



Manufactured By: HYPHEN BioMed

## Hyphen Biomed – Biophen FVIII Chromogenic Cat # A221402

### Material Definition:

FVIIIc R1

Instrument Actions Analysis QC Calibration NPP Setup System Help

General Information Stir, Rinse & Clean Information Lot Specific Information

Material index: 522 Category: Reagents  
Material name: FVIIIc R1 Material type: Intermediate reagent  
Manufacturer: Hyphen Biomed Bottle type: 4mL

Volume tracking  
 Enable volume threshold: 0.50 mL  
 Enable expiration tracking  
 Enable warning threshold: 1 Days

On-board stability  
 Enable refrigerated on-board stability tracking  
On-board stability: 24 Hours  
 Enable warning threshold: 1 Hours  
 Enable ambient on-board stability tracking  
On-board stability: 1 Hours  
 Enable warning threshold: 1 Hours  
 Test not feasible when stability is expired

Comments:

Track Identifier	Rack Identifier	Rack Pos. Identifier	Lot ID
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Analyzer status: Not connected  
LIS status: Not connected  
Auto Run status: Ready

Instrument Actions Analysis QC Calibration NPP Setup System Help

General Information Stir, Rinse & Clean Information Lot Specific Information

Rinse  
Frequency: Between changes in material only  
Rinse time: 1 s  
 Enable agitation  
 Stringing required

Clean & Rinse  
Number of clean & rinse cycles: 1  
Clean cycle  
Clean material: System Clean  
Number of aspiration cycles: 1  
Clean airgap: 15 uL  
Clean volume: 130 uL  
Clean transport airgap: 0 uL  
Clean total volume: 145 uL  
Hold time: 0 s  
 Enable agitation  
Clean material volume for all cycles: 130 uL  
Rinse cycle  
Frequency: Between changes in material only  
Rinse after clean time: 1 s  
 Enable agitation

Analyzer status: Not connected  
LIS status: Not connected  
Auto Run status: Ready



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# FVIIIc R2

Instrument Actions Analysis QC Calibration NPP Setup System Help

General Information Stir, Rinse & Clean Information Lot Specific Information

Material index: 523 Category: Reagents  
 Material name: FVIIIc R2 Material type: Intermediate reagent  
 Manufacturer: Hyphen Biomed Bottle type: 4mL

Volume tracking  
 Enable volume threshold: 0.50 mL  
 Enable expiration tracking  
 Enable warning threshold: 1 Days

On-board stability  
 Enable refrigerated on-board stability tracking  
 On-board stability: 24 Hours  
 Enable warning threshold: 1 Hours  
 Enable ambient on-board stability tracking  
 On-board stability: 1 Hours  
 Enable warning threshold: 1 Hours  
 Test not feasible when stability is expired

Comments:

Track Identifier	Rack Identifier	Rack Pos. Identifier	Lot ID

Analyzer status: Not connected  
 LIS status: Not connected  
 Auto Run status: Ready

Instrument Actions Analysis QC Calibration NPP Setup System Help

General Information Stir, Rinse & Clean Information Lot Specific Information

Rinse  
 Frequency: Between changes in material only  
 Rinse time: 1 s  
 Enable agitation  
 Stirring required

Clean & Rinse  
 Number of clean & rinse cycles: 1  
 Clean cycle  
 Clean material: Clean B Diluted  
 Number of aspiration cycles: 1  
 Clean airgap: 15 uL  
 Clean volume: 130 uL  
 Clean transport airgap: 0 uL  
 Clean total volume: 145 uL  
 Hold time: 0 s  
 Enable agitation  
 Clean material volume for all cycles: 130 uL  
 Rinse cycle  
 Frequency: Between changes in material only  
 Rinse after clean time: 1 s  
 Enable agitation

Analyzer status: Not connected  
 LIS status: Not connected  
 Auto Run status: Ready

# FVIIIc R3

Instrument Actions Analysis QC Calibration NPP Setup System Help

General Information Stir, Rinse & Clean Information Lot Specific Information

Material Index: 524 Category: Reagents  
 Material name: FVIIIc R3 Material type: Start reagent  
 Manufacturer: Hyphen Biomed Bottle type: 4mL

Volume tracking  
 Enable volume threshold: 0.50 mL  
 Enable expiration tracking  
 Enable warning threshold: 1 Days

On-board stability  
 Enable refrigerated on-board stability tracking  
 On-board stability: 24 Hours  
 Enable warning threshold: 1 Hours  
 Enable ambient on-board stability tracking  
 On-board stability: 1 Hours  
 Enable warning threshold: 1 Hours  
 Test not feasible when stability is expired

Comments:

Track Identifier	Rack Identifier	Rack Pos. Identifier	Lot ID

Analyzer status: Not connected  
 LIS status: Not connected  
 Auto Run status: Ready

Instrument Actions Analysis QC Calibration NPP Setup System Help

General Information Stir, Rinse & Clean Information Lot Specific Information

Rinse  
 Frequency: Between changes in material only  
 Rinse time: 3 s  
 Enable agitation  
 Stirring required

Clean & Rinse  
 Number of clean & rinse cycles: 1  
 Clean cycle  
 Clean material: System clean  
 Number of aspiration cycles: 1  
 Clean airgap: 15 uL  
 Clean volume: 130 uL  
 Clean transport airgap: 0 uL  
 Clean total volume: 145 uL  
 Hold time: 0 s  
 Enable agitation  
 Clean material volume for all cycles: 130 uL  
 Rinse cycle  
 Frequency: Between changes in material only  
 Rinse after clean time: 1 s  
 Enable agitation

Analyzer status: Not connected  
 LIS status: Not connected  
 Auto Run status: Ready

# FVIIIc R4

Instrument Actions Analysis QC Calibration NPP Setup System Help

General Information Stir, Rinse & Clean Information Lot Specific Information

Material index: 525 Category: Diluents  
 Material name: FVIIIc R4 Material type: Sample Diluent  
 Manufacturer: Hyphen Biomed Bottle type: 10mL

