

# DM-CAL PLUS

## HEMATOLOGY CALIBRATOR

Assay values and ranges provided by DYMIND

**CALIBRATOR**

LOT NK0721

2021-06-12

2021-08-10

| Instrument   | Parameter | Unit               | Reference Value | Deviation  |
|--|-----------|--------------------|-----------------|------------|
| D1-CRP, D3-CRP, D5-CRP<br>DH51CRP, DH53CRP, DH56CRP<br>(Technical File Version A9.0 to A11.9)    | WBC       | $\times 10^9/L$    | 9.01            | $\pm 0.20$ |
|  | RBC       | $\times 10^{12}/L$ | 4.41            | $\pm 0.08$ |
|  | HGB       | g/L                | 135             | $\pm 2$    |
|  | MCV       | fL                 | 93.7            | $\pm 2.0$  |
|  | PLT       | $\times 10^9/L$    | 258             | $\pm 12$   |
| D1-CRP, D3-CRP, D5-CRP<br>DH51CRP, DH53CRP, DH56CRP<br>(Technical File Version A11.11)           | WBC       | $\times 10^9/L$    | 9.69            | $\pm 0.20$ |
|  | RBC       | $\times 10^{12}/L$ | 4.45            | $\pm 0.08$ |
|  | HGB       | g/L                | 136             | $\pm 2$    |
|  | MCV       | fL                 | 88.5            | $\pm 2.0$  |
|  | PLT       | $\times 10^9/L$    | 258             | $\pm 12$   |
| D1-CRP, D3-CRP, D5-CRP<br>DH51CRP, DH53CRP, DH56CRP<br>(Technical File Version A11.12 or higher) | WBC       | $\times 10^9/L$    | 10.05           | $\pm 0.20$ |
|  | RBC       | $\times 10^{12}/L$ | 4.49            | $\pm 0.08$ |
|  | HGB       | g/L                | 137             | $\pm 2$    |
|  | MCV       | fL                 | 88.2            | $\pm 2.0$  |
|  | PLT       | $\times 10^9/L$    | 256             | $\pm 12$   |
| UN71, UN73, UN76, DH73<br>(Technical File Version A2.0 to A5.3)                                  | WBC       | $\times 10^9/L$    | 9.50            | $\pm 0.20$ |
|  | RBC       | $\times 10^{12}/L$ | 4.46            | $\pm 0.08$ |
|  | HGB       | g/L                | 140             | $\pm 2$    |
|  | MCV       | fL                 | 94.6            | $\pm 2.0$  |
|  | PLT       | $\times 10^9/L$    | 259             | $\pm 12$   |

**【NOTE】**

1. The calibrator should be stored in refrigerator (2°C~8°C). After opening, it will keep stable for 7 days when it is stored airtight at 2°C~8°C.
2. Before mixing and running the calibrator after take it out from the refrigerator, please keep it at least 15 minutes until reaching room temperature(15°C~30°C).
3. Calibrator must be well mixed before using. Please mix gently, to avoid cells rupture and/or generating bubbles.
4. After using, put the calibrator back into the refrigerator to prevent contamination and evaporation.

