

To: Clients of URMCLabs

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Re: Coagulation Testing--Changes in Reference ("Normal") Ranges

Date: 12/3/2012

Effective 12:01 p.m. on 12/5/2012, URMCLabs Automated Laboratories of the University of Rochester Medical Center and Highland Hospital will switch to new instrumentation from Instrumentation Laboratory (IL) for coagulation testing. Attached are individual tables for Strong Memorial Hospital, Highland Hospital, and Ridgeland Road lab showing tests involved along with old (before December 5, 2012) and new (after December 5, 2012) reference ranges.

PT and INR

There is a slight decrease in the Prothrombin Time (PT) reference range. In-house correlation studies of the International Normalized Ratio (INR) between the old and new assays reveal good linear correlation ($r = 0.95$); however, the new INR assay results are higher than old assay results at INRs above 2 (i.e., old assay INR values of 2 and 3 correspond to a new INR values of 2.2 and 3.3. Although the INR has been developed to minimize differences among assays, especially as related to monitoring of warfarin therapy; small discrepancies are common and expected. Thus, it should be noted that these changes may in some instances result in slight decreases in the amount of warfarin needed to maintain patients in the typical therapeutic range of 2-3.

PTT as related to heparin therapeutic range

There is a slight increase in the reference range of the new Activated Partial Thromboplastin Time (PTT) assay. Use of the PTT for monitoring therapy with unfractionated heparin is based upon achieving a therapeutic range of heparin between 0.3 and 0.7 U/mL. In-house studies have shown that the corresponding PTT range to these heparin levels has decreased (old assay, 69 – 109 sec; new assay 62 – 96 sec). ****See page 2 for note on PTT ordering recommendations**

D-dimer

The D-dimer assay will continue to use an immunoturbidimetric methodology and will continue to be reported using FEU ug/mL units.

The following table shows our old & new reference ranges Note: potentially significant changes **indicated** *

URMC Labs Old & New Reference Ranges: Coag 12/5/2012

TEST	UNITS	AGE	Current Reference Range	New Reference RANGE
ROUTINE				
PT	sec	ALL	11.9-14.7	9.2 – 12.3 *
INR		ALL	0.9-1.1	1.0-1.2
APTT	sec	ALL	22.3-35.3	25.8 – 37.9 *
FIBRINOGEN	mg/dL	ALL	199 - 463	172 - 409
THROMB TIME	sec	ALL	14.6 -19.2	11.7-15.0 *
D-DIMER	ug/L	ALL	0.00 -0.48	0.00 – 0.50
FACTOR ASSAYS				
FACTOR II	% Activity	ALL	70-120	89 -136
FACTOR V	% Activity	ALL	70-120	67 – 139
FACTOR VII	% Activity	ALL	50-170	66 -159
FACTOR VIII	% Activity	ALL	75-170	68 – 156
FACTOR IX	% Activity	ALL	60-150	92 -161
FACTOR X	% Activity	ALL	70-120	78 - 147
FACTOR XI	% Activity	ALL	60-150	69 - 154
FACTOR XII	% Activity	ALL	60-150	57 - 163
SPECIAL COAGULATION				
APCR		ALL	>1.9	>2.5
AntiThrombin III	% Activity	ALL	80 - 120	81 - 125
Protein-C	% Activity	ALL	70 -150	77 – 147
Protein- S	% Activity	ALL	55 - 143	51 – 140
Von Willebrand				
VWF-Ag	% Normal	ALL	50 - 160	44 - 166
VWF- Activity (RCO)	% Activity	ALL	60 - 200	37 – 174 *

****Please note:** PTT is not needed (and would not be reimbursed) for monitoring patients on Coumadin/warfarin therapy, only the PT/INR is useful. In the outpatient setting, a PTT is mostly needed in patients with history, or suspicion of a condition known to be associated with the risk of hemorrhage or thrombosis.