

Provider of Preclinical Research Services (GLP/non-GLP) for Drug Discovery Efficacy and Pharm/Tox IND contract research studies (clients worldwide) 100+ Xenograft Models (validated in-house) and IND-enabling Toxicology studies 100% IP belongs to client, experienced IACUC-regulated barrier facility

Teratoma Formation and Analysis Services

Contact us: **info@altogenlabs.com** | Read more at **AltogenLabs.com** ALTOGEN® 11200 Menchaca Road 203 • Austin • TX • 78748 • USA 512-433-6177

Background

Human embryonic stem cells (hES cells) and human induced-pluripotent stem cells (iPS cells) are uniquely defined by their pluripotent differentiation potential and endless self-renewing ability.

 iPS cells are genetically altered through transfection to become morphologically and biochemically similar to pluripotent stem cells.

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Clinical Implications

 This capability to become any somatic cell type within the human body has garnered significant attention and interest in the fields of cell biology and regenerative medicine.



Histological sections of teratomas

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Key Characteristics

• Teratomas: Benign tumors characterized by their rapid growth *in vivo* and their haphazard mixture of tissues, and thus often have semi-semblances of organs, teeth, hair, muscle, cartilage, and even bone. They contain remnants of all three germ layers. These are key characteristics of robust pluripotency and explain why teratoma formation is widely viewed in stem cell research as the "gold standard" for assessing pluripotency.

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Histology

The field of hESCs is moving rapidly towards clinical applications, with the first spinal injury patient being recently transplanted with hESC derived cells (Mayor et al., 2010). A key hazard in the implementation of hESCbased cell therapy is potential tumor formation caused by the presence of pluripotent hESCs within the transplanted cell preparations.



Stem cells serve as a "blank slate" from which different tissues can be derived askdrray.com

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Summary of Tests Generally Used in Determining Pluripotency

Assay	Parameter	Length	Nature	Definitiveness
1. Colony morphology	ESC colony like morphology	10 min	In vitro	Low
2. Immunohistochemistry	Stain for standard pluripotetency markers like Sox2, Tra1-81 and SSEA	1-4 days	In vitro	Medium
3. Real Time PCR	Detect and quantify the expression levels of pluripotent genes	4-6 h	In vitro	Medium-high
4. Embryoid body formation	Test differentiation capabilities of PSCs to tissue of all 3 germ layers. Coupled with RT-PCR of pluripotent genes from all the 3 layers	2-3 weeks	In vitro or in vivo	Medium-high
5. Micro array	Comprehensive measurement of gene expression levels	1-2 days	In vitro	Medium-high
6. Teratoma formation	Test differentiation capabilities in to 3 different germ layers in vivo	1-2 months	In vivo	High

http://www.stembook.org/node/723

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Teratoma Detection

 Teratoma assays are not only important for assessing hESC pluripotency, but also for evaluating the tumorigenic potential of hESCderived progeny.

As clinical translation of hPSCs progresses, the utilization of "gold standard" teratoma formation to test pluripotency as well as other hPSC behavior *in vivo* will continue to be indispensable for investigators.

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Standard Protocol for Teratoma Services

Example of Standard Protocol:

Teratoma is created via the injection of a customer's embryonic stem (ES) cells or induced pluripotent stem (iPS). As a first step in the establishment of teratomas, we quantify the cells to obtain the number of cells to be used per inoculation. Usually, 1 million cells are used per injection per site. Prior to transplantation, FACS analysis of the percentage of cells expressing pluripotency-associated cell surface markers like Tra-1-60, Tra-1-81, and SSEA-4 is performed. The cells are injected subcutaneously (s.c.) since transplantation to this site is easy to perform, does not involve an invasive surgical procedure, and allows simple monitoring of teratoma formation. Upon engraftment, teratoma formation is affected by three main factors: PSC type, cell number, and delivery route. To minimize the risk of immune rejection, the cells are transplanted into NOD/SCID mice. Following their establishment *in vivo*, teratomas typically progress by remodeling their microenvironment to support their growth and the formation of blood vessels for nutrients.

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Services

In addition to our Teratoma assays, Altogen Labs also offers a full spectrum of additional pre-clinical and biological CRO services:

- Generation of stable cell lines and cell banking services
- A-to-Z RNA interference services
- Cell Biology services including in-house/custom cell lines, cell-based assay development and antibody production
- Molecular biology services including gene synthesis, vector construction, sub cloning and expression
- Xenograft mice services
- Pharmacology and toxicology studies
- In vivo Pharmacology and Toxicology

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Contact Us

- At Altogen Labs we strive to transition stem cell research into safe, effective, and consistent therapies for diseases and cancers affecting populations worldwide.
- Our qualified staff fully understand the risks and complexities associated with potential stem cell therapies and aim to identify all complications, interactions, and factors that could limit or affect stem cell therapeutics.



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Contact us to discuss details, timeline estimates, and price!

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