UV-VIS SPECTROSCOPY

Lambda 365

Lambda 365 System
Performance Validation Software

PerkinElmer

Part No.	Revision Level	Release Date	Software Version
09931329	B	September 2016	System Performance Validation Software 4.1.1.

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Table of Contents

I. Introduction

I-1. PerkinElmer System Qualification

This system qualification package is provided by PerkinElmer to guide users to perform system validation and qualification of the Lambda 365 Double Beam UV-Visible Spectrophotometer. It contains documents and tools to ensure the system is compliant with FDA, cGMP, and other related regulatory guidelines. It includes software, documentation materials and information regarding the required standard materials.

I-2. Regulatory Requirements

Qualification and validation procedures are designed to guide users to meet regulatory requirements. The following validation requirements and guidelines for the pharmaceutical industry have been used to design these procedures:

1. ISO 9001: 2008 requirements by International Standards Organization.
2. Current good manufacturing practice(cGMP) requirements - Code of Federal Regulations(21 CFR), Part 820 – in Quality System Regulation.
3. Current good manufacturing Practice(cGMP) requirements - Code of Federal Regulations(21 CFR), Parts 210 & 211- in Manufacturing, Processing, Packing or Holding of Drugs; General and Current Good Manufacturing Practice For Finished Pharmaceuticals.
4. Current good manufacturing Practice(cGMP) requirements- Code of Federal Regulations(21 CFR), Part 11-in Electronic Records, Electronic Signatures, Final Rule.
5. European Pharmacopoeia (EP), United States Pharmacopoeia (USP)

I-3. Validation Overview

Validation is the evaluation process used to ensure that products or analytical methods comply with requirements. Prerequisites for fulfilling requirements in an analytical laboratory include properly functioning and well-documented:

- Instrumentation hardware and firmware

- Computer hardware and software
- Validated analytical methods

Once the equipment and method have been selected and validated, the equipment for the method goes through a system suitability test before and during sample analysis. Validation may also include checking functions related to data integrity, security and traceability. One of the most popular definitions for validation originates from the U.S. FDA's General Principles of Validation issued 1987.

I-3-1. Method Validation

Method validation is the process used to confirm that the analytical procedure employed for a specific test is suitable for its intended use. Results from method validation can be used to judge the quality, reliability and consistency of analytical results; it is an integral part of any good analytical practice.

Analytical methods need to be validated or revalidated before their introduction into routine use; whenever the conditions change for which the method has been validated (e.g., an instrument with different characteristics or samples with a different matrix); and whenever the method is changed and the change is outside the original scope of the method. Method validation has received considerable attention in the literature and from industrial committees and regulatory agencies.

- ISO/IEC 17025 includes a chapter on the validation of methods with a list of nine validation parameters.
- The U.S. EPA prepared a guide for method development and validation for the Resource Conservation and Recovery Act (RCRA). The AOAC, the EPA and other scientific organizations provide methods that are validated through multi-laboratory studies.
- The ICH has developed a consensus text on the validation of analytical procedures. The document includes definitions for eight validation characteristics. ICH also developed a guide with detailed methodology.
- The U.S. FDA CGMP request in section 211.165 (e) methods to be validated: The accuracy, sensitivity, specificity, and reproducibility of test methods employed by the firm shall be established and documented. Such validation and documentation may be accomplished in accordance with Sec. 211.194(a). These requirements include a statement of each method used in testing the sample to meet proper standards of

accuracy and reliability, as applied to the tested product. The U.S. FDA has also proposed industry guidance for Analytical Procedures and Methods Validation.

The USP has published specific guidelines for method validation for compound evaluation. USP defines eight steps for validation:

- Accuracy
- Precision
- Specificity
- Limit of detection
- Limit of quantitation
- Linearity and range
- Ruggedness
- Robustness

I-3-2. Software Validation

Software validation part of the design validation for a finished device, but is not separately defined in the Quality System regulation. For the purpose of this guidance, FDA considers software validation to be “confirmation by examination and provision of objective evidence that software specifications confirm to user needs and intended uses, and that the particular requirements implemented through software can be consistently fulfilled.” In practice, software validation activities may occur both during, as well as at the end of the software development life cycle to ensure that all requirements have been fulfilled. Since software is usually part of a larger hardware system, the validation of software typically includes evidence that all software requirements have been implemented correctly and completely and that they are traceable to system requirements. A conclusion that software is validated is highly dependent upon comprehensive software testing, inspections, analyses, and other verification tasks performed at each stage of the software development life cycle. Testing of device software functionality in a simulated use environment, and user site testing are typically included as components of an overall design validation program for a software automated device.

I-4. Qualification Overview

Qualification is a process of ensuring that a system's specification is appropriate for its use and that the system performs according to that specification.
System qualification comprises the following four components.

- Design Qualification (DQ)
- Installation Qualification (IQ)
- Operation Qualification (OQ)
- Performance Qualification (PQ)

I.4-1. Design Qualification (DQ)

Design Qualification is concerned with what the instrument is required to do and links directly to fitness for purpose. DQ provides an opportunity for the user to demonstrate that the instrument's fitness for purpose has been considered at an early stage and built into the procurement process.

I-4-2. Installation Qualification (IQ)

IQ covers the installation of the instrument, including its response to the initial application of power. IQ involves formal checks to confirm that the instrument, its modules and accessories have been supplied as ordered and that the instrument is properly installed in the appropriately selected environment.

I-4-3. Operation Qualification (OQ)

The purpose of Operation Qualification (OQ) is to verify that key aspects of instrumental performance (*e.g.* wavelength, absorbance, resolution, stray light, noise and drift) are satisfactory and within specification, in the absence of any contributory effects, which may be introduced by the analytical method. OQ tests are designed to check the performance of an individual instrument in such a way that any variation noted is attributable to the instrument itself, rather than cells, or particular solvents or chromophores.

I-4-4. Performance Qualification (PQ)

The purpose of PQ is to provide evidence that, following initial assembly, the entire instrument is functioning correctly and within specification and that its performance remains satisfactory during routine use. PQ can, therefore, be considered as having two stages:

- Initial holistic testing to provide evidence that the complete instrument functions correctly

- System suitability checking (SSC) to provide evidence of fitness for purpose and satisfactory performance during actual use

Customers are responsible for designing their own PQ protocols to suit their intended purpose in compliance with their organization's standard operating procedures.

II. Design Qualification

II-1. Introduction to Design Qualification

Design Qualification is concerned with what the instrument is required to do and is directly related to fitness for purpose. DQ provides an opportunity for the user to demonstrate that the instrument's fitness for purpose has been considered at an early stage and built into the procurement process.

DQ should, where possible, establish the intended or likely use of the instrument and should define an appropriate user requirement specification (URS). The URS defines the key performance characteristics of the instrument and the ranges over which the instrument is required to operate and consistently perform along with other critical factors relating to its use. The URS may be a compromise between the ideal and the practicalities of what is actually available. Whilst it is the responsibility of the user to ensure that specifications exist, and that they are appropriate, they may be prepared by the user, the supplier(s), or by discussion between the two.

In undertaking DQ, information and knowledge of existing equipment should be taken into account. If an instrument is mature in design and has a proven track record, this may provide basic confidence and evidence about its suitability for use. For new techniques or instruments, DQ may require more effort. For a variety of reasons, customers may favor particular manufacturers.

The selection of the supplier and instrument is entirely at the discretion of the user. One possible way to do this is to score candidate instruments according the extent to which they meet the user's requirements. However, in making this selection, the user should bear in mind that regulatory authorities may require, and in some cases are likely to require, evidence that the manufacturer has used:

1. fully documented quality control and quality assurance procedures, including design and specification;
2. suitably qualified and experienced personnel;
3. comprehensive and planned testing of all parts of the system, and;

4. stringent change control, error reporting and corrective procedures.

A suitable questionnaire, third party audit, or independent certification of the supplier to an approved quality scheme may provide the user with the necessary evidence that regulatory requirements have been met during design and manufacture of the instrument. Where such evidence is not available, it is the responsibility of the user to carry out more extensive qualification in order to provide the necessary assurance of the instrument's fitness for use. It would be reasonable for the supplier to assist the customer with this stage.

Where instruments are intended to be used to make measurements which support regulatory studies, the user may also need to seek confirmation that the manufacturer is prepared, if required, to allow regulatory authorities access to detailed information and records relating to the instrument's manufacture and development, for example: source codes; instrument development records and procedures; calibration and qualification documentation; batch test records and reports; hardware and software qualification documentation; and credentials of staff involved with the development of the instrument.

II-2. Design Qualification of the Spectrophotometer

II-2-1. General Features

Feature	Consideration
Instrument set-up & control	Lambda 365 Double Beam UV-Visible spectrophotometer is based on a PC controlled system.
General Installation features	UV Express Software Package PC with monitor Printer (Optional)
Installation requirements	Instrument Size :491 mm(W) x 538 mm(L) x 258 mm(H) [19.3 in. x (W) 21.1 in. x (L) 10.1 in. (H)] Instrument Weight : 23.5kg (51lbs) Power consumption :100-240 VAC
Operational requirements	Communication Cable, Power Cable Microsoft® Windows 7 PC (Intel® Core 1.5 GHz or faster Processor) - RAM: At least 1 GB - Hard disk: 50 GB with 1 GB free - CD-ROM disk drive
Environmental conditions	Temperature condition: 15 ~ 35ºC (59 ~95°F) Humidity condition: Less than 80% relative, non-condensing
Manual CD	Qualification Manual (DQ/IQ/OQ/PQ) Lambda 365 Users Guide UV Express Software Users Guide Service Manual (Not for customer) Accessory Manuals
Health and Safety	Ozone from Deuterium lamp (Not significant)
Software Algorithm & Functionality	Regression algorithm in Quantification Savitzky-golay algorithm in smoothing and derivative Spline algorithm for interpolating wavelength interval and peak finding Baseline correction Wavelength monitoring Peak finding Derivative Calculator User defined method User selectable report Absorbance, Transmittance, Reflectance, Intensity (Energy)

II-2-2. Optical Specifications of Lambda 365

Model	Lambda 365
Wavelength range	190 nm ~ 1100 nm
Spectral bandwidth	Variable (0.5, 1, 2, 5, 20 nm)
Data interval	0.05, 0.1, 0.5, 1, 2 nm
EP resolution test	> 1.6 (Toluene in Hexane) > 0.2 (Toluene in Methanol)
Stray light	< 0.02% at 340 nm (Sodium Nitrite; ASTM) < 1.0% at 300 nm (Acetone; ASTM) < 0.02% at 220 nm (Sodium Iodide; ASTM) < 1.0% at 198 nm (Potassium Chloride; EP, ASTM)
Wavelength accuracy	±0.3 nm for entire range ±0.1 nm at D_2 peak 656.1 nm
Wavelength reproducibility	±0.1 nm at D_2 peak 656.1 nm
Photometric accuracy	±0.002 AU (0.2 AU Neutral Density glass filter) ±0.002 AU (0.5 AU Neutral Density glass filter) ±0.004 AU (1.0 AU Neutral Density glass filter) ±0.01 AU (60, 600 mg/L Potassium Dichromate)
Photometric reproducibility	±0.001 AU at 0.5 AU and 1.0 AU ±0.001 AU with 60 mg/L $K_2Cr_2O_7$ (ASTM)
Noise level	< 0.00005 AU (at 700 nm, RMS)
Stability (Drift)	<0.0003 AU/hr (700 nm, after 1 hr warm up)
Maximum scan rate	3000 nm/min
Maximum slew rate	8000 nm/min

II-2-3. Specifications of UV Express Software

Operating Environment

Supports Double Beam UV-Visible Spectrophotometer

· Lambda 365 UV-Visible Spectrophotometer

Controls Accessories

· 8-Position Multi-Cell Holder
· Water Jacketed 8-Position Multi-Cell Holder
· Advanced Transmission Holder
· Micro Cell Holder
· Test Tube Holder
· Film Holder
· Variable Pathlength Cuvette Holder
· Auto Sipper System with Software Control
· Single Cell Peltier Holder, Controller
· 6-Position Peltier Controlled Cell Changer, Controller
· Fixed Angle Reflectance Holder
· Autosampler
· 50 mm Transmission / Reflectance Sphere
. Magnetic Stirrer Assembly (Auto Type)
. Magnetic Stirrer Assembly (Manual Type)

Computer Requirements

· PC (Intel® Core 1.5 GHz or faster)
· RAM: At least 1 GB
· Hard disk: 50 GB with 1 GB free
· Input devices : Mouse and keyboard
· Monitor : 1024x768 (minimum)
· Media: CD-ROM Drive
· Port: USB port for the data acquisition

Operating System

· Microsoft® Windows 7

Output Device

· Microsoft® Windows compatible printer

UV Express
- Instrument Control, Data Acquisition and Standard Experiments

Data Analysis	
Instrument Parameters	· SBW: 0.5, 1, 2, 5, 20 nm · Data Interval: 0.05, 0.1, 0.5, 1, 2 nm · Scan Rate: 1 ~ 3000 nm/min
Spectrum Display	· Virtually unlimited number of spectra (The limitation depends on the memory of the computer) · Data Type: Absorbance (AU), Transmittance (%T), Reflectance(%R), Energy (cnt)
Math Processing	· Scalar Add : Add a user-specified constant value to the selected spectrum (up to 30,000) · Scalar Multiply : Multiply a spectrum by a user specified constant (up to 30,000) · Scalar Divide : Divides user specified constant (up to 30,000) · Add : Add selected spectra together · Subtract : Subtract the second selected spectrum form the first selected spectrum · LOG : Use up to selected 500 selected spectra · Average : Use up to selected 500 selected spectra · Derivate : Up to 4th derivation · Smoothing: Using Savisky-Golay Method
Internal Reference	· Single Point : use one wavelength for correction · Range Average : use the average absorbance value over a wavelength range · Three Points : correction of slant baseline
Smoothing	· Using Savitsky-Golay Method

File System	
Save File Type	· *.dgdt : Scan Mode Data Files · *.dqdt : Quantification Mode Data Files · *.dsqdt : Scanning Quantification Mode Data Files · *.dkdt : Kinetics Mode Data Files · *.dskdt : Scanning Kinetics Mode Data Files · *.dsrdt : Wavelength Program Mode Data Files · *.dbdt : Nucleic Acid Mode Data Files · *.dpdt : Protein Mode Data Files · *.dcdt : Cell Density Mode Data Files · *.dthdt : Thermal Denaturation Mode Data Files · *.dmcdt : Multicomponent Analysis Data Files · *.dvdt : Validation Mode Data Files
Method File	· Contains all parameters for sampling system · Saves in a single file on disk as *.gmtd
Export Data	· Data Spectrum: Clipboard Copy, *.CSV Format File,*.ASCII Format File, *.JCAMP Format File *.BMP Format File, *.WMF Format File · Result Data: Clipboard Copy, Excel Format File

Print	
Print & Preview Window	· Supports a variety of printing options with which any spectrum or result data can be selected and printed.

UV Express Software	
Scan Mode	
Scan Setup	· Photometric values measurement of a sample in the selected wavelength range
Equation Calculation	· Allows the user to enter support equation for the evaluation of data · Support Equation : +, - , /, *, ABS, Exp, LN, LOG10, SQRT
Find/Peak Valley	· Find up to 20 of peaks or valleys automatically or manually

Quantification Mode	
Quantification	· Virtually unlimited number of standards (The limitation depends on the memory of the computer) · Concentration Unit: All units user-specifiable · Replicate number of standard and Sample: up to 5 · Fit Order: Linear, Quadratic, Cubic · Support intercept of calibration curve · Calculation of correlation coefficient

Scanning Quantification Mode	
Scanning Quantification	· Measures Absorbance, Transmittance, Reflection at the full or selected wavelength range · Concentration Unit: All units user-specifiable · Fit Order: Linear, Quadratic, Cubic · Supports intercept of calibration curve · Calculation of correlation coefficient

Kinetics Mode	
Kinetics	· Virtually unlimited number of spectra (The limitation depends on the memory of the computer) · Real time graphical display of data · Pause function · Time Unit : Second, Minute · Time limit on Time Interval, Initial Delay and Total Time · Zero Order, Initial Rate, First Order, Delta AU · Data from single wavelength can be extracted for rate calculation

Scanning Kinetics Mode	
Scanning Kinetics	· Monitors Absorbance, Transmittance continuously over time at selected wavelength range · Time Unit: Min, Sec · Zero Order, Initial Rate, First Order, Delta Au · Data from single wavelength can be extracted for rate calculation

Wavelength Program Mode	
Wavelength Program	· The Absorbance or Transmittance measurement of a sample at selected multiple wavelengths

Nucleic Acid Analysis	
Nucleic Acid Analysis	· General Ratio with two wavelengths for the calculation of user specified ratios · Determine concentration of protein and nucleic acid using coefficients · Baseline Correction

Protein Analysis Mode	
Protein Analysis	· Predefined methods Bradford Protein Analysis at 595 nm Bicinchoninate (BCA) at 562 nm Biuret Protein Analysis at 540 nm Lowry Protein Analysis high sensitivity at 750 nm Lowry Protein Analysis low sensitivity at 500 nm Lowry Protein Analysis at 740 nm Trinitrobenzene Sulfonate at 416 nm

Cell Density Mode	
Cell Density	· Predefined methods · Cell Density is calculated with absorbance of 600 nm

Thermal Denaturation Mode	
Thermal Denaturation	· Temperature Unit: ℃ · Temperature limit: from -5 to 100℃ · Tm calculated with average method & 1st Derivative · User defied equation allows calculation from Tm value (ex: %G-C)

Multi-Component Analysis Software (Optional)	
Multi-Component Analysis (MCA)	· Analyze complex compound containing several components · Define the concentration of each component · This can be added to UV Express Software upon request.

ColorMaster Viewer Software (Optional)	
ColorMaster Viewer	· Color Difference Formular Function · Available File format: *.dgdt, *.sp, *.spa, and *.dx are available to open · This can be added to UV Express Software upon request.

System Performance Validation Software(Optional) - Contains the Validation program of UV or visible range	
Validation	· Validation & Qualification document (Design, Installation, Operation and Performance Qualifications) · Automatic Validation Wizard

UV Express Security Software (Optional)	
UV Express Security Software	· UV Express Software Security Manual · Enhanced Security based on Windows 7 Professional, Ultimate or Enterprise · Electronic Signature and Traceability

III. Installation Qualification

III-1. Introduction to Installation Qualification

IQ covers the installation of the instrument and including its response to the initial application of power. IQ involves formal checks to confirm that the instrument, its modules and accessories have been supplied as ordered and that the instrument is properly installed in the selected environment.

IQ may be carried out either by the supplier and/or the user. However, it should be noted that, in some cases, the complexity of the instrument alone may preclude the user performing IQ and, in others, the unpacking of the equipment by the user may invalidate the warranty.

IQ must be undertaken in accordance with the supplier's instructions and procedures. The success or failure of each of the IQ checks performed should be formally recorded and, where these have been carried out by the supplier, the results of these tests must be communicated to the user.

The principles relating to IQ are primarily generic in nature. For convenience, a checklist covering the main requirements for IQ is provided below:

1. Has the instrument been delivered as ordered, *e.g.* according to the DQ or purchase order?
2. Has the instrument been checked and verified as undamaged?
3. Has the appropriate documentation been supplied, is it of correct issue and is it uniquely identified by a part number, version number and date?
4. Have details of all services and utilities required to operate the instrument been provided (preferably in advance of the delivery)?
5. Is it clear which maintenance, calibration and performance tests should be carried out by the user and which should be carried out by the supplier or their agent?
6. Have details of recommended service and calibration intervals (carried out by the supplier) been provided?
7. Have intervals, methods and instructions for user-maintenance and calibration been provided along with contact points for service and spare parts?
8. Has the correct hardware, firmware and software been supplied and is it of correct

issue and uniquely identified by part number?

9. Has information been provided on consumables required during the normal operation of the instrument system?
10. Is the selected environment for the instrument system suitable, with adequate room for unpacking, installation, operation and servicing, and have appropriate services and utilities (electricity, water, *etc.*) been provided?
11. Has health and safety and environmental information relating to the operation of the instrument been provided and is the proposed working environment consistent with these requirements?
12. Is the response of the instrument to the initial application of power as expected and have any deviations been recorded?