Volume tracking  
 Enable volume threshold: 2.10 mL  
 Enable expiration tracking  
 Enable warning threshold: 1 Days

On-board stability  
 Enable refrigerated on-board stability tracking  
 On-board stability: 24 Hours  
 Enable warning threshold: 1 Hours  
 Enable ambient on-board stability tracking  
 On-board stability: 1 Hours  
 Enable warning threshold: 1 Hours  
 Test not feasible when stability is expired

Comments:

Track Identifier	Rack Identifier	Rack Pos. Identifier	Lot ID

Analyzer status: Not connected  
 LIS status: Not connected  
 Auto Run status: Ready

Instrument Actions Analysis QC Calibration NPP Setup System Help

General Information Stir, Rinse & Clean Information Lot Specific Information

Rinse  
 Frequency: Between changes in material only  
 Rinse time: 1 s  
 Enable agitation  
 Stirring required

Clean & Rinse  
 Number of clean & rinse cycles: 1  
 Clean cycle  
 Clean material: System clean  
 Number of aspiration cycles: 1  
 Clean airgap: 15 uL  
 Clean volume: 130 uL  
 Clean transport airgap: 0 uL  
 Clean total volume: 145 uL  
 Hold time: 0 s  
 Enable agitation  
 Clean material volume for all cycles: 130 uL  
 Rinse cycle  
 Frequency: Between changes in material only  
 Rinse after clean time: 1 s  
 Enable agitation

Analyzer status: Not connected  
 LIS status: Not connected  
 Auto Run status: Ready

## Test Definition: FVIII c

Instrument Actions Analysis QC Calibration NPP Setup System Help

Test Definition - FVIIIc

**General information**

Test code: FVIIIc Test name: FVIII Chromogenic

LIS number: Test number:  IL test:  For investigation of:

**Assay**

Assay release number: 6.6

Test modification number: 2

User revision comment: Copy of PLG P14.6

IL revision comment:

Enable as shadow test

Parent test:

Enable as paired test

Master paired test:

Enable paired test dependency

**Consistency Check. (Double click to go to the inconsistency).**

Analyzer status: Not connected  
 LIS status: Not connected  
 Auto Run status: Ready

Instrument Actions Analysis QC Calibration NPP Setup System Help

Test Definition - FVIIIc

**Analytical cycle definition**

**Acquisition - wavelength**

Primary wavelength: W-495 nm

**Acquisition - time**

Standard time: 150 s  
 Delay time: 20 s

Enable extended test mode

Extended time: 30 s

LIS number: Test code: FVIIIc(E)

**Load cycle**

Number of replicates: 1

Material Name	Type	Load Volume	Incubation Range
Sample		50	20.000 - 60.000
FVIIIc R1	Int. Reagent	50	20.000 - 60.000
FVIIIc R2	Int. Reagent	50	300.000 - 320.000
FVIIIc R3	Start Reagent	50	

Total cuvette volume: 200 uL

**Consistency Check. (Double click to go to the inconsistency).**

Analyzer status: Not connected  
 LIS status: Not connected  
 Auto Run status: Ready

