

Proceed with Confidence

Cell Line Authentication Guide

A Guide to Improving your NIH Grant Application

CellCheck authentication service is the industry gold standard and utilizes methods recommended by the American National Standards Institute (ANSI ASN-0002-2011) to ensure your success in meeting authentication requirements. CellCheck provides one easy step for one low price, combining STR-based DNA profiling and multiplex PCR to detect both contamination and misidentification. Additionally, we will provide data analysis and interpretation, comparative analysis, and will even help develop a contamination recovery plan, if needed.

Your authentication solution starts here.

CellCheck™ for human cell lines, tumors and tissues

- ✔ Human cell lines are authenticated using nine species-specific markers (eight STR loci and amelogenin)¹ or 16 markers (15 STR loci and amelogenin)
- ✔ Verifies the identity of a cell line by STR profiling
- ✔ The genetic profile can be used to authenticate the cell line against a reference profile or for further comparison
- ✔ Detects presence of DNA of 5 most common research species (human, mouse, rat, African green monkey or Chinese hamster) using a multiplex PCR assay
- ✔ Detects as little as 5% interspecies cross-contamination

CellCheck™ 9 for Human Specimens

Profile includes:

- Human 9 species-specific STR marker profile recommended in current standards
- Interspecies contamination check for human, mouse, rat, African green monkey and Chinese hamster cells
- Comparative analysis
- Data interpretation and expert consultation

CellCheck 9 Plus

Profile includes all services listed above in CellCheck 9 as well as *Mycoplasma spp.* testing.

CellCheck™ 16 for Human Specimens

This expanded profile is suggested for newly established cell lines/tumors and for comparison of derivative cell lines to parental cell lines.

- Human 9-marker STR profile recommended in current standards as well as 7 additional human STR markers
- Interspecies contamination check for human, mouse, rat, African green monkey and Chinese hamster cells
- Comparative analysis
- Data interpretation and expert consultation

CellCheck 16 Plus

Includes all services in CellCheck 16 as well as *Mycoplasma spp.* testing.

Donor Tissue 16-Marker Profile (Donor tissue only)

Includes: Human 16-marker STR profile. Used to establish a profile when developing new cell lines or tumors from patient-derived materials.

Why authenticate cell lines?

Authentication is a standard quality assurance practice when working with cell lines and transplantable tumors.

- A reported 18-36% of all cell lines are cross-contaminated or misidentified²
- Contamination and misidentification results in invalid data as well as wasted time and money
- More journals are requiring authentication of cell lines prior to publication
- NIH NOT-OD-16-011 Implementing Rigor & Transparency requires grant applicants to include an authentication plan for key biological materials.

When to test

- When a new cell line is acquired or when banking frozen materials for later use.
- As a standard quality control measure at the beginning and end of experiments.
- As a standard quality control measure for cell lines in continuous use.
- When cell line performance is inconsistent or results are unexpected.
- To establish a genetic profile for a new or unique human cell line for which a reference profile is not available.
- Prior to publication in some journals or, as discussed in recent NIH notice, prior to grant applications.

Biological Quality Assurance

Trust our industry-leading expertise for confirmation of quality, safety, and authenticity of your materials to advance your research with confidence. We provide an unparalleled breadth of biological testing services.

- Genetic Contamination Testing – CellCheck™
- *Mycoplasma* Contamination Testing – STAT-Myco™
- Microbial Contamination – Sterility Testing
- Human or rodent viral pathogen contamination testing – IMPACT testing

CellCheck™ for other species cell lines, tumors and tissues

- ✔ Detects presence of DNA of the most commonly used species of origin in the laboratory – human, mouse, rat, African green monkey and Chinese hamster using a multiplex PCR assay
- ✔ Detects as little as 5% interspecies cross-contamination
- ✔ Verifies the identity of a cell line by STR profiling
- ✔ The genetic profile can be used to authenticate the cell line against a reference profile or establish a profile for further comparison

CellCheck™ Mouse

Profile includes:

- Establishes a genetic profile of the cell line using a panel of 9 species-specific STR markers, as published by NIST³
- Detects the presence of interspecies contamination for human, rat, African green monkey and Chinese hamster cells
- Comparative analysis, if published profile available
- Data interpretation and expert consultation

CellCheck Mouse Plus

Includes all services listed above in CellCheck-Mouse as well as *Mycoplasma spp.* testing

CellCheck™ Canine

Profile includes:

