

Haematology

Analytical Performance Specifications

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Full Blood Count / Hemoscreen			
Analyte	Lower Limit	Upper Limit	Assessment category
WCC	+ or - 0.5 ≤ 5.0 x10 ⁹ /L	+ or - 10% > 5.0 x10 ⁹ /L	Measurement system
RCC	+ or - 0.2 ≤ 2.0 x10 ¹² /L	+ or - 10% > 2.0 x10 ¹² /L	
Hb	+ or - 5 ≤ 100 g/L	+ or - 5% > 100 g/L	
Hct	+ or - 0.04 ≤ 0.20	+ or - 20% > 0.20	
MCV	+ or - 5 ≤ 50 fL	+ or - 10% > 50 fL	
MCH	+ or - 2 ≤ 20 pg	+ or - 10% > 20 pg	
MCHC	+ or - 30 ≤ 300 g/L	+ or - 10% > 300 g/L	
RDW-CV	+ or - 2 ≤ 10%	+ or - 20% > 10%	
PLT	+ or - 25 ≤ 100 x10 ⁹ /L	+ or - 25% > 100 x10 ⁹ /L	
MPV	+ or - 2 ≤ 10 fL	+ or - 20% > 10 fL	

Automated Differential / POC- HemoCue / Hemoscreen			
Analyte	Lower Limit	Upper Limit	Assessment category
WCC	+ or - 0.5 ≤ 5.0 x10 ⁹ /L	+ or - 10% > 5.0 x10 ⁹ /L	Measurement system
Neutrophils / Granulocytes	+ or - 1.0 ≤ 10.0%	+ or - 10% > 10.0%	
Lymphocytes	+ or - 2.0 ≤ 10.0%	+ or - 20% > 10.0%	
Monos / Eosinos / Basos / LUC / IG	+ or - 3.0 ≤ 10.0%	+ or - 30% > 10.0%	

Reticulocyte (Automated)			
Analyte	Lower Limit	Upper Limit	Assessment category
Percentage	+ or - 1.0 ≤ 10.0 %	+ or - 10% > 10.0 %	Measurement system
Absolute count	+ or - 10 ≤ 100	+ or - 10% > 100 x10 ⁹ /L	

Reticulocyte (Manual)			
Analyte	Lower Limit	Upper Limit	Assessment category
Percentage	+ or - 0.6 ≤ 2.0 %	+ or - 30% > 2.0 %	Analytical principle
Absolute count	+ or - 21.0 ≤ 70.0	+ or - 30% > 70.0 x10 ⁹ /L	

ESR			
Analyte	Lower Limit	Upper Limit	Assessment category
ESR	+ or - 3.0 ≤ 10.0 mm/hr	+ or - 30% > 10.0 mm/hr	Measurement system



G6PD			
Analyte	Lower Limit	Upper Limit	Assessment category
G6PD assay	+ or - $3.0 \leq 10.0$ U/g Hb	+ or - 30% > 10.0 U/g Hb	Reagent
G6PD Screen and assay Interpretation	Assessed on qualitative result		N/A

Haemoglobinopathy			
Analyte	Lower Limit	Upper Limit	Assessment category
Hb A ₂	+ or - $0.3 \leq 2.0\%$	+ or - 10% > 2.0%	Measurement system
Hb F	+ or - $0.5 \leq 1.50\%$	+ or - 30% > 1.50%	
Hb Variant	+ or - $4 \leq 20\%$	+ or - 20% > 20%	
Final interpretation	Assessed on qualitative result		Consensus and expert advisory

Sickling Test			
Analyte	Lower Limit	Upper Limit	Assessment category
Red cell sickling	Assessed on qualitative result		N/A

Malaria Rapid Kit			
Analyte	Lower Limit	Upper Limit	Assessment category
Malaria Rapid Test result	Assessed on qualitative result		N/A

