

***DS01-301001B*生产物料清单（***I1***）**

**第一部分：新增（或变更后）生产物料清单**

| 项目-工序 | 项目 | 物料编码 | 名称 | 单位 | 批用量 | 配方文本 | 替代组 | 替代关系 | 库位 |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| IBI301 2nd-配液 | 0010 | W01010004 | CD CHO AGT | G | 1215 | IBI301 2nd种子培养基 | A1 | 主料 | ZB00 |
| IBI301 2nd-配液 | 0020 | W01010002 | CD CHO AGT | G | 1215 | IBI301 2nd 种子培养基 | A1 | 辅料 | ZB00 |
| IBI301 2nd-配液 | 0030 | W01010004 | CD CHO AGT | G | 4252.5 | IBI301 2nd 去压种子培养基 | A2 | 主料 | ZB00 |
| IBI301 2nd-配液 | 0040 | W01010002 | CD CHO AGT | G | 4252.5 | IBI301 2nd去压种子培养基 | A2 | 辅料 | ZB00 |
| IBI301 2nd-配液 | 0050 | W01010004 | CD CHO AGT | G | 18832.5 | IBI301 2nd去压种子培养基 | A3 | 主料 | ZB00 |
| IBI301 2nd-配液 | 0060 | W01010002 | CD CHO AGT | G | 18832.5 | IBI301 2nd去压种子培养基 | A3 | 辅料 | ZB00 |
| IBI301 2nd-配液 | 0070 | W01010104 | Dynamis AGT Medium | G | 40755 | IBI301 2nd基础培养基 | A4 | 主料 | ZB00 |
| IBI301 2nd-配液 | 0080 | W01010062 | Dynamis AGT Medium | G | 40755 | IBI301 2nd基础培养基 | A4 | 辅料 | ZB00 |
| IBI301 2nd-配液 | 0090 | W01010097 | Cell Boost 7a (Singapore) | G | 136000 | IBI301 2nd流加试剂A | N/A | N/A | ZB00 |
| IBI301 2nd-配液 | 0100 | W01010098 | Cell Boost 7b (Singapore) | G | 7658.5 | IBI301 2nd流加试剂B | N/A | N/A | ZB00 |
| IBI301 2nd-配液 | 0110 | W02010098 | 氢氧化钠 | G | 4000 | IBI301 2nd 5mol/L氢氧化钠-01 | A5 | 主料 | ZB00 |
| IBI301 2nd-配液 | 0120 | W02010073 | 氢氧化钠 | G | 4000 | IBI301 2nd 5mol/L氢氧化钠-01 | A5 | 辅料 | ZB00 |
| IBI301 2nd-配液 | 0130 | W02010098 | 氢氧化钠 | G | 6000 | IBI301 2nd 5mol/L氢氧化钠-02 | A6 | 主料 | ZB00 |
| IBI301 2nd-配液 | 0140 | W02010073 | 氢氧化钠 | G | 6000 | IBI301 2nd 5mol/L氢氧化钠-02 | A6 | 辅料 | ZB00 |
| IBI301 2nd-配液 | 0150 | W02010046 | 半乳糖 | G | 20700 | IBI301 2nd流加试剂C | A7 | 主料 | ZB00 |
| IBI301 2nd-配液 | 0160 | W02010050 | 半乳糖 | G | 20700 | IBI301 2nd流加试剂C | A7 | 辅料 | ZB00 |
| IBI301 2nd-配液 | 0170 | W02010061 | 尿嘧啶核苷 | G | 5652 | IBI301 2nd流加试剂C | A8 | 主料 | ZB00 |
| IBI301 2nd-配液 | 0180 | W02010056 | 尿嘧啶核苷 | G | 5652 | IBI301 2nd流加试剂C | A8 | 辅料 | ZB00 |
| IBI301 2nd-配液 | 0190 | W02010055 | 四水氯化锰 | G | 9.07 | IBI301 2nd流加试剂C | N/A | N/A | ZB00 |
| IBI301 2nd-配液 | 0200 | W02010074 | 无水葡萄糖 | KG | 60 | IBI301 2nd 葡萄糖浓缩液 | A9 | 主料 | ZB00 |
