



Quality Assurance in Medical Laboratory Technology: Current Practices and Future Innovations

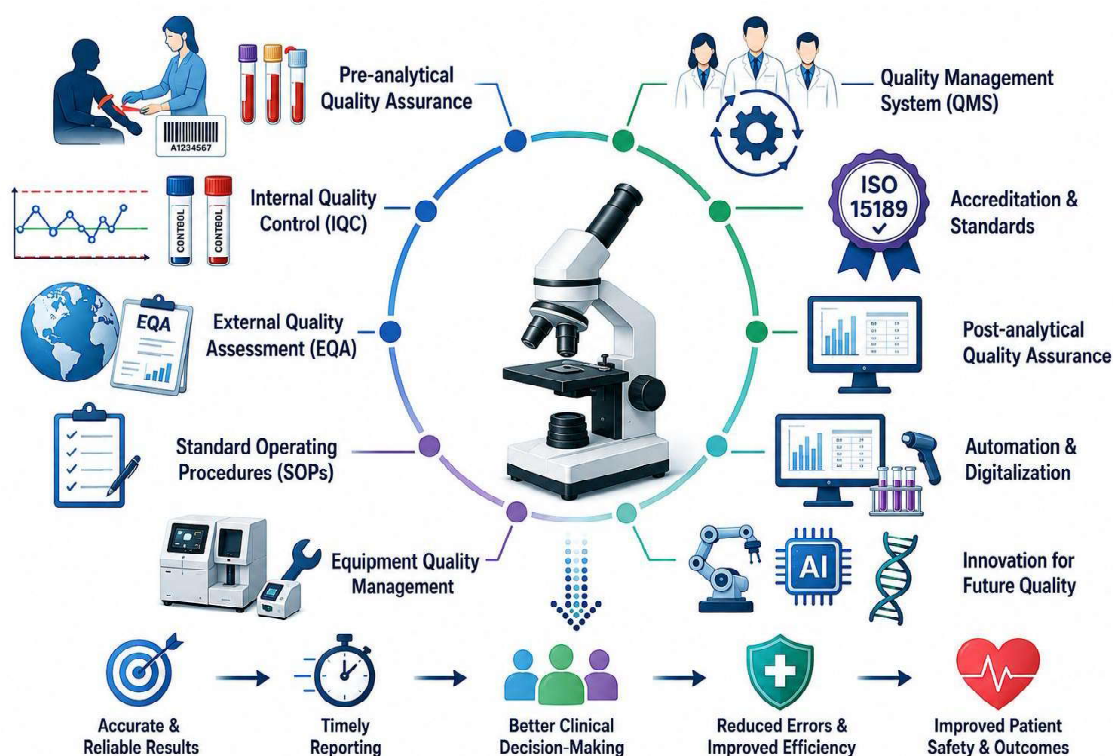
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ABSTRACT

Medical laboratory sciences are a part of modern healthcare. They give us information that helps doctors make decisions about patient care. This review looks at what's happening in medical laboratory sciences right now. It also looks at technologies and what might happen in the future. By looking at what has been written and what new technologies are available this review finds some big trends. Medical laboratory sciences are using intelligence more and more. We are also seeing personalized medicine. This means that treatments are tailored to patients. Laboratory information systems are becoming more important too. The COVID-19 pandemic has sped up the development of diagnostic technologies. This review is useful for healthcare professionals, laboratory scientists and policymakers. It gives them an idea of what's happening in medical laboratory sciences. It also shows them how important medical laboratory sciences are for improving healthcare outcomes. Medical laboratory sciences play a role in this. Medical laboratory sciences are essential, for advancing healthcare outcomes. Diagnostic quality assurance in labs is the important part of modern healthcare. The accuracy of test results plays a role in what doctors decide to do. It affects how patients feel and how well the whole system works. QA is a way to check look at and make better the steps in a lab. This helps stop mistakes keep things the same and follow the rules. These days labs do billions of tests every year. If the results are wrong it can make doctors make the choices. It can also slow down treatment. Cause extra steps that aren't needed. This can make people sicker more likely to die and cost money. For example in hospitals up to 70% of the choices doctors make are based on lab results. Even small mistakes in accuracy can cause problems, for patients. The ISO 9000 documents are like a guide for companies that make things and for companies that provide services. They help these companies make sure they are doing a job. The ISO 9001 rules are for any kind of company no matter how big or small it is.

