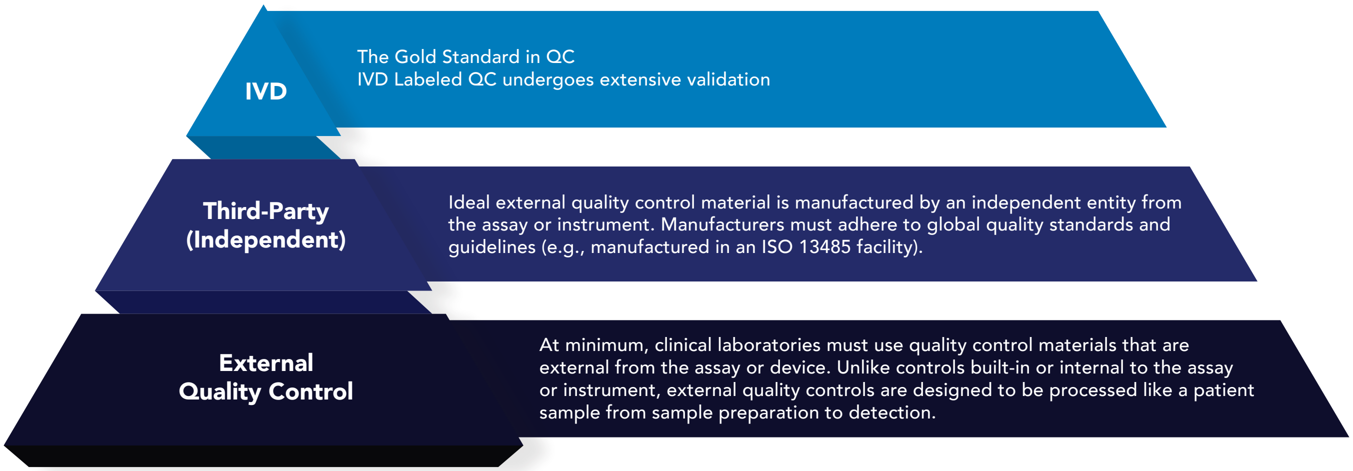
GETTING DIAGNOSTICS RIGHT MEANS EXTERNAL, THIRD-PARTY, IVD QC

EXTERNAL • THIRD-PARTY • IVD

Diagnostic testing impacts a staggering 70% of healthcare decisions. The critical importance of clinical testing leaves no room for misdiagnosis and misguided treatment. **How do you ensure patient test results are true and accurate?**

NOT ALL CONTROLS ARE CREATED EQUAL

Quality controls (QC) challenge a laboratory's internal processes, methodologies, instrumentation, and assays to ensure accurate reporting of patient results. Without the reliability of the right QC, a laboratory may sacrifice diagnostic accuracy, profit margins, and risk mitigation. Any compromise in QC can jeopardize a laboratory’s ability to serve current and future patients. To ensure the accuracy patients deserve, make sure your quality controls are external, third-party, and IVD.



WHY EXTERNAL CONTROLS (STAND-ALONE, NON-INTEGRATED)

Typically, a built-in (internal) control provides the bare minimum confirmation, demonstrating an assay’s operability, not its accuracy. Only an external control can monitor and challenge every step of diagnosis, from sample handling to detection.

WHY THIRD-PARTY CONTROLS (INDEPENDENT OF THE ASSAY MANUFACTURER)

Even when engineered to the highest standards, manufacturer-supplied control materials are often made of the same materials as assay reagents and calibrators, thus amplifying bias when used for routine QC. Only external controls produced by independent, third-party manufacturers fulfill the basic goal of QC by providing comprehensive, objective performance assessments for the assays and procedures.

WHY IVD CONTROLS (IN VITRO DIAGNOSTIC)

The IVD label represents the extensive validations required to be registered with FDA, European Commission, MHRA, and other regulatory bodies for an intended use in clinical diagnostics. An IVD label signifies exactly what you look for in an external, third-party control: uncompromising quality, according to the highest standards.

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Contact us to learn more:
+1.320.253.7400
info@microbiologics.com

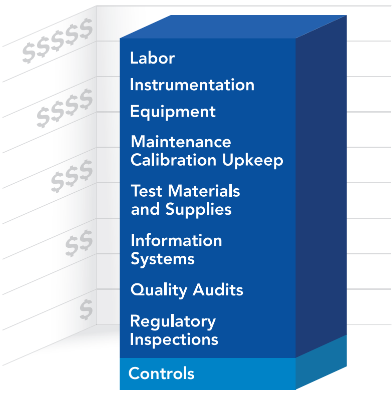
WHY IVD QC FOR CLINICAL DIAGNOSTICS

RUO VS IVD

Unlike IVD products, materials labeled for Research Use Only (RUO) are in the laboratory phase of development and must have no intended medical purpose or objective, as these materials do not require validations or regulatory compliance.[1,2] As such, RUO materials are to be used only for testing with no direct impact on patient diagnostics. RUO materials may pose unnecessary threats to diagnostic precision, laboratory efficiency and operating margins, and risk management systems designed to prevent legal penalties, litigation, and loss of patient confidence if used in clinical settings.

IVD products are subject to numerous regulatory requirements, from labeling to post-market surveillance. [3,4] An IVD control is also extensively validated, so you can rely on its label claims and stability. RUO materials do not share these requirements, thus increasing risks for the laboratories and patients when used in clinical settings. A lack of technical support may intensify these drawbacks. In some regions, manufacturers may be forbidden from providing technical support for RUO materials used in clinical settings. Quality control depends on the right product matched with the right knowledge. Given the complexity of clinical diagnostics, technical expertise from the IVD control manufacturer is essential for quality assurance.

Product Development Requirements	IVD
Clinical performance	✓
Analytical performance	✓
Manufacturability and reproducibility	✓
Shipping and stability	✓
Failure mode analysis	✓
Label requirements	✓



THE UNMATCHED ASSURANCE OF EXTERNAL, THIRD-PARTY IVD QC

It costs far less to do the job right the first time than to recover from error—especially when cost gets measured in patient health. In a quality assurance budget, quality controls form the least expensive but most critical layer of quality management. By trusting your QC to IVD External, Third-Party controls, you minimize risks, while providing the highest accuracy at the lowest costs.

[1] European Commission. (2004, February). Guidance document - In vitro diagnostic medical devices - Research Use Only products - MEDDEV 2.14/2 rev.1. European Commission. https://ec.europa.eu/docsroom/documents/10292/attachments/1/translations
[2] Center for Devices and Radiological Health. (2013, November 25). Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only. Guidance for Industry and Food and Drug Administration Staff. U.S. Food and Drug Administration. https://www.fda.gov/media/87374/download
[3] Center for Devices and Radiological Health. (2021, October 21). Overview of IVD Regulation. U.S. Food and Drug Administration. https://www.fda.gov/medical-devices/ivd-regulatory-assistance/overview-ivd-regulation#1
[4] 21CFR809, Subpart B, In Vitro Diagnostic Products for Human Use. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=809&showFR=1

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