

	文件类型	技术文件	文件版本	V8.3.0		
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	文件编号	GL DM-56-03-en				
文件名称： <p style="text-align: center;">CONTROL DM-3D B0822 2022-11-10</p> 适用范围：公司所有三分类仪器						
编制：		审核：		批准：		
日期：		日期：		日期：		
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
V8.3.0	/	新建		陈霁田	郑剑通	2022.07.22
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-3D

HEMATOLOGY CONTROL

Reference Values provided by DYMIND

CONTROL

2022-07-14

2022-11-10

Applicable Instrument	Parameter	Unit	LOT B0822L	LOT B0822N	LOT B0822H
DYMIND DH31 DH33 DH36 (Technical File Version A5.0 or higher) DH31 Vet DH36 Vet (Technical File Version A1.0 to A4.0)	WBC	×10 ⁹ /L	1.96 ±0.60	7.74 ±1.00	20.90 ±2.50
	Gran%	%	61.4 ±9.0	32.0 ±8.0	13.1 ±8.0
	Lym%	%	28.6 ±9.0	60.9 ±8.0	82.5 ±8.0
	Mid%	%	10.0 ±10.0	7.1 ±6.0	4.4 ±4.0
	Gran#	×10 ⁹ /L	1.20 ±0.30	2.48 ±0.70	2.74 ±2.00
	Lym#	×10 ⁹ /L	0.56 ±0.30	4.71 ±0.70	17.24 ±2.00
	Mid#	×10 ⁹ /L	0.20 ±0.20	0.55 ±0.50	0.92 ±0.50
	RBC	×10 ¹² /L	2.30 ±0.24	4.74 ±0.24	5.89 ±0.30
	HGB	g/L	55 ±6	136 ±6	190 ±8
	HCT	%	17.5 ±2.0	41.9 ±3.0	57.0 ±4.0
	MCV	fL	76.1 ±5.0	88.3 ±5.0	96.8 ±5.0
	MCH	pg	23.4 ±2.5	28.0 ±2.5	31.4 ±2.5
	MCHC	g/L	311 ±30	318 ±30	328 ±30
	RDW-CV	%	17.5 ±3.0	16.9 ±3.0	16.8 ±3.0
	RDW-SD	fL	45.5 ±8.0	51.2 ±8.0	55.4 ±8.0
	PLT	×10 ⁹ /L	70 ±20	271 ±40	544 ±60
	MPV	fL	9.1 ±3.0	9.9 ±3.0	9.8 ±3.0
	PDW	fL	11.4 ±3.0	12.8 ±3.0	13.0 ±3.0
	PCT	%	0.065 ±0.065	0.273 ±0.200	0.542 ±0.200
	P-LCR	%	21.5 ±10.0	27.3 ±10.0	26.6 ±10.0
P-LCC	×10 ⁹ /L	15 ±15	75 ±25	147 ±30	
PDW	/	15.9 ±3.0	16.2 ±3.0	16.3 ±3.0	

【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.



Low



Normal



High

DM-3D

HEMATOLOGY CONTROL

Reference Values provided by DYMIND

CONTROL

2022-07-14

2022-11-10

Applicable Instrument	Parameter	Unit	LOT B0822L	LOT B0822N	LOT B0822H
DYMIND DH20 DH21 DH22 DH23 DH25 DH26 (Technical File Version A1.0 or higher)	WBC	×10 ⁹ /L	1.97 ±0.60	7.68 ±1.00	20.47 ±2.50
	Gran%	%	61.8 ±9.0	31.5 ±8.0	12.8 ±8.0
	Lym%	%	28.2 ±9.0	62.5 ±8.0	83.2 ±8.0
	Mid%	%	10.0 ±10.0	6.0 ±6.0	4.0 ±4.0
	Gran#	×10 ⁹ /L	1.22 ±0.30	2.42 ±0.70	2.62 ±2.00
	Lym#	×10 ⁹ /L	0.55 ±0.30	4.80 ±0.70	17.03 ±2.00
	Mid#	×10 ⁹ /L	0.20 ±0.20	0.46 ±0.46	0.82 ±0.50
	RBC	×10 ¹² /L	2.30 ±0.24	4.60 ±0.24	5.64 ±0.30
	HGB	g/L	54 ±6	132 ±6	185 ±8
	HCT	%	16.9 ±2.0	37.7 ±3.0	50.4 ±4.0
	MCV	fL	73.4 ±5.0	81.9 ±5.0	89.3 ±5.0
	MCH	pg	23.4 ±2.5	28.9 ±2.5	32.9 ±2.5
	MCHC	g/L	324 ±30	355 ±30	371 ±30
	RDW-CV	%	16.8 ±3.0	15.6 ±3.0	15.0 ±3.0
	RDW-SD	fL	46.0 ±8.0	47.3 ±8.0	49.6 ±8.0
	PLT	×10 ⁹ /L	64 ±20	272 ±40	558 ±60
	MPV	fL	10.2 ±3.0	10.4 ±3.0	10.3 ±3.0
	PDW	fL	11.0 ±3.0	11.6 ±3.0	11.9 ±3.0
	PCT	%	0.067 ±0.067	0.288 ±0.200	0.585 ±0.200
	P-LCR	%	28.8 ±10.0	30.0 ±10.0	29.3 ±10.0
P-LCC	×10 ⁹ /L	19 ±15	83 ±25	167 ±30	

【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.



