

Healthcare sector Update

Private Diagnostics chain to benefit from COVID-19 testing

The fast spread of novel coronavirus, or COVID-19, globally is raising concerns in India. Given the high population density, India faces a very high chance of the outbreak spreading rapidly. As a result, the government has decided to increase its coverage of testing services by partnering with private diagnostic and hospital chains to detect coronavirus. The move is a huge positive for healthcare services providers in India. The Indian Council of Medical Research (ICMR) has approved 26 private laboratories for COVID -19 testing and increasing day by day. These include: Apollo Hospitals – 3, SRL Diagnostics (Fortis) – 2 and Dr Lal PathLabs, Metropolis Healthcare, Thyrocare, Max Hospitals – 1 each. It has also laid down guidelines for COVID-19 testing in private labs. Around 119 government labs have been approved by ICMR, of which 104 are functional for COVID-19 testing and 15 are in the process of turning operational. ICMR is also in the process of fast tracking approval for Indian COVID-19 testing kits for commercial use at lower cost.

The key ICMR guidelines are:

1. Testing for COVID-19 only offered when prescribed by a qualified physician.
2. Labs have to follow safety guidelines in relation to collection of samples, PCR-based diagnosis and staff training.
3. Real time reporting of tests should be followed by private labs.
4. **Cost of testing:** The maximum cost should not exceed INR 4,500 (INR 1,500 for screening test + INR 3,000 for confirmation test). Moreover, ICMR said it encourages free or subsidised testing in this hour of national public health emergency.

ICMR fast tracks approval for Indian COVID-19 testing kits

ICMR is in process of fast tracking approval for Indian COVID-19 testing kits for commercial use. It has recommended two RT-PCR (reverse transcription polymerase chain reaction) test kits for use in its approved government and private labs. These test kits have been found to have 100% concordance among true positive and negative samples. Three organisation have received 100% concordance among true positive and negative samples: Mylab, Altona Diagnostics and Seegene. As per media reports, the testing kit by Mylab would cost nearly one-fourth the current procurement cost. Also, duration of test and screening will reduce from current protocols (2.5 hours versus over 7 hours at present). Mylab is expected to manufacture 50,000-60,000 test kits per month and will further raise it if required. It has started manufacturing from March 24 and can start supplies in 48 hours (by March 26).

Outlook

The managements of diagnostics laboratories are coming forward to support the government in this challenging environment. However, they are also facing hurdles in relation to support staff and their training, logistics and costings. As per the managements, they will not even breakeven at the capped pricing, however, they will have to evaluate profitability as raw material prices are dynamic in nature. They believe that in coming days more private laboratories will be added for testing – one per district in India or almost 500 labs. At present, around 15,000 collection centres are operational. The average lab, with automated PCR, can test more than 1,000 patients a day. This will create huge visibility for diagnostic chains.

COVID-19 will be sentimentally positive for business rather than financial. The fear caused by the COVID-19 pandemic will have a long-lasting impact in the minds of people, with private diagnostics set to gain after the crisis passes as these events are likely to create a behavioural change. People may opt for preventive testing in case of any infection. We like the diagnostic chain sector as there is a huge unmet opportunity against the current low penetration of large diagnostic chains.

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Metropolis Healthcare: Leader in coronavirus testing in India

Metropolis Healthcare (METROHL) is one of the largest diagnostic chains in western India. The region accounts for over 50% of sales. The management is focusing on increasing its B2C business by extensively expanding its collection network. The company has delivered healthy financials over the past five years – revenue/EBITDA/PAT CAGR of 14/14/15%, respectively, with consistent EBITDA margin of ~27%. The company works on an asset-light model and earns an RoCE of over 40%.

