WHITE PAPER

THE CRITICAL ROLE OF QUALITY CONTROLS IN INFECTIOUS DISEASE MOLECULAR DIAGNOSTICS

ZeptoMetrix®

an antylia scientific company

THE CRITICAL ROLE OF QUALITY CONTROLS IN INFECTIOUS DISEASE MOLECULAR DIAGNOSTICS
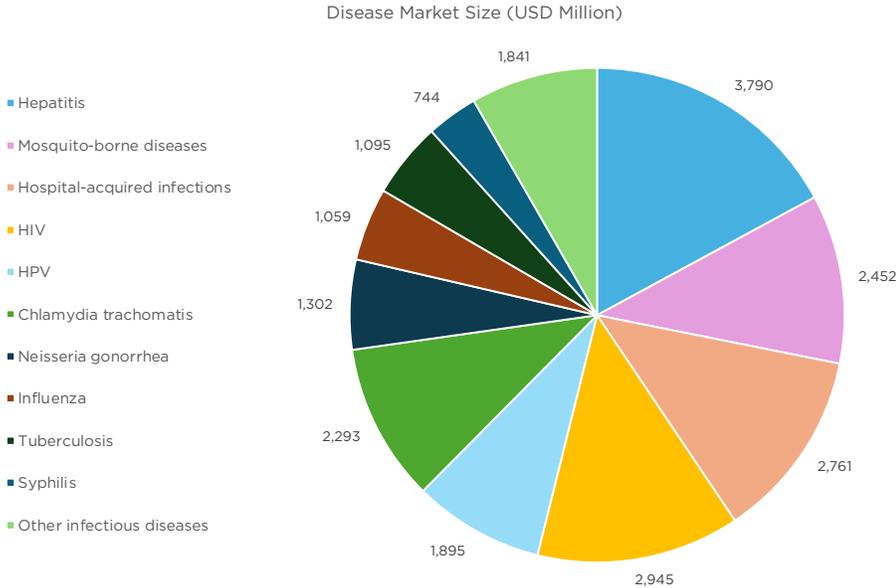
1. EXECUTIVE SUMMARY

In the rapidly evolving healthcare field, the precision and accuracy of diagnostic tests are crucial, especially for infectious diseases. Quality controls are vital to ensure these desired outcomes of precision and accuracy are met. They act as essential checkpoints to prevent errors and uphold the integrity of diagnostic data. This white paper delves into the critical role of quality controls in infectious disease molecular diagnostics. It examines their significance, implementation methods, and substantial impact on clinical outcomes. By providing real-world examples and practical recommendations, this paper aims to highlight the need for robust quality control measures. It also advocates for the integration of advanced external quality control solutions in clinical laboratories worldwide.

2. INTRODUCTION

2.1 The Importance of Infectious Disease Diagnostics

Infectious diseases continue to pose significant challenges to global health. This requires rapid and accurate diagnostic methods to effectively manage and contain outbreaks. The field of molecular diagnostics has revolutionized the way we detect and monitor these diseases, offering unparalleled sensitivity and specificity. However, the reliability of these diagnostic tests depends on stringent quality control measures that ensure consistent and accurate results. This directly influences patient care and public health outcomes.

Image 1: Global burden of infectious diseases

Disease Market Size (USD Million)

- Hepatitis
- Mosquito-borne diseases
- Hospital-acquired infections
- HIV
- HPV
- Chlamydia trachomatis
- Neisseria gonorrhea
- Influenza
- Tuberculosis
- Syphilis
- Other infectious diseases

3,790
2,452
2,761
2,945
1,895
2,293
1,302
1,059
1,095
744
1,841

2.2 Objectives of the White Paper

This white paper aims to:

- Educate healthcare professionals, laboratory technicians, and decision-makers about the critical role of quality controls in infectious disease molecular diagnostics.

- Highlight the best methodologies for implementing effective quality control measures.

