# IC System Operational and Performance Qualification User's Guide



Document No. 031726 - 02
November 2000

**PRINTING HISTORY**

Revision 01, August 2000
Revision 02, November 2000

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# 1 Introduction

Validation is becoming increasingly important to analytical laboratories. Documented evidence must be provided to demonstrate the integrity of data collected and validate the results obtained on laboratory instrumentation.

The following institutes set and control industry instrumentation standards:

**NIST**. The National Institute of Standards and Technology is an administrative body of the US Department of Commerce. Together with the industry, the NIST develops new technologies and sets technological standards countrywide.

**ASTM.** The American Society for Testing and Materials sets technical standards and rules for the industry worldwide.

These standards are written in broad terms to make them as widely applicable as possible. All stipulate general requirements specifying instruments must be fit for purpose, technically checked in defined periods, calibrated and make sure that test results are documented according to international quality standards. The OQ/PQ procedure used to qualify Dionex Ion Chromatography Systems meets the requirements established by NIST and ASTM.

This QQ/PQ procedure provides qualification testing for **DX-500, DX-600, DX-320 and BioLC** systems.

OQ/PQ results can be influenced by unusual laboratory conditions. For example, direct sunlight will cause thermal irregularities that will affect baseline drift on conductivity detectors. In these cases it may happen that the manufacturer's specifications are not met, and the specifications may have to be adjusted accordingly.

All OQ/PQ activities must be formally recorded, all instruments must be clearly identified, and test reports and supporting documentation must include the following information:

- Module name, type and serial number
- Software and firmware version
- Test data
- Service interval
- Signature of the Dionex Service Engineer/Qualification Executor who performed the OQ/PQ
- Signature of the customer who reviewed and accepted the OQ/PQ results

## 1.1 Operational Qualification (OQ)

The purpose of OQ is to test a new instrument according to the manufacturer's specifications within a specific environment. Therefore, the manufacturer must define the test conditions and the test specifications, both which must be observed.

OQ should be performed after initial system installation or when an additional new module is added to an existing system. It is necessary that OQ be done according to the instructions outlined in this manual and all tests should be performed by a qualified Dionex Service Engineer.

## 1.2 Performance Qualification (PQ)

The purpose of PQ is to determine if a system that has been subjected to daily routine operation functions within the Dionex recommended limits of acceptable system performance.

Since PQ is performed on a system that is no longer considered new, the specifications for PQ are less restrictive than those for OQ, even though the same test procedures are used for both. PQ results must be either within the limits recommended by Dionex or be adapted to the limits required by the customer. If customer-specified limits are used, those limits must not be tighter than the Dionex specification.

PQ should be performed at regular intervals after the initial installation and OQ. Dionex recommends performing PQ every six months. It is necessary that PQ be done according to the instructions outlined in this manual and all tests should be performed by a qualified Dionex Service Engineer.

## 1.3 OQ/PQ Specifications

| Instrument | Test | Limits | |
|---|---|---|---|
| | | OQ | PQ |
| **AD25** | Baseline Noise | 30 µAU | 40 µAU |
| | Drift | 200 µAU/hr | 200 µAU/hr |
| | Wavelength Accuracy | +/- 2.00 nm | +/- 2.00 nm |
| | Linearity | $R^2 \geq 0.999$<br>RSD $\leq$ 5 % | $R^2 \geq 0.999$<br>RSD $\leq$ 5 % |
| **AD20** | Baseline Noise | 40 µAU | 50 µAU |
| | Drift | 200 µAU/hr | 200 µAU/hr |
| | Wavelength Accuracy | +/- 3.00 nm | +/- 3.00 nm |
| | Linearity | $R^2 \geq 0.999$<br>RSD $\leq$ 5.0 % | $R^2 \geq 0.999$<br>RSD $\leq$ 5.0 % |
| **Conductivity**<br>**CD20/ED40, CD25/ED50, IC20/IC25** | Baseline Noise | 1.0 nS | 2 nS |
| | Drift | 10 nS/hr | 20 nS/hr |
| | Linearity | $R^2 \geq 0.999$<br>RSD $\leq$ 5.0 % | $R^2 \geq 0.999$<br>RSD $\leq$ 5.0 % |
| **Integrated Amperometry** | Baseline Noise | 3 pC | 4 pC |
| | Drift | 3 pC/hr | 5 pC/hr |
| **DC Amperometry** | Baseline Noise | 3 pA | 4 pA |
| | Drift | 4 pA/hr | 8 pA/hr |
| **PDA -100** | Baseline Noise | 0.04 mAU | 0.10 mAU |
| | Drift | 0.5 mAU/h | 1.0 mAU/h |
| | Wavelength Accuracy | +/- 2.00 nm | +/- 2.00 nm |
| | Linearity | $R^2 \geq 0.999$<br>RSD $\leq$ 5.0 % | $R^2 \geq 0.999$<br>RSD $\leq$ 5.0 % |
| **AS50** | Injector Precision | RSD $\leq$ 0.8% | RSD $\leq$ 1.0% |
| | Injection Volume Linearity | $R^2 \geq 0.999$<br>RSD $\leq$ 1.0% | $R^2 \geq 0.999$<br>RSD $\leq$ 1.0% |
| | Carry Over | < 0.1 % | < 0.1 % |
| | Sample Prep Precision | RSD $\leq$1.5% | RSD $\leq$ 2.0% |
| **GP40/GP50 Standard Bore, GS50** | Gradient Accuracy | $\leq$ 1.5% | $\leq$ 2.0% |
| | Step Noise (Ripple) | $\leq$ 0.2% | $\leq$ 0.2% |
| **GP40/GP50 Microbore** | Gradient Accuracy | $\leq$ 2.0% | $\leq$ 2.0% |
| | Step Noise (Ripple) | $\leq$ 0.5% | $\leq$ 0.5% |

**Note:** The instrument's specifications can only be met if the conditions described in the accompanying manual are strictly observed.

# 2 Qualification Preparation

## 2.1 Materials in Kit

Before starting the qualification procedure confirm that all the materials needed are present. If any items from these tables are not present, do not continue with the validation process until these items are available.

| Part Description | Part Number | Quantity |
|---|---|---|
| OQ/PQ User's Manual Version 1.0 | 031726 | 1 |
| Tubing, 0.010" ( 0.25 mm) ID black PEEK | 042690 | 24", 81 cm |
| Tubing, 0.003" (0.075 mm) ID yellow PEEK | 049715 | 50", 127 cm |
| 25 µL Sample Loop | 042857 | 1 |
| 100 µL Sample Loop | 042951 | 1 |
| Fittings | 043275 | 6 |
| Ferrules | 043276 | 6 |
| Validation stickers | 050837 | 6 |
| Certificate of Functional Performance | 031423 | 6 |
| 1000 ppm Caffeine Solution | 056822 | 1 |
| 1000 ppm Nitrate Solution | 056497 | 1 |
| Backpressure Coil, 0.005" (0.125 mm) ID PEEK x 512" (13 m) | 2251.5999 | 1 |
| ED/CD Validation Test Cell* | 049928 | 1 |
| EG40 Validation Test Cell* | 054970 | 1 |
| AD20 Holmium Oxide Test Cell* | 046172 | 1 |
| OQ/PQ Validation Software for CM/PN 6 | 057601 | 1 |
| Test Binder | 035863 | 1 |

* Included in the PeakNet 6 IC OQ/PQ Kit with Test Cells (Dionex P/N 057599) only. If using the PeakNet 6 IC OQ/PQ Basic/Refill Kit (Dionex P/N 057608), the Dionex Service Engineer must provide test cells.

## 2.2 Materials Needed

The following items will be needed:

| Description | Quantity |
|---|---|
| ASTM Type 1 (or better) deionized water (18 MΩ, filtered) | 2 L |
| Reagent Grade or better Potassium Chloride for OQ/PQ tests using a Conductivity Detector | 1 g |
| HPLC grade Acetone for OQ/PQ Tests using an Absorbance or Photodiode Array Detector | 3 mL |
| Voltmeter with milliamp (mA) setting. Must be capable of displaying 0.00 to 220 mA. | 1 |
| **PeakNet** ™ Version 6.01 or higher | 1 |

## 2.3 Preparation of Standards

Two standards are provided in the OQ/PQ kit. Use the caffeine standard to qualify systems with an AD20, AD25 or PDA-100 detector. Use the nitrate standard to qualify systems with an ED40/ED50, CD20/CD25 or IC20/IC25 Conductivity detector. Only one set of standards needs to be prepared depending on the type of detector used in the qualification.

### 2.3.1 Caffeine Standard Preparation

Prepare caffeine standards using the Dionex 1000 ppm caffeine standard (P/N 056822). Pipette the amount of 1000 ppm caffeine standard (listed in the table below) into five individual 100 mL volumetric flasks. Fill each flask to the mark with ASTM Type 1 (or better) deionized water (18 M Ω, filtered).

| Concentration (ppm) | Amount of 1000 ppm Caffeine Standard | Final Volume (mL) |
|---|---|---|
| 15 | 1.5 mL | 100 |
| 40 | 4.0 mL | 100 |
| 60 | 6.0 mL | 100 |
| 80 | 8.0 mL | 100 |
| 100 | 10.0 mL | 100 |

### 2.3.2 Nitrate Standard Preparation

Prepare nitrate standards using the Dionex 1000 ppm nitrate standard (P/N 056497). Pipette the amount of 1000 ppm nitrate standard listed in the table below into five individual 100 mL volumetric flasks. Fill each flask to the mark with ASTM Type 1 (or better) deionized water (18 MΩ, filtered).

| Concentration (ppm) | Amount of 1000 ppm Caffeine Standard | Final Volume (mL) |
|---|---|---|
| 5 | 0.5 mL | 100 |
| 10 | 1.0 mL | 100 |
| 25 | 2.5 mL | 100 |
| 50 | 5.0 mL | 100 |
| 100 | 10.0 mL | 100 |

## 2.4 Preparation of Eluents

All eluents must be prepared using ASTM Type 1,18 MΩ or better, filtered, deionized water.

### 2.4.1 Preparation of Eluents for use with Conductivity Detection

These eluents are used for qualification with an ED40/ED50, CD20/CD25 or IC20/25 Conductivity Detector.

Prepare the following eluents and connect them to lines A, B, C and D of the pump. All eluents must be degassed. Eluent bottles must be pressurized when using a GP40 or IP20 pump. Eluent lines A and C can be inserted into one eluent bottle containing 1 L of water. Eluent lines B and D can be inserted into one bottle containing 1 L of 1 mM KCl.

| Eluent | Description |
|---|---|
| A | Water |
| B | 1.0 mM KCl |
| C | Water |
| D | 1.0 mM KCl |

**Note:** Eluents B, C and D are needed for the Gradient Pump Accuracy Test only and should be prepared only if the pump configured has gradient capabilities. Do not prepare these eluents if the pump configured is an IP20/IP25, IC20/IC25, or IS25 Isocratic pump.

**1 mM KCl Preparation:**

Prepare one liter of 10 mM KCl by weighing 0.746 grams of KCl. Place the KCl in a 1L volumetric flask. Fill flask to the mark with ASTM Type 1 (or better) deionized water (18 MΩ, filtered) water.

Pipette 100 mLs of the 10 mM KCl solution into another 1L volumetric flask, filling flask to the mark with ASTM Type 1 (or better) deionized water (18 MΩ, filtered) water.

### 2.4.2 Preparation of Eluents for use with Absorbance Detection

These eluents are for used for qualification with an AD25 or AD20 Absorbance Detector or the PDA-100 Photodiode Array Detector.

Prepare the following eluents and connect them to lines A, B, C and D of the pump. All eluents must be degassed. Eluent bottles must be pressurized when using a GP40 or IP20 pump. Eluent lines A and C can be inserted into one eluent bottle containing 1 L of water. Eluent lines B and D can be inserted into one bottle containing 1 L of 0.3% Acetone in Water.

| Eluent | Description |
|---|---|
| A | Water |
| B | 0.3% Acetone in Water |
| C | Water |
| D | 0.3% Acetone in Water |

**Note:** Eluents B, C and D are needed for the Gradient Pump Accuracy Test only and should be prepared only if the pump configured has gradient capabilities. Do not prepare these eluents if the pump configured is an IP20/IP25, IC20/IC25, or IS25 Isocratic pump.

**0.3% Acetone in Water Preparation:**

Pipette 3 mLs of HPLC grade Acetone into a 1L volumetric flask. Fill flask to the mark with ASTM Type 1 (or better) deionized water (18 MΩ, filtered) water.

## 2.5 IC System Preparation

**Note:** The AD25 and PDA-100 Detector UV and Visible lamps must be turned on at least two hours prior to performing the qualification. AD20 Detector UV and visible lamps must be turned on for at least 24 hours before performing the qualification.

1. Open Server Configuration. Double click on the detector/s to be qualified to view the properties page for that detector. Select the **Signals** page and confirm that the signal factor is 1.000. If it is not, change the factor to 1.000 for the qualification. Exit the properties page and save the configuration.

2. Connect Eluents A, B, C and D to the pump and prime each eluent line individually for approximately 3 minutes each, longer if the vacuum degas option is installed. Eluent bottles must be pressurized when using GP40 and IP20 pumps.

3. Disconnect the column and suppressor from the system and thoroughly rinse all fluid connections with water for approximately 15 minutes.

4. Leaving the gradient mixer in-line, connect the pump line directly to port 2 on the injection valve. If an EG40 is in-line with the IC system, bypass all plumbing to the EG40 and connect the pump directly to the injection valve.

5. Connect one end of the Backpressure Coil (P/N 2251.5999) to port 3 on the injection valve and the other end directly to the inlet of the conductivity or absorbance cell, bypassing all columns and suppressors.

6. Thoroughly rinse the autosampler fluidics with water. This can be accomplished on the AS50 by flushing the sample syringe two or three times and on the AS40 by running two or three rinse vials.

7. For systems using an AS50 Autosampler, install the 100 µL sample loop on the injection valve. Then, from the front panel of the AS50, go to the **Main Menu**, select **Module Set-Up** and then **Plumbing Configuration**. Change the sample loop size to 100 µL. For systems using an AS40 Autosampler or manual injector, install the 25 µL sample loop on the injection valve.

8. Select 100% of Eluent A (water) and a flow rate of 1.00 mL min. Turn the pump flow on and let the system equilibrate for a minimum of 15 minutes.

9. Check that there are no fluctuations in pressure when changing from 'Load' to 'Inject' and vice versa. Failure for the pressure to remain stable when the injection valve actuates could indicate a leak, blockage, or contamination in the system, which must be eliminated before starting the qualification.

10. If using an AS40 autosampler, connect the 'LOAD IN' relay on the rear panel of the AS40 to RLY 1 OUT on the pump.

11. Transfer the standards prepared in Section 2.3 into autosampler vials and place them in the following position/order according to the tables below. To qualify an IC system by manual injection, use the AS40 table for the injection order.

| Absorbance or Photodiode Array Detector with AS50 | Conductivity Detector with AS50 | Vial Tray Position |
|---|---|---|
| 15 ppm Caffeine Std | 5 ppm Nitrate Std | 1 |
| 40 ppm Caffeine Std | 10 ppm Nitrate Std | 2 |
| 60 ppm Caffeine Std | 25 ppm Nitrate Std | 3 |
| 80 ppm Caffeine Std | 50 ppm Nitrate Std | 4 |
| 100 ppm Caffeine Std | 100 ppm Nitrate Std | 5 |
| 1000 ppm Caffeine Std | 1000 ppm Nitrate Std | 6 |
| Water | Water | 7 |
| Empty Vial* | Empty Vial* | 8 |
| Empty Vial* | Empty Vial* | 9 |
| Empty Vial* | Empty Vial* | 10 |

* Needed only if qualifying Sample Prep Option. AS50 10 mL vials are required for Sample Prep Qualification.

| Absorbance or Photodiode Array Detector with AS40 | Conductivity Detector with AS40 | Sample Order |
|---|---|---|
| 40 ppm Caffeine Std | 50 ppm Nitrate Std | Vial 1 |
| 40 ppm Caffeine Std | 50 ppm Nitrate Std | Vial 2 |
| 40 ppm Caffeine Std | 50 ppm Nitrate Std | Vial 3 |
| 40 ppm Caffeine Std | 50 ppm Nitrate Std | Vial 4 |
| 40 ppm Caffeine Std | 50 ppm Nitrate Std | Vial 5 |
| 40 ppm Caffeine Std | 50 ppm Nitrate Std | Vial 6 |
| 15 ppm Caffeine Std | 5 ppm Nitrate Std | Vial 7 |
| 40 ppm Caffeine Std | 10 ppm Nitrate Std | Vial 8 |
| 60 ppm Caffeine Std | 25 ppm Nitrate Std | Vial 9 |
| 80 ppm Caffeine Std | 50 ppm Nitrate Std | Vial 10 |
| 100 ppm Caffeine Std | 100 ppm Nitrate Std | Vial 11 |
| 1000 ppm Caffeine Std | 1000 ppm Nitrate Std | Vial 12 |
| Water | Water | Vial 13 |

## 2.6 OQ/PQ Sequence Installation

### 2.6.1 Installing Sequences from the PeakNet 6.20 CD

1. Create a directory in the local datasource called **Validation**.
2. Insert the PeakNet 6.20 CD into the computer's CD drive
3. From the PeakNet Browser, go to **File** and then to **Mount Datasource**, and select **Browse**.
4. From the PeakNet 6.20 CD, select the **IC_OQ_PQ_R02** directory. Select cm_local.mdb. The IC_OQ_PQ_R02 datasource will now be available from the PeakNet Browser. Open the datasource, and then open either the IC_OQ or IC_PQ directory, depending on the qualification that will be performed.
5. Proceed to Step 8 in Section 2.6.2.

