

COAGULATION TESTS: REPORTABLE LIMITS AND NORMAL/THERAPEUTIC VALUES

RC.HM.CG.PR.002.r23

PLATELET AGGREGATIONS NORMAL RANGES

Normal Ranges in Hyper Aggregation		
Reagent	Concentration	Aggregation (%)
ADP	10.0 mcM	65 - 100 % (Max)
ADP	2.0 mcM	13 - 82 % (Max)
ADP	1.0 mcM	4 - 35 % (Max)
ADP	0.5 mcM	0 - 30 % (Max)
Epinephrine	10.0 mcM	70 - 95 % (Max)
Epinephrine	1.0 mcM	7 - 85 % (Max)
Epinephrine	0.5 mcM	5 - 84 % (Max)
Spontaneous	NA	Absent
Arachidonic Acid	500 mcg/mL	60-100%

Normal Ranges in Routine Aggregation		
Reagent	Concentration	Aggregation
ADP	10 mcM	≥65% (Max)
ADP	5 mcM	≥60% (Max)
Ristocetin	1.5 mg/mL	≥70% (Max)
Ristocetin	1.0 mg/mL	≥65% (Max)
Ristocetin	0.5 mg/mL	≤15 (Max)
Collagen	2 mcg/mL	≥65% (Max & Rate)
Collagen Lag Phase	NA	15-70 seconds
Arachidonic Acid	500 mcg/mL	≥60%

Normal Ranges in Lumi Aggregation		
Reagent	Concentration	Aggregation
ADP Max	20mcM	≥ 65% (Max & Rate)
Collagen Max	2 mcg/mL	≥ 65% (Max & Rate)
Collagen T1/2	2 mcg/mL	≤ 99 sec
TRAP Max	100mcM	≥ 40% (Max & Rate)
LUMI ADP	20mcM	0.30 – 0.93 nM
LUMI Collagen	2 mcg/mL	0.5 – 1.4 nM
LUMI TRAP	10mcM	0.4 – 1.2 nM
Arachidonic Acid	500 mcg/mL	≥ 60%

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ASSAY	METHOD	REPORTABLE LIMITS	NORMAL/ THERAPEUTIC VALUES
PT	IL ACL-TOP	9-100 seconds	9.2-13.5 seconds
aPTT	IL ACL-TOP	21-200 seconds	25-38 seconds/ 56-81 seconds (ACS: 50-75 seconds)
Fibrinogen	IL ACL-TOP	35-1000 mg/dL	200-400 mg/dL
Thrombin Time	IL ACL-TOP	6-100 seconds	16-25 seconds
Inhibitor Screen (Mixing Studies)	IL ACL-TOP	Negative/Positive	Negative
Inhibitor Assay (Bethesda)	BCSXP	<1 - >200 Bethesda Units/mL	<1 Bethesda Units/mL
PFA-Coll/Epi	PFA-100	0-300 seconds	≤ 160 seconds
PFA-Coll/ADP	PFA-100	0-300 seconds	≤ 106 seconds
D-dimer; Quantitative	IL ACL-TOP	250 – 10,000 ng/mL FEU	< 600 ng/mL FEU (VTE: <500 ng/mL FEU)
Fibrin Split Products	Latex/Manual	<10 to >40 mcg/mL	< 10 mcg/mL
ATIII	IL ACL TOP	0 - >150%	85-150 %
Factor II Activity)	IL ACL TOP	10-600%	75-135%
Factor V Activity	IL ACL TOP	10-600%	60-145%
Factor VII Activity	IL ACL TOP	10-600%	50-150 %
Factor VIII Activity	IL ACL TOP	10-600%	50-175%
Factor IX Activity	IL ACL TOP	10-600%	70-150%
Factor X Activity	IL ACL TOP	10-600%	70-150%
Factor XI Activity	IL ACL TOP	10-600%	65-150%
Factor XII Activity	IL ACL TOP	10-600%	60-180%
Factor Assays Low	IL ACL TOP	1-15%	Refer to individual ranges
DRVVT Screen	IL ACL TOP	0-100 seconds	<44 seconds
DRVVT Confirm	IL ACL TOP	0-100 seconds	< 35 seconds
DRVVT Normalized Ratio	IL ACL TOP	0-100 seconds	< 1.30
VWF Antigen	IL ACL TOP	10-300%	50-175%
Fibrin Stabilizing Factor	Manual	Present/Absent	Present
Reptilase Time	IL ACL TOP	0-100 seconds	16-21 seconds
VWF Activity	IL ACL TOP	20 -300%	50-175%
Heparin anti-Xa, LMWH	IL ACL TOP	0-2.0 Units/mL	0 Units/mL 0.6-1.0 Units/mL twice daily dosing 1.0-2.0 Units/mL once daily dosing
Heparin anti-Xa, unfractionated	IL ACL TOP	0-2.0 Units/mL	0 Units/mL Therapeutic:0.3-0.7 Units/mL
Hexagonal Phase Phospholipid	ST4	0-100 seconds	≤ 7 seconds
Protein C Activity	IL ACL TOP	10-250%	70-185%
Protein S Activity	IL ACL TOP	10-250%	Females 50-160% Males 60-160%
Activated Protein C Resistance	IL ACL TOP	15-200 seconds	≥ 2.3 Normal (ratio)
Plasminogen	IL ACL TOP	10-270%	70-145%
Plasmin Inhibitor	IL ACL TOP		90-140%
Argatroban (Dilute Thrombin Time)	BCSXP	0.0-2.0 mcg/mL	0.6-1.8 mcg/mL
Dabigatran (Dilute Thrombin Time)	BCSXP	0.03-0.47 mcg/mL	Literature established therapeutic ranges: 0.09-0.18 mcg/mL