Keywords: *Medical laboratory Technology, Quality management, Equipment quality, Automation & Digitalization, improve patient safety & outcomes.*



GRAPHICAL ABSTRACT

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1. INTRODUCTION

Quality assurance in a laboratory is a planned and thorough way to make sure that the test results and data created in an analysis setting are correct, trustworthy and the same every time. It includes a group of methods, rules and activities that help reduce mistakes and differences in the work done by people in the lab. The main purpose of quality assurance is to keep and make better the quality and honesty of lab testing. This is very important in areas, like health care checking the environment and doing research. Quality assurance in a laboratory includes important parts. One part is making sure there are standard operating procedures (Khattak et al., 2024). Another part is using equipment that is properly calibrated and tested. Training the people who work in the lab is also important. Diagnostic quality assurance in labs is the important part of modern healthcare. The accuracy of test results plays a role in what doctors decide to do. It affects how patients feel and how well the whole system works.

QA is a way to check look at and make better the steps in a lab. This helps stop mistakes keep things the same and follow the rules. These days labs do billions of tests every year. If the results are wrong it can make doctors make the choices. It can also slow down treatment. Cause extra steps that aren't needed. This can make people sicker more likely to die and cost money. For example in hospitals up to 70% of the choices doctors make are based on lab results. Even small mistakes in accuracy can cause problems, for patients (Rodriguez et al., 2019).

2. INTERNAL AND EXTERNAL QUALITY CONTROL

2.1. Internal Quality Control (IQC)

IQC is performed at specified intervals, such as at the beginning of each shift, after instrument service or calibration, and whenever a new lot of reagents is introduced. The results are typically plotted on Levey-Jennings charts, which provide a simple visual method for detecting random error (imprecision) and systematic error (shifts or trends in performance). To provide an objective basis for decision-making, statistical rules, most notably the multi-rule system developed by Westgard, are applied to the IQC data. These rules help determine if an analytical run is “in control” and patient results can be released, or if it is “out of control,” necessitating rejection of the run and investigation into the cause of the error. (khattak et al., 2004)

Internal Quality Control:

We run control materials that have known concentrations every day along with patient samples. This helps us check how precise and accurate our results are.

Statistical Process Control:

We use tools like Levey-Jennings charts and Westgard multi-rules. These help us find any errors or changes, in the instruments before we send out patient reports. Pre- and Post-Analytical Tracking: We keep track of how samples are rejected the condition of the samples while they are being moved and how quickly we get results. We use a Laboratory Information System to do this.

Competency Assessments:

We regularly train our staff check methods and do internal audits. This helps us stay compliant. Makes sure that people make fewer mistakes when they are working.

2.2. External Quality Assessment (EQA) and Proficiency Testing (PT)

External Quality Assessment is really important for a laboratory. It gives an opinion about how well the laboratory is doing. This is different from Internal Quality Control which checks if the laboratory is doing things consistently. The common way to do External Quality Assessment is through something called Proficiency Testing. This is when a separate organization sends samples to laboratories without telling them what is in the samples. External Quality Assessment is very useful for finding mistakes or biases that might not be seen when just checking internally. It helps laboratories see how they are doing compared to others check if their methods and equipment are working over time and find out if the staff needs more training. Studies have shown that if laboratories regularly take part in External Quality

Assessment they will get better at what they do, over time. External Quality Assessment and Proficiency Testing are essential for laboratories to make sure they are doing a job.