### 2.6.2 Installing Sequences from the OQ/PQ CD (P/N 057601)

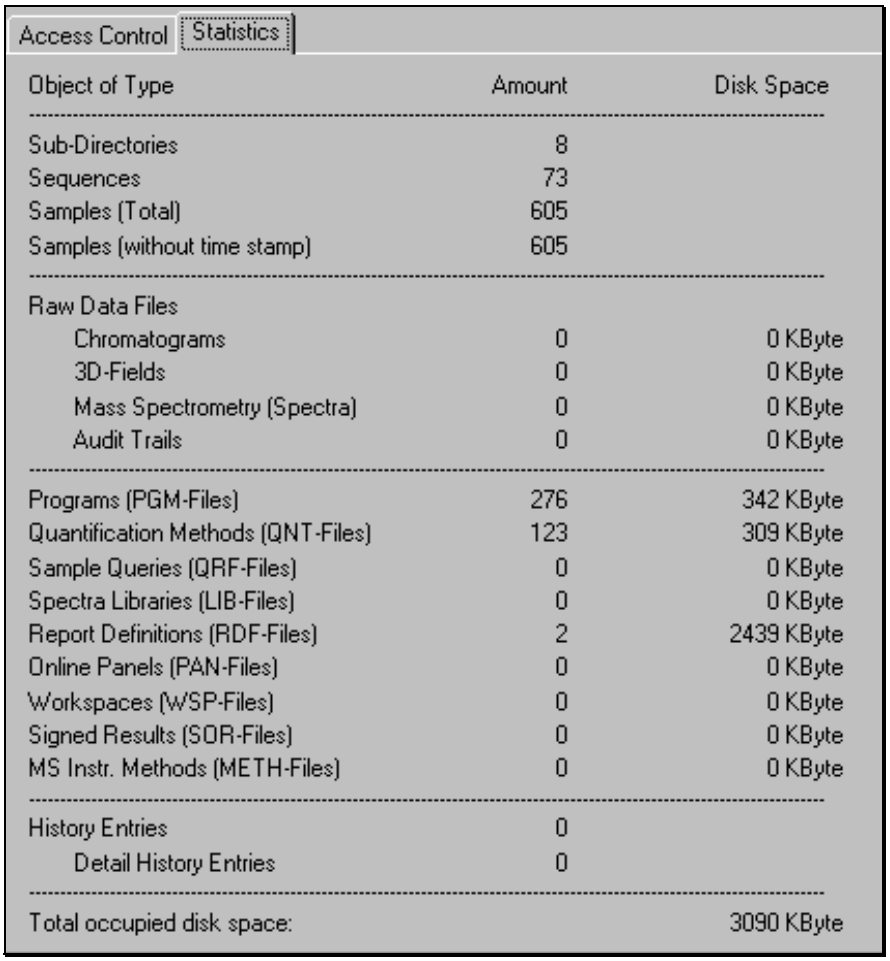
The OQ/PQ CDROM (Dionex P/N 057601) is included in the PeakNet 6 IC OQ/PQ Kit with Test Cells (Dionex P/N 057599) and the PeakNet IC OQ/PQ Basic/Refill Kit (Dionex P/N 057608).

1. Create a directory in the local datasource called **Validation**.
2. Insert the OQ/PQ CD into the computer's CD drive.
3. Open Windows Explorer and confirm that the PeakNet cmb file names, file size and modified date/time on the CD matches those in the table below:

| File Name | Size | Modified Date | Modified Time |
|---|---|---|---|
| IC_OQ_R02.cmb | 1369 KB | 11/6/00 | 4:29 PM |
| IC_PQ_R02.cmb | 1369 KB | 11/6/00 | 4:31 PM |

4. From the PeakNet Browser, highlight the local datasource (i.e.Dionex_local). Then select **File**, **Import/Restore**, and **Restore...**
5. Open the **IC_OQ.cmb** or **IC_PQ.cmb** file depending on the qualification that will be performed.
6. Select **Other** in the **Destination** box. The local datasource should be displayed. If it is not, use the Browse function to select it. Click on **OK** to install the cmb file into the local datasource.

7. Right click on the newly installed IC_OQ or IC_PQ directory and select **Properties**. Go to the Statistics tab and confirm that the statistics in the **Amount** column match the screen below. Both cmb files will have these statistics:



Access Control | Statistics

| Object of Type | Amount | Disk Space |
|---|---|---|
| Sub-Directories | 8 | |
| Sequences | 73 | |
| Samples (Total) | 605 | |
| Samples (without time stamp) | 605 | |
| Raw Data Files | | |
| Chromatograms | 0 | 0 KByte |
| 3D-Fields | 0 | 0 KByte |
| Mass Spectrometry (Spectra) | 0 | 0 KByte |
| Audit Trails | 0 | 0 KByte |
| Programs (PGM-Files) | 276 | 342 KByte |
| Quantification Methods (QNT-Files) | 123 | 309 KByte |
| Sample Queries (QRF-Files) | 0 | 0 KByte |
| Spectra Libraries (LIB-Files) | 0 | 0 KByte |
| Report Definitions (RDF-Files) | 2 | 2439 KByte |
| Online Panels (PAN-Files) | 0 | 0 KByte |
| Workspaces (WSP-Files) | 0 | 0 KByte |
| Signed Results (SOR-Files) | 0 | 0 KByte |
| MS Instr. Methods (METH-Files) | 0 | 0 KByte |
| History Entries | 0 | |
| Detail History Entries | 0 | |
| Total occupied disk space: | | 3090 KByte |

8. Before performing the qualification, sequence templates must be selected and copied from the **IC_OQ** or **IC_PQ** directory into the **Validation** directory. Having the sequences in one location will make them easier to find when starting the batch in Section 3.

9. The OQ/PQ qualification tests are performed in the following order:

A. Wavelength Accuracy Test for Absorbance Detectors
B. Detector Noise and Drift Test
C. Injector Precision Test
D. Detector Linearity Test
E. Injector Linearity Test - *AS50 only*
F. Carry Over Test
G. Sample Prep Precision Test - *AS50 with Sample Prep Option only*
H. Gradient Accuracy Test*
I. DC Amperometry Baseline Noise and Drift*
J. Integrated Amperometry Baseline Noise and Drift*
K. EG40 Current Qualification Test*

* Perform this test only if module is configured and/or used in this mode on the timebase to be qualified.

10. Test A is done manually and does not require a sequence template. Sequence templates must be selected for all other tests. Tests B - G are contained in one sequence template. Tests H - K have individual sequence templates.

11. To begin copying sequences, a Detector_Pump sequence template must be selected. The Detector_Pump sequence performs Tests B-G.

    **Note:** Full qualification can only be performed with the **AD20, AD25, PDA-100** or **Conductivity** Detectors. If the system to be qualified only contains an Integrated Amperometry or DC Amperometry detector, this part of the qualification can not be performed. Go on to step 16.

12. Open the **DX320** or **DX500_DX600_BioLC** directory depending on the system to be qualified.

13. Next open the **AS40 and Man Inj** or **AS50** directory, depending on the autosampler or injector configured on the timebase to be qualified. For systems configured with manual or automated injection valves, use the AS40 sequences. For systems configured with an AS50, open the AS50_TC or AS50_CC directory and choose a standard or sample prep (SP) sequence.

    Example: If the system to be qualified consists of an AD25, an IP25 and an AS50 with Sample Prep and CC options, you would select the **AD25_CC_SP_Pump** sequence.

    Example: If the system to be qualified consists of a CD20, a GP40 and an AS40, you would select the **ED_CD_AS40_Pump** sequence

    Example: If the system to be qualified consists of an AD20 and a GP50 with a manual or automated injection valve, you would select the **AD20_AS40_Pump** sequence.

14. Right click on the Detector_Pump sequence template and select **Copy**. Right click on the **Validation** directory and select **Paste**.

15. If a gradient pump is to be qualified, select the appropriate **Grad Accuracy** sequence template and copy it to the **Validation** directory. If the system contains an isocratic pump go on to Step 16.

    **Note:** Microbore (MB) and Standard Bore (SB) pump configurations use different sequences for the Gradient Accuracy Test. GP40 and GP50 microbore pumps should be qualified using the GP40_GP50_MB_Grad_Accuracy sequences. GS50 and standard bore GP50 pumps should be qualified using the GP50_GS50_SB_Grad_Accuracy sequences. Standard bore GP40 pumps should be qualified using the GP40_SB_Grad_Accuracy sequences.

16. If the system to be qualified contains an ED40 or ED50 Detector used as an Amperometry Detector, select the **Int_Amp_Noise_Drift** and/or the **DC_Amp_Noise_Drift** sequence template. Copy the template into the **Validation** directory. These tests should only be performed if the ED40 or ED50 Detector is used in the Integrated Amperometry or DC Amperometry mode.

17. If the system to be qualified contains and EG40 Eluent Generator, select the **EG40 Current Qual** sequence template and copy it into the **Validation** directory.

18. Lastly, copy the report file into the **Validation** directory. Select the **OQ_UV.rdf** or the **PQ_UV.rdf** for qualification with an AD20, AD25 or PDA-100 detector. Select the **OQ_ECD.rdf** or the **PQ_ECD.rdf** file for qualification with a Conductivity Detector.

19. Open the **Validation** directory. Right click on the first sequence template and select **Properties.** Select the timebase that will be qualified in the **Timebase** entry field. In the **Preferred Report and Channel** section, select the report (rdf) file newly copied into the directory of the timebase. Confirm that the correct detector channel is selected.

20. Repeat step 19 for all other OQ/PQ sequence templates in the **Validation** directory.

## 2.7 OQ/PQ Report Set Up

All relevant information such as the serial number, module type, moduleware version and customer information must be entered into the SPECIFICATION sheet of the OQ and PQ report file.

1. Open the OQ.rdf or PQ.rdf file copied into the validation directory in Section 2.6. Locate the row of sheet names at the bottom of the report. Click on the first sheet of the report titled **SPECIFICATION**. Go to **Edit** and turn **Layout Mode** on.
2. In the **Instruments** section of the **SPECIFICATION** sheet, enter the **Model**, **Supplier's Name** (if other than Dionex), **Serial Number** and **Moduleware Version** for the pump, detector, autosampler, software and LC module configured on the IC system. Type N/A in the boxes for any modules in the SPECIFICATION sheet that were not used.
3. In the Additional Information section located on page 2 of the **SPECIFICATION** sheet, enter the **Customer Name/Company** and **Qualification Executor/Company** information.
4. Right click anywhere on the sheet and select **Save Report Definition**. Click on **Edit** and turn **Layout Mode** off. Close the report file.

# 3 Performing the Qualification

## 3.1 When to Perform Operational Qualification

Operational Qualification (OQ) should be performed following the initial installation of an IC system and on any new individual module installed on an existing system.

## 3.2 When to Perform Performance Qualification

Performance Qualification (PQ) can be performed at any time after the initial installation and OQ. Dionex recommends that a performance qualification be performed on IC systems every 6 months. PQ should be performed only after preventive maintenance has been completed on the system.

## 3.3 OQ/PQ Test Order

The OQ/PQ qualification tests are performed in the following order:

A. Wavelength Accuracy Test for Absorbance Detectors
B. Detector Noise and Drift Test
C. Injector Precision Test
D. Detector Linearity Test
E. Injector Linearity Test - *AS50 only*
F. Carry Over Test
G. Sample Prep Precision Test - *AS50 with Sample Prep Option only*
H. Gradient Accuracy Test*
I. DC Amperometry Baseline Noise and Drift*
J. Integrated Amperometry Baseline Noise and Drift*
K. EG40 Current Qualification Test*

* Perform this test only if module is configured and/or used in this mode on the timebase to be qualified.

## 3.4 What to Do if a Test Fails

If at any point the instrument results do not pass within Dionex specified limits, the instrument must be serviced. See Section 5 for troubleshooting assistance. When the repair is complete, rerun all tests from the original point of failure on in the sequence. For example, if the instrument passes Tests A, B, and C and fails Test D, make the appropriate repairs and then repeat tests D - G only.

## 3.5 Starting the Sequences

The OQ and PQ sequences are system-specific test procedures. If different module options or configurations are used, the program files located in the standard sequences must be modified accordingly.

## 3.5.1 Wavelength Accuracy

### 3.5.1.1 AD25 and PDA - 100

The flow cell must be free from colored reagents before this test is run. If there is colored reagent in the flow cell (for example, PAR used in transition metal analysis), the flow cell must be thoroughly flushed prior to running the test.

1. Select 100% water and a flow rate of 1.00 mL/min. Turn the pump on and allow the detector to equilibrate.

#### 3.5.1.1.1 Wavelength Accuracy from a Wellness Panel

1. If PeakNet 6.11 is installed, open the **Dionex_pump_absorbance_wellness** panel from the \Panels\Wellness directory to perform the wavelength accuracy test. This panel will work for the AD25 and PDA -100 detectors.

2. **Note:** The AD25 detector must be configured for System Wellness to use the Wellness Panel. If Wellness is not configured, perform the Wavelength accuracy test from the AD25 front panel using the steps in Section 3.5.1.1.2.

3. Go to the Diagnostic Tests section of the panel, then to the Wavelength Verification section and select the **verify** button.

4. After approximately two minutes, the Wellness panel will display the theoretical and measured wavelengths, and the delta between the theoretical and measured values.

5. Open the **OQ_UV.rdf** or **PQ_UV.rdf** report file, depending on the qualification being performed. Locate the row of sheet names at the bottom of the report. Click on the **DET_AD25_PDA_WAVE** sheet.

6. Go to **Edit** and turn **Layout Mode** on. Enter today's date in the **Additional Information** section. Enter the **Measured** wavelength values into the table on the sheet. The deviation and pass/fail results will be calculated automatically. Print the sheet. Click on **Edit** and turn **Layout Mode** off. Close the report file.

7. If any part of the test does not pass, refer to Section 5 for troubleshooting assistance.

#### 3.5.1.1.2 Wavelength Accuracy from the AD25 Front Panel

This test can be performed on the AD25 only.

1. From the AD25 front panel, access the Main Menu and press (8) to enter the Diagnostic Menu.

2. From the AD25 Diagnostic Menu, press (5) for Wavelength Verify.

3. Select **Run** and press **Enter**.

4. After approximately two minutes, the front panel will display the theoretical and measured wavelengths, and the delta between the theoretical and measured values.

5. Open the **OQ_UV.rdf** or **PQ_UV.rdf** report file, depending on the qualification being performed. Locate the row of sheet names at the bottom of the report. Click on the **DET_AD25_PDA_WAVE** sheet.

6. Go to **Edit** and turn **Layout Mode** on. Enter today's date in the **Additional Information** section. Enter the **Measured** wavelength values into the table on the sheet. The deviation and pass/fail results will be calculated automatically. Print the sheet. Click on **Edit** and turn **Layout Mode** off. Close the report file.

7. If any part of the test does not pass, refer to Section 5 for troubleshooting assistance.

### 3.5.1.2 AD20

1. Remove the AD20 Sample cell from the photodiode and disconnect the beamsplitter cable.

2. Install the AD20 Holmium Oxide Test cell (Dionex P/N 046172) onto the photodiode and connect the beamsplitter cable.

3. Make sure the UV and Vis lamps are set to HI. Set the detector wavelength to 354 nm and then press **Enter** on the front panel. Allow the detector to equilibrate with the test cell installed for at least 10 minutes before performing the Wavelength Accuracy test.

4. Open the **OQ_UV.rdf** or **PQ_UV.rdf** report file, depending on the qualification being performed. Locate the row of sheet names at the bottom of the report. Click on the **DET_AD20_WAVE** sheet. Print the sheet. This will allow for manual recording of test results. Test can also be directly entered into the report (see Step 10). Close the report.

5. From the front panel of the AD20 detector, press the **Offset** button to zero the detector reading. Allow the detector to equilibrate for approximately 20 seconds. Record the offset absorbance value as the measured absorbance for 354 nm. This value should be approximately 0.0000 AU.

6. Manually change the wavelength setting on the front panel of the AD20 to 355 nm and press **Enter** on the front panel. Allow the detector to equilibrate for approximately 20 seconds. Record the resulting absorbance value for 355 nm.

7. Repeat Step 6 for the remaining 13 wavelength settings in the **DET_AD20_WAVE** sheet.

8. After all wavelength absorbance values have been recorded, find the wavelength setting that produced the maximum absorbance value.

9. Record the wavelength setting that produced the maximum absorbance value.

10. Open the **OQ_UV.rdf** or **PQ_UV.rdf** report file and go to the **DET_AD20_WAVE** sheet. Go to **Edit** and turn **Layout Mode** on. Enter today's date in the **Additional Information** section. Enter all previously recorded values in the table on the sheet. The deviation and pass/fail results will be calculated automatically. Print the sheet. Click on **Edit** and turn **Layout Mode** off. Close the report file.

