	文件类型	技术文件	文件版本	V4.1.0
	项目代号	/	页 码	第0页 共 2页
	文件编号	GLDM-56-17-en		

文件名称:

CONTROL DM-RET RET0124 2024-03-10

适用范围: 1116 项目、7003 项目

编制: 夏琳 日期: 2023.12.29	审核: 刘金盈 日期: 2023.12.29	批准: 郑剑通 日期: 2023.12.29
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修 订 记 录

版本	TCN/ECR/PCN 编号	修订内容概要	修改人	批准人	批准日期
V4.1.0	/	新建	夏琳	郑剑通	2023.12.29

发至:	<input type="checkbox"/> 总经办 <input type="checkbox"/> 质量部 <input type="checkbox"/> 财务部 <input checked="" type="checkbox"/> 营销部 <input checked="" type="checkbox"/> 客服 <input type="checkbox"/> 计划 <input type="checkbox"/> 采购 <input checked="" type="checkbox"/> 工程 <input type="checkbox"/> 仓库 <input checked="" type="checkbox"/> 设备研发 <input checked="" type="checkbox"/> 试剂研发 <input type="checkbox"/> 物料质量 <input type="checkbox"/> 设备生产 <input type="checkbox"/> 试剂生产 <input checked="" type="checkbox"/> 试剂质检 <input checked="" type="checkbox"/> 设备质检
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由试剂研发

DM-RET

HEMATOLOGY CONTROL

CONTROL

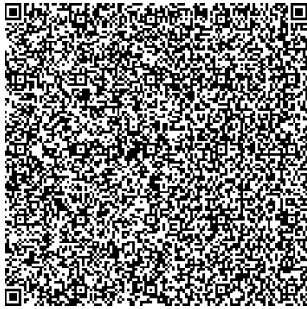
📅 2023-12-12

🕒 2024-03-10

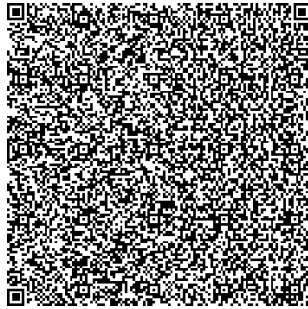
Applicable Instruments	Parameter	Unit	LOT RET0124L	LOT RET0124N	LOT RET0124H
DYMIND	RET#	×10 ¹² /L	0.0454 ±0.0227	0.2390 ±0.1316	0.3084 ±0.1200
DH-600	RET%	%	0.79 ±0.39	5.12 ±2.05	13.33 ±4.50
DH-602	LFR	%	89.9 ±27.0	82.0 ±25.0	89.5 ±27.0
DH-605	MFR	%	8.0 ±12.0	16.7 ±25.0	8.5 ±13.0
DH-610	HFR	%	2.2 ±3.0	1.3 ±2.0	2.1 ±3.0
DH-612	IRF	%	10.1 ±15.0	18.0 ±27.0	10.5 ±16.0
DH-615	RHE	pg	15.4 ±6.0	16.2 ±6.0	15.4 ±6.0
(Technical File Version A2.0 or higher)					

【NOTE】

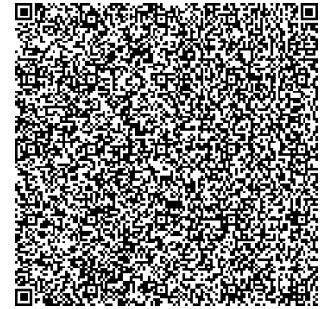
1. The controls should be stored in refrigerator (2℃~8℃). After opening, it will keep stable for 14 days when it is stored airtight at 2℃~8℃.
2. Before mixing and running the control after take it out from the refrigerator, please keep it at least 15 minutes until reaching room temperature(15℃~30℃).
3. Controls must be well mixed before using. Please mix gently, to avoid cells rupture and/or generating bubbles.
4. After using, put the controls back into the refrigerator to prevent contamination and evaporation.



RET0124L



RET0124N





RET0124H

DM-RET

HEMATOLOGY CONTROL

CONTROL

 2023-12-12

 2024-03-10

Applicable Instruments	Parameter	Unit	LOT RET0124L	LOT RET0124N	LOT RET0124H
DYMIND DM60 Vet DM61 Vet DM62 Vet DM63 Vet (Technical File Version A1.4 or higher)	RET#	$\times 10^{12}/L$	0.0274 ± 0.0219	0.1525 ± 0.0763	0.1791 ± 0.0896
	RET%	%	0.47 ± 0.38	3.23 ± 1.62	7.47 ± 3.74

【NOTE】

1. The controls should be stored in refrigerator (2°C~8°C). After opening, it will keep stable for 14 days when it is stored airtight at 2°C~8°C.
2. Before mixing and running the control after take it out from the refrigerator, please keep it at least 15 minutes until reaching room temperature(15°C~30°C).
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RET0124L



RET0124N



RET0124H