- Discuss the advantages of external quality control products and solutions, particularly those developed by ZeptoMetrix (**www.zeptometrix.com**).

- Provide real-world examples and statistical analyses to demonstrate the impact of quality controls on diagnostic accuracy and clinical outcomes.

- Offer practical recommendations for laboratories to enhance their quality control protocols and ensure compliance with regulatory standards.

3. THE NECESSITY OF QUALITY CONTROLS IN MOLECULAR DIAGNOSTICS

3.1 Ensuring Diagnostic Accuracy

Diagnostic accuracy is essential for effective healthcare delivery. In the case of infectious diseases, precise diagnostics are crucial for identifying the causative agents, guiding treatment decisions, and controlling the spread of disease. Quality controls are vital tools to ensure that diagnostic tests are consistently and accurately performed. By using known standards and benchmarks, quality controls help detect deviations in test performance, thereby preventing false positives and false negatives, which can have serious implications for patient care.

For instance, in HIV diagnostic testing, internal controls help ensure that the testing reagents are working correctly. A positive internal control, which contains a known quantity of HIV RNA, ensures that the test can detect HIV if it is present in a patient sample. Conversely, a negative internal control, which contains no HIV RNA, ensures that there is no contamination in the testing process. External controls, provided by third-party companies, help validate the overall accuracy of the HIV test kits used, by comparing the results to established standards.

3.2 Enhancing Reproducibility and Reliability

Reproducibility and reliability are essential qualities of any diagnostic test. Reproducibility refers to the test's ability to yield consistent results when performed under the same conditions, while reliability indicates the test's consistency over time. Quality controls play an important role in achieving both of these desired outcomes of reproducibility and reliability.

Laboratories need to integrate quality controls into their diagnostic workflows to monitor and maintain the performance of their assays. This continuous monitoring helps in identifying any variations that may affect test results. For example, external or third-party controls processed alongside patient samples can reveal lot-to-lot variability in reagents, ensuring that only consistent and reliable results are reported.

3.3 Compliance with Regulatory Standards

It is crucial for clinical laboratories to strictly adhere to regulatory standards to ensure the credibility and safety of their diagnostic processes. Regulatory bodies such as the FDA, CDC, ISO, CAP, WHO, and CLIA, have established stringent guidelines for implementing quality controls in molecular diagnostics. These standards are specifically designed to safeguard patient health by ensuring the accuracy and reliability of diagnostic tests.

Quality controls play a pivotal role in meeting these regulatory requirements. They provide the necessary documentation and evidence to demonstrate that tests have been conducted correctly and that the results are reliable. Regular utilization of quality controls also assists laboratories in successfully passing audits and inspections, thus maintaining their accreditation and certification status.

Table 1: Key Regulatory Standards for Quality Controls

Regulatory Body	Region	Standard/Guideline	Requirement for Quality Controls
FDA	USA	FDA Guidelines	Use of both internal and external controls for consistent and reliable performance
CDC	USA	CDC Recommendations	High standards of accuracy and reliability with robust quality control measures
ISO	Global	ISO 15189	Quality controls for accuracy and reliability in different laboratory settings
CAP	Global	CAP Accreditation	Comprehensive quality control practices
CLIA	USA	CLIA Regulations	Quality standards for accuracy, reliability, and timeliness of patient test results
WHO	Global	WHO Guidelines	Global recommendations for consistent and reliable diagnostic practices

4. METHODOLOGIES FOR IMPLEMENTING QUALITY CONTROLS

4.1 Types of Quality Controls

Quality controls in molecular diagnostics can be broadly categorized into Internal and External/Third-Party Controls, each serving distinct purposes.

Internal Quality Controls (IQCs): These controls are included within the assay to monitor the performance of the test itself. Internal controls can be internal processing controls, sample adequacy controls, amplification controls, etc. Internal controls also include positive and negative controls, which are further described below:

- Positive Controls: Known positive samples that ensure the assay can detect the target pathogen.