11. If any part of the test does not pass, refer to Section 5 for troubleshooting assistance.

## 3.5.2 Performing the Main Qualification

The main part of the OQ/PQ consists of the tests in the Detector_Pump sequence. They include:

**Detector Noise and Drift (Absorbance and Conductivity detectors)**
**Injector Precision**
**Detector Linearity**
**Injector Linearity (AS50 sequences only)**
**Carry Over**
**Sample Prep Precision (AS50 SP sequences only)**

This part of the qualification requires that an AD20, AD25, PDA-100 or Conductivity Detector be configured on the system being qualified. If an Amperometry Detector is the only detector configured on the system, go on to Section 3.5.4 for DC Amperometry qualification or Section 3.5.5 for Integrated Amperometry qualification.

If the qualification will be performed using a manual injection valve, use full loop injections and overfill the loop a minimum of 3 times. Use the AS40 sequence templates. Inject standards at the beginning of each sample in the sequence. There will be a 2.5 minute delay before the sample is injected.

**Note:** AD20 and AD25 sequences contain both 254 nm and 520 nm Noise and Drift Tests. If you do not want to perform the Noise and Drift tests at both wavelengths, change the sequence status line of the test you do not want to run to **Finished,** then save the sequence. The PDA - 100 sequences collect data at both wavelengths simultaneously.

1. The IC must be set up and running as described in Section 2.5.

2. From the Browser, go to the Panel directory and open the panel that best matches your system configuration. Go to **Control** and select the timebase to be qualified.

3. Go to **Batch** and **Edit. Remove** any existing sequences. Click on **Add** and select the Detector_Pump sequence chosen in Section 2.6.

4. Click on **Ready Check** to confirm the program and method files contained in the sequence are compatible with the configured system. Make modifications to the program files if necessary.

   **Note:** If an EG40 is configured on the system, the following message will occur at the Ready Check: **"Flow rate not specified at time 0.0, using a flow setting 1.00."** This refers to the EG40 flow rate, not the pump flow rate. It is not necessary to take any action since the EG40 is not used for this part of the qualification. Proceed with starting the batch.

5. **Start** the Batch. Run times are as follows:

   AS40 Detector_Pump sequences have a run time of approximately 1 hr and 10 mins.
   AS50 CC/TC Detector_Pump sequences have a run time of approximately 2 hrs, 10 mins.
   AS50 CC/TC SP Detector_Pump sequences have a run time of approximately 2 hrs, 40 mins.

   At the end of the sequence, the system will automatically stop.

6. When the Batch is finished, go to the Browser and right click on the Detector_Pump sequence. Go to **Batch Report**. Confirm that the correct report (rdf) file is selected and **Print** the report.

7. Review the report for Pass/Fail results. If any test does not pass, make the appropriate instrument repair/adjustments and rerun all tests from the original point of failure on. Refer to Section 5 for troubleshooting assistance.

### 3.5.3 Gradient Accuracy

The Gradient Accuracy test only needs to be performed on gradient pumps. If the gradient pump is used only in isocratic mode, this test does not need to be run.

The Gradient Accuracy test can be run on standard bore and microbore GP40 and GP50 pumps, and on all GS50 pumps. GP40 and GP50 microbore pumps should be qualified using the GP40_GP50_MB_Grad_Accuracy sequences. GS50 and standard bore GP50 pumps should be qualified using the GP50_GS50_SB_Grad_Accuracy sequences. Standard bore GP40 pumps should be qualified using the GP40_SB_Grad_Accuracy sequences.

1. Make sure all pump lines are primed well, according to the system preparation in Section 2.5.

2. Turn the pump flow off.

3. Remove the Backpressure Coil and replace it with approximately 30" of yellow PEEK tubing.

4. Set the pump flow rate to 1.00 mL minute. Monitor the system backpressure and confirm the reading is between 1500 and 2000 psi. If the backpressure reading falls outside of this range, adjust the length of the yellow PEEK tubing accordingly.

5. Allow the pump to equilibrate for approximately 10 minutes.

6. From the Browser, go to the Panel directory and open the panel that best matches your system configuration. Go to **Control** and select the timebase to be qualified.

7. Go to **Batch** and **Edit.** Click on **Add** and select the Grad Accuracy sequence chosen in Section 2.6. The sequence templates are different for GP40 and GP50/GS50 pumps.

8. Click on **Ready Check** to confirm the program and method files contained in the sequence are compatible with the configured system. Make modifications to the program files if necessary.

9. **Start** the Batch. Run times are as follows:

   GP40 Grad Accuracy sequences have a run time of approximately 37 mins.
   GP50_GS50 sequences have a run time of approximately 62 mins.

10. At the end of the sequence, the system will automatically stop.

11. When the Batch is finished, go to the Browser and right click on the Grad Accuracy sequence. Go to **Batch Report**. Confirm that the correct report (rdf) file is selected and **Print** the report.

12. Review the report for Pass/Fail results. If any part of the test does not pass, make the appropriate repair/adjustments and rerun the test. Refer to Section 5 for troubleshooting assistance.

### 3.5.4 DC Amperometry Noise and Drift

This test should only be performed if the ED40 or ED50 Detector is used in the DC Amperometry mode.

1. Disconnect the Amperometry cell cable from the ED40/ED50 Detector.

2. Plug the ED/CD Validation Test Cell Amperometry cable into the ED40/ED50 Amperometry Cell connector.

3. From the front panel of the detector, turn the cell on.

4. Let the detector equilibrate with the validation cell for approximately five minutes.

5. From the Browser, go to the Panel directory and select the **ED40_DC_Amp panel**. This panel will work with either the ED40 or ED50 detector. Go to **Control** and select the timebase configured with the detector to be qualified.

6. Go to **Batch** and **Edit.** Click on **Add** and select the **DC_Amp_Noise_Drift** sequence chosen in Section 2.6.

7. Click on **Ready Check** to confirm the program and method files contained in the sequence are compatible with the configured system. Make modifications to the program files if necessary.

8. **Start** the Batch. The run time is 20 minutes. The pump flow for this sequence is 0.00 mL/min.

9. When the Batch is finished, go to the Browser and right click on the **DC_Amp_Noise_Drift** sequence. Go to **Batch Report**. Confirm that the OQ_ECD or PQ_ECD report (rdf) file is selected and **Print** the report.

10. Review the report for Pass/Fail results. If any part of the test does not pass, make the appropriate repair/adjustments and rerun the test. Refer to Section 5 for troubleshooting assistance.

### 3.5.5 Integrated Amperometry Noise and Drift

This test should only be performed if the ED40 or ED50 Detector is used in the Integrated Amperometry mode.

1. Disconnect the Amperometry cell cable from the ED40/ED50 Detector.

2. Plug the ED/CD Validation Test Cell Amperometry cable into the ED40/ED50 Amperometry Cell connector.

3. From the front panel of the detector, turn the cell on.

4. Let the detector equilibrate with the validation cell for approximately five minutes.

5. From the Browser, go to the Panel directory and select the **ED40_Integrated_Amp panel**. This panel will work with either the ED40 or ED50 detector. Go to **Control** and select the timebase configured with the detector to be qualified.

6. Go to **Batch** and **Edit.** Click on **Add** and select the **Int_Amp_Noise_Drift** sequence chosen in Section 2.6.

7. Click on **Ready Check** to confirm the program and method files contained in the sequence are compatible with the configured system. Make modifications to the program files if necessary.

8. **Start** the Batch. The run time is 20 minutes. The pump flow for this sequence is 0.00 mL/min.

9. When the Batch is finished, go to the Browser and right click on the **Int_Amp_Noise_Drift** sequence. Go to **Batch Report**. Confirm that the OQ_ECD or PQ_ECD report (rdf) file is selected and **Print** the report.

10. Review the report for Pass/Fail results. If any part of the test does not pass, make the appropriate repair/adjustments and rerun the test. Refer to Section 5 for troubleshooting assistance.

### 3.5.6 EG40 Current Qualification

The EG40 Current Qualification test can be used for both KOH and MSA EG40 Cartridges.

1. Disconnect the Eluent Generator Cartridge cable from the EG40.

2. Plug the EG40 Validation Test Cell cable into the EG40 Cartridge connector.

   Note: This test requires EG40 Validation Test Cell Rev 02 or higher. To modify a Rev 01 cell to use for the current test, see Section 8.

3. Turn on the Voltmeter and set the display to mA. This test requires mA readings from 0.00 to 220 mA.

4. Connect the positive lead of the voltmeter to the Test Cell red wire connection closest to the EG40 cartridge connection.

5. Connect negative lead of the voltmeter to the other Test Cell red wire connection.

6. From the Browser, go to the Panel directory and select the pump_EG40_detector panel appropriate for the system being qualified. Go to **Control** and select the timebase configured with the EG40 to be qualified.

7. From the EG40 section of the panel, select the cartridge type to be used. The panel will recognize previously configured KOH and MSA cartridges even though the EG40 Validation cell is plugged into the cartridge connector.

8. Go to **Batch** and **Edit.** Click on **Add** and select the **EG40 Current Qual** sequence chosen in Section 2.6.

9. Click on **Ready Check** to confirm the program and method files contained in the sequence are compatible with the configured system. Make modifications to the program files if necessary. The pump flow for this sequence is set to 1.00 mL/min to keep the pressure above the minimum pressure limit required for the EG40.

10. **Start** the Batch. This sequence is an EG40 step gradient. Each step is held for one minute. There is a delay of 0.4 seconds between when the EG40 program steps to the next concentration and when the voltmeter registers the new milliamp reading. Record the milliamp reading for each step. These values will be entered into the **EG40_CUR_KOH** or **EG40_CUR_MSA** sheets after the run is complete. The run time is 16 minutes. Data acquisition is off during this run.

11. When the run is complete, open the **OQ_UV.rdf** or **PQ_UV.rdf** report file, depending on the qualification being performed. Locate the row of sheet names at the bottom of the report. Click on the **EG40_CUR_KOH** or **EG40_CUR_MSA** sheet, depending on the type of cartridge to be qualified.

12. Go to **Edit** and turn **Layout Mode** on. Enter today's date in the **Additional Information** section. Enter the milliamp reading for each step in the **EG40_CUR_KOH** or **EG40_CUR_MSA** sheet. The deviation and pass/fail results will be calculated automatically. Print the sheet, click on **Edit** and turn **Layout Mode** off. Close the report.

13. If any part of the test does not pass, make the appropriate repair/adjustments and rerun the test. Refer to Section 5 for troubleshooting assistance.

14. To qualify another cartridge, select the new cartridge type in the control panel and repeat steps 7 – 12.

# 3.6 OQ/PQ Completion

## 3.6.1 Customer Review

1. The results should be reviewed by the instrument owner/user. If the qualification is accepted, both the Customer and Qualification Executor need to sign the printed reports.
2. Fill out the Validation Stickers and Certificates of Functional Performance for the qualified modules.
3. Place the reports and certificates into the binder provided in the OQ/PQ kit and leave it with the customer.

## 3.6.2 Returning the System to the Original Configuration

1. If the Signal factor was modified in the system preparation, it must be set back to its original value. Open **Server Configuration**. Double click on the detector/s that were qualified to view the properties page. Select the **Signals** page and change the factor back to the original value. Exit the properties page and save the configuration.

2. Disconnect the Backpressure Coil and/or yellow PEEK tubing and restore the system plumbing to its original configuration with the appropriate columns, suppressors, and EG40 in line.

3. Install the original sample loop back onto the injection valve. For systems using an AS50 Autosampler, go to the **Main Menu** on the front panel of the autosampler. Access the **Module Set Up** screen and then go to **Plumbing Configuration**. Change the sample loop size back to its original value.

4. Reconnect the original eluents to the pump and prime each line individually.

5. Flush the system with an eluent recommended by the customer and confirm that there are no leaks.

# 4 Explanation of Test Procedures

## 4.1 Wavelength Accuracy of Absorbance Detectors

### 4.1.1 Theory

Wavelength accuracy is evaluated using a holmium oxide filter. Three holmium oxide maxima are compared with the theoretical maxima at 360.9 nm, 418.7 nm and 536.2 nm for AD25 and PDA – 100 detectors. Absorbance readings are measured with a holmium oxide filter at varying wavelength settings for the AD20 wavelength accuracy test.

### 4.1.2 Performing and Evaluating the Test

The wavelength accuracy test is triggered from the front panel of the AD25 or through a PeakNet™ Wellness panel for either the AD25 or PDA-100. When the verification is complete, test results are displayed either on the front panel of the AD25 or in the Wellness panel. Measured wavelengths, deltas and pass/fail results are recorded manually. The test is performed from the front panel of the AD20 by setting wavelengths manually and recording the resulting absorbance values.

## 4.2 Baseline Noise and Drift

### 4.2.1 Theory

A 20-minute detector baseline is collected using water as the eluent at a flow rate of 1.00 mL/min. For absorbance detectors, data is collected at 254 nm, 520 nm, or both.

### 4.2.2 Performing the Test and Evaluating the Results

Noise and drift evaluation for all IC detectors is the first test in the Detector_Pump sequence and is called Noise and Drift. This is Test B in the OQ/PQ test order.

Noise is calculated by splitting the 20-minute baseline signal into 20 one-minute intervals. The noise is the distance between two parallel lines through the measured minimum and maximum values and the regression line. The measured noise values are then averaged to establish the final value. To calculate drift, PeakNet™ uses a method of least squares and calculates a regression line from the measured values. The slope of the curve indicates the drift of the measured signal, and the amount of the slope indicates the amount of drift.

## 4.3 Injector Precision

### 4.3.1 Theory

Injector precision is determined by making six replicate injections of a standard using a fixed sample volume. A 40 ppm caffeine standard is injected when using absorbance detection at a wavelength of 272 nm. A 50 ppm nitrate standard is injected when using conductivity detection. Water is used as the eluent at a flow rate of 1.00 mL/min.

### 4.3.2 Performing and Evaluating the Test

Injector precision evaluation is the second set of samples in the Detector_Pump sequence and the samples are called Inj Precision_1 through Inj Precision_6. This is Test C in the OQ/PQ test order. The concentration of the nitrate or caffeine standard and the sample volume injected is included in the QNT file used for injector linearity.

Precision is determined by calculating the relative standard deviation of the peak areas for the six injections.

## 4.4 Detector Linearity

### 4.4.1 Theory

Detector linearity for absorbance detectors is determined at 272 nm using a sequence of five caffeine standard injections at 15, 40, 60, 80 and 100 ppm. Linearity for conductivity detectors uses a sequence of five nitrate standard injections at 5, 10, 25, 50, and 100 ppm. Water is used as the eluent at a flow rate of 1.00 mL/min.

### 4.4.2 Performing the Test and Evaluating the Results

Detector linearity evaluation is the third test in the Detector_Pump sequence and the samples are called Detector linearity_1 through Detector linearity_5. This is Test D in the OQ/PQ test order. The concentrations for the nitrate and caffeine standards are included in the QNT file used for detector linearity.

PeakNet™ calculates the peak height for each standard. A plot of peak height vs. concentration is generated and the regression line is determined. The correlation coefficient and the relative standard deviation of this line indicate linearity.

## 4.5 Injection Volume Linearity

### 4.5.1 Theory

Injection volume linearity is determined by making five injections of a standard using injection volumes of 10, 20, 30, 40 and 50 µL. A 60 ppm caffeine standard is injected when using absorbance detection at a wavelength of 272 nm. A 100 ppm nitrate standard is injected when using a conductivity detection. Water is used as the eluent at a flow rate of 1.00 mL/min. This test is only performed on autosamplers with variable injection volume capability.

### 4.5.2 Performing the Test and Evaluating the Results

Injection volume linearity evaluation is the fourth test in the Detector_Pump sequence and the samples are called Injector linearity_1 through Injector linearity_5. This is Test E in the OQ/PQ test order. The concentrations for the nitrate and caffeine standard and the injection volumes are included in the QNT file used for detector linearity.

PeakNet™ calculates the peak area for each injection. A plot of peak area vs. injection volume is generated and the regression line is determined. The correlation coefficient and the relative standard deviation of this line indicate linearity.

## 4.6 Sample Carry-over

### 4.6.1 Theory

Sample carry-over is determined by injecting a highly concentrated sample followed by a blank injection. The blank in this case is water. Nitrate at a concentration of 1000 ppm is injected when this test is performed with a conductivity detector. Caffeine at a concentration of 1000 ppm is injected when this test is performed with an absorbance detector. Ideally, the chromatogram of the blank injection should not contain any peaks. If, however, a peak is detected, the ratio of the peak areas is compared. Water is used as the eluent at a flow rate of 1.00 mL/min.

### 4.6.2 Performing the Test and Evaluating the Results

Sample carry-over evaluation is the fifth test in the Detector_Pump sequence and the samples are called Carry over and Water. This is Test F in the OQ/PQ test order.

A peak area ratio is calculated for the two injections determine sample carry-over.

## 4.7 Sample Prep Precision

### 4.7.1 Theory

Sample Prep precision is determined by making three separate injections using a fixed injection volume. Each of the three standards is prepared individually using the autosampler's sample preparation option. The autosampler prepares the three samples by first transferring 15 µL of a 1000 ppm caffeine or nitrate standard into three empty sample vials and then adding 1485 µL of water to each. Injections are then made from each vial. Water is used as the eluent at a flow rate of 1.00 mL/min. If an absorbance detector is used the wavelength is set to 272 nm. This test is only performed on autosamplers with the sample prep option.

