

SystemsQT Instrument and System Qualification Setup Procedure for e2695 eAlliance Systems with a 2489/2998 Detector

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This setup procedure applies to e2695 eAlliance® systems with a 2489 or 2998 detector. Follow this procedure to prepare a Waters®-installed system for qualification testing.

Requirement: Unless they are newly installed, these systems must receive appropriate performance maintenance before you run the SystemsQT™.

This procedure requires these items:

- HPLC-grade water
- HPLC-grade methanol
- Dedicated column: XBridge™ C18 4.6 × 50 mm, 3.5 µm, (part number 186003031)
- Waters UV Detector Standards Kit (part number 700003741)
- Vials, LCGC certified clear glass 12 × 32 mm screw neck with cap and preslit PTFE/silicone septa, 2-mL volume, 100/pkg (part number 186000307C)
- Pipettes

Requirement: To maximize efficiency performing this procedure with eAlliance systems, ensure that these conditions are met:

- 100% methanol in all solvent lines.
- The needle wash and plunger seal wash solutions are compatible with methanol and water.
- The detector was well flushed with methanol before the setup.

You must perform the following manual tests before you perform the SystemsQT automated tests:

- Sample manager heater/cooler temperature accuracy test
- Column heater or column heater/cooler temperature accuracy test
- Flow rate accuracy test

Preparing the mobile phase

Note: When changing from a buffered solvent to an organic solvent and before connecting solvent lines, follow the recommendations in the Waters 2695 Separations Module Operator's Guide.

To prepare the mobile phase:

1. Vacuum degas 1 L each of HPLC-grade water and HPLC-grade acetonitrile.
2. Use a 1000-mL graduated cylinder to measure 1 L of degassed HPLC-grade water, and then transfer the water to a 1-L reservoir bottle.

3. Label the reservoir bottle, "100% water AB".
4. Use a 1000-mL graduated cylinder to measure 1 L of degassed HPLC-grade methanol, and then transfer the methanol to a 1-L reservoir bottle.
5. Label the reservoir bottle, "100% methanol CD".
6. Submerge lines A and B in reservoir bottle labeled "100% water AB" and place the reservoir bottles on the solvent tray.
7. Submerge lines C and D in reservoir bottle labeled "100% methanol CD" and place the reservoir bottles on the solvent tray.

Preparing the seal wash

To prepare the seal wash:

1. Use a 1000-mL graduated cylinder to measure 700 mL of degassed HPLC-grade water, and then transfer the water to a 1-L reservoir bottle.
2. Use a 1000-mL graduated cylinder to measure 300 mL of degassed HPLC-grade methanol, and then transfer the methanol to the reservoir bottle that contains the degassed HPLC grade water.
3. Label the reservoir bottle "Seal wash 70:30 water/methanol".
4. Submerge the seal wash line in the reservoir bottle labeled "Seal wash 70:30 water/methanol" and place the reservoir bottle on the solvent tray.

Preparing the needle wash

Submerge the needle wash line in the reservoir bottle labeled "100% methanol CD".

Solvent lines and solvent compositions

Table 1 describes the solvent lines and solvent compositions used in this SystemsQT.

Table 1 Solvent lines and solvent composition:

Instrument	Solvent line	Solvent composition
e2695	A, B	100% HPLC grade water
	C, D	100% HPLC grade methanol
	Seal wash	70:30 HPLC grade water/methanol
	Needle wash	100% HPLC grade methanol

Priming and equilibration using the System Prep function

To use the "System Prep" function of the e2695 eAlliance:

1. Power-on all system instruments, except for the 2489/2998 detector.

2. Ensure that all initialization/startup diagnostic tests run to completion on all instruments.
3. On the Main screen of the e2695 display, press System Prep.
4. Enter the following parameters:
 - Flow rate: 1 mL/min
 - Solvent line composition: 25%A, 25%B, 25%C, 25%D
 - Sample temperature: Off
 - Column temperature: 35 °C, or Off if no column heater is present
5. Press Next.
6. Select the solvent lines to be primed.
7. Press Next.

Note: If the solvent lines are dry, run the Dry Prime function before running “System Prep”.
8. Press Start.

Startup procedure

1. Start Empower® software.
2. Power-on the 2489/2998 detector.

Requirements:

 - Mobile phase must be flowing through the 2489 or 2998 detector before it is powered-on.
 - For the 2489 detector, allow a 30-minute lamp equilibration period. For the 2998 detector, allow a 60-minute lamp equilibration period.
3. Ensure that all initialization/startup diagnostic tests run to completion on all instruments.

