



FIND SIMPLICITY IN STABILITY

Streamline Your Genetic Stability Testing with the NGS-based Aptegra™ Platform

The genetic stability testing package for biopharmaceutical cell banks has remained relatively unchanged for decades. This traditional approach to genetic stability testing relies on a complex set of assays to meet ICH Q5B requirements, many of which have limitations in discovery power and sensitivity and require long timelines for completion.

The Aptegra™ CHO genetic stability assay delivers the first streamlined, single-test replacement of traditional methods, returning results in a third of the time. This assay taps into the combined power of whole genome sequencing (WGS) and expert bioinformatics to deliver a faster, all-in-one solution for a comprehensive testing package, including:

- Gene of interest (GOI) sequence analysis
- Copy number determination
- Sequence analysis of flanking regions
- Integration site determination
- Analysis of insertions or deletions

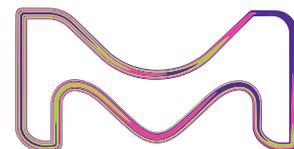
The Aptegra™ CHO genetic stability assay operates under a GMP-validated workflow to return expert-reviewed results in 30 days using less of your precious cell bank.

Aptegra™ CHO Genetic Stability assay vs the traditional package of five assays

| | Aptegra™ CHO Genetic Stability Assay | Comprehensive Traditional Package |
|--------------------------------------|--------------------------------------|-------------------------------------|
| Number of assays recommended | 1 | 5 |
| Multiple genes tested per assay | Yes | No |
| Proposal required | No | Yes |
| Development work / primer design | No | Yes |
| Client time investment | Sample Submission | Project kick-off meetings as needed |
| Sample requirement | 2.0 x 10e6 cells | 2.3 x 10e8 cells |
| Growing cells required | No | Yes* |
| Side-by-side sample testing for EOPC | No | Yes** |
| Time to complete project | 30 days | 3-5 months (minimum) |

* Actively growing cells required for FISH analysis

** Recommended for ddPCR and Southern blot assays



Stability testing should be simple. By tapping into the whole genome, it can be.

The Aptegra™ CHO genetic stability assay:

- Replaces Southern, Sanger sequencing, PCR, and FISH with a single technology
- Utilizes expert bioinformatics to address all genetic stability regulatory requirements
- Eliminates primer bias, design time, and assay optimization
- Eradicates any guesswork in data interpretation
- Reduces upfront client time with off-the-shelf ordering
- Consistently delivers fast, reliable results

Simplify your genetic stability testing with the Aptegra™ platform.

Talk to an expert today

SigmaAldrich.com/Aptegra

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