Haemostasis / Coagulation Factors / D-Dimer / POC-INR			
Analyte	Lower Limit	Upper Limit	Assessment category
PT	+ or - $2.0 \leq 10.0$ sec	+ or - 20% > 10.0 sec	Reagent
INR / POC INR	+ or - $0.3 \leq 2.0$ ratio	+ or - 15% > 2.0 ratio	
APTT	+ or - $10 \leq 40$ sec	+ or - 25% > 40 sec	
Fibrinogen	+ or - $0.20 \leq 1.0$ g/L	+ or - 25% > 1.0 g/L	
Thrombin Time	+ or - $3 \leq 12$ sec	+ or - 25% > 12 sec	Calibrator
Factor II, V, VII, VIII, IX, X, XI, XII	+ or - $3 \leq 10$ IU/dL	+ or - 30% > 10 IU/dL	
D-Dimer (Automated)	+ or - $0.25 \leq 0.50$ DD mg/L	+ or - 50% > 0.50 DD mg/L	Reagent
D-Dimer (Automated)	+ or - $0.5 \leq 1.0$ FEU mg/L	+ or - 50% > 1.00 FEU mg/L	
D-Dimer (Semi quantitative)	Assessment on interpretation		N/A



Lupus Anticoagulant			
Analyte	Lower Limit	Upper Limit	Assessment category
APTT	+ or - 9.0 ≤ 30 sec	+ or - 30% > 30 sec	Reagent
APTT Screen Ratio	+ or - 0.3 ≤ 0.9 ratio	+ or - 30% > 0.9 ratio	
DRVVT screen	+ or - 9.0 ≤ 30 sec	+ or - 30% > 30 sec	
DRVVT screen ratio	+ or - 0.3 ≤ 0.9 ratio	+ or - 30% > 0.9 ratio	
Final interpretation	Assessment on interpretation		

Thrombophilia			
Analyte	Lower Limit	Upper Limit	Assessment category
Protein C Functional	+ or - 12 ≤ 60 %	+ or - 20% > 60 %	Reagent
Protein S Total Antigen	+ or - 10 ≤ 40 %	+ or - 25% > 40 %	
Protein S Free Antigen	+ or - 10 ≤ 40 %	+ or - 25% > 40 %	
Protein S Free Functional	+ or - 10 ≤ 40 %	+ or - 25% > 40 %	
AT Functional	+ or - 10 ≤ 40 %	+ or - 25% > 40 %	

APC Resistance			
Analyte	Lower Limit	Upper Limit	Assessment category
APCR APTT, APTT V, APCR RVVT, RVVT V, APCR Staclot	Assessed on interpretation		N/A

Von Willebrand Factor			
Analyte	Lower Limit	Upper Limit	Assessment category
FVIII:C	+ or - 3 ≤ 10 %	+ or - 30% > 10 %	Reagent
VWF:Ag	+ or - 3 ≤ 10 %	+ or - 30% > 10 %	
VWF:RCo	+ or - 4 ≤ 10 %	+ or - 40% > 10 %	
VWF:CB	+ or - 4 ≤ 10 %	+ or - 40% > 10 %	
VWF:Activity	+ or - 4 ≤ 10 %	+ or - 40% > 10 %	
Ratios and final interpretation	Assessment on interpretation		

Factor VIII Inhibitor			
Analyte	Lower Limit	Upper Limit	Assessment category
Inhibitor level BU	Assessed on interpretation		Reagent deficient plasma



PFA 100 / 200			
Analyte	Lower Limit	Upper Limit	Assessment category
Closure time	Assessed on interpretation		N/A

Multiplate			
Analyte	Lower Limit	Upper Limit	Assessment category
Inhibition level	Assessed on inhibition level interpretation		N/A

Unfractionated Heparin Monitoring / Low Molecular Weight Heparin			
Analyte	Lower Limit	Upper Limit	Assessment category
APTT	+ or - 10 ≤ 40 sec	+ or - 25% > 40 sec	Reagent
Anti Xa	+ or - 0.1 ≤ 0.4 U/mL	+ or - 25% > 0.4 U/mL	

Dabigatran (Direct Thrombin Inhibitor)			
Analyte	Lower Limit	Upper Limit	Assessment category
DTI	+ or - 25 ≤ 100 ng/mL	+ or - 25% > 100 ng/mL	Reagent

