



# Immunology

## Analytical Performance Specifications



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## High Sensitivity CRP (HC)

Measurand	Lower Limit	Upper Limit
hsCRP	$\pm 0.60 \leq 3.00$ mg/L	$\pm 20\% > 3.00$ mg/L

## IgD (ID)

Measurand	Lower Limit	Upper Limit
IgD	$\pm 0.2 \leq 1.0$ g/L	$\pm 20\% > 1.0$ g/L

## IgE (IE)

Measurand	Lower Limit	Upper Limit
IgE	$\pm 20 \leq 100$ kU/L	$\pm 20\% > 100$ kU/L

## Specific Proteins (IM)

Measurand	Lower Limit	Upper Limit
IgG	$\pm 0.6 \leq 6.0$ g/L	$\pm 10\% > 6$ g/L
IgA	$\pm 0.06 \leq 0.60$ g/L	$\pm 10\%$ if $> 0.6$ g/L
IgM	$\pm 0.08 \leq 0.50$ g/L	$\pm 15\% > 0.5$ g/L
C3	$\pm 0.10 \leq 1.0$ g/L	$\pm 10\%$ if $> 1.0$ g/L
C4	$\pm 0.02 \leq 0.20$ g/L	$\pm 10\%$ if $> 0.20$ g/L
$\alpha 1$ AT	$\pm 0.10 \leq 0.50$ g/L	$\pm 20\%$ if $> 0.50$ g/L
C1inh	$\pm 0.03 \leq 0.20$ g/L	$\pm 15\%$ if $> 0.20$ g/L
Haptoglobin	$\pm 0.10 \leq 0.80$ g/L	$\pm 10\%$ if $> 0.80$ g/L
Caeruloplasmin	$\pm 0.03 \leq 0.20$ g/L	$\pm 15\%$ if $> 0.20$ g/L
Prealbumin	$\pm 0.04 \leq 0.20$ g/L	$\pm 20\%$ if $> 0.20$ g/L



## Immunophenotyping (PH)

Measurand	Lower Limit	Upper Limit
CD3+%	$\pm 1.5 \leq 30\%$	$\pm 5\%$ if $> 30\%$
CD3+CD4+%	$\pm 3 \leq 40\%$	$\pm 7.5\%$ if $> 40\%$
CD3+CD8+%	$\pm 1.5 \leq 15\%$	$\pm 10\%$ if $> 15\%$
CD3-CD16+%	$\pm 2$ to $\leq 10\%$	$\pm 20\%$ if $> 10\%$
CD3-CD56+%	$\pm 2 \leq 10\%$	$\pm 20\%$ if $> 10\%$
CD3-CD16+56+%	$\pm 2 \leq 10\%$	$\pm 20\%$ if $> 10\%$
CD3+ Alpha-beta %	$\pm 4.5 \leq 30\%$	$\pm 15\%$ if $> 30.0\%$
CD19+%	$\pm 2 \leq 10\%$	$\pm 20\%$ if $> 10\%$
CD3x10 <sup>9</sup> /L	$\pm 0.02 \leq 0.10 \times 10^9/L$	$\pm 20\%$ if $> 0.10 \times 10^9/L$
CD4x10 <sup>9</sup> /L	$\pm 0.02 \leq 0.10 \times 10^9/L$	$\pm 20\%$ if $> 0.10 \times 10^9/L$
CD8x10 <sup>9</sup> /L	$\pm 0.02 \leq 0.10 \times 10^9/L$	$\pm 20\%$ if $> 0.10 \times 10^9/L$
CD19x10 <sup>9</sup> /L	$\pm 0.02 \leq 0.10 \times 10^9/L$	$\pm 20\%$ if $> 0.10 \times 10^9/L$

## Procalcitonin (PC)

Measurand	Lower Limit	Upper Limit
Procalcitonin	$\pm 0.05 \leq 0.15 \text{ ng/mL}$	$\pm 30\%$ if $> 0.15 \text{ ng/mL}$

## Rheumatoid Factor (RF)

Measurand	Lower Limit	Upper Limit
Rheumatoid Factor	$\pm 12 \leq 60 \text{ IU/mL}$	$\pm 20\%$ if $> 60 \text{ IU/mL}$

## Tryptase (TR)

Measurand	Lower Limit	Upper Limit
Tryptase	$\pm 0.6 \text{ ug/L} \leq 4.0 \text{ ug/L}$	$\pm 15\%$ if $> 4.0 \text{ ug/L}$