Key highlights from the management concall on March 24:

COVID-19 testing: An opportunity for METROHL

- METROHL is the first private diagnostic chain to receive ICMR's approval (March 21) for COVID-19 testing. It started testing at its Mumbai lab (Kohinoor Mall, Mumbai) from March 24.
- **Home collection capacity:** As per the management, METROHL will currently undertake 100 test per day through home collections. It will not face any challenges in increasing testing to 1,000 per day as the company has the requisite reagents and PCR machine. The only issue is of test kits. The company has planned to double its PCR machine capacity by adding 10-15 more by next week, which will further enhance its testing capacity.
- **Testing kit, reagents and PCR machine:** The management does not see any challenges in acquiring reagents and PCR machines, while testing kits are currently in short supply.
- **Pricing:** The Centre has capped the price of COVID-19 testing at INR 4,500. The company said it will not incur any loss at the capped price. However, they will have to evaluate profitability as raw material prices are dynamic in nature.
- **Additional laboratories:** Currently, METROHL has one approved lab for COVID-19 testing though they are collecting samples from across India through their ~2,900 collection centres. The management said it will add one more lab in coming weeks in different regions for COVID-19 testing. The company has 7 laboratories, which are capable of conducting such high-end tests, but the management said it will be very selective in lab coverage as that will impact its existing business.
- **Domestic procurement of testing kits:** Mylab has started manufacturing after approval from ICMR and METROHL being the pioneer in conducting COVID-19 tests in India will prefer to procure from a local manufacturer. Private players are expected to significantly increase COVID-19 tests in coming days. At present, public healthcare departments are performing 50-60 tests per day and have capacity for ~500 tests per day, the lower testing because of ICMR strict screening criteria. However, the management expects this screening criteria to ease in coming days. Public healthcare departments have 70% coverage in India in terms of infrastructure and 30% in terms of requirement of the population as against private players. Thus, the operational efficiency of private players, and with their participation in COVID-19 testing, will increase the number of tests in coming days just like the US.

Existing business update

- Due to a lockdown in the country, METROHL's business has been impacted due to reduction in walk-in patients and disruption in B2B volumes.
- The company has raw material inventory of 40-50 days and has not seen any impact on procurement so far.
- Employee/staff: Expected to face challenges related to front-end staff due to the lockdown, which has impacted home collections that account for 18-19% of sales.
- The company is cash positive. Hence, it can pay its fixed expenses for a couple of months in cash in case of a total shut down.
- The management has reduced its pledged shares to 19% from 26% (over Apr-19 till date). These shares are under a 1-year lock in period, which ends in the first week of April. The management has promised to revoke all pledges within the next 12 months.