III-2. Performing Installation Qualification

Perform installation qualification as follows:

III-2-1. Review the Installation Qualification (IQ) Process

Installer should review the installation qualification process with the customer using PerkinElmer's Qualification Manual for the Lambda 365 UV-Visible spectrophotometer. Does the operator (customer) fully understand the IQ process?

Answer	□ Yes □ No	Installer	
Comments			

III-2-2. Complete Customer and Shipment Information

Fill in the customer information located in IQ-1 Worksheet. This document includes the information that the shipment was received according to the actual purchase order placed and all relevant customer information.

III-2-3. Check the Installation Requirements

Confirm that the installation requirements located in the IQ-2 Worksheet are available prior to performing the installation. In this step, the followings requirements must be fulfilled. Installation space, electrical conditions, humidity, temperature, etc.,as detailed in worksheet IQ-2.

III-2-4. Install the System

A. Unpacking

1) Check all shipping boxes for visible damage. If there is any damage, document the details in the IQ-5 Worksheet.
2) Remove any packing material.
3) Confirm that the module is not damaged. If damage is visible, inform the customer and transport company immediately. If necessary, take photographs and note names of witnesses to prove the damage. Document all details in IQ-5 Worksheet.
4) Confirm that the system, accessories, software and all other items have been provided. Record all unpacking information in Document IQ-3.

B. Placing the Instrument on the Bench

1) Place the base modules on a firm, vibration free surface.
2) Confirm that the bench where the system is to be installed is not exposed to temperature fluctuations, high humidity, or direct sunlight.
3) When all instrument components have been set up on the bench, record this in the IQ-4 Worksheet.

C. Computer and Software Installation

1) Install the computer in an appropriate location near the instrument or in accordance with the customer's request.
2) If not using a pre-installed computer with software, install the UV Express software following III-3-4 System Installation and System Check Procedures.
3) When all computer and software components have been set up on the bench, record this in the IQ-4 Worksheet.

D. IQ Completion

1) After completing the installation qualification, all IQ results should be reviewed by the instrument installer and owner (customer or operator).If all procedures are accepted, both the Customer and the Qualification Executor should sign each page of the IQ Worksheet.
2) The customer should appropriately file and maintain all IQ worksheets in a secure location.

III-3. Installation Qualification Worksheets

III-3-1. Customer and Shipment Information

IQ-1. Customer and Shipment Information

Company Name	
Customer Name	
Street Address	
City, State, Zip	
Phone	
Customer Purchase Order	
Manufacturer Order Number	
Date of Delivery	
Date of Installation	
IQ Executor/Company	

Do the items on Customer Purchase Order match to Packing Check List?	□Yes □No
Are the items on Packing Check List included with the system shipment?	□Yes □No

Installer's signature : Date:

Customer's signature : Date:

III-3-2. Installation Requirements

IQ-2. Installation Requirements

Requirement	Specification & Measurement	Availability
Temperature Range	15ºC～35ºC Measurement:	□Yes □No
Humidity Range	Less than 80% relative, non-condensing Measurement:	□Yes □No
Power	100~240 VAC, 50/60 Hz Measurement:	□Yes □No
Bench Space	Lambda 365 UV-Visible Spectrophotometer needs sufficient space for a computer and printer. Generally, it will fit on almost any laboratory bench.	□Yes □No
Instrument location	Bench for the instrument installation should not be vibrated or tilted.	□Yes □No
Electric load check	All outlets and extensions should meet the requirements.	□Yes □No
Computer Requirement	**Operating System** · General Purpose : Windows 7 · With UV Express Security Software: Windows 7 Professional, Ultimate or Enterprise	□Yes □No
	PC performance · PC (Intel® Core 1.5 GHz or faster) · RAM: At least 1 GB · Hard disk: 50 GB with 1 GB free · Input devices : Mouse and keyboard · Monitor : 1024x768 (minimum) · Media: CD-ROM Drive · Port: USB port for the data acquisition · Windows compatible printer	□Yes □No

Installer's signature : Date:

Customer's signature : Date:

III-3-3. System Information

IQ-3. System Information

Item	Check List	Result
System	Instrument Serial No : _____	□Yes □No
	The date of manufacture: _____	□Yes □No
	Single Cell Holder	□Yes □No
	Communication Cable (USB Cable)	□Yes □No
	Power Cord for Spectrophotometer	□Yes □No
	UV Express Software CD Package Name : _____	□Yes □No
	Document Pack CD	□Yes □No
Accessories	Model:_____ Part No. :_____	□Yes □No
	Model:_____ Part No. :_____	□Yes □No
	Model: _____ Part No. :_____	□Yes □No
PC (Optional)	PC: Model name: _____ Serial No:_____ Manufacturer:_____	□Yes □No
	Monitor: Model name: _____ Serial No:_____ Manufacturer:_____	□Yes □No
	Printer: Model name: _____ Serial No:_____ Manufacturer:_____	□Yes □No
	Other components: _____ Serial No:_____ Manufacturer:_____	□Yes □No

CRM (Certified Reference Materials)	Wavelength accuracy test : Holmium Oxide Solution Serial No: _____	□Yes □No
	Photometric accuracy test : 600 mg/L Potassium Dichromate($K_2Cr_2O_7$) Serial No: _____	□Yes □No
	Photometric accuracy and reproducibility test : 60 mg/L Potassium Dichromate($K_2Cr_2O_7$) Serial No: _____	□Yes □No
	Photometric accuracy and reproducibility test : Perchloric acid Blank ($HClO_4$) Serial No: _____	□Yes □No
	Photometric accuracy and reproducibility test : 0.2 AU Neutral Density Glass Filter Serial No: _____	□Yes □No
	Photometric accuracy and reproducibility test : 0.5 AU Neutral Density Glass Filter Serial No: _____	□Yes □No
	Photometric accuracy and reproducibility test : 1.0 AU Neutral Density Glass Filter Serial No: _____	□Yes □No
	Stray light test : Acetone (CH_3COCH_3) Serial No: _____	□Yes □No
	Stray light test : 12 g/L Potassium Chloride (KCl) Serial No: _____	□Yes □No
	Stray light test : 10 g/L Sodium Iodide (NaI) Serial No: _____	□Yes □No
	Stray light test : 50 g/L Sodium Nitrite ($NaNO_2$) Serial No: _____	□Yes □No
	Stray light test : Water Blank Serial No: _____	□Yes □No

	Resolution test : 0.02% Toluene in Methanol Serial No: _____	□Yes □No
	Resolution test : Methanol Blank Serial No: _____	□Yes □No
	Resolution test : 0.02% Toluene in Hexane Serial No: _____	□Yes □No
	Resolution test : Hexane Blank Serial No: _____	□Yes □No
	Other Standard 1 Usage :_____ Serial No: _____	□Yes □No
	Other Standard 2 Usage :_____ Serial No: _____	□Yes □No
	Other Standard 3 Usage :_____ Serial No: _____	□Yes □No

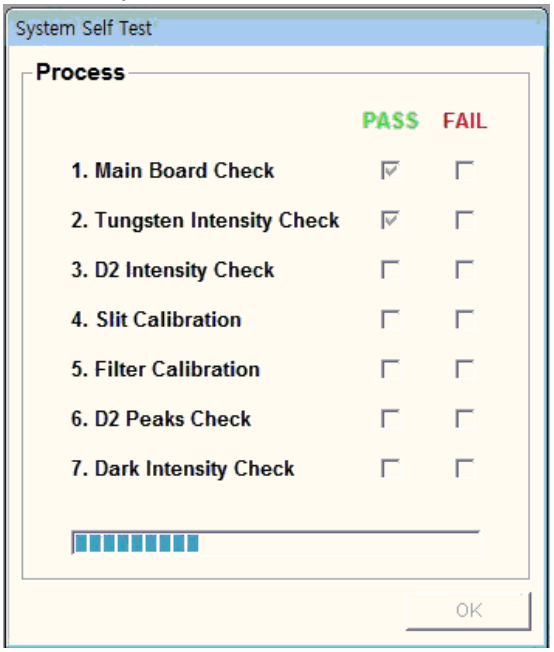
Installer's signature : Date:

Customer's signature : Date:

III-3-4. System Installation and System Check Procedure

IQ-4. System Installation and System Check Procedure

Item	Check List	Result
Computer	1. Install the computer and monitor any optional components near the instrument.	□Yes □No
	2. Install the operation system to the computer.	□Yes □No
	3. Turn on the power to the computer and monitor any optional computer components such as a printer.	□Yes □No
Software & Hardware Installation * Please refer to the Lambda 365 Users Guide	4. **UV Express software Installation** Insert UV Express installation CD in CD-ROM. UV Express InstallShield® Wizard starts, then click **Next**. Setup has completed installing UV Express on your PC, click **Finish.**	□Pass □Fail
	5. **System performance Validation software Installation** Insert System performance Validation installation CD in CD-ROM. System performance Validation InstallShield® Wizard starts, and then click **Next**. Setup has completed installing System performance validation software on your PC, and then click **Finish**.	□Pass □Fail
	7. Cell holder installation or accessory installation (Please refer to the accessory manuals when installing accessories.)	□Pass □Fail
	8. Connect the communication cable to PC.	□Pass □Fail
	9. Connect a power cord to the system.	□Pass □Fail
	10. Turn on the power of the Lambda 365	□Pass □Fail
	11. Execute the UV Express software. Check if the grating moves by the sound.	□Pass □Fail

	12. Check System Self Test. The test is performed as below. After testing the system, check all the test items are passed.  	□Pass □Fail
	13. Check **Power** LED. The Power LED (Blue) will be illuminated at the bottom left side of the front panel when the system is turned on.	□Pass □Fail
	14. Check **Ready** LED. If the communication of between PC and system is ok, Ready LED (White) will be illuminated.	□Pass □Fail
	15. Check **System** LED. The System LED (White) will be illuminated while checking the system status itself. After the system self test, the White LED is turned off.	□Pass □Fail

Installer's signature : Date:

Customer's signature : Date:

III-3-5. Comments of Installation Qualification

IQ-5. Comments of Installation Qualification

Items	Comments/Action

Installer's signature : Date:

Customer's signature : Date:

III-4. Installation Re-Qualification Procedure

Instrument Validation should not be viewed as a one-time event – confidence in analytical results is required for the whole of the instrument's working life. To ensure that this confidence is retained, the instrument validation process should be repeated at regular intervals during the instruments operational life.
PerkinElmer offers a Re-Qualification service that meets these requirements. The difference between Installation Qualification and Re-Qualification services is that IQ can be omitted for the Re-Qualification service.

1. If there is any change in instrument space, location or environmental condition after IQ or RQ is completed, IQ must be repeated completely to verify the instrument operation in the new location or environmental condition.

2. If any major component of the hardware or software is altered after IQ or RQ is complete, IQ must be performed again to verify the instrument operation with the new configuration. In this case, major components include: light source, detector, optical component, and upgraded terms in software.

3. After running steps 1 or 2above, OQ should be performed to verify the instrument's operation.

4. If there is no change, or if there is some minor component change of hardware or software, run the OQ for RQ without IQ process.

Re-Qualification should be performed at least annually and should be performed more frequently for applications whose test results have critical implications.

IV. Operation Qualification

IV-1. Introduction to Operation Qualification

The purpose of Operation Qualification (OQ) is to verify that key aspects of instrumental performance (*e.g.* wavelength, absorbance, resolution, stray light, noise and drift) are satisfactory, and within specification, in the absence of any contributory effects which may be introduced by the analytical method. OQ tests are designed to check the performance of an individual instrument in such a way that any variation noted is attributable to the instrument itself, rather than cells, or particular solvents or chromophores.

While many methods might be robust to small differences between the selected and actual value of an operating condition (*e.g.* wavelength range, absorbance range, resolution), significant differences may impact the validity of the method and the data generated by it. The role of OQ can, therefore, be considered as the process of verifying that key operating conditions are within specified limits for accuracy and precision.

OQ testing should be carried out after the initial installation of the instrument and again at defined intervals throughout the instrument's life. It is usually carried out either periodically or following an event, which may affect the performance of the instrument. Some aspects of performance (such as stray light) may be more sensitive to a particular event than other aspects (such as resolution). Thus, a full suite of OQ verifications may not be required on every occasion and the planning for OQ should tailor the testing program to concentrate on the parameters most likely to be affected.
The responsibility for defining the frequency and extent of OQ testing rests with instrument users. However, manufacturers should provide advice on recommended intervals and identify the sort of verifications that will be required following particular events. The frequency at which periodic OQ testing is undertaken will typically depend on:

- manufacturer's recommendations;
- required instrument performance;
- level of instrument use (higher workloads may accelerate component wear, leading to more rapid deterioration in overall performance)

- operating environment (an instrument in a mobile laboratory is likely to require more frequent OQ testing than a similar model housed in a permanent location)
- use inconsistent with manufacturer's recommendations
- experience of intervals during which the instrument has been found to remain within required performance limits under the conditions used

For event-driven OQ, the extent to which OQ is repeated will depend on the impact that the event has on the performance of the instrument. For example, while the replacement of the pump tubing is likely to affect the performance of a peristaltic pump based 'sipper' system, it is unlikely to impact the optical performance of the spectrometer. Therefore, although it will be necessary to repeat OQ to verify the performance of the sample introduction by the sipper, it should not be necessary to repeat OQ testing to verify the optical performance of the spectrophotometer. However changes made inside the sample cell compartment, such as reconfiguration of the sample cell holders, would prompt an examination that stray light levels were still acceptable, or a check on absorbance accuracy to confirm that vignetting has not occurred.

Examples of events that may necessitate repeating OQ include:

- routine maintenance, servicing and replacement of parts
- movement or relocation
- interruption to services and/or utilities (other than by accepted close-down procedures)
- modification or upgrades
- as part of troubleshooting / fault-finding following PQ failure

* After finishing the OQ process, report the test result using the OQ-1 Worksheet.
* If failures in the Qualification Process, please report the problem(s)in detail using the OQ-2 Worksheet.
*PerkinElmer or a certified distributor should offer training to the Customer (Operator) about the qualification process and method. Report training received on the OQ-3 Worksheet.

IV-2. Check List for UV-Visible Spectrophotometer

Operation Qualification includes the following tests using the UV Express System Performance Validation Software Wizard.

- ☑ Wavelength Validation
- ☑ Photometric Validation
- ☑ Stray Light Validation
- ☑ Resolution Validation
- ☑ Noise Validation
- ☑ Stability Validation
- ☑ Baseline Flatness Validation

To complete the above qualification process, the tester must prepare the CRM provided by PerkinElmer or other certified organization.

IV-3. Standard Materials

The following standard materials are needed to perform this validation procedure.

Type of Test	Standard Material List
Wavelength	▪ Holmium Oxide Solution ▪ Deuterium Lamp
Photometric	▪ 0.2 AU of Neutral Density Glass Filter ▪ 0.5 AU of Neutral Density Glass Filter ▪ 1.0 AU of Neutral Density Glass Filter ▪ 60 mg/L Potassium Dichromate ($K_2Cr_2O_7$) solution and corresponding blank ▪ 600 mg/L Potassium Dichromate ($K_2Cr_2O_7$) solution and corresponding blank
Stray Light	At least one of the following standards and corresponding blank: ▪ 50 g/L Sodium Nitrite ($NaNO_2$) ▪ 10 g/L Sodium Iodide (NaI) ▪ 12 g/L Potassium Chloride (KCl) ▪ Acetone
Resolution	▪ 0.02% Toluene in Hexane and Hexane blank ▪ 0.02% Toluene in Methanol and Methanol blank
Noise	▪ None
Stability (Drift)	▪ None
Baseline	▪ None

- UV Express System Performance Validation Software includes software only. Standard materials must be purchased separately.

IV-4. Acceptance Criteria

Test limits and acceptance criteria are provided in the software and in this document.

Type	Specification	Comments
Wavelength accuracy	± 0.3 nm	Holmium Oxide Solution
	± 0.1 nm	At 656.1 nm of D_2 peak
Wavelength reproducibility	± 0.1 nm	At 656.1 nm of D_2 peak
Photometric accuracy	± 0.002 AU	At 440, 465, 546.1, 590, 635 nm, 0.2 AU of Neutral density glass filter
	± 0.002 AU	At 440, 465, 546.1, 590, 635 nm, 0.5 AU of Neutral density glass filter
	± 0.004 AU	At 440, 465, 546.1, 590, 635 nm, 1.0 AU of Neutral density glass filter
	± 0.01 AU	At 235, 257, 313, 350 nm, 60 mg/L Potassium dichromate
	± 0.01 AU	At 430 nm, 600 mg/L Potassium dichromate
Photometric reproducibility	± 0.001 AU	At 440, 465, 546.1, 590, 635 nm, 0.5 AU of Neutral density glass filter
	± 0.001 AU	At 440, 465, 546.1, 590, 635 nm, 1.0 AU of Neutral density glass filter
	± 0.001 AU	At 235, 257, 313, 350 nm, 60 mg/L Potassium dichromate
Noise	<0.00005 AU	At 700 nm
Resolution	>1.6	Ratio of absorbance of peak/valley around 269 and 266 nm, Toluene in Hexane
	>0.2	Combined ratio of 2nd derivative absorbance of peak and valleys around 261, 263 and 265 nm, Toluene in Methanol
Stray light	<0.02%	At 340 nm, Sodium Nitrite (50 g/L)
	<1%	At 300 nm, Acetone
	<0.02%	At 220 nm, Sodium Iodide (10 g/L)
	<1%	At 198 nm, Potassium Chloride (12 g/L)
Stability (Drift)	<0.0003 AU/hr	At 700 nm
Baseline Flatness	<0.002 AU	At 190 ~ 1100 nm

IV-5. Starting a Validation in UV Express

IV-5-1. Execute the Validation program

After the program installation has completed successfully, execute the Validation mode of UV Express software using the following procedure.

1. Turn on the power switch at the rear of the instrument.

CAUTION: *Do not run UV Express software before finishing the initialization of Grating.*

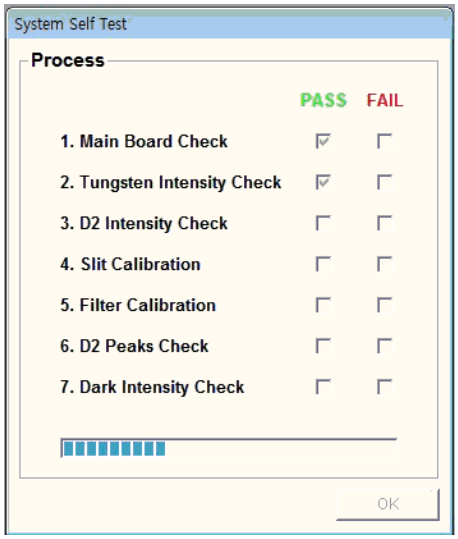
CAUTION: *Do not install any accessories except single cell holder while the Validation program is being used.*

2. Double-click the [UV Express] folder and execute the Validation mode.

3. Select **On-Line** in the UV Express Selection Mode. Click **OK**.

4. The message of '*Please confirm there is empty in the cell holders and close the sample compartment cover firmly before the initialization*.' will be displayed. Empty the cell holder and close the lid firmly. Click **OK**.