### 4.7.2 Performing the Test and Evaluating the Results

Sample prep precision evaluation is the last set of samples in the Detector_Pump sequence and the samples are called Sample Prep_1 through Sample Prep_3. This is Test G in the OQ/PQ test order.

Precision is determined by calculating the relative standard deviation of the peak areas for the three injections.

## 4.8 Gradient Accuracy

### 4.8.1 Theory

Gradient accuracy is determined by performing a step gradient using varying compositions of water and either 0.3% Acetone or 1 mM KCL. When performing the test with an absorbance detector, water is used for eluents A and C and 0.3% Acetone is used for eluents B and D with a wavelength setting of 254 nm. When performing the test with a conductivity detector, water is used for eluents A and C and 1 mM KCl is used for eluents B and D. Gradient composition is measured at 0, 20, 50, 80, and 100% of eluents B and D at a flow rate of 1.00 mL/min with a backpressure of 1500 -2000 psi. Step noise (ripple) is measured for each step in the gradient. No injection is required.

### 4.8.2 Performing the Test and Evaluating the Results

Gradient Accuracy evaluation is contained in the GP40_Grad Accuracy or GP50_GS50 Grad Accuracy sequences. This is Test H in the OQ/PQ test order.

The measured step height is compared to the theoretical step height and a percent deviation is calculated. Step noise is evaluated for all steps. Each step has a defined one-minute interval where noise is evaluated. Based on a method of least squares, PeakNet™ calculates a regression line from the measured values of each interval. The noise is the distance between two parallel lines through the measured minimum and maximum values and the regression line.

## 4.9 DC Amperometry Noise and Drift

### 4.9.1 Theory

A 20-minute detector baseline is collected using an amperometry validation test cell.

### 4.9.2 Performing the Test and Evaluating the Results

Noise and drift evaluation for the DC Amperometry detector is contained in the DC_Amp_Noise _Drift sequence. This is Test I in the OQ/PQ test order.

Noise is calculated by splitting the 20-minute baseline signal into 20 one-minute intervals. The noise is the distance between two parallel lines through the measured minimum and maximum values and the regression line. The measured noise values are then averaged to establish the final value. To calculate drift, PeakNet™ uses a method of least squares and calculates a regression line from the measured values. The slope of the curve indicates the drift of the measured signal, and the amount of the slope indicates the amount of drift.

## 4.10 Integrated Amperometry Noise and Drift

### 4.10.1 Theory

A 20-minute detector baseline is collected using an amperometry validation test cell.

### 4.10.2 Performing the Test and Evaluating the Results

Noise and drift evaluation for the Integrated Amperometry detector is contained in the Int_Amp_Noise _Drift sequence. This is Test J in the OQ/PQ test order.

Noise is calculated by splitting the 20-minute baseline signal into 20 one-minute intervals. The noise is the distance between two parallel lines through the measured minimum and maximum values and the regression line. The measured noise values are then averaged to establish the final value. To calculate drift, PeakNet™ uses a method of least squares and calculates a regression line from the measured values. The slope of the curve indicates the drift of the measured signal, and the amount of the slope indicates the amount of drift.

## 4.11 EG40 Current Qualification

### 4.11.1 Theory

EG40 Current Qualification is determined by performing an EG40 step gradient using varying eluent concentration set points. The EG40 applies a specific current to the EluGen cartridge depending on the concentration of eluent and type of cartridge selected. An EG40 validation test cell is used in place of the EluGen cartridge and the applied current for each step is measured using a voltmeter that is connected to the test cell.

### 4.11.2 Performing the Test and Evaluating the Results

The EG40 current qualification test is contained in the EG40_Current_Qual sequence. This is Test K in the OQ/PQ test order. Current readings in mA are displayed on the voltmeter for each concentration step in the gradient. Values for each step and pass/fail results are manually recorded.

# 5 Troubleshooting

## 5.1 General Hints

If the system pressure is above 1500 psi after connecting the PEEK Backpressure coil with a flow rate of 1.00 mL/min, the coil has a blockage. Replace the coil.

Dips before or after the main nitrate or caffeine peak indicate extra dead volume in the system. This is caused by small voids between the end of a liquid line and the bottom of the port it is installed in. One by one disconnect each line from the injection valve to the detector cell. Push the ferrule and fitting up and away from the end of the tubing. Make sure the tubing is cut straight. If it is not, recut the end. When reinstalling all liquid connections, first insert the tubing all the way into the port until it touches the bottom. Hold the tubing in this position while inserting and tightening ferrule and fitting down into the port.

## 5.2 Failure of Individual Tests

### 5.2.1 Absorbance Detector

| Test | Reason | Action |
|---|---|---|
| Wavelength Accuracy | Optics not calibrated | Perform wavelength calibration and then repeat the wavelength accuracy test |
| | Air bubbles in flow cell | Flush out flow cell |
| | Colored reagent in flow cell | Flush out flow cell |
| Baseline Noise | Poor water quality | Replace with an alternate water source |
| | Lamp is reaching maximum lifetime | Replace lamp |
| | Air bubbles in flow cell | Flush out flow cell |
| Drift | Detector not warmed up | Allow recommended warm up period (refer to test procedure) |
| | System not equilibrated | Allow longer flush/equilibration time |
| | Lamp defective | Replace lamp |
| Lamp Intensity (PDA-100 only) | Lamp is reaching maximum lifetime | Replace lamp |
| | Flow cell inserted incorrectly | Reinstall flow cell |
| Detector Linearity | Lamp is reaching maximum lifetime | Replace lamp |
| | Concentration of standards is incorrect | Remake standards |
| | Liquid leak | Find source of leak |

### 5.2.2 Conductivity Detector Tests

| Test | Reason | Action |
|---|---|---|
| Baseline Noise | Poor water quality | Replace with an alternate water source |
| | Air bubbles in flow cell | Flush out flow cell |
| | Cell temperature regulation failure | Replace cell |
| Drift | System not equilibrated | Allow longer flush/equilibration time |
| | Lab temperature not stable | Regulate temperature (block vents, close windows, etc.) |
| Detector Linearity | Concentration of standards is incorrect | Remake standards |
| | Liquid leak | Find source of leak |
| | Injection volume not consistent (manual injections only) | Overfill sample loop at least 3x when loading. |

### 5.2.3 Autosampler

| Test | Reason | Action |
|---|---|---|
| Injector Precision | Air injected from vial or from sample syringe when doing manual injections<br><br>Air bubbles in AS50 sample syringe<br><br>Liquid leak in autosampler or injection valve | Too little sample volume in vial - refill vial or flush bubbles out of injection syringe.<br><br>Flush out syringe<br><br>Find source of leak |
| Injection Volume Linearity | Detector failure<br><br>Defective sample syringe | See Detector linearity troubleshooting section<br><br>Replace sample syringe |
| Carry Over | Contaminated injection valve<br><br>Contamination in autosampler<br><br>Contamination in sample vial or in syringe used for manual injections | Replace/clean injection valve rotor and stator face<br><br>Flush autosampler liquid lines completely<br><br>Use new sample vial for water blank, rinse vial thoroughly before using, flush syringe or use a new one |
| Sample Prep Precision | Air injected from vial<br>Liquid leak<br><br>Air bubbles in AS50 sample syringe or prep syringe<br><br>Defective prep syringe<br><br>Liquid leak in autosampler or injection valve | Too little sample volume in vial, refill vial.<br><br>Flush out syringe<br><br>Replace prep syringe<br><br>Find source of leak |

### 5.2.4 Pump

| Test | Reason | Action |
|---|---|---|
| Gradient Step Accuracy | Air in system | Prime pump - prime each line individually for 3 - 5 minutes, flush system |
| | System not equilibrated | Allow longer flush/equilibration time. |
| | Old eluent in vacuum degas chamber | Prime pump - prime each line individually for 3 - 5 minutes |
| | Incorrect eluent concentration for eluents B and D | Remake 0.3% Acetone or 1mM KCL solutions |
| | GP40 pump eluents not pressurized | Pressurize eluent bottles |
| | GP50/GS50 eluent bottles not vented | Vent eluent bottles |
| Step Noise (ripple) | Air in system | Prime pump, flush system |
| | Air in flow cell | Flush flow cell |
| | System not equilibrated | Allow longer flush/equilibration time |
| | Check valve or piston seal failure | Replace check valve/piston seal |

### 5.2.5 DC and Integrated Amperometry Detector Tests

| Test | Reason | Action |
|---|---|---|
| Baseline Noise | Validation cell not connected properly | Reconnect test cell cable to amperometry cell connection on SP board |
| | Validation cell defective | Replace validation test cell |
| Drift | Detector not equilibrated | Allow longer equilibration time |
| | Lab temperature not stable | Regulate temperature (block vents, close windows, etc.) |

### 5.2.6 EG40

| Test | Reason | Action |
|---|---|---|
| Current | Validation cell not connected properly | Reconnect test cell cable to the EG40, confirm voltmeter leads are making contact with test cell wires |
| | Voltmeter on wrong setting | Voltmeter should be set to read current (mA). Range should be set to view 0.00 to 210.00 mA |
| | Validation cell defective | Replace validation test cell |

# 6 Modifying an EG40 Validation Test Cell

If using an EG40 Rev 01 Validation Test Cell, the cable needs to be modified to perform the EG40 Current Qualification Test with PeakNet 6. Rev 02 Validation Test Cells have been modified for use with this test already.

1. Using a razor blade carefully cut the heat shrink tubing on the test cell cable lengthwise. Make a cut approximately 2 inches long in the cable mid-section. This will expose a black and red wire.

2. Cut the red wire and strip off about a ¼ inch of the red insulation, exposing the bare wire. Connect each end of the bare wire to the voltmeter as directed in Section 3.5.6.

# 7 Example Reports

Following are two example PQ Reports. The PQ_UV report is for a system configured with an AD25, GS50, and an AS50 with a CC. An example AD20 Wavelength Accuracy report is also included at the end of the PQ_UV report.

The PQ_ECD report is for a system configured with an ED40 (conductivity and integrated amperometry modes), GP40, EG40 and an AS50 with a CC. The OQ and PQ reports are the same except the test limits differ according to the table in Section 1.3.

# Performance Qualification

## Instruments

| Instrument name | Model | Supplier's Name | Serial Number | Moduleware Version |
|---|---|---|---|---|
| Pump | GS50 | Dionex | 00071255 | 1.00 |
| LC Module or LC Oven | CC | Dionex | 99125564 | N/A |
| Absorbance Detector | AD25 | Dionex | 00012233 | 1.02 |
| Chromeleon Datasystem | 6.20 Build 527 (Demo-Installation) | Dionex | 12345678 | N/A |
| Autosampler | AS50 | Dionex | 00052145 | 1.07 |

## Accessories

| Name | Description |
|---|---|
| Backpressure Tubing | 0.13 mm (0.005") ID PEEK, 13 m (512") |
| Backpressure Tubing | 0.003" ID PEEK, 50" |
| UV Sample 1 | Caffeine, 15 ppm |
| UV Sample 2 | Caffeine, 40 ppm |
| UV Sample 3 | Caffeine, 60 ppm |
| UV Sample 4 | Caffeine, 80 ppm |
| UV Sample 5 | Caffeine, 100 ppm |
| UV Sample 6 | Caffeine, 1000 ppm |
| Blank | Water |
| Eluent A | Water |
| Autosampler Reservoir A | Water |
| AD20 Holumium Oxide Test Cell | |

Customer Signature | Qualification Executor | Date

***Customer signature indicates that all information in the following reports has been reviewed and accepted.***

## Limits

| Test | Customized Limits | Dionex Recommended Limits |
|---|---|---|
| Noise - AD20 UV and Vis (µAU) | 50.000 | 50.000 |
| Drift - AD20 UV and Vis (µAU/hr) | 200.000 | 200.000 |
| Noise - AD25 UV and Vis (µAU) | 40.000 | 40.000 |
| Drift - AD25 UV and Vis (µAU/hr) | 200.000 | 200.000 |
| Noise - PDA - 100 UV and Vis (mAU) | 0.100 | 0.100 |
| Drift - PDA - 100 UV and Vis (mAU/hr) | 1.000 | 1.000 |
| AD25, PDA - 100 Wavelength Accuracy (nm, +/-) | 2 | 2 |
| AD20 Wavelength Accuracy (nm, +/-) | 3 | 3 |
| Detector Linearity (Corr.) | 0.999 | 0.999 |
| Detector Linearity (%RSD) | 5.000 | 5.000 |
| Injector Precision (Area %RSD) | 1.000 | 1.000 |
| Carry Over (Area %) | 0.100 | 0.100 |
| Injector Linearity (Corr.) | 0.999 | 0.999 |
| Injector Linearity (%RSD) | 1.000 | 1.000 |
| Sample Prep Precision (%RSD) | 2.000 | 2.000 |
| Standard Bore Gradient Pump Step Accuracy % | 2.000 | 2.000 |
| Standard Bore Pump Noise | 0.20% | 0.20% |
| Microbore Gradient Pump Step Accuracy % | 2.000 | 2.000 |
| Microbore Pump Noise | 0.50% | 0.50% |

## Additional Information

Customer/Company: **Mr. Turner/ XYZ Company** Date: **08-28-00**

Qualification Executor/Company: **Mr. Smith / Dionex** Next Qualification: **Feb-01**

Customer Signature | Qualification Executor | Date

DIONEX

# Performance Qualification

## *Wavelength Accuracy*

### • *Instruments and Fluidics*

| *Instrument name* | *Model* | *Supplier's Name* | *Serial Number* | *Moduleware Version* |
|---|---|---|---|---|
| Absorbance Detector | AD25 | Dionex | 00012233 | 1.02 |
| Chromeleon Datasystem | 6.20 Build 527 (Demo-Installation) | Dionex | 12345678 | N/A |

### • *Accessories*

| *Name* | *Desription* |
|---|---|
| None | |

### • *Additional Information*

Customer/Company: **Mr. Turner/ XYZ Company**

Date: **08-28-00**

Qualification Executor/Company: **Mr. Smith / Dionex**

Next Qualification: **Feb-01**

### • *Data for the Wavelength Accuracy Test*

| *Theoretical Wavelength (nm)* | *Measured Wavelength (nm)* | *Delta (nm)* | *+/- Limit (nm)* | *Result* |
|---|---|---|---|---|
| 360.9 | 361.0 | 0.1 | 2 | ***PASS*** |
| 418.7 | 418.9 | 0.2 | 2 | ***PASS*** |
| 536.2 | 536.3 | 0.1 | 2 | ***PASS*** |

Customer Signature

Qualification Executor

Date

DIONEX

# Performance Qualification

## *AD25 Detector Noise and Drift: 520 nm*

### • *Instruments and Fluidics*

| *Instrument name* | *Model* | *Supplier's Name* | *Serial Number* | *Moduleware Version* |
|---|---|---|---|---|
| Pump | GS50 | Dionex | 00071255 | 1.00 |
| Absorbance Detector | AD25 | Dionex | 00012233 | 1.02 |

### • *Accessories*

| *Name* | *Description* |
|---|---|
| Backpressure Tubing | 0.13 mm (0.005") ID PEEK, 13 m (512") |
| Eluent | Water |

### • *Additional Information*

Customer/Company: **Mr. Turner/ XYZ Company** Date: **08-28-00**

Qualification Executor/Company: **Mr. Smith / Dionex** Next Qualification Due: **Feb-01**

### • *Test Results Summary*

| *Test* | *Result* |
|---|---|
| Noise | ***PASS*** |
| Drift | ***PASS*** |

Customer Signature | Qualification Executor | Date

## • Data for Detector Noise

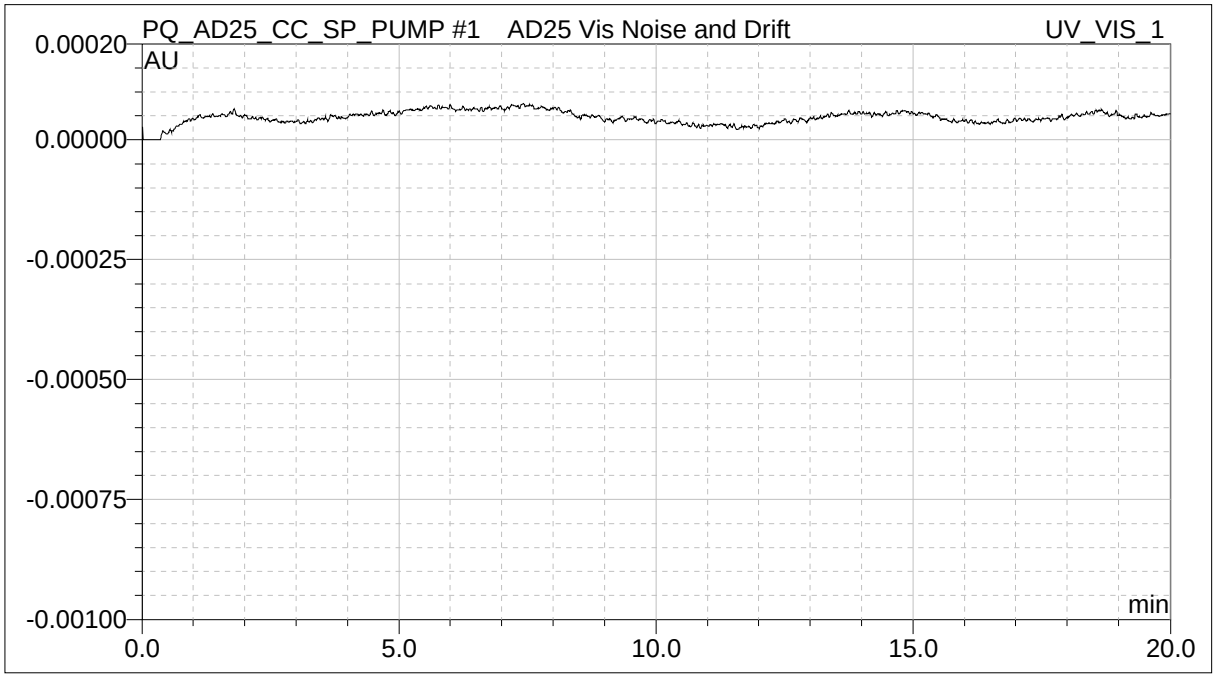
| Segment No. | Noise, µAU |
|---|---|
| 1 | 16.294 |
| 2 | 19.354 |
| 3 | 9.218 |
| 4 | 13.404 |
| 5 | 13.488 |
| 6 | 11.191 |
| 7 | 15.872 |
| 8 | 17.090 |
| 9 | 15.184 |
| 10 | 14.510 |
| 11 | 11.528 |
| 12 | 12.572 |
| 13 | 14.657 |
| 14 | 11.976 |
| 15 | 12.794 |
| 16 | 11.333 |
| 17 | 11.973 |
| 18 | 13.820 |
| 19 | 15.897 |
| 20 | 11.623 |
| ***Average (µAU)*** | **13.958** |
| ***Limit (µAu)*** | **40.000** |
| ***Result*** | ***PASS*** |