| IBI301 2nd-配液 | 0210 | W02010057 | 无水葡萄糖 | G | 60000 | IBI301 2nd 葡萄糖浓缩液 | A9 | 辅料 | ZB00 |
| IBI301 2nd-配液 | 0220 | W01010049 | Sheff-CHO Plus PF ACF | G | 13054.5 | IBI301 2nd 水解物浓缩液 | N/A | N/A | ZB00 |
| IBI301 2nd-配液 | 0230 | W02010058 | 碳酸氢钠 | G | 1598 | IBI301 2nd 碳酸氢钠溶液 | N/A | N/A | ZB00 |
| IBI301 2nd-配液 | 0240 | W02010064 | Tris | G | 2600 | IBI301 2nd亲和平衡液 | N/A | N/A | ZB00 |
| IBI301 2nd-配液 | 0250 | W02010065 | Tris-HCl | G | 28200 | IBI301 2nd亲和平衡液 | N/A | N/A | ZB00 |
| IBI301 2nd-配液 | 0260 | W02010072 | 氯化钠 | G | 87700 | IBI301 2nd亲和平衡液 | B1 | 主料 | ZB00 |
| IBI301 2nd-配液 | 0270 | W02010013 | 氯化钠 | G | 87700 | IBI301 2nd亲和平衡液 | B1 | 辅料 | ZB00 |
| IBI301 2nd-配液 | 0280 | W02010064 | Tris | G | 780 | IBI301 2nd亲和冲洗液 | N/A | N/A | ZB00 |
| IBI301 2nd-配液 | 0290 | W02010065 | Tris-HCl | G | 8,460 | IBI301 2nd亲和冲洗液 | N/A | N/A | ZB00 |
| IBI301 2nd-配液 | 0300 | W02010072 | 氯化钠 | G | 17,5320 | IBI301 2nd亲和冲洗液 | B2 | 主料 | ZB00 |
| IBI301 2nd-配液 | 0310 | W02010013 | 氯化钠 | G | 17,5320 | IBI301 2nd亲和冲洗液 | B2 | 辅料 | ZB00 |
| IBI301 2nd-配液 | 0320 | W01010036 | 冰醋酸 | ML | 18,000 | IBI301 2nd 亲和再生液 | N/A | N/A | ZB00 |
| IBI301 2nd-配液 | 0330 | W01010113 | 醋酸钠 | G | 1080 | IBI301 2nd 亲和洗脱液 | B3 | 主料 | ZB00 |
| IBI301 2nd-配液 | 0340 | W01010035 | 醋酸钠 | G | 1080 | IBI301 2nd 亲和洗脱液 | B3 | 辅料 | ZB00 |
| IBI301 2nd-配液 | 0350 | W01010036 | 冰醋酸 | ML | 8550 | IBI301 2nd 亲和洗脱液 | N/A | N/A | ZB00 |
| IBI301 2nd-配液 | 0360 | W01010113 | 醋酸钠 | G | 9,660 | IBI301 2nd ADF平衡液 | B4 | 主料 | ZB00 |
| IBI301 2nd-配液 | 0370 | W01010035 | 醋酸钠 | G | 9,660 | IBI301 2nd ADF平衡液 | B4 | 辅料 | ZB00 |
| IBI301 2nd-配液 | 0380 | W01010036 | 冰醋酸 | ML | 240 | IBI301 2nd ADF平衡液 | N/A | N/A | ZB00 |
| IBI301 2nd-配液 | 0390 | W02010014 | 枸橼酸（一水） | G | 6120 | IBI301 2nd阳离子平衡液 | B5 | 主料 | ZB00 |
| IBI301 2nd-配液 | 0400 | W02010032 | 枸橼酸（一水） | G | 6120 | IBI301 2nd阳离子平衡液 | B5 | 辅料 | ZB00 |
| IBI301 2nd-配液 | 0410 | W02010031 | 枸橼酸钠（二水） | G | 14960 | IBI301 2nd阳离子平衡液 | B6 | 主料 | ZB00 |
| IBI301 2nd-配液 | 0420 | W02010030 | 枸橼酸钠（二水） | G | 14960 | IBI301 2nd阳离子平衡液 | B6 | 辅料 | ZB00 |
| IBI301 2nd-配液 | 0430 | W02010014 | 枸橼酸（一水） | G | 2470 | IBI301 2nd 阳离子稀释液 | B7 | 主料 | ZB00 |