5. Start System Self Test.

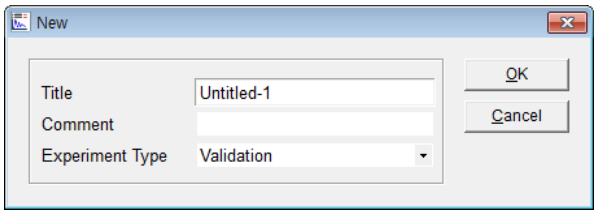


CAUTION: *System Self Test is performed automatically whenever the system's main power is turned on.*

CAUTION: *Do not open the lid while the System Self Test is performed.*

6. After System Self Test is completed, click **OK**.

7. The following window will be displayed. Enter title and comment and click **OK**.



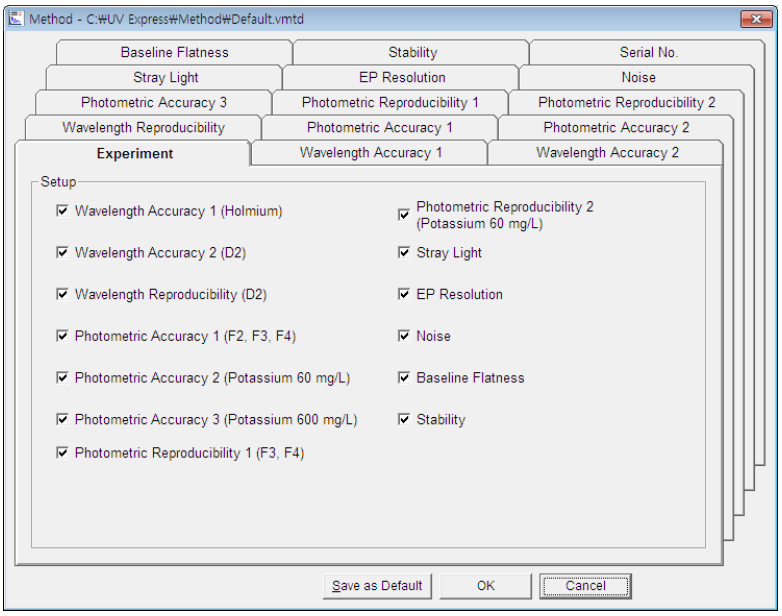
8. The main window will be displayed.

IV-5-2. Setting Method

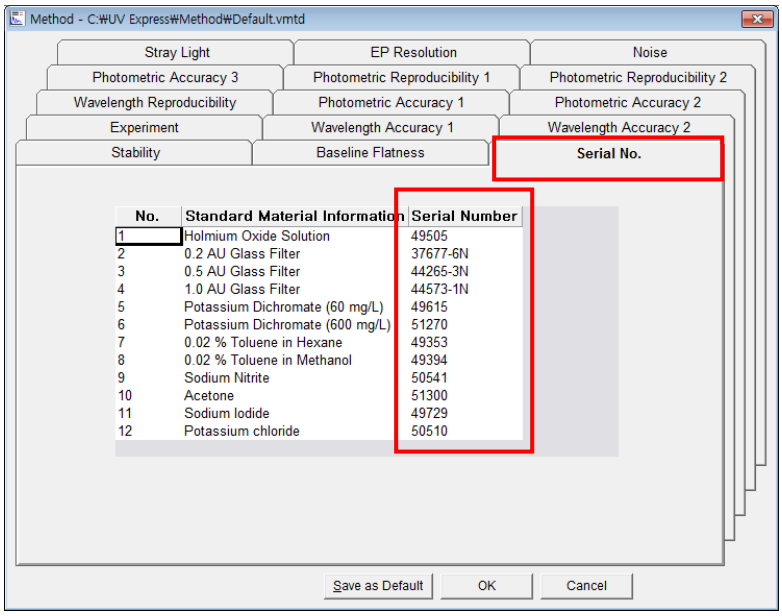
1. Click **Method** in the main menu or 

icon.

2. Method dialog box will be displayed. Check each test item check box you want to test in the Experiment tab.



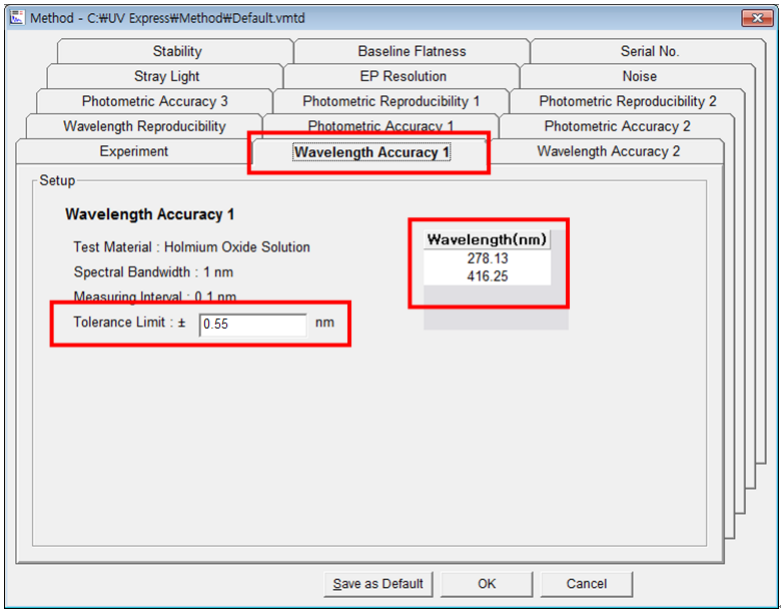
3. Click the **Serial No.** tab. Enter the Serial Number of the standard materials.



4. Set the tolerance limit or verify if the value of the checked test item is the same as that of the standard material.

a. Wavelength Accuracy 1

Enter the Tolerance Limit and Wavelength of Holmium Oxide solution standard material.

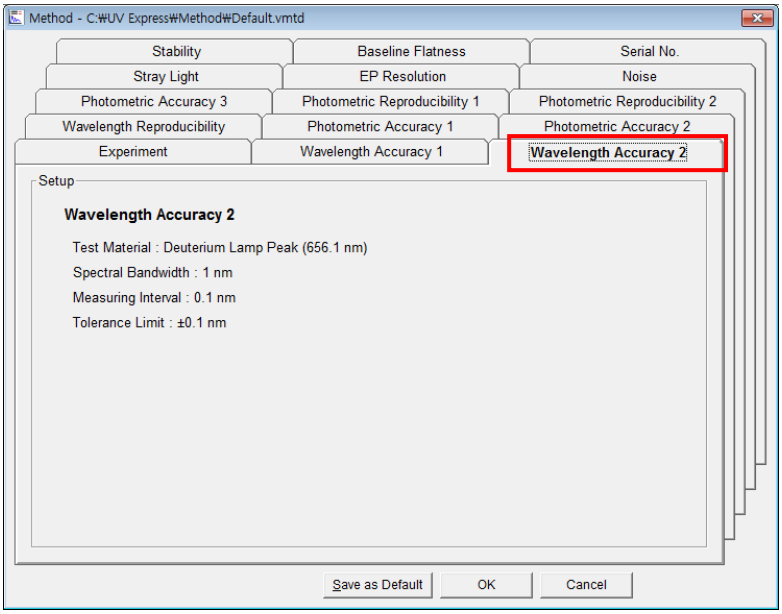


1) **Tolerance Limit**: Enter the value used to evaluate the result of wavelength accuracy. Enter the total accuracy limit value [Instrument limit + Holmium Oxide Solution's uncertainty]

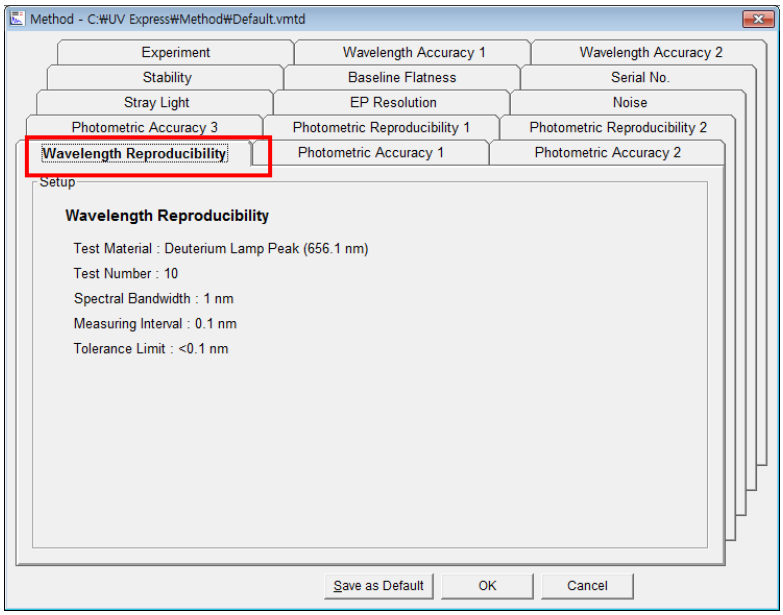
NOTE: *Holmium Oxide solution's uncertainty is stated in the certificate.*

2) **Wavelength (nm):** Enter the two standard wavelength values near 278 and 416 nm.

b. Wavelength Accuracy 2

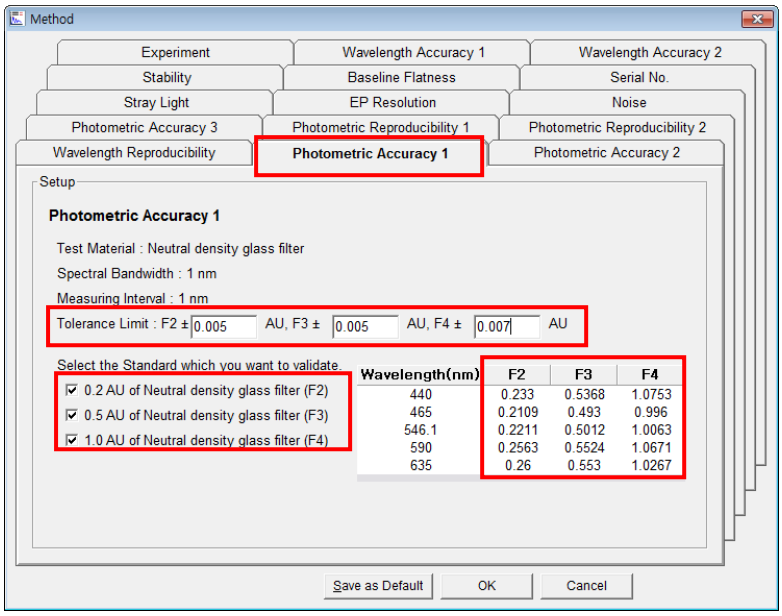


c. Wavelength Reproducibility



d. Photometric Accuracy 1

Enter the Tolerance Limit and absorbance values of Neutral density glass filter standard materials. And then check the standards to validate.



1) **Tolerance Limit**: Enter the value used to evaluate the result of photometric accuracy. Enter the total accuracy limit value [Instrument limit + Neutral Density Filter uncertainty]

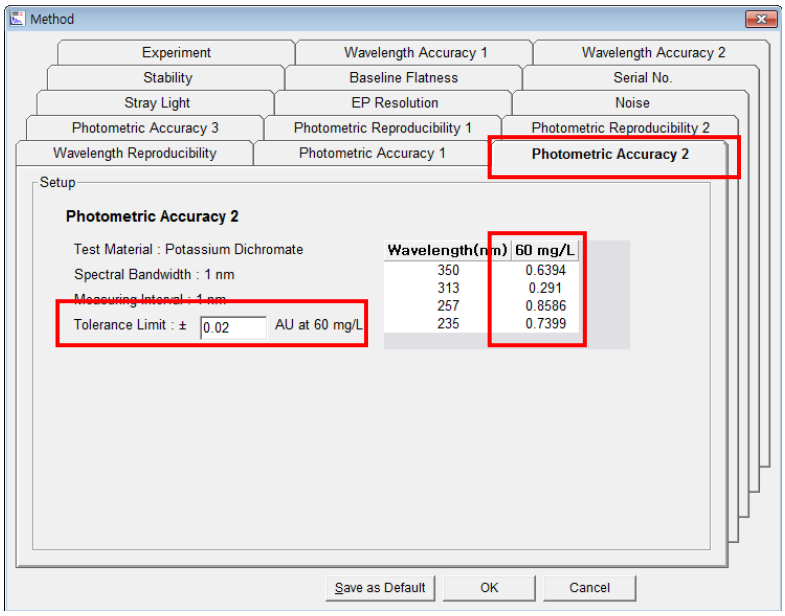
NOTE: *Neutral Density Filter's uncertainty is stated in the certificate.*

2) **Check box:** Select the standards which you want to validate.

3) **F2/G1, F3/G3, F4/G2**: Enter the absorbance values of each standard material.

e. Photometric Accuracy 2

Enter the Tolerance limit and absorbance values of 60 mg/L Potassium Dichromate standard material.



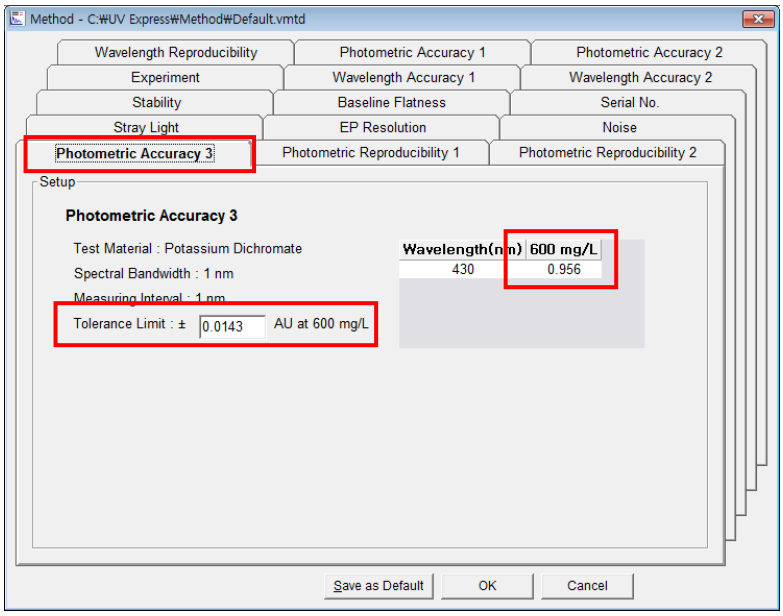
1) **Tolerance Limit**: Enter the value used to evaluate the result of photometric accuracy. Enter the total accuracy limit value [Instrument limit + 60 mg/L potassium dichromate uncertainty]

NOTE: *Potassium Dichromate's uncertainty is stated in the certificate.*

2) **60 mg/L:** Enter the absorbance value of a 60 mg/L Potassium Dichromate standard.

f. Photometric Accuracy 3

Enter the Tolerance limit and absorbance values of 600 mg/L Potassium Dichromate standard material.

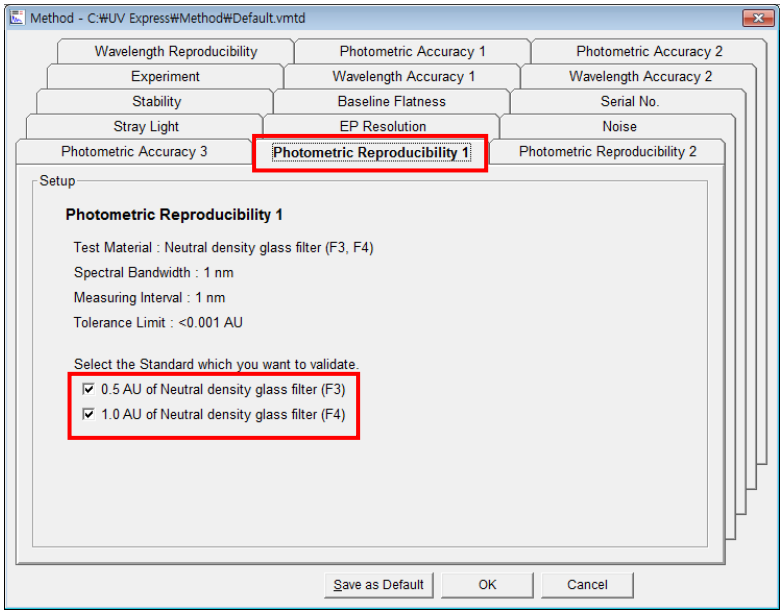


1) **Tolerance Limit**: Enter the value used to evaluate the result of photometric accuracy. Enter the total accuracy limit value [Instrument limit + 600 mg/L potassium dichromate uncertainty]

NOTE: *Potassium Dichromate's uncertainty is stated in the certificate.*

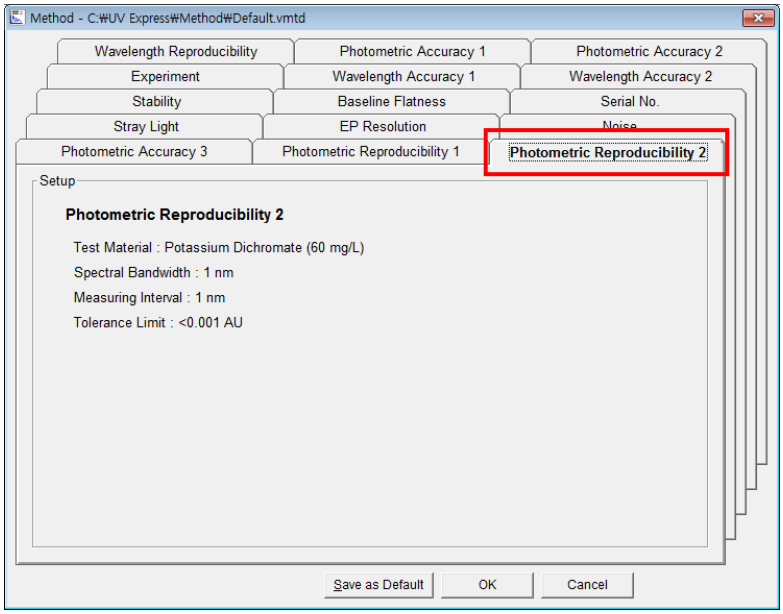
2) **600 mg/L:** Enter the absorbance value of a 600 mg/L Potassium Dichromate.

g. Photometric Reproducibility 1

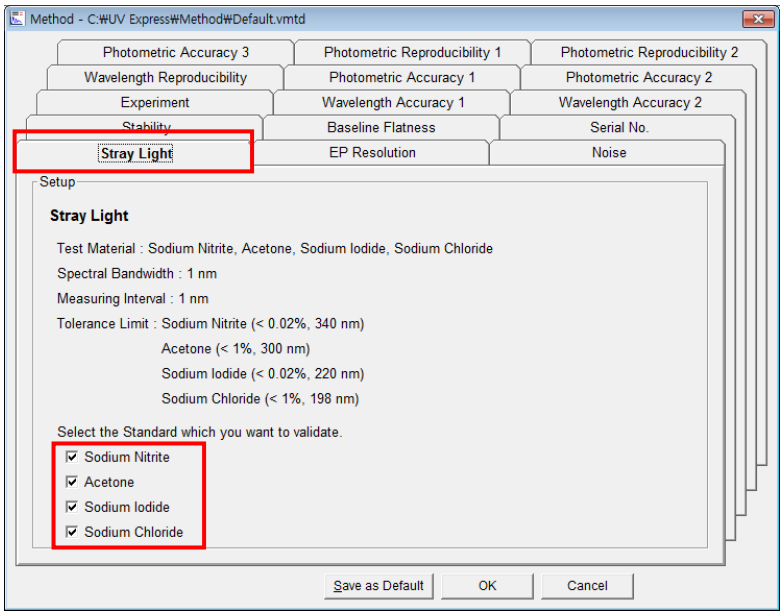


1) **Check box:** Select the standards which you want to validate.