List of private laboratories approved for COVID-19 testing

S. No.	Names of States	Names of Laboratory and Address
1	Delhi (4)	<ol style="list-style-type: none"> 1. Lal Path Labs, Block -E, Sector 18, Rohini, Delhi 2. Dr Dangs Lab, C-2/1, Safadarjung Development Area, New-Delhi 3. Laboratory Services, Indraprastha Apollo Hospitals, Sarita Vihar, New Delhi 4. Max Lab, Max Super Speciality Hospital, Saket, New-Delhi
2	Gujarat(3)	<ol style="list-style-type: none"> 1. Unipath Specialty laboratory limited, 102, Sanoma Plaza, Opposite Parimal Garden, Besides JMC House, Ellisbridge, Ahmedabad 2. Supratech Micropath Laboratory & Research Institute Pvt Ltd, Kedar, Ahmedabad 3. SN GeneLab Pvt Ltd, President Plaza –A, Near Mahavir Hospital, Nanpura, Surat
3	Haryana (2)	<ol style="list-style-type: none"> 1. Strand Life Sciences, A-17, Sector 34, Gurugram 2. SRL Limited, GP26, Sector 18, Gurugram
4	Karnataka (3)	<ol style="list-style-type: none"> 1. Neuberg Anand Reference Laboratory, Anand Tower, #54, Bowring Hospital Road, Bengaluru 2. Kasturba Hospital Lab Services, Kasturba Hospital, Madhavanagar, Manipal 3. Cancyte Technologies Pvt Ltd, Sri Shankara Research Centre, Bengaluru
5	Maharashtra (8)	<ol style="list-style-type: none"> 1. Thyrocare Technologies Limited, D37/1, TTC MIDC, Turbhe, Navi Mumbai 2. Suburban Diagnostics (India) Pvt. Ltd., 306, 307/T, 3rd Floor, Sunshine Bld., Andheri (W), Mumbai 3. Metropolis Healthcare Ltd, Unit No. 409-416, 4th Floor, Commercial Building-1, Kohinoor Mall, Mumbai 4. Sir H.N. Reliance Foundation Hospital and Research Centre, Molecular Medicine, Reliance Life Sciences Pvt. Ltd., R-282, TTC Industrial Area, Rabale, Navi Mumbai 5. SRL Limited, Prime Square Building, Plot No 1, Gaiwadi Industrial Estate, SV Road, Goregaon, Mumbai 6. A.G. Diagnostics Pvt Ltd, Nayantara Building, Pune 7. Kokilaben Dhirubhai Ambani Hospital Laboratory, Four Bungalows, Mumbai 8. InfeXn Laboratories Private Limited, A/131, Therelek Compound, Road No 23, Wagle Industrial Estate, Thane (W)
6	Tamil Nadu (3)	<ol style="list-style-type: none"> 1. Dept. of Clinical Virology, CMC, Vellore 2. Department of Laboratory Services, Apollo Hospitals Enterprise Ltd, Chennai 3. Neuberg Ehrlich Lab Pvt Ltd, 46-48 Masilamani Road, Balaji Nagar, Chennai
7	Telangana (3)	<ol style="list-style-type: none"> 1. Laboratory Services, Apollo Hospitals, 6th Floor, Health Street Building, Jubilee Hills, Hyderabad 2. Vijaya Diagnostic Centre Pvt Ltd, Street No 19, Himayath Nagar, Hyderabad 3. Vimta Labs Ltd, Plot No 142, Phase 2, IDA Cherlapally, Hyderabad

Source: Edelweiss Professional Investor Research

Accredited private labs in India

There are 1,076 NABL (National Accreditation Board for Testing and Calibration Laboratories) accredited diagnostics labs in India, which is just 1% of the 1 lakh labs present in the country. NABL accredited labs have grown to 1,076 in 2019 at a CAGR of 17%. The major diagnostic chains: METROHL, Dr Lal PathLabs, SRL Diagnostics and Thyrocare together constitute ~32% of total NABL labs in India.

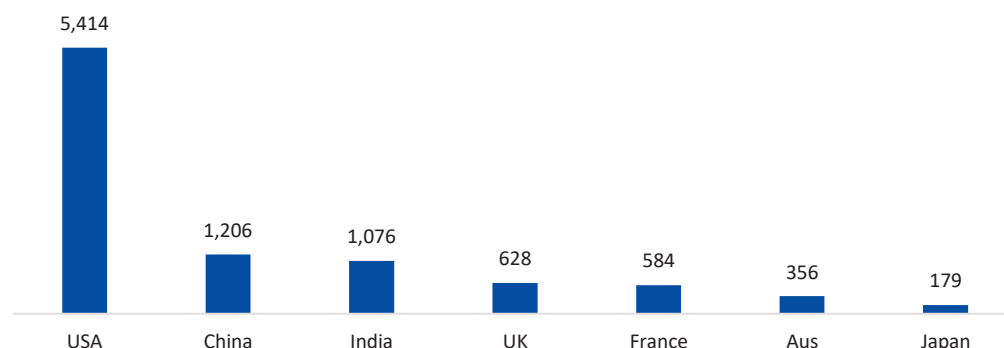
NABL labs in most populated cities and presence of organised players