**Shenzhen Dymind Biotechnology Co., Ltd**

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|--|-----------|--------------------|-----------------|------------|
| UN71, UN73, UN76, DH73<br>(Technical File Version A5.5 to A6.2)  | WBC       | $\times 10^9/L$    | 9.27            | $\pm 0.20$ |
|  | RBC       | $\times 10^{12}/L$ | 4.38            | $\pm 0.08$ |
|  | HGB       | g/L                | 138             | $\pm 2$    |
|  | MCV       | fL                 | 89.6            | $\pm 2.0$  |
|  | PLT       | $\times 10^9/L$    | 245             | $\pm 12$   |
| UN71, UN73, UN76, DH73<br>(Technical File Version A6.3 or higher)  | WBC       | $\times 10^9/L$    | 9.19            | $\pm 0.20$ |
|  | RBC       | $\times 10^{12}/L$ | 4.45            | $\pm 0.08$ |
|  | HGB       | g/L                | 139             | $\pm 2$    |
|  | MCV       | fL                 | 88.7            | $\pm 2.0$  |
|  | PLT       | $\times 10^9/L$    | 248             | $\pm 12$   |
| DH73Vet<br>(Technical File Version B5.5 or higher)   | RBC       | $\times 10^{12}/L$ | 4.53            | $\pm 0.08$ |
|  | HGB       | g/L                | 140             | $\pm 2$    |
|  | MCV       | fL                 | 94.0            | $\pm 2.0$  |
|  | PLT       | $\times 10^9/L$    | 255             | $\pm 12$   |
| DF50, DF51, DF52<br>DF53, DF55, DF56<br>(Technical File Version A10.0 to A11.1)<br>DF50 Vet<br>(Technical File Version A2.0 to A7.0) | WBC       | $\times 10^9/L$    | 8.85            | $\pm 0.20$ |
|  | RBC       | $\times 10^{12}/L$ | 4.57            | $\pm 0.08$ |
|  | HGB       | g/L                | 137             | $\pm 2$    |
|  | MCV       | fL                 | 90.5            | $\pm 2.0$  |
|  | PLT       | $\times 10^9/L$    | 257             | $\pm 12$   |

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2. Before mixing and running the calibrator after take it out from the refrigerator, please keep it at least 15 minutes until reaching room temperature(15°C~30°C).
3. Calibrator must be well mixed before using. Please mix gently, to avoid cells rupture and/or generating bubbles.
4. After using, put the calibrator back into the refrigerator to prevent contamination and evaporation.

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|---|-----------|--------------------|-----------------|------------|
| DF50, DF51, DF52<br>DF53, DF55, DF56<br>(Technical File Version A11.2 to A11.6)                                     | WBC       | $\times 10^9/L$    | 8.85            | $\pm 0.20$ |
|   | RBC       | $\times 10^{12}/L$ | 4.62            | $\pm 0.08$ |
|   | HGB       | g/L                | 137             | $\pm 2$    |
|   | MCV       | fL                 | 92.2            | $\pm 2.0$  |
|   | PLT       | $\times 10^9/L$    | 253             | $\pm 12$   |
| DF50, DF51, DF52<br>DF53, DF55, DF56<br>(Technical File Version A12.0 or higher)                                    | WBC       | $\times 10^9/L$    | 9.08            | $\pm 0.20$ |
|   | RBC       | $\times 10^{12}/L$ | 4.64            | $\pm 0.08$ |
|   | HGB       | g/L                | 139             | $\pm 2$    |
|   | MCV       | fL                 | 88.1            | $\pm 2.0$  |
|   | PLT       | $\times 10^9/L$    | 254             | $\pm 12$   |
| DF50, DF51, DF52<br>DF53, DF55, DF56<br>(Technical File Version B1.0 or higher)                                     | WBC       | $\times 10^9/L$    | 8.99            | $\pm 0.20$ |
|   | RBC       | $\times 10^{12}/L$ | 4.65            | $\pm 0.08$ |
|   | HGB       | g/L                | 139             | $\pm 2$    |
|   | MCV       | fL                 | 87.7            | $\pm 2.0$  |
|   | PLT       | $\times 10^9/L$    | 258             | $\pm 12$   |
| DH71, DH76<br>(Technical File Version A4.1 to A10.3)<br>DH51, DH53, DH56<br>(Technical File Version A8.1 or higher) | WBC       | $\times 10^9/L$    | 9.09            | $\pm 0.20$ |
|   | RBC       | $\times 10^{12}/L$ | 4.52            | $\pm 0.08$ |
|   | HGB       | g/L                | 137             | $\pm 2$    |
|   | MCV       | fL                 | 96.1            | $\pm 2.0$  |
|   | PLT       | $\times 10^9/L$    | 254             | $\pm 12$   |

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2. Before mixing and running the calibrator 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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4. After using, put the calibrator back into the refrigerator to prevent contamination and evaporation.

