

	文件类型	技术文件	文件版本	V4.4.0		
	项目代号	/	页码	第0页 共3页		
	文件编号	GL DM-56-18-en				
文件名称： <p style="text-align: center;"><b>CONTROL DM-6D 6D0824 2024-10-10</b></p> 适用范围： 1116项目、1117项目、K1116项目						
编制：石丽岐 日期：2024.07.29		审核：刘金盈 日期：2024.07.29		批准：郑剑通 日期：2024.07.29		
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
V4.4.0	/	新建		石丽岐	郑剑通	2024.07.29
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					
由试剂研发						

# DM-6D

## HEMATOLOGY CONTROL

Reference Values provided by DYMIND

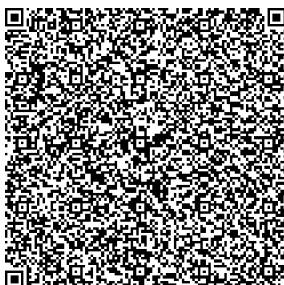
**CONTROL**
 2024-07-13

 2024-10-10

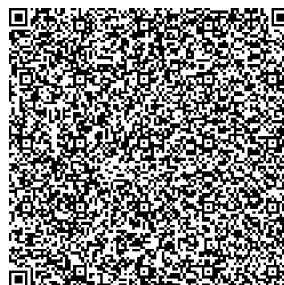
Applicable Instruments	Parameter	Unit	LOT 6D0824L	LOT 6D0824N	LOT 6D0824H
DYMIND DH-600 DH-602 DH-605 DH-610 DH-612 DH-615 (Technical File Version A2.0 or higher)	WBC	$\times 10^9/L$	<b>4.40</b> $\pm 1.20$	<b>7.75</b> $\pm 1.80$	<b>22.36</b> $\pm 3.00$
	Neu#	$\times 10^9/L$	3.12 $\pm 0.40$	4.80 $\pm 0.80$	15.96 $\pm 2.00$
	Lym#	$\times 10^9/L$	0.73 $\pm 0.40$	2.06 $\pm 0.70$	4.63 $\pm 1.80$
	Mon#	$\times 10^9/L$	0.34 $\pm 0.34$	0.52 $\pm 0.50$	0.86 $\pm 0.80$
	Eos#	$\times 10^9/L$	0.22 $\pm 0.22$	0.37 $\pm 0.37$	0.91 $\pm 0.91$
	Bas#	$\times 10^9/L$	3.41 $\pm 0.40$	5.54 $\pm 0.70$	16.47 $\pm 1.60$
	IG#	$\times 10^9/L$	0.57 $\pm 0.50$	0.86 $\pm 0.86$	2.71 $\pm 2.50$
	Neu%	%	70.8 $\pm 12.0$	61.9 $\pm 12.0$	71.4 $\pm 12.0$
	Lym%	%	16.6 $\pm 10.0$	26.6 $\pm 10.0$	20.7 $\pm 10.0$
	Mon%	%	7.6 $\pm 7.6$	6.8 $\pm 6.8$	3.8 $\pm 3.8$
	Eos%	%	5.0 $\pm 5.0$	4.8 $\pm 4.8$	4.1 $\pm 4.1$
	Bas%	%	77.6 $\pm 10.0$	71.5 $\pm 10.0$	73.6 $\pm 10.0$
	IG%	%	12.9 $\pm 10.0$	11.1 $\pm 10.0$	12.1 $\pm 10.0$
	RBC	$\times 10^{12}/L$	<b>2.35</b> $\pm 0.20$	<b>4.63</b> $\pm 0.30$	<b>5.32</b> $\pm 0.50$
	HGB	g/L	<b>62</b> $\pm 4$	<b>136</b> $\pm 6$	<b>174</b> $\pm 8$
	HCT	%	18.4 $\pm 2.0$	40.3 $\pm 2.5$	51.4 $\pm 3.0$
	MCV	fL	<b>78.7</b> $\pm 5.0$	<b>86.9</b> $\pm 5.0$	<b>96.7</b> $\pm 5.0$
	MCH	pg	26.6 $\pm 2.5$	29.4 $\pm 2.5$	32.7 $\pm 2.5$
	MCHC	g/L	338 $\pm 30$	338 $\pm 30$	338 $\pm 30$
	RDW-CV	%	17.0 $\pm 5.0$	15.1 $\pm 5.0$	14.5 $\pm 6.0$
	RDW-SD	fL	48.9 $\pm 10.0$	48.6 $\pm 10.0$	51.2 $\pm 12.0$
	PLT	$\times 10^9/L$	<b>67</b> $\pm 20$	<b>259</b> $\pm 45$	<b>517</b> $\pm 65$
	MPV	fL	7.4 $\pm 3.0$	7.2 $\pm 3.0$	7.6 $\pm 3.0$
	PDW	fL	8.9 $\pm 5.0$	8.8 $\pm 5.0$	9.9 $\pm 5.0$
	PCT	%	0.050 $\pm 0.050$	0.185 $\pm 0.100$	0.395 $\pm 0.200$
	P-LCR	%	11.6 $\pm 11.6$	9.0 $\pm 9.0$	11.0 $\pm 11.0$
P-LCC	$\times 10^9/L$	10 $\pm 10$	24 $\pm 24$	58 $\pm 50$	
IPF	%	2.4 $\pm 2.4$	1.9 $\pm 1.9$	2.0 $\pm 2.0$	