h. Photometric Reproducibility 2

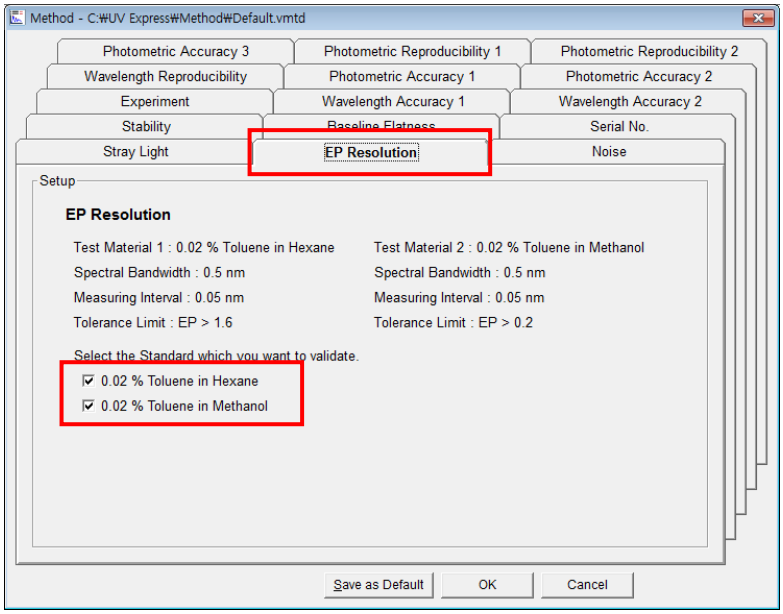


i. Stray Light



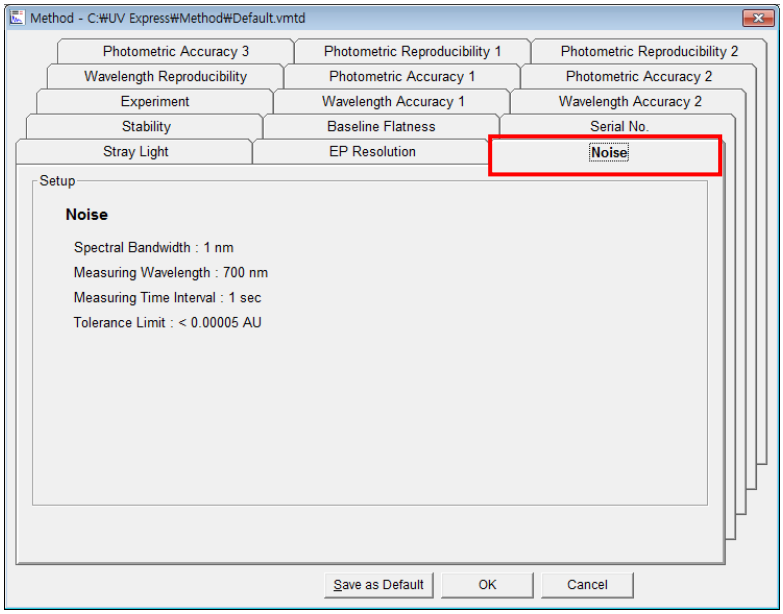
1) **Check box:** Select the standards which you want to validate.

j. EP Resolution

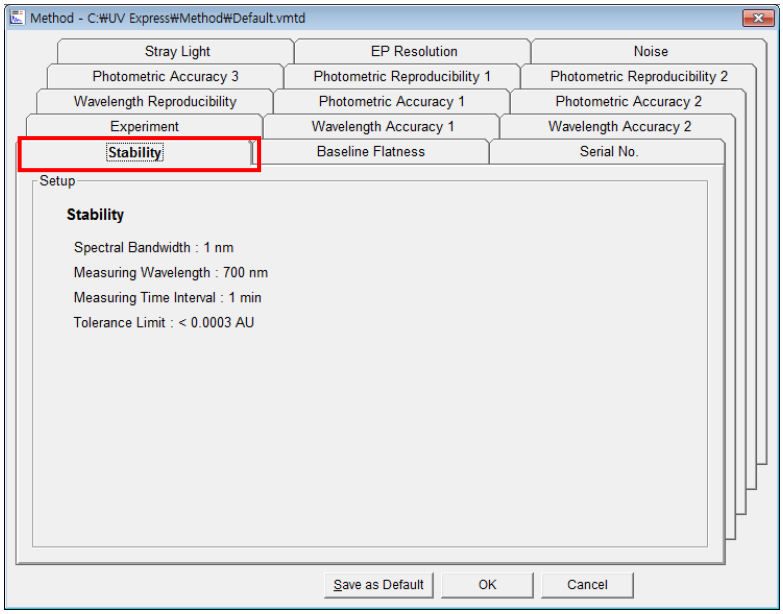


1) **Check box:** Select the standards which you want to validate.

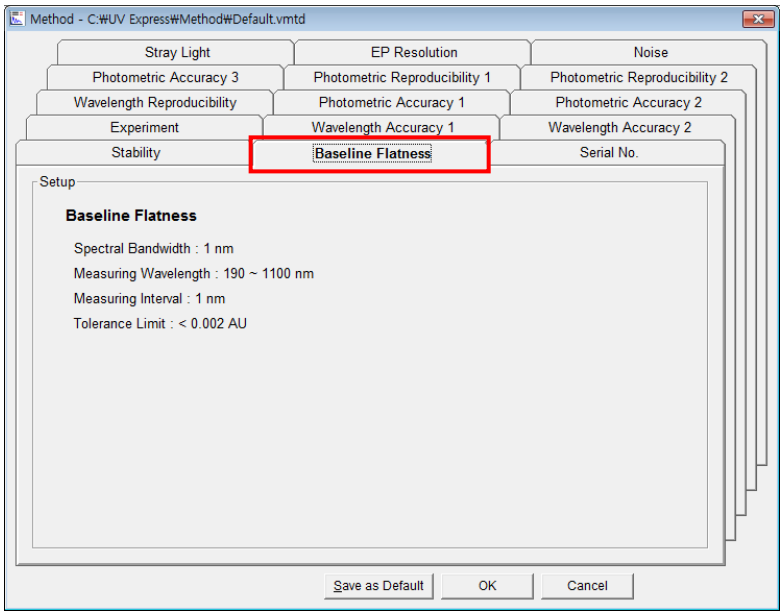
k. Noise



l. Stability

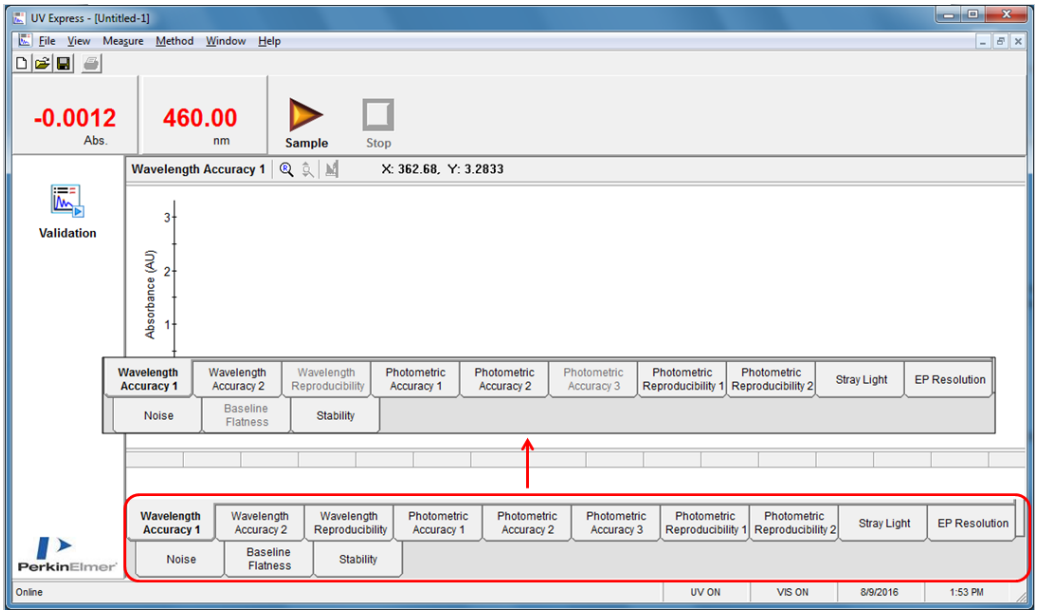


m. Baseline Flatness



5. After entering standard values and tolerance limits for each test item, click **OK**. If the value of the Standard Material is changed, save it by clicking **Save as Default**.

6. The checked test items are activated in the main window as below.

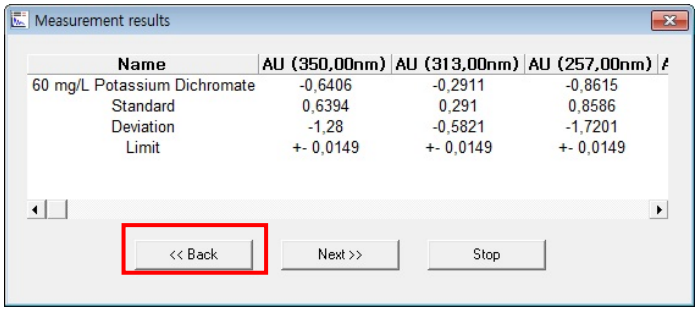


7. Click the **Sample** 

icon.

8. Run the validation following the messages in each step.

NOTE: *Each test item can be measured again at the end of each step by clicking the back button. Ex. User can measure a standard sample again when the wrong standard sample was measured.*

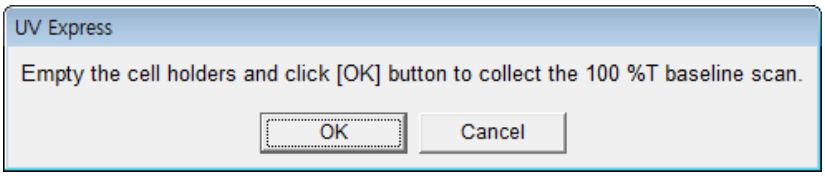


IV-5-3. Wavelength Accuracy

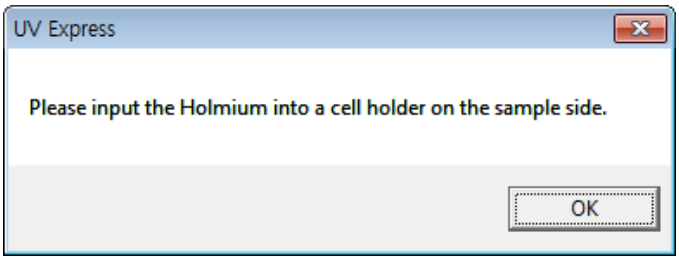
Wavelength accuracy is an important test item when comparing data with the one measured by a different instrument. The use of calibration standards, which have a series of narrow transmittance valleys over the wavelength range, normally checks wavelength accuracy. The Holmium Oxide Solution and Deuterium peaks (The instrument's own source) are used to validate the wavelength accuracy.

IV-5-3-1 Performing Wavelength Accuracy 1

1. The following message box will be displayed when clicking the sample button. After emptying the cell holder, click **OK**.



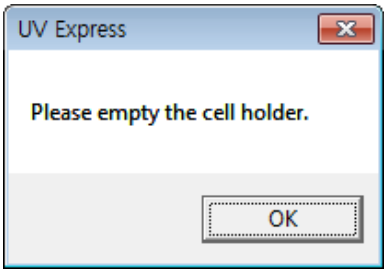
2. The following message box will be displayed after finishing the Baseline scan. Insert the Holmium Oxide solution into the cell holder on the Sample side and click **OK** to measure.



3. After the measurement, check the result. Click **Next**.

IV-5-3-2 Performing Wavelength Accuracy 2

1. The following message box will be displayed, and then click **OK** after emptying the cell holder.



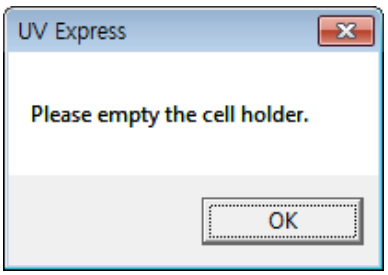
2. After the measurement, check the result. Click **Next**.

IV-5-4. Wavelength Reproducibility

Wavelength reproducibility evaluates the reproducibility of irradiating at a specified wavelength. Deuterium peak (656.1 nm) is used to validate the wavelength reproducibility. The standard deviation of 10 measurements must be less than the tolerance limit

Performing Wavelength Reproducibility

1. If the following message box will be displayed, and then click **OK** after emptying the cell holder.



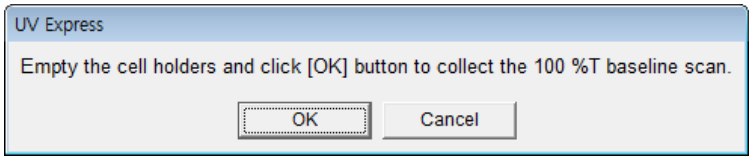
2. After the measurement, check the result. Click **Next**.

IV-5-5. Photometric Accuracy

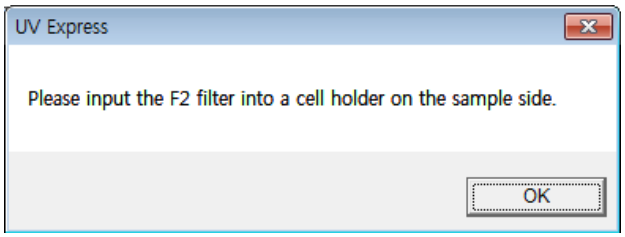
Photometric accuracy is the most important criterion for quantitative analysis when extinction coefficients or factors are used. Neutral density glass filters (respectively for visible range), a solution of 60mg/L Potassium Dichromate (for UV range) and a solution of 600 mg/L Potassium Dichromate (for Vis range) are used in the following experiment.
When the test is performed, if the result is below the upper tolerance limit, or higher than the lower tolerance limit, the test is passed.

IV-5-5-1 Performing Photometric Accuracy 1

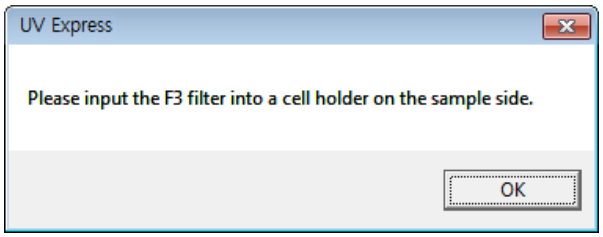
1. The following message box will be displayed, and then click **OK** after emptying the cell holder.



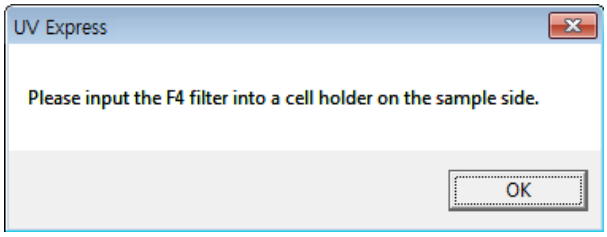
2. The following message box will be displayed after finishing the Baseline scan. Insert a F2/G1 filter into a cell holder on the Sample side and click **OK** to measure.



3. The following message box is displayed after finishing the measurement of the F2/G1 filter, insert a F3/G3 filter into a cell holder on the Sample side and click **OK** to measure.



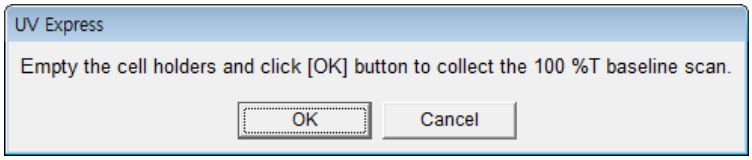
4. The following message box displayed after finishing the measurement of the F3/G3 filter, insert a F4/G2 filter into a cell holder on the Sample side and click **OK** to measure.



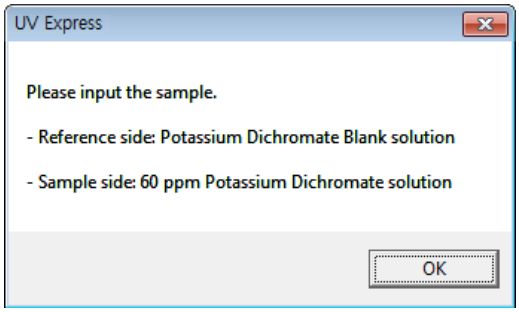
5. After the measurement, check the result. Click **Next**.

IV-5-5-2 Performing Photometric Accuracy-2

1. If the following message box will be displayed, and then click **OK** after emptying the cell holder.



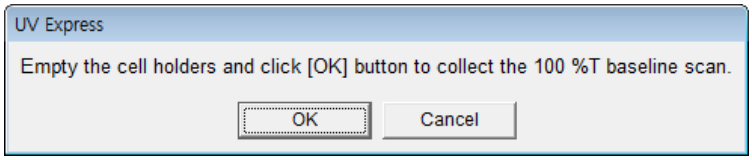
2. The following message box will be displayed after finishing the Baseline scan. Insert the standard reference and standard sample into the cell holders and click **OK**.



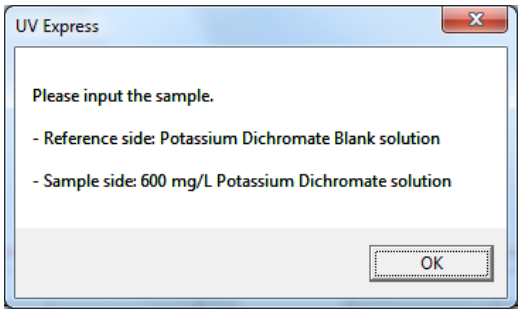
3. After the measurement, check the result. Click **Next**.

IV-5-5-3 Performing Photometric Accuracy-3

1. The following message box will be displayed, and then click **OK** after emptying the cell holder.



2. The following message box will be displayed after finishing the Baseline scan. Insert the standard reference and standard sample into the cell holders and click **OK**.



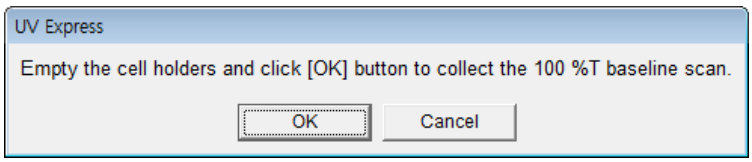
3. After the measurement, check the result. Click **Next**.

IV-5-6. Photometric Reproducibility

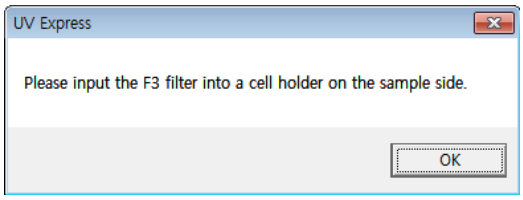
The Neutral density filter (F3/G3, F4/G2) and 60 mg/L Potassium Dichromate are used. The calculated standard deviation of the 10 measurements must be less than the tolerance limit .

IV-5-6-1 Performing Photometric Reproducibility 1

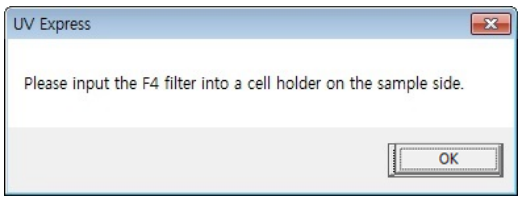
1. The following message box will be displayed, and then click **OK** after emptying the cell holder.



2. The following message box will be displayed after finishing the Baseline scan. Insert the F3/G3 filter into the cell holder on the sample side and click **OK**.

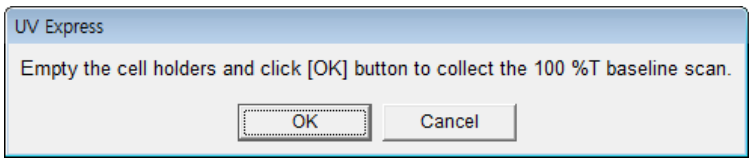


3. The following message box will be displayed after finishing the measurement of F3/G3 filter. Insert a F4/G2 filter into the cell holder on the sample side and click **OK**. After the measurement, check the result. Click **Next**.

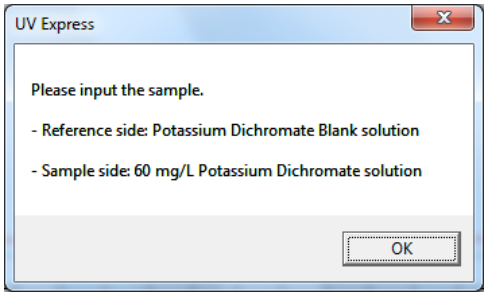


IV-5-6-2 Performing Photometric Reproducibility 2

1. The following message box will be displayed, and then click **OK** after emptying the cell holder.



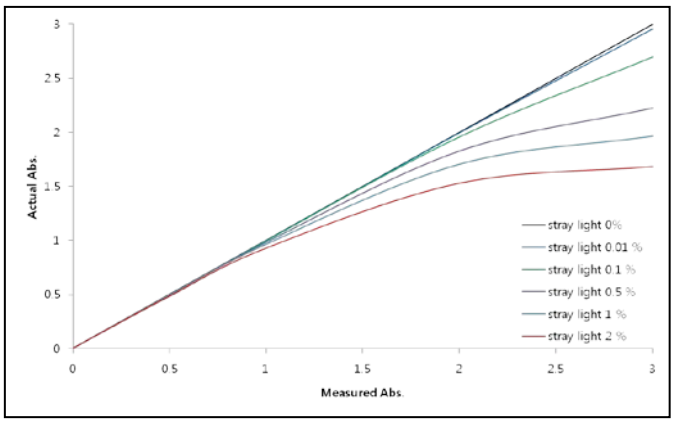
2. The following message box will be displayed after finishing the Baseline scan. Insert the standard reference and 60 mg/L Potassium Dichromate standard sample into the cell holders and click **OK**.



