



## Cell Line Characterization Standard Protocols

Effective January 2, 2024

All analysis packages can be tailored to suit your needs. If you require different quantities of cells analyzed than those listed under the following protocols, we will be happy to provide you with testing under a customized protocol. Please direct all custom protocol requests and quote requests to [agl@appliedgenetics.com](mailto:agl@appliedgenetics.com).

### Conventional Cytogenetic Analysis Testing Packages:

Two primary conventional cytogenetic analysis techniques are offered at AGL. G-banded analysis is used to determine the karyotype and species of the cell line. Non-banded analysis (performed separately from G-banded analysis) is used to obtain chromosome count and aberration data on a larger set of metaphases. AGL provides combined G-banded and non-banded analysis under protocol 2024-AGL-CCP.2. Non-banded analysis only (for sponsors who do not need G-banded data and/or species for which a reference karyotype is not available) is provided under protocol 2024-AGL-CCP.9. Commonly ordered protocol options are outlined below.

Protocol	G-banded Analysis of	Non-banded Analysis of
2024-AGL-CCP.2	5 metaphases	50 metaphases
2024-AGL-CCP.2	5 metaphases	100 metaphases
2024-AGL-CCP.2	10 metaphases	100 metaphases
2024-AGL-CCP.2	10 metaphases	200 metaphases
2024-AGL-CCP.2	20 metaphases	100 metaphases
2024-AGL-CCP.2	20 metaphases	200 metaphases
2024-AGL-CCP.9	NA	100 metaphases

### Molecular Cytogenetic Analysis Testing Packages:

AGL offers fluorescence *in situ* hybridization (FISH) as a method of molecular cytogenetic analysis. All FISH analysis packages are conducted under protocol 2024-AGL-CCP.15. Testing options under this protocol include analysis of 200 interphase cells, analysis of 20 metaphase cells, or M-FISH (multicolor FISH) analysis of 5 metaphase cells. M-FISH is available for human, mouse, and CHO.

CCP.15 Analysis Option	Probe(s) Used
200 Interphase Cells	Custom (commercial, sponsor- or AGL-provided)
20 Metaphase Cells	Custom (commercial, sponsor- or AGL-provided)
5 Metaphase Cells by M-FISH	Commercial Multicolor FISH Probes

#### NOTES:

- All protocols listed include the following: cell culture, up to three chromosome harvests, slide preparation, slide pretreatment (as needed), slide staining or hybridization, analysis, study-specific phase inspection, data reviews, and a detailed final report.
- All protocols listed are performed according to GLP guidelines and their final reports are intended for submission to the FDA. All karyotypes provided are suitable for publication.
- For cell lines with a modal chromosome number of >80 chromosomes (as determined via non-banded analysis) and a CCP.2 analysis, standard protocols include 3 karyotypes instead of 5 (also for CCP.15 with M-FISH), 6 karyotypes instead of 10, or 12 karyotypes instead of 20.
- Standard turnaround times generally range between 4-8 weeks. Timelines may vary depending on cell type, study design, protocol customization, and caseloads.

1335 Gateway Drive, Suite 2001 • Melbourne, FL 32901  
(321) 768-2048 • Fax (321) 727-2643  
[agl@appliedgenetics.com](mailto:agl@appliedgenetics.com) • [www.appliedgenetics.com](http://www.appliedgenetics.com)