## • Data for Detector Drift

| 20 Minute Drift, µAU | Drift, µAu/hr | Limit, µAu/hr | Result |
|---|---|---|---|
| 0.047 | 0.140 | 150.000 | ***PASS*** |

Customer Signature | Qualification Executor | Date

## • *Chromatogram of Detector Noise and Drift*




Customer Signature | Qualification Executor | Date

DIONEX

# Performance Qualification

## *Injector Precision*

### • *Instruments and Fluidics*

| *Instrument name* | *Model* | *Supplier's Name* | *Serial Number* | *Moduleware Version* |
|---|---|---|---|---|
| Pump | GS50 | Dionex | 00071255 | 1.00 |
| LC Module or LC Oven | CC | Dionex | 99125564 | N/A |
| Absorbance Detector | AD25 | Dionex | 00012233 | 1.02 |
| Autosampler | AS50 | Dionex | 00052145 | 1.07 |

### • *Accessories*

| *Name* | *Description* |
|---|---|
| Backpressure Tubing | 0.13 mm (0.005") ID PEEK, 13 m (512") |
| UV Sample 2 | Caffeine, 40 ppm |
| Eluent A | Water |

### • *Additional Information*

| | | | |
|---|---|---|---|
| Customer/Company: | **Mr. Turner/ XYZ Company** | Date: | **08-28-00** |
| Qualification Executor/Company: | **Mr. Smith / Dionex** | Next Qualification: | **Feb-01** |

### • *Test Results Summary*

| *Test* | *Result* |
|---|---|
| Injector Precision (Area %RSD) | ***PASS*** |

Customer Signature _____ Qualification Executor _____ Date _____

## • *Data for Injector Precision Test* *25.0 µl*

| | ***Injector Precision*** |
|---|---|
| ***Sample Name*** | ***Peak Area***<br>***AU***<br>***Caffeine***<br>***UV_VIS_1*** |
| Inj Precision_1 | 0.049 |
| Inj Precision_2 | 0.049 |
| Inj Precision_3 | 0.050 |
| Inj Precision_4 | 0.050 |
| Inj Precision_5 | 0.050 |
| Inj Precision_6 | 0.050 |
| ***Average:*** | ***0.050*** |
| ***Std Dev:*** | ***0.000*** |
| ***% RSD:*** | ***0.358 %*** |
| ***Limit:*** | ***1.000 %*** |
| ***Result:*** | ***PASS*** |

Customer Signature  Qualification Executor  Date

DIONEX

# Performance Qualification

## *Detector Linearity*

### • *Instruments and Fluidics*

| *Instrument name* | *Model* | *Supplier's Name* | *Serial Number* | *Moduleware Version* |
|---|---|---|---|---|
| Pump | GS50 | Dionex | 00071255 | 1.00 |
| LC Module or LC Oven | CC | Dionex | 99125564 | N/A |
| Absorbance Detector | AD25 | Dionex | 00012233 | 1.02 |
| Autosampler | AS50 | Dionex | 00052145 | 1.07 |

### • *Accessories*

| *Name* | *Description* |
|---|---|
| Backpressure Tubing | 0.13 mm (0.005") ID PEEK, 13 m (512") |
| UV Sample 1 | Caffeine, 15 ppm |
| UV Sample 2 | Caffeine, 40 ppm |
| UV Sample 3 | Caffeine, 60 ppm |
| UV Sample 4 | Caffeine, 80 ppm |
| UV Sample 5 | Caffeine, 100 ppm |
| Eluent A | Water |

### • *Additional Information*

Customer/Company: **Mr. Turner/ XYZ Company**

Date: **08-28-00**

Qualification Executor/Company: **Mr. Smith / Dionex**

Next Qualification Due: **Feb-01**

### • *Test Results Summary*

| *Test* | *Result* |
|---|---|
| Detector Linearity (Corr.) | ***PASS*** |
| Detector Linearity (RSD) | ***PASS*** |

Customer Signature

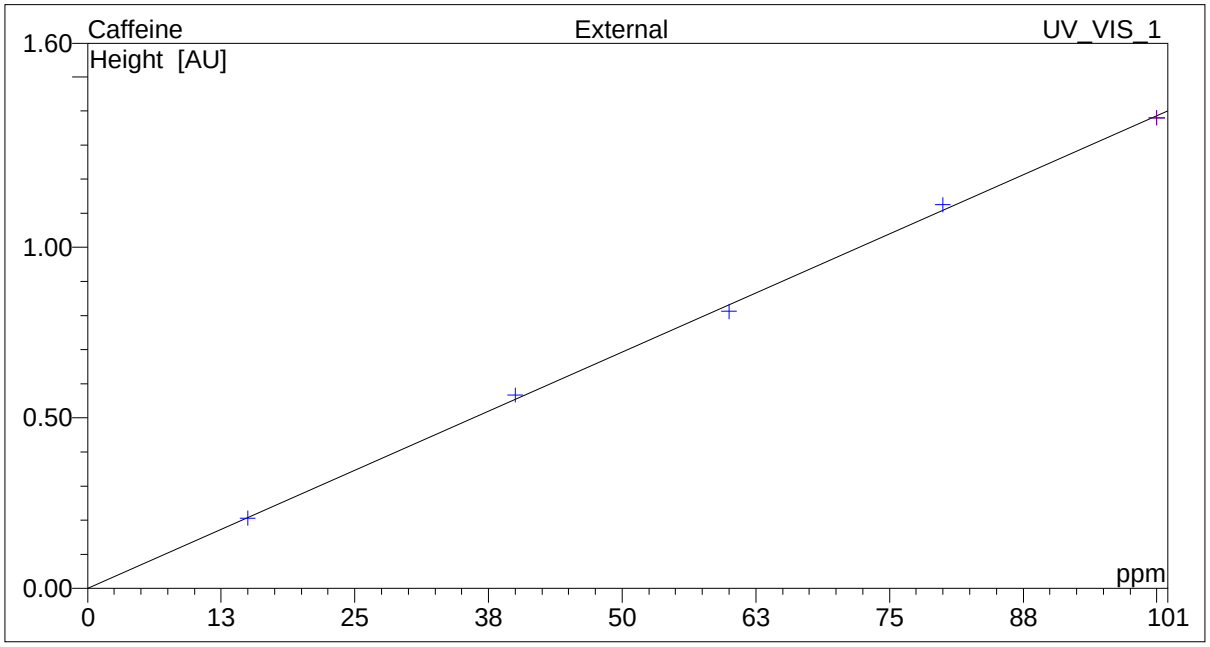
Qualification Executor

Date

## • *Data for Detector Linearity*

| Sample Name | Amount<br>ppm<br>Caffeine | Height<br>AU<br>Caffeine<br>UV_VIS_1 |
|---|---|---|
| Detector linearity_1 | 15 | 0.206 |
| Detector linearity_2 | 40 | 0.567 |
| Detector linearity_3 | 60 | 0.812 |
| Detector linearity_4 | 80 | 1.125 |
| Detector linearity_5 | 100 | 1.380 |

## • *Linearity Plot*




| *Cal.Type* | *Number of Points* | *Offset* | *Slope* |
|---|---|---|---|
| XLin | 5 | 0.000 | 0.014 |

| | *Correlation Coefficient* | *% RSD* |
|---|---|---|
| ***UV LInearity*** | 1.000 | 2.208 % |
| ***Limit:*** | ***0.999*** | ***5.000 %*** |
| ***Result:*** | ***PASS*** | ***PASS*** |

Customer Signature

Qualification Executor

Date

DIONEX

# Performance Qualification

## *Injector Linearity*

### • *Instruments and Fluidics*

| *Instrument name* | *Model* | *Supplier's Name* | *Serial Number* | *Moduleware Version* |
|---|---|---|---|---|
| Pump | GS50 | Dionex | 00071255 | 1.00 |
| LC Module or LC Oven | CC | Dionex | 99125564 | N/A |
| Absorbance Detector | AD25 | Dionex | 00012233 | 1.02 |
| Autosampler | AS50 | Dionex | 00052145 | 1.07 |

### • *Accessories*

| *Name* | *Description* |
|---|---|
| Backpressure Tubing | 0.13 mm (0.005") ID PEEK, 13 m (512") |
| UV Sample 3 | Caffeine, 60 ppm |
| Eluent A | Water |

### • *Additional Information*

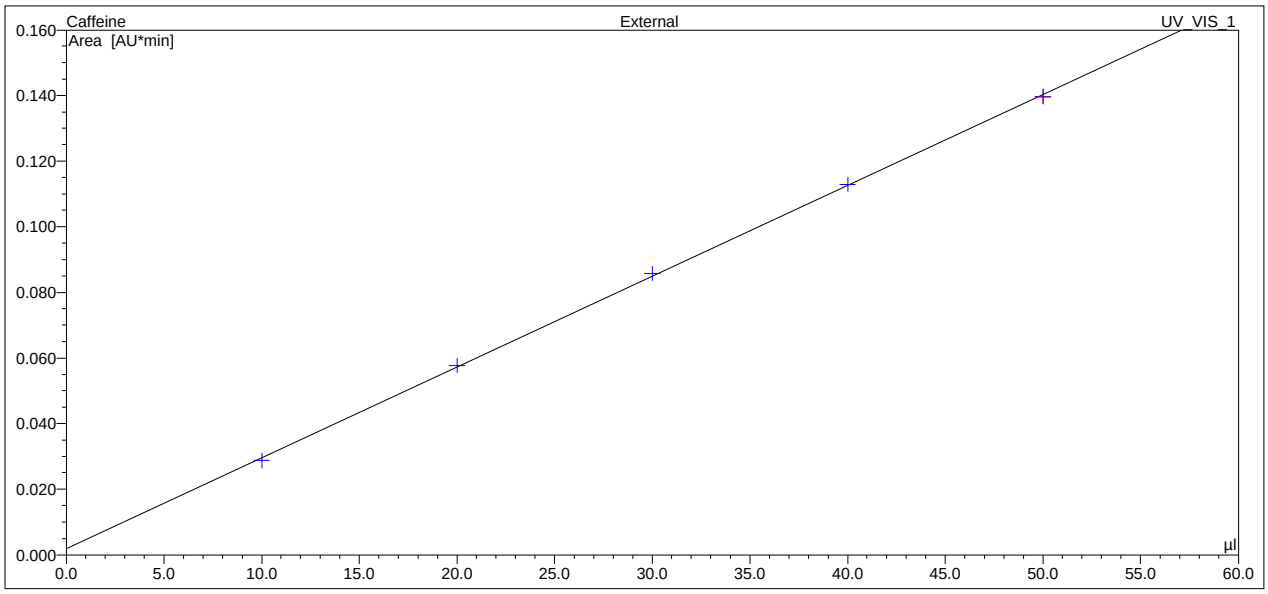
| | | | |
|---|---|---|---|
| Customer/Company: | **Mr. Turner/ XYZ Company** | Date: | **08-28-00** |
| Qualification Executor/Company: | **Mr. Smith / Dionex** | Next Qualification: | **Feb-01** |

### • *Test Results Summary*

| *Test* | *Result* |
|---|---|
| Injector Linearity (Corr.) | ***PASS*** |
| Injector Linearity (%RSD) | ***PASS*** |

Customer Signature | Qualification Executor | Date

## • *Linearity Plot*




## • *Data for Injector Linearity Test*

| *Sample Name* | *Retention Time*<br>*min*<br>*Caffeine*<br>*UV_VIS_1* | *Inj.Vol.*<br>*µl* | *Peak Area*<br>*AU*<br>*Caffeine*<br>*UV_VIS_1* |
|---|---|---|---|
| Injector linearity_1 | 0.47 | 10.0 | 0.029 |
| Injector linearity_2 | 0.49 | 20.0 | 0.058 |
| Injector linearity_3 | 0.49 | 30.0 | 0.086 |
| Injector linearity_4 | 0.49 | 40.0 | 0.113 |
| Injector linearity_5 | 0.49 | 50.0 | 0.140 |

| *Cal.Type* | *Number of Points* | *Offset* | *Slope* |
|---|---|---|---|
| LOff | 5 | 0.002 | 0.003 |

| | *Correlation Coefficient* | *% RSD* |
|---|---|---|
| ***Injector Linearity*** | 1.000 | 0.976 % |
| ***Limit:*** | ***0.999*** | ***1.000 %*** |
| ***Result:*** | ***PASS*** | ***PASS*** |

DIONEX

# Performance Qualification

## *Injector Carry Over*

### • *Instruments and Fluidics*

| *Instrument name* | *Model* | *Supplier's Name* | *Serial Number* | *Moduleware Version* |
|---|---|---|---|---|
| Pump | GS50 | Dionex | 00071255 | 1.00 |
| LC Module or LC Oven | CC | Dionex | 99125564 | N/A |
| Absorbance Detector | AD25 | Dionex | 00012233 | 1.02 |
| Autosampler | AS50 | Dionex | 00052145 | 1.07 |

### • *Accessories*

| *Name* | *Description* |
|---|---|
| Backpressure Tubing | 0.13 mm (0.005") ID PEEK, 13 m (512") |
| UV Sample 6 | Caffeine, 1000 ppm |
| Blank | Water |
| Eluent A | Water |

### • *Additional Information*

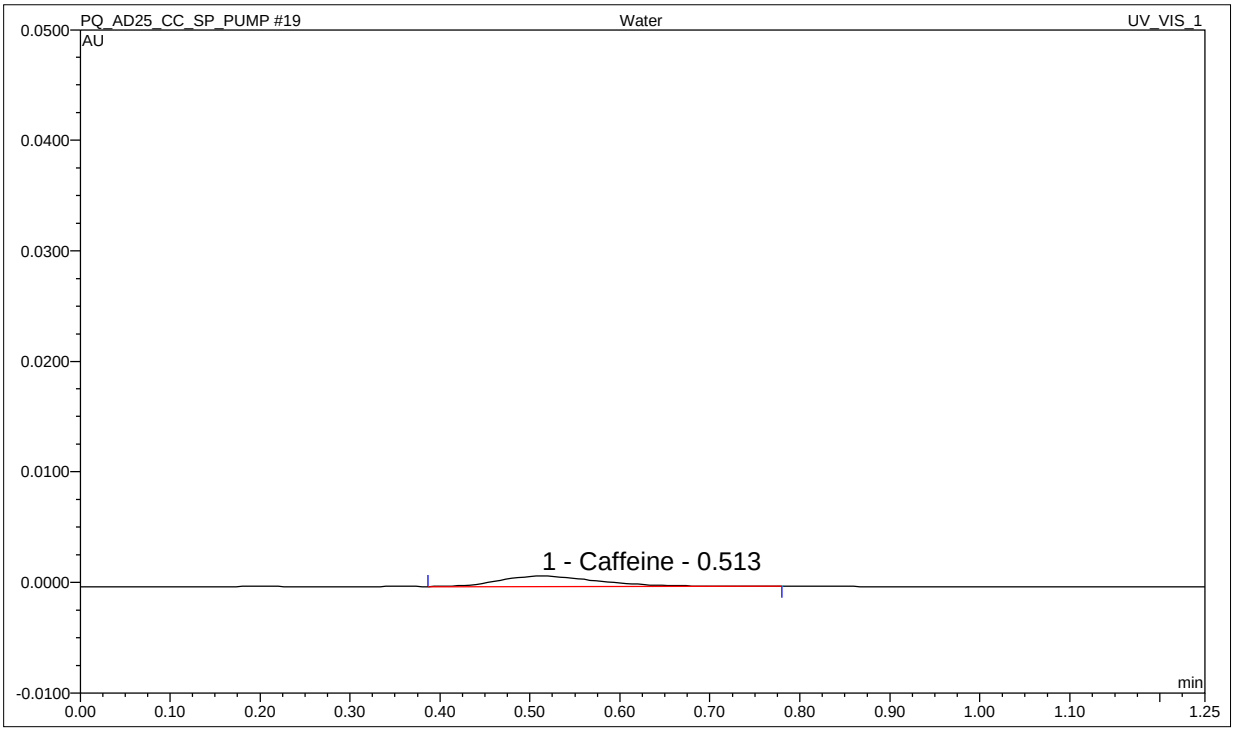
| | | | |
|---|---|---|---|
| Customer/Company: | **Mr. Turner/ XYZ Company** | Date: | **08-28-00** |
| Qualification Executor/Company: | **Mr. Smith / Dionex** | Next Qualification: | **Feb-01** |