3. After the measurement, check the result. Click **Next**.

IV-5-7. Stray Light

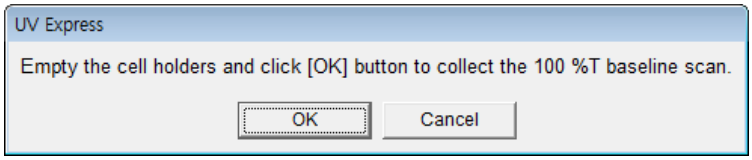
Stray light can be described as an indication of the existing scattered or transmitted light in the instrument when in reality there is no light being transmitted through the sample. The causes for stray light are scattering, higher order diffraction or poor instrument design. The presence of more stray light than specified in the instrument operator's manual may cause errors in analysis. Stray light can be a problem for any wavelength range of the instrument but the problem increases the further into the UV range that the measurement is being made. Stray light causes an apparent decrease in absorbance and reduces the linearity range of the instrument. High absorbance measurements are more severely impacted by stray light Stray light is also the primary influence on the upper limit of the linear dynamic range for an analysis.



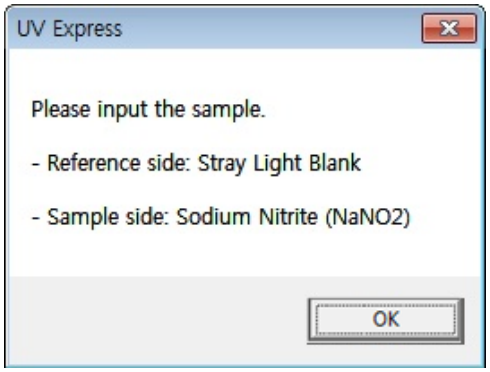
Stray light reference materials are useful in determining the amount of stray light in an instrument because each material stops transmitting light below a specified wavelength. Hence, below the specified "cutoff" wavelength, any indication of light transmission must be stray light. For the stray light test, various cut-off filters or solutions can be chosen depending on the wavelengths of interest. These solutions have the optical characteristics to allow light at slightly higher wavelengths than the measuring wavelengths to pass through and block off light at the measuring wavelength.

Performing Stray Light

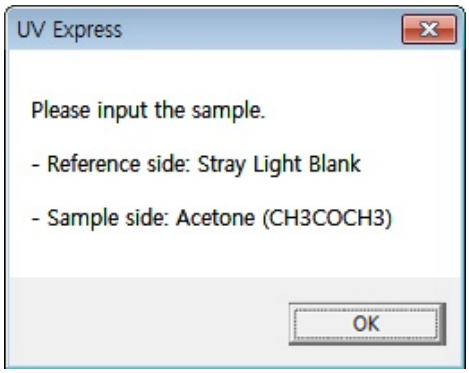
1. The following message box will be displayed, and then click **OK** after emptying the cell holder.



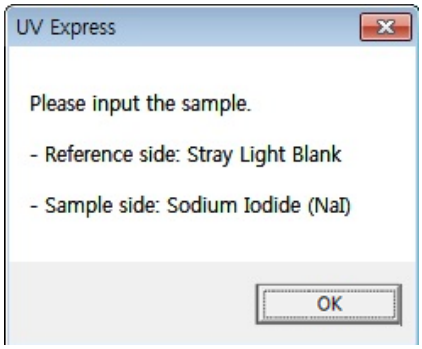
2. The following message box will be displayed after finishing the Baseline scan. Insert the standard reference and standard sample into the cell holders and click **OK**.



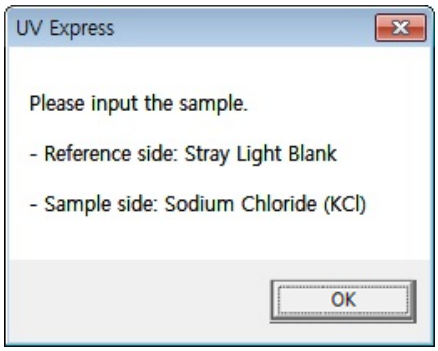
3. The following message box will be displayed after finishing measurement of Sodium Nitrite. Insert the standard reference and standard sample into the cell holders and click **OK**.



4. The following message box will be displayed after finishing measurement of Acetone. Insert the standard reference and standard sample into the cell holders and click **OK**.



5. The following message box will be displayed after finishing measurement of Sodium Iodide. Insert the standard reference and standard sample into the cell holders and click **OK**.



6. After performing the measurement, check the result. Click **Next**.

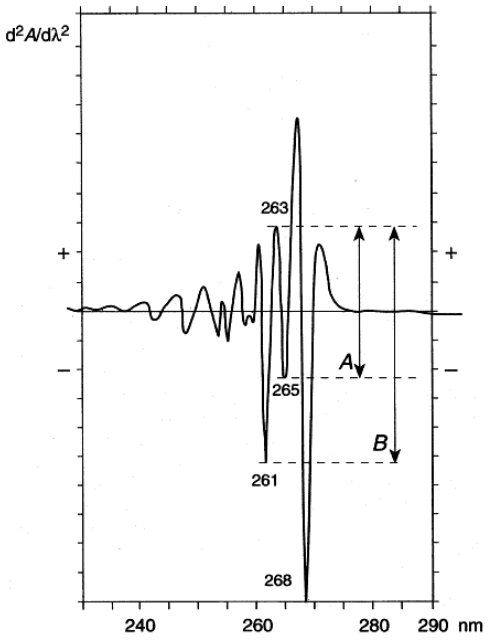
IV-5-8. EP Resolution

Resolution is a critical factor in determining the shape of measured peaks. If the instrumental resolution is insufficient, the absorbance value can be lower than the true one. Resolution can be estimated by two methods; one is measuring the ratio of the absorbance of the maximum at 269 nm to that of the minimum at 266 nm using a toluene solution in n-hexane. The other method, calculated by second order-derivative spectrum using a toluene solution in methanol.

Evaluation

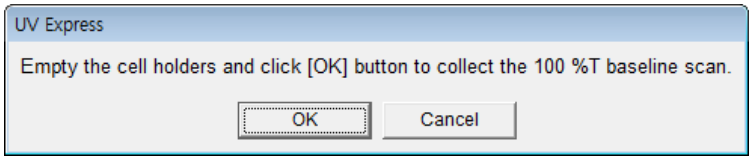
- **Toluene in n-hexane solution** : Calculate the absorbance ratio value A_{269}/A_{266}. If the ratio is greater than 1.6, the test is passed.

- **Toluene in Methanol**: Calculate the second order-derivative spectrum and then calculate the ratio A/B as below figure. If the result is greater than 0.2, the test is passed.

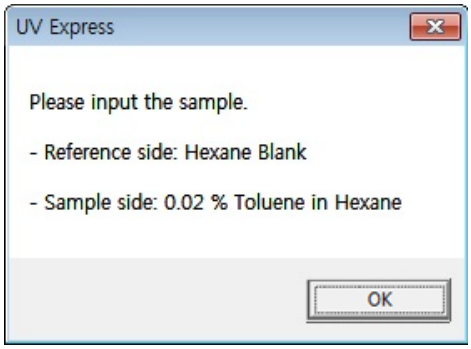


Performing EP Resolution

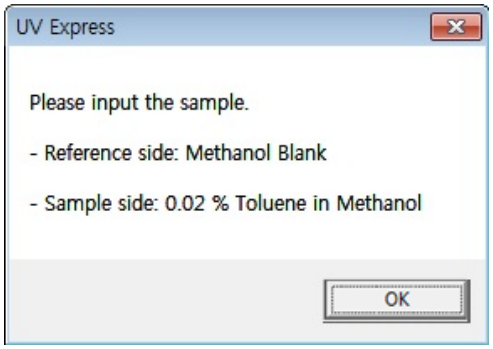
1. The following message box will be displayed, and then click **OK** after emptying the cell holder.



2. The following message box will be displayed after finishing the Baseline scan. Insert the standard reference and standard sample into the cell holders and click **OK**.



3. The following message box will be displayed after finishing the measurement of Toluene in Hexane. Insert the standard reference and standard sample into the cell holders and click **OK**.



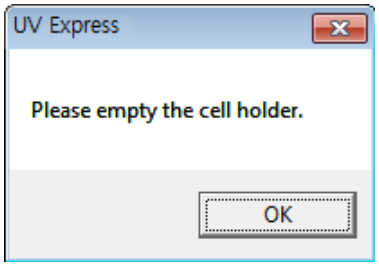
4. After performing the measurement, check the result. Click **Next**.

IV-5-9. Noise

Photometric noise is the major factor affecting the precision of the absorbance measurement. It is a limiting factor at low absorbance.
Photometric noise is typically measured at a single wavelength (700 nm) for one minute. No standard material or solutions are required. The result is calculated the standard deviation at a single wavelength and absorbance. The result must be less than the tolerance limit.

Performing Noise

1. The following message box will be displayed, click **OK** after emptying the cell holder.



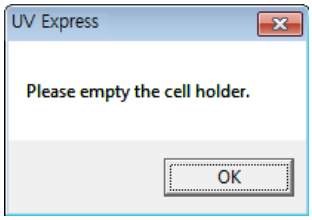
2. After performing the measurement, check the result. Click **Next**.

IV-5-10. Stability

Stability affects the accuracy of absorbance measurements as a function of time. Drift of absorbance values causes systematic errors in photometric accuracy.
Stability is typically measured without samples for 60 minutes by monitoring and calculating the trend of measured absorbance at 700 nm wavelength. The instrument needs a warm-up time of approximately 30 minute.

Performing Stability

1. The following message box will be displayed, and then click **OK** after emptying the cell holder.



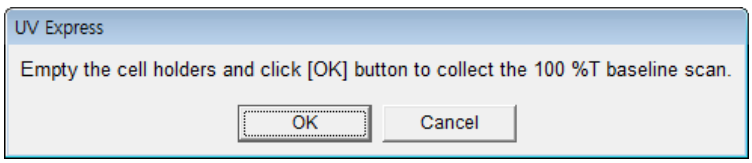
2. After the measurement, check the result.

IV-5-11. Baseline Flatness

Baseline flatness is typically measured at zero absorbance over the specification range of the instrument with no sample in the light path. If the result is below the limit, the test is passed.

Performing Stability

1. The following message box will be displayed, and then click **OK** after emptying the cell holder.

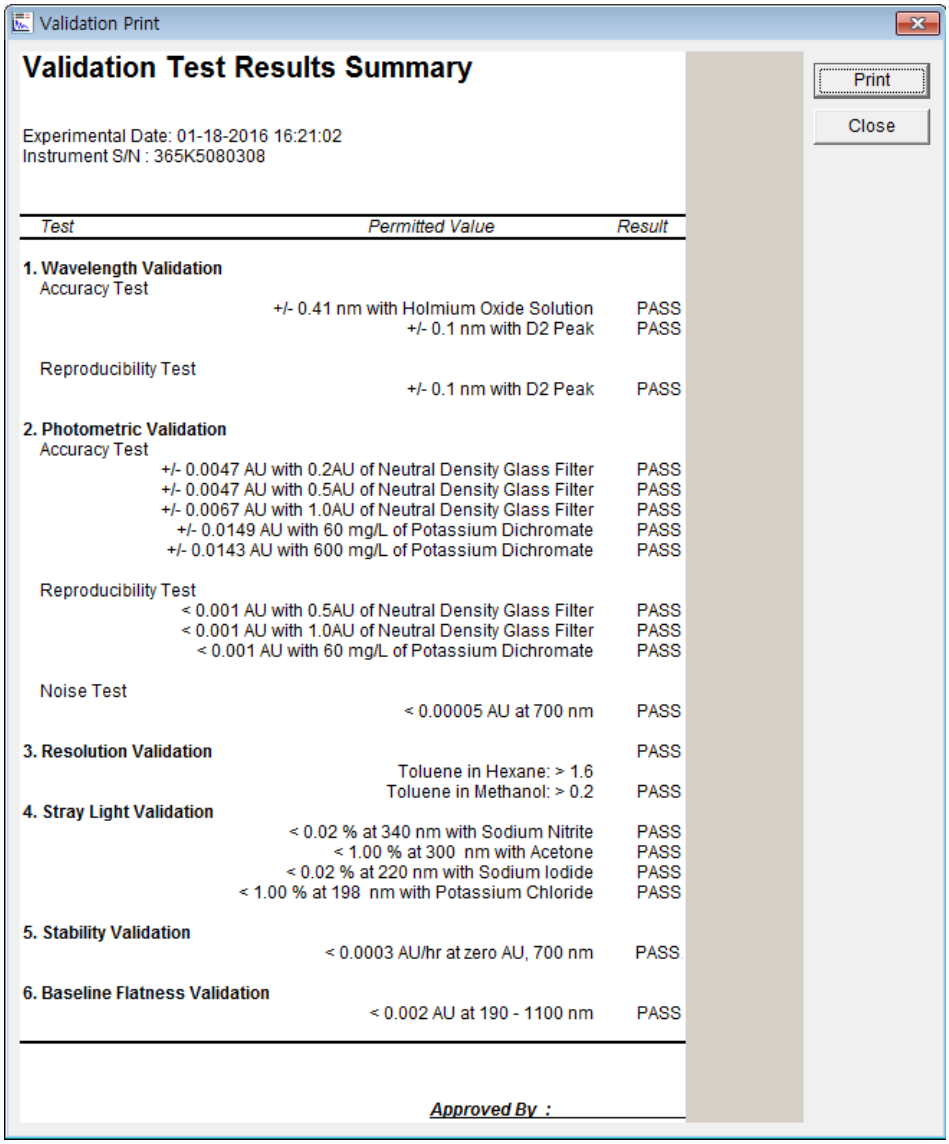


2. After the measurement, check the result.

IV-6. Saving the Result

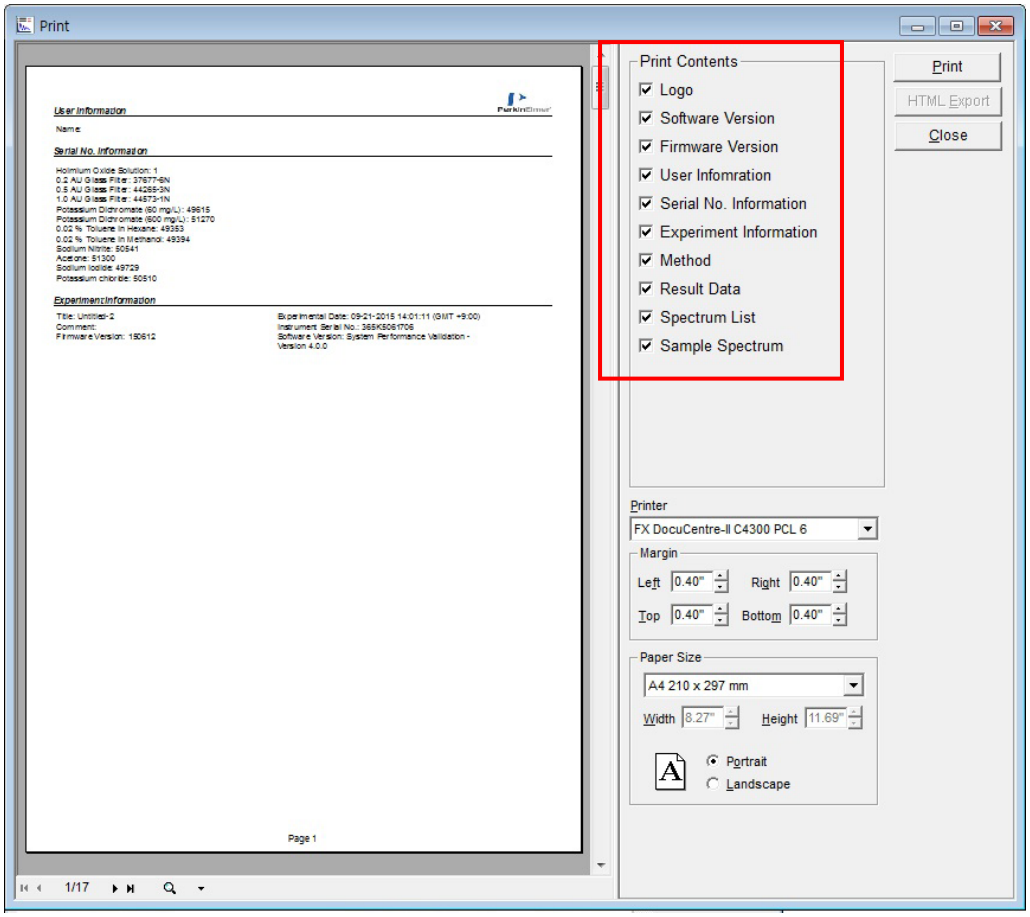
Print the result of all the test items and report the test results using OQ-1 Worksheet.

1. When clicking [File]→[Print Report], the validation test results summary is displayed.



2. Click **Print**

3. Or when clicking [File]→[Print], the following [Print Preview] validations test result is displayed, which includes the full validation test results and can be edited to select the desired contents.



4. Select the print contents, and then click **Print**.

IV-7. Check List for UV Express Software

- ☑ Acquisition of data and absorbance calculation
- ☑ Automatic Peak Find
- ☑ Quantification Algorithm
- ☑ Baseline Correction Algorithm
- ☑ Derivative Algorithm

IV-7-1. Data Acquisition Test

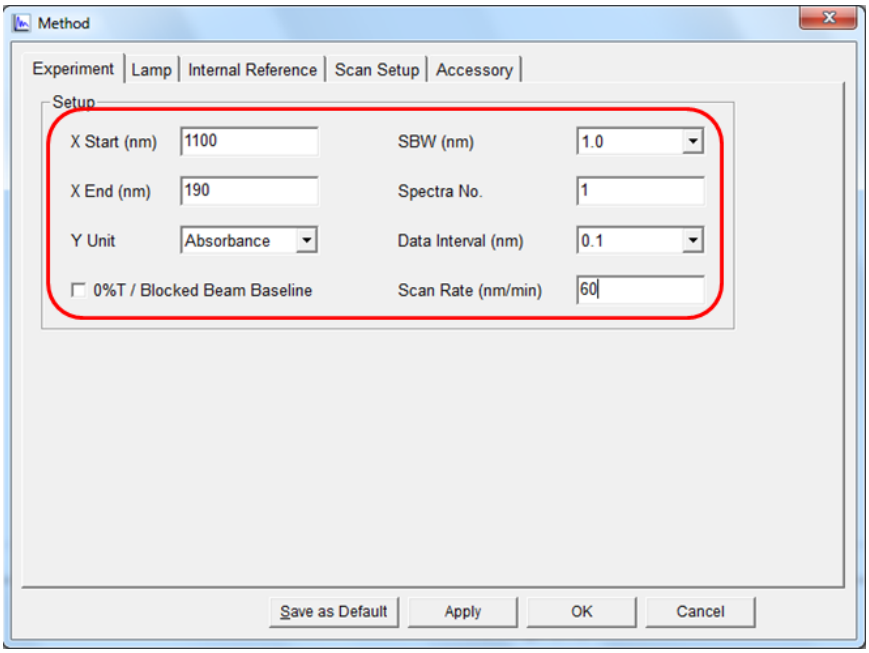
To test the Data Acquisition function in the UV Express software, follow the steps below.

