

Accelerating CHO Bulk Harvest Testing Requires Rapid Methods

The Blazar® CHO AOF panel can be considered for use as an **alternative** to the *in vitro* virus assay for **bulk harvest material**, as part of a rapid testing package*

Breakthrough Performance

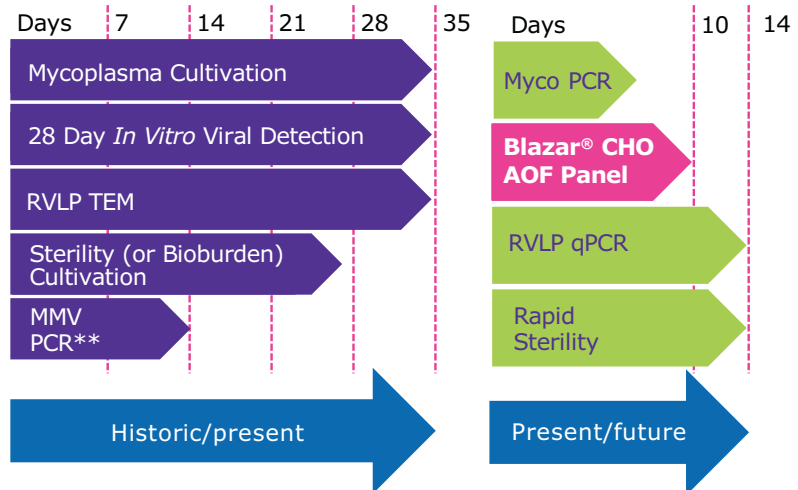
➔ **10-Day Turnaround Time** enables rapid decision-making for batch release, offering **expedited fill/finish operations and faster regulatory filing**.

➔ **Superior Detection Capability** spanning 15 virus families (DNA and RNA viruses) with **thousands of variants** detected via degenerate PCR. Validated for 10 genomic copies per reaction sensitivity. Emerging viruses included for future-proof protection.

➔ **More than 90 GMP studies completed** for 12 clients since launch in 2024, aiding **rapid lot release to fill/finish and overcoming matrix cytotoxicity limitations** of traditional *in vitro* adventitious virus testing.***

Primary intended use

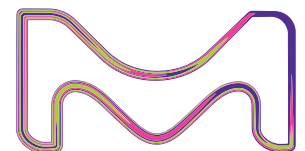
- ✓ Cell bank pre-screening
- ✓ Raw materials screening
- ✓ **Bulk harvest lot release**
- ✓ Risk mitigation for early release



*The following conditions must be met for the use of the Blazar® CHO AOF Panel: CHO cells are used for production, there are no materials of animal origin used in the manufacturing process (AOF) and Master and working cell banks (and EOPC, where available) have been fully characterized, including broad virus spectrum detection assays and species-specific virus testing

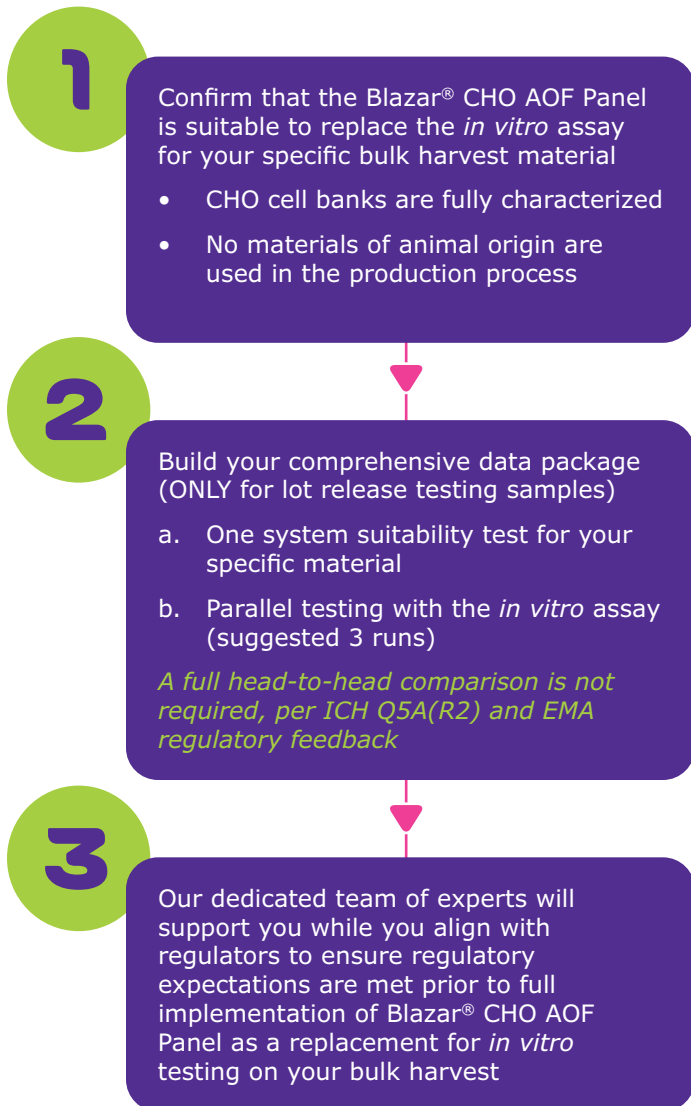
**MMV is included as a target in the Blazar® CHO AOF Panel (separate PCR not required in accelerated package)

***The figure is as of 30July2025



Streamlining regulatory submissions with the Blazar® CHO AOF Panel

Our regulatory experts will support all discussions to **build your success**



Our **data package** to support your path to **regulatory success**

- | | |
|---|---|
| ✓ Technical specification for assay performance | ✓ Full validation report* |
| ✓ Validation summary report | ✓ Standard operating procedures* |
| ✓ White paper | ✓ Product-specific qualification summary report (generated for late-stage products) |
| ✓ Equivalency to <i>in vitro</i> Report | ✓ Position statement |

*Proprietary information, such as validation reports and standard operating procedures, can be provided directly to regulators to support regulatory submissions. For FDA submissions, these documents are contained within a Biologics Master File (#3493) and a Letter of Authorization will be issued to permit the FDA to review the documents in relation to the client's submission.

Learn more at:
SigmaAldrich.com/rapidmethods

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