- Establishes a genetic profile of the cell line using a panel of 14 species-specific STR markers
- Detects the presence of interspecies contamination for human, mouse, African green monkey and Chinese hamster cells
- Comparative analysis, if published profile available
- Data interpretation and expert consultation

CellCheck-Canine Plus

Includes all services listed above in CellCheck Canine as well as *Mycoplasma spp.* testing

CellCheck™ Rat

Profile includes:

- Establishes a genetic profile of the cell line using a panel of 31 species-specific STR markers
- Detects the presence of interspecies contamination for human, mouse, African green monkey and Chinese hamster cells
- Comparative analysis, if published profile available
- Data interpretation and expert consultation

CellCheck-Rat Plus

Includes all services listed above in CellCheck Rat as well as *Mycoplasma spp.* testing

Interspecies Contamination-Only Testing

- Human, mouse, rat, African green monkey and Chinese hamster
- Additional species-specific assays are available for canine, swine, feline, and laboratory rabbit

CO1 DNA Barcoding

- Confirms the cell line species of origin.
- Utilizes sequence data for appx 660 base pair region of the mitochondrial cytochrome c oxidase subunit 1 (CO1) gene
- Complies with American National Standards Institute (ANSI) guidelines for species identification of animal cell lines⁴.
- Appropriate for less commonly used species of origin cell lines such as insect, drosophila, cow, pig, Syrian hamster, ferret and other mammalian species.
- Call for more information.

New NIH Authentication Guidelines? No problem!

Download our Authentication Guide for a roadmap to simplify compliance with the new grant requirements.

Visit www.idexbioanalytics.com/authenticate

Sterility Testing

Microbial contamination is not a rare event. IDEXX BioAnalytics offers researchers comprehensive and reliable protocols for the detection of microbial contamination of cell lines and other research materials.

Sterility Testing you can trust

- Use of a proprietary battery of multiple media designed to detect a wide variety of aerobic and microaerophilic bacteria, yeasts, and fungi
- Cultivation capability spans hundreds of genera of bacteria and fungi
- 3 Standard profiles (including CFR 21 compliant profile) to choose from as well as customized testing available
- Microbial identification by MALDI-TOF mass spectrometry, the fastest and most reliable technology available.

When working with cell culture, let IDEXX BioAnalytics help assure that your materials are free of microbial contamination.

STAT-Myco™

Mycoplasma Testing for Quality Assurance

Mycoplasma species are common in many cell cultures, and can profoundly affect research results by decreasing cell growth, altering phenotypic and metabolic characteristics, inhibiting differentiation and even causing cell death. Assure that your research isn't compromised by *Mycoplasma*, have confidence in the validity of your results and align with regulatory guidance for products derived from mammalian cell cultures.

Our STAT-Myco assay:

- Detects as few as 1-10 organisms
- Detects all species of *Mycoplasma* known to infect cell culture as well as many other *Mycoplasma* species, and *Acholeplasma spp.*, also known to contaminate cultured cells
- Shown to detect *Mycoplasma* species not detected by commercially available kits
- Provides results in just 3 business days!

To order CellCheck, other biological tests or for your free Cell Line Authentication Guide contact: 1-800-544-5205, option #1 • idexxbioanalytics.com

References:

1. ATCC Standards Development Organization Workgroup. Authentication of Human Cell Lines: Standardization of STR Profiling. ANSI/ATCC ASN-0002-2011. Manassas, VA: American Type Culture Collection Standards and American National Standards Institute; 2011.
2. Hughes P, Marshall D, Reid Y, Parkes H, Gelber C (2007) The costs of using unauthenticated, overpassaged cell lines: how much more data do we need? *Biotechniques* 43: 575, 577-578, 581-572 passim. PMID: 18072596
3. Almeida, J. A., Steffen, C.R., and Cole, K.D., Eds., NIST Materials Measurement Laboratory Website, Biosystems and Biomaterials, National Institute of Standards and Technology, Gaithersburg MD, 20899, <https://www.nist.gov/mml/bbd/cell-measurements/cell-line-identification-authentication/mouse-cell-line-authentication>, (retrieved November 9, 2016).
4. ATCC Standards Development Organization Workgroup. ASN-0003, Species-Level Identification of Animal Cells through Mitochondrial Cytochrome c Oxidase Subunit 1 (CO1) DNA Barcodes. ANSI/ATCC ASN-0003-2015. Manassas, VA: American Type Culture Collection Standards and American National Standards Institute, 2015.

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