Authorized Reviewers

Chair, Pathology and Laboratory Medicine
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Document History

Signature	Date	Revision #		Related Documents Reviewed/ Updated
Prepared by: Karri Henderson, MT (ASCP)	03/20/07			
Approved by: Marc Smith, MD	03/28/07			
Reviewed by: (Signature)	Date	Revision #	Modification	Related Documents Reviewed/ Updated
Marc Smith MD	03/28/2007	00	New procedure/format	
Marc Smith MD	11/01/2007	01	Pg 2 Change Coll/ADP and Coll/EPI normal values. Pg 2 Added Factor VIII Activity normal values and reportable limits.	
Marc Smith MD	3/12/2008	02	Pg 1 Change normal range for PT CA1500, BCS and ST4. Change normal range for Thrombin time. Change Plt agg Lumi ADP normal range.	
Marc Smith, MD	07/22/2008	03	Updated method from CA1500 to CA7000. Updated PTT normal and reportable range; updated Thrombin normal reference range; updated fibrinogen reportable limits for all analyzers.	
Marc Smith, MD	02/11/2009	04	Updated normal values range for PT, aPTT, TT and vWF Ag and lumi agg ADP; added Heparin aPTT, hexagonal phase phospholipid, inhibitor assay (Bethesda) and Euglobulin Lysis time.	
Marc Smith, MD	06/16/2009	05	Updated ristocetin normal range max and rate.	
Marc Smith, MD	11/20/2009	06	Changed the method for PT and aPTT to CA Series.	
Marc Smith, MD	02/23/2010	07	Changed normal range for PT, PTT and Heparin aPTT.	
Marc Smith, MD	10/15/2010	08	Changed normal range for Protein S free antigen test.	
Marc Smith, MD	05/27/2011		RC added to SOP#; new format	
Marc Smith, MD	09/22/2011	09	Changed factor reference ranges. Deleted Heparin	

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			aPTT. Added therapeutic range to aPTT. Changed Bethesda reference range. Changed ST4 and BCS aPTT reportable limits to 21 secs. Changed BCS PT reportable limits to 9 secs. Deleted semi-quantitative d-dimer.	
Marc Smith, MD	02/21/2012	10	Updated PT normal range.	
Marc Smith, MD	07/10/2013	11	Updated normal ranges for hyper aggregation, routine aggregation, fibrinogen, TT; added collagen lag phase; changed reportable limits for Inhibitor assay (Bethesda) and Ristocetin.	NA
Marc Smith, MD	11/13/2013	12	Deleted ADP 20 mcM from hyper aggregation list.	NA
Marc Smith, MD	07/13/2014	13	Pg 2: changed aPTT normal range to 23-30 seconds	NA
Marc Smith, MD	04/02/2015	14	Pg 2, added normal and therapeutic range for Argatroban; added literature established therapeutic range for Dabigatran.	NA
Marc Smith, MD	07/24/2015	15	Pg 2, changed Bethesda inhibitor normal range to <1 BU/mL and reportable to <1 to >200 BU/mL	NA
Marc Smith, MD	04/01/2016	16	Pg 2 changed reptilase normal range to 16-21 seconds; changed direct thrombin inhibitor to dilute thrombin time in the test name for argatroban and dabigatran.	NA
Marc Smith, MD	04/04/2017	17	Pg2 deleted Euglobulin clot lysis (retired); updated ug to mcg.	NA
Marc Smith, MD	09/11/2017	18	P2 deleted normal ranges for Protein C antigen and Total and Free Protein S antigen	NA
Elizabeth Sykes, MD	02/22/2018		No changes	NA
Marc Smith, MD	10/02/2018	19	For aPTT, PT, FIB, TT, D-dimer, and Inhibitor Screen updated method, reportable limits, and reference ranges/therapeutic ranges for IL ACL-TOP. Removed References for BCS-XP and ST4 for PT, PTT, and Fib tests.	NA
Peter Millward, MD	09/27/2018			NA
Marc Smith, MD	1/11/2019	20	For an AT, PC, PS, PLG, VWAG, Intrinsic and Extrinsic factors, DRVVT, APCR, change RCF test to VWF activity and added plasmin inhibitor test. All	

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