| IBI301 2nd-配液 | 0440 | W02010032 | 枸橼酸（一水） | G | 2470 | IBI301 2nd 阳离子稀释液 | B7 | 辅料 | ZB00 |
| IBI301 2nd-配液 | 0450 | W02010031 | 枸橼酸钠（二水） | G | 6110 | IBI301 2nd阳离子稀释液 | B8 | 主料 | ZB00 |
| IBI301 2nd-配液 | 0460 | W02010030 | 枸橼酸钠（二水） | G | 6110 | IBI301 2nd阳离子稀释液 | B8 | 辅料 | ZB00 |
| IBI301 2nd-配液 | 0470 | W01010113 | 醋酸钠 | G | 24480 | IBI301 2nd 阳离子洗脱液A | B9 | 主料 | ZB00 |
| IBI301 2nd-配液 | 0480 | W01010035 | 醋酸钠 | G | 24480 | IBI301 2nd 阳离子洗脱液A | B9 | 辅料 | ZB00 |
| IBI301 2nd-配液 | 0490 | W01010036 | 冰醋酸 | ML | 4250 | IBI301 2nd 阳离子洗脱液A | N/A | N/A | ZB00 |
| IBI301 2nd-配液 | 0500 | W01010113 | 醋酸钠 | G | 549450 | IBI301 2nd 阳离子洗脱液B | C1 | 主料 | ZB00 |
| IBI301 2nd-配液 | 0510 | W01010035 | 醋酸钠 | G | 549450 | IBI301 2nd 阳离子洗脱液B | C1 | 辅料 | ZB00 |
| IBI301 2nd-配液 | 0520 | W01010036 | 冰醋酸 | ML | 9300 | IBI301 2nd 阳离子洗脱液B | N/A | N/A | ZB00 |
| IBI301 2nd-配液 | 0530 | W01010036 | 冰醋酸 | ML | 4470 | IBI301 2nd阴离子平衡液 | N/A | N/A | ZB00 |
| IBI301 2nd-配液 | 0540 | W02010064 | Tris | G | 9150 | IBI301 2nd阴离子平衡液 | N/A | N/A | ZB00 |
| IBI301 2nd-配液 | 0550 | W01010036 | 冰醋酸 | ML | 3800 | IBI301 2nd阴离子洗脱液 | N/A | N/A | ZB00 |
| IBI301 2nd-配液 | 0560 | W02010064 | Tris | G | 7575 | IBI301 2nd阴离子洗脱液 | N/A | N/A | ZB00 |
| IBI301 2nd-配液 | 0570 | W02010072 | 氯化钠 | G | 73050 | IBI301 2nd阴离子洗脱液 | C2 | 主料 | ZB00 |
| IBI301 2nd-配液 | 0580 | W02010013 | 氯化钠 | G | 73050 | IBI301 2nd阴离子洗脱液 | C2 | 辅料 | ZB00 |
| IBI301 2nd-配液 | 0590 | W01010036 | 冰醋酸 | ML | 2980 | IBI301 2nd除病毒平衡缓冲液 | N/A | N/A | ZB00 |
| IBI301 2nd-配液 | 0600 | W02010064 | Tris | G | 9089 | IBI301 2nd除病毒平衡缓冲液 | N/A | N/A | ZB00 |
| IBI301 2nd-配液 | 0610 | W01010036 | 冰醋酸 | ML | 4,470 | IBI301 2nd 超滤平衡缓冲液 | N/A | N/A | ZB00 |
| IBI301 2nd-配液 | 0620 | W02010064 | Tris | G | 13,634 | IBI301 2nd 超滤平衡缓冲液 | N/A | N/A | ZB00 |
| IBI301 2nd-配液 | 0630 | W01010033 | 枸橼酸钠（二水） | G | 40500 | IBI301 2nd 洗滤缓冲液 | N/A | N/A | ZB00 |
| IBI301 2nd-配液 | 0640 | W01010032 | 氯化钠 | G | 33075 | BI301 2nd 洗滤缓冲液 | N/A | N/A | ZB00 |
| IBI301 2nd-配液 | 0650 | W01010033 | 枸橼酸钠（二水） | G | 270 | IBI301 2nd 50倍聚山梨酯80母液 | N/A | N/A | ZB00 |
| IBI301 2nd-配液 | 0660 | W01010032 | 氯化钠 | G | 221 | IBI301 2nd 50倍聚山梨酯80母液 | N/A | N/A | ZB00 |