Low



Normal



High

DM-3D

HEMATOLOGY CONTROL

Reference Values provided by DYMIND

CONTROL

2022-07-14

2022-11-10

Applicable Instrument	Parameter	Unit	LOT B0822L	LOT B0822N	LOT B0822H
DYMIND DH31 Vet DH36 Vet (Technical File Version A5.0 or higher)	WBC	×10 ⁹ /L	1.85 ±0.60	7.47 ±1.00	20.06 ±2.50
	Gran%	%	59.2 ±9.0	30.9 ±8.0	12.2 ±8.0
	Lym%	%	30.0 ±9.0	63.0 ±8.0	83.8 ±8.0
	Mid%	%	10.8 ±10.0	6.1 ±6.0	4.0 ±4.0
	Gran#	×10 ⁹ /L	1.10 ±0.30	2.31 ±0.70	2.45 ±2.00
	Lym#	×10 ⁹ /L	0.55 ±0.30	4.70 ±0.70	16.81 ±2.00
	Mid#	×10 ⁹ /L	0.20 ±0.20	0.46 ±0.46	0.80 ±0.50
	RBC	×10 ¹² /L	2.20 ±0.24	4.46 ±0.24	5.50 ±0.30
	HGB	g/L	53 ±6	128 ±6	178 ±8
	HCT	%	17.6 ±2.0	40.3 ±3.0	54.4 ±4.0
	MCV	fL	80.0 ±5.0	90.2 ±5.0	98.9 ±5.0
	MCH	pg	23.4 ±2.5	27.8 ±2.5	31.6 ±2.5
	MCHC	g/L	296 ±30	312 ±30	324 ±30
	RDW-CV	%	16.2 ±3.0	14.8 ±3.0	14.1 ±3.0
	RDW-SD	fL	51.0 ±8.0	52.2 ±8.0	54.4 ±8.0
	PLT	×10 ⁹ /L	66 ±20	263 ±40	550 ±60
	MPV	fL	10.9 ±3.0	11.7 ±3.0	11.5 ±3.0
	PDW	fL	10.8 ±3.0	11.9 ±3.0	12.0 ±3.0
PCT	%	0.073 ±0.073	0.313 ±0.200	0.643 ±0.200	

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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.
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Low



Normal



High

DM-3D

HEMATOLOGY CONTROL

Reference Values provided by DYMIND

CONTROL

2022-07-14

2022-11-10

Applicable Instrument	Parameter	Unit	LOT B0822L	LOT B0822N	LOT B0822H
DYMIND DH36X (Technical File Version A1.0 or higher)	WBC	×10 ⁹ /L	1.95 ±0.60	7.72 ±1.00	20.59 ±2.50
	Gran%	%	69.1 ±9.0	36.4 ±8.0	15.2 ±8.0
	Lym%	%	27.9 ±9.0	57.6 ±8.0	79.3 ±8.0
	Mid%	%	3.0 ±3.0	6.0 ±6.0	5.5 ±4.0
	Gran#	×10 ⁹ /L	1.35 ±0.30	2.81 ±0.70	3.13 ±2.00
	Lym#	×10 ⁹ /L	0.54 ±0.30	4.45 ±0.70	16.33 ±2.00
	Mid#	×10 ⁹ /L	0.06 ±0.06	0.46 ±0.46	1.13 ±0.50
	RBC	×10 ¹² /L	2.26 ±0.24	4.57 ±0.24	5.61 ±0.30
	HGB	g/L	54 ±6	132 ±6	182 ±8
	HCT	%	17.3 ±2.0	39.0 ±3.0	52.7 ±4.0
	MCV	fL	76.4 ±5.0	85.4 ±5.0	93.9 ±5.0
	MCH	pg	23.3 ±2.5	28.1 ±2.5	31.7 ±2.5
	MCHC	g/L	311 ±30	331 ±30	343 ±30
	RDW-CV	%	17.2 ±3.0	15.7 ±3.0	15.0 ±3.0
	RDW-SD	fL	48.8 ±8.0	49.8 ±8.0	51.7 ±8.0
	PLT	×10 ⁹ /L	68 ±20	267 ±40	549 ±60
	MPV	fL	9.6 ±3.0	10.4 ±3.0	10.2 ±3.0
	PDW	fL	13.0 ±3.0	14.1 ±3.0	14.4 ±3.0
	PCT	%	0.067 ±0.067	0.285 ±0.200	0.576 ±0.200
	P-LCR	%	30.1 ±10.0	35.3 ±10.0	34.1 ±10.0
P-LCC	×10 ⁹ /L	21 ±15	97 ±25	193 ±30	

【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.
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