DVVtest®/DVVconfirm® – REF 810, REF 815

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
DVVtest® 10	810	1300079431	10 x 2 mL
DVVconfirm® 5	815	1300079433	10 x 1 mL
LAtrol™ Abnormal Control Plasma	816A	1300079434	10 x 0.5 mL
LAtrol™ Normal Control Plasma	816N	1300079435	10 x 1 mL
Small glass vial adaptor			

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 to add a new program. Enter DRVVT as the “Short Name”, enter DRVVT as the “Name.”

   Note, the application for the DVVtest is identical to the application for DVVconfirm. Enter DRVVC and DRVVC as the “Short Name” and “Name” when adding it to the test menu.

2. There are six (6) screens for the application: Analysis, Reaction, Calibration, Control, Output and Repeat.

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

DVVtest or DVVconfirm

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 200, Lag time as 7.

Screen 2 (Reaction)

1. Enter under “Sample”: Volume as 100, Incubation as 30 and Rate as 1/1.
2. Enter under “Reag nr”: 1
3. On the “1” line enter “DVVtest” as Name and set the following values:

   Vol: 100
   Mixing, Cuv: 2, Pip: 0
   Before Wash: No
   After Wash: Intensive
   Wait Time: 40
   Nr of meas: 1
   Max diff: 10
   Total Count: 0

Screen 3 (Calibration)

Select “Mean”

Screen 4 (Control)

1. Enter under “Level nr”: 2
2. On the “1.” Line, enter LAtrol N
3. On the “2.” line, enter LAtrol A
4. Enter under “Time Period”: 24

Screen 5 (Output)

Select the Output options for Screen, Print, Online and QC.

Screen 6 (Repeat)

As repeating the DVVtest/DVVconfirm is not required, the Repeat Screen is left blank. Do not make any selections or enter any values.

Catalogue Configuration:

1.1 DVVtest

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

Select Type ‘Reagent’
Enter ‘DVVtest’ as the ‘Name’
Enter the reagent lot number printed on the vial as ‘Lot’
Enter ‘810’ 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 small glass’ as ‘Vial Type’
Enter “XX.X” as Mean (this is the mean of your laboratory’s Normal Reference Range)

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

1.2. DVVconfirm

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

Select Type ‘Reagent’
Enter ‘DVVconfirm’ as the ‘Name’
Enter the reagent lot number printed on the vial as ‘Lot’,
Enter ‘815’ as ‘Ref Number’
Enter the expiration date printed on the vial as ‘ExpDate’
Enter ‘8’ as Onboard Time’
Enter ‘1’ as ‘Nominal Volume’
Select ‘Vial small glass’ as ‘Vial Type’
Enter “XX.X” as Mean (this is the mean of your laboratory’s Normal Reference Range)

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

1.3. 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 ‘LAtrol N’ as the ‘Name’
Enter the control lot number printed on the vial as ‘Lot’
Enter ‘816N’ 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: ‘DRVVT’ as ‘Test’, ‘s’ as ‘Unit’, ‘XX’ as ‘Min’, ‘XX’ as ‘Max’
Line 2: ‘DRVVC’ as ‘Test’, ‘s’ as ‘Unit’, ‘XX’ as ‘Min’, ‘XX’ as ‘Max’

Press “OK” icon to confirm the ‘LAtrol N’ configuration.
Press the “Save” icon in the reagent screen footer to save the control configuration.

1.4. 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 ‘LAtrol A’ as the ‘Name’
Enter the control lot number printed on the vial as ‘Lot’,

Enter '816A' as 'Ref Number'
Enter the expiration date printed on the vial as 'ExpDate'
Enter '8' as Onboard Time'
Enter '0,5' as 'Nominal Volume'
Select 'Eppendorf cup' as 'Vial Type'

In Control panel, select:

Line 1: 'DRVVT' as 'Test', 's' as 'Unit', 'XX' as 'Min', 'XX' as 'Max'
Line 2: 'DRVVC' as 'Test', 's' as 'Unit', 'XX' as 'Min', 'XX' as 'Max'

Press "OK" icon to confirm the 'LAtrol A' configuration.
Press the "Save" icon in the reagent screen footer to save the control configuration.

Data Summary

Normal Reference Range

A normal reference range for DVVtest and DVVconfirm was determined using frozen plasma samples from apparently normal healthy donors (n=120 samples, n=120 samples, respectively). The ranges at a 95% Confidence Interval (CI), determined following CLSI Guideline EP28-A3c, are as follows:

REF	n	Mean Clot Time	Lower Limit	Upper Limit
DVVtest	120	46.0 sec	37.9 sec	54.3 sec
DVVconfirm	120	37.1 sec	31.4 sec	44.3 sec

Diagnostic Ratios

The cut-offs indicating a positive test for the presence of Lupus Anticoagulants were calculated as the mean DVVtest/DVVconfirm ratio + 2 SD (Standard Deviation), and as the Normalized Ratio + 2 SD. Refer to the DVVtest/DVVconfirm Instructions For Use for a detailed explanation of the calculations and the decision flow chart. The results are as follows:

Method	Mean Ratio	SD	Mean Ratio + 2 SD
DVVtest/DVVconfirm	1.24	0.10	1.44
Normalized Ratio	1.00	0.08	1.16

Precision

Repeatability, Precision (within instrument) and Reproducibility for DVVtest and DVVconfirm at a 95% CI was determined by testing a normal pooled plasma and an LA positive 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.

DVVtest	Test Sample	Repeatability CV at 95% CI	Within-instrument Precision CV at 95% CI	Reproducibility CV at 95% CI
	816N	2.0% (1.7 – 2.4)	2.2% (1.9 – 3.0)	6.8% (4.4 – 18.8)
	816A	3.3% (2.8 – 4.0)	4.3% (3.6 – 6.3)	5.6% (4.5 – 12.1)

DVVconfirm	Test Sample	Repeatability CV at 95% CI	Within-instrument Precision CV at 95% CI	Reproducibility CV at 95% CI
	816N	1.8% (1.6 – 2.3)	2.2% (1.9 – 3.1)	2.3% (2.0 – 3.8)
	816A	3.6% (3.0 – 4.4)	4.5% (3.8 – 6.4)	4.7% (4.0 – 7.9)

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
DVVtest	17°C, On-Board Open Vial	8 hours
DVVconfirm	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 DVVtest or DVVconfirm by the presence of the following substances up to the noted concentrations.

Substance	Concentration
Unfractionated Heparin (UFH)	1.2 U/mL
Low Molecular Weight Heparin (LMW)	0.9 U/mL
Hemoglobin	420 mg/dL
Bilirubin, Conjugated	16.5 mg/dL
Bilirubin, Unconjugated	16.2 mg/dL
Triglycerides	360 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. DVVtest® and DVVconfirm® 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