ACTICLOT® C – REF ACC-45

Instrument Application for the HORIBA ABX SAS Yumizen G800/G1500/G1550 Analysers

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The following instrument application has been validated on the HORIBA Yumizen G800 coagulation analyser. The programming instructions suggested are based on our knowledge of the analyser and our reagents. These instructions should be used as guidelines in conjunction with your Quality Control Program for validation in accordance with local, state and/or federal regulation or accreditation requirements. If you require assistance or have any questions, please contact your local HORIBA Medical representative.

Materials Required

Item	BioMedica Diagnostics Catalogue No.	Horiba Medical Catalogue No.	Packaging
ACTICLOT® C	ACC-45	1300081527	3 x 1.5 mL 3 x 1.5 mL 3 x 0.5 mL 3 x 5 mL
Special Coagulation Calibrator	C.BMD.SCC030-01ML-A	1300081561	6 x 1 mL
Special Coagulation Control Normal	C.BMD.SCCN180-01ML-A	1300081529	10 x 1 mL
Special Coagulation Control Abnormal	C.BMD.SCCA180-01ML-A	1300081560	10 x 1 mL
$CaCl_2$		1300036386	12 x 4 mL
Clean Vial Big Glass			
Eppendorf Cups			

Yumizen G800/G1500/G1550 Programming Instructions

To start, log in as “Admin”

1. Select “Test Setup” and press the “**+**Add” icon in the footer of the G800/G1500/G1550 screen to add a new program. Enter Pc ac as the “Short Name”, enter PC activity as the “Name.”

2. There are seven (7) screens for the application: Analysis, Reaction, Calibration, Control, Output, Repeat and Postcheck.

3. When finished, press the “Save” icon in the screen footer to save the program in the test menu.

Screen 1 (Analysis)

1. Select Test Method as Clotting.
2. Select Wavelength as 640.
3. Select Algorithm as APTT.
4. Select Warm reagent as Start.
5. Enter Min time as 15, Max time as 180, Lag time as 10

Screen 2 (Reaction)

1. Enter under “Sample”: Volume as 50, Incubation as 0 and Rate as 1/8.
2. Enter under “Diluent Name”: PC Diluent.
3. Enter under “Reag nr”: 3
4. On the “1” line enter “PCDP” as Name and set the following values:

Vol	50
Incubation:	0
Mixing:	Cuv: 3, Pip: 0
Before Wash:	Intensive
After Wash:	Intensive
Spec cleaner:	leave blank
Wash after spec:	leave blank
Calib:	√

5. On the “2” line enter “PC ACT” as Name and set the following values:

Vol	50
Incubation:	240
Mixing:	Cuv: 3, Pip: 0
Before Wash:	No
After Wash:	Intensive
Spec cleaner:	leave blank
Wash after spec:	leave blank
Calib:	√

6. On the “3” line enter “CaCl2” as Name and set the following values:

Vol	50
Incubation:	
Mixing:	Cuv: 3, Pip: 0
Before Wash:	No
After Wash:	Intensive
Spec cleaner:	leave blank
Wash after spec:	leave blank
Calib:	√
Wait Time:	180
Nr of meas:	1
Max diff:	10

Screen 3 (Calibration)

On the “1” line set the following values:

Unit:	%
Calibrator:	SCC
Diluent Name:	PC Diluent
Mode:	Linear regression
Fit:	Lin-Lin
Level nr.:	6
Rates:	1/8, 1/12, 1/20, 1/32, 1/64, 0
Extrapolation:	√
Extrapolation Range:	0, 130
Conversion:	A = 1, B = 0

Screen 4 (Control)

1. Select Level nr. as 2
2. On the “1” line enter “SCCN” as Name
3. On the “2” line enter “SCCA” as Name
4. In the Time Period (h) enter “24”

Screen 5 (Output)

1. Enter under “Unit nr.”: 2
2. On the “1” Line set the following values:

Name:	%
Screen:	√
Print:	√
QC:	√

3. On the “2” Line set the following values:

Name:	s
Print:	√
Online:	√
QC:	√

Screen 6 (Repeat)

No selection/entries made.

