



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 : BMG2406
 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

	<u>METHOD/</u> <u>方法</u>	<u>RED CELL</u> <u>红细胞</u>	<u>END POINT</u> <u>终点</u>	<u>TOTAL SCORE</u> <u>总分</u>	<u>ACCEPTANCE</u> <u>CRITERIA</u> <u>接受标准</u>
POTENCY/ 效价:	15mins @ 18- 25°C IgM	R ₀ r	1:1024	32.5	≥1:64
	30mins @ 37±1°C IAT IgG	R ₀ r	1:512	28.5	≥1:128

MICROBIOLOGICAL STATE : This material has been filtered through a 0.2 µm filter and 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
 微生物声明 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。

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Millipore is a division of Merck KGaA



DATE OF MANUFACTURE 生产日期 : 2024-08-01

EXPIRY DATE/失效日期 : 2027-07-31



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: Louise Borne DATE/日期: 10 Jul 2025.

For Quality Assurance (Revision 1)

质量保证部门 (修订 1)

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