The Answer is Simpler:

7 Best Practices for Molecular POCT

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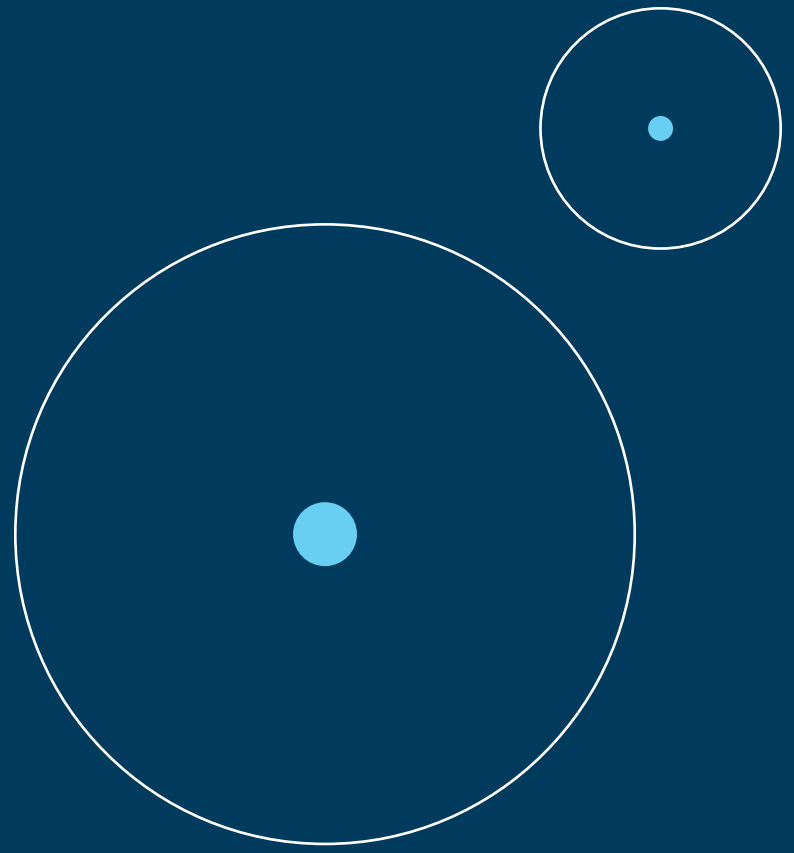

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INTRODUCTION

7 Best Practices for Molecular POCT

As a result of the COVID-19 pandemic, molecular point-of-care testing (POCT) has become increasingly prevalent in recent years.[1] To meet the high demand for testing during the peak of the pandemic, healthcare facilities frequently utilized multiple testing platforms.[1] However, as demand decreases, facilities are now focusing on streamlining and optimizing their testing strategies.

Molecular tests that utilize nucleic acid amplification, such as PCR tests, have been regarded as the "gold standard" due to their higher accuracy compared to other POCT methods.[2-4] To ensure the best performance and deliver optimal clinical care, it is vital for facilities to control factors that could potentially affect test results when conducting molecular testing.

This guide will focus on molecular POCT approved for waiver under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) criteria. CLIA-waived tests are simple to perform and have minimal risk of producing an incorrect result[5] but are not error-proof. In this guide, we've laid out seven best practices to help you simplify the process of obtaining accurate and reliable molecular POCT results.

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DEFINITIONS TO KNOW

- **POCT: Point-of-care testing**
- **PCR: Polymerase chain reaction**
- **CLIA: Clinical Laboratory Improvement Amendments of 1988**

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Ask your test manufacturer if they provide onsite or virtual training.

BEST PRACTICE 1

Provide essential training to ensure safety and reliability

Errors can occur anywhere in the testing process, especially when testing personnel are unfamiliar with aspects of the test system.[6] So, even though staff of any level can carry out CLIA-waived POCT, all operators who perform testing must receive adequate training.

Some CLIA-waived tests have the potential for negative health impacts if performed incorrectly.[6] For example, results from waived tests can be used to adjust medication dosages or provide diagnoses, and an error in testing can have unintended consequences.

