CALIBRATION/AMR VERIFICATION - COAGULATION
(AMR - also known as Reportable Range or Linearity)

Regulatory requirements now state that hemostasis methods that are calibrated and directly measure the concentration or activity of an analyte by employing enzyme immunoassay (EIA), including ELISA and fluorescence immunoassay, immunoturbidity and chromogenic methods must employ the methods of calibration verification and analytical measurement range (AMR) verification. The coagulation analytes affected by these new requirements include:

Chromogenic	Immunoturbidimetric
Antithrombin III	vWF Antigen
Anti-Xa (UFH)	vWF Activity
Anti-Xa (LMWH)	D-dimer
Protein C	Factor XIII
Factor X Chrom.	

CALIBRATION VERIFICATION

To satisfy the requirements for calibration verification, UR Medicine Labs Automated Coagulation Laboratory has opted to recalibrate the test systems minimally every six months (see SH.CP.AU.gen.0021) for analytes whose calibration has three or more points and where the highest calibrator is greater than or equal to the upper limit of the reportable range i.e. D-dimer, Anti-Xa (UFH and LMWH), Factor XIII.

If the highest calibrator is less than or equal to the upper limit of the reportable range (±10%), then AMR verification will also be required.

ANALYTICAL MEASUREMENT RANGE VERIFICATION (AMR)

The ANALYTICAL MEASUREMENT RANGE (AMR) is the range of analyte values that a method can directly measure on the specimen without any dilution, concentration, or other pretreatment not part of the usual assay process.

Verification of the AMR may be accomplished by demonstrating a linear relationship for an appropriate set of samples that cover the AMR. A plot of measured results for an analyte obtained across the AMR vs. expected concentrations or concentration relationships (or expected activity or activity relationships) in a set of samples should show a linear relationship. *Note that for some commercially available "linearity"* sample sets, it is not expected that the measured values are the same as the target values if the "linearity" samples are not commutable with clinical samples. For commercially available "linearity" sample sets, it is expected that a plot of the measured values vs. the target values has a linear relationship because there is a known quantitative relationship between the concentrations or activities in the sample set.

Refer to the following chart for details on running calibration verification and AMR verification for coagulation analytes at UR Medicine Labs:

	IL Linear Range	Calib. Value or Calib. range	Calibration Verification	AMR Verification needed?	Material Used	Range of Lineate Material
Antithrombin III (%)	**10 - 150**	**(varies with lot)**	**Every 6 months**	**Yes**	**CVL-LN35**	**10-130**
ANTI-Xa (UFH) (U/mL)	**0.0 - 2.0**	**0.0 0.8 2.0**	**Every 6 months**	**No**		
ANTI-Xa (LMWH) (U/mL)	**0.0 – 2.0**	**0.0 0.8 2.0**	**Every 6 months**	**No**		
PROTEIN C (%)	**25 - 101**	**(varies with lot)**	**Every 6 months**	**Yes**	**Normal Assayed and Special Test 2 Controls**	**10-150**
vWF ANTIGEN (%)	**8.5 – 250***	**(varies with lot)**	**Every 6 months**	**Yes**	**CVL-LN37**	**10-140**
vWF ACTIVITY (%)	**19 - 130**	**(varies with lot)**	**Every 6 months**	**Yes**	**Normal Assayed and Special Test 2 Controls**	**10-130**
D-DIMER (µg/mL FEU)	**0.22–128.0 (dilutes at 7.65)**	**7.0–8.0* (varies with lot)**	**Every 6 months**	**No**		
FACTOR XIII (%)	**3.8 - 150**	**0 - 180**	**Every 6 months**	**No**		
FACTOR X - Chromogenic	**10 - 150**	**(varies with lot)**	**Every 6 months as needed**	**Yes**	**Normal Assayed Control**	**10-182**

***vWF Antigen: Although the IL claim is linear to 250%, UR labs has chosen to automatically dilute at 130%, to correlate with the lineate material range.

******D-dimer results will dilute automatically when the value is >7.65 µg/mL FEU. Since the calibrator for this analyte falls in the 7.0-8.0 µg/mL FEU range, calibration for this analyte satisfies the requirement for calibration verification and AMR.

CALIBRATION VERIFICATION PROCEDURE:

See SH.CP.AU.gen.0021

VERIFICATION OF THE REPORTABLE RANGE (AMR) PROCEDURE:

See SH.CP.AU.gen.0021

REFERENCES:

1. CAP Hematology and Coagulation Checklist, HEM.38006, HEM.38009, HEM.38010, April 2014.
2. SH.CP.AU.gen.0021, Calibration/Calibration Verification and Reportable Range Verification Procedures