Screen 7 (Postcheck)

Enter the following values:

DMin:	100
MinStep:	50
WeakCoag:	50
SlopeDX:	0
SlopeDY:	0
MinRecTime:	50
MaxValue:	3500
Discontinue:	60
HistWidth:	15
HistLimit:	150

Catalogue Configuration:

1.1. Protein C Activator

Press the “+Add” icon in the footer of the G800/G1500/G1550 reagent screen to add a new Reagent.

Select Type “Reagent”
Enter “PC ACT” as the “Name”
Enter the reagent lot number printed on the vial as “Lot”,
Enter ACC-45A as “Ref Number”
Enter the expiration date printed on the vial as “ExpDate”
Enter “8” as “Onboard Time”
Enter “1.5” as “Nominal Volume”’
Select “Eppendorf Cup” as “Vial Type”
Press “OK” icon to confirm the Protein C Activator configuration.

Press the “Save” icon in the reagent screen footer to save the reagent configuration.

1.2. Protein C Deficient Plasma

Press the “+Add” icon in the footer of the G800/G1500/G1550 reagent screen to add a new Reagent.

Select Type “Reagent”’
Enter “PCDP” as the ‘Name’
Enter the reagent lot number printed on the vial as “Lot”
Enter “ACC-45P” as ‘Ref Number’
Enter the expiration date printed on the vial as “ExpDate”
Enter “8” as “Onboard Time”
Enter “1.5” as “Nominal Volume”
Select “Eppendorf Cup” as “Vial type”

Press “OK” icon to confirm the Protein C Deficient Plasma configuration.
Press the “Save” icon in the reagent screen footer to save the reagent configuration.

1.3. Dilution Buffer

Note: Dilution Buffer is supplied as a concentrate. Prepare working strength Dilution Buffer by diluting the concentrate 1:10 with filtered deionized water.

Press the “+Add” icon in the footer of the G800/G1500/G1550 reagent screen to add a new Reagent.

Select Type “Other”’
Enter “PC Diluent” as the “Name”
Enter the reagent lot number printed on the vial as “Lot”
Enter “ACC-45D” as “Ref Number”
Enter the expiration date printed on the vial as “ExpDate”
Enter “8” as “Onboard Time”
Enter “15” as “Nominal Volume”
Select “Vial big glass” as “Vial Type”

Press “OK” icon to confirm the Dilution Buffer configuration.
Press the “Save” icon in the reagent screen footer to save the reagent configuration.

1.4. Calibrator

Press the “+Add” icon in the footer of the G800/G1500/G1550 reagent screen to add a new Calibrator.

Select Type “Calibrator”
Enter “SCC” as the “Name”

Enter the Calibrator lot number printed on the vial as “Lot”
Enter “SCC030” as “Ref Number”
Enter the expiration date printed on the vial as “ExpDate”
Enter “8” as “Onboard Time”
Enter “1” as “Nominal Volume”
Select “Eppendorf Cup” as “Vial Type”

In Calibrator panel, select:

Line 1: “PC ac ”’ as “Test”, “%” as “Unit” “XX” as “Value”

Press “OK” icon to confirm the Calibrator configuration.
Press the “Save” icon in the reagent screen footer to save the Calibrator configuration.

1.5. Normal Control

Press the “+Add” icon in the footer of the G800/G1500/G1550 reagent screen to add a new Control.

Select Type “Control”
Enter “SCCN” as the “Name”
Enter the control lot number printed on the vial as “Lot”
Enter “SCCN180” as “Ref Number”
Enter the expiration date printed on the vial as “ExpDate”
Enter “8” as “Onboard Time”
Enter “1” as “Nominal Volume”
Select “Eppendorf Cup” as “Vial Type”

In Control panel, select:

Line 1: “PC ac”’ as “Test”, “%” as “Unit”, “XX” as “Min”, “XXX” as “Max”

Press “OK” icon to confirm the Normal Control configuration.
Press the “Save” icon in the reagent screen footer to save the Normal Control configuration.