2.3. Proficiency Testing (PT)

Proficiency Testing is a part of laboratory quality assurance. In this process laboratories examine samples to check the accuracy of their testing. They compare their findings with laboratories or with known reference values. Using control materials that act like patient samples helps make the quality assessments more reliable and more relevant to actual patient care. Following rules and passing audits is also important. Laboratories must join approved testing programs. Follow the guidelines such as CLIA and ISO 15189 to maintain their accreditation. If there are any differences or if the results, from the testing are not good they perform a root-cause analysis. This helps find problems in the testing methods any biases or other issues. Then they take steps to fix the problems. In the future new ideas will make External Quality Assessment stronger. Artificial intelligence can look at data from places, spot trends based on the type of equipment used and find unusual changes in the testing. EQA super challenges could let many different companies use the test samples at the same time. This helps track how well diagnostic kits work after they are sold. More digital and remote tools will take the place of paper reports. They will use sharing, cloud systems and real-time analysis. Also better ways to track measurements will help make standards the same, around the world. This will set target values using measurement systems instead of just using what other labs agree on.

2.4. Future Innovations and Emerging Trends

Quality assurance is a part of medical laboratory technology. It makes sure that the results from the lab are correct, dependable and the same every time. Good quality assurance means checking all parts of the testing process. This includes the time before the test during the test and after the test. Checking performance helps labs find mistakes look at how staff and machines are working and fix problems before they happen. Total Quality Management gives a way to keep improving quality.

AI and real-time analytics:

Artificial intelligence takes the place of tracking by using predictive algorithms that spot machine drift or reagent problems before they lead to failures.

Digital List:

Advanced Laboratory Information Systems (LIS) connect with check logs and external EQA data to cut down on mistakes made by people when they type in information.

Advanced connectivity in PoCT:

Point-of-care testing devices now have built-in checks and can send data instantly through wireless networks back to quality control teams, in the center.

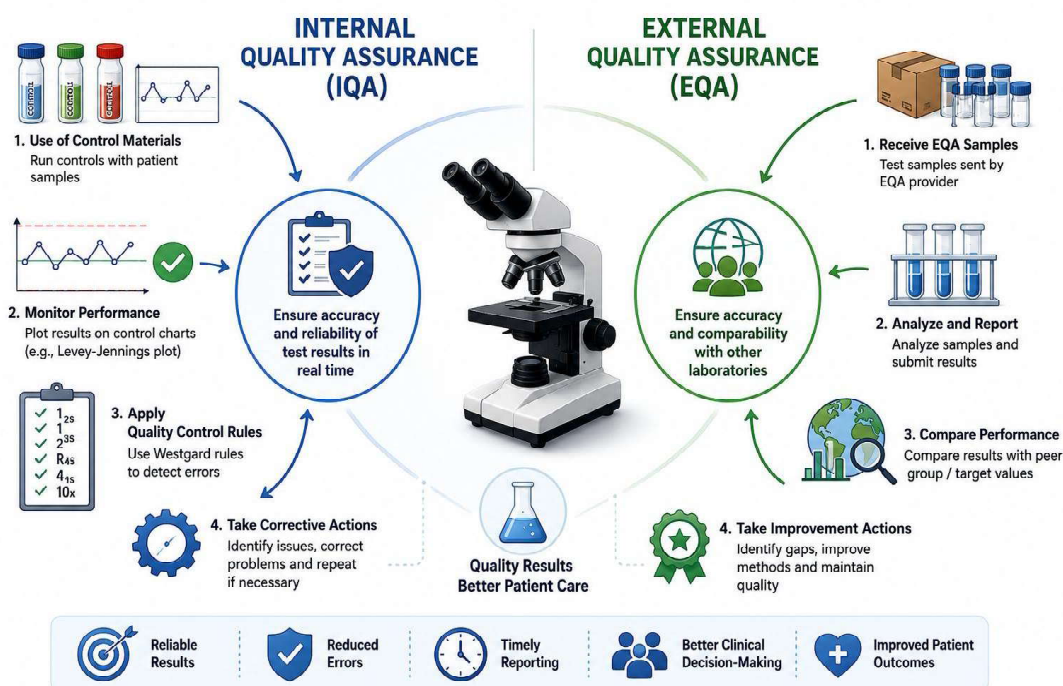


Fig.1: Internal and External Quality assurance monitors the accuracy and reliability of laboratory tests within the laboratory on a regular basis. External quality assurance compares laboratory performance with other laboratories or reference standards.