**Material/Sample Load Cycle Definition**

Material: **Sample**

Enhanced Dispense

Head volume: 0  $\mu\text{L}$

Airgap: 15  $\mu\text{L}$

Head volume airgap: 0  $\mu\text{L}$

Material/Sample volume: 50  $\mu\text{L}$

Transport airgap: 30  $\mu\text{L}$

Total volume: 95  $\mu\text{L}$

Rinse

Time: 1 s

Enable agitation: 1

Clean & rinse

Clean & rinse cycles: 1

Clean material: System clean

Aspiration cycles: 1

Clean airgap: 15  $\mu\text{L}$

Clean volume: 150  $\mu\text{L}$

Clean transport airgap: 0  $\mu\text{L}$

Clean total volume: 165  $\mu\text{L}$

Hold time: 0

Enable agitation: 1

Clean volume (all cycles): 150  $\mu\text{L}$

Frequency: Between changes in material only

Rinse time: 1 s

Enable agitation: 1

Enable mix

Mix: 50 %

Rinse time after mix: 3 s

Number of cycles: 1

Enable incubation time

Incubation range: 20.000 - 60.000 s

OK Cancel

**Material/Sample Load Cycle Definition**

Material: **PVIII.R1**

Enhanced Dispense

Head volume: 0  $\mu\text{L}$

Airgap: 15  $\mu\text{L}$

Head volume airgap: 0  $\mu\text{L}$

Material/Sample volume: 50  $\mu\text{L}$

Transport airgap: 30  $\mu\text{L}$

Total volume: 95  $\mu\text{L}$

Rinse

Time: 0 s

Enable agitation: 1

Clean & rinse

Clean & rinse cycles: 1

Clean material: System clean

Aspiration cycles: 1

Clean airgap: 15  $\mu\text{L}$

Clean volume: 150  $\mu\text{L}$

Clean transport airgap: 0  $\mu\text{L}$

Clean total volume: 165  $\mu\text{L}$

Hold time: 0

Enable agitation: 1

Clean volume (all cycles): 150  $\mu\text{L}$

Frequency: Between changes in material only

Rinse time: 1 s

Enable agitation: 1

Enable mix

Mix: 50 %

Rinse time after mix: 3 s

Number of cycles: 1

Enable incubation time

Incubation range: 20.000 - 60.000 s

OK Cancel

**Material/Sample Load Cycle Definition**

Material: **PVIII.R2**

Enhanced Dispense

Head volume: 0  $\mu\text{L}$

Airgap: 15  $\mu\text{L}$

Head volume airgap: 0  $\mu\text{L}$

Material/Sample volume: 50  $\mu\text{L}$

Transport airgap: 40  $\mu\text{L}$

Total volume: 105  $\mu\text{L}$

Rinse

Time: 0 s

Enable agitation: 1

Clean & rinse

Clean & rinse cycles: 1

Clean material: System clean

Aspiration cycles: 1

Clean airgap: 15  $\mu\text{L}$

Clean volume: 130  $\mu\text{L}$

Clean transport airgap: 0  $\mu\text{L}$

Clean total volume: 145  $\mu\text{L}$

Hold time: 0

Enable agitation: 1

Clean volume (all cycles): 130  $\mu\text{L}$

Frequency: Between changes in material only

Rinse time: 1 s

Enable agitation: 1

Enable mix

Mix: 100 %

Rinse time after mix: 3 s

Number of cycles: 1

Enable incubation time

Incubation range: 300.000 - 320.000 s

OK Cancel

**Material/Sample Load Cycle Definition**

Material: **FVIIIc R3**

Enhanced Dispense

Head volume:   $\mu\text{L}$

Airgap:   $\mu\text{L}$

Head volume airgap:   $\mu\text{L}$

Material/Sample volume:   $\mu\text{L}$

Transport airgap:   $\mu\text{L}$

Total volume:   $\mu\text{L}$

Rinse:

Time:  s

Enable agitation:  s

Clean & rinse:

Clean & rinse cycles:  s

Clean material:  s

System clean:  s

Aspiration cycles:  s

Clean airgap:   $\mu\text{L}$

Clean volume:   $\mu\text{L}$

Clean transport airgap:   $\mu\text{L}$

Clean total volume:   $\mu\text{L}$

Hold time:  s

Enable agitation:  s

Clean volume (all cycles):   $\mu\text{L}$

Frequency:  s

Rinse time:  s

Enable mix

Mix:  %

Rinse time after mix:  s

Number of cycles:  s

Enable incubation time

Incubation range:  -  s

OK Cancel

Instrument Actions Analysis QC Calibration NPP Setup System Help

Test Definition - FVIIIc

- General information
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- Rerun - Rules

Enable sample pre-dilution

**General** Sample/Mixture Diluent

Dilution definition

Number of parts sample:

Number of parts diluent:

Minimum aspiratable volume:   $\mu\text{L}$

Volumes ( $\mu\text{L}$ )		
Sample	Mixture	Diluent
5		195

Enable mix

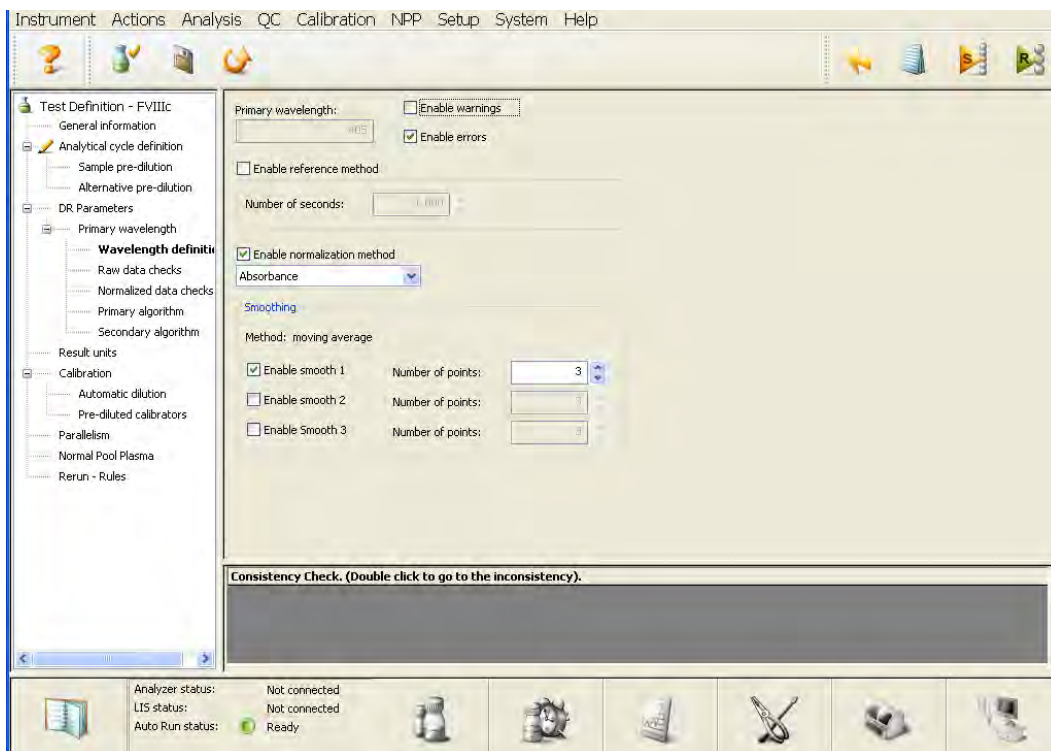
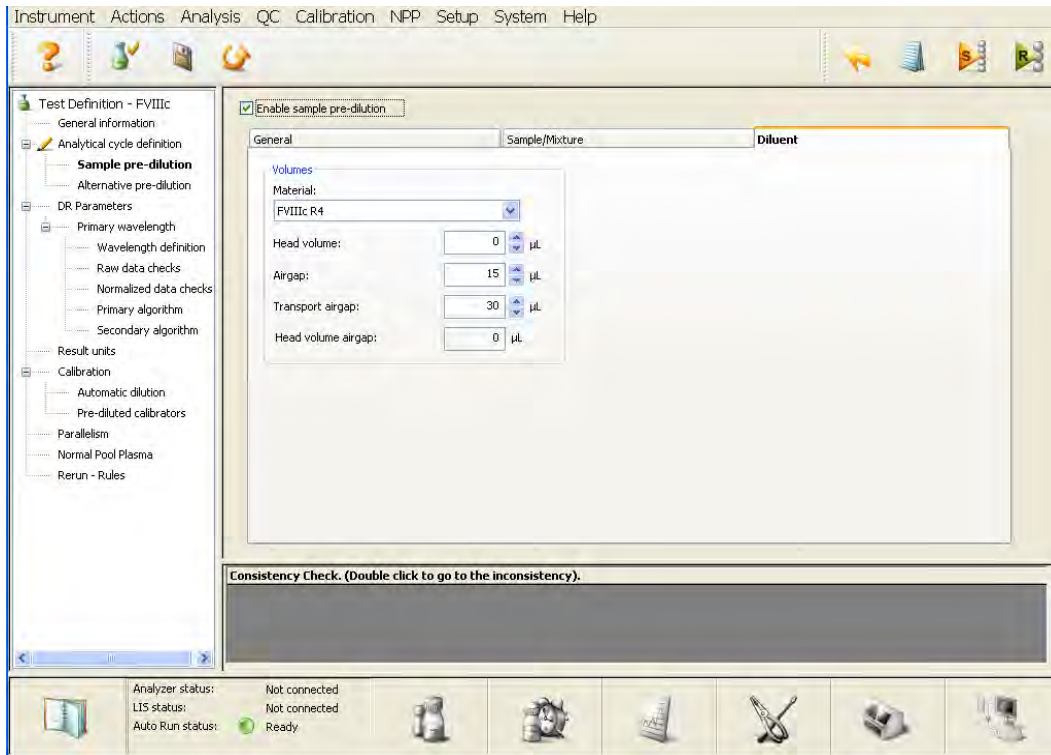
Mix volume:  %