A designated trainer, such as an experienced staff member, outside consultant, or representative of the test manufacturer, should be appointed to ensure proper training. The trainer must demonstrate the performance of the test(s), good laboratory practices, and effective safety practices, including universal precautions,[1] hazardous waste handling and disposal, and appropriate use of personal protective equipment (PPE). Training should be documented for future reference, and staff should be regularly updated on new developments, techniques, and guidelines in testing.

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BEST PRACTICE 2

Stick to the script – Follow the Manufacturer's Instructions for Use (IFU)

Following the manufacturer's instructions when performing CLIA-waived testing is essential to ensure accurate results. While there are few strict requirements, deviating from the instructions could affect the reliability of the tests.

Did you know? Changing the testing protocol from what is in the intended use, precautions, limitations, or other sections of the IFU of a CLIA-waived test system defaults the test to the high-complexity testing category under CLIA regulations. Once a test is labeled high-complexity, the sites must meet all applicable CLIA requirements for high-complexity testing.[7]

Keep a copy of the manufacturer's IFU or Quick Reference Instructions (QRI) handy for easy reference. Check for new or updated IFUs with each new lot and shipment of test kits.

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IF QC TESTS GIVE UNEXPECTED RESULTS

1. Confirm that operators followed IFUs
2. Troubleshoot potential sources of error or contamination
3. Check to see if reagents were properly stored
4. Consult previous QC test results for accuracy
5. Contact the manufacturer or testing supervisor

TRACK YOUR QC TESTS TO ENSURE TESTS ARE BEING PERFORMED CORRECTLY OVER TIME.

BEST PRACTICE 3

Run quality control for reliable results

Quality Control (QC) testing is essential to ensure your results are reliable; it helps identify potential problems, such as test kit quality issues, equipment failure, environmental conditions, or human error. Follow the manufacturer's instructions on the frequency of external quality control testing.

Molecular POC tests often have built-in controls that help ensure the accuracy of the test results. These controls include a **sample processing control** that checks if the sample has been processed correctly. It might also monitor for potential inhibitors in the amplification (such as PCR or isothermal) reaction, ensuring that the reaction conditions are appropriate and that the reagents are functional.

Another type of control is a **reagent control** that ensures test components are in working order. A useful reagent control is a **probe check control**, a pre-amplification control used in PCR reactions containing fluorescent probes. It checks for the presence and functionality of reaction components by measuring the fluorescence signal from the PCR probes.

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BEST PRACTICE 4

Secure your samples – Embrace proper sample collection and handling

Proper sample collection, transport, and storage are critical to achieving reliable and accurate test performance. Tests may provide false results if samples are not collected, handled, or transported correctly. Operators should follow IFUs to prevent contamination and degradation of patient samples.[7]

Depending on sample type, storage medium, and testing platform, samples can be stored at room temperature for minutes to days. Some test procedures allow for sample refrigeration for convenience or retesting. Tests must be run within a specified time after the sample is added to the test consumable; for convenience, tests with more leeway (e.g., 15-30 minutes) may be preferable.

Always consult the IFUs for sample collection, transport, and storage to ensure reliable results.

