

KIMBLE® DISPOSABLE CULTURE TUBES

An Often Overlooked Detail for Scientists Seeking Reproducible Results

QUALITY STANDARDS

ARE YOU OBSESSED WITH GETTING REPRODUCIBLE RESULTS?

Laboratories are tasked with verifying the quality of everything we hold dear; our food, our health, the drugs we take, the materials with which we build our world, even the value of our money. Quality is important in our lives.

Each year the scientific community invests significant resources in new solutions designed to improve analytical results. Detection sensitivity is enhanced and automation capabilities are increased. However, one important part of the analysis has remained unchanged throughout the years: the disposable culture tube (DCT).

A compelling question is raised: Is the quality of disposable culture tubes important to the analytical result?

When asked, scientists feel the quality of the DCTs used to collect, store, transport, and transfer samples are important to analytical results. However, global sourcing has created inexpensive supply alternatives that reduce cost while also reducing quality thus jeopardizing the accuracy of results.

SPECIFICITY AND IMPURITY As detection sensitivity increases, the potential to detect analytical trace contaminants in the sample may also increase. Unregulated or inferior DCTs can leach out heavy metals, such as arsenic.

STANDARDS AND QUALITY Every industry is expected to contiunally improve quality standards. Unexpected compounds and particulate found in inferior DCTs jeopardize compliance.

CONSISTENCY AND REPRODUCIBILITY If the conditions of the analysis are not reproducible, accuracy suffers. DCTs must offer optical clarity, durability under stress, and the absence of particulate. SAFETY AND LIABILITY Workplace injuries and mishaps are not acceptable. Labs have reported batches of DCTs that are prone to fracture and breakage. Management must include an assessment of DCT quality in its risk analysis.

THE IMPORTANCE OF QUALITY DWK Life Sciences, the world's largest manufacturer of laboratory glass products, set out to answer the question: What is the quality of disposable culture tubes commonly available today? The company commissioned an independent lab to find out.

Accepted quality standards for laboratory glass have been in place for many years. Tests were performed according to the collective quality standards established by the U.S. Pharmacopeial Convention (USP), the Japanese Pharmacopoeia (JP), and the European Pharmacopoeia of the Council of Europe (EP), as well as the international standards organization, ASTM International.

TABLE I. COEFFICIENT OF EXPANSION (COE) COMPARISON, 0 - 300°C, cm/cm x C x 10^{-7}

ASTM E438	ASTM E438 Type I, Class B Linear COE	Suppliers		
Type I, Class A Linear COE		Cardinal Health DCT	Globe Scientific DCT	Kimble DCT
32 - 33 (+/- 1.5)	48 - 56 (+/- 2.0)	70	73	54

The physical requirements of DCTs are defined by the linear coefficient of thermal expansion, which establishes the nominal tolerances of borosilicate glass when exposed to 300° C. The ASTM recognized specifications are Type I, Class A, defined as 33 expansion glass, and Type I, Class B, defined as 51 expansion glass.

Clearly, the case for establishing a known level of quality for DCTs exists in every laboratory that uses them

UNKNOWN QUALITY The test results revealed troubling findings: Several DCTs tested were comprised of a type of borosilicate glass with a coefficient of thermal expansion exceeding ASTM specifications. Although suppliers claimed the products were Type I, Class B (51 expansion) glass, tests indicated that the material these products consist of is a glass with no known classification in ASTM or any major Pharmacopoeia. The glass material was subsequently referred to as 70 expansion glass. 70 expansion glass does not meet Class B standards, and does not carry an ASTM designation. Coefficients of expansion in glass above 51 are associated with lower chemical resistance properties or "chemical durability," which is defined as the lasting quality (physical and chemical) of a glass surface. For scientists concerned about their sample being affected by the glass containment device, should avoid using products with a high glass coefficient (>56 COE).

	ASTM E438 Type 1,	Suppliers		
Chemistry	Class B Target Percentage by Weight	Cardinal Health DCT	Globe Scientific DCT	Kimble° DCT
Silicon Dioxide	73	70	71	74
Boron Trioxide	10	7	6.3	11.5
Aluminum Trioxide	7	6.3	5.9	6.8
Barium Oxide	0 - 2	1.956	1.94	0.07
Calcium Oxide/ Sodium Oxide/ Potassium Oxide/ Combined	8	14.8	14.9	9.6

TABLE II. CHEMICAL COMPOSITION COMPARISON

The chemical durability of glassware is dictated by the percentage-to-weight ratio of silicon, boron and aluminium trioxide; between the ASTM target and individual results, the higher the ratio, the better the chemical durability. Test data revealed the Kimble^{*} DCTs exhibited ratios of 1.01, 1.82, and 1.15 vs. the target. The Cardinal Health DCTs showed ratios of 0.96, 0.7 and 0.90, while Globe Scientific DCTs had ratios of 0.97, 0.9 and 0.93. In this case the higher the value, the higher the chemical durability.

The overall amount of calcium, sodium and potassium oxide contained in glass is an indication of hydrolytic resistance: the measure of how glass reacts with different substances when packaged in contact with them. Cardinal Health's 70 expansion glass tubes had a combined value of 14.8 percent-to-weight ratio, while the value for Globe Scientific DCTs was 14.9. The value for Kimble[®] DCTs was 9.6. In this case, a lower value is consistent with a more stable product, that is less prone to extractables.

	ASTM E438 Maximum PPM	Suppliers		
Trace Constituents		Cardinal Health DCT	Globe Scientific DCT	Kimble® DCT
Arsenic	1,000	>689	>159	BDL
Lead	1,000	2.6	3.7	BDL
Mercury	10,000	BDL	BDL	BDL
Cadmium	10,000	1.8	1.2	BDL

TABLE III. COMPARISON OF HEAVY METALS, ACTUAL PPM

BDL = Below Detection Limits

Tests showed that 70 expansion Cardinal and Globe DCTs contained contaminants and extractable constituents in excess of values accepted. In some cases, values were in excess of 20x higher than those measured in Kimble[°] DCTs.

70 expansion glass tubes are more brittle and prone to breakage. Any savings laboratories may expect using DCTs of unknown quality are overshadowed by the wasteful, potentially dangerous breakage that occurs.

KNOWN QUALITY As the world's largest manufacturer of laboratory glassware, DWK Life Sciences manufactures over 3 million DCTs each day. The company has defined the process for producing DCTs in compliance with global quality standards for borosilicate glass. DWK Life Sciences is able to control the manufacturing process from sourcing raw materials to delivering a finished product. In addition, DWK Life Sciences has an extensive and devoted workforce with the expertise to understand the application of its products, and support their use in laboratories every day.

Sample collection and short term storage are crucial to the veracity of your analysis, and the DCT you use everyday matters...



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