1.6. Abnormal Control

Press the “+Add” icon in the footer of the G800/G1500/G1550 reagent screen to add a new Control.

Select Type “Control”
Enter “SCCA” as the “Name”
Enter the control lot number printed on the vial as “Lot”
Enter “SCCA180” as “Ref Number”
Enter the expiration date printed on the vial as “ExpDate”

Enter “8” as “Onboard Time”
Enter “1” as “Nominal Volume”
Select “Eppendorf Cup” as “Vial Type”

In Control panel, select:

Line 1: “PC ac”’ as “Test”, “%” as “Unit”, “XX” as “Min”, “XX” as “Max”

Press “OK” icon to confirm the Abnormal Control configuration.
Press the “Save” icon in the reagent screen footer to save the Abnormal Control configuration.

Data Summary

Linearity

The linearity of ACTICLOT C was determined by assaying plasma samples at eleven (11) different levels, prepared as eleven(11 dilutions of a normal plasma, within the stated working range of the assay. Each sample was prepared by direct dilution of the original high sample rather than by serial dilutions. Triplicate measurements were made on each sample and the mean of the triplicates calculated.

ACTICLOT C is linear from 2.5% – 130% of normal.

Limit of Detection

The Limit of Detection, LoD, for ACTICLOT C at a 95% Confidence Interval is 2.5%. This level was established by testing a blank (Protein C deficient) plasma sample and a low (5%) Protein C plasma sample in 20 replicates each per day over 3 days. The LoD was calculated following CLSI EP17-A: Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline.

Precision

Repeatability, Precision (within instrument) and Reproducibility for ACTICLOT C at a 95% CI was determined by testing a normal pooled plasma and an abnormal Protein C plasma over 5 days with 5 replicates per day for each sample. The Coefficient of Variation, CV, was calculated following CLSI EP05-A3: Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition, Section 4.6 for a 3x5x5 study format.

The following Coefficient of Variations were determined.

ACTICLOT C	Test Sample	Repeatability CV at 95% CI	Within-instrument Precision CV at 95% CI	Reproducibility CV at 95% CI
	Normal	8.7%	9.3%	9.3%
	Abnormal	9.4%	12.5%	13.1%

On-Board Reconstituted Reagent Stability

The stability of reconstituted reagents stored on board the Yumizen G800/G1500/G1550 analyser was confirmed as follows:

Reagent	Storage Temperature	Stability
ACTICLOT Activator	17°C, On-Board Open Vial	8 hours
Protein C Deficient Plasma	17°C, On-Board Open Vial	8 hours
Dilution Buffer	17°C, On-Board Open Vial	8 hours
Special Coagulation Calibrator	17°C, On-Board Open Vial	8 hours
Special Coagulation Control Normal	17°C, On-Board Open Vial	8 hours
Special Coagulation Control Abnormal	17°C, On-Board Open Vial	8 hours

The stability data presented above have been established under controlled laboratory conditions. Due to possible differences in "ambient conditions" between each laboratory and reagent, the on-board stability may vary from the values stated above.

Interference Studies

The results demonstrate no significant interference in the performance of ACTICLOT C by the presence of the following substances up to the noted concentrations.

Substance	Concentration
Hemoglobin	500 mg/dL
Bilirubin, Conjugated	20 mg/dL
Bilirubin, Unconjugated	20 mg/dL
Triglycerides	750 mg/dL

Note – For an explanation on how to set up or change a test protocol on the G800/G1500/G1550, please refer to the respective HORIBA ABX SAS Operator's Manual System Set-Up.

Reference

1. ACTICLOT® is a registered trademark of BioMedica Diagnostics Inc., Windsor, NS, Canada

2. Yumizen G800, Yumizen G1550, Yumizen G1550 are marks of HORIBA ABX SAS, Montpellier, France