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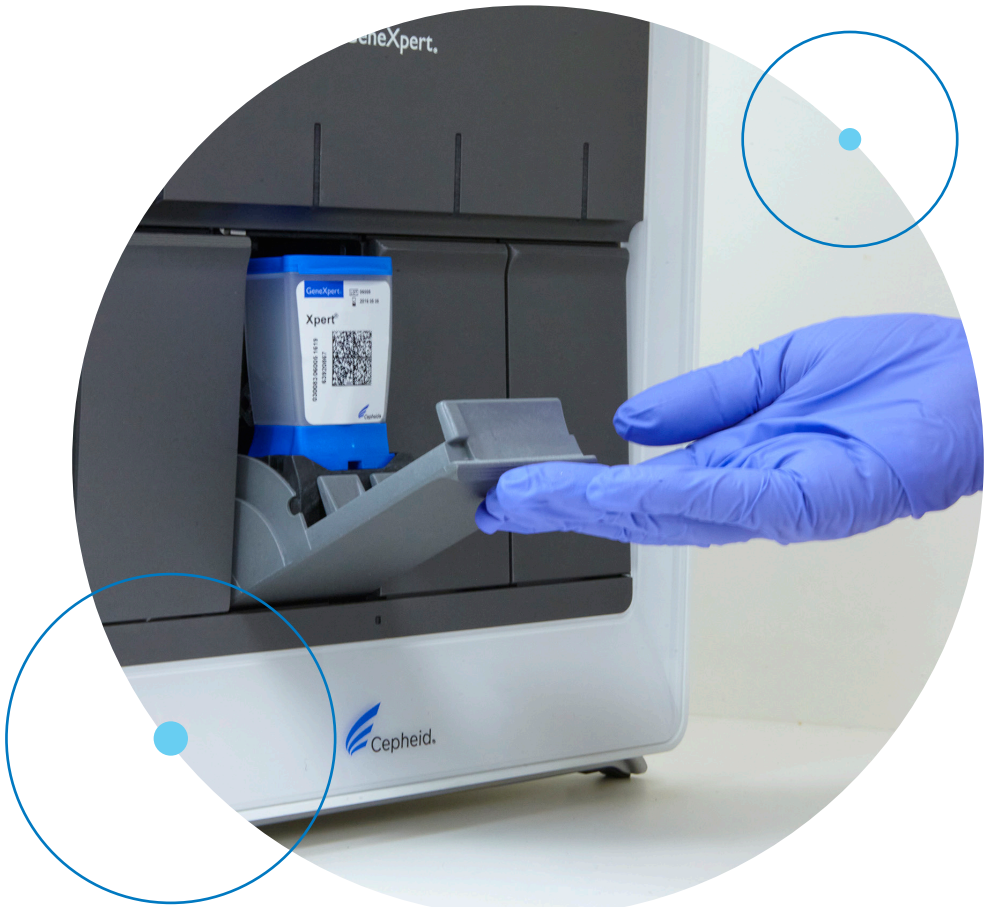

BEST PRACTICE 5

Maintain your equipment

Remember, regular maintenance is crucial for accurate testing results. Some POC molecular analyzers require daily proactive maintenance and calibration, while others have an internal automated calibration system.

It is best to follow the manufacturer's recommendations to maintain equipment properly. Modern, connected analyzers make it easier to monitor and troubleshoot remotely, simplifying ongoing maintenance and ensuring accurate results over time.

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BEST PRACTICE 6

Preserve the integrity of test results with contamination control

To ensure efficient workflow and accurate POCT results, it is vital to prevent contamination. One way to do this is by enforcing strict PPE protocol. For instance, test operators should wear PPE like lab coats and gloves and change gloves between each specimen they handle.

Another way to reduce contamination is to choose consumables with user-friendly designs that are easy to handle without risk of contamination. Consider testing methods with simple workflows, the fewest possible manual steps, and self-contained, single-use test consumables (such as test cartridges, cassettes, or pouches) to minimize spillage and cross-contamination.

A WORD ABOUT
BIOHAZARD DISPOSAL

Handle and dispose of biological specimens and related materials carefully to avoid the risk of spreading infectious agents. Follow your institution's procedures for disposing of used test consumables, unused reagents, and any specific protocols for hazardous waste. If there are no clear directives for your region, use the World Health Organization's medical waste handling and disposal guidelines.[8]

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BEST PRACTICE 7

Certify results with data analysis and reporting

Using validated data analysis and interpretation software is crucial for getting precise results. Ideally, the testing system you choose should have built-in software, easy-to-understand results, and options for integration with your Electronic Medical Record or Laboratory Information System. Additionally, a patient-sample tracking mechanism, such as a scannable barcode on each test, may be useful for reporting and record-keeping.

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CONCLUSION

Simplify molecular POC testing

POC facilities must provide reliable test results to their patients to build trust and ensure their return for future healthcare needs.

Refer to this seven-step guide to simplify testing in your POC facility. To avoid potential testing errors, streamlining processes is crucial to ensure that you continue providing accurate, reliable patient results.