3. LABORATORY ACCREDITATION AND INTERNATIONAL STANDARDS

The ISO 15189 Framework:

The standard brings together governance, structural requirements, resource allocation and process evaluation specifically designed for clinical medicine. The standard brings together governance, structural requirements, resource allocation and process evaluation specifically designed for clinical medicine. (Assfaw et al., 2024).

Phased Process Control:

Quality assurance happens by following test orders and collecting samples before testing begins. This includes how testing is done and how equipment is checked for accuracy. It also includes reporting results. Letting people know about important findings after testing is done.

National Harmonization:

Organizations such as the National Accreditation Board for Testing and Calibration Laboratories, in India ensure that local rules match the standards. This helps make sure that diagnostic processes are the same

Internal & External Audits:

Reviews, checking staff skills and involvement in testing programs or External Quality Assessment schemes help make sure that accuracy is always high. The need for laboratories to comply with quality

requirements approved by well known international bodies started around twenty years ago. At that time medical laboratories over the world used the available standards to satisfy this need. Many laboratories got accredited according to the EN 45000 standard and later the ISO 17025 standard or national standards issued by bodies like CCKL and CPA. In Italy laboratories were certified according to the ISO 9001 standard. However these standards were not very useful for laboratories. This led to the development of a standard for medical laboratories. The first draft of this standard was issued in 1997. It was not until 2003 that the first revised standard was released. The standard is based on management requirements from the ISO 9001 standard requirements from the ISO 17025 standard and specific professional requirements from the European Communities Confederation of Clinical Chemistry. This standard considers all the needs of laboratories including every step of the testing process. It starts from the test request. Goes all the way to the notification of laboratory reports and further clinical advice from laboratory professionals. The standard focuses on the -analytical phase, which includes things like verifying and validating examination procedures measurement uncertainty and metrological aspects. It also looks at the post-analytical phases, which are unique to medical laboratories compared to other testing laboratories (Taylor et al., 2021). The adoption of this standard was limited in some countries because each single test had to be accredited separately as required by the ISO 17025 accreditation process. It was not until 2008 that the European Cooperation for Accreditation approved accreditation with a scope. After that medical laboratories started getting accredited according to the ISO 15189 standard at a level. The identification of a national accreditation body also helped to promote the accreditation of medical laboratories by making it clear who was, in charge of managing it. Managing risks and reducing errors in laboratories is about finding problems before they happen thinking about how bad they could be and making rules to prevent mistakes. Laboratories use things like ISO 15189 and Failure Mode and Effects Analysis to find the spots and keep patient test results safe and accurate.

4. RISK MANAGEMENT AND ERROR REDUCTION IN DIAGNOSTIC LABORATORIES

No lab test or process is free of risk. Also since the lab testing process has steps the chance of errors can be high. That is why it is important to look at the risks and decide which ones are the serious. It is also important to figure out what level of risk is okay in a lab. A FMEA is used to find the parts of the process check how likely it is that harm could happen from mistakes, in those parts and explain the ways to find and stop those mistakes.

Pre-analytical phase:

This is the part before the testing starts. It is where most of the mistakes happen, more than half of all lab errors. The problems that happen here include patient names on samples blood draws that do not go well or blood tubes that get damaged. Analytical phase: This is the part when the testing is actually happening. Mistakes that happen here include machines that are not working, bad chemical kits or quality checks that are missed every day.

Post-analytical phase:

This is the part after the testing is done. Errors that happen here include typing the test results sending reports to the wrong doctor or delaying important phone calls(Feng et al., 2021).



Fig. 2: Risk management and Error reduction in diagnostics identifies and controls possible errors during sample collection, testing, and reporting. Proper quality control, staff training, standard procedures, and regular monitoring help reduce errors and improve patient safety.

