| **Assay**  **<<005070>>GMP** | **Test for the Presence of Inapparent Viruses Using Suckling Mice, Adult Mice Guinea Pigs and Embryonated Eggs in Accordance with CBER Draft Guidance (Sept 2006).** | **Inventory Control** | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| **Supplier Catalogue Number** | **Oracle Part Number** | **Inventory Control** | **Release**  **Specification** | **In House/ secondary**  **BOM** |
| **Material type** | **Name** | **Y/N** | **Y/N** | **Y/N** |
| Raw Material | SPF Chicken Eggs | SPF Premium Plus Eggs | 100001722 | Y | Y | N/A |
| Raw Material | Terumo 1ml Syringes | SYR6200 | A0000029 | Y | Y | N/A |
| Raw Material | Terumo 5ml Syringes | SYR6204 | A0000031 | Y | Y | N/A |
| Raw Material | Terumo 2ml Syringes | SYR6202 | A0000030 | Y | Y | N/A |
| Raw Material | DMEM | 31885-023 | 100000647.500ml | Y | Y | N/A |
| Raw Material | PBS (500ml) | 14040-091 | 100000718.500ml | Y | Y | N/A |
| Raw Material | Pen Strep | 15140-122 | 100000777.100ml | Y | Y | N/A |
| Raw Material | Needles (23G, 31mm) | SYR6246 | 100007046 | Y | Y | N/A |
| Raw Material | Needles (20G, 25mm) | SYR6230 | 100007043 | Y | Y | N/A |
| Raw Material | Needles (21G, 50mm) | SYR6240 | 100007045 | Y | Y | N/A |
| Raw Material | Needles (25G, 25mm) | SYR6247 | 100007042 | Y | Y | N/A |
| Raw Material | Needles (26G, 9mm) | SYR6120 | 100007044 | Y | Y | N/A |
| Raw Material | 96 well HA Plates | 163320 | A0000014 | Y | Y | N/A |
| Raw Material | Cryovials | 368632 | A0000021 | Y | Y | N/A |
| Raw Material | 200ul non-sterile tips | SLS5040 | A0000003 | Y | Y | N/A |
| Raw Material | 1000ul non-sterile tips | GNT-1000- 960 | A0000004 | Y | Y | N/A |
| Raw Material | 200ul sterile tips | TF-200-R-S | A0000100.96PK | Y | Y | N/A |
| Raw Material | 1000ul sterile tips | TF-1000-R-S | A0000005.100PK | Y | Y | N/A |

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| --- | --- | --- | --- | --- | --- | --- |
| **Supplier Catalogue Number** | **Oracle Part Number** | **Inventory Control** | **Release**  **Specification** | **In House/ secondary**  **BOM** |
| **Material type** | **Name** | **Y/N** | **Y/N** | **Y/N** |
| Raw Material | Sterile 15ml tubes | 570086-1 | 100004472.50PK | Y | Y | N/A |
| Raw Material | Sterile 50ml tubes | BRS037 | A0000002.25PK | Y | Y | N/A |
| Erythrocyte | Human Blood | Z416 | A0000096 | Y | Y | N/A |
| Erythrocyte | Guinea Pig Blood | PB030 | 100006039 | Y | Y | N/A |
| Erythrocyte | Chicken Blood | FB010 | 100006040 | Y | Y | N/A |
| Raw Material | Paper Shaving Bedding | B/PS10 | 100005055 | Y | N1 | N/A |
| Raw Material | Guinea Pig Diet | D/813174 | 100005056 | Y | N1 | N/A |
| Raw Material | Rodent Diet | D/811002 | 100005057 | Y | N1 | N/A |
| Raw Material | Mouse Tunnels | E/TUNSM | 100005058 | Y | N1 | N/A |
| Raw Material | Guinea Pig Tunnels | E/TUNSTPLUS | 100005060 | Y | N1 | N/A |
| Raw Material | Small Chew Sticks | E/ABI | 100005061 | Y | N1 | N/A |
| Raw Material | Large Chew Sticks | E/AB2 | 100005062 | Y | N1 | N/A |
| Raw Material | G6 Bedding | B/GR6 | 100005063 | Y | N1 | N/A |
| Raw Material | Wood Shaving Bedding | B/DFSPLUS | 100005064 | Y | N1 | N/A |

1 No release specification is applied as the materials are not considered to have a significant direct impact on the performance of the assay but the materials are inventory controlled via Oracle.

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| --- | --- | --- | --- | --- | --- | --- |
| **Supplier Catalogue Number** | **Oracle Part Number** | **Inventory Control** | **Release**  **Specification** | **In House/ secondary**  **BOM** |
| Material type | Name | **Y/N** | **Y/N** | **Y/N** |
| Raw Material | Adult Mice | SPF, strain CD1 | N/A | N1 | Y | N |
| Raw Material | Suckling Mice | SPF, strain CD1 | N/A | N1 | Y | N |
| Raw Material | Guinea Pigs | SPF, strain Dunkin Hartley | N/A | N1 | Y | N |
| Raw Material | Tap Water 2 | N/A | N/A | N/A | N2 | N |
| Supplemented Media | DMEM P/S 1% | N/A | N/A | N3 | N3 | PRP 008.02 |
| Supplemented Media | DMEM P/S 2% | N/A | N/A | N3 | N3 | PRP 006.03 |
| In-House Reagent | 0.5% Human Blood | N/A | N/A | N3 | N3 | KPBT7061 |
| In-House Reagent | 0.5% Guinea Pig Blood | N/A | N/A | N3 | N3 | KPBT7061 |
| In-House Reagent | 0.5% Chicken Blood | N/A | N/A | N3 | N3 | KPBT7061 |
| Positive control | Allantoic fluids from eggs inoculated with *Influenza* *A* *virus* | VR-1469 | 100002004 | Y | Y | Y |

1 No inventory control is applied as this is not practical. Animals are received and acclimatised as outlined in SOP KPBT7022. Animals are received from approved suppliers into a designated animal receiving room, given a visual health check and all relevant Health Certificates are checked. Animals are then placed in filtered cages, labelled with the relevant batch details etc., and are given at least 24 hours acclimatisation prior to use within studies. Animal stock levels are controlled via routine laboratory scheduling of studies which indicates the number of animals required on a weekly basis.

2 Tap water only is provided for study animals to drink and water quality is monitored via routine checking of Certificate of Analysis supplied by relevant Water Board by BioReliance Management as outlined in SOP KPMP1157.

3 No release specification or inventory control applied these materials, these materials are prepared in house and controlled via routine laboratory housekeeping procedures and relevant SOPs.

**Approvals**

**Prepared By \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Approval (Ops) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Approval (QA) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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| **Revision History** | |
| **Revision .R00** | **New Document** |