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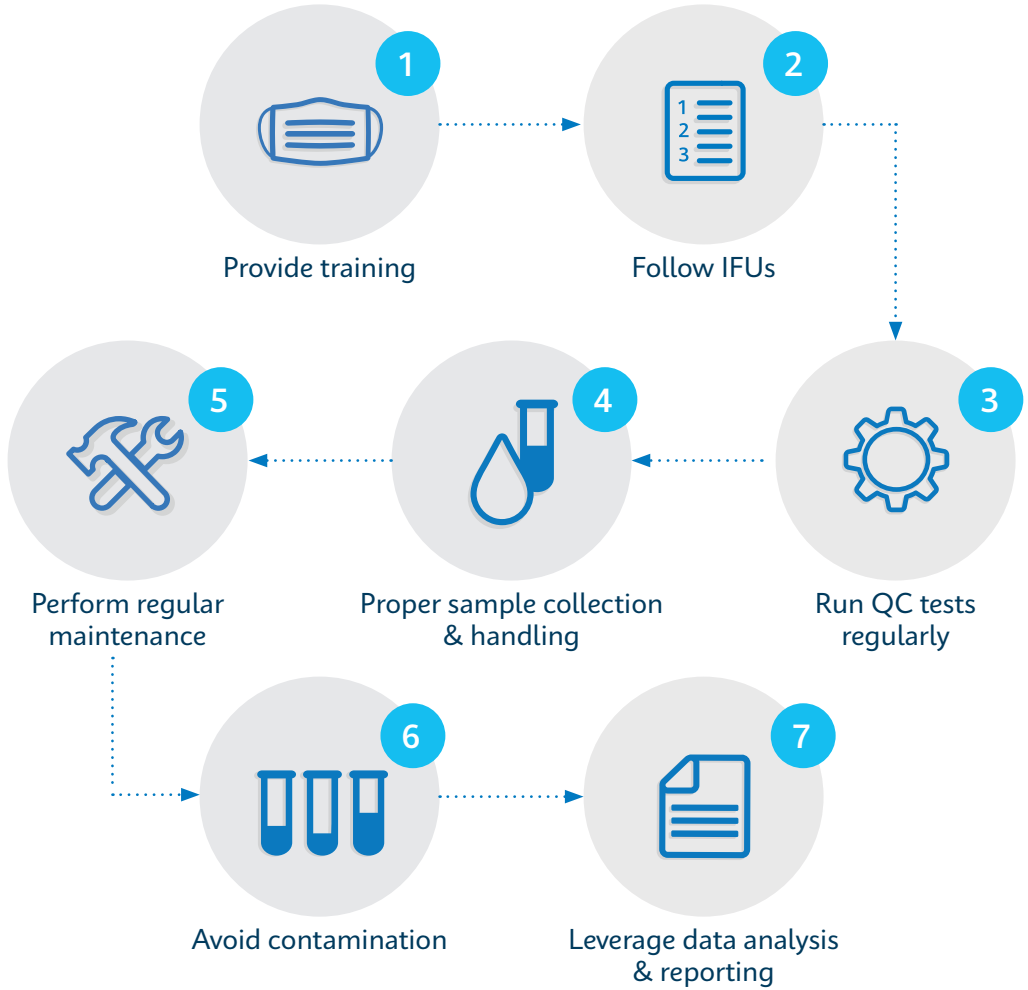
SEVEN STEPS TO SIMPLER POCT:



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The Answer is Simpler with Cepheid

Accurate and reliable molecular POCT goes beyond just following best practices. That's why Cepheid has designed a holistic solution to simplify and improve the entire point-of-care testing ecosystem.

Learn how Cepheid is simplifying molecular POCT with **GeneXpert Xpress**.

- Get Simpler
- Talk to Sales

GENEXPERT XPRESS SIMPLIFIES MOLECULAR POCT

- **Fully automated sample extraction, PCR amplification, and detection**
- **Simplified workflows with minimal hands-on time**
- **Fast and accurate PCR results**
- **Reduced risk of contamination**
- **Random-access, mix-and-match testing for optimal flexibility**

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US-IVD. In Vitro Diagnostic Medical Device.

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