Laboratory Validation of cryocheck™ Chromogenic Factor VIII Across Multiple Coagulation Analyzers

Introduction
cryocheck Chromogenic Factor VIII (Precision BioLogic, Dartmouth, Canada) is a chromogenic assay for the determination of factor VIII (FVIII) coagulation activity in human plasma. Our objective was to characterize the performance of cryocheck Chromogenic Factor VIII on three different automated coagulation analyzers manufactured by Diagnostica Stago (STA-R Evolution), Siemens Healthineers (BCS XP) and Instrumentation Laboratory (ACL TOP CTS).

Methods
Precision was determined through a 20 day × 2 replicate or a 5 day × 2 replicate study using three reagent lots.

The reference interval was measured by testing 120 normal 3.2% citrated plasma samples with three reagent lots and calculated using a non-parametric method.

The limits of detection and quantification of the assay were determined by quantifying 8 congenital hemophilia A (HA) plasma samples in a 3 replicate × 5 day × 3 lot study design.

Assay performance was assessed relative to Coatest SP FVIII (Chromogenix/Instrumentation Laboratory, Bedford USA), in a method comparison study by testing 300+ normal and HA plasma samples on an IL ACL TOP. Sixty normal and HA samples were measured on each of the other two analyzer platforms and compared with the ACL TOP results.

Results
The assay total precision was <10% CV and the limits of detection and quantification were 0.5% (FVIII) on each of the three coagulation analyzers. The reference intervals were comparable across analyzers ranging from 41 to 164% FVIII. cryocheck Chromogenic Factor VIII and Coatest SP FVIII results on the IL ACL TOP were similar with a correlation (r) of >0.9 and a bias of <10% up to 150% FVIII activity. cryocheck Chromogenic Factor VIII results on the BCS and STA-R Evolution were comparable to the ACL TOP.

Conclusions
We observed excellent performance and consistency of cryocheck Chromogenic Factor VIII on three common coagulation analyzers when measuring precision, reference interval and limits of detection and quantification. Our findings also suggest that cryocheck Chromogenic Factor VIII performs comparably to another in-market chromogenic FVIII assay for the quantification of FVIII activity while offering compatibility with multiple analyzer platforms and a frozen format that expedites reagent preparation.