Cities	NABL accredited labs	Metropolis	DLPL	SRL
Delhi + NCR	202	5	26	19
Mumbai + Navi Mumbai	70	16	3	29
Bengaluru	72	3	4	9
Kolkata	88	4	7	6
Hyderabad	69	1	2	3
Vishakhapatnam	6	1	1	0
Chennai	15	1	1	2
Ahmedabad	40	2	4	2
Surat	9	5	0	0
Jaipur	28	1	1	3
Pune	25	2	2	3
Nagpur	10	1	1	0
Patna	5	0	2	0
Lucknow	18	1	1	2
Dehradun	12	0	1	1
Varanasi	7	1	4	2
Bhopal	8	1	2	0
Agra	5	0	2	0
Ludhiana	6	1	4	0
Vadodara	7	1	1	0

Source: Edelweiss Professional Investor Research

1,076 NABL Accredited Labs in India as in CY18

No of Accredited Labs



Source: Edelweiss Professional Investor Research

ICMR fast tracking approval for Indian COVID-19 testing kits

ICMR has established a fast-track mechanism for validation of non-US Food & Drug Administration (USFDA) EUA/CE IVD approved kits at ICMR's National Institute of Virology (NIV). The test kits with 100% concordance among true positive and negative samples will be approved for commercial use in India. ICMR-NIV has completed evaluation of 14 non-USFDA EUA/CE IVD kits. Three organisations have received 100% concordance among true positive and negative samples: Mylab, Altona Diagnostics and Seegene.

The results of the validation are summarised in the following table:

Name of Company	Name of the Kit	Concordance among true negative (%)	Concordance among true positive (%)
1. Altona Diagnostics	RealStar SARS-CoV-2 RT-PCR kit 1.0	100%	100%
2. MY LAB	Patho Detect	100%	100%
3. BGI	Real Time Fluorescent RT-PCR Kit for detecting 2019-nCoV	100%	90%
4. Krishgen Bio System	SARS-CoV-2 Coronavirus Real Time RT-PCR (RT-qPCR) Detection Kit v1	100%	80%
5. ABI	TaqMan 2019-nCoV Control Kit v1	100%	90%
6. HIMEDIA	Hi-PCR Corona Virus (CoViD-19) Probe PCR Kit	100%	5%
7. HUWEL	Quantiplus Coronavirus (2019nCoV) detection kit	100%	40%
8. IIT-Delhi	SYBR Green based one step QRT-PCR	98%	10%
9. KILPEST (BLACKBIO)	TRUPCR	100%	75%
10. Genesisig	Coronavirus (COVID19) genesisig Real Time PCR Assay	100%	84%
11. Roche	LightMix Modular SARS and Wuhan CoV E gene	91%	100%
12. Roche	LightMix Modular SARS and Wuhan CoV N gene	93%	67%
13. Roche	LightMix Modular Wuhan RdRp gene	100%	60%
14. Seegene	Allplex 2019-nCoV assay	100%	100%

Source: Edelweiss Professional Investor Research

Details of global private diagnostics performing COVID-19 testing

Private labs roped in to fill the supply gap

The US government has announced that anyone who meets the testing criteria laid down by CDC (Centre for Disease Control and Prevention) shall be allowed for COVID-19 testing. To fill the gap between the increasing requirement of the number of tests to be carried out and the constraints faced by the public healthcare infrastructure, the US government decided to rope in the commercial labs -- Quest Diagnostics and LabCorp -- to substantially increase their testing capacities, which is visible in the rise in testing numbers post that.

Both new tests were introduced after the USFDA issued a new policy in late February allowing certain laboratories to develop a diagnostic test for the disease. The LabCorp test became available from March 5, whereas Quest Diagnostics tests were made available from March 9.

In order to carry out the tests swiftly and without any administrative hurdles, the USFDA allowed family doctors to prescribe the test in case the patient shows symptoms of COVID-19. Doctors are not required to take the permission of the Department of Health or CDC for the same. In the entire process, Quest Diagnostics and LabCorp are only allowed to carry out tests and the samples must essentially come from the patient's healthcare provider.

Cost of COVID-19 tests

As far as the costing for the tests developed by LabCorp and Quest Diagnostics are concerned, it is roughly \$50-100 per test.

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