### • *Test Results Summary*

| *Test* | *Result* |
|---|---|
| Carry Over (Area %) | **PASS** |

Customer Signature _____ Qualification Executor _____ Date _____

## • Chromatogram for Carry Over Test




## • Data for Carry Over Test

| ***Sample Name*** | ***Ret.Time*** ***min*** ***Caffeine*** ***UV_VIS_1*** | ***Area*** ***AU*min*** ***Caffeine*** ***UV_VIS_1*** |
|---|---|---|
| Carry over | 0.53 | 0.657 |
| Water | 0.51 | 0.000 |
| ***Carry over:*** | | ***0.018 %*** |
| ***Limit:*** | | ***0.100 %*** |
| ***Result:*** | | ***PASS*** |

Customer Signature | Qualification Executor | Date

# Performance Qualification

## *Sample Prep Precision*

### • *Instruments and Fluidics*

| *Instrument name* | *Model* | *Supplier's Name* | *Serial Number* | *Moduleware Version* |
|---|---|---|---|---|
| Pump | GS50 | Dionex | 00071255 | 1.00 |
| LC Module or LC Oven | CC | Dionex | 99125564 | N/A |
| Absorbance Detector | AD25 | Dionex | 00012233 | 1.02 |
| Autosampler | AS50 | Dionex | 00052145 | 1.07 |

### • *Accessories*

| *Name* | *Description* |
|---|---|
| Backpressure Tubing | 0.13 mm (0.005") ID PEEK, 13 m (512") |
| UV Sample 6 | Caffeine, 1000 ppm |
| Eluent A | Water |
| Autosampler Reservoir A | Water |

### • *Additional Information*

| | | | |
|---|---|---|---|
| Customer/Company: | **Mr. Turner/ XYZ Company** | Date: | **08-28-00** |
| Qualification Executor/Company: | **Mr. Smith / Dionex** | Next Qualification: | **Feb-01** |

### • *Test Results Summary*

| *Test* | *Result* |
|---|---|
| Sample Prep Precision (%RSD) | ***PASS*** |

Customer Signature _____ Qualification Executor _____ Date _____

## • *Data for Sample Prep Precision Test*

| ***Sample Name*** | ***Peak Area*** <br> ***AU*** <br> ***Caffeine*** <br> ***UV_VIS_1*** |
|---|---|
| Sample Prep_1 | 0.001 |
| Sample Prep_2 | 0.001 |
| Sample Prep_3 | 0.001 |
| ***Average:*** | ***0.001*** |
| ***Std Dev:*** | ***0.000*** |
| ***% RSD:*** | ***0.730 %*** |
| ***Limit:*** | ***2.000 %*** |
| ***Result:*** | ***PASS*** |

Customer Signature | Qualification Executor | Date

DIONEX

# Performance Qualification

## *Gradient Pump Accuracy and Noise*

### • *Instruments and Fluidics*

| *Instrument name* | *Model* | *Supplier's Name* | *Serial Number* | *Moduleware Version* |
|---|---|---|---|---|
| Pump | GS50 | Dionex | 00071255 | 1.00 |
| Absorbance Detector | AD25 | Dionex | 00012233 | 1.02 |

### • *Accessories*

| *Name* | *Description* |
|---|---|
| Backpressure Tubing | 0.003" ID PEEK |
| Eluent A | Water |
| Eluent B | Water/0.3% acetone (v/v) |
| Eluent C | Water |
| Eluent D | Water/0.3% acetone (v/v) |

### • *Additional Information*

Customer/Company: **Mr. Turner/ XYZ Company**

Date: **08-28-00**

Qualification Executor/Company: **Mr. Smith / Dionex**

Next Qualification: **Feb-01**

### • *Test Results Summary*

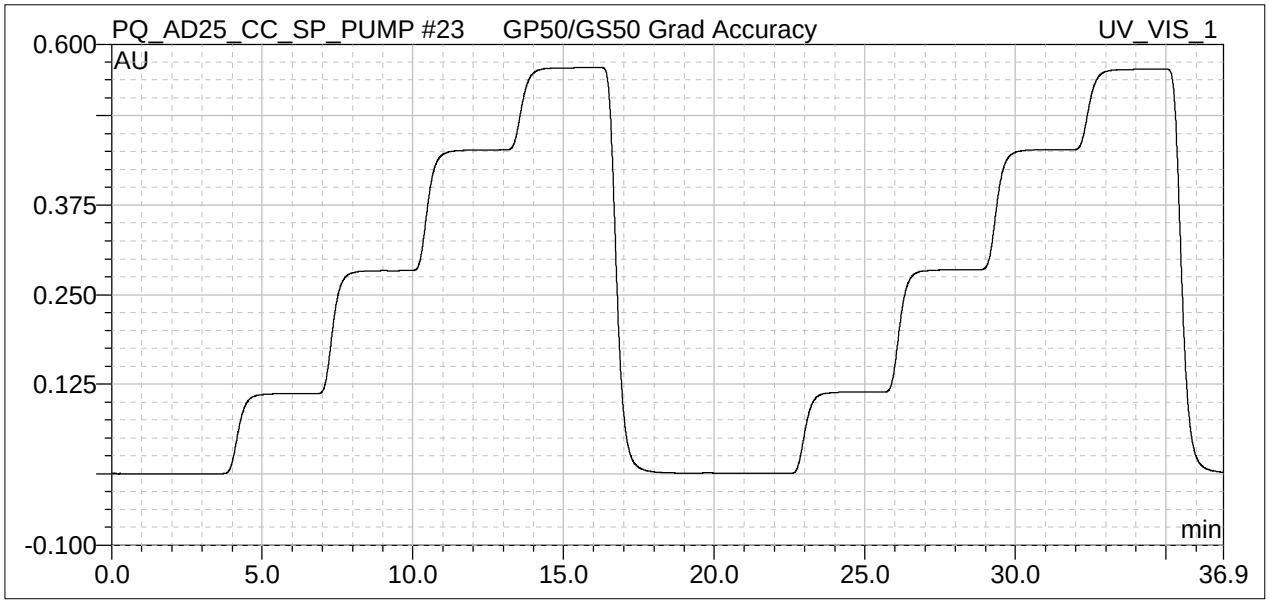
| *Test* | *Result* |
|---|---|
| Step Accuracy - A, B | ***PASS*** |
| Step Accuracy - C, D | ***PASS*** |
| Step Noise - A, B | ***PASS*** |
| Step Noise - C, D | ***PASS*** |

Customer Signature

Qualification Executor

Date

## • Chromatogram of Gradient Pump Accuracy




## • Step Accuracy - Valves A, B

| Theoretical Value (%) | Absorbance (AU) | Calculated Value (%) | Deviation (%) | Limit (+/- , %) | Result |
|---|---|---|---|---|---|
| 0.00 | 0.0000 | 0.00 | 0.00 | N/A | ---- |
| 20.00 | 0.1116 | 19.67 | -0.33 | 2.00 | ***PASS*** |
| 50.00 | 0.2835 | 49.99 | -0.01 | 2.00 | ***PASS*** |
| 80.00 | 0.4520 | 79.71 | -0.29 | 2.00 | ***PASS*** |
| 100.00 | 0.5671 | 100.00 | 0.00 | 2.00 | ***PASS*** |

## • Step Accuracy - Valves C, D

| Theoretical Value (%) | Absorbance (AU) | Calculated Value (%) | Deviation (%) | Limit (+/- , %) | Result |
|---|---|---|---|---|---|
| 0.00 | 0.0002 | 0.00 | 0.00 | N/A | ---- |
| 20.00 | 0.1137 | 20.09 | 0.09 | 2.00 | ***PASS*** |
| 50.00 | 0.2846 | 50.37 | 0.37 | 2.00 | ***PASS*** |
| 80.00 | 0.4524 | 80.07 | 0.07 | 2.00 | ***PASS*** |
| 100.00 | 0.5649 | 100.00 | 0.00 | 2.00 | ***PASS*** |

Customer Signature | Qualification Executor | Date

## • Step Noise - Valves A, B

| Step (%) | Noise (AU) | Calculated Noise (%FS) | Limit (%) | Result |
|---|---|---|---|---|
| 0.00 | 0.0000 | 0.00% | 0.20% | **PASS** |
| 20.00 | 0.0002 | 0.03% | 0.20% | **PASS** |
| 50.00 | 0.0004 | 0.06% | 0.20% | **PASS** |
| 80.00 | 0.0003 | 0.05% | 0.20% | **PASS** |
| 100.00 | 0.0002 | 0.03% | 0.20% | **PASS** |

## • Step Noise - Valves C, D

| Step (%) | Noise (AU) | Calculated Noise (%FS) | Limit (%) | Result |
|---|---|---|---|---|
| 0.00 | 0.0000 | 0.00% | 0.20% | **PASS** |
| 20.00 | 0.0002 | 0.04% | 0.20% | **PASS** |
| 50.00 | 0.0003 | 0.05% | 0.20% | **PASS** |
| 80.00 | 0.0002 | 0.04% | 0.20% | **PASS** |
| 100.00 | 0.0002 | 0.03% | 0.20% | **PASS** |

Customer Signature | Qualification Executor | Date

# Performance Qualification

## *AD20 Wavelength Accuracy*

### • *Instruments and Fluidics*

| *Instrument name* | *Model* | *Supplier's Name* | *Serial Number* | *Moduleware Version* |
|---|---|---|---|---|
| Absorbance Detector | AD20 | Dionex | 97072214 | 3.02 |

### • *Accessories*

| *Name* | *Description* |
|---|---|
| AD20 Holumium Oxide Test Cell | |

### • *Additional Information*

Customer/Company: **Mr. Turner/ XYZ Company**

Date: **08-28-00**

Qualification Executor/Company: **Mr. Smith / Dionex**

Next Qualification: **Feb-01**

Customer Signature

Qualification Executor

Date

## • *Data for the Wavelength Accuracy Test*

| *Wavelength (nm)* | *Measured Absorbance (AU)* |
|---|---|
| 354 | 0.0000 |
| 355 | 0.0140 |
| 356 | 0.0385 |
| 357 | 0.0621 |
| 358 | 0.0947 |
| 359 | 0.1222 |
| 360 | 0.1356 |
| 361 | 0.1427 |
| 362 | 0.0487 |
| 363 | 0.1470 |
| 364 | 0.1368 |
| 365 | 0.1193 |
| 366 | 0.1070 |
| 367 | 0.0893 |
| 368 | 0.0773 |

| *Theoretical Wavelength of Max Absorbance (nm)* | *Actual Wavelength of Maximum Absorbance (nm)* | *Limit* | *Result* |
|---|---|---|---|
| 361 | 362.0000 | +/- 3nm | ***PASS*** |

Customer Signature

Qualification Executor

Date

# Performance Qualification

## Instruments

| Instrument name | Model | Supplier's Name | Serial Number | Moduleware Version |
|---|---|---|---|---|
| Pump | GP40 | Dionex | 98112345 | 3.40 |
| LC Module or LC Oven | CC | Dionex | 99025621 | N/A |
| Chromeleon Datasystem | 6.20 Build 527 (Demo-Installation) | Dionex | 12345678 | N/A |
| ECD Detector | ED40 | Dionex | 98103254 | 3.03 |
| Autosampler | AS50 | Dionex | 99026688 | 1.04 |
| Eluent Generator | EG40 | Dionex | 99037452 | 2.13 |

## Accessories

| Name | Description |
|---|---|
| Backpressure Tubing | 0.13 mm (0.005") ID PEEK, 13 m (512") |
| Backpressure Tubing | 0.003" ID PEEK, 50" |
| Blank | Water |
| ECD Sample 1 | Nitrate, 5 ppm |
| ECD Sample 2 | Nitrate, 10.0 ppm |
| ECD Sample 3 | Nitrate, 25.0 pm |
| ECD Sample 4 | Nitrate, 50 ppm |
| ECD Sample 5 | Nitrate, 100 ppm |
| ECD Sample 6 | Nitrate, 1000 ppm |
| Eluent A | Water |
| Autosampler Reservoir A | Water |
| ED/CD Validation Test Cell | |
| EG40 Validation Test Cell | |

Customer Signature  Qualification Executor  Date

***Customer signature indicates that all information in the following reports has been reviewed and accepted.***

## Limits

| Test | Customized Limits | Dionex Recommended Limits |
|---|---|---|
| Conductivity Noise (nS) | 2.000 | 2.000 |
| Conductivity Drift (nS/hr) | 20.000 | 20.000 |
| Conductivity Linearity (Corr.) | 0.999 | 0.999 |
| Conductivity Linearity (%RSD) | 5.000 | 5.000 |
| DC Amperometry Noise (pA) | 4.000 | 4.000 |
| DC Amperometry Drift (pA/hr) | 8.000 | 8.000 |
| Integrated Amperometry Noise (pC) | 4.000 | 4.000 |
| Integrated Amperometry Drift (pC/hr) | 5.000 | 5.000 |
| Injector Precision (Area %RSD) | 1.000 | 1.000 |
| Carry Over (Area%) | 0.100 | 0.100 |
| Injector Linearity (Corr.) | 0.999 | 0.999 |
| Injector Linearity (%RSD) | 1.000 | 1.000 |
| Sample Prep Precision (%RSD) | 2.000 | 2.000 |
| Standard Bore Gradient Step Accuracy % | 2.000 | 2.000 |
| Standard Bore Pump Noise | 0.20% | 0.20% |
| Microbore Gradient Step Accuracy % | 2.000 | 2.000 |
| Microbore Pump Noise | 0.50% | 0.50% |
| EG40 Step Current (mA) | See Worksheet | See Worksheet |

## Additional Information

Customer/Company: **Mr. Turner/ XYZ Company** Date: **08-28-00**

Qualification Executor/Company: **Mr. Smith / Dionex** Next Qualification: **Feb-01**

Customer Signature _____ Qualification Executor _____ Date _____

# Performance Qualification

## *Conductivity Detector Noise and Drift*

### • *Instruments and Fluidics*

| *Instrument name* | *Model* | *Supplier's Name* | *Serial Number* | *Moduleware Version* |
|---|---|---|---|---|
| Pump | GP40 | Dionex | 98112345 | 3.40 |
| ECD Detector | ED40 | Dionex | 98103254 | 3.03 |

### • *Accessories*

| *Name* | *Description* |
|---|---|
| Backpressure Tubing | 0.13 mm (0.005") ID PEEK, 13 m (512") |
| Eluent | Water |

### • *Additional Information*

Customer/Company: **Mr. Turner/ XYZ Company** Date: **08-28-00**

Qualification Executor/Company: **Mr. Smith / Dionex** Next Qualification Due: **Feb-01**

### • *Test Results Summary*

| *Test* | *Result* |
|---|---|
| Conductivity Noise (nS) | ***PASS*** |
| Conductivity Drift (nS/hr) | ***PASS*** |

Customer Signature | Qualification Executor | Date

## • Data for Detector Noise

| Segment No. | Noise (nS) |
|---|---|
| 1 | 0.376 |
| 2 | 0.438 |
| 3 | 0.391 |
| 4 | 0.486 |
| 5 | 0.394 |
| 6 | 0.402 |
| 7 | 0.427 |
| 8 | 0.365 |
| 9 | 0.309 |
| 10 | 0.324 |
| 11 | 0.286 |
| 12 | 0.291 |
| 13 | 0.296 |
| 14 | 0.296 |
| 15 | 0.318 |
| 16 | 0.331 |
| 17 | 0.328 |
| 18 | 0.299 |
| 19 | 0.288 |
| 20 | 0.341 |
| ***Average (nS)*** | **0.359** |
| ***Limit (nS)*** | **2.000** |
| ***Result*** | ***PASS*** |

