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文件名称： <p style="text-align: center;">Table of C-Reactive Protein Control (CRP) Reference Value 2025073101</p> 适用范围： DM3113项目、DM3513项目					
编制：刘金盈 日期：2025.08.27		审核：冯会娟 日期：2025.08.27		批准：程军 日期：2025.08.27	
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版本	TCN/ECR/PCN编号	修订内容概要	修改人	批准人	批准日期
V6.3.0	/	新建	刘金盈	程军	2025.08.27
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由工程					

Table of C-Reactive Protein Control (CRP) Reference Value

C-Reactive Protein Control

LOT 2025073101


 2026-07-30

Applicable Instruments	Level	Reference Value (mg/L)	Deviation Range (mg/L)	Applicable Instruments	Level	Reference Value (mg/L)	Deviation Range (mg/L)
DH51CRP, DH53CRP, DH56CRP, D1-CRP, D3-CRP, D5-CRP (Technical file version A11.10 or higher with heating)	Control 1	4.2	±1.2	DH51CRP, DH53CRP, DH56CRP, D1-CRP, D3-CRP, D5-CRP (Technical file version A11.10 or higher without heating)	Control 1	4.2	±1.3
	Control 2	16.3	±4.9		Control 2	16.2	±4.9
	Control 3	36.5	±10.9		Control 3	37.2	±11.2
DH71CRP, DH73CRP, D2-CRP, D7-CRP (Technical file version A6.0 or higher with heating)	Control 1	3.4	±1.0	DH71CRP, DH73CRP, D2-CRP, D7-CRP (Technical file version A6.0 or higher without heating)	Control 1	3.8	±1.1
	Control 2	15.1	±4.5		Control 2	16.9	±5.1
	Control 3	36.5	±10.9		Control 3	40.6	±12.2
D6-CRP, DH76CRP (Technical file version B2.0)	Control 1	3.3	±1.0	D6-CRP, DH76CRP (Technical file version B2.2 or higher)	Control 1	3.3	±1.0
	Control 2	15.3	±4.6		Control 2	14.9	±4.5
	Control 3	39.3	±11.8		Control 3	35.6	±10.7
DF1-CRP, DF3-CRP, DF5-CRP, DF50CRP, DF52CRP, DF53CRP (Technical file version A6.0 or higher with heating)	Control 1	2.9	±0.9	DF1-CRP, DF3-CRP, DF5-CRP, DF50CRP, DF52CRP, DF53CRP (Technical file versions A8.1 and below without heating)	Control 1	3.5	±1.1
	Control 2	14.7	±4.4		Control 2	17.9	±5.4
	Control 3	36.8	±11.0		Control 3	43.1	±12.9

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C-Reactive Protein Control

LOT 2025073101

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Applicable Instruments	Level	Reference Value (mg/L)	Deviation Range (mg/L)	Applicable Instruments	Level	Reference Value (mg/L)	Deviation Range (mg/L)
DM79X, DM78X, DM72X (Technical file version A1.0 or higher)	Control 1	3.78	±1.1	DH36X, DH33X, DH31X (Technical file versions A1.0 or higher)	Control 1	3.5	±1.1
	Control 2	15.68	±4.7		Control 2	14.9	±4.5
	Control 3	37.33	±11.2		Control 3	35.4	±10.6
DP-H10, DP-H12, DP-H13, DP-H15, DP-H16, DP-H17 (Technical file versions A1.0 or higher)	Control 1	4.2	±1.3	DH-800 CRP series DH-800 CS series (Technical file Version A1.3 or higher)	Control 1	3.00	±0.90
	Control 2	17.2	±5.1		Control 2	15.46	±4.64
	Control 3	44.2	±13.2		Control 3	35.76	±10.73
DH-2000T series , DH-100T, DH-102T DH-103T, DH-105T DH-106T, DH-108T (Technical file version A2.0 or higher)	Control 1	3.18	±0.95	/	Control 1	/	/
	Control 2	15.19	±4.56		Control 2	/	/
	Control 3	38.72	±11.62		Control 3	/	/