Ways to Reduce Errors:

Use Automation:

Use of tracking can stop mistakes from happening by making sure the right patient gets the right test results right away. It helps for better output production.

Train Staff Well:

The people who work in the laboratory need to make sure they are doing their jobs correctly like drawing blood or running the machines.

Build a Safety Culture:

The staff should feel safe to tell if something almost went wrong without being afraid of getting in trouble.

Monitor Quality Continuously:

Laboratories should run control samples every day and check the equipment for any warning codes. This helps to find problems before they cause mistakes. Diagnostic laboratories need to do these things to reduce errors and keep patient test results correct. Managing risks and reducing errors in laboratories is very important, for patient safety.

5. DIGITAL QUALITY MANAGEMENT AND AUTOMATION

Medical laboratories are set up to be very good at what they do. They handle a lot of specimens every day. They have to make sure everything is done just right. The laboratory workflow has a main

parts: getting ready to test actually doing the tests and what happens after the tests. Each part needs people who really know what they are doing. They have to check everything carefully. Some people, like Miller and Jones have written about this. They said that before the tests are even done there are a lot of things that can go wrong. This is called the -analytical part. It includes collecting specimens moving them around and getting them ready for testing. This part is where most of the mistakes happen, 60 to 70 percent of the time. So it is very important to get this part right so that the tests are good quality. Medical laboratories have to do a job, with this or the test results will not be accurate. Medical laboratories and their work are very important. Quality Management Systems are really important in laboratories. They used to be about things like quality control but now they are about Quality Management Systems that cover everything that happens in the laboratory (Miller & Jones, 2021). The people who make these rules like the International Organization for Standardization created the ISO 15189 standard for medical laboratories. This standard gives us a framework for Quality Management Systems that makes sure the laboratory is good at what it does and that it is managed well according to the International Organization, for Standardization in 2022. Quality Management Systems like this help medical laboratories do their job better. Catering to automated solutions that combine hardware, software and robotics to make lab processes easier and improve research and development efficiency.

5.1. Robotic systems

Robotic systems help workers do tasks quicker and with accuracy and same results, which helps to increase the number of tasks done. Some examples of systems in lab settings are automated liquid handlers, centrifuges and auto samplers which can handle hundreds of samples when a human worker can only handle a few.

5.2. Data integration platforms

Laboratory Information Management Systems (LIMS) and Electronic Lab Notebooks (ELN) are two examples of systems that store manage and get data in one place. These systems make it easier to handle data. They let workers collaborate better by having a flow of information.

5.3. AI-enabled tools

At the time artificial intelligence (AI) makes lab automation better by making task schedules better and looking at big sets of data instantly.

5.4. Increased efficiency

Automation cuts the time spent on repeating tasks letting researchers focus on complex and important parts of their work. These time-saving benefits can result in:

- Increased output
- Experiments
- Faster decisions
- Faster progress in development

5.5. Enhanced accuracy

Also lab automation helps make things more accurate and reliable compared to manual work that depends on people. Automation makes sure that procedures are the same every time lowers changes in testing conditions and results and helps make things more accurate and precise which's very important in areas like clinical testing and drug research (Rodriguez et al.,2019).

5.6. Cost savings

Even though lab automation systems need a start-up cost they can save a lot of money in the long run because of faster results, less waste and better use of resources.

5.7. Scalability

At the time automation also lets labs handle more work without needing more workers or other resources. For example Mayo Clinic Laboratories increased the number of samples tested every day to between 12,000 and 15,000 because of automated processes. This helped them meet needs, in medical research without lowering the quality.

