BIOSPECTRA

100 Majestic Way, Bangor, PA 18013 / www.biospectra.us

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LAMBDA 25 UV VIS OPERATION AND CALIBRATION

1. PURPOSE:

1.1. To provide the Quality Control (QC) Laboratory personnel with operation and calibration instructions for the PerkinElmer Lambda 25 UV/Vis Spectrophotometers.

2. SCOPE:

2.1. Applies to the operation and calibration of the PerkinElmer Lambda 25 Spectrophotometers located at both the Stroudsburg and Bangor, PA facilities.

3. RESPONSIBILITIES:

3.1. The QC Manager, or other qualified designated individual, is responsible for the implementation, control, training and maintenance of this procedure.

3.2. All QC laboratory personnel are responsible for complying with the requirements of this procedure.

3.3. If any abnormalities are determined during routine use of the spectrophotometer or during calibration, the QC Manager shall be promptly notified. If necessary, the spectrophotometer will be serviced and recalibrated by an outside calibration firm before being approved for use.

4. REFERENCES:

4.1. PerkinElmer Lambda 25, 35, 45 Spectrophotometer User's Guide.

4.2. Calibration

5. EQUIPMENT:

5.1. PerkinElmer Lambda 25 Spectrophotometer.

5.2. 10.00mm Rectangular Sample Cells.

5.3. 100.0mm Rectangular Sample Cells.

5.4. PerkinElmer Secondary Absorbance Standards Kit.

6. OPERATION PROCEDURE:

6.1. For optimal performance, the lamps should be allowed to warm up for one hour prior to use.

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6.1.1. The instrument will go through a start-up procedure that will take approximately 3 minutes.

6.1.1.1. Ensure that there is nothing obstructing the light path during the startup procedure.

6.2. Open the UV WinLab software and log in.

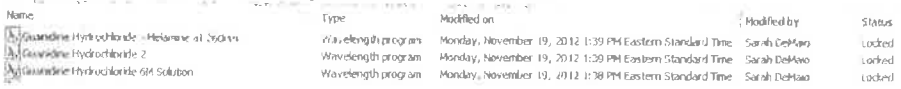
6.2.1. Each analyst has a unique login. The username is the first initial and last name of the analyst performing the analysis and the password is known only to that analyst.

6.2.2. Once the software is loaded, the home screen will open.

6.3. Selecting and Using a Method

6.3.1. Selecting Method

6.3.1.1. Select the folder containing the method desired.



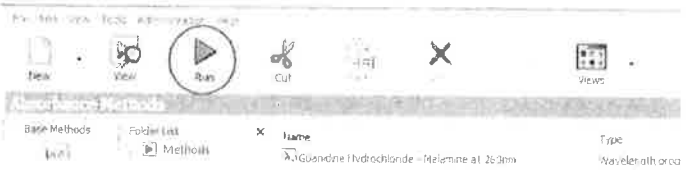
6.3.1.2. When selecting a method, ensure that the method Status is "Locked."

6.3.1.2.1. If the status is locked, this means that the QC Manager or qualified designee has approved this method as acceptable for use and it cannot be edited without approval.

6.3.1.2.2. If the method needed is not locked, notify the QC Manager.

6.3.1.2.3. If the method required is not yet developed, notify the QC Manager for assistance.

6.3.1.2.4. Highlight desired method with cursor and select "Run" at the top of the home screen.



6.3.1.2.5. The method will load and open to the Sample info tab of the method process.

6.3.1.2.6. This is where all sample information will be entered. The number of samples to be run can be changed here as well.

6.3.1.2.7. None of the other parameters will be able to be adjusted as the method is locked for editing by the QC Management or QC Compliance.

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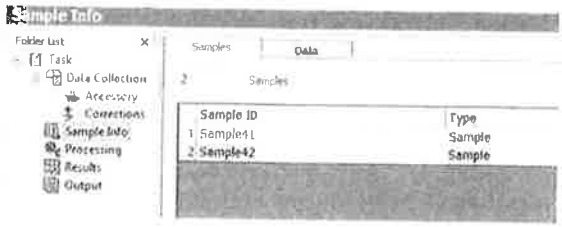
6.3.1.2.8.6.3.1.2.8.



