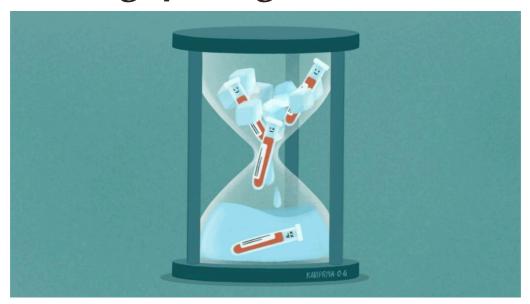
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HEALTH ROULETTE

At-home blood tests are soaring, and throwing up wrong results



By Shivani Verma

The diagnostics industry is transforming post-Covid, favouring blood-sample collections at your doorsteps. Yet, the reliability hinges on the journey your sample undertakes

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Shivani writes about the impact of business, technology, and public policy on society.

Last year, Anuj's parents, both in their 60s, experienced a harrowing two days. The 37-year-old from Mumbai watched them struggle with "immense stress, unable to eat properly", convinced they had diabetes.

For Anuj, who preferred to go by his first name, routine full-body checkups are a family tradition. So, when he discovered Thyrocare, a diagnostics chain owned by healthtech Pharmeasy, offering home-collection tests for Rs 1,200 (US\$14) per person—at "a 60% discount"—he thought he'd found a great deal.

Soon, the deal turned sour.

"Pharmeasy gave a fake HbA1c report," Anuj told *The Ken*. The HbA1c test, crucial for diagnosing and monitoring diabetes, indicated his parents were pre-diabetic.

Countless worries later, Anuj got his parents tested at Suburban, a diagnostic centre in the neighbourhood. The results and a doctor's review concluded that his parents were perfectly "normal".

"The whole [diagnostics] industry is a mess. They're treating home collection like a food-delivery service," Anuj fumed. He swore off "discounted brands" forever, a sentiment likely to resonate with many in the days to come.

The Covid-19 pandemic—which drove people indoors—sparked a home-collection boom. Accredited molecular-testing labs sprang up like mushrooms. In the year ended March 2021 itself, revenues of major diagnostic chains, such as Dr Lal Pathlabs and Max Labs, jumped by 25–30%, according to a report by consulting firm Praxis Global Alliance in February.

But what was then unavoidable soon became a habit. And now, more and more opt for home collections, lured by branded service providers and a focus on preventive care.

In interviews with *The Ken*, 19 home-collection users revealed why they made the switch: convenience, ease, and economical pricing topped the list. They're getting everything from routine checkups like complete blood count (CBC), diabetes, and thyroid tests to preventive screenings.

But now, some doctors, citing inaccuracy, "don't trust" reports from many e-diagnostic platforms.

Consider Parikshit Shah, a 30-year-old resident of Mumbai. He relies on these services as he is wheelchair-bound and lives with his single mother. "One of the doctors told me Pharmeasy reports sometimes show 'normal' results even when symptoms suggest an illness," he said.

"They prefer [home collections from] Agilus Diagnostics (formerly SRL Diagnostics), Apollo Diagnostics, Metropolis Healthcare, etc."

But, then, are all tests cut out for this?

Just as you'd think twice before ordering a paneer sizzler for home delivery due to "quality concerns" but might go for a pizza, certain lab tests fit the home-collection bill while others don't, clarified Vishu Bhasin, director at Dr P Bhasin Pathlabs, a Delhibased diagnostics lab. "Since some samples can be collected at home without getting affected, they are widely accepted. But there are some that will [get affected]."

Test results are only accurate if the sample is collected properly, transported under specific conditions, and deposited at the lab promptly, at least 10 former and current executives, phlebotomists, lab technicians, and pathologists told *The Ken*. Many admitted that these ideal conditions are often not met.

Bhasin, with over a decade in the diagnostics industry, noted that the travel time from sample collection to a testing lab for many companies, including startups like Healthians, can be up to six hours.

So, *The Ken* reviewed 17 reports from home-collection-services users. The time from sample collection to lab receipt ranged from 3.5 to 9 hours. Only Orange Health Labs managed to receive a sample within 20 minutes. Max Labs and even the

listed companies like Dr Lal Pathlabs and Metropolis did not specify the time the samples reached their labs.

Most of them, except Tata 1mg and Healthians, did not respond to *The Ken*'s queries.

The unregulated and unorganised diagnostics industry became ripe for a transformation during and after the pandemic. But in the chase for ease (with everyone scrambling to offer homecollection services), the business is becoming a victim of intermediation and is losing its grip on accuracy.

