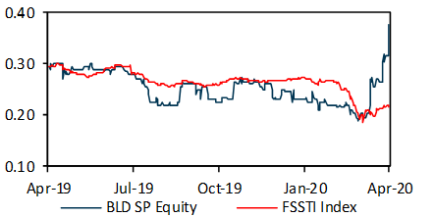
MAJOR SHAREHOLDERS (%)

CLEARBRIDGE BSA PTE LTD	23.1%
SEEDS CAPITAL PTE LTD	9.9%
TRAUWIN PTE LIMITED	7.3%

PRICE PERFORMANCE (%)

	1MTH	3MTH	1YR
COMPANY	64.1	37.0	6.8
STI RETURN	6.9	(19.9)	(18.5)

PRICE VS. STI



Source: Bloomberg, PSR

KEY FINANCIALS

Y/E Dec	FY16	FY17	FY18	FY19
Revenue (SGD mn)	0.80	1.94	2.08	1.27
EBITDA (SGD mn)	(0.92)	(1.19)	(1.46)	(1.55)
NPAT (SGD mn)	(8.03)	(6.87)	(7.21)	(6.25)
P/BV, (X)	-	-	4.6	8.2

Source: Company, PSR

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MCI (P) 006/10/2019
Ref. No.: SG2020_0044

It may be used as a point-of-care test (POCT) in a wide range of healthcare settings by clinical personnel who are not trained in complex clinical laboratory procedures. The LFA technology used by Biolidics' rapid test kit is not new and has been largely deployed in several past pandemics. Hence, the rapid test kit may be used as a screening tool as it has high throughput, quick turnaround time and at the same time, cost effective to deploy.

The rapid test kit may also be used as a diagnostic support/ triage to false negatives by nuclei acid test (i.e. to tell if a patient has COVID-19 previously). Hence, it can serve as an additional tool to provide more information to health authorities to shape their policies and measures to combat COVID-19.

The Company had supplied its COVID-19 Rapid Test Kits on the 3 April 2020, to conduct validation studies in conjunction with the National Public Health Laboratory/NCID. Additionally, the Company will begin a separate study with NUH commencing on 6 April 2020. The clinical validation to be performed at National Public Health Laboratory/NCID and NUH is to : a) verify the clinical performance claim in the product insert (i.e. sensitivity and specificity) using local patient samples; b) evaluate the feasibility of using finger pricking instead of venepuncture sampling methodology to obtain whole blood samples

3. What is the weakness of your test?

Rapid test kit – that work like pregnancy tests (but detect antiviral antibodies instead of pregnancy hormones) – It generates results faster and is potentially cheaper, but is less accurate compared to the RT-PCR test.

The results from our rapid test kit are not to be used for confirmatory testing or as sole basis for diagnosis. The results will have to be interpreted together with clinical presentation and are to be confirmed with supplementary testing.

4. Where does Biolidics source their test kit and are they branded under Biolidics name?

The manufacturing of the rapid test kit is outsourced to a diagnostic kit manufacturer which adheres to ISO13485 standards for medical devices manufacturing. The rapid test kit is branded under Biolidics' name.

5. Why should countries choose Biolidics' rapid test kit rather over others?

Biolidics works closely with the local health authorities of the respective countries to obtain the relevant authorisation/approval for use. We coordinated with local health authorities, collecting more data for the refinement of rapid test kits before introduction.

Once test kits are approved for use, we can then deploy the rapid test kit, simultaneously collecting more clinical data and information, which is proprietary to Biolidics as no one else can use and lay claim to such information.

6. What was required by EU and Philippine FDA to approve your rapid test kit?

We submitted the relevant technical dossier/information of the rapid test kit and it was left to the EU and Philippine FDA to derive their conclusions.

7. What is the status of Biolidics FDA application?

As per the 20 April 20 announcement, Biolidics has completed the Listing of its COVID-19 Rapid Test Kits under Policy D*. With the completion of the Listing, the Company is now able to distribute, market and sell its COVID-19 Rapid Test Kits in the USA. The test has not been reviewed by the FDA.

**More details about Policy D: https://www.fda.gov/media/135659/download*

Corporate announcements by Biolidics on their rapid test kit for the Novel Coronavirus 2019 (COVID-19):

20Apr20: *Biolidics completed the Listing with the FDA of its Rapid Test Kits under Policy D on 17 April 2020.*

15Apr20: *CK Life Sciences International is appointed as a non-exclusive distributor of Biolidics's rapid test kits in Hong Kong for three years.*

13Apr20: *Biolidics completed the notification process with the FDA for the intended distribution of its rapid test kits.*

6Apr20: *Received confirmation of CE Marking for Biolidics rapid test kit. Enables Biolidics to market and sell its rapid test kit in the EU.*

1Apr20: *Biolidics rapid test kit has obtained the relevant authorisation from the Food and Drug Administration of the Philippines to be used in the country.*

30Mar20: *Entered into a manufacturing agreement with a diagnostic kit manufacturer to customise and manufacture the rapid test kits.*

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