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|--|-----------|--------------------|-----------------|------------|
| DH71, DH76<br>(Technical File Version A10.4)                                   | WBC       | $\times 10^9/L$    | 8.62            | $\pm 0.20$ |
|  | RBC       | $\times 10^{12}/L$ | 4.64            | $\pm 0.08$ |
|  | HGB       | g/L                | 138             | $\pm 2$    |
|  | MCV       | fL                 | 89.0            | $\pm 2.0$  |
|  | PLT       | $\times 10^9/L$    | 258             | $\pm 12$   |
| DH71, DH76<br>(Technical File Version A10.5 or higher)                         | WBC       | $\times 10^9/L$    | 9.20            | $\pm 0.20$ |
|  | RBC       | $\times 10^{12}/L$ | 4.45            | $\pm 0.08$ |
|  | HGB       | g/L                | 137             | $\pm 2$    |
|  | MCV       | fL                 | 89.0            | $\pm 2.0$  |
|  | PLT       | $\times 10^9/L$    | 253             | $\pm 12$   |
| D2-CRP, D7-CRP<br>DH71-CRP, DH73-CRP<br>(Technical File Version A3.0 to A5.11) | WBC       | $\times 10^9/L$    | 9.16            | $\pm 0.20$ |
|  | RBC       | $\times 10^{12}/L$ | 4.50            | $\pm 0.08$ |
|  | HGB       | g/L                | 137             | $\pm 2$    |
|  | MCV       | fL                 | 94.6            | $\pm 2.0$  |
|  | PLT       | $\times 10^9/L$    | 252             | $\pm 12$   |
| D2-CRP, D7-CRP<br>DH71-CRP, DH73-CRP<br>(Technical File Version A6.0 to A6.5)  | WBC       | $\times 10^9/L$    | 9.15            | $\pm 0.20$ |
|  | RBC       | $\times 10^{12}/L$ | 4.46            | $\pm 0.08$ |
|  | HGB       | g/L                | 138             | $\pm 2$    |
|  | MCV       | fL                 | 88.5            | $\pm 2.0$  |
|  | PLT       | $\times 10^9/L$    | 258             | $\pm 12$   |

**【NOTE】**

1. The calibrator should be stored in refrigerator (2°C~8°C). After opening, it will keep stable for 7 days when it is stored airtight at 2°C~8°C.
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|---|-----------|--------------------|-----------------|------------|
| D2-CRP, D7-CRP<br>DH71-CRP, DH73-CRP<br>(Technical File Version A6.6 or higher) | WBC       | $\times 10^9/L$    | 9.51            | $\pm 0.20$ |
|   | RBC       | $\times 10^{12}/L$ | 4.43            | $\pm 0.08$ |
|   | HGB       | g/L                | 137             | $\pm 2$    |
|   | MCV       | fL                 | 87.9            | $\pm 2.0$  |
|   | PLT       | $\times 10^9/L$    | 253             | $\pm 12$   |
| D6-CRP, DH76-CRP<br>(Technical File Version B1.0 to B2.0)                       | WBC       | $\times 10^9/L$    | 8.98            | $\pm 0.20$ |
|   | RBC       | $\times 10^{12}/L$ | 4.42            | $\pm 0.08$ |
|   | HGB       | g/L                | 136             | $\pm 2$    |
|   | MCV       | fL                 | 88.5            | $\pm 2.0$  |
|   | PLT       | $\times 10^9/L$    | 251             | $\pm 12$   |
| D6-CRP, DH76-CRP<br>(Technical File Version B2.2 or higher)                     | WBC       | $\times 10^9/L$    | 9.32            | $\pm 0.20$ |
|   | RBC       | $\times 10^{12}/L$ | 4.48            | $\pm 0.08$ |
|   | HGB       | g/L                | 137             | $\pm 2$    |
|   | MCV       | fL                 | 88.1            | $\pm 2.0$  |
|   | PLT       | $\times 10^9/L$    | 256             | $\pm 12$   |
| DF50 Vet<br>(Technical File Version A8.0 or higher)                             | WBC       | $\times 10^9/L$    | 8.84            | $\pm 0.20$ |
|   | RBC       | $\times 10^{12}/L$ | 4.59            | $\pm 0.08$ |
|   | HGB       | g/L                | 138             | $\pm 2$    |
|   | MCV       | fL                 | 92.4            | $\pm 2.0$  |
|   | PLT       | $\times 10^9/L$    | 255             | $\pm 12$   |

