



MILLIPORE (UK) LTD CERTIFICATE OF ANALYSIS
MILLIPORE (UK) LTD 检验报告
MONOCLONAL BLOOD GROUPING REAGENT
血型定型试剂 (单克隆抗体)

PRODUCT SKU/物料号 : BM-10X10ML-CN
SPECIFICITY/特异性 : Anti-D/抗 D 抗体
CELL LINE/细胞系 : TH-28/MS-26
LOT NUMBER/批号 : BMG2405
PRODUCT APPEARANCE/外观 : CLEAR LIQUID/澄清液体
PROTEIN CONTENT/蛋白质含量 : 18 mg/mL RANGE/范围: 10-25 mg/mL
pH : 7.2 RANGE/范围: 7.1-7.3



	METHOD/ 方法	RED CELL 红细胞	END POINT 终点	TOTAL SCORE 总分	ACCEPTANCE CRITERIA 接受标准
POTENCY/ 效价:	15mins @ 18- 25°C IgM	RoR	1:1024	34.0	≥1:64
	30mins @ 37±1°C IAT IgG	RoR	1:512	27.5	≥1:128

MICROBIOLOGICAL STATE : This material has been filtered through a 0.2 µm filter and
微生物声明 has passed a Bioburden test after 3 to 5 days incubation in
Tryptic Soy Agar and 5 to 7 days incubation in Sabouraud
Dextrose Agar <1CFU/30mL
该产品经过 0.2 µm 过滤器过滤, 并在胰蛋白大豆琼脂上孵
育 3 到 5 天以及在沙氏葡萄糖琼脂上孵育 5 到 7 天后通过
了生物负载测试, 结果满足<1CFU/30mL 的要求。

STORAGE/存储 : REFRIGERATE AT 2-8°C/在 2-8°C 下冷藏。

COUNTRY OF MANUFACTURE : UNITED KINGDOM/英国
原产国

Bovine materials are obtained from USDA approved sources or from sources for which origin information is available. The donor animals for bovine material have been inspected and certified disease free and are deemed to have low TSE (Transmissible Spongiform Encephalopathy) risk.
牛源原料来自美国农业部 (USDA) 批准的来源或可以提供来源信息的来源。供体动物经过检查并认证为无疾病, 且被认为具有低传播性海绵状脑病 (TSE) 风险。

VIRUS TESTING/病毒检测 : Source material from which this Cell Line was tested non-
reactive for HIV, HBsAg and HCV.
此细胞系相关的原材料在 HIV、HBsAg 和 HCV 检测中均显示为阴性。

Millipore (U.K.) Limited
2-4 Fleming Rd, Kirkton Campus, Livingston EH54 7BN
Tel: +44 (0)15 0640 4000
Fax: +44 (0)15 0640 4001
Registered Number 04130249

www.merckgroup.com
Registered office:
Bedfont Cross, Stanwell Road
Feltham, Middlesex, TW14 8NX

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DATE OF MANUFACTURE生产日期 : 2024-07-19

EXPIRY DATE/失效日期 : 2027-07-18

The Certificate of Analysis for lot is applicable to sublots which are uniquely identified by a letter following the lot number./该批次的检验报告适用于在该批号后面增加字母作为唯一标识的子批次。

Sodium azide is present as a preservative, at a concentration of 0.1% w/v./叠氮化钠作为防腐剂存在, 浓度为 0.1% (w/v)。

No evidence of contaminating antibodies./没有抗体受到污染的证据。

Millipore confirms that the lot met all current specifications and was released for sale./ Millipore 确认该批次符合当前规定质量标准, 并已获准出售。



SIGNED/签字: Couise Banie

DATE/日期: 10 Jul 2025.

For Quality Assurance (Revision 1)

质量保证部门 (修订 1)

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