- Negative Controls: Samples free of the target pathogen, ensuring there is no contamination and the assay does not produce false positives.

External/Third-Party Quality Controls (EQCs): These controls are vital in ensuring the accuracy and reliability of test results, particularly in infectious disease molecular controls. They help to monitor variables, such as test and

operation variation, lot-to-lot test kit performance, the effective of adverse environmental conditions, and can aid in the identification of random or systematic error. These controls often consist of inactivated non-infectious materials with known quantities of the infectious agent's genetic material and may be full-process controls. They are routinely processed by clinical laboratories as part of their standard operating procedures (SOPs).

Key Benefits of External/Third-Party Controls:

- Independent Verification: External controls provide an unbiased benchmark, ensuring objective test results that are unaffected by internal laboratory processes. This objectivity is crucial for maintaining credibility in diagnostic testing.

- Consistency Assurance: They play a vital role in monitoring test performance consistency across different batches of reagents and kits, ensuring reliable test outcomes over time and under varying conditions, thereby supporting quality assurance in diagnostic testing.

- Support for Training and Proficiency Testing: External controls are integral for training laboratory personnel and conducting proficiency testing. Incorporating external controls into routine testing ensures staff proficiency and upholds high standards of accuracy and precision in medical diagnostics.

Table 2: Comparison of Internal versus external Quality Controls

Aspect	Internal Quality Controls (IQCs)	External/Third-Party QCs (EQCs)
Pros	Integrated into assay	Comprehensive monitoring
	Immediate detection of errors	Independent verification
	Streamlined process	Regulatory compliance
Cons	Limited scope	Additional training required
	Potential for overlooking systemic errors	Logistical integration necessary
	Dependency on assay design	
Monitoring	Specific parts of the assay	Entire diagnostic process
Use in Training/Proficiency	Not typically used	Integral for training and proficiency testing

4.2 Development and Validation of Quality Controls

The development of quality controls involves a rigorous process to ensure they accurately mimic patient samples and provide reliable benchmarks for testing. This process includes:

- Design and Selection: Identifying appropriate materials and designing controls that reflect the test's intended use.

- Preparation: Creating controls using purified intact organisms or synthetic materials to ensure consistency and reliability.

- Validation: Conducting extensive testing to confirm that the controls perform as expected under various conditions. Controls often include stability testing, precision testing, and inter-laboratory comparisons.

Once developed, quality controls must be validated to ensure they meet the necessary standards for accuracy and reliability. Validation involves testing the controls under real-world conditions to confirm their performance and effectiveness.

4.3 Implementation Strategies

Effective implementation of quality controls requires a strategic approach that integrates them seamlessly into the diagnostic workflow. Key strategies include:

- Standard Operating Procedures (SOPs): Developing and adhering to SOPs that outline the proper use and handling of quality controls. These procedures ensure consistency and reliability across all diagnostic tests.

- Training and Education: Ensuring that laboratory personnel are well-trained in the use of quality controls and understand their importance. Regular training sessions and proficiency testing help maintain high standards.

  Initial Training: Comprehensive training on QC procedures and the importance of quality controls.

  Refresher Courses: Regular refresher courses to keep staff updated on best practices and new developments.

  Competency Assessments: Regular assessments to ensure staff maintain high standards of performance.

- Routine Use of Quality Controls: Routine incorporation of QCs are essential and their use is determined by each laboratory's SOP. This practice helps detect deviations from expected performance, allowing for immediate corrective actions. It also builds a comprehensive data set to monitor ongoing assay performance..

  - Daily Use: Incorporate QCs in every batch of tests to monitor daily performance.

  - Weekly Analysis: Review QC data weekly to identify trends and potential issues.

  - Monthly Reports: Generate monthly reports summarizing QC performance and any corrective actions taken.

