

ACTICHROME® AT III – REF 838

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

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
ACTICHROME® AT III	838	1300081528	6 x 2.0 mL (R1) 6 x 2.0 mL (R2) 6 x 5.0 mL (R3)
Special Coagulation Calibrator	C.BMD.SCC030-01ML-A	1300081561	10 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
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 AT chromo as the “Short Name”, enter AT chromogenic 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 Kinetic.
2. Select Wavelength as 405.
3. Select Algorithm as Chromogenic.
4. Select Warm reagent as Start.
5. Enter First Time as 10, End time as 40.

Screen 2 (Reaction)

1. Enter under “Sample”: Volume as 60, Incubation as 30 and Rate as 1/60.
2. Enter under “Diluent Name”: “AT R3”.
3. Enter under “Reag nr”: 2
4. On the “1” line enter “AT R1” as Name and set the following values:

Vol	40
Incubation:	60
Mixing:	Cuv: 3, Pip: 0
Before Wash:	Intensive
After Wash:	Special
Spec cleaner:	SORB
Wash after spec:	1
Calib:	√

5. On the “2” line enter “AT R2” as Name and set the following values:

Vol	50
Mixing:	Cuv: 3, Pip: 0
Before Wash:	No
After Wash:	Intensive
Calib:	√

6. Enter the following values:

Wait Time: 80
Nr of meas: 1
Max diff: 10

Screen 3 (Calibration)

1. Select Unit as %
2. Select Mode as Linear regression
3. Select Fit as Lin-Lin
4. Select Level nr. as 5
5. Enter the following values:

Dilution: √
Calibrator: SCC
Diluent Name: AT R3
Rates: 1/50, 1/65, 1/90, 1/150, 0
Extrapolation: √
Extrapolation range: 0, 170

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: √
Online: √
QC: √

3. On the "2" Line set the following values:

Name: OD/min
Print: √
Online: √
QC: √

Screen 6 (Repeat)

No selection/entries made.

Screen 7 (Postcheck)

Enter the following values:

Linearity: 0.98

Catalogue Configuration:

1.1. Thrombin

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

Select Type “Reagent”

Enter “AT R1” as the “Name”

Enter the reagent lot number printed on the vial as “Lot”,

Enter 838THR as “Ref Number”

Enter the expiration date printed on the vial as “ExpDate”

Enter “8” as “Onboard Time”

Enter “2” as “Nominal Volume”

Select “Vial glass” as “Vial Type”

Press “OK” icon to confirm the Thrombin configuration.

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

1.2. SPECTROZYME® TH Substrate

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

Select Type “Reagent”

Enter “AT R2” as the ‘Name’

Enter the reagent lot number printed on the vial as “Lot”

Enter “838SUB” as ‘Ref Number’

Enter the expiration date printed on the vial as “ExpDate”

Enter “8” as “Onboard Time”

Enter “2” as “Nominal Volume”

Select “Vial glass” as “Vial Type”

Press “OK” icon to confirm the Substrate configuration.

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

1.3. Assay Buffer

Note: Assay Buffer is supplied as a concentrate. Preparation of working strength Assay Buffer by diluting the concentrate to a volume of 25 mL (1:5) with filtered deionized water. This differs from the ACTICHROME AT III Instructions for Use.

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

Select Type “Other”
Enter “AT R3” as the “Name”
Enter the reagent lot number printed on the vial as “Lot”
Enter “838AB” 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 Assay 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 “4” as “Onboard Time”
Enter “1” as “Nominal Volume”
Select “Eppendorf Cup” as “Vial Type”

In Calibrator panel, select:

Line 1: “AT chromo” 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 “4” as “Onboard Time”

Enter “1” as “Nominal Volume”

Select “Eppendorf Cup” as “Vial Type”

In Control panel, select:

Line 1: “AT chromo” 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 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 “4” as “Onboard Time”

Enter “1” as “Nominal Volume”

Select “Eppendorf Cup” as “Vial Type”

In Control panel, select:

Line 1: “AT chromo” 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 control configuration.

Data Summary

Linearity

The linearity of ACTICHROME AT III 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.

ACTICHROME AT III is linear from 10% – 170% of normal.

Limit of Detection

The Limit of Detection, LoD, for ACTICHROME AT III at a 95% Confidence Interval was found to be 7.9%.

Precision

Repeatability, and Reproducibility for ACTICHROME AT III at a 95% CI was determined by testing the Special Coagulation Control Normal and Special Coagulation Control Abnormal plasma over twenty (20) days, two (2) replicates per run for each sample on a single (1) instrument. 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 2x2x20 study format.

The following Coefficient of Variations were determined.

Test Sample	Mean AT III Level	Repeatability CV at 95% CI	Reproducibility CV at 95% CI
Special Coagulation Control Normal	106.0%	2.6% (2.1-3.3)	4.9% (4.1-6.5)
Special Coagulation Control Abnormal	37.1%	8.2% (6.7–10.4)	9.7% (8.5–12.3)

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
Thrombin	17°C, on-board open vial	8 hours
SPECTROZYME® TH Substrate	17°C, on-board open vial	8 hours
Assay Buffer	Ambient, on-board open vial	8 hours
Special Coagulation Calibrator	Ambient, on-board open vial	8 hours
Special Coagulation Control Normal	Ambient, on-board open vial	8 hours
Special Coagulation Control Abnormal	Ambient, 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 ACTICHROME AT III by the presence of the following substances up to the noted concentrations.

Substance	Concentration
Hemoglobin	350 mg/dL
Bilirubin, Conjugated	15 mg/dL
Bilirubin, Unconjugated	14.5 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. ACTICHROME and SPECTROZYME are registered trademarks of BioMedica Diagnostics Inc., Windsor, NS, Canada
2. Yumizen G800, Yumizen G1550, Yumizen G1550 are marks of HORIBA ABX SAS, Montpellier, France