## • Data for Detector Drift

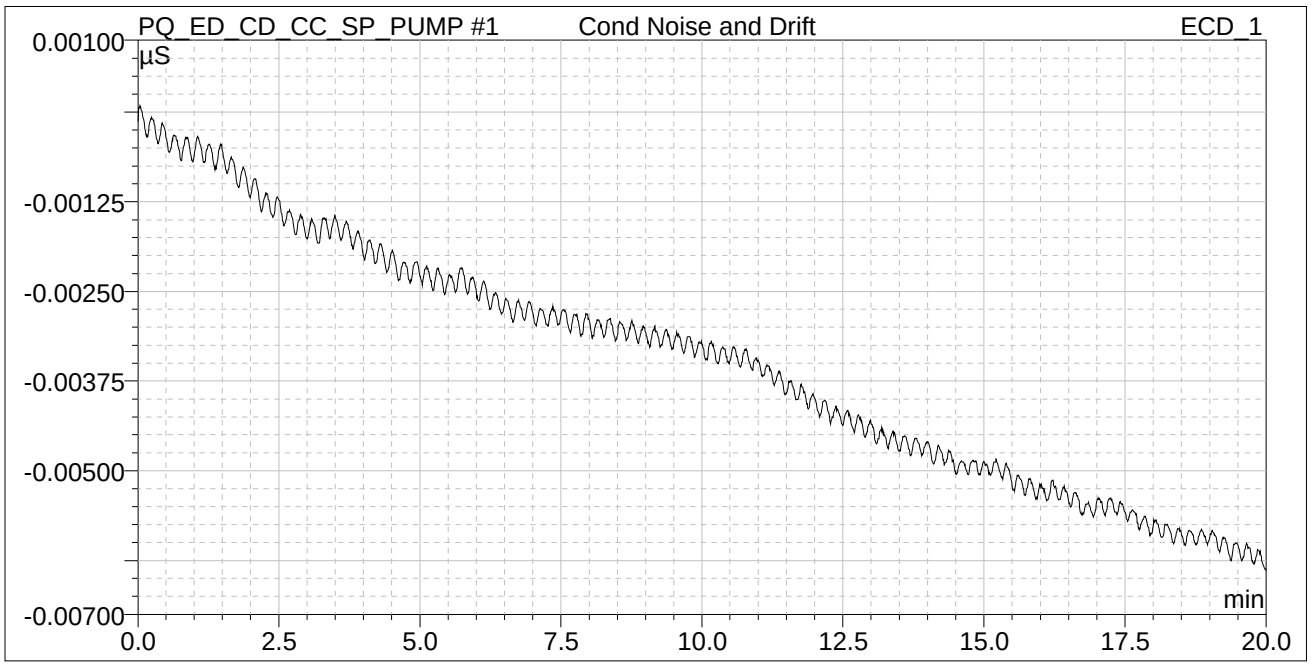
| 20 Minute Drift, nS | Drift, nS/hr | Limit, nS/hr | Result |
|---|---|---|---|
| 0.291 | 0.873 | 20.000 | ***PASS*** |

Customer Signature

Qualification Executor

Date

## • *Chromatogram of Detector Noise and Drift*




Customer Signature

Qualification Executor

Date

# Performance Qualification

## *Injector Precision*

### • *Instruments and Fluidics*

| *Instrument name* | *Model* | *Supplier's Name* | *Serial Number* | *Moduleware Version* |
|---|---|---|---|---|
| Pump | GP40 | Dionex | 98112345 | 3.40 |
| Autosampler | AS50 | Dionex | 99026688 | 1.04 |
| ECD Detector | ED40 | Dionex | 98103254 | 3.03 |
| LC Module or LC Oven | CC | Dionex | 99025621 | N/A |

### • *Accessories*

| *Name* | *Description* |
|---|---|
| Backpressure Tubing | 0.13 mm (0.005") ID PEEK, 13 m (512") |
| ECD Sample 5 | Nitrate, 100 ppm |
| Eluent A | Water |

### • *Additional Information*

| | | | |
|---|---|---|---|
| Customer/Company: | **Mr. Turner/ XYZ Company** | Date: | **08-28-00** |
| Qualification Executor/Company: | **Mr. Smith / Dionex** | Next Qualification: | **Feb-01** |

### • *Test Results Summary*

| *Test* | *Result* |
|---|---|
| Injector Precision (Area %RSD) | ***PASS*** |

Customer Signature | Qualification Executor | Date

## • *Data for Injector Precision Test* *25.0 µl*

| | ***Injector Precision*** |
|---|---|
| ***Sample Name*** | ***Peak Area***<br>***µS***<br>***Nitrate***<br>***ECD_1*** |
| Inj Precision_1 | 0.514 |
| Inj Precision_2 | 0.515 |
| Inj Precision_3 | 0.513 |
| Inj Precision_4 | 0.511 |
| Inj Precision_5 | 0.517 |
| Inj Precision_6 | 0.516 |
| ***Average:*** | ***0.514*** |
| ***Std Dev:*** | ***0.002*** |
| ***% RSD:*** | ***0.378 %*** |
| ***Limit:*** | ***1.000 %*** |
| ***Result:*** | ***PASS*** |

Customer Signature | Qualification Executor | Date

DIONEX

# Performance Qualification

## *Conductivity Detector Linearity*

### • *Instruments and Fluidics*

| *Instrument name* | *Model* | *Supplier's Name* | *Serial Number* | *Moduleware Version* |
|---|---|---|---|---|
| Pump | GP40 | Dionex | 98112345 | 3.40 |
| LC Module or LC Oven | CC | Dionex | 99025621 | N/A |
| ECD Detector | ED40 | Dionex | 98103254 | 3.03 |
| Autosampler | AS50 | Dionex | 99026688 | 1.04 |

### • *Accessories*

| *Name* | *Description* |
|---|---|
| Backpressure Tubing | 0.13 mm (0.005") ID PEEK, 13 m (512") |
| ECD Sample 1 | Nitrate, 5 ppm |
| ECD Sample 2 | Nitrate, 10.0 ppm |
| ECD Sample 3 | Nitrate, 25.0 pm |
| ECD Sample 4 | Nitrate, 50 ppm |
| ECD Sample 5 | Nitrate, 100 ppm |
| Eluent A | Water |

### • *Additional Information*

Customer/Company: **Mr. Turner/ XYZ Company**

Qualification Executor/Company: **Mr. Smith / Dionex**

Date: **08-28-00**

Next Qualification Due: **Feb-01**

### • *Test Results Summary*

| *Test* | *Result* |
|---|---|
| Detector Linearity (Corr.) | ***PASS*** |
| Detector Linearity (RSD) | ***PASS*** |

Customer Signature

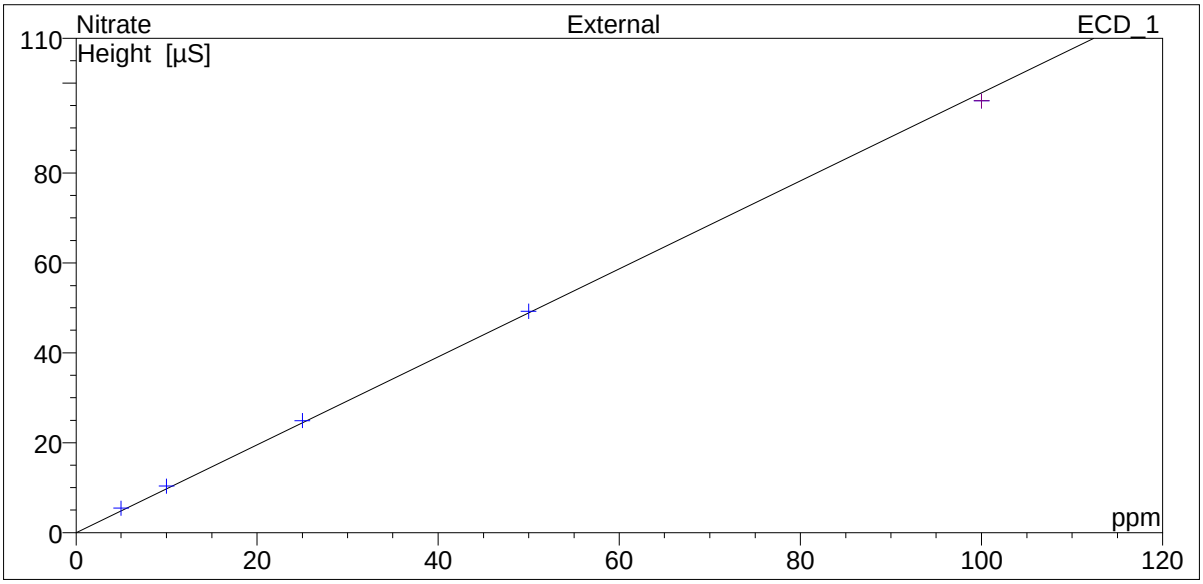
Qualification Executor

Date

## • *Data for Detector Linearity*

| Sample Name | Amount<br>ppm<br>Nitrate | Height<br>µS<br>Nitrate<br>ECD_1 |
|---|---|---|
| Detector linearity_1 | 5.0 | 5.409 |
| Detector linearity_2 | 10.0 | 10.337 |
| Detector linearity_3 | 25.0 | 24.928 |
| Detector linearity_4 | 50.0 | 49.216 |
| Detector linearity_5 | 100.0 | 96.009 |

## • *Linearity Plot*




| *Cal.Type*<br>*ECD_1* | *Number of Points*<br>*ECD_1* | *Offset*<br>*ECD_1* | *Slope*<br>*ECD_1* |
|---|---|---|---|
| XLin | 5 | 0.000 | 0.978 |

| | *Correlation Coefficient* | *% RSD* |
|---|---|---|
| ***ECD LInearity*** | 1.000 | 4.812 % |
| ***Limit:*** | ***0.999*** | ***5.000 %*** |
| ***Result:*** | ***PASS*** | ***PASS*** |

Customer Signature

Qualification Executor

Date

DIONEX

# Performance Qualification

## *Injector Linearity*

### • *Instruments and Fluidics*

| *Instrument name* | *Model* | *Supplier's Name* | *Serial Number* | *Moduleware Version* |
|---|---|---|---|---|
| Pump | GP40 | Dionex | 98112345 | 3.40 |
| Autosampler | AS50 | Dionex | 99026688 | 1.04 |
| ECD Detector | ED40 | Dionex | 98103254 | 3.03 |
| LC Module or LC Oven | CC | Dionex | 99025621 | N/A |

### • *Accessories*

| *Name* | *Description* |
|---|---|
| Backpressure Tubing | 0.13 mm (0.005") ID PEEK, 13 m (512") |
| ECD Sample 5 | Nitrate, 100 ppm |
| Eluent A | Water |

### • *Additional Information*

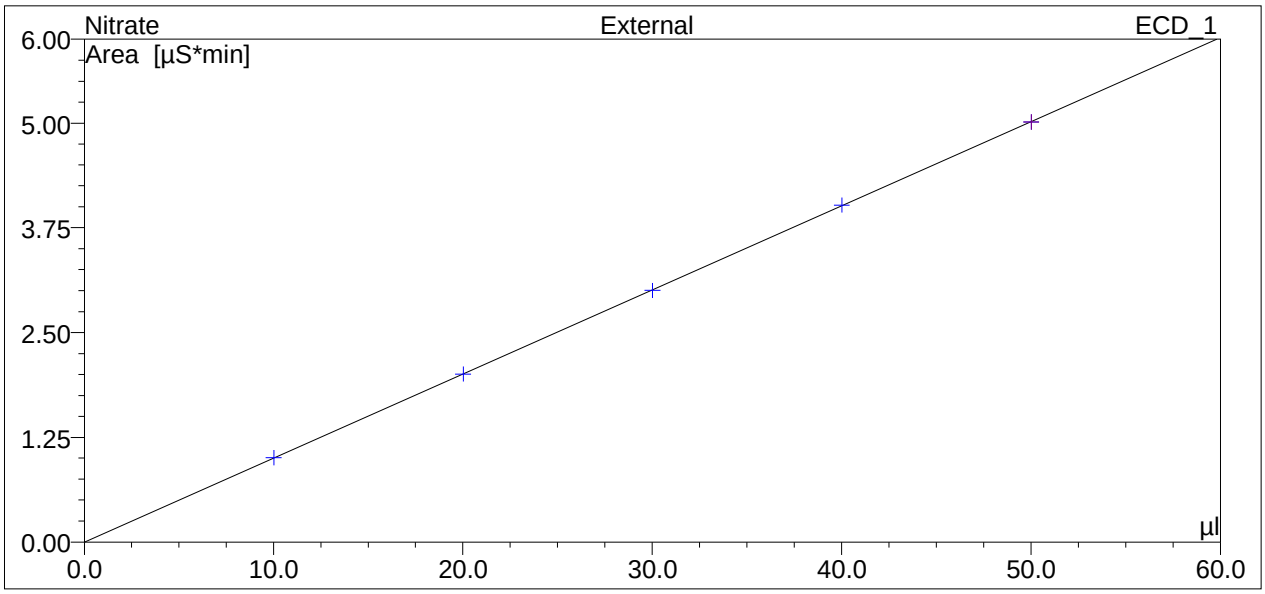
| | | | |
|---|---|---|---|
| Customer/Company: | **Mr. Turner/ XYZ Company** | Date: | **08-28-00** |
| Qualification Executor/Company: | **Mr. Smith / Dionex** | Next Qualification: | **Feb-01** |

### • *Test Results Summary*

| *Test* | *Result* |
|---|---|
| Injector Linearity (Corr.) | ***PASS*** |
| Injector Linearity (%RSD) | ***PASS*** |

Customer Signature _____ Qualification Executor _____ Date _____

## • Linearity Plot




## • Data for Injector Linearity Test

| Sample Name | Retention Time<br>min<br>Nitrate<br>ECD_1 | Inj.Vol.<br>µl | Peak Area<br>µS<br>Nitrate<br>ECD_1 |
|---|---|---|---|
| Injector linearity_1 | 0.48 | 10.0 | 1.005 |
| Injector linearity_2 | 0.47 | 20.0 | 2.005 |
| Injector linearity_3 | 0.48 | 30.0 | 3.003 |
| Injector linearity_4 | 0.49 | 40.0 | 4.020 |
| Injector linearity_5 | 0.49 | 50.0 | 5.014 |

| Cal.Type<br>ECD_1 | Number of Points<br>ECD_1 | Offset<br>ECD_1 | Slope<br>ECD_1 |
|---|---|---|---|
| LOff | 5 | 0.000 | 0.100 |

| | Correlation Coefficient | % RSD |
|---|---|---|
| **Injector Linearity** | 1.000 | 0.191 % |
| **Limit:** | **0.999** | **1.000 %** |
| **Result:** | **PASS** | **PASS** |

Customer Signature

Qualification Executor

Date

DIONEX

# Performance Qualification

## *Injector Carry Over*

### • *Instruments and Fluidics*

| *Instrument name* | *Model* | *Supplier's Name* | *Serial Number* | *Moduleware Version* |
|---|---|---|---|---|
| Pump | GP40 | Dionex | 98112345 | 3.40 |
| Autosampler | AS50 | Dionex | 99026688 | 1.04 |
| ECD Detector | ED40 | Dionex | 98103254 | 3.03 |
| LC Module or LC Oven | CC | Dionex | 99025621 | N/A |

### • *Accessories*

| *Name* | *Description* |
|---|---|
| Backpressure Tubing | 0.13 mm (0.005") ID PEEK, 13 m (512") |
| ECD Sample 6 | Nitrate, 1000 ppm |
| Blank | Water |
| Eluent A | Water |

### • *Additional Information*

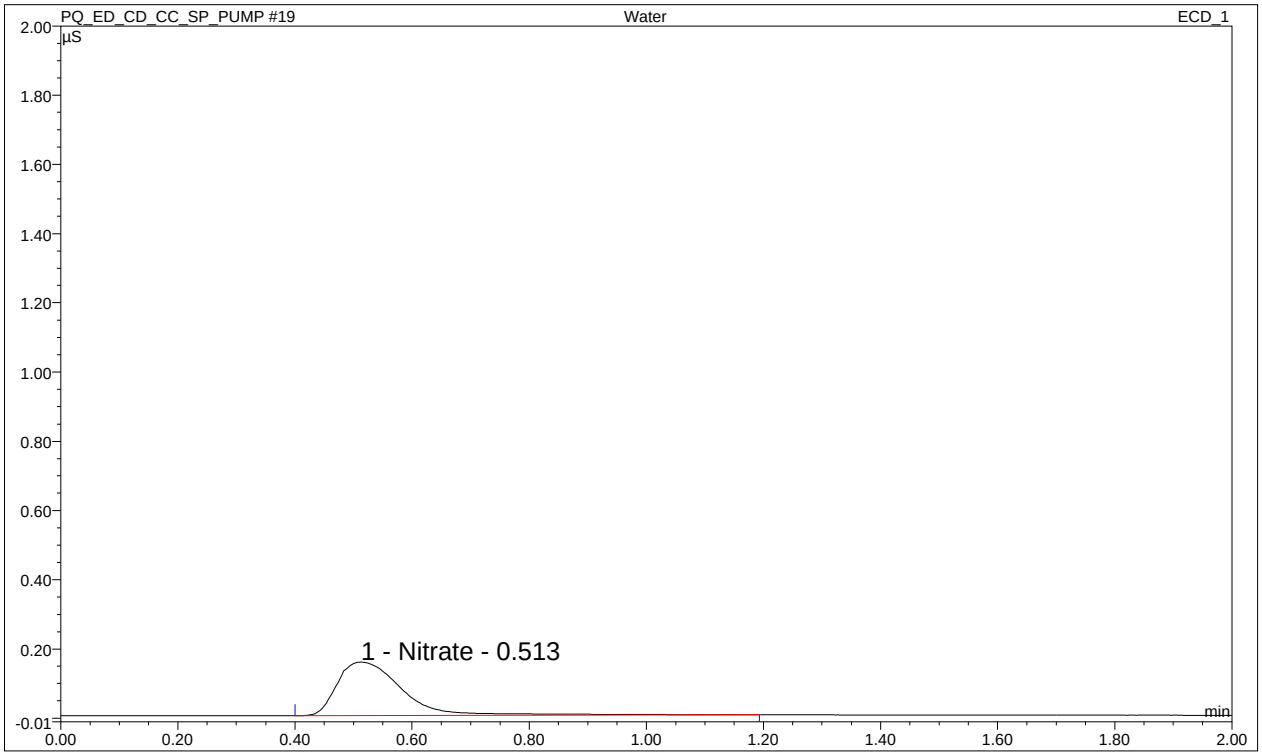
| | | | |
|---|---|---|---|
| Customer/Company: | **Mr. Turner/ XYZ Company** | Date: | **08-28-00** |
| Qualification Executor/Company: | **Mr. Smith / Dionex** | Next Qualification: | **Feb-01** |