6.3.1.2.9. Enter the lot number into the Sample ID column. The type of sample should not change. Once all sample information is entered, ensure that the instrument is free of cuvettes and that nothing is blocking the light path of the instrument.

6.3.1.2.10. Select "Start" from the top of the screen.

6.3.1.2.11. 100% / 0A Baseline (Autozero) upon task start. The instrument will prompt this at the start of each method. Blank the instrument by filling each cuvette with the diluent or solvent that the sample will be dissolved in. Ensure that the cuvette is clean and free of any smudges or dust prior to placing the matched cells into the cell holder.

6.3.1.2.11.1. When the sample of interest is the diluent perform the 100% / 0A Baseline (Autozero) using empty cuvette holders.

6.3.1.2.12. Once the baseline is complete, the instrument will prompt to add the sample.

6.3.1.2.13. Remove the cell from the front cell holder and empty.

6.3.1.2.14. Prepare the sample as indicated by the designated method, and transfer to the cuvette. Ensure that the cuvette is clean and free of smudges prior to running. Place the cell in the front cell holder. Leave the diluent blank from the autozero task in the rear cell holder.

6.3.1.2.15. Once both the sample and the diluent blank are in place, click "OK" to the prompt. The instrument will then run the absorbance versus the blank and report the results.

6.3.1.2.15.1. If multiple samples are being run, the instrument will continue to prompt to add samples until all samples in the sample info table have been analyzed.

6.3.1.2.15.2. The instrument will prompt when all sample analysis is completed.

6.3.1.2.16. Results are printed upon closure of the method and saved into the audit trail.

6.3.1.2.17. The method MUST be closed in order for the results to print.

6.3.1.2.18. When the report is printed, sign and date at the top of the report page. If the report is multiple pages, staple them together and initial and date the subsequent pages.

7. MONTHLY INSTRUMENT PERFORMANCE VERIFICATION:

7.1. Three tests will be performed on a monthly basis to ensure that the instrument is still within calibration.

7.2. The UV Standard Set to be used is calibrated by PerkinElmer without a due date of next calibration. As per advice from PerkinElmer, the standards will be given a three year calibration time frame.

7.3. Baseline Stability Test

7.3.1. Select the Baseline method from the Calibration Methods folder located in the BioSpectra folder.

7.3.2. No Standards or solutions are required for this analysis.

7.3.3. The instrument will perform a baseline, and then analyze the absorbance from 200-1100 nm at a speed of 240nm per minute. The lamp change over point should be set to 326 nm.

7.3.4. The baseline flatness limit should be set to 0.001 A.

7.3.5. Once the analysis is completed an IPV (Instrument Performance Verification) Report will print.

7.3.5.1. On the top of page 2, in the fourth column, will be the IPV test result.

7.3.5.2. If the result is FAIL, please notify the QC Manager immediately.

7.4. Photometric Accuracy Glass

7.4.1. Select the Photometric Accuracy Glass from the Calibration Methods folder located in the BioSpectra folder.

7.4.2. The UV Standards set will be needed for this calibration.

7.4.3. The following standards will be used: G1, G2 and G3.

7.4.4. When filling out the Sample Info file, the following information is required:

Sample ID	Wavelength (nm)	Nominal Absorbance (A)	Measured Absorbance (A)	Difference (A)	Accuracy Limit (A)	IPV Test Result
G1.Sample	440.00	0.2986	0.2994	0.00079	0.0030	PASS
G2.Sample	440.00	1.0097	1.0107	0.00104	0.0030	PASS
G3.Sample	440.00	0.4936	0.4944	0.00078	0.0030	PASS

7.4.5. The Nominal Absorbance is obtained from the certificate of calibration for the standards.

7.4.6. The Accuracy Limit is obtained from the instrument deviation (±0.003) and the limit from the certificate of calibration (0.0025).