Powered by convenience

Vineet Kaul, a New Delhi-based fintech professional, books Max Lab's services a couple of times a year, for various tests complete health checkups to specific assessments like thyroid, CBC, and lipid profiles.

Then, the 48-year-old noticed a concerning pattern. On three occasions, the potassium levels in his Max Labs reports spiked, indicating hyperkalemia . Doubting the accuracy, he sought a repeat test for potassium alone from Dr Lal Pathlabs, and the results were "normal". Kaul shared these reports with an independent doctor to confirm.

But Kaul's family was gripped by anxiety throughout the ordeal, costing them both peace of mind and extra money. "Everyone was worried that something was wrong with me. You can't put a cost to this and can't let go of a wrong test," he reflected.





"Within general health checkups, potassium is the test that gets most impacted due to transportation conditions," warned Bhasin. "Hemolysis, the destruction of red blood cells, can increase potassium levels. If the values are off the charts or missing from the report, it's a clear sign the sample was compromised."

Potassium test, vital for kidney-function assessment, is indeed time-sensitive, attests Shantakumar Muruda, a doctor, lead assessor at the National Accreditation Board for Testing and Calibration Laboratories (NABL), and founder of Bengalurubased QXL Diagnostics.



If there's leakage, delay in transportation, or poor temperature maintenance, the potassium value would be erroneously high. Many other tests are similarly affected.

SHANTAKUMAR MURUDA, LEAD ASSESSOR, NABL

Kaul's Max Labs reports omitted crucial information about sample arrival times, providing details about when it was collected and when the report was released. Same with Lal Pathlabs. Even with a comprehensive package like the Wellwise Essential body checkup from Max Labs, reports only displayed collection dates and times.

Full rundown // Each accredited lab report must include specific details such as the date and time of sample collection, reception, and reporting, per NABL guidelines

Potassium isn't just a footnote in blood work. Muruda says it plays a critical role in kidney function tests (KFT), as kidneys are often one of the first organs affected in diabetics. This parameter is standard in blood work for patients with kidney disease, hypertension, and heart issues.

Max Labs includes potassium values in packages priced above Rs 2,000 (US\$24) within their "kidney detailed profiles". However, the KFT test on Pharmeasy also doesn't include potassium. Even on Healthians' website, which boasts eight comprehensive packages with 111 parameters, there is no mention of potassium.

"During sample transit, variations were noticed prominently in reports. That's why [Healthians] removed this parameter from the packages," revealed a former Healthians lab executive. "Earlier, a potassium test used to be marked as urgent and the sample was prioritised."

But the problem extends to other tests, too. Various platforms collect samples for tests such as PT INR and aPTT—ideal for processing within an hour or two.

Three pathologists voiced concerns about the accuracy of results for these tests given the prolonged transit time. Maintaining blood-sample temperature of 2–8 degree Celsius, with an upper limit of 20 degree Celsius, is critical, asserts Bhasin.

Any delay in transportation or centrifugation can compromise test parameters like electrolytes, glucose, and CBC, warns Muruda. "These delays can lead to hemolysis, change cellular metabolism , and degrade certain analytes , impacting the accuracy of test results," he cautioned.

It's all an equation with three variables: pre-analytic (before the sample reaches the lab), analytic (during lab processing), and post-analytic (after the test is conducted).

Each plays a key role in accuracy; but with home collection, the spotlight is on the pre-analytic stage. Here, phlebotomists and runners play a crucial role, ensuring everything's in order. They hold the keys to a sample's fate and accuracy.

Passing the parcel

At the break of dawn, phlebotomists across India hit the ground running, uniformed and equipped, their square bags slung over their shoulders. Some wear masks, some in a rush. Assigned specific areas, they embark on extensive journeys, covering 15 km or more to collect samples.

Tata 1mg employs over 800 phlebotomists, while Healthians has a fleet of around 1,800, according to Prashant Nag, vice president (diagnostics) at Tata 1mg, and Deepak Sahni, founder and CEO of Healthians.

While Sahni claimed that Healthians' phlebotomists collect eight to nine samples daily, *The Ken* has learnt that the figure can go up to 22 for some of these platforms, allowing for typically 15 minutes or less per patient.

To go deeper into the process, *The Ken* booked serum electrolytes tests—a blood test assessing levels of key electrolytes: sodium, potassium, and chloride—from six labs across three metro cities. Some phlebotomists were ill-prepared, relying on scant ice packs or opting for ice boxes instead. Their names have been withheld to safeguard their identities.