1. Turn on the Lambda 365 UV-Visible spectrophotometer.

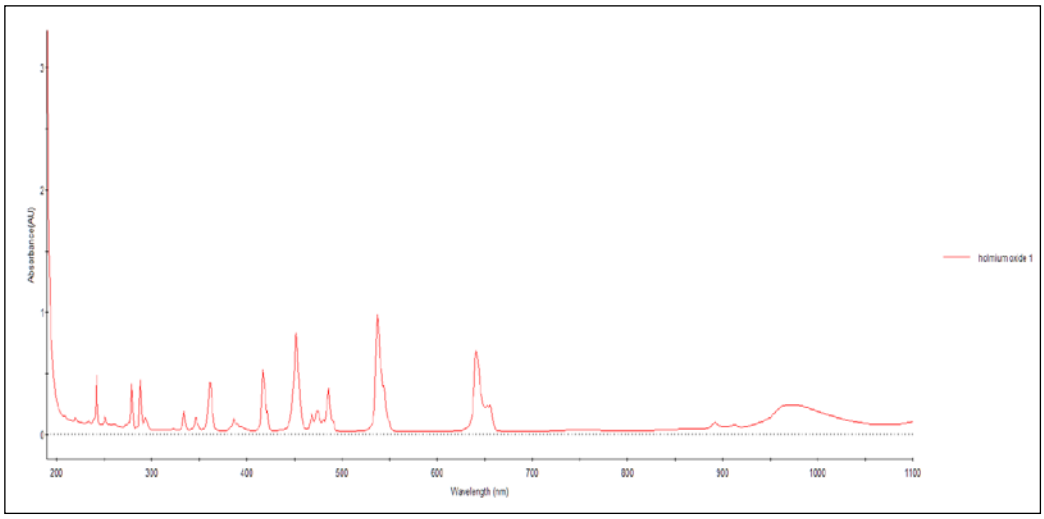
2. Warm up the system for at least 20 minutes.

3. Execute the UV Express software, and the system self test is performed automatically.

4. Click **Method** and set the parameters as below.



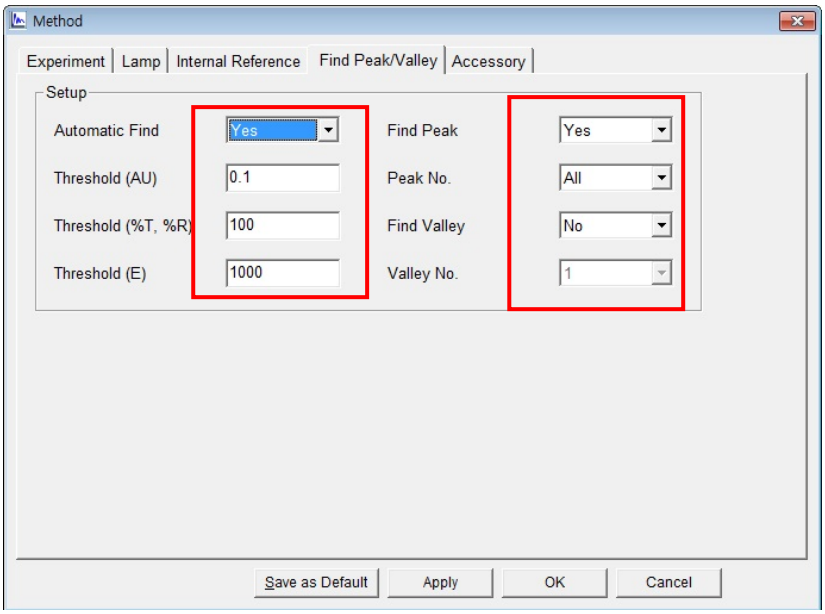
5. Empty the cell holder.
6. Click **Baseline** to measure the blank.
7. Place the Holmium Oxide solution in the sample side.
8. Click **Sample** to measure the sample.
9. If the spectrum collected is comparable to the one below, UV Express software is working properly.



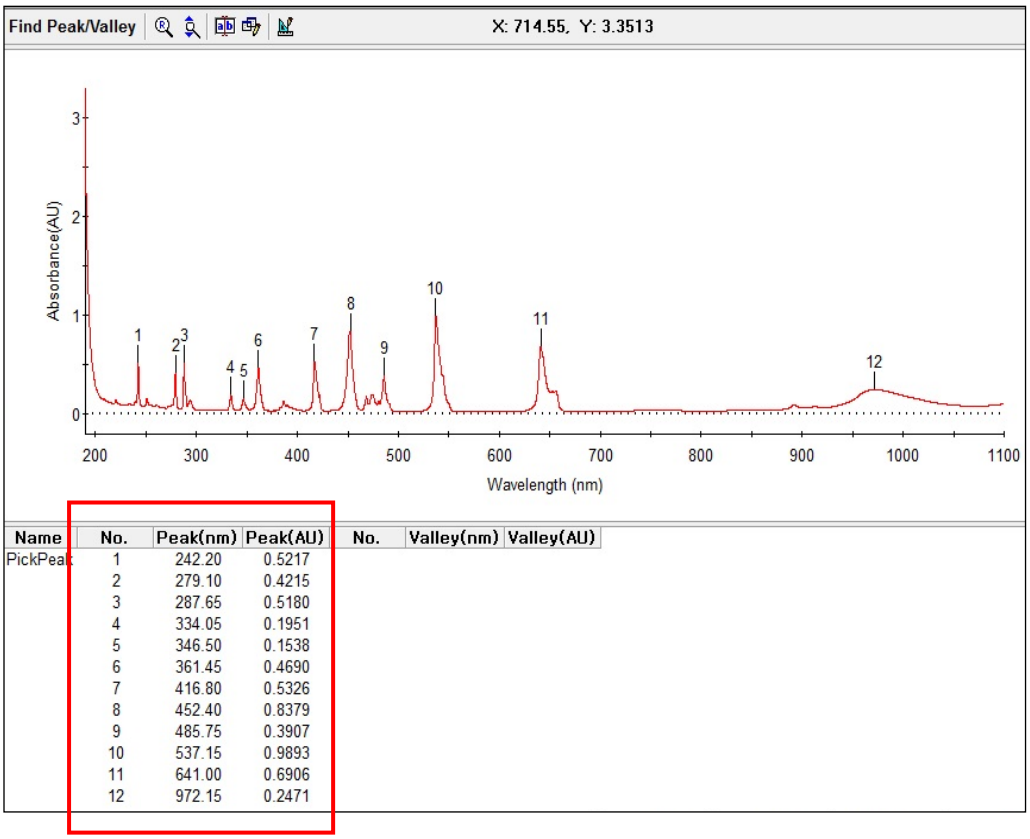
IV-7-2. Automatic Peak Find Test

To test the Automatic Peak Find function in the UV Express software, follow the steps below.

1. Execute the Scan mode of UV Express software.
2. From the menu bar choose **File** then **Open** and navigate to the Folder 'C:\UV Express\SW Validation'. Highlight the file **PickPeak.dgdt** and select **Open**.
3. Click **Find Peak/Valley** icon.
4. Enter parameters as shown below.



5. Click **Apply** and then **OK**. Results of Find Peak are displayed. If the results are comparable to those as shown below, the Automatic Find Peak test is operating correctly.



IV-7-3. Quantification Test

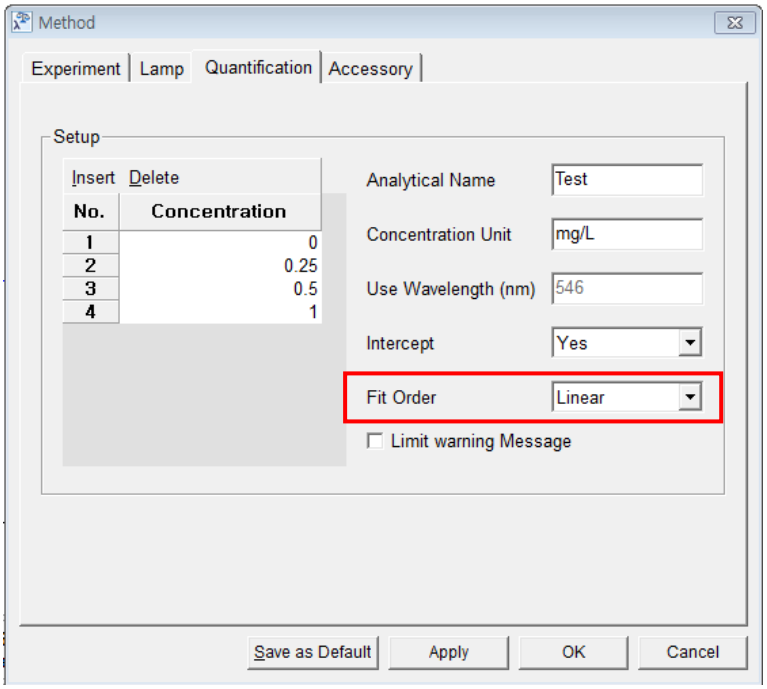
A. Linear Calibration Test

To test the linear Calibration function in the UV Express software, follow the steps below.

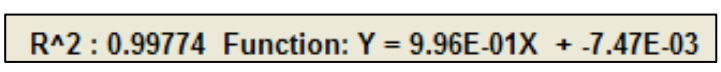
1. Execute the Quantification mode of UV Express software.

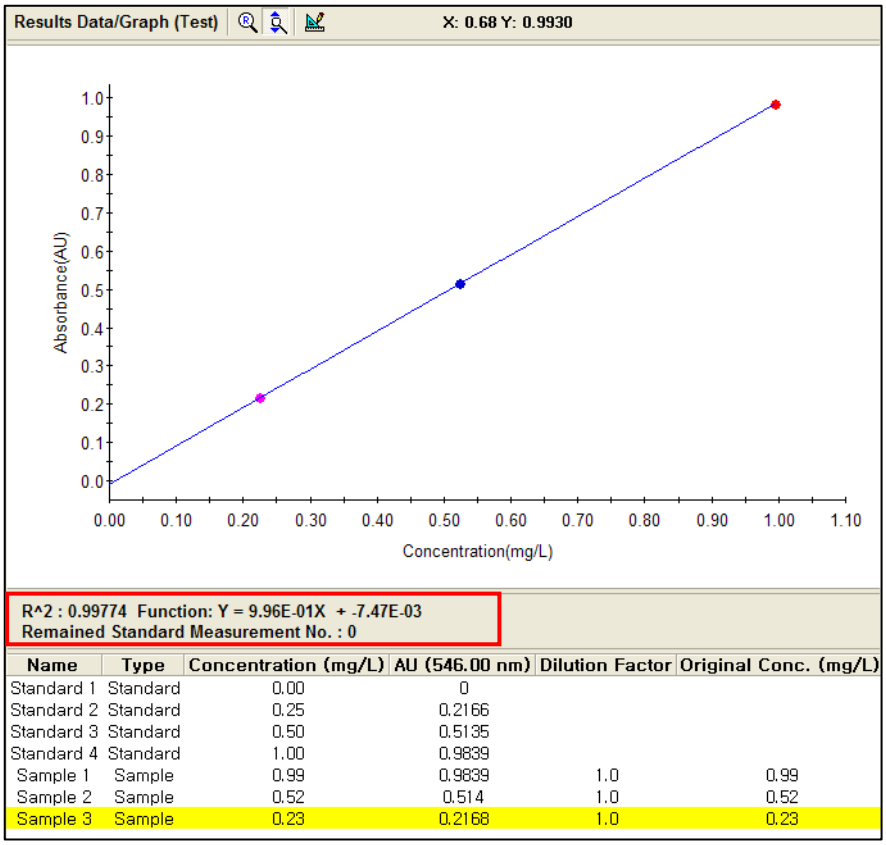
2. From the menu bar choose **File** then **Open** and navigate to the Folder 'C:\UV Express\SW Validation'. Highlight the file **Quant.dqdt** and select **Open**.

3. Click the **Quantification** icon and set the parameters as shown below. Click **Apply** and **OK.**



4. The Result Spectrum and Calibration Curve are displayed as shown below. Verify the result of the regression is R^2: 0.99774 and Function : Y=9.96E-01X -7.47E-03.





Name	Type	Concentration (mg/L)	AU (546.00 nm)	Dilution Factor	Original Conc. (mg/L)
Standard 1	Standard	0.00	0		
Standard 2	Standard	0.25	0.2166		
Standard 3	Standard	0.50	0.5135		
Standard 4	Standard	1.00	0.9839		
Sample 1	Sample	0.99	0.9839	1.0	0.99
Sample 2	Sample	0.52	0.514	1.0	0.52
Sample 3	Sample	0.23	0.2168	1.0	0.23

5. Verify the concentration values of the samples are 0.99, 0.52 and 0.23mg/L. If the Concentration results are comparable to those as shown below, the 1st regression quantification test is passed.

Name	Type	Concentration (mg/L)	AU (546.00 nm)	Dilution Factor	Original Conc. (mg/L)
Standard 1	Standard	0.00	0		
Standard 2	Standard	0.25	0.2166		
Standard 3	Standard	0.50	0.5135		
Standard 4	Standard	1.00	0.9839		
Sample 1	Sample	0.99	0.9839	1.0	0.99
Sample 2	Sample	0.52	0.514	1.0	0.52
Sample 3	Sample	0.23	0.2168	1.0	0.23

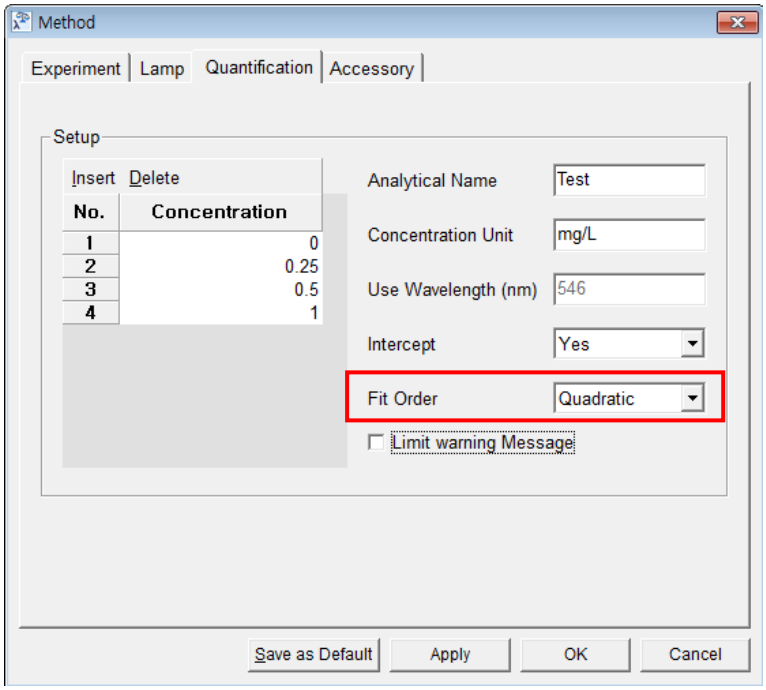
B. Quadratic Calibration Test

To test the quadratic Calibration function in the UV Express software, please follow the next procedures.

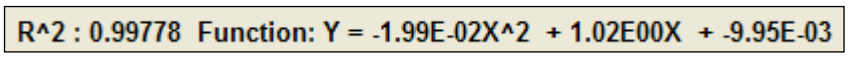
1. Execute the Quantification mode of UV Express software.

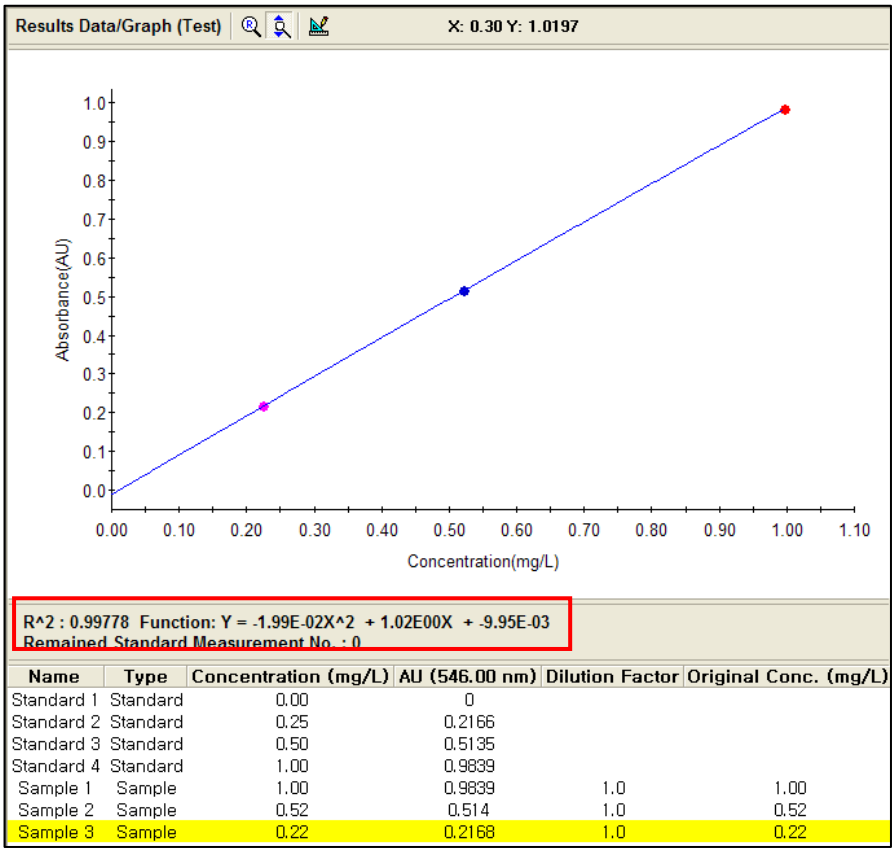
2. From the menu bar choose **File** then **Open** and navigate to the Folder 'C:\UV Express\SW Validation'. Highlight the file **Quant.dqdt** and select **Open**.

3. Click the **Quantification** icon and set the parameters as shown below. Click **Apply** and **OK.**



4. The Result Spectrum and Calibration Curve are displayed as shown below. Verify the result of the regression is R^2: 0.99778 and Function : Y= -1.99E-02X^2 +1.02E00X - 9.95E-03.





Name	Type	Concentration (mg/L)	AU (546.00 nm)	Dilution Factor	Original Conc. (mg/L)
Standard 1	Standard	0.00	0		
Standard 2	Standard	0.25	0.2166		
Standard 3	Standard	0.50	0.5135		
Standard 4	Standard	1.00	0.9839		
Sample 1	Sample	1.00	0.9839	1.0	1.00
Sample 2	Sample	0.52	0.514	1.0	0.52
Sample 3	Sample	0.22	0.2168	1.0	0.22

5. Verify the concentration values of the samples are 1.00, 0.52 and 0.22 mg/L. If the Concentration results are comparable to those as shown below, the 1st regression quantification test is passed.

Name	Type	Concentration (mg/L)	AU (546.00 nm)	Dilution Factor	Original Conc. (mg/L)
Standard 1	Standard	0.00	0		
Standard 2	Standard	0.25	0.2166		
Standard 3	Standard	0.50	0.5135		
Standard 4	Standard	1.00	0.9839		
Sample 1	Sample	1.00	0.9839	1.0	1.00
Sample 2	Sample	0.52	0.514	1.0	0.52
Sample 3	Sample	0.22	0.2168	1.0	0.22

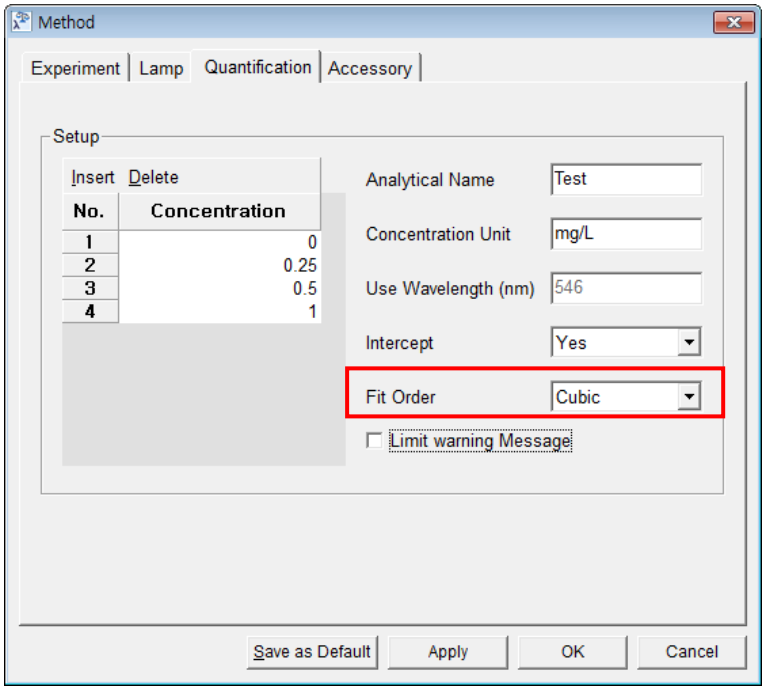
C. Cubic Regression Calibration Test

To test the Cubic Calibration function in the UV Express software, please follow the next procedures.