### • *Test Results Summary*

| *Test* | *Result* |
|---|---|
| Carry Over (Area%) | ***PASS*** |

Customer Signature _____ Qualification Executor _____ Date _____

## • *Chromatogram for Carry Over Test*




## • *Data for Carry Over Test*

| ***Sample Name*** | ***Ret.Time*** ***min*** ***Nitrate*** ***ECD_1*** | ***Peak Area*** ***µS*min*** ***Nitrate*** ***ECD_1*** |
|---|---|---|
| Carry over | 0.51 | 202.975 |
| Water | 0.51 | 0.020 |
| ***Carry over:*** | | ***0.010 %*** |
| ***Limit:*** | | ***0.100 %*** |
| ***Result:*** | | ***PASS*** |

Customer Signature  Qualification Executor  Date

# Performance Qualification

## *Sample Prep Precision*

### • *Instruments and Fluidics*

| *Instrument name* | *Model* | *Supplier's Name* | *Serial Number* | *Moduleware Version* |
|---|---|---|---|---|
| Pump | GP40 | Dionex | 98112345 | 3.40 |
| Autosampler | AS50 | Dionex | 99026688 | 1.04 |
| ECD Detector | ED40 | Dionex | 98103254 | 3.03 |
| LC Module or LC Oven | CC | Dionex | 99025621 | N/A |

### • *Accessories*

| *Name* | *Description* |
|---|---|
| Backpressure Tubing | 0.13 mm (0.005") ID PEEK, 13 m (512") |
| ECD Sample 6 | Nitrate, 1000 ppm |
| Eluent A | Water |
| Autosampler Reservoir A | Water |

### • *Additional Information*

| | | | |
|---|---|---|---|
| Customer/Company: | **Mr. Turner/ XYZ Company** | Date: | **08-28-00** |
| Qualification Executor/Company: | **Mr. Smith / Dionex** | Next Qualification: | **Feb-01** |

### • *Test Results Summary*

| *Test* | *Result* |
|---|---|
| Sample Prep Precision (%RSD) | ***PASS*** |

Customer Signature | Qualification Executor | Date

## • *Data for Sample Prep Precision Test*

| ***Sample Name*** | ***Peak Area***<br>***µS***<br>***Nitrate***<br>***ECD_1*** |
|---|---|
| Sample Prep_1 | 1.017 |
| Sample Prep_2 | 1.029 |
| Sample Prep_3 | 1.020 |
| ***Average:*** | ***1.022*** |
| ***Std Dev:*** | ***0.006*** |
| ***% RSD:*** | ***0.633 %*** |
| ***Limit:*** | ***2.000 %*** |
| ***Result:*** | ***PASS*** |

Customer Signature | Qualification Executor | Date

DIONEX

# Performance Qualification

## *Gradient Pump Accuracy and Noise*

### • *Instruments and Fluidics*

| *Instrument name* | *Model* | *Supplier's Name* | *Serial Number* | *Moduleware Version* |
|---|---|---|---|---|
| Pump | GP40 | Dionex | 98112345 | 3.40 |
| ECD Detector | ED40 | Dionex | 98103254 | 3.03 |

### • *Accessories*

| *Name* | *Description* |
|---|---|
| Backpressure Tubing | 0.003" ID PEEK |
| Eluent A | Water |
| Eluent B | 1 mM KCL |
| Eluent C | Water |
| Eluent D | 1 mM KCL |

### • *Additional Information*

Customer/Company: **Mr. Turner/ XYZ Company** Date: **08-28-00**

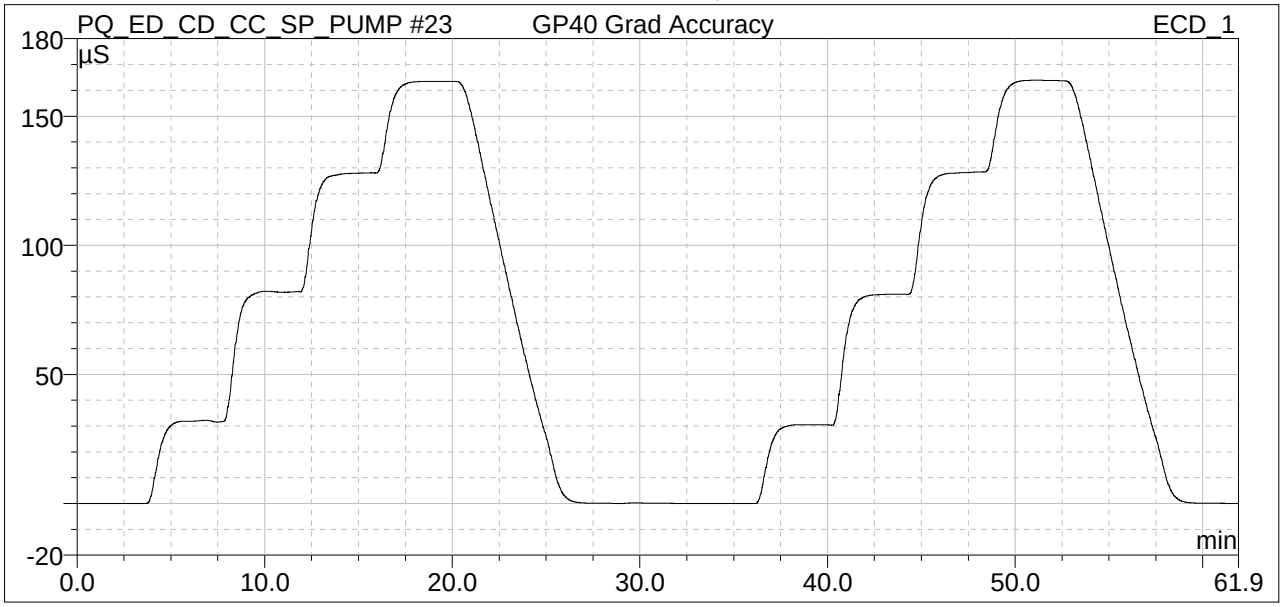
Qualification Executor/Company: **Mr. Smith / Dionex** Next Qualification: **Feb-01**

### • *Test Results Summary*

| *Test* | *Result* |
|---|---|
| Step Accuracy - A, B | ***PASS*** |
| Step Accuracy - C, D | ***PASS*** |
| Step Noise - A, B | ***PASS*** |
| Step Noise - C, D | ***PASS*** |

Customer Signature _____ Qualification Executor _____ Date _____

## • *Chromatogram of Gradient Pump Accuracy*




## • *Step Accuracy - Valves A, B*

| *Theoretical Value (%)* | *Conductivity (µS)* | *Calculated Value (%)* | *Deviation (%)* | *Limit (+/- , %)* | *Result* |
|---|---|---|---|---|---|
| 0.00 | -0.0061 | 0.00 | 0.00 | N/A | ---- |
| 20.00 | 32.0310 | 19.60 | -0.40 | 2.00 | ***PASS*** |
| 50.00 | 81.8666 | 50.08 | 0.08 | 2.00 | ***PASS*** |
| 80.00 | 127.9348 | 78.26 | -1.74 | 2.00 | ***PASS*** |
| 100.00 | 163.4794 | 100.00 | 0.00 | 2.00 | ***PASS*** |

## • *Step Accuracy - Valves C, D*

| *Theoretical Value (%)* | *Conductivity (µS)* | *Calculated Value (%)* | *Deviation (%)* | *Limit (+/- , %)* | *Result* |
|---|---|---|---|---|---|
| 0.00 | 0.0319 | 0.00 | 0.00 | N/A | ---- |
| 20.00 | 30.4887 | 18.59 | -1.41 | 2.00 | ***PASS*** |
| 50.00 | 80.9523 | 49.39 | -0.61 | 2.00 | ***PASS*** |
| 80.00 | 128.2142 | 78.23 | -1.77 | 2.00 | ***PASS*** |
| 100.00 | 163.8793 | 100.00 | 0.00 | 2.00 | ***PASS*** |

Customer Signature | Qualification Executor | Date

## • Step Noise - Valves A, B

| Step (%) | Noise (µS) | Calculated Noise (%FS) | Limit (%) | Result |
|---|---|---|---|---|
| 0.00 | 0.0039 | 0.00% | 0.20% | **PASS** |
| 20.00 | 0.1485 | 0.09% | 0.20% | **PASS** |
| 50.00 | 0.3392 | 0.10% | 0.20% | **PASS** |
| 80.00 | 0.0719 | 0.04% | 0.20% | **PASS** |
| 100.00 | 0.0279 | 0.02% | 0.20% | **PASS** |

## • Step Noise - Valves C, D

| Step (%) | Noise (µS) | Calculated Noise (%FS) | Limit (%) | Result |
|---|---|---|---|---|
| 0.00 | 0.0038 | 0.00% | 0.20% | **PASS** |
| 20.00 | 0.0441 | 0.03% | 0.20% | **PASS** |
| 50.00 | 0.0724 | 0.04% | 0.20% | **PASS** |
| 80.00 | 0.0858 | 0.05% | 0.20% | **PASS** |
| 100.00 | 0.0366 | 0.02% | 0.20% | **PASS** |

Customer Signature | Qualification Executor | Date

DIONEX

# Performance Qualification

## *Integrated Amperometry Detector Noise and Drift*

### • *Instruments and Fluidics*

| *Instrument name* | *Model* | *Supplier's Name* | *Serial Number* | *Moduleware Version* |
|---|---|---|---|---|
| ECD Detector | ED40 | Dionex | 98103254 | 3.03 |

### • *Accessories*

| *Name* |
|---|
| ED/CD Validation Test Cell |

### • *Additional Information*

Customer/Company: **Mr. Turner/ XYZ Company** Date: **08-28-00**

Qualification Executor/Company: **Mr. Smith / Dionex** Next Qualification Due: **Feb-01**

### • *Test Results Summary*

| *Test* | *Result* |
|---|---|
| Integrated Amperometry Noise (pC) | ***PASS*** |
| Integrated Amperometry Drift (pC/hr) | ***PASS*** |

Customer Signature | Qualification Executor | Date

## • Data for Detector Noise

| Segment No. | Noise (pC) |
|---|---|
| 1 | 0.991 |
| 2 | 1.172 |
| 3 | 1.082 |
| 4 | 1.083 |
| 5 | 1.087 |
| 6 | 0.830 |
| 7 | 1.469 |
| 8 | 1.129 |
| 9 | 1.471 |
| 10 | 0.958 |
| 11 | 0.965 |
| 12 | 0.787 |
| 13 | 0.779 |
| 14 | 0.827 |
| 15 | 0.628 |
| 16 | 1.256 |
| 17 | 1.282 |
| 18 | 1.344 |
| 19 | 0.703 |
| 20 | 1.199 |
| ***Average (pC)*** | **1.095** |
| ***Limit (pC)*** | **4.000** |
| ***Result*** | ***PASS*** |

## • Data for Detector Drift

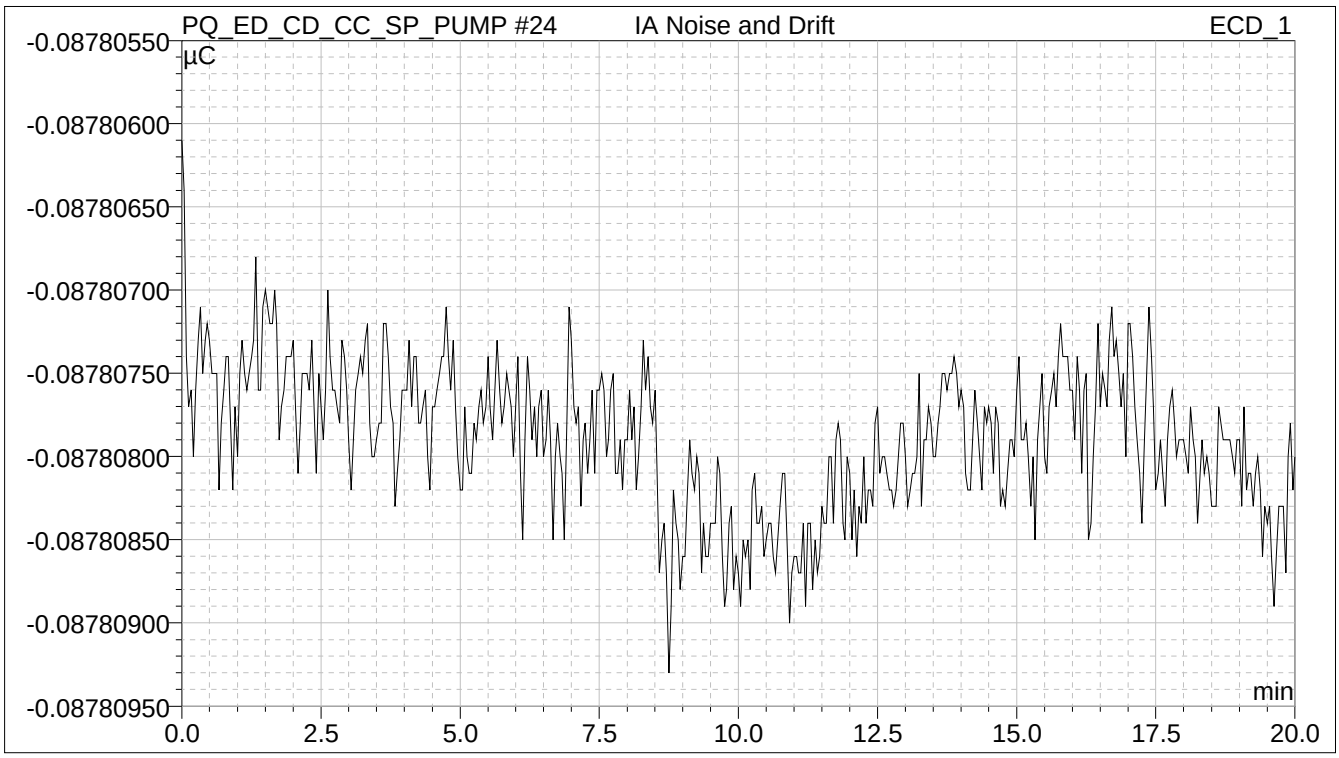
| 20 Minute Drift, pC | Drift, pC/hr | Limit, pC/hr | Result |
|---|---|---|---|
| 0.023 | 0.069 | 5.000 | ***PASS*** |

Customer Signature

Qualification Executor

Date

## • *Chromatogram of Detector Noise and Drift*




Customer Signature

Qualification Executor

Date

DIONEX

# Performance Qualification

## *EG40 KOH Current Qualification*

### • *Instruments and Fluidics*

| *Instrument name* | *Model* | *Supplier's Name* | *Serial Number* | *Moduleware Version* |
|---|---|---|---|---|
| Eluent Generator | EG40 | Dionex | 99037452 | 2.13 |

### • *Accessories*

| *Name* | *Desription* |
|---|---|
| EG40 Validation Test Cell | |
| Voltmeter | |

### • *Additional Information*

Customer/Company: **Mr. Turner/ XYZ Company** Date: **08-28-00**

Qualification Executor/Company: **Mr. Smith / Dionex** Next Qualification: **Feb-01**

Customer Signature | Qualification Executor | Date

## • *Data for KOH Current Qualification Test*

| *Concentration (mM)* | *Theoretical Current (mA)* | *Measured Current (mA)* | *Limit (+/-)* | *Result* |
|---|---|---|---|---|
| 0 | 0.00 | 0.00 | 0.50 | ***PASS*** |
| 2 | 3.22 | 3.24 | 0.50 | ***PASS*** |
| 3 | 4.82 | 4.88 | 0.50 | ***PASS*** |
| 4 | 6.43 | 6.45 | 0.60 | ***PASS*** |
| 5 | 8.04 | 8.04 | 0.70 | ***PASS*** |
| 10 | 16.08 | 16.10 | 1.00 | ***PASS*** |
| 15 | 24.12 | 24.40 | 1.00 | ***PASS*** |
| 20 | 32.16 | 32.20 | 1.30 | ***PASS*** |
| 25 | 40.20 | 40.31 | 1.60 | ***PASS*** |
| 30 | 48.24 | 48.28 | 1.90 | ***PASS*** |
| 35 | 56.28 | 56.28 | 2.30 | ***PASS*** |
| 40 | 64.32 | 64.33 | 2.60 | ***PASS*** |
| 50 | 80.41 | 80.44 | 3.20 | ***PASS*** |
| 60 | 96.49 | 96.58 | 3.80 | ***PASS*** |
| 80 | 128.65 | 128.64 | 5.20 | ***PASS*** |
| 100 | 160.81 | 160.88 | 6.40 | ***PASS*** |

Customer Signature  Qualification Executor  Date