- Continuous Monitoring and Improvement: Regularly monitoring the performance of quality controls and diagnostic tests to identify any deviations or issues. This can involve routine checks and periodic reviews of control data.

  - Data Collection: Collect QC data from each diagnostic run.

  - Analysis: Regularly analyze QC data to identify trends and deviations.

  - Action: Implement corrective actions as needed.

  - Review: Periodically review the effectiveness of corrective actions and make adjustments as necessary.

- Documentation and Record-Keeping: Documentation and Record-Keeping: Maintaining detailed records of quality control use and performance is crucial for regulatory compliance and issue troubleshooting. Proper documentation facilitates audits, inspections, and supports compliance with regulatory standards.

Table 3: Key Implementation Strategies for Quality Controls

Implementation Strategy	Key Components	Steps
Planning and Assessment	Needs assessment, goal setting & resource allocation	1. Conduct needs assessment 2. Set clear goals 3. Allocate resources
Standard Operating Procedures	SOP development, documentation, & training	1. Develop SOPs 2. Document procedures 3. Train staff
Quality Control Measures	Selection of controls, validation, & monitoring	1. Select appropriate controls 2. Validate controls 3. Monitor performance
Data Management	Data collection, storage, & analysis	1. Collect relevant data 2. Store data securely 3. Analyze data for insights
Regular Audits and Reviews	Internal audits, external reviews, & continuous improvement	1. Conduct internal audits 2. Arrange external reviews 3. Implement continuous improvements
Stakeholder Engagement	Communication, feedback, & collaboration	1. Communicate with stakeholders 2. Gather feedback 3. Foster collaboration

5. THE VALUE OF EXTERNAL QUALITY CONTROL PRODUCTS AND SOLUTIONS

5.1 Internal vs. External Quality Controls

Both internal and external quality controls are essential in ensuring the reliability of diagnostic tests, each offering distinct advantages and addressing specific aspects of the diagnostic process.

Internal Quality Controls (IQCs)

Pros:

- Integrated into Assay: IQCs are designed to be part of the diagnostic test itself, providing continuous monitoring of the test's performance.

- Immediate Detection of Errors: Since IQCs are part of each test run, they promptly identify issues such as reagent failure or contamination.

- Streamlined Process: IQCs can simplify the testing process as they are inherently part of the assay design.

Cons:

- Limited Scope: IQCs usually monitor specific parts of the assay and may not cover the entire diagnostic process.

- Potential for Overlooking Systemic Errors: IQCs may not detect systemic issues that affect multiple tests or the entire diagnostic process.

- Dependency on Assay Design: The effectiveness of IQCs depends on how well they are integrated into the assay, which can vary between manufacturers.

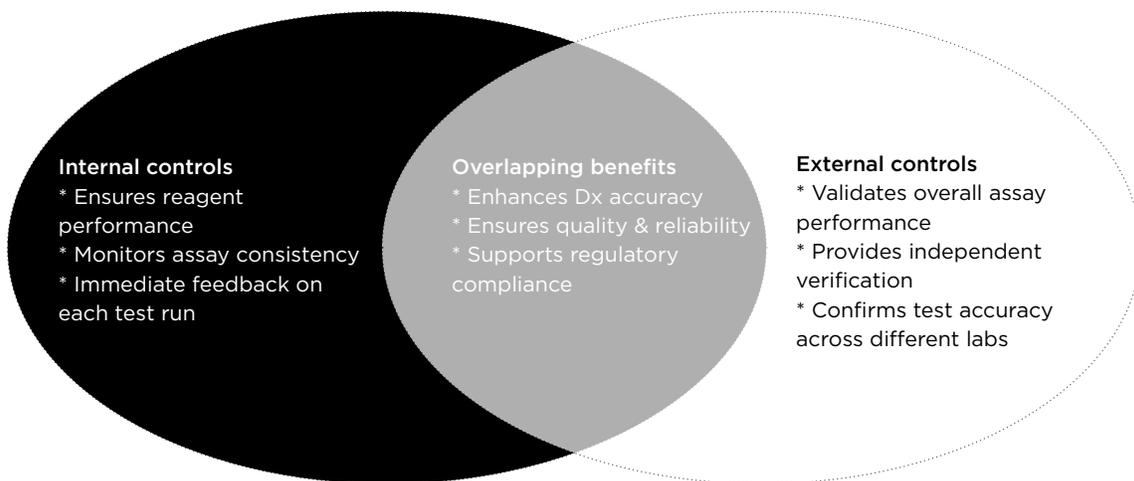## External/Third Party Quality Controls (EQCs)