**【NOTE】**

- 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.
- 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).
- Controls must be well mixed before using. Please mix gently, to avoid cells rupture and/or generating bubbles.
- After using, put the controls back into the refrigerator to prevent contamination and evaporation.



6D0824L




6D0824N




6D0824H

# DM-6D

## HEMATOLOGY CONTROL

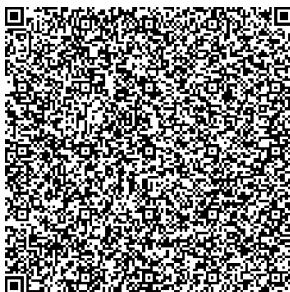
**Reference Values provided by DYMIND**
**CONTROL**
 2024-07-13

 2024-10-10

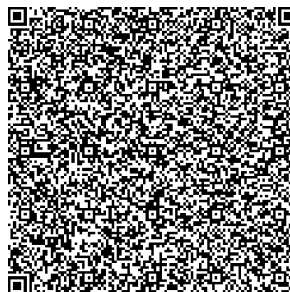
Applicable Instruments	Parameter	Unit	LOT 6D0824L	LOT 6D0824N	LOT 6D0824H
DYMIND DH-800 series DH-800 CRP series DH-800 CS series (Technical File Version A1.3 or higher)	<b>WBC</b>	$\times 10^9/L$	<b>3.99</b> $\pm 1.20$	<b>7.53</b> $\pm 1.80$	<b>20.77</b> $\pm 3.00$
	Neu#	$\times 10^9/L$	2.88 $\pm 0.40$	4.76 $\pm 0.80$	15.22 $\pm 2.00$
	Lym#	$\times 10^9/L$	0.63 $\pm 0.40$	1.93 $\pm 0.70$	4.00 $\pm 1.80$
	Mon#	$\times 10^9/L$	0.28 $\pm 0.28$	0.48 $\pm 0.48$	0.70 $\pm 0.70$
	Eos#	$\times 10^9/L$	0.20 $\pm 0.20$	0.36 $\pm 0.36$	0.85 $\pm 0.85$
	Bas#	$\times 10^9/L$	0.12 $\pm 0.12$	0.21 $\pm 0.21$	0.64 $\pm 0.64$
	IG#	$\times 10^9/L$	0.54 $\pm 0.50$	0.85 $\pm 0.85$	2.60 $\pm 2.50$
	Neu%	%	72.1 $\pm 12.0$	63.2 $\pm 12.0$	73.3 $\pm 12.0$
	Lym%	%	15.8 $\pm 10.0$	25.6 $\pm 10.0$	19.3 $\pm 10.0$
	Mon%	%	7.1 $\pm 7.1$	6.4 $\pm 6.4$	3.4 $\pm 3.4$
	Eos%	%	5.0 $\pm 5.0$	4.8 $\pm 4.8$	4.1 $\pm 4.1$
	Bas%	%	3.0 $\pm 3.0$	2.7 $\pm 2.7$	3.1 $\pm 3.1$
	IG%	%	13.4 $\pm 10.0$	11.3 $\pm 10.0$	12.5 $\pm 10.0$
	<b>RBC</b>	$\times 10^{12}/L$	<b>2.43</b> $\pm 0.20$	<b>4.73</b> $\pm 0.30$	<b>5.44</b> $\pm 0.50$
	<b>HGB</b>	g/L	<b>64</b> $\pm 4$	<b>139</b> $\pm 6$	<b>177</b> $\pm 8$
	HCT	%	19.9 $\pm 2.0$	42.8 $\pm 2.5$	54.4 $\pm 3.0$
	MCV	fL	<b>82.0</b> $\pm 5.0$	<b>90.4</b> $\pm 5.0$	<b>99.9</b> $\pm 5.0$
	MCH	pg	26.2 $\pm 2.5$	29.4 $\pm 2.5$	32.5 $\pm 2.5$
	MCHC	g/L	319 $\pm 30$	325 $\pm 30$	326 $\pm 30$
	RDW-CV	%	18.5 $\pm 5.0$	15.8 $\pm 5.0$	14.6 $\pm 6.0$
	RDW-SD	fL	52.7 $\pm 10.0$	50.5 $\pm 10.0$	51.7 $\pm 12.0$
	<b>PLT</b>	$\times 10^9/L$	<b>71</b> $\pm 20$	<b>248</b> $\pm 45$	<b>494</b> $\pm 65$
	MPV	fL	8.4 $\pm 3.0$	7.8 $\pm 3.0$	8.4 $\pm 3.0$
	PDW	fL	8.6 $\pm 5.0$	8.0 $\pm 5.0$	8.8 $\pm 5.0$
	PCT	%	0.059 $\pm 0.050$	0.193 $\pm 0.100$	0.416 $\pm 0.200$
	P-LCR	%	14.1 $\pm 14.1$	10.6 $\pm 10.6$	13.0 $\pm 13.0$
	P-LCC	$\times 10^9/L$	10 $\pm 10$	26 $\pm 26$	63 $\pm 50$
	IPF	%	12.4 $\pm 12.4$	12.4 $\pm 12.4$	12.6 $\pm 12.6$
NRBC#	$\times 10^9/L$	0.24 $\pm 0.24$	0.04 $\pm 0.04$	1.42 $\pm 0.40$	
NRBC%	%	5.8 $\pm 4.0$	0.6 $\pm 0.6$	6.8 $\pm 4.0$	