Ideally, samples should be nestled between several ice packs, according to multiple lab technicians.

This is crucial, especially for companies operating on a hub-and-spoke model. For instance, Dr Lal Pathlabs and Metropolis' phlebotomists take the samples to their nearby centres, which then send them to a regional or central hub.

Those who work for Tata 1mg, Healthians, Pharmeasy, and Redcliffe meet the runners periodically in designated areas to hand over samples. These runners transport the samples in chiller boxes to labs, which may be situated far away.

Take Healthians, for instance. Most of the tests collected in Delhi NCR are processed at its Gurugram lab, according to six people, including three former phlebotomists and lab technicians at the company. The distance between New Delhi and the lab is around 33 km, while places like Ghaziabad and Greater Noida are farther away. All typically congested with traffic.

Sahni, however, claimed there is another lab in east Delhi. Even in Bengaluru, he said, there are two labs in the southeastern and western areas. Although, "the one at Kengeri isn't operational right now," said a company executive.

What if blood samples don't survive the journey? It's a nightmare scenario for phlebotomists, who have to bear the financial burden.

A Pharmeasy phlebotomist, earning Rs 160 (US\$2) per collection, receives no extra pay to collect samples a second time. [Some of the platforms offer fixed salaries of Rs 18,000–20,000 (US\$216–240).]

Two phlebotomists, with years in the field, highlighted the struggle of maintaining sample integrity. While they are provided with ice packs, the onus falls on them to keep them cool.



Over 90% of the phlebotomists in metro cities are migrants. How can a phlebotomist who pays Rs 5,000 (US\$60) in rent afford a fridge?

-PHLEBOTOMIST, WHO HAS WORKED FOR TATA 1MG, HEALTHIANS, THYROCARE, AND LAL PATHLABS

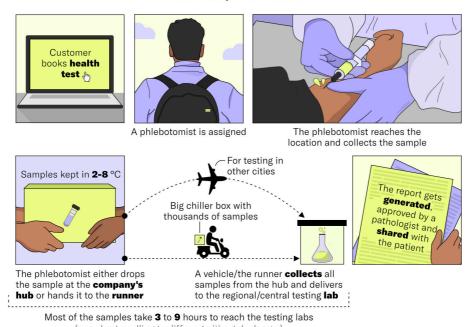
Some labs like Dr Lal Pathlabs give ice-pack replacements to the phlebotomists, but others, like Redcliffe, 1mg, Pharmeasy, and Healthians, don't provide such facilities.

Besides, from sample collection to handover to a runner, before finally reaching the lab, it's a lengthy process.

As one phlebotomist put it, "Let's say, I collected your sample at 6 a.m. I will keep collecting till 7:30 a.m. I'll meet the runner at around 8, who will spend another hour or so collecting the samples from other phlebotomists. Your sample will keep travelling for at least three hours."

Miles to go

Experts advise blood-test samples reach labs within hours, but reality often differs



(samples travelling to different cities take longer)

THE KEN

Graphic by Aishwarya N, 28 May '24

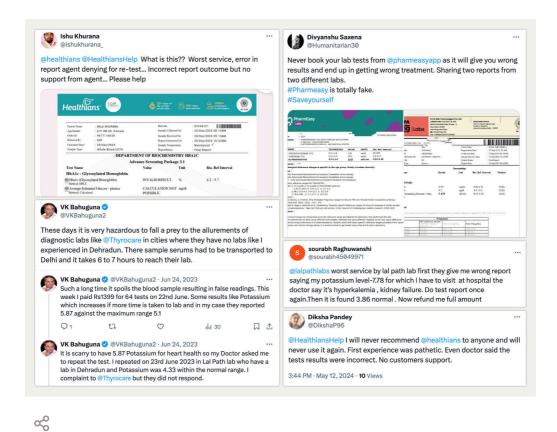
Source: The Ken research

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All the samples except one *The Ken* gave for the serum electrolytes test took more than three hours to reach the labs. The tests were done from 1 mg, Pharmeasy, Orange Health, Lal Pathlabs, and Metropolis. Only Orange Health's sample reached in ~2 hours.

Where the error creeps in

On X (formerly Twitter), many have voiced concerns about inaccurate and incomplete reports from various labs, adding to the growing chorus of scepticism.