Number of cycles:

Rinse after mix:  s

**Consistency Check. (Double click to go to the inconsistency).**

Analyzer status: Connecting...  
 LIS status: Not connected  
 Auto Run status: Ready



Instrument Actions Analysis QC Calibration NPP Setup System Help

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**Enable raw data checks**

Enable first point check

Enable spike removal

Error threshold:  Max. % of curve delta:

Warning threshold:  Max. % of illegal points:

Enable last point check

Enable substitution method

Error threshold:  Extrapolate

Warning Threshold:

Enable signal check

Enable baseline by moving SD

Signal minimum:   Enable percentage of time

Signal maximum:  Percentage:  %

Maximum illegal values:  %  Enable absolute time

Enable substitution method

Extrapolate

Time:  s

Enable curve sequence check

Min follows max

Size of window:  s

**Consistency Check. (Double click to go to the inconsistency).**

Analyzer status: Not connected  
 LIS status: Not connected  
 Auto Run status: Ready

Instrument Actions Analysis QC Calibration NPP Setup System Help

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**Enable normalized data checks**

Normalized Signal Check

Enable Normalized Curve Delta Upper Limit

Error limit (Upper):  Warning limit (Upper):

Enable Normalized Curve Delta Lower Limit

Error limit (Lower):  Warning limit (Lower):

Enable calibrated result delta check

Max. Tolerance:  % Max. Tolerance warning:  %

**Baseline Check** Endpoint Check Multiple Threshold Check

Enable baseline check

Number of seconds:

Enable mean check

Target value:

Error tolerance:  % Error range:  -

Warning tolerance:  % Warning range:  -

Enable SD check

Error limit:  Warning limit:

**Consistency Check. (Double click to go to the inconsistency).**

Analyzer status: Not connected  
 LIS status: Not connected  
 Auto Run status: Ready

Instrument Actions Analysis QC Calibration NPP Setup System Help

Test Definition - FVIIIc

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Enable primary algorithm

Endpoint  
 Linear Kinetic  
 Threshold  
 First derivative  
 Second derivative  
 Delta  
 Final minus initial  
 Statistic

Linear kinetic

Slope of curve  
 Start time: 0.000 s Time: 25.000 s

Delta of curve  
 Method: Baseline/Endpoint averages  
 Start time: 0.000 s Baseline time: 1.000 s  
 End time: 25.000 s Endpoint time: 1.000 s

Enable linear regression SD error check  Enable linear regression SD warning check

SD error limit: 10.000 SD warning limit: 19.000

Enable negative calculation  
 Enable initial slope check

Time: 0.000 s Maximum error limit: 0.000  
 Maximum warning limit: 10.000

Consistency Check. (Double click to go to the inconsistency).

Analyzer status: Not connected  
 LIS status: Not connected  
 Auto Run status: Ready

Instrument Actions Analysis QC Calibration NPP Setup System Help

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Result unit definition

Unit	Unit Type	Label	dec.	Normal Range	Therapeutic Range	Linear Range	Test Range
Milliabsorbance...	Measured	mAbs/min	2				10.00 8800.00
%	Calibrated	%	0	50 150		10 200	10 200
U/mL	Calibrated	U/mL	2	0.50 1.50		0.10 2.00	0.10 2.00

Patient result selection  
 Unit 1: U/mL  
 Unit 2: %  
 Unit 3: Milliabsorbance/min  
 Unit 4:

Primary unit cfg.  
 Primary unit: %  
 Enable max difference  
 Max difference: 10 %

Measured result curve display settings  
 Enable auto scale  
 Raw  
 Normalized (Absorbance)  
 Y-Axis minimum: 0.000 Y-Axis maximum: 3000.000 mAbs

Consistency Check. (Double click to go to the inconsistency).