**【NOTE】**

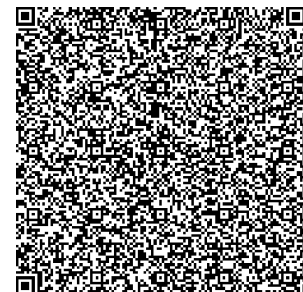
- The controls should be stored in refrigerator (2°C~8°C). After opening, it will keep stable for 14 days when it is stored airtight at 2°C~8°C.
- Before mixing and running the control after take it out from the refrigerator, please keep it at least 15 minutes until reaching room temperature(15°C~30°C).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



6D0824L



6D0824N





6D0824H

# DM-6D

## HEMATOLOGY CONTROL

Reference Values provided by DYMIND

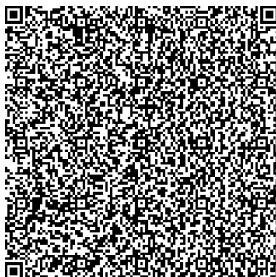
**CONTROL**
 2024-07-13

 2024-10-10

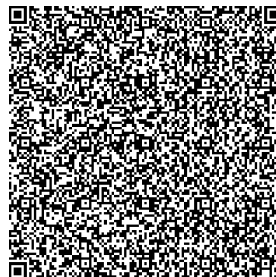
Applicable Instruments	Parameter	Unit	LOT 6D0824L	LOT 6D0824N	LOT 6D0824H
DYMIND  H7100 (Technical File Version A2.5 or higher)	WBC	$\times 10^9/L$	<b>4.40</b> $\pm 1.20$	<b>7.75</b> $\pm 1.80$	<b>22.36</b> $\pm 3.00$
	Neu#	$\times 10^9/L$	3.12 $\pm 0.40$	4.80 $\pm 0.80$	15.96 $\pm 2.00$
	Lym#	$\times 10^9/L$	0.73 $\pm 0.40$	2.06 $\pm 0.70$	4.63 $\pm 1.80$
	Mon#	$\times 10^9/L$	0.34 $\pm 0.34$	0.52 $\pm 0.50$	0.86 $\pm 0.80$
	Eos#	$\times 10^9/L$	0.22 $\pm 0.22$	0.37 $\pm 0.37$	0.91 $\pm 0.91$
	Bas#	$\times 10^9/L$	3.41 $\pm 0.40$	5.54 $\pm 0.70$	16.47 $\pm 1.60$
	IG#	$\times 10^9/L$	0.57 $\pm 0.50$	0.86 $\pm 0.86$	2.71 $\pm 2.50$
	Neu%	%	70.8 $\pm 12.0$	61.9 $\pm 12.0$	71.4 $\pm 12.0$
	Lym%	%	16.6 $\pm 10.0$	26.6 $\pm 10.0$	20.7 $\pm 10.0$
	Mon%	%	7.6 $\pm 7.6$	6.8 $\pm 6.8$	3.8 $\pm 3.8$
	Eos%	%	5.0 $\pm 5.0$	4.8 $\pm 4.8$	4.1 $\pm 4.1$
	Bas%	%	77.6 $\pm 10.0$	71.5 $\pm 10.0$	73.6 $\pm 10.0$
