

Beaumont Laboratory

Effective Date: 09/12/2019 Supersedes: 1/11/2019 Royal Oak

Related Documents: NA

COAGULATION TESTS: REPORTABLE LIMITS AND NORMAL/THERAPEUTIC VALUES

RC.HM.CG.PR.002.r21

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	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	<u>≥</u> 60%			

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	25-37 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	≤ 41 seconds
DRVVT Confirm	IL ACL TOP	0-100 seconds	≤ 34 seconds
DRVVT Normalized Ratio	IL ACL TOP	0-100 seconds	< 1.21
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 Medical Director, Coagulation

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Clinical Pathology: Coagulation BEAUMONT LABORATORY, Royal Oak, MI 48073 DATE: 09/12/2019 RC.HM.CG.PR.002.r21

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Location of Master: Coagulation Procedure Manual

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S:\HEMACOAG\Document Control\Coagulation\Procedures\Coag Normal Ranges

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Document History

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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	opautou.
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	NA
			hyper aggregation, routine	
			aggregation, fibrinogen, TT;	
			added collagen lag	
			phase;changed reportable	
			limits for Inhibitor assay	
			(Bethesda) and Ristocetin.	
Marc Smith, MD	11/13/2013	12	Deleted ADP 20 mcM from	NA
Maro Criman, MB	11/10/2010		hyper aggregation list.	1.0.
Marc Smith, MD	07/13/2014	13	Pg 2:changed aPTT normal	NA
Ware officer, MB	07/10/2014	10	range to 23-30 seconds	1471
Marc Smith, MD	04/02/2015	14	Pg 2, added normal and	NA
Ware Stiller, WD	04/02/2010	14	therapeutic range for	14/7
			Argatroban; added literature	
			established therapeutic range	
Maria Oneith MD	07/04/0045	4.5	for Dabigatran.	NIA
Marc Smith, MD	07/24/2015	15	Pg 2, changed Bethesda	NA
inhibitor normal range to				
			BU/mL and reportable to <1 to	
			>200 BU/mL	
Marc Smith. MD	04/01/2016	16	Pg 2 changed reptilase normal	NA
			range to 16-21 seconds;	
			changed direct thrombin	
			inhibitor to dilute thrombin time	
			in the test name for argatroban	
			and dabigatran.	
Marc Smith, MD	04/04/2017	17	Pg2 deleted Euglobulin clot	NA
			lysis (retired); updated ug to	
			mcg.	
Marc Smith, MD	09/11/2017	18	P2 deleted normal ranges for	NA
			Protein C antigen and Total	
			and Free Protein S antigen	
Elizabeth Sykes, MD	02/22/2018		No changes	NA
Marc Smith, MD	10/02/2018	19	For aPTT, PT, FIB, TT, D-	NA
	10,02,2010		dimer, and Inhibitor Screen	, .
			updated method, reportable	
			limits, and reference	
			ranges/therapeutic ranges	
	for IL ACL-TOP.	for IL ACL-TOP.		
			Removed References for	
			BCS-XP and ST4 for PT,	
			PTT, and Fib tests.	
Peter Millward, MD	09/27/2018		i i i, and i ib tests.	
Marc Smith, MD	1/11/2019	20	For an AT, PC, PS, PLG,	
iviaic Silliui, ivid	1/11/2019	20		
			VWAG, Intrinsic and	
			Extrinsic factors, DRVVT,	
			APCR, change RCF test to	
			VWF activity and added	
			plasmin inhibitor test. All	
			p.2.311111 1111121101 10011 7111	1

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			above tests to be ran on IL ACL TOP and change the normal/therapeutic ranges. Removed References for	
			BCS-X	
Peter Millward, MD	2/13/2019		New Medical Director	
Marc Smith, MD	09/06/2019	21	Change PT Normal Range and PTT Heparin Therapeutic range	
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