Requirement: If any test failed to fully run, follow the appropriate procedure in the applicable instruments’ operator’s guide.
4. Connect the qualification column to the system.
5. Use the following procedure to disable the eAlliance “stop on column heater fault” function:
 - a. On the eAlliance Main menu, press Develop Methods.
 - b. Select the “Default” method and then press Edit.
 - c. Press Next as needed to scroll to page 4 (Column page) of the method.
 - d. Scroll to the “On Error” field and then press Edit.
 - e. In the pop-up window select “Log Quietly” and press Enter.

Result: Upon sensing a column heater fault, the alarm will be logged in the error log but the run will not stop.

Manual OQ tests performed prior to SystemsQT automated tests

Perform these procedures each time you perform a qualification:

1. Perform the following manual tests before you perform the automated tests of the SystemsQT:
 - Sample manager heater/cooler temperature accuracy test
 - Column heater or column heater/cooler temperature accuracy test
 - Flow rate accuracy test
2. After successfully performing the manual tests, continue with the detector response test.

Performing the detector response check

Notes:

- This is not a manual or automated test. To ensure that the caffeine peak height reflects the UV detector's full linear range, this check calculates an appropriate injection volume that will cause the detector to produce a caffeine peak between 1.80 to 2.20 absorbance units (AU) for a 2998 detector, or 1.80 to 2.40 AU for a 2489 detector, when performing the system readiness check and the UV detector linearity and sensitivity test.
- The detector response check is not a qualification test, therefore there is no RM RS report. However, the RM report will be available for printing but does not include the signature template.

To perform the detector response check:

1. Place a vial in location 100 that contains 0.03 uracil with 0.22 caffeine mg/mL standard (solution 5 from the UV Detector Standards Kit [part number 700003741]).
2. Open the Run Samples window and click File > Load Samples.
3. In the Load Samples dialog box, select "Load using a previously created sample set method", and then click OK.
4. In the Open an existing sample set method dialog box, select "Detector Response Check SSM", and then click Open.
5. After the Detector response check SSM sample set method is loaded in Run Samples, click the Run icon in the toolbar.
6. In the Run Sample Set dialog box, from the Run Mode list select Run and Report, select a printer, and then click Run.

Result: The Detector response SSM sample set method acquires data in Run and Report mode, and a detector response check report is printed at the selected printer.

7. Review the information on the report and note the "Injection Volume (µL) for Linear Detector Response" that is reported on the detector response report.
8. Update all injection volumes in the following two sample sets with the injection volume before continuing to the automated tests:
 - 01a System Readiness Check SSM.
 - 04b Detector Lin Sens SSM

9. Save the revised sample sets, and include a comment that the injection volumes were updated based on the detector response check.
10. After successfully performing the detector response check, continue with the automated qualification tests.

Vial positions and sample concentrations

Table 2 shows vial positions and sample concentrations for the e2695 eAlliance with a 2489 or 2998 detector with a 10-mm flow cell.

Note: Fill each vial with approximately 1.5 mL of sample.

Table 2 Vial positions and sample concentrations for a 2489/2998 detector with a 10-mm flow cell:

Solution Number	Vial Position	SystemsQT Test	10-mm Flow Cell Sample Concentration (Use Waters UV Detector Standards Kit, part number 700003741)
1	26	Injector linearity and accuracy	0.03 uracil with 0.01 caffeine mg/mL
		Detector linearity and sensitivity	
2	50	Detector linearity and sensitivity	0.03 uracil with 0.035 caffeine mg/mL
3	4	Compositional precision	0.03 uracil with 0.06 caffeine mg/mL
	74	System precision (for both 100 μ L and 250 μ L syringe)	
		Wavelength accuracy	
		Signal to noise	
	75	Detector linearity and sensitivity	
4	98	Detector linearity and sensitivity	0.03 uracil with 0.14 caffeine mg/mL
5	100	Detector linearity and sensitivity	0.03 uracil with 0.22 caffeine mg/mL
		System readiness check (not a qualification test)	
		Detector response check (not a qualification test)	
6	10	Flow rate linearity and accuracy	0.01 uracil mg/mL
7	61	Injector carryover	0.4 caffeine mg/mL (0.01%)

Table 2 Vial positions and sample concentrations for a 2489/2998 detector with a 10-mm flow cell: (Continued)

Solution Number	Vial Position	SystemsQT Test	10-mm Flow Cell Sample Concentration (Use Waters UV Detector Standards Kit, part number 700003741)
8	62	Injector carryover	4.0 caffeine mg/mL (100%)
9	60	Injector carryover	Solvent (70:30 water/methanol)
		System precision (for both 100 µL and 250 µL syringe)	
	63	Injector carryover	