

Cell Inoculation Using SeptaVent™

Standard Operating Procedure (SOP)

Version 1.0

1. References:

1. Aseptic technique SOP

2. Equipment:

1. Laminar Flow Hood
2. Incubator or water bath to warm media
3. Incubator, shaking
4. Pipettor

3. Materials:

| # | | Description | Lot # | Qty |
|---|--------------------------|-----------------------------------|-------|-----------|
| 1 | <input type="checkbox"/> | SeptaVent™ – 50mL centrifuge tube | | 1 |
| 2 | <input type="checkbox"/> | Cell inoculum | | X mL |
| 3 | <input type="checkbox"/> | Media in bag, spike adapted | | X mL |
| 4 | <input type="checkbox"/> | IV vented spike - Luer | | 1 |
| 5 | <input type="checkbox"/> | Disinfectant | | As Needed |
| 6 | <input type="checkbox"/> | IV vented spike – spike set | | 1 |

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4. Procedure:

Media Addition, using media in bag with spike.

| <i>Step</i> | <i>Procedure</i> | <i>Data</i> | <i>Initials</i> |
|-------------|--|-----------------|-----------------|
| 1 | Warm media to 37 ⁰ C. Ensure all clamps are closed. If media bag does not have spike, aseptically attach IV spike with Luer connection. | Record temp: | |
| 2 | Remove SeptaVent™ from package. | | |
| 3 | Aseptically spike SeptaVent™ cap with media bag spike. | | |
| 4 | Ensure connection is secure. Open clamps on media bag and line. | | |
| 5 | Gravity feed required amount of media to SeptaVent™ tube by holding media bag above level of tube. | mL media added: | |
| 6 | When media addition is completed, close clamps. Remove spike. | | |

Media addition using aseptic procedure in laminar flow hood.

| <i>Step</i> | <i>Procedure</i> | <i>Data</i> | <i>Initials</i> |
|-------------|--|-----------------|-----------------|
| 1 | Warm media to 37 ⁰ C. Ensure all clamps are closed. | Record temp: | |
| 2 | Remove SeptaVent™ from package and place within laminar flow hood. | | |
| 3 | Wipe down media with disinfectant and place within laminar flow hood. | | |
| 4 | Working within the laminar flow hood and using aseptic technique; pipette required amount of media to SeptaVent™ tube. | mL media added: | |
| 5 | Aseptically cap SeptaVent™ tube. | | |

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Cell inoculation using SeptaVent™ equipped starter vessel and spike.

| <i>Step</i> | <i>Procedure</i> | <i>Data</i> | <i>Initials</i> |
|-------------|--|--|-----------------|
| 1 | Remove IV vented spike – spike from packaging. Ensure clamps are shut. | | |
| 2 | Spike one end of IV vented spike into inoculum containing SeptaVent™. Spike other end of IV vented spike into new SeptaVent™ with fresh media. | | |
| 3 | Raise and invert inoculum containing SeptaVent™ being careful to keep spike intact. Open clamp and gravity feed cell inoculum to new SeptaVent™. | Record time and date: Record mL inoculum transferred: | |
| 4 | Clamp off line and remove spikes. | | |
| 5 | Transfer SeptaVent™ to shaker incubator. | Record shaker incubator rpm and temperature: | |

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Cell inoculation using pipette in laminar flow hood.

| <i>Step</i> | <i>Procedure</i> | <i>Data</i> | <i>Initials</i> |
|-------------|--|--|-----------------|
| 1 | Wipe down with disinfectant the cell inoculum and SeptaVent™ with fresh media. Transfer to laminar flow hood. | | |
| 2 | Working within the laminar flow hood and using aseptic technique; pipette required amount of cell inoculum to SeptaVent™ tube. | Record time and date: Record mL inoculum transferred: | |
| 3 | Aseptically cap SeptaVent™ tube. | | |
| 4 | Transfer SeptaVent™ to shaker incubator. | Record shaker incubator rpm and temperature: | |