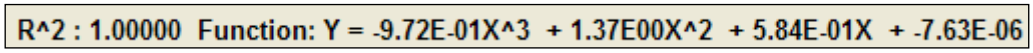
1. Execute the Quantification mode of UV Express software.

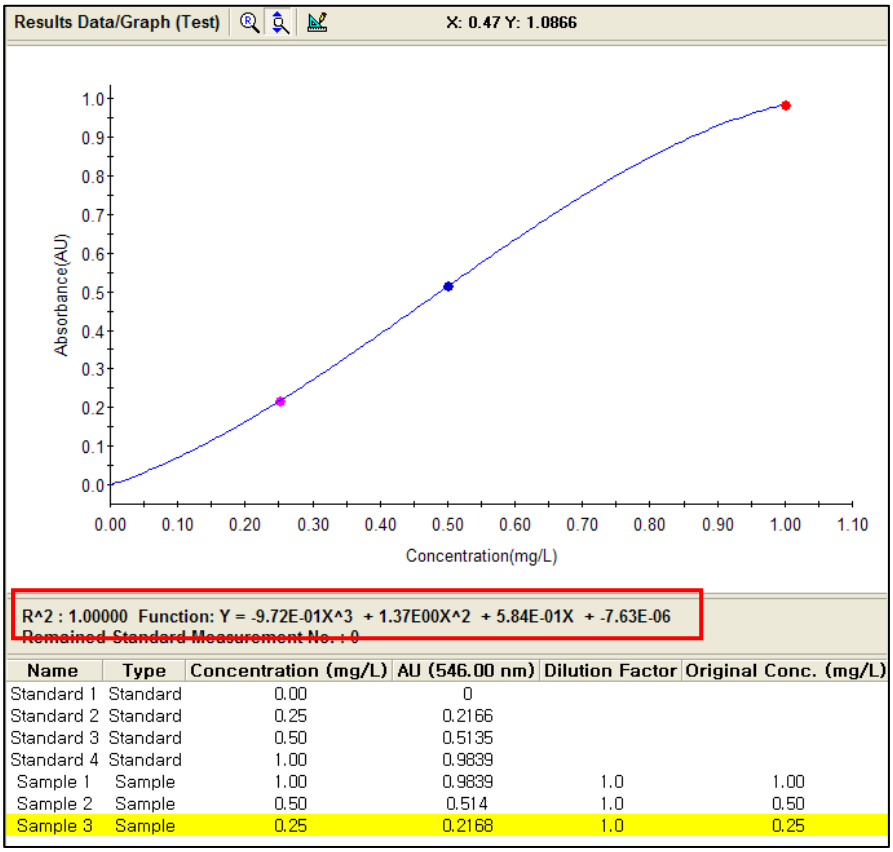
2. From the menu bar choose **File** then **Open** and navigate to the Folder 'C:\UV Express\SW Validation'. Highlight the file **Quant.dqdt** and select **Open**.

3. Click the **Quantification** icon and set the parameters as shown below. Click **Apply** and **OK.**



4. The Result Spectrum and Calibration Curve are displayed as shown below. Verify the result of the regression is R^2: 1.00000 and Function : Y = -9.72E-01X^3+1.37E00X^2 + 5.84E-01X -7.63E-06.





Name	Type	Concentration (mg/L)	AU (546.00 nm)	Dilution Factor	Original Conc. (mg/L)
Standard 1	Standard	0.00	0		
Standard 2	Standard	0.25	0.2166		
Standard 3	Standard	0.50	0.5135		
Standard 4	Standard	1.00	0.9839		
Sample 1	Sample	1.00	0.9839	1.0	1.00
Sample 2	Sample	0.50	0.514	1.0	0.50
Sample 3	Sample	0.25	0.2168	1.0	0.25

5. Verify the concentration values of the samples are 1.00, 0.50 and 0.25 mg/L. If the Concentration results are comparable to those as shown below, the 1st regression quantification test is passed.

Name	Type	Concentration (mg/L)	AU (546.00 nm)	Dilution Factor	Original Conc. (mg/L)
Standard 1	Standard	0.00	0		
Standard 2	Standard	0.25	0.2166		
Standard 3	Standard	0.50	0.5135		
Standard 4	Standard	1.00	0.9839		
Sample 1	Sample	1.00	0.9839	1.0	1.00
Sample 2	Sample	0.50	0.514	1.0	0.50
Sample 3	Sample	0.25	0.2168	1.0	0.25

IV-7-4. Baseline Correction Test

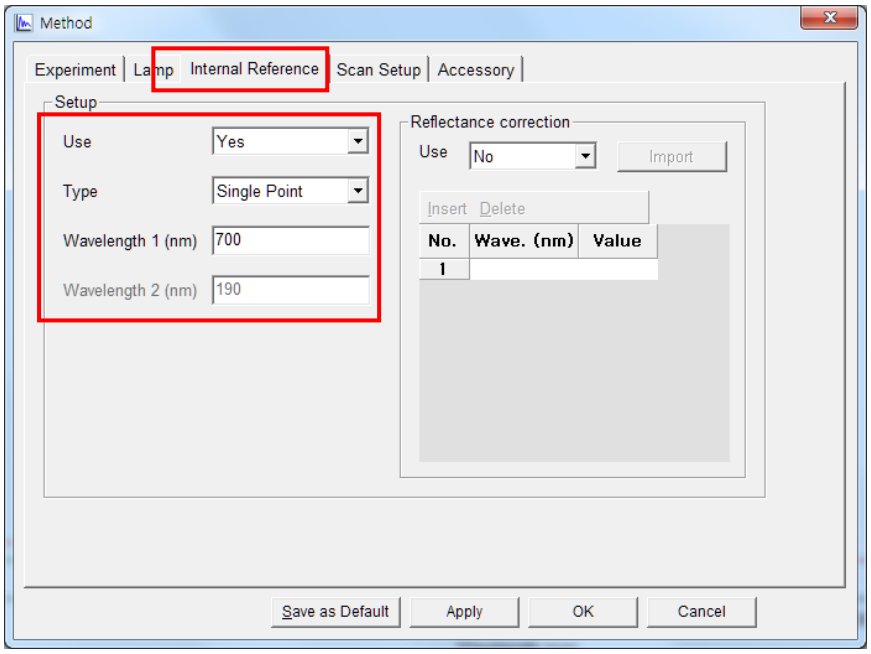
A. Single Point Baseline Correction Test

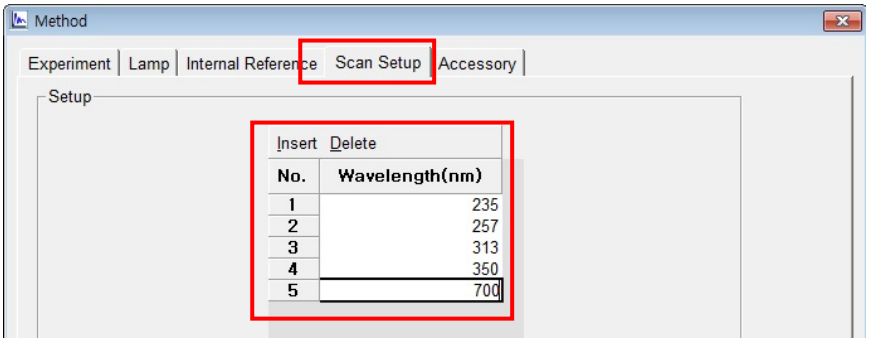
To test the Single Point Baseline Correction function in the UV Express software, follow the steps below. Refer to the UV Express Software Users Guide for detailed information on baseline correction.

1. Execute the Scan mode of UV Express software.

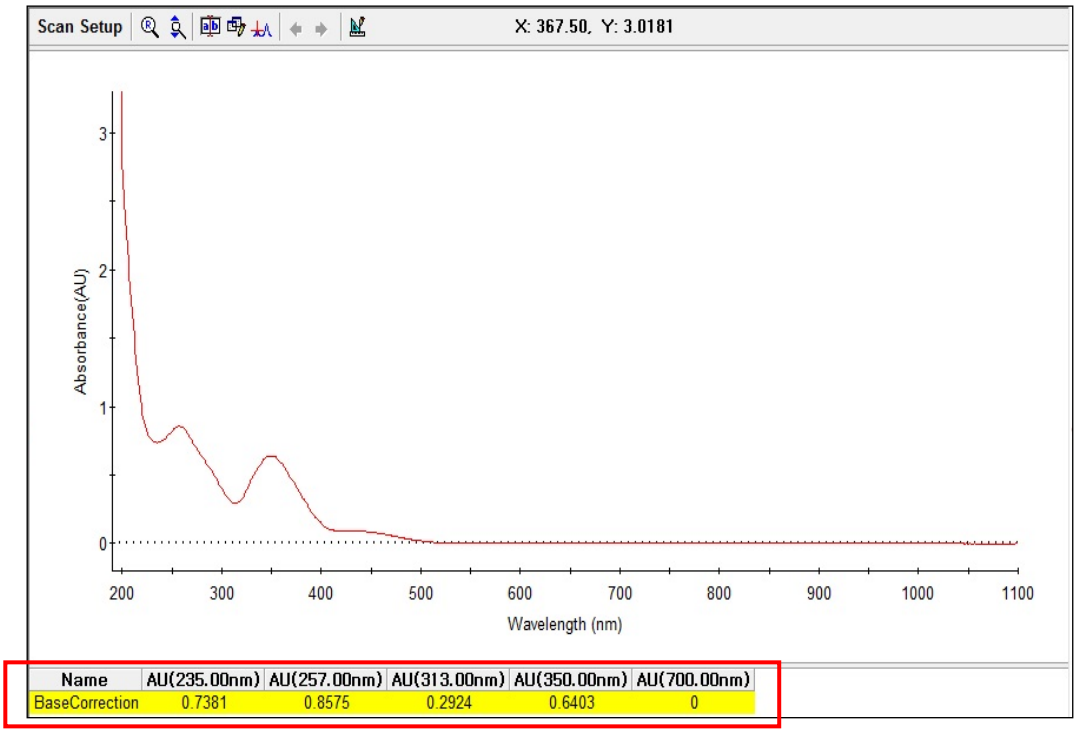
2. From the menu bar choose **File** then **Open** and navigate to the Folder 'C:\UV Express\SW Validation'. Highlight the file **BaseCorrection.dgdt** and select **Open**.

3. Click **Method** or **Scan Setup** icon, enter parameters of Internal Reference and Scan Setup tabs as shown below and click **Apply** and then **OK.**





4. Verify the results are the same as shown below. The values at each wavelength 235 nm, 257nm, 313 nm, 350 nm, 700 nm are 0.7381, 0.8575, 0.2924, 0.6403 and 0. If the results are the same, the single wavelength baseline correction test is passed.



Name	AU(235.00nm)	AU(257.00nm)	AU(313.00nm)	AU(350.00nm)	AU(700.00nm)
BaseCorrection	0.7381	0.8575	0.2924	0.6403	0

B. Range Average Baseline Correction

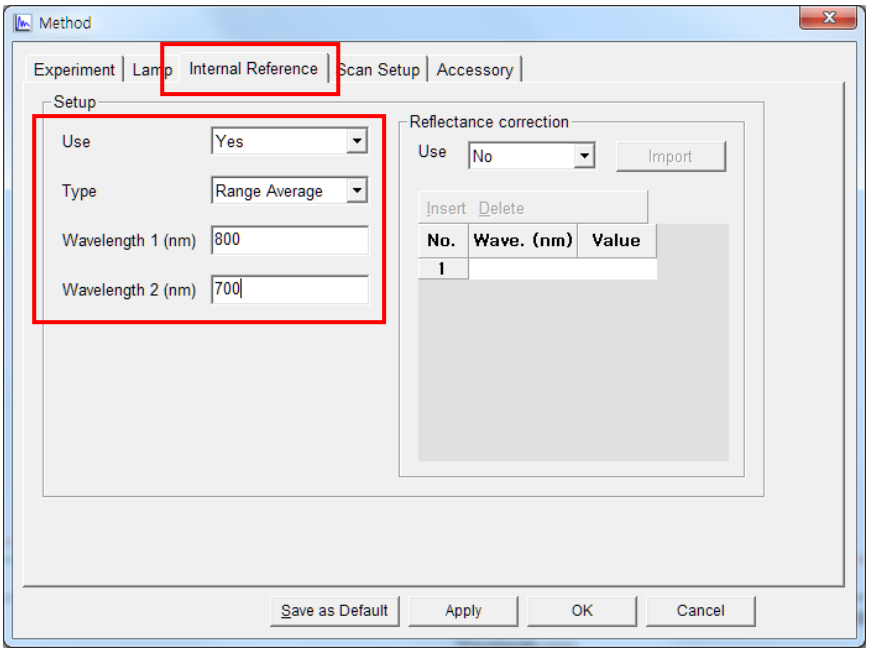
To test the Range Average Baseline Correction function in the UV Express software, follow the steps below.

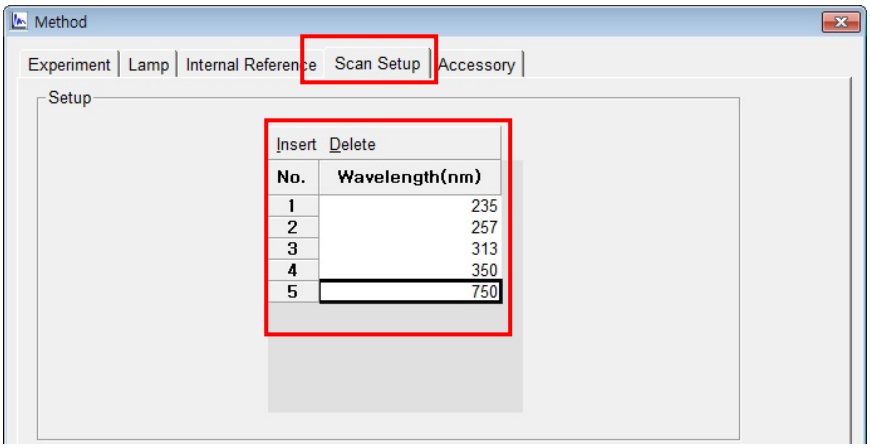
Refer to the Software User Guide for detailed information on baseline correction.

1. Execute the Scan mode of UV Express software.

2. From the menu bar choose **File** then **Open** and navigate to the Folder 'C:\UV Express\SW Validation'. Highlight the file **BaseCorrection.dgdt** and select **Open**.

3. Click **Method** or **Scan Setup** icon, enter parameters of Internal Reference and Scan Setup tabs as shown below and click **Apply** and then **OK.**





4. Verify the results are the same as shown below. The values at each wavelength 235 nm, 257 nm, 313 nm, 350 nm, 750 nm are 0.7381, 0.8574, 0.2924, 0.6403 and 0.0001. If the results are the same, the single wavelength baseline correction test is passed.

Name	AU(235.00nm)	AU(257.00nm)	AU(313.00nm)	AU(350.00nm)	AU(750.00nm)
BaseCorrection	0.7381	0.8574	0.2924	0.6403	0.0001

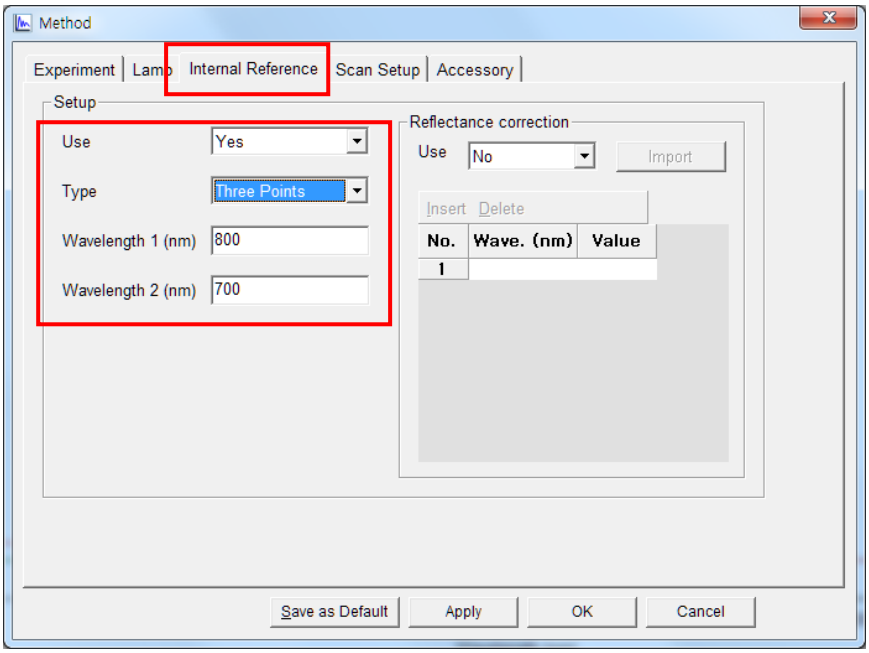
C. Three Points Baseline Correction

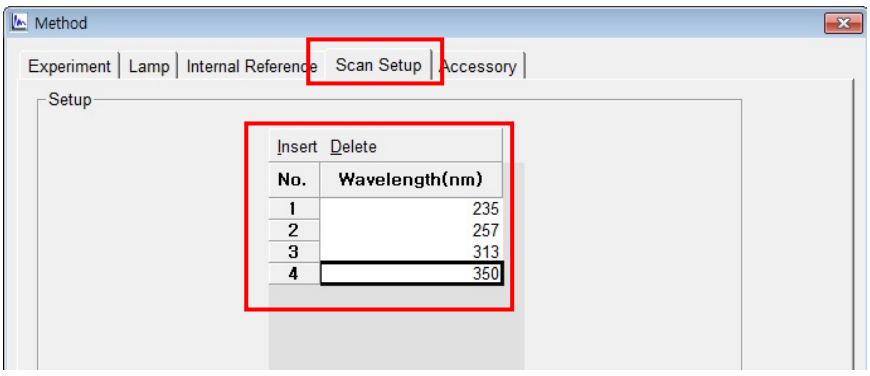
To test the Three Points Baseline correction function in the UV Express software, follow the steps below. Please refer to the software manual about the detailed information on the baseline correction.

1. Execute the Scan mode of UV Express software.

2. From the menu bar choose **File** then **Open** and navigate to the Folder 'C:\UV Express\SW Validation'. Highlight the file **BaseCorrection.dgdt** and select **Open**.

3. Click **Method** or **Scan Setup** icon, enter parameters of Internal Reference and Scan Setup tabs as shown below and click **Apply** and then **OK.**





4. Verify the results are the same as shown below. The values at each wavelength 235 nm, 257 nm, 313 nm, 350 nm are 0.7383, 0.8576, 0.2926 and 0.6405. If the results are the same, the single wavelength baseline correction test is passed.