Pros:

- Comprehensive Monitoring: EQCs evaluate the entire diagnostic process, from sample preparation to result interpretation, providing a holistic assessment of assay performance.

- Independent Validation: EQCs offer an independent check of the assay, helping to identify issues that internal controls might miss.

- Regulatory Compliance: Many regulatory bodies require the use of EQCs to ensure the reliability of diagnostic tests. EQCs help laboratories meet these standards.

- Benchmarking and Comparison: EQCs allow laboratories to compare their performance with other labs, facilitating benchmarking and continuous improvement.

- Enhanced Confidence: EQCs can provide an extra layer of assurance, enhancing the credibility of test results and supporting laboratory accreditation efforts.

Cons:

- Additional Training: Laboratories may require additional training to implement and interpret EQCs effectively.

- Logistical Integration: Managing and incorporating EQCs into routine workflows requires careful planning, especially for high-throughput laboratories.

Image 2: Key benefits of internal and external controls.

Internal controls
* Ensures reagent performance
* Monitors assay consistency
* Immediate feedback on each test run

Overlapping benefits
* Enhances Dx accuracy
* Ensures quality & reliability
* Supports regulatory compliance

External controls
* Validates overall assay performance
* Provides independent verification
* Confirms test accuracy across different labs

5.2 Demonstrating the Utility of External Controls (EQCs)

While both internal and external controls are essential, external controls offer several advantages that make them superior in many contexts, particularly for ensuring comprehensive assay performance.

Case Study: External Controls in COVID-19 Testing

During the COVID-19 pandemic, the rapid development and deployment of molecular diagnostic tests emphasized the importance of robust quality control measures. External controls played a pivotal role in ensuring the reliability of these tests across various platforms and laboratories.

Impact:

- Enhanced Accuracy: External controls helped identify false negatives and positives, which were crucial for controlling the spread of the virus.

- Standardization: By using standardized external controls, laboratories ensured consistent performance and comparability of results.

- Regulatory Approval: Diagnostic tests may gain faster regulatory approval because they demonstrated reliable performance through the use of external controls.

Comparative Analysis: Influenza and HIV Diagnostics

Comparing the use of internal and external controls in influenza and HIV diagnostics further illustrates the benefits of external controls.

Influenza Diagnostics:

- Internal Controls: Often limited to checking specific steps of the assay.

- External Controls: Provided a comprehensive check, detecting assay degradation and ensuring accurate results across different test batches.

HIV Viral Load Testing:

- Internal Controls: Monitored amplification efficiency but sometimes missed extraction issues.

- External Controls: Evaluated the entire process, ensuring the accuracy of viral load measurements critical for patient management.

5.3 Practical Recommendations for Laboratories

To maximize the benefits of external quality controls, laboratories should consider the following practical recommendations:

- Integrate Both IQCs and EQCs: Using both types of controls can provide a more comprehensive assessment of assay performance.

- Regularly Update QC Procedures: Updating QC procedures as new pathogens and diagnostic technologies emerge ensures continued reliability.

- Invest in Training: Continuous education and training for laboratory personnel on using both IQCs and EQCs are essential for maintaining high diagnostic standards.

- Leverage EQCs for Regulatory Compliance: Utilizing external controls helps meet and exceed regulatory requirements, enhancing the credibility of diagnostic tests.

