RiboNAT Rapid Sterility Test

Faster test results. Faster patient delivery.

Traditional sterility test methods can take days for incubation, using up valuable time and delaying the release of therapies that have a short shelf-life. **RiboNAT Rapid Sterility Test** meets the growing need for faster sterility tests without compromising patient safety.

Reduce at-risk drug and therapy delivery

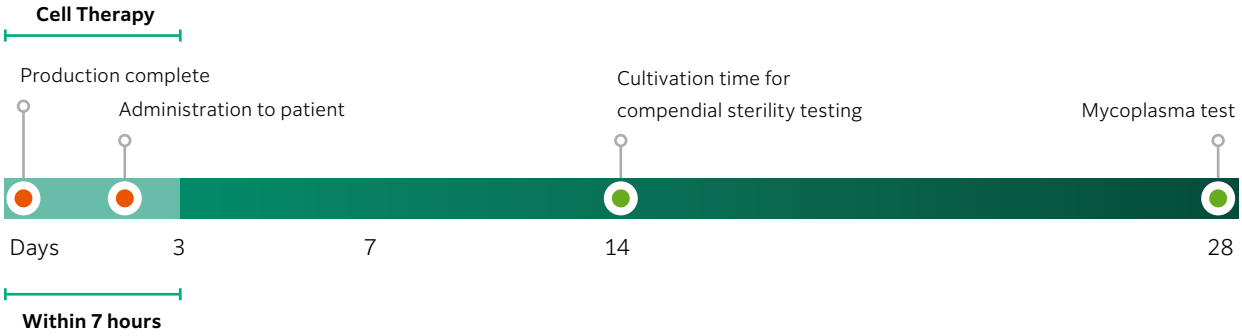

Figure 1. In the USP <71> Sterility Tests and Ph. Eur 2.6.1 Sterility, a 14-day incubation period is required. Regarding rapid test methods, the USP <1071> Rapid Microbial Tests and Ph. Eur. 5.1.6 Alternative Methods for Control allow for the use of rapid methods as alternatives and outlines important considerations for rapid tests.

Benefits of RiboNAT Rapid Sterility Test

Results in as little as 7 hours by using the Nucleic Acid Amplification Test (NAT) method to deliver drugs and therapies that have a shorter shelf-life without needing to administer at risk

Reduce false positives that are typical in traditional testing methods from residual DNA or dead microorganisms

Higher test sensitivity by targeting ribosomal RNA (rRNA) using RT-rtPCR technology instead of genomic DNA (gDNA)

Add a crucial QC sterility control point into your workflow that detects a range of aerobic/anaerobic bacteria and fungi

Connect with Us and Streamline Your Sterility Testing Method

Visit **fujifilmbiosciences.fujifilm.com/us/sterility-testing** contact your local sales representative.

Reduce False Positive Outcomes When Using RiboNAT Rapid Sterility Test

Conventional NAT methods can produce false positives due to residual DNA derived from dead microorganisms. When testing for the same species of microorganisms from the same sterile sample as a traditional DNA detection kit, RiboNAT delivered more reliable results.

Table 1. Tested Microorganisms

Strain Names	Strain #
Aspergillus brasiliensis	ATCC 16404
Bacillus subtilis subsp spizizenii	ATCC 6633
Candida albicans	ATCC 10231
Clostridium sporogenes	ATCC 11437
Pseudomonas aeruginosa	ATCC 9027
Staphylococcus aureus	ATCC 6538

Results of RiboNAT Rapid Sterility Test Versus Traditional DNA Detection Kit

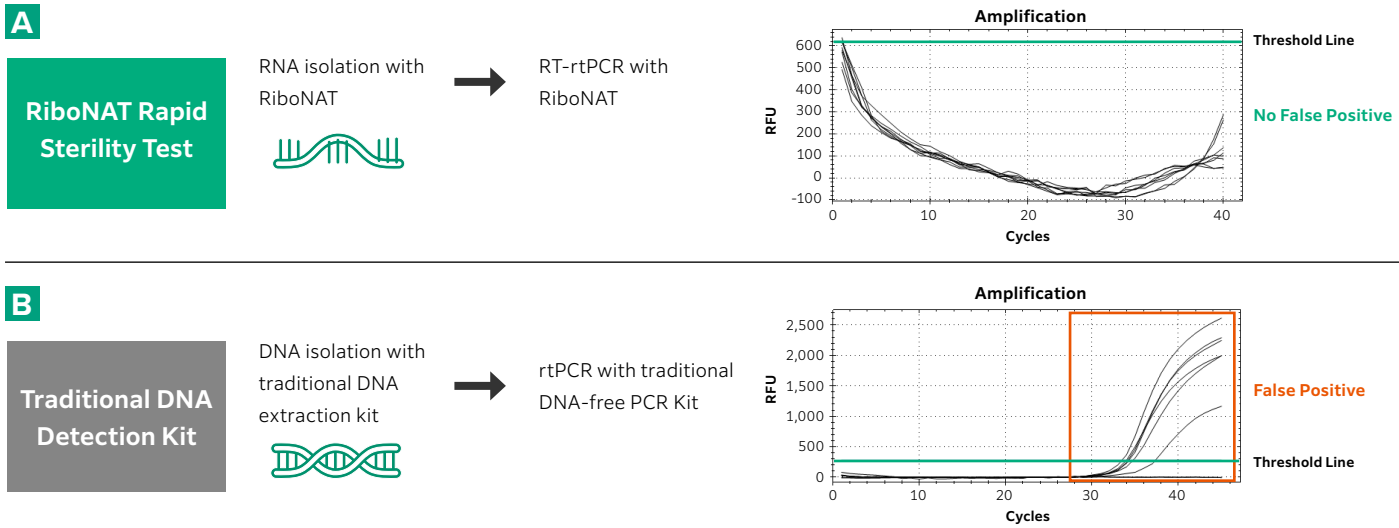

Figure 2. (A) Results indicated that when a sterile sample of PBS(-) was tested for a set of 6 microorganism species shown in **Table 1**, with the RT-rtPCR method using RiboNAT Rapid Sterility Test, no false positives were reported. **(B)** However, when the same test was conducted using a traditional DNA detection sterility test, false positives were reported for all 6 microorganism species.

ORDERING INFORMATION

Product Description	Catalog #	Size*
RiboNAT Rapid Sterility Test - RNA Isolation Kit 1	291-98401	50 Tests
RiboNAT Rapid Sterility Test - RNA Isolation Kit 2	297-98001	50 Tests
RiboNAT Rapid Sterility Test - Detection Kit	293-98101	100 Tests

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