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|---|-----------|--------------------|-----------------|------------|
| DF50 Vet, DF55 Vet, DF56 Vet<br>(Technical File Version B1.0 or higher)   | WBC       | $\times 10^9/L$    | 8.92            | $\pm 0.20$ |
|   | RBC       | $\times 10^{12}/L$ | 4.62            | $\pm 0.08$ |
|   | HGB       | g/L                | 138             | $\pm 2$    |
|   | MCV       | fL                 | 92.2            | $\pm 2.0$  |
|   | PLT       | $\times 10^9/L$    | 258             | $\pm 12$   |
| DF1-CRP, DF3-CRP, DF5-CRP<br>DF50CRP, DF52CRP, DF53CRP<br>(Technical File Version A4.0 to A5.7)                     | WBC       | $\times 10^9/L$    | 8.85            | $\pm 0.20$ |
|   | RBC       | $\times 10^{12}/L$ | 4.54            | $\pm 0.08$ |
|   | HGB       | g/L                | 136             | $\pm 2$    |
|   | MCV       | fL                 | 92.2            | $\pm 2.0$  |
|   | PLT       | $\times 10^9/L$    | 253             | $\pm 12$   |
| DF1-CRP, DF3-CRP, DF5-CRP<br>DF50CRP, DF52CRP, DF53CRP<br>(Technical File Version A6.0)                             | WBC       | $\times 10^9/L$    | 9.44            | $\pm 0.20$ |
|   | RBC       | $\times 10^{12}/L$ | 4.56            | $\pm 0.08$ |
|   | HGB       | g/L                | 138             | $\pm 2$    |
|   | MCV       | fL                 | 88.4            | $\pm 2.0$  |
|   | PLT       | $\times 10^9/L$    | 257             | $\pm 12$   |
| DF1-CRP, DF3-CRP, DF5-CRP<br>DF50CRP, DF52CRP, DF53CRP<br>(Technical File Version A6.1 or higher)<br>Single channel | WBC       | $\times 10^9/L$    | 9.47            | $\pm 0.20$ |
|   | RBC       | $\times 10^{12}/L$ | 4.56            | $\pm 0.08$ |
|   | HGB       | g/L                | 137             | $\pm 2$    |
|   | MCV       | fL                 | 88.7            | $\pm 2.0$  |
|   | PLT       | $\times 10^9/L$    | 256             | $\pm 12$   |

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|--|-----------|--------------------|-----------------|------------|
| DF1-CRP, DF3-CRP, DF5-CRP<br>DF50CRP, DF52CRP, DF53CRP<br>(Technical File Version A6.1 or higher)<br>Two channel | WBC       | $\times 10^9/L$    | 9.44            | $\pm 0.20$ |
|  | RBC       | $\times 10^{12}/L$ | 4.56            | $\pm 0.08$ |
|  | HGB       | g/L                | 138             | $\pm 2$    |
|  | MCV       | fL                 | 87.9            | $\pm 2.0$  |
|  | PLT       | $\times 10^9/L$    | 260             | $\pm 12$   |
| DM71X, DM72X, DM78X, DM79X<br>DM71, DM72, DM78, DM79<br>(Technical File Version A1.0 or higher)                  | WBC       | $\times 10^9/L$    | 8.84            | $\pm 0.20$ |
|  | RBC       | $\times 10^{12}/L$ | 4.49            | $\pm 0.08$ |
|  | HGB       | g/L                | 138             | $\pm 2$    |
|  | MCV       | fL                 | 88.3            | $\pm 2.0$  |
|  | PLT       | $\times 10^9/L$    | 261             | $\pm 12$   |

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