7.4.7. The instrument will prompt the user to insert the correct standards at the appropriate time.

7.4.8. Once the analysis is completed an IPV Report will print.

7.4.8.1. In the middle of the first page, in the seventh column, will be the IPV test results.

7.4.8.2. If any of the results are FAIL, please notify the QC Manager immediately.

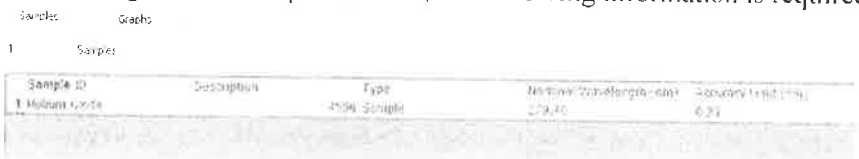
7.5. Wavelength Accuracy

7.5.1. Select the Wavelength Accuracy Glass from the Calibration Methods folder located in the BioSpectra folder.

7.5.2. The UV Standards set will be needed for this calibration.

7.5.3. The following standards will be used: Holium Oxide

7.5.4. When filling out the Sample Info file, the following information is required:



7.5.5. The Nominal Wavelength is obtained from the certificate of calibration for the standard.

7.5.6. The Accuracy Limit is obtained from the limit from the certificate of calibration (0.25nm).

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7.5.7. The instrument will prompt the user to insert the correct standard at the appropriate time.
7.5.8. Once the analysis is completed an IPV Report will print.
7.5.8.1. In the bottom of the first page, in the seventh column, will be the IPV test result.
7.5.8.2. If the result is FAIL, please notify the QC Manager immediately.
7.6. Calibration documentation will be kept in the QC Lab in the binder labeled Lambda 25 Calibration Documentation.
7.7. It is not necessary to write the analysis up in the calibration notebook.
7.8. Calibration is performed annually by a certified PerkinElmer Service Technician. This calibration data will also be kept in the Lambda 25 Calibration Documentation binder. PerkinElmer will place an additional calibration sticker on the instrument.
7.8.1. When stating the due date of next calibration, the date that is soonest should be used if the BioSpectra due date and the PerkinElmer due date are different.

8. MAINTENANCE:

8.1. To protect the optical system from dust and fumes, keep the sample compartment closed except for when in use.
8.2. Immediately clean all spilled materials from the affected area with a KimWipe.
8.2.1. If the sample compartment windows need to be wiped make sure not to scratch the windows.
8.3. Do not leave samples in the sample compartment for longer than necessary.
8.4. Cleaning the sample compartment:
8.4.1. The sample compartment must be cleaned every time something is spilled. This prevents corrosion and contamination
8.4.2. The instrument is equipped with sample compartment baseplate that has drain holes in the bottom to allow spilled liquid to run off onto the bench top.
8.4.2.1. Remove the cell holder from sample compartment.
8.4.2.2. Use a soft cloth and mild laboratory detergent to lightly scrub away any foreign material.
8.4.2.3. Use a clean dampened cloth to rinse the surfaces carefully.
8.4.2.4. Dry with a KimWipe.
8.5. Cleaning the sample compartment windows:
8.5.1. Leave the window installed.
8.5.2. Wipe the window with a soft cloth moistened with ethanol.
8.6. Replacing a Lamp
8.6.1. Due to the extensive procedure, please refer to the PerkinElmer User's guide pages 83-92.
8.7. Cleaning the UV Cells
8.7.1. If the cells become contaminated, or if they are foggy and this cannot be removed with water, soak the cells in 3N hydrochloric acid overnight.
8.7.1.1. Using a Q-tip, clean all sides and corners of the optical cell and then rinse several times with purified water.
8.8. PerkinElmer Maintenance should be scheduled on an annual basis. The next due date should appear on the PerkinElmer sticker and should be replaced upon their visit.
8.8.1. Any documentation from this visit at the Stroudsburg Facility should be stored in the Lambda 25 Documentation binder.
8.8.2. Any documentation from this visit at the Bangor facility should be stored in the PerkinElmer Lambda 25 binder under the Maintenance section.

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