



Verifying the Authenticity of Diagnostic Labs: Need of the Hour

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Submitted:	22. April 2024
Published:	22. April 2024
Volume:	11
Issue:	2
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Languages:	English
Keywords:	Hematopathology, Medical Council of India (MCI), Laboratory Reports, Malpractice, Patient Care
Categories:	News and Views, Life Sciences, Medicine
DOI:	10.17160/josha.11.2.982

Abstract:

In my hematological practice, I have come across several cases of blood reports signed by technician-owned labs. Despite clear MCI (Medical Council of India) guidelines stating that DMLT technicians are not authorized to sign laboratory reports, this malpractice continues. The problem with such labs is that their reports are unreliable and may have been illegally modified for various motives and gains. These technician-run labs may either be self-signed or pathologist-signed. Such labs offer tests at lower prices at the cost of poor quality reporting. People do not mind getting their tests done at these labs as long as they get a good discount. Ideally, one must visit a lab which has a qualified pathologist available to answer patient queries, discuss reports and provide guidance. Today, we as a society are extremely cautious while making even simple lifestyle choices such as organic food, chemical-free products, etc. Then why not make prudent choices when it comes to healthcare, instead of falling into the trap of discounted substandard testing facilities. We are already lucky in terms of being able to get a specialist's appointment

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Abstract

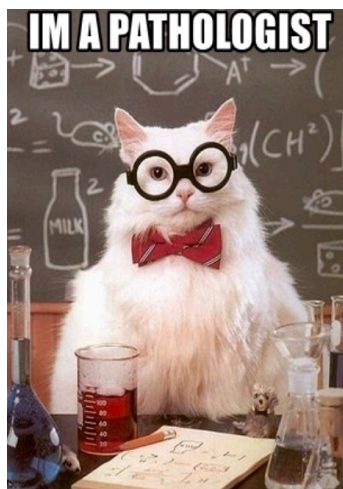
In my hematological practice, I have come across several cases of blood reports signed by technician-owned labs. Despite clear MCI (Medical Council of India) guidelines stating that DMLT technicians are not authorized to sign laboratory reports, this malpractice continues. The problem with such labs is that their reports are unreliable and may have been illegally modified for various motives and gains. These technician-run labs may either be self-signed or pathologist-signed. Such labs offer tests at lower prices at the cost of poor quality reporting. People do not mind getting their tests done at these labs as long as they get a good discount. Ideally, one must visit a lab which has a qualified pathologist available to answer patient queries, discuss reports and provide guidance. Today, we as a society are extremely cautious while making even simple lifestyle choices such as organic food, chemical-free products, etc. Then why not make prudent choices when it comes to healthcare, instead of falling into the trap of discounted substandard testing facilities. We are already lucky in terms of being able to get a specialist's appointment in no time, in our country. Make the most of this privilege! Dr. Ketki's blog was first published on "K2's Blog" (<https://ketkivijayramanan.wordpress.com/2022/06/18/verifying-the-authenticity-of-diagnostic-labs-need-of-the-hour/comment-page-1/#comment-5147>) in June, 2022.



A few weeks ago, a young male patient was brought in an inebriated state at midnight to the casualty ward of the tertiary-care hospital that I visit. He was immediately shifted to the medical ICU. The following early morning, my hematology lecturer informed the clinician (treating doctor) of the blood cancer subtype she was suspecting in this patient. His blood sample was sent for specialized molecular testing for the confirmation of our morphological finding, and our diagnosis was confirmed barely within six hours. Unfortunately, this adrenaline rush which lasted for 12 hours from both the clinical and laboratory sides, given the clinical nature of this cancer, was futile because the patient died within hours of diagnosis. **The next day, our hematologist informed us that the young man's previous hemograms were reported by technician-run labs.** We looked at each other in utter dismay, wondering what wrong this young man had done to deserve such an unfortunate outcome. This is just one of the many cases I have seen in my practice.

Scientist working in specialized molecular lab for early diagnosis

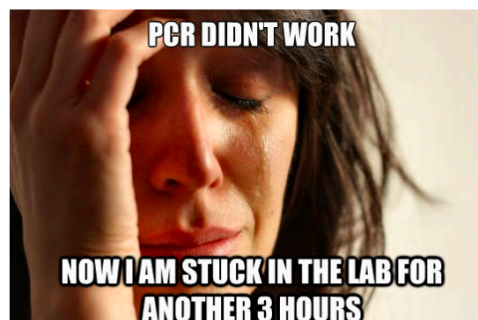
I have come across several cases of blood reports signed by technician-owned labs. The problem with such labs is twofold. First, their reports are unreliable; this is quite understandable because they are not reported by a pathologist (read MBBS with a post graduate MD/DNB/DCP degree). Second, (shocking, but true) the reports may have been illegally modified for various motives and gains. We have seen many patients land in critical care units and many lives lost due to incorrect and/or late diagnosis. To understand more about such labs, **these technician-run labs may either be self-signed or pathologist-signed.** Pathologists at such labs usually give their signatures at scrap prices, without actually visiting the lab facilities regularly, or many a times not even knowing their locations. Quite a few pathologists are known to give their signatures to umpteen labs based all over Maharashtra, while comfortably sitting at their homes. Such labs offer tests at lower prices at the cost of poor quality reporting. People do not mind getting their tests done at these labs as long as they get a good discount. Earlier, DMLT (Diploma in Medical Laboratory Technology) technician-run labs were mainly set up in rural areas or city outskirts to help clinicians (doctors) manage their patients better. However, such labs have now sprung up everywhere. **Despite clear MCI (Medical Council of India) guidelines stating that DMLT technicians are not authorized to sign laboratory reports, this malpractice continues.** Surprisingly, several nursing homes/small hospital ICUs have in-house labs run by technicians who are not



serious about their business because they receive support from clinicians who run these hospitals.