By following these strategies, laboratories can enhance the accuracy and reliability of their diagnostic tests, ensuring high standards of patient care. Here's a structured summary of the practical recommendations for laboratories.

GENERAL RECOMMENDATIONS

• Keep detailed records of all procedures and results

• Ensure all staff undergo regular training sessions

• Implement a robust quality management system

QUALITY CONTROLS

• Use internal controls to monitor assay consistency

• Monitor assay performance by using external controls

• Use proficiency testing to confirm test accuracy

EQUIPMENT AND REAGENTS

• Schedule regular maintenance for all equipment

• Source reagents from reputable suppliers

• Verify reagent performance with quality controls

SAMPLE HANDLING

• Ensure proper sample collection techniques

• Maintain optimal storage conditions for samples

• Implement a tracking system for sample integrity

DATA MANAGEMENT

• Ensure data security and confidentiality

• Record data accurately and promptly

• Use validated software for data analysis

COMPLIANCE AND ACCREDITATION

• Adhere to local and international regulatory standards

• Aim for accreditation from recognized bodies

• Regularly review and improve laboratory processes

6. IMPACT OF QUALITY CONTROLS ON DIAGNOSTIC ACCURACY

6.1 Case Studies and Real-World Examples

Quality controls significantly impact diagnostic accuracy, as evidenced by various case studies and real-world examples. One such example is the application of quality controls in COVID-19 testing. Throughout the pandemic, laboratories worldwide heavily relied on internal and external controls to ensure the precision of their tests.

COVID-19 Testing Case Study: During the initial outbreak of COVID-19, the swift development and deployment of diagnostic tests were vital. Internal controls were used to confirm the proper functioning of test reagents, while external controls validated the accuracy of the tests across different batches and manufacturers. This rigorous quality assurance process helped prevent false positives and false negatives, ensuring that patients received accurate diagnoses and appropriate care. The use of external controls provided an additional layer of verification, confirming the consistency and reliability of test results across various settings.

Influenza Diagnostics Case Study: During flu season, laboratories deal with a high volume of samples, making reliable and accurate diagnostic tests essential. Internal controls are routinely used to monitor the test reagents' performance and ensure that each batch functions correctly.

The introduction of external controls however offers a more comprehensive perspective. External controls in influenza diagnostics are used to validate the entire diagnostic process, from sample preparation to result interpretation. For instance, during a significant flu outbreak, a laboratory integrated external controls into their testing protocol to verify the consistency and reliability of their assays. These controls helped identify subtle variations in test performance that internal controls might have missed, such as slight reagent degradation over time or differences between reagent lots. By using external controls, the laboratory ensured that their diagnostic tests remained accurate and reliable throughout the flu season, providing critical information for patient care and public health responses.

Table 4: Role of Quality Controls in Infectious Disease Outbreaks

Year	Outbreak	Role of Quality Controls
2003	SARS Outbreak	Introduction of internal controls to ensure the sensitivity and specificity of newly developed assays.
2009	H1N1 Influenza Pandemic	Use of internal controls to ensure reagent performance and prevent false results.
2014	Ebola Outbreak	Implementation of external controls for assay validation to confirm the reliability of diagnostic tests.
2016	Zika Virus Outbreak	Deployment of both internal and external controls to validate molecular diagnostic tests and ensure accurate detection.
2020	COVID-19 Pandemic	Extensive use of both internal and external controls to validate test accuracy across multiple platforms and prevent false positives and/or false negatives.
2022	Mpox Outbreak	Use of external controls to ensure the reliability of newly developed diagnostic tests for a reemerging infectious disease.

6.2 Statistical Analysis of QC Data

Statistical analysis of quality control (QC) data is essential for understanding the performance and reliability of diagnostic tests. Laboratories routinely collect and analyze QC data to monitor test performance, identify trends, and address potential issues. Key statistical methods used in QC data analysis include:

- Mean and Standard Deviation: Calculating the mean and standard deviation of control results to assess test consistency.