Analyzer status: Not connected  
 LIS status: Not connected  
 Auto Run status: Ready

**Non IL - Result Unit Definition**

Unit selection  
Unit type: Measured  
Unit: Millabsorbance/min  
Decimals: 2

Calibrated unit data  
 Enable conversion  
Conversion unit:  
Conversion factor:  
User defined label:  
 Enable transform negative results to zero  
Negative value limit: -999999.99

Paired result data  
Paired unit:  
INR unit data  
ISI material:  
ISI value:

Allow negative results  
Negative value limit: -999999.99

Enable result correlation  
Correlation range  
Minimum: -999999.99 Maximum: 999999.99  
Method: Linear  
Factor: 1.000 Offset: 0.000

Ranges  
 Enable normal range  
Minimum: -999999.99 Maximum: 999999.99  
 Enable therapeutic range  
Minimum: -999999.99 Maximum: 999999.99  
 Enable linear range  
Minimum: -999999.99 Maximum: 999999.99  
Minimum Extended time Maximum  
-999999.99 999999.99  
Alternative pre-dilution: Minimum: -999999.99 Maximum: 999999.99  
 Enable test range  
Minimum: 10.00 Maximum: 8800.00  
Minimum Extended time Maximum  
0.00 0.00  
Alternative pre-dilution: Minimum: 0.00 Maximum: 0.00

OK Cancel

**Non IL - Result Unit Definition**

Unit selection  
Unit type: Calibrated  
Unit: %  
Decimals: 0

Calibrated unit data  
 Enable conversion  
Conversion unit:  
Conversion factor:  
User defined label:  
 Enable transform negative results to zero  
Negative value limit: -999999

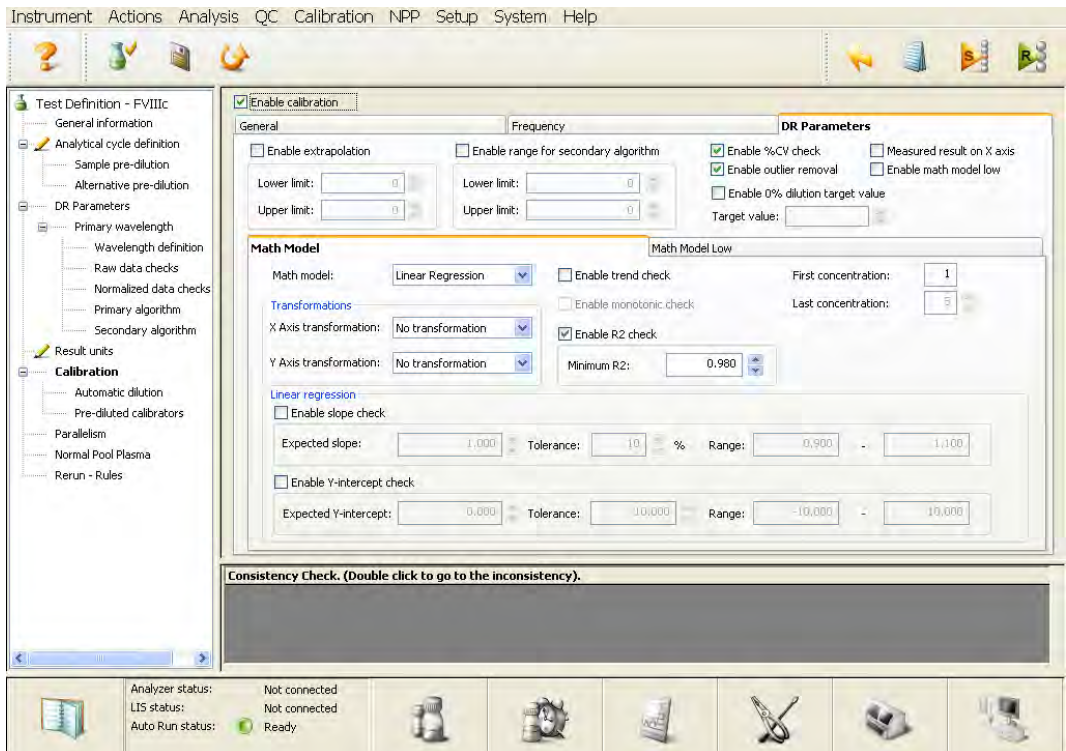
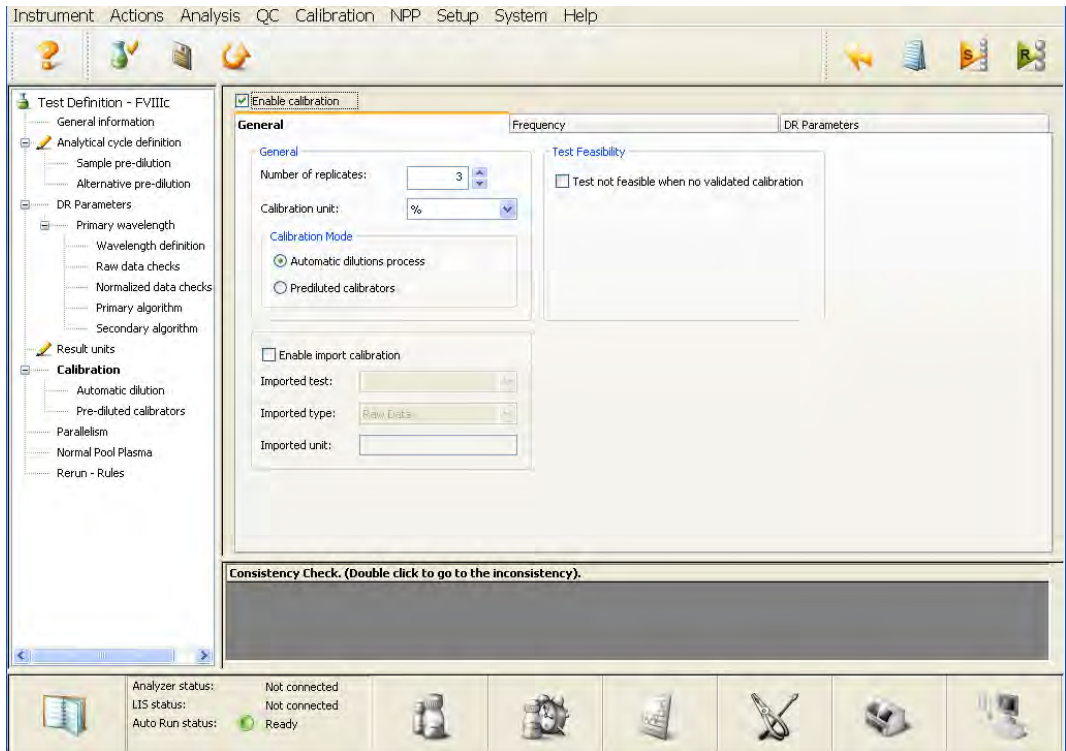
Paired result data  
Paired unit:  
INR unit data  
ISI material:  
ISI value:

Allow negative results  
Negative value limit: -999999

Enable result correlation  
Correlation range  
Minimum: -999999 Maximum: 999999  
Method: Linear  
Factor: 1.000 Offset: 0.000

Ranges  
 Enable normal range  
Minimum: 50 Maximum: 150  
 Enable therapeutic range  
Minimum: 10 Maximum: 130  
 Enable linear range  
Minimum: 10 Maximum: 200  
Minimum Extended time Maximum  
0 0  
Alternative pre-dilution: Minimum: 0 Maximum: 0  
 Enable test range  
Minimum: 10 Maximum: 200  
Minimum Extended time Maximum  
0 0  
Alternative pre-dilution: Minimum: 0 Maximum: 0

OK Cancel



Instrument Actions Analysis QC Calibration NPP Setup System Help

Test Definition - FVIIIc

- General information
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**General** Calibrator Diluent

Dilution Points

Define points by % dilution  
 Define points by target concentration

Dilution Process

Direct  Single dilution  
 Serial  Batch

Calibrator target value: 106 %

Concentration	Target Value	Min. Replicates	% CV Max.	Volumes (µL)			Predilution volumes (µL)		
				Calibrator	Mixture	Diluent	Sample	Mixture	Diluent
150.00	159	1	7.500	80			5		128
100.00	106	1	7.500	140			5		195
50.00	53	1	7.500		60	60	5		195
20.00	21	1	10.000		40	60	5		195

Enable mix

Mix: 100 % Minimum aspiratable volume: 4

Number of cycles: 1  
 Rinse after mix: 1 s

1st dilution  2nd dilution

Volumes that bypass calibration strip loading.  
 (Total volume required to perform sample predilution or reaction)

Consistency Check. (Double click to go to the inconsistency).

Analyzer status: Not connected  
 LIS status: Not connected  
 Auto Run status: Ready

Instrument Actions Analysis QC Calibration NPP Setup System Help

Test Definition - FVIIIc

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**General** Calibrator Diluent

Volumes

Material: HemosIL Cal Plasma ← May be different

Head volume: 0 µL  
 Airgap: 15 µL  
 Transport airgap: 30 µL  
 Head volume airgap: 0 µL

Rinse

Time: 1 s

Consistency Check. (Double click to go to the inconsistency).

Analyzer status: Not connected  
 LIS status: Not connected  
 Auto Run status: Ready

Instrument Actions Analysis QC Calibration NPP Setup System Help

Test Definition - FVIIIc

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    - Normal Pool Plasma
    - Rerun - Rules

General | Calibrator | **Diluent**

Volumes

Material: FVIIIc R4

Head volume: 0 µL

Airgap: 15 µL

Transport airgap: 30 µL

Head volume airgap: 0 µL

Consistency Check. (Double click to go to the inconsistency).

Analyzer status: Not connected  
 LIS status: Not connected  
 Auto Run status: Ready

Instrument Actions Analysis QC Calibration NPP Setup System Help

Test Definition - FVIIIc

- General information
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Enable rerun

Result Ranges

Result unit to test: %

Rule	Same Test	Extended Test	Alternative pre-dilution
Above Normal Range	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Below Normal Range	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Above Therapeutic Range	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Below Therapeutic Range	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Above Linear Range	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Below Linear Range	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Above Test Range	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Below Test Range	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Above Extrapolation Range	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Below Extrapolation Range	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Above Secondary Algorithm Range	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Below Secondary Algorithm Range	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(Range) Above measured result test range	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(Range) Below measured result test range	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Consistency Check. (Double click to go to the inconsistency).

Analyzer status: Not connected  
 LIS status: Not connected  
 Auto Run status: Ready

Instrument Actions Analysis QC Calibration NPP Setup System Help

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  - Pre-diluted calibrators
- Parallelism
- Normal Pool Plasma
- Rerun - Rules**

Enable rerun

Result Ranges DR Errors

Generic failure on measured result:

Rule	Same Test	Extended Test	Alternative pre-dilution
(Data) First point out of range	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(Data) Last point out of range	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(Data) Curve min. and max. not in correct sequence	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(Data) Curve sequence unknown	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(Data) Incorrect number of raw data points	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(Data) Too many invalid raw data points	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(Data) Number of spikes exceeds error limit	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(Data) Insufficient points remaining for calculation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(Data) Normalized curve delta too high	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(Data) Normalized curve delta too low	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(Data) Normalized curve delta less than lowest calibrator delta	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(Data) Baseline average high	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(Data) Baseline average low	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(Data) Baseline SD exceeds error limit	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(Data) Endpoint average high	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(Data) Endpoint average low	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(Data) Endpoint SD exceeds error limit	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(Coag) First derivative peak not found	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(Coag) Second derivative peak not found	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Consistency Check. (Double click to go to the inconsistency).

Analyzer status: Not connected  
 LIS status: Not connected  
 Auto Run status:  Ready

Instrument Actions Analysis QC Calibration NPP Setup System Help

Test Definition - FVIIIc

- General information
- Analytical cycle definition
  - Sample pre-dilution
  - Alternative pre-dilution
- DR Parameters
  - Primary wavelength
    - Wavelength definition
  - Raw data checks
  - Normalized data checks
  - Primary algorithm
  - Secondary algorithm
- Result units
- Calibration
  - Automatic dilution
  - Pre-diluted calibrators
- Parallelism
- Normal Pool Plasma
- Rerun - Rules**