Name	AU(235.00nm)	AU(257.00nm)	AU(313.00nm)	AU(350.00nm)
BaseCorrection	0.7383	0.8576	0.2926	0.6405

IV-7-5 Derivative Test

A. 1st Derivative Test

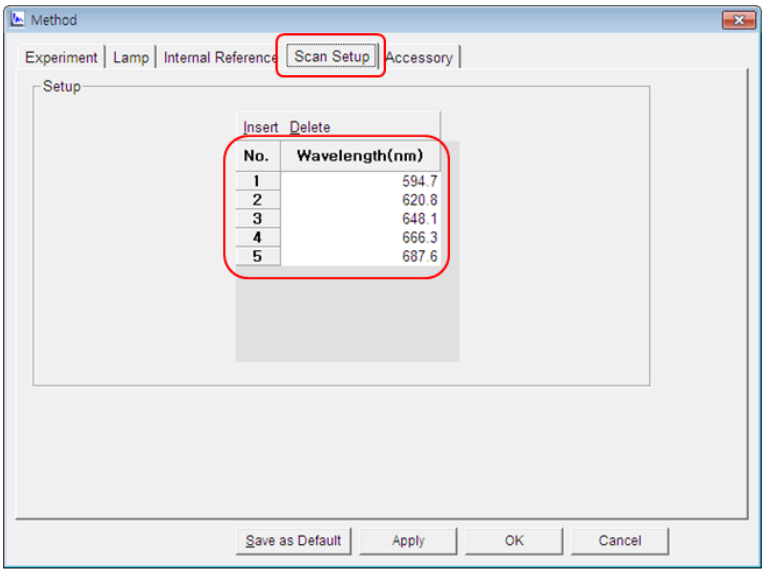
To test the 1st Derivative function in the UV Express software, follow the steps below.

1. Execute the Scan mode of UV Express software.

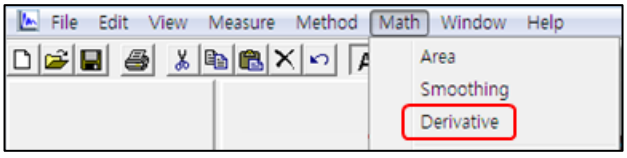
2. From the menu bar choose **File** then **Open** and navigate to the Folder 'C:\UV Express\SW Validation'. Highlight the file **Derivative.dgdt** and select **Open**.

3. Click **Method** or **Scan Setup** icon.

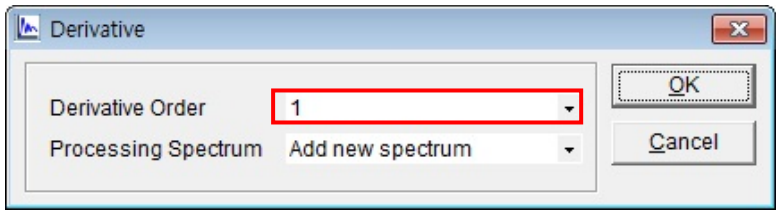
4. Enter wavelength values in the Scan Setup tab as shown below and click **Apply** and **OK**.



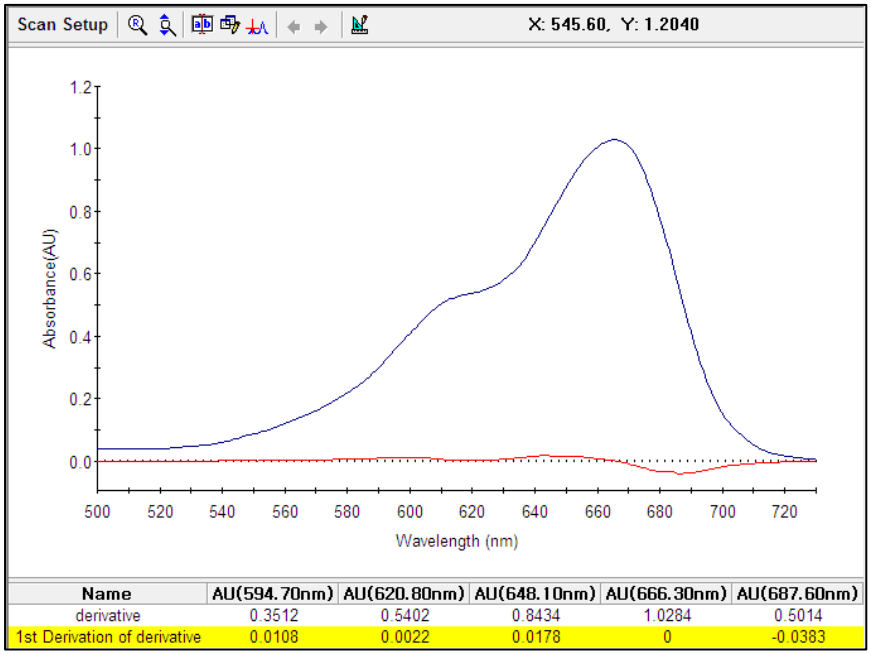
5. Click **Math** in the main menu and select **Derivative**.



6. Select 1 for Derivative order and click **OK**.



7. Verify the results are the same as shown below. The values at each wavelength 594.7 nm, 620.8 nm, 648.1 nm, 666.3 nm and 687.6 nm are 0.0108, 0.0022, 0.0178, 0 and -0.0383. If the results are the same, the 1st Derivative order test is passed.

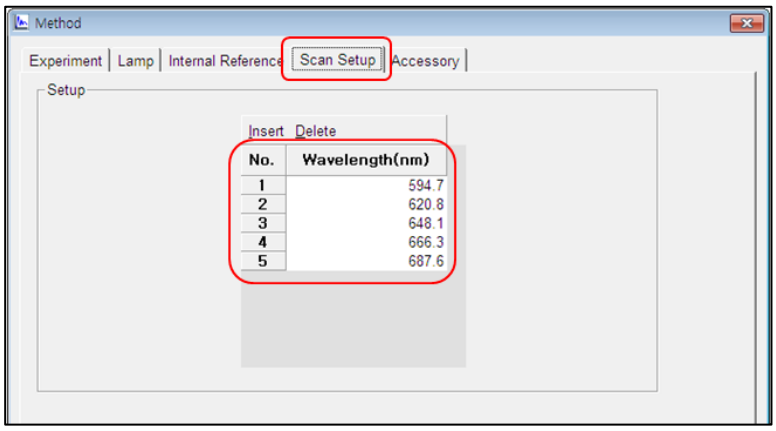


Name	AU(594.70nm)	AU(620.80nm)	AU(648.10nm)	AU(666.30nm)	AU(687.60nm)
derivative	0.3512	0.5402	0.8434	1.0284	0.5014
1st Derivation of derivative	0.0108	0.0022	0.0178	0	-0.0383

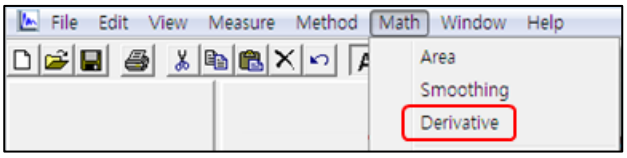
B. 2nd Derivative Test

To test the 2nd Derivative function in the UV Express software, follow the steps below.

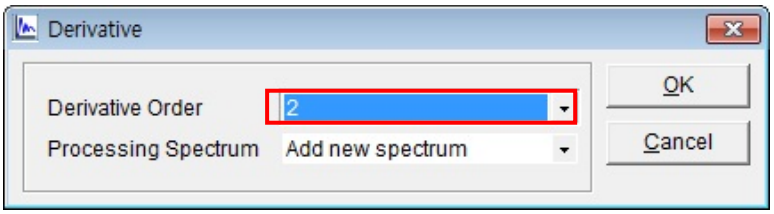
1. Execute the Scan mode of UV Express software.
2. From the menu bar, choose **File** and **Open,** and navigate to the Folder 'C:\UV Express\SW Validation'. Highlight the file **Derivative.dgdt** and select **Open**.
3. Click **Method** or **Scan Setup**. Enter wavelength values in the Scan Setup tab as shown below and click **Apply** and **OK**.



4. Click **Math** in the main menu and select **Derivative**.



5. Select 2 for Derivative order and click **OK**.



6. Verify the results are the same as shown below. The values at each wavelength 594.7 nm, 620.8 nm, 648.1 nm, 666.3 nm and 687.6 nm are 0, 0, -0.0001, -0.0017 and 0.0008. If the results are the same, the 2nd Derivative order test is passed.

Name	AU(594.70nm)	AU(620.80nm)	AU(648.10nm)	AU(666.30nm)	AU(687.60nm)
derivative	0.3512	0.5402	0.8434	1.0284	0.5014
2nd Derivation of derivative	0	0	-0.0001	-0.0017	0.0008

C. 3rd Derivative Test

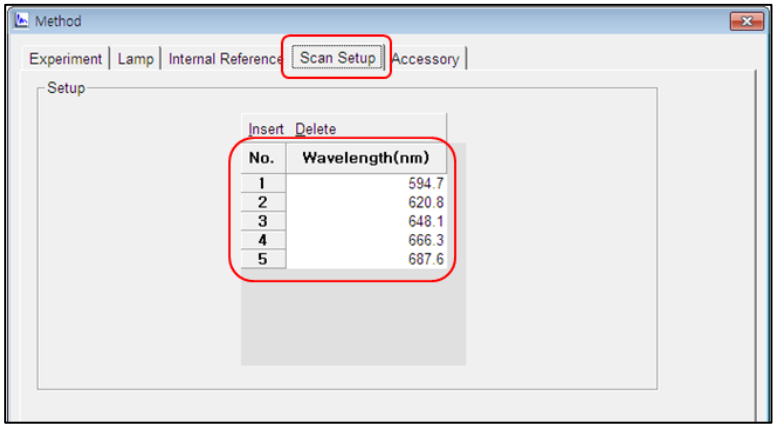
To test the 3rd Derivative function in the UV Lab software, follow the steps below.

1. Execute the Scan mode of UV Express software.

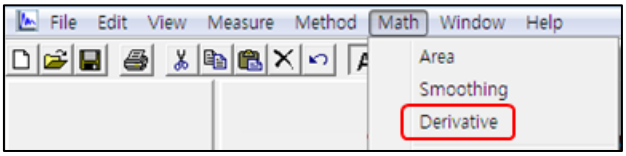
2. From the menu bar choose **File** and **Open,** and navigate to the Folder 'C:\UV Express\SW Validation'. Highlight the file **Derivative.dgdt** and select **Open**.

3. Click **Method** or **Scan Setup**.

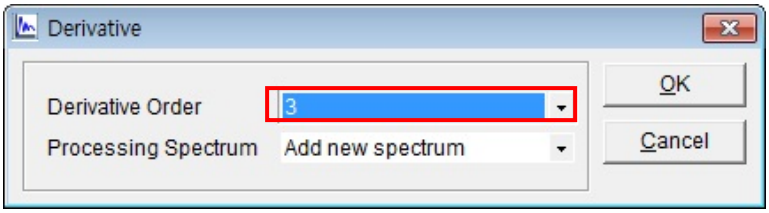
4. Enter wavelength values in the Scan Setup tab as shown below and click **Apply** and **OK**.



5. Click **Math** in the main menu and select **Derivative**.



6. Select 3 for Derivative order and click **OK**.



7. Verify the results are the same as shown below. The values at each wavelength 594.7 nm, 620.8 nm, 648.1 nm, 666.3 nm and 687.6 nm are -0.0001, 0.0002, -0.0002, -0.0001 and 0.002. If the results are the same, the 3rd Derivative order test is passed.

Name	AU(594.70nm)	AU(620.80nm)	AU(648.10nm)	AU(666.30nm)	AU(687.60nm)
derivative	0.3512	0.5402	0.8434	1.0284	0.5014
3rd Derivation of derivative	-0.0001	0.0002	-0.0002	-0.0001	0.002

D. 4th Derivative Test

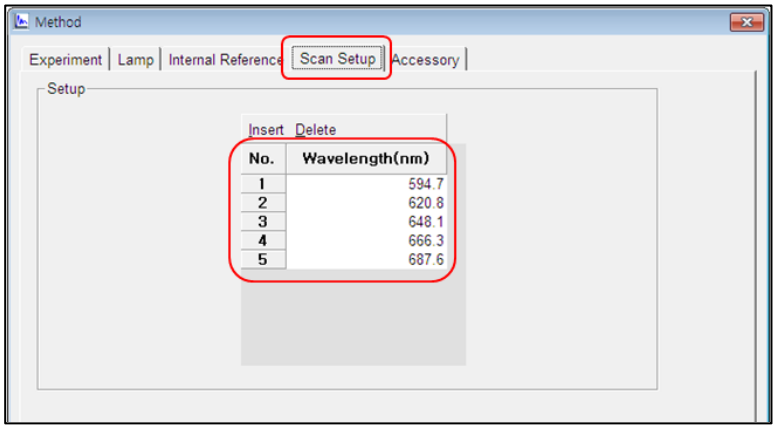
To test the 4th Derivative function in the UV Lab software, follow the steps below.

1. Execute the Scan mode of UV Express software.

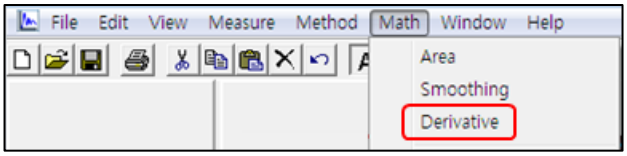
2. From the menu bar choose **File** and **Open,** and navigate to the Folder 'C:\UV Express\SW Validation'. Highlight the file **Derivative.dgdt** and select **Open**.

3. Click **Method** or **Scan Setup**.

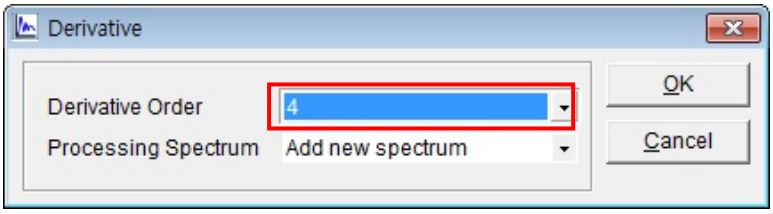
4. Enter wavelength values in Scan Setup tab as shown below and click **Apply** and **OK**.



5. Click **Math** in the main menu and select **Derivative**.



6. Select 4 for Derivative order and click **OK**.



7. Verify the results are the same as shown below. The values at each wavelength 594.7 nm, 620.8 nm, 648.1 nm, 666.3 nm and 687.6 nm are 0, 0.0002, -0.0003, 0.0001 and 0.0011. If the results are the same, the 4th Derivative order test is passed.

Name	AU(594.70nm)	AU(620.80nm)	AU(648.10nm)	AU(666.30nm)	AU(687.60nm)
derivative	0.3512	0.5402	0.8434	1.0284	0.5014
4th Derivation of derivative	0	0.0002	-0.0003	0.0001	0.0011

IV-8. Operation Qualification Worksheets

IV-8-1. Qualification Test Result

OQ-1. Qualification Test Result

System: Serial Number:

□Test of Spectrophotometer □UV Express Test Run Number:

Test Item	Equipment Information	Measured Result	Result
			□Pass □Fail
			□Pass □Fail
			□Pass □Fail
			□Pass □Fail
			□Pass □Fail
			□Pass □Fail
			□Pass □Fail
			□Pass □Fail
			□Pass □Fail
			□Pass □Fail
			□Pass □Fail

UV Express Validation Test Result Summary Attached? □Yes □No

Tester's signature : _____ Date:

Witness's signature (only sign if test passed): _____ Date:

IV-8-2. Comments of Operation Qualification

OQ-2. Comments of Operation Qualification

Items	Comments/Action

Tester's signature : _____ Date: _____

Customer's signature : _____ Date: _____

IV-8-3. Training of OQ process

OQ-3. Training Result Worksheet

Items	Action

Tester's signature : _____ Date: _____

Customer's signature : _____ Date: _____

V. Performance Qualification

V-1. Introduction to Performance Qualification

The aim of PQ is to provide evidence that, following initial assembly, the entire UV-Visible instrument is functioning correctly and within specification and that its performance remains satisfactory during routine use. The customer should be able to ask the supplier for guidance in designing their own PQ protocols.

For convenience, PQ can be considered as having two stages:

1) **Initial PQ** - performance testing following OQ to provide evidence that the complete UV-Visible instrument system functions correctly (some suppliers may include this type of holistic testing as part of OQ); and
2) **Ongoing PQ** - system suitability checking (SSC) to ensure fitness for purpose and continued satisfactory performance during actual use.

Following OQ, a supplier would normally be expected to carry out a holistic performance test to verify the correct functioning and performance of the entire instrument system. This 'Initial PQ' usually involves measuring a 'test sample' under defined operating conditions. This enables the performance of the method to be established over a period of time. It also enables the performance of the instrument to be compared with that of other instruments, either in the same laboratory or elsewhere. As such, this provides evidence that the instrument is functioning not only correctly, but that its performance is also predictable, comparable and within specification. However, while this type of holistic testing provides valuable evidence of satisfactory performance under one particular set of conditions, the actual conditions or range of conditions under which an instrument is normally used may be different. During normal routine use it is also highly likely that the performance of a UV-Visible instrument will change over time. Gradual deterioration in performance may result from contamination and normal wear of parts (*e.g.* contamination of mirrors, wear to mechanical wavelength drive, or loss of intensity from a source). There may also be more sudden changes in performance due to the failure of the instrument or one of its components. The user must, therefore, carry out further verification to demonstrate system suitability

and satisfactory instrumental performance before and during use. The user should establish appropriate procedures to monitor key performance characteristics and set warning and action thresholds outside which the instrument's performance is deemed to be no longer be acceptable for use (*e.g.* when the response to a CRM is not as expected). These verifications do not need to be burdensome and can be built into system suitability checking and analytical quality control (AQC). They may need to be established for a variety of conditions.

For example, prior to performing a fixed wavelength measurement, absorbance linearity should be assessed by calibrating the instrument with, *e.g.* a series of neutral density filters, covering the range of anticipated results, plus a suitable safety margin (typically a further 20%). This type of calibration should be performed before sample analysis or at an interval specified in a standard operating procedure, the frequency of which should, as a minimum, be based on the period over which the instrument has previously been found to remain within calibration. The precision should be determined from the coefficient of variation (CV) of responses to replicate measurements of a CRM. Acceptable precision is often defined in methods as part of system suitability requirements but, as a rule of thumb, CVs greater than, *e.g.* 1%, are generally unacceptable. During use, a control sample should be analyzed at regular intervals to confirm that the instrument remains within calibration. SSC can also provide an indication of which parts of the measurement system are not performing satisfactorily. Using a variety of tests may be beneficial for tracing faults when they occur.

For routine use, the most important parameters are wavelength reproducibility, photometric reproducibility and photometric linearity. Calibration under the same environmental conditions as used for samples usually compensates for temperature effects on wavelength and photometric inaccuracies.

V-2. Performance Qualification Procedure

The PQ procedure typically comprises the following steps;

1. **Defining the performance criteria and test procedures**
   This information can be derived from the Operation Qualification (OQ) tests.
   If you purchase the Standard Kit for validation from PerkinElmer, OQ can be easily performed using UV Express Validation Package.

2. **Select the test item**
   For example, if wavelength accuracy is important for the customer site, this should be added in the test item.

3. **Defining acceptance level and the equipment used**

4. **Defining the PQ testing interval**
   i. Daily
   ii. Weekly
   iii. Every 30, 90, 180 days
   iv. Annually

5. **Defining the time of PQ testing**
   i. Before every production run
   ii. As specified hours
   iii. On specified days

The operator must make a plan for Performance Testing using the PQ-1 Worksheet and report the test result using OQ-1 Worksheet after finishing the PQ test. When the Qualification
process is performed or service action is done by the manufacturer, record the action result in the PQ-2 Worksheet (System Maintenance Log).

V-3. Performance Qualification Worksheet

V-3-1. Performance Qualification Plan

PQ-1. Qualification Plan

System:			Serial Number:	
□ Spectrophotometer □UV Express software			Test Run Number:	
Test Item	Equipment	Acceptance Level	Test period	Test Time

Planner's signature :_____ Date: _____

Witness's signature:_____ Date: _____

V-3-2. System Maintenance Log

PQ-2. System Maintenance Log

System: Serial Number:

Test Item	Observation	Action	Decision	Operator
			□Pass □Fail Date:_____	
			□Pass □Fail Date:_____	
			□Pass □Fail Date:_____	
			□Pass □Fail Date:_____	
			□Pass □Fail Date:_____	
			□Pass □Fail Date:_____	
			□Pass □Fail Date:_____	
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			□Pass □Fail Date:_____	
			□Pass □Fail Date:_____	
			□Pass □Fail Date:_____