| IBI301 2nd-配液 | 0670 | W01010017 | 聚山梨酯-80 | G | 1050 | IBI301 2nd 50倍聚山梨酯80母液 | N/A | N/A | ZB00 |
| IBI301 2nd-配液 | 0680 | W01010033 | 枸橼酸钠（二水） | G | 90 | IBI301 2nd制剂缓冲液 | N/A | N/A | ZB00 |
| IBI301 2nd-配液 | 0690 | W01010032 | 氯化钠 | G | 74 | IBI301 2nd制剂缓冲液 | N/A | N/A | ZB00 |
| IBI301 2nd-配液 | 0700 | W01010017 | 聚山梨酯-80 | G | 7 | IBI301 2nd制剂缓冲液 | N/A | N/A | ZB00 |
| IBI301 2nd-配液 | 0710 | W02010073 | 氢氧化钠 | G | 300000 | IBI301 2nd 0.5mol/L 氢氧化钠 | C3 | 主料 | ZB00 |
| IBI301 2nd-配液 | 0720 | W02010015 | 氢氧化钠 | G | 300000 | IBI301 2nd 0.5mol/L 氢氧化钠 | C3 | 辅料 | ZB00 |
| IBI301 2nd-配液 | 0730 | W02010073 | 氢氧化钠 | G | 24,000 | IBI301 2nd 0.1mol/L 氢氧化钠 | C4 | 主料 | ZB00 |
| IBI301 2nd-配液 | 0740 | W02010015 | 氢氧化钠 | G | 24,000 | IBI301 2nd 0.1mol/L 氢氧化钠 | C4 | 辅料 | ZB00 |
| IBI301 2nd-配液 | 0750 | W01010036 | 冰醋酸 | ML | 24000 | IBI301 2nd 2mol/L HAC | N/A | N/A | ZB00 |
| IBI301 2nd-配液 | 0760 | W02010064 | Tris | G | 48456 | IBI301 2nd 2 mol/L Tris | N/A | N/A | ZB00 |
| IBI301 2nd-配液 | 0770 | W03040066 | 苯甲醇 | ML | 40000 | IBI301 2nd 2% 苯甲醇 | N/A | N/A | ZB00 |
| IBI301 2nd-配液 | 0780 | W01040002 | 20L Flexboy生物工艺袋 | 个 | 1 | N/A | N/A | N/A | PBY0 |
| IBI301 2nd-配液 | 0790 | W01040012 | 50L Flexboy生物工艺袋 | 个 | 1 | N/A | N/A | N/A | PBY0 |
| IBI301 2nd-配液 | 0800 | W02040080 | 200L配液袋（Basic） | 个 | 4 | N/A | N/A | N/A | PBY0 |
| IBI301 2nd-配液 | 0810 | W02040080 | 200L配液袋（Basic） | 个 | 2 | N/A | N/A | N/A | PBX0 |
| IBI301 2nd-配液 | 0820 | W01040042 | 250L储液袋（带取样管路，RIM) | 个 | 2 | N/A | C8 | 主料 | PBX0 |
| IBI301 2nd-配液 | 0830 | W01040022 | 250L储液袋（底部出液） | 个 | 2 | N/A | C8 | 辅料 | PBX0 |
| IBI301 2nd-细胞 | 0840 | ICW301-GSB | IBI301二代细胞株（M1b）工作细胞库 | 支 | 1 | N/A | N/A | N/A | PBA3 |
| IBI301 2nd-细胞 | 0850 | W02040121 | 125 ml一次性无菌锥形瓶 | 个 | 1 | N/A | N/A | N/A | PBA3 |
| IBI301 2nd-细胞 | 0860 | W02040125 | 1000ml一次性无菌锥形瓶 | 个 | 1 | N/A | N/A | N/A | PBA3 |
| IBI301 2nd-细胞 | 0870 | W02040049 | 2000ml一次性无菌锥形瓶 | 个 | 5 | N/A | N/A | N/A | PBA3 |
| IBI301 2nd-细胞 | 0880 | W01040056 | 储液袋500L 3D BAG | 个 | 1 | N/A | C5 | 主料 | PBB3 |
| IBI301 2nd-细胞 | 0890 | W01040031 | 500L储液袋 | 个 | 1 | N/A | C5 | 辅料 | PBB3 |
| IBI301 2nd-细胞 | 0900 | W01040057 | 储液袋200L 3D BAG | 个 | 3 | N/A | C6 | 主料 | PBB3 |
