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
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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.
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
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.
**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 hESC-based 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](http://askdrray.com)
## Summary of Tests Generally Used in Determining Pluripotency

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

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

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

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