- Control Charts: Utilizing control charts to plot QC data over time, helping to visualize trends and detect any deviations from expected performance.

- Proficiency Testing Scores: Analyzing proficiency testing scores to evaluate laboratory performance and compare it against established benchmarks.

By employing these statistical techniques, laboratories can ensure that their diagnostic tests consistently meet the required standards of accuracy and reliability. For example, control charts can highlight shifts or trends in test performance, allowing laboratories to take corrective actions before these issues impact patient results.

6.3 Impact on Clinical Outcomes

The implementation of robust quality controls directly influences clinical outcomes by ensuring the accuracy of diagnostic tests. Accurate diagnostics are critical for timely and effective patient care. Some key impacts include:

- Timely Diagnosis: Quality controls enable healthcare providers to make accurate diagnoses quickly, which is crucial for infectious diseases where early detection can significantly improve patient outcomes.

- Effective Treatment: Reliable diagnostic results guide appropriate treatment decisions, leading to more effective and targeted therapies. This is particularly important in cases where prompt treatment can prevent disease progression and complications.

- Preventive Measures: By identifying potential errors before they affect patient care, quality controls allow for the implementation of preventive measures. This proactive approach enhances overall healthcare quality and safety.

- Trust and Credibility: Consistent and reliable test results build trust between healthcare providers and patients, fostering confidence in the quality of care delivered.

Below is the pathway from quality controls to improved clinical outcomes:

IMPLEMENTATION OF QUALITY CONTROLS

- Establish and maintain internal and external QC measures

- Ensure standardized procedures and protocols

ACCURATE AND RELIABLE TEST RESULTS

- Perform tests with high precision and consistency

- Validate test results through rigorous QC measures

EARLY AND CORRECT DIAGNOSIS

- Facilitate accurate diagnosis through reliable test results

- Reduce the chances of misdiagnosis

EFFECTIVE TREATMENT PLANS

- Enable healthcare providers to develop effective treatment plans

- Base treatments on accurate diagnostic information

IMPROVED PATIENT OUTCOMES

- Achieve better health outcomes for patients

- Ensure timely and appropriate interventions

7. REGULATORY PERSPECTIVES AND COMPLIANCE

7.1 Regulatory Requirements for Quality Controls

The implementation of quality controls in molecular diagnostics is subject to strict regulatory requirements established by various global and regional organizations. These guidelines are essential for ensuring the accuracy, reliability, and safety of diagnostic tests, although their application may vary by region.

Key Regulatory Standards Include:

- FDA Guidelines: The FDA mandates rigorous quality control practices for the development and validation of diagnostic tests. These guidelines emphasize the use of both internal and external controls to ensure consistent and reliable test performance.

- CDC Recommendations: The CDC provides essential guidelines for laboratories to maintain high standards of accuracy and reliability in diagnostic testing. These recommendations support the implementation of robust quality control measures.

- ISO 15189: This international standard specifies requirements for quality and competence in medical laboratories. It includes provisions for quality controls to ensure the accuracy and reliability of diagnostic tests across different laboratory settings.

Additional Standards:

- CAP (College of American Pathologists): CAP accreditation ensures laboratories adhere to stringent quality assurance standards, including comprehensive quality control practices.

- CLIA (Clinical Laboratory Improvement Amendments): CLIA regulations establish quality standards for all laboratory testing to ensure the accuracy, reliability, and timeliness of patient test results.

- WHO (World Health Organization): WHO guidelines provide global recommendations for quality assurance in laboratory testing, supporting consistent and reliable diagnostic practices worldwide.

Regional Variations:

While these guidelines and standards are broadly recognized internationally, their implementation and interpretation may vary regionally based on local regulatory requirements and healthcare practices. Laboratories must adhere to both global standards and local regulations to ensure compliance and maintain high-quality diagnostic testing practices.