Apixaban (Anti Xa)			
Analyte	Lower Limit	Upper Limit	Assessment category
Anti Xa	+ or - 25 ≤ 100 ng/mL	+ or - 25% > 100 ng/mL	Reagent

Rivaroxaban (Anti Xa)			
Analyte	Lower Limit	Upper Limit	Assessment category
Anti Xa	+ or - 25 ≤ 100 ng/mL	+ or - 25% > 100 ng/mL	Reagent

Factor XIII			
Analyte	Lower Limit	Upper Limit	Assessment category
Factor XIII	Assessment on diagnostic interpretation		N/A

Thromboelastometry ROTEM (Delta / Sigma)			
Analyte	Lower Limit	Upper Limit	Assessment category
Clotting Times	Assessment on final interpretation		N/A



Thromboelastography TEG (5000 / 6s)

Analyte	Lower Limit	Upper Limit	Assessment category
Clotting Times	Assessment on final interpretation		N/A

Activated Clotting Time

Analyte	Lower Limit	Upper Limit	Assessment category
Clotting Times	Clotting time interpretation		N/A

CD34+

Analyte	Lower Limit	Upper Limit	Assessment category
%CD34	+ or - 0.05 ≤ 0.20 %	+ or - 25% > 0.20 %	Measurement system
Total CD34	+ or - 5 ≤ 20.0	+ or - 25% > 20.0 μL	

Immunophenotyping

Analyte	Lower Limit	Upper Limit	Assessment category
CD markers	Assessment by Z-Score		N/A
CD marker interpretation and Final interpretation	Assessment on interpretation		Consensus and expert advisory

PNH

Analyte	Lower Limit	Upper Limit	Assessment category
Markers	Assessment by Z-Score		N/A
Final interpretation	Assessment on interpretation		Consensus and expert advisory

Blood Film

Analyte	Lower Limit	Upper Limit	Assessment category
Neutrophils, Total lymphocytes	+ or - 12 ≤ 40 %	+ or - 30% > 40	N/A
Monocytes, Eosinophils, Basophils, Lymphocytes Abnormal, other cells	+ or - 6 ≤ 20 %	+ or - 30% > 20	N/A
Blasts, Promyelocytes, Myelocytes, metamyelocytes, lymphocytes reactive, Nucleated red cells	+ or - 4 ≤ 15 %	+ or - 30% > 15	N/A



Morphology			
Analyte	Lower Limit	Upper Limit	Assessment category
White cell, Red and platelet morphology description	Assessed using scoring		Consensus and expert advisory
Diagnostic interpretation	Assessment on interpretation using terminology		Consensus and expert advisory

Paediatric Morphology			
Analyte	Lower Limit	Upper Limit	Assessment category
White cell, Red and platelet morphology description	Assessed using scoring		Consensus and expert advisory
Diagnostic interpretation	Assessment on interpretation using terminology		Consensus and expert advisory

Bone Marrow Morphology Differential			
Analyte	Lower Limit	Upper Limit	Assessment category
Blasts, Promyelocytes, Plasma cells	+ or - 4 ≤ 15 %	+ or - 30% > 15	N/A
Myelocytes, metamyelocytes, Neutrophils / band forms, Erythroblasts, Lymphocytes,	+ or - 12 ≤ 40 %	+ or - 30% > 40	N/A
Monocytes, Eosinophils, Basophils, other cells	+ or - 6 ≤ 20 %	+ or - 30% > 20	N/A
Myeloid / Erythroid ratio	+ or - 1 ≤ 3.0	+ or - 30% > 3	N/A
Diagnostic Interpretation	Assessment on interpretation using terminology		Consensus and expert advisory

Malaria Morphology			
Analyte	Lower Limit	Upper Limit	Assessment category
Size of parasitised red cells	Assessed using scoring		Consensus and expert advisory
Blood film / parasite description	Assessed using scoring		Consensus and expert advisory
Diagnostic interpretation	Assessment on interpretation using terminology		Consensus and expert advisory