| IBI301 2nd-细胞 | 0910 | W01040029 | 200L储液袋 | 个 | 3 | N/A | C6 | 辅料 | PBB3 |
| IBI301 2nd-细胞 | 0920 | W02040341 | WAVE50L 培养袋 | 个 | 1 | N/A | N/A | N/A | PBB3 |
| IBI301 2nd-细胞 | 0930 | W02010059 | 消泡剂 | ML | 1,500 | N/A | C7 | 主料 | PBB3 |
| IBI301 2nd-细胞 | 0940 | W10010001 | 消泡剂 | ML | 1,500 | N/A | C7 | 辅料 | PBB3 |
| IBI301 2nd-细胞 | 0950 | W10040056 | 1 m2纸板囊式过滤器 | 个 | 6 | N/A | C8 | 主料 | PBB3 |
| IBI301 2nd-细胞 | 0960 | W02040059 | D0HC 1.1 m2澄清过滤膜包 | 个 | 5 | N/A | C8 | 辅料 | PBB3 |
| IBI301 2nd-细胞 | 0970 | W10040059 | 1 m2纸板囊式过滤器 | 个 | 18 | N/A | C9 | 主料 | PBB3 |
| IBI301 2nd-细胞 | 0980 | W02040058 | X0HC 1.1 m2澄清过滤膜包 | 个 | 15 | N/A | C9 | 辅料 | PBB3 |
| IBI301 2nd-纯化 | 0990 | W01040032 | 12L celsius FFT 冻融容器 | 个 | 100 | N/A | N/A | N/A | PBC3 |
| IBI301 2nd-纯化 | 1000 | W02040086 | VPF 0.55m2除病毒预过滤器 | 个 | 10 | N/A | N/A | N/A | PBC3 |
| IBI301 2nd-纯化 | 1010 | W02040239 | 即用型接头工具包 | EA | 3 | N/A | N/A | N/A | PBC3 |
| IBI301 2nd-纯化 | 1020 | W02040085 | Vpro Magnus 2.1除病毒过滤膜 | 个 | 10 | N/A | N/A | N/A | PBC3 |
| IBI301 2nd-纯化 | 1030 | W02040058 | X0HC 1.1㎡澄清过滤膜包 | 个 | 14 | N/A | N/A | N/A | PBC3 |
| IBI301 2nd-纯化 | 1040 | W02040238 | 除病毒过滤系统接头套件 | EA | 2 | N/A | N/A | N/A | PBC3 |
| IBI301 2nd-纯化 | 1050 | CH301-ACB-2 | M2b三线IBI301 2nd亲和层析柱 | EA | 1 | N/A | N/A | N/A | PBC3 |
| IBI301 2nd-纯化 | 1060 | CH301-CEXB-2 | M2b三线IBI301 2nd阳离子层析柱 | EA | 2 | N/A | N/A | N/A | PBC3 |
| IBI301 2nd-纯化 | 1070 | CH301-AEXB-2 | M2b三线IBI301 2nd阴离子层析柱 | EA | 1 | N/A | N/A | N/A | PBC3 |
| IBI301 2nd-纯化 | 1080 | W02040379 | Pellicon3超滤膜包1.14 m2（30KD) | 个 | 20 | N/A | N/A | N/A | PBC3 |
| IBI301 2nd-纯化 | 1090 | W02040038 | 1000L配液袋（Plus) | 个 | 2 | N/A | N/A | N/A | PBC3 |

**第二部分：变更前后差异**

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| **变更前物料相关信息** | | | | | | | | | |
| 项目-工序 | 项目 | 物料编码 | 名称 | 单位 | 批用量 | 配方文本 | 替代组 | 替代关系 | 库位 |
| N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| **变更后物料相关信息** | | | | | | | | | |
| 项目-工序 | 项目 | 物料编码 | 名称 | 单位 | 批用量 | 配方文本 | 替代组 | 替代关系 | 库位 |
| N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |

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| **变更理由：**  新增M2 IBI301二代细胞株生产物料清单。 |