	IG%	%	12.9 $\pm 10.0$	11.1 $\pm 10.0$	12.1 $\pm 10.0$
	RBC	$\times 10^{12}/L$	<b>2.35</b> $\pm 0.20$	<b>4.63</b> $\pm 0.30$	<b>5.32</b> $\pm 0.50$
	HGB	g/L	<b>62</b> $\pm 4$	<b>136</b> $\pm 6$	<b>174</b> $\pm 8$
	HCT	%	18.4 $\pm 2.0$	40.3 $\pm 2.5$	51.4 $\pm 3.0$
	MCV	fL	<b>78.7</b> $\pm 5.0$	<b>86.9</b> $\pm 5.0$	<b>96.7</b> $\pm 5.0$
	MCH	pg	26.6 $\pm 2.5$	29.4 $\pm 2.5$	32.7 $\pm 2.5$
	MCHC	g/L	338 $\pm 30$	338 $\pm 30$	338 $\pm 30$
	RDW-CV	%	17.0 $\pm 5.0$	15.1 $\pm 5.0$	14.5 $\pm 6.0$
	RDW-SD	fL	48.9 $\pm 10.0$	48.6 $\pm 10.0$	51.2 $\pm 12.0$
	PLT	$\times 10^9/L$	<b>67</b> $\pm 20$	<b>259</b> $\pm 45$	<b>517</b> $\pm 65$
	MPV	fL	7.4 $\pm 3.0$	7.2 $\pm 3.0$	7.6 $\pm 3.0$
	PDW-SD	fL	8.9 $\pm 5.0$	8.8 $\pm 5.0$	9.9 $\pm 5.0$
	PDW-CV	%	12.6 $\pm 5.0$	12.6 $\pm 5.0$	13.3 $\pm 5.0$
	PCT	%	0.050 $\pm 0.050$	0.185 $\pm 0.100$	0.395 $\pm 0.200$
	P-LCR	%	11.6 $\pm 11.6$	9.0 $\pm 9.0$	11.0 $\pm 11.0$
	P-LCC	$\times 10^9/L$	10 $\pm 10$	24 $\pm 24$	58 $\pm 50$
IPF#	$\times 10^9/L$	8.0 $\pm 5.0$	32.0 $\pm 10.0$	63.0 $\pm 20.0$	
IPF%	%	12.2 $\pm 12.0$	12.1 $\pm 12.0$	12.0 $\pm 12.0$	

**【NOTE】**

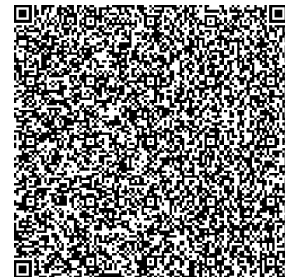
1. The controls should be stored in refrigerator (2°C~8°C). After opening, it will keep stable for 14 days when it is stored airtight at 2°C~8°C.
2. Before mixing and running the control after take it out from the refrigerator, please keep it at least 15 minutes until reaching room temperature(15°C~30°C).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



6D0824L



6D0824N



6D0824H