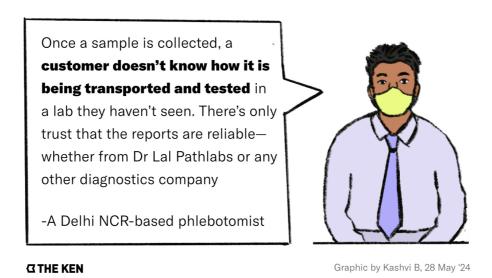
All the people in the industry *The Ken* spoke to said that most of the errors occur between the collection and the time at which the sample reaches a lab.

Take the serum electrolytes test, for example. It requires a blood sample collected in a serum separator tube or yellow tube with gel. After collection, the sample needs to be handled carefully to ensure its quality.

The preferred method is to transport the sample to the lab within two hours for the centrifuge process that separates the blood components, making the sample ready for testing, explained Muruda. If that doesn't happen, the sample should be kept refrigerated after centrifugation $(2-8^{\circ}C)$, transported to the lab, and tested within four hours.

Neither happened in *The Ken*'s case, yet the potassium values across the reports fell in the "normal" range.

"Sometimes, in regular patients, they give out a standard report in compromised samples [for potassium testing] also," explained Bhasin. This sentiment was echoed by another seasoned phlebotomist, who, based on customer feedback, confirmed its prevalence across diagnostic companies.



Then, qualification, quality control, and accountability are also a concern.

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For one, most runners lack the expertise to understand the nuances of sample handling and maintenance, a phlebotomist noted.

Then, many diagnostics companies, such as Redcliffe and Healthians, outsource some of their tests to third-party labs. A Healthians executive said the company outsources a small fraction—1–2%—of its tests to Metropolis.

However, in 2020, all tests in Delhi NCR were handled by the likes of Thyrocare, Accuprobe Diagnostics, and Dr Lalchandani Labs, according to two former Healthians phlebotomists and lab technicians.



In a private setup, doctors are responsible for every test. In corporate labs, there's mostly a digitised signature. Half of the time, the doctor is not even in the lab during testing; the technicians authorise results

A CONSULTANT PATHOLOGIST

Patients need to put more focus on whether a qualified doctor/pathologist is sitting at the lab where their samples are tested rather than focusing on the brand name, suggested a consultant pathologist.

Regardless, convenience trumps all—even accuracy. Why else are home collections skyrocketing?

'A neighbourhood business'

In essence, home collections are shaking up the diagnostics industry.

Healthians has seen bookings triple since the pre-pandemic era, Sahni told *The Ken*. Now, the company handles 12,500–13,000 bookings daily, with nearly three-quarters of its business coming from home collections.

Meanwhile, giants like Dr Lal PathLabs, Thyrocare, and Metropolis see less than 30% of their business from home collections. But even Dr Lal PathLabs has seen a jump, with home collections making up 12% of its business in the year ended March 2022, up from 5–6% pre-Covid.

Post-Covid riches // Lal Pathlabs clocked over Rs 2,000 crore (US\$240 million) in revenue in the year ended March 2023, up 35% from the year ended March 2020. Thyrocare, too, saw an over 20% jump to Rs 527 crore in the same period

Sure, there's the ease. But the allure of discounted prices also plays a big role, believes Anuj. People feel like they're getting a deal at Rs 1,500 (US\$18) instead of the usual Rs 3,000 (US\$36), he adds.

Bhasin calls this a "neighbourhood business," but adds, "just like a restaurant, it needs to be fresh," emphasising the critical importance of sample integrity.



While Lal has multiple regional labs, Healthians or Pharmeasy only has a lab or two in NCR.

VISHU BHASIN, DIRECTOR AT DR P BHASIN PATHLABS

In India, anyone with a licence can operate a diagnostics lab—NABL accreditation isn't mandatory. And while both Tata 1mg and Healthians cited annual audits, doctors' authentication of reports, repeat collection of compromised samples, and the NABL accreditation, the truth is that the autonomous body under the Ministry of Commerce and Industry is not a regulator.

"It [NABL] does not have the authority to penalise a lab or initiate any action," said Muruda. "Unfortunately, it's also not mandatory for a lab to have qualified doctors such as a pathologist or a microbiologist. Anyone can run it."

Covid let the convenience genie out of the bottle, making doorstep collections more popular than ever. But without the necessary rigour, it's a game of roulette in the name of health checkups from the comfort of home.

CREDITS

Written by Shivani Verma

Edited by Sumit Chakraborty

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