Enable rerun

Result Ranges DR Errors

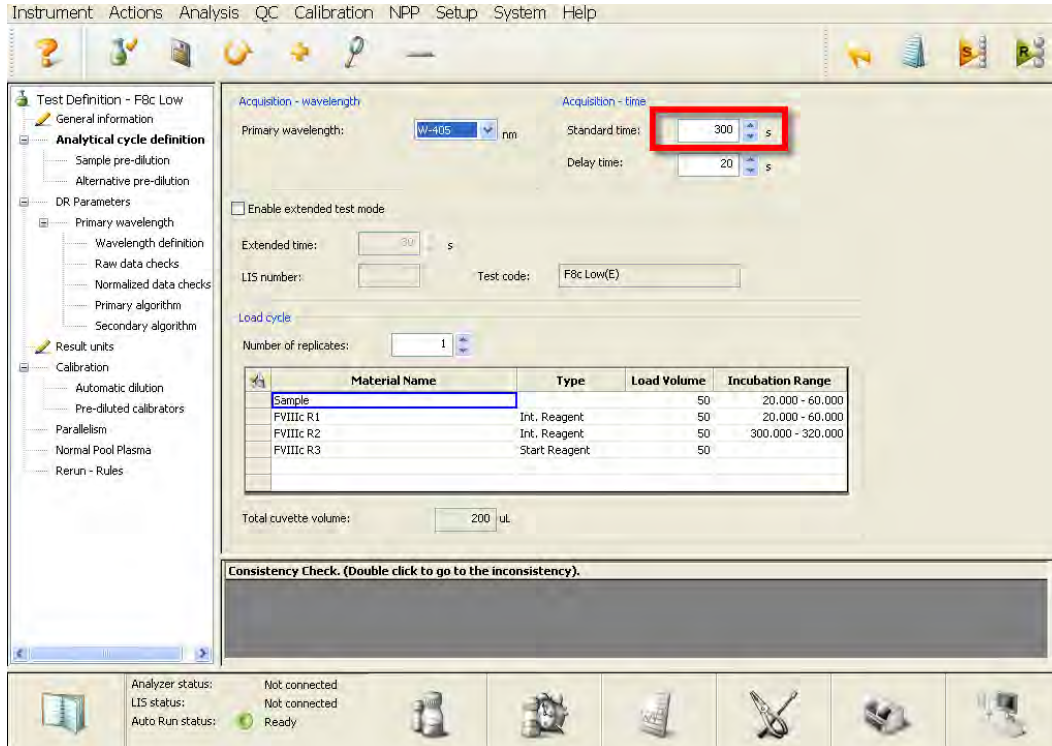
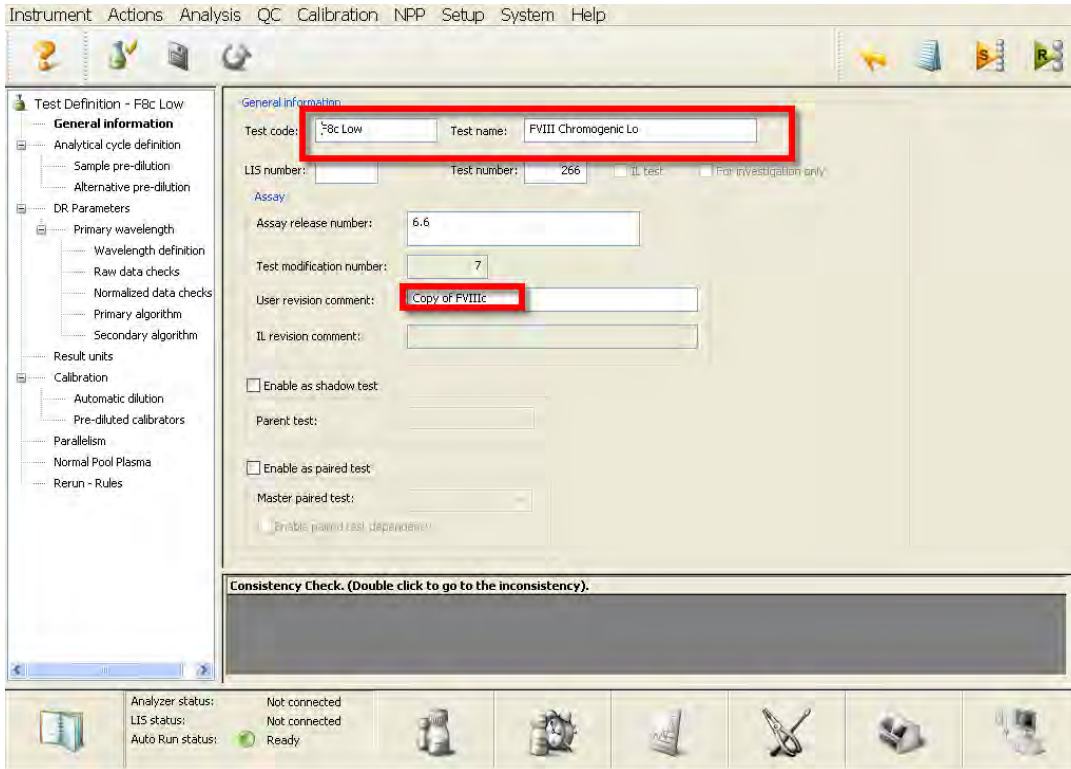
Generic failure on measured result:

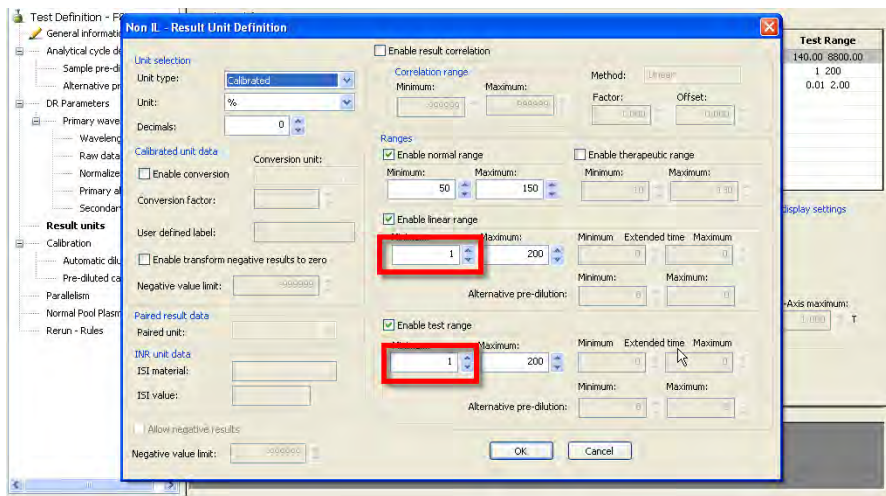
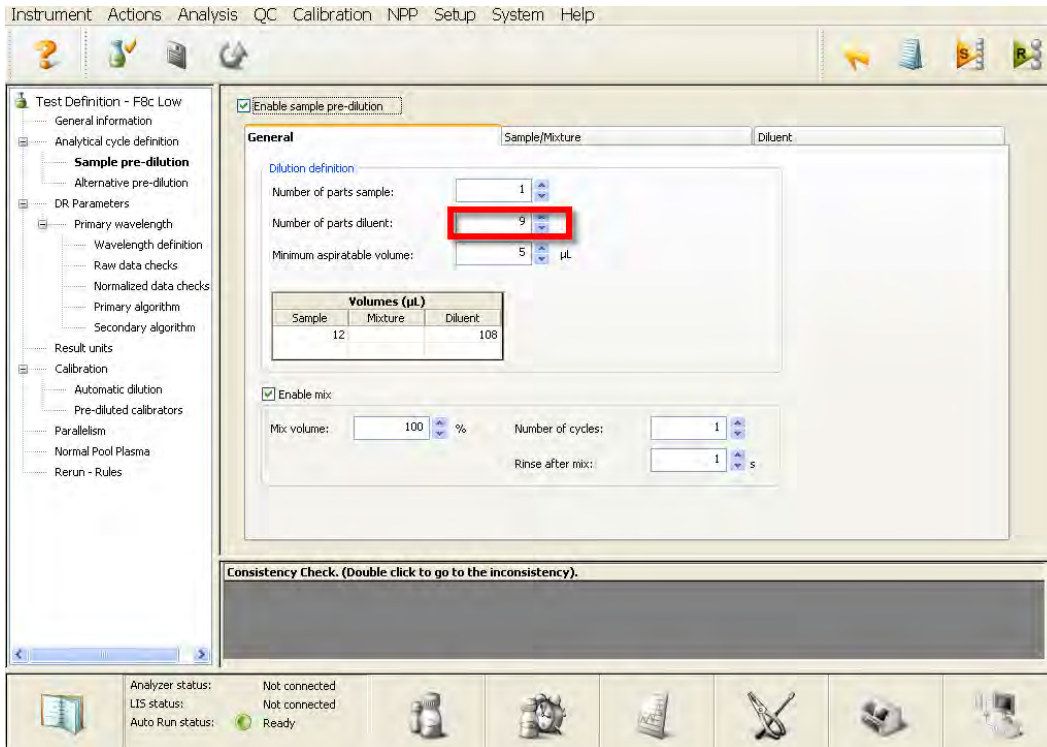
Rule	Same Test	Extended Test	Alternative pre-dilution
(Data) Endpoint SD exceeds error limit	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(Coag) First derivative peak not found	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(Coag) Second derivative peak not found	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(Coag) Too many first derivative peaks	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(Coag) Too many second derivative peaks	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(Coag) First threshold limit not found	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(Coag) Second threshold limit not found	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(Coag) Max (min) time span violation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(Reaction) Initial slope exceeds error limit	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(Reaction) Linear Regression SD exceeds error limit	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(Data) Result exceeds Negative Value Limit	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(Data) Result Check failed	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(Data) Calculation error	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(Data) Interference error	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(Prep) Aspiration Baseline Error	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(Prep) Unexpected LLD Error	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
%Max difference of replicates exceeded	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(Data) Normalized data contains multiple thresholds	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Consistency Check. (Double click to go to the inconsistency).

Analyzer status: Not connected  
 LIS status: Not connected  
 Auto Run status:  Ready

**Test Definition: F8c Low** - Copy FVIIIc and make the changes as shown below.





Calibration is performed with a commercially available plasma calibrator, with a known factor VIII: C concentration. Following reconstitution, the calibrator must be appropriately diluted in Factor VIII deficient plasma in order to obtain a Factor VIII: C concentration of 25%.

Instrument Actions Analysis QC Calibration NPP Setup System Help

Test Definition - F8c Low

- General Information
- Analytical cycle definition
  - Sample pre-dilution
  - Alternative pre-dilution
- DR Parameters
  - Primary wavelength
    - Wavelength definition
    - Raw data checks
    - Normalized data checks
    - Primary algorithm
    - Secondary algorithm
  - Result units
  - Calibration
    - Automatic dilution**
      - Pre-diluted calibrators
    - Parallelism
    - Normal Pool Plasma
    - Rerun - Rules

**General**      Calibrator      Diluent

Dilution Points

Define points by % dilution      Dilution Process

Define points by target concentration

Calibrator target value: 27

Direct       Single dilution

Serial       Batch

Concentration	Target Value	Min. Replicates	% CV Max.	Volumes (µL)		
				Calibrator	Mixture	Diluent
100.00	27	1	7.500	177		
50.00	14	1	7.500		76	76
20.00	5	1	7.500		51	77
5.00	1	1	10.000		26	78

Predilution volumes (µL)		
Sample	Mixture	Diluent
12		108
12		108
12		108
12		108

Enable mix

Mix: 100 %      Minimum aspiratable volume: 4

Number of cycles: 1      Rinse after mix: 1 s

1st dilution       2nd dilution

Volumes that bypass calibration strip loading. (Total volume required to perform sample predilution or reaction)

**Consistency Check. (Double click to go to the inconsistency).**

Analyzer status: Not connected

LIS status: Not connected

Auto Run status: Ready