



# STEM CELL LABORATORY (STCL)



**DOCUMENT NUMBER:**

**DOCUMENT TITLE:**

**DOCUMENT NOTES:**

## Document Information

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## Date Information

**Creation Date:**

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## Control Information

**Author:**

**Owner:**

**Previous Number:**

**Change Number:**

# STCL MATERIAL SPECIFICATION FORM

MSPEC #: STCL-MSPEC-

Material/Supply:

Part Number(s):

Manufacturer:

Vendor:

Description/Intended use:

Criticality Determination:

- ☐ Directly contacts or impacts safety of product
- ☐ Reagent used in specification determination
- ☐ Can only be obtained by current manufacturer

Material Classification:

- ☐ Critical ☐ Non-Critical

Storage Requirements

- ☐ Room Temperature/Humidity (15-25°C / 10-70%)
- ☐ Refrigerator (2 to 8°C)
- ☐ Freezer (-5 to -30°C)

Other: (ie. Protect from Light)

Material/Supply Receipt Specifications

• Quality Documents Required Prior to QA Release: ☐ NA

- ☐ Package Insert ☐ Critical Component Verification (Describe):
- ☐ Certificate Document (Describe):

Reason for MSPEC creation:

- ☐ New Process
- ☐ New supply interchangeable with in-use product. In-use product MSPEC #: \_\_\_\_\_
- ☐ New supply replacing in-use product, enter previous supply MSPEC #: \_\_\_\_\_  
Reason: \_\_\_\_\_
- ☐ Other. Please Describe: \_\_\_\_\_

## Instructions

1. Material/Supply	Record name of material/supply.
2. Part Number(s)#	Record Part # used to order the material.
3. Manufacturer	Record manufacturer, which might be different from vendor/supplier.
4. Vendor	Record vendor name.
5. Description/Intended use	Record supply description and information of how it is used in STCL
6. Criticality Determination	Check any that apply.
7. Material Classification	If any of the criteria above (#6) are checked, then mark as critical. Otherwise, mark non-critical.
8. Storage Requirements	Use check boxes to indicate storage temperature requirements. Use Other for special requirements, for example, protect from light.
9. Quality Documents required prior to QA release	Mark NA if not required. Otherwise, check the required documents: Package insert, Certificate or Critical Component Verification
10. Package Insert	Check if required (required for all FDA license products)
11. Certificate Document	Check if required. Describe type of document: CoA, CoC, etc
12. Critical Component Verification	Check when qualification of supply is required. Describe requirements. For example, 14 sterility testing for new lots of DMSO.
13. Reason for MSPEC creation	Check option that applies AND record previous/existing MSPEC when required.

## Signature Manifest

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### STCL-GEN-002 FRM5 STCL Material Specification Form

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#### Document Release

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