7.2 Achieving and Maintaining Compliance

Achieving and maintaining compliance with regulatory standards requires a comprehensive approach that includes:

- Regular Audits and Inspections: Conducting routine audits and inspections to ensure adherence to regulatory guidelines. This can involve internal audits as well as external inspections by regulatory bodies.

- Continuous Training and Education: Providing ongoing training and education for laboratory personnel to keep them updated on regulatory requirements and best practices for quality control.

- Robust Documentation Practices: Maintaining detailed records of quality control activities, including the use and performance of internal and external controls. This documentation is essential for demonstrating compliance during audits and inspections.

- Implementation of Quality Management Systems (QMS): Adopting QMS that incorporate quality control measures into all laboratory operations. QMS helps streamline processes, ensure consistency, and support continuous improvement.

By prioritizing these strategies, laboratories can achieve and maintain compliance with regulatory standards, ensuring the highest levels of accuracy and reliability in their diagnostic tests.

8. CONCLUSION

8.1 The Critical Role of Quality Controls

Quality controls are fundamental to molecular diagnostics' accuracy, reliability, and overall quality. They serve as essential checkpoints that safeguard against errors, enhance reproducibility, and ensure compliance with regulatory standards. By implementing robust quality control measures, laboratories can deliver consistent and trustworthy diagnostic results, ultimately improving patient care and clinical outcomes.

8.2 Future Directions

The field of molecular diagnostics is continually evolving, driven by advancements in technology and a growing understanding of infectious diseases. Future directions in quality control will likely involve:

- Automation: Increasing automated systems to streamline quality control processes and reduce the potential for human error.

- Artificial Intelligence (AI): Leveraging AI to analyze vast amounts of QC data, optimize test performance, and predict potential issues before they arise.

- Predictive Analytics: Utilizing predictive analytics to forecast trends in diagnostic performance and implement proactive measures to maintain quality.

These innovations will enhance the effectiveness of quality controls, leading to more personalized and precise patient care.

8.3 Final Thoughts

The critical role of quality controls in infectious disease molecular diagnostics cannot be overstated. They are indispensable for ensuring the accuracy and reliability of diagnostic tests, safeguarding patient safety, and maintaining the credibility of healthcare institutions. By embracing innovation, addressing challenges, and prioritizing patient safety, laboratories can uphold the highest quality standards in healthcare delivery. Trusted brands like ZeptoMetrix provide essential third-party molecular diagnostic controls that further ensure the accuracy and reliability of test results, supporting better patient outcomes and advancing public health.

9. REFERENCES

- Berte, L. M. (2011). Quality Management System: A Model for Laboratory Services; Approved Guideline. Clinical and Laboratory Standards Institute.

- Mok, D., & Ang, E. (2016). ISO 15189: 2012 implementation: an update of related international standards and guidance documents for medical laboratory quality management. New Zealand Journal of Medical Laboratory Science, 70(2), 42-66.

- ZeptoMetrix Corporation. (2023). NATtrol™ MOLECULAR CONTROLS. Retrieved from ZeptoMetrix

- World Health Organization. (2021). Laboratory Quality Management System: Handbook. Geneva: WHO Press.

- U.S. Food and Drug Administration. (2022). Guidance for Industry: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Provisions. Washington, D.C.: FDA.

LEARN MORE & CONTACT

The Americas
1.800.274.5487
diagnostic.cs@zeptometrix.com

Europe, Middle East, & Africa
+44 1480 272279
zepto.EMEA@antylia.com

China
+86 21 5109 9909
zepto.China@antylia.com

India
+91 22 6139 4444
zepto.India@antylia.com

Australia & New Zealand
+61738293996
zepto.AustraliaNewZealand@antylia.com

East Asia
zepto.EastAsia@antylia.com

ZeptoMetrix®
an antylia scientific company