6. FUTURE CHALLENGES AND OPPORTUNITIES

The future of quality assurance in medical laboratory technology will be shaped by changes in automation, artificial intelligence (AI) machine learning, digital laboratory systems, molecular diagnostics and real-time quality control. Big problems include making sure that AI-created results are correct and dependable keeping data safe and secure having the same standards in all laboratories checking that new technologies work well dealing with rising costs and giving ongoing training to lab workers. More automated testing and point-of-care testing also need good quality monitoring and proper rules and regulations. At the time these changes offer great chances to make labs work better cut down on mistakes made by people get results faster find issues sooner and make patients safer. AI-powered quality control can help find errors as they happen while automated systems can make working with samples and checking results easier. Digital quality-management systems can also keep an eye on how the lab is doing record everything and look at the data (Williams & Garcia, 2022). So the future of quality assurance needs to focus on risk-based data-driven quality management mixing new technology with experienced lab workers, strong testing, consistent standards, security and regular learning to make sure the results, for patients are accurate and reliable.

Area	Future Challenges	Future Opportunities	References
Laboratory Accreditation	The rules for accreditation are getting more complicated. The paperwork for accreditation grows bigger.	If more labs get accreditation the trust and quality of laboratory work will grow.	(Van der Gijp, A., et al. 2022)
International Standards	Keeping laboratories up to date with standards like ISO 15189 is hard.	Unifying laboratory practices around the world makes work smoother.	(Brown, A. S., & Badrick, T. 2023)
Quality Management	Always improving quality and staying compliant is a task.	Building Quality Management Systems helps labs stay reliable.	(Herman, D. S., Rhoads, D. D., Schulz, W. L.,

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Area	Future Challenges	Future Opportunities	References
Technology & Automation systems	Advanced instruments cost a lot. Keeping them working is tough.	Automation makes tests more accurate, faster and repeatable.	& Durant, T. J. S. 2021) (Mannello, F., & Plebani, M. 2022)
Digitalization	Cybersecurity, keeping data private and linking laboratory information systems are concerns.	Lab Information Systems, AI and digital records are tools we use.	(Hou, H., Zhang, R., & Li, J. 2024)
Artificial Intelligence programs	AI can give results and we often lack trained people to check.	AI can help with diagnosis monitoring quality and spotting errors.	(Rabbani, N., Kim, G. Y. E., Suarez, C. J., & Chen, J. H. 2022)
Skilled Workforce	There are not trained lab professionals.	Ongoing training and teaching based on skills improve the quality of the workforce.	(Bunch, D. R., Durant, T. J. S., & Rudolf, J. W. 2023)
External Quality Control System	Joining EQA can cost a lot for labs.	EQA makes results from labs easier to compare.	(Lippi, G., Mattiuzzi, C., & Favaloro, E. J. 2024)
Patient Safety	Stopping errors before during and, after tests keeps patients safe.	Using quality signs and risk management systems cuts down mistakes	(Sciacovelli, L., Padoan, A., Aita, A., Basso, D., & Plebani, M. 2023)
Resource Limited Laboratories	Small labs often have money, equipment, buildings and trained staff.	Tech and simple quality systems can help labs get accreditation.	(Pennestrì, F., & Banfi, G. 2022)
Data Management	More lab data means risk of data breaches.	Analyzing data sets can spot trends and boost lab performance.	(Master, S. R., Badrick, T. C., Bietenbeck, A., & Haymond, S. 2023)
Global Collaboration	Countries have rules and lab habits	Working together worldwide can set lab practices.	(Padoan, A., & Plebani, M. 2024)
Sustainability	Handling waste, saving energy and reducing environmental harm are tasks.	Eco friendly lab ways cut waste and lower costs.	(Rupp, N., Ries, R., Wienbruch, R., & Zuchner, T. 2024)

7. CONCLUSION

Quality assurance in medical laboratory technology is important for getting results that're accurate and reliable. These results need to be available in time and help doctors treat patients properly. To make sure this happens there are things labs do. They check their work, with internal quality control. They also take part in quality assessments. They use quality indicators to track performance. (Miller & Jones, 2021). They make sure machines are properly calibrated. They test methods before using them. They check that staff are skilled and trained. They also look for risks. Manage them. All these steps help avoid mistakes in the stages of testing. These stages are pre-analytical, analytical and post-analytical.

Author contribution S.D: Date collection, writing original draft, Editing, visualization; A.B.: Data search and collection, writing original draft, Methodology, Editing draft.

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