No comments!

PCR Didn't work Now I am stuck in the lab for another 3 hours



It is well-known that during the Covid-19 pandemic, many RT-PCR labs were newly set up all over due to the increased demand for testing. We also are a witness to the discrepancies in the RT-PCR testing and the resulting chaos and loss of faith in the overall Covid-19 RT-PCR reporting system, wherein Covid-19 positive RT-PCR report in one lab turned up as negative RT-PCR report in another. **If NABL-accredited (National**

Accreditation Board for Testing and Calibration Laboratories) labs, which follow strict quality control guidelines face this discrepancy, imagine the chaos when simple blood tests are signed by non-doctors. Post Covid-19, many giant companies have jumped into the diagnostic business and have started offering tests at unbelievable prices. We need to be vigilant while getting ourselves tested at such labs because the quality of the reports may have been compromised. It can also be quite difficult to approach the consultant pathologists at such labs when faced with a doubt.

A few years ago, there was a huge fad of getting genetic testing done amongst a few of my diet- and health-conscious friends. These friends spent exorbitant amounts on certain genetic tests and later asked me to interpret such reports. In my opinion, such detailed and costly testing is only required in cases of severe and obscure ailments; the obvious ones do not warrant it. A person addicted to fatty foods is very likely to develop coronary ailments, and you do not need genetic

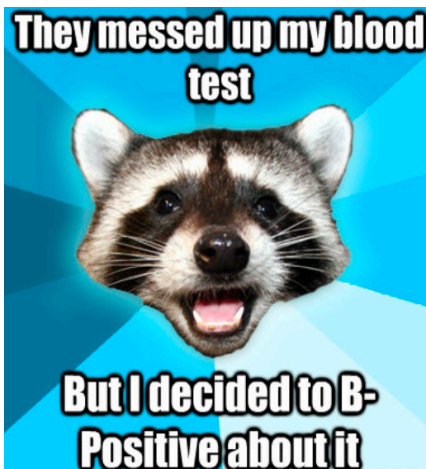


testing to confirm this. Just as the probability of you getting killed on an express highway is nearly 100% if you drive at a speed of 150 kmph with failed brakes, and you don't need complex genetic calculations to predict this. I am indeed lucky to be



a part of a state-of-the-art genetic lab that focuses purely on clinician need-based testing. Having said that, the only solution currently for small private labs is to continuously upgrade themselves, introduce new tests to cater to clinician demands, collaborate with contemporaries to provide comprehensive testing services, and be communicative with patients.

Disaster waiting to happen



On an ending note, the next time you visit a lab for blood tests, do follow a few checklists. **The lab need not always be NABL accredited but needs to have a qualified pathologist who is available to answer patient queries, discuss reports, and provide guidance so that patients feel confident about their reports.** Furthermore, for Covid-19 RT-PCR testing, please visit only standard labs. "Compromise" or "cheap" is not the word when it comes to health, and never take any chances in this regard. Today, we as a society are extremely

cautious while making even simple lifestyle choices such as organic food, chemical-free products, etc. **Then why not be informed and make prudent choices when it comes to healthcare, instead of falling into the trap of discounted substandard testing facilities.** We all desire a fast and accurate diagnosis when faced with a health problem and wish that we be treated by the best in the field. We are already lucky in terms of being able to get a specialist's appointment in no time, in our country. Make the most of this privilege and stay healthy, stay fit!



Acknowledgements

I extend my heartfelt thanks to Dr. Vijay Ramanan, Consultant Clinical Hematologist at Yashoda Hematology Clinic and Ruby Hall Clinic, as well as Dr. Suyog Gurav and my pathologist friends for their valuable inputs.



About the Author



Dr. Ketki Kelkar (Ramanan) is an experienced hematopathologist and molecular pathologist, boasting a 16-year career in the field. She obtained her M.B.B.S and M.D (Pathology) degrees from B.J Medical College, Pune. In 2008, she established Anjali Diagnostic Pathology Laboratory, focusing on hematology and offering specialized services in bone marrow reporting, coagulation, and thrombophilia testing. Currently, Dr. Kelkar leads the Pathology Department at GenePath Dx, a cutting-edge molecular diagnostic center in Pune renowned for NGS-based testing. For the past 14 years, she has served as an Associate consultant in the Hematology Department at K.E.M Hospital, Pune, while also mentoring postgraduate pathology students.

Her work is published in various national and international journals, and she has actively participated as a faculty member in hematology and oncology conferences, presenting numerous papers on molecular hematology. Furthermore, Dr. Kelkar holds the position of Director at MVR Welfare Foundation, an NGO in Pune dedicated to providing free medical services, diagnostics, and treatment to disadvantaged individuals. Beyond her professional pursuits, she is an avid fitness enthusiast and enjoys writing blogs on both technical and non-technical topics.