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BIOSPECTRA

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SPECTRUM TWO UATR SOP

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1. PURPOSE:

1.1. To provide the Quality Control (QC) Laboratory personnel with operation and calibration instructions for the PerkinElmer Spectrum Two FT-IR Spectrometer and UATR attachment.
1.2. To provide the QC Laboratory personnel with a procedure to verify the identity of a specified material by examining absorption in the Infrared region of the electromagnetic spectrum.

2. SCOPE:

2.1. Applies to the operation and calibration of the PerkinElmer Spectrum Two Spectrometers located at both the Stroudsburg and Bangor facilities.
2.2. Finished Goods and Stability samples must be prepared according to the product's LOD procedure, unless the product does not require LOD analysis.
2.3. Raw Material samples: analyze As-is.
2.4. Repack samples: analyze As-is.
2.4.1. Note: There is no discrepancy if a Raw material sample or repack sample is analyzed with a LOD sample.
2.5. The user settings set forth in this SOP are recommended for optimal performance of the ES software.

3. RESPONSIBILITIES:

3.1. The Director of Quality Control or other qualified designated individual is responsible for the implementation, control, training and maintenance of this procedure.
3.2. The Director of Quality Control, or other qualified designated individual, is responsible for the visual inspection of spectra with a correlation below 0.95.
3.3. All QC laboratory personnel are responsible for complying with the requirements of this procedure.
3.4. If any abnormalities are determined during routine use of the spectrometer or during calibration, the Director of Quality Control shall be promptly notified. If necessary, the spectrometer will be serviced and recalibrated by PerkinElmer before being approved for use.

4. REFERENCES:

4.1. Calibration
4.2. PerkinElmer Spectrum Two User's Guide
4.3. USP Reference Standards Catalog

5. EQUIPMENT:

5.1. PerkinElmer Spectrum Two Spectrometer
5.2. PerkinElmer UATR Two Attachment

6. MAINTENANCE:

6.1. To protect UATR crystal from moisture or damage, place the plastic cover over the UATR attachment when not in use.
6.2. Clean the UATR crystal and swinging arm with a KimWipe and methanol.
6.3. Immediately clean any spilled materials on or around the instrument with a paper towel.
6.4. For optimal performance, the instrument should remain on at all times and be connected to a battery back-up source.

6.4.1. In the case of a power outage, the battery backup will allow enough time to properly shutdown the instrument.

6.4.1.1. In order to shut the instrument down, press the standby button located on the front right side of the instrument. Once the light turns orange, the power plug can be disconnected from the back of the instrument.

7. PREPARATION OF REFERENCE STANDARDS:

7.1. Each product must have a USP or in-house prepared Reference Standard.

7.2. USP standards should be prepared according to the recommendations listed on the vial.

7.3. In-house Reference Standards for solid materials should be prepared by weighing approximately 5.0 grams of material from an outside source and drying according to that product's LOD procedure.

7.3.1. Allow the standard to cool and store in a desiccator. Cap the LOD vial once it has cooled.

7.3.2. Record the preparation in the Solution Preparation laboratory notebook and assign a one year expiration date.

7.3.3. Label the LOD vial with the Solution Preparation Lot Number, expiration date, whom it was prepared by, and the date it was prepared.

7.4. Run the Reference Standard once and compare it to a previously approved reference scan.

7.5. If a USP standard is available, scan the USP standard once and compare it to the Reference Standard.

7.5.1. The Correlation must be greater than 0.95 between each scan.

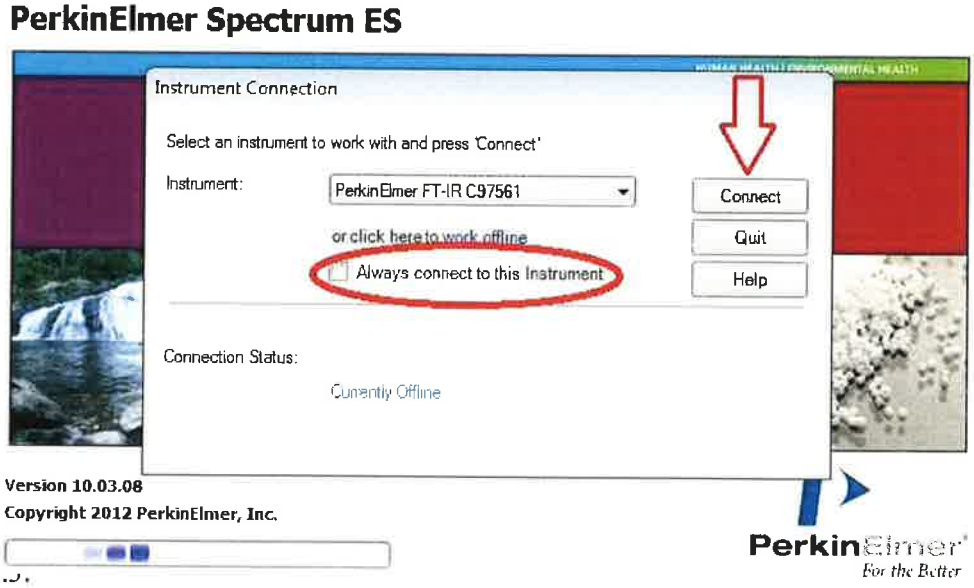
8. OPERATION:

8.1. Log in to the computer using the General Windows login for the computer. The Password will be changed on a frequency established by the internal IT department at Biospectra.

8.2. Open the Spectrum software and log in.

8.2.1. 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.

8.2.2. After logging in, the following screen will appear:



8.2.3.8.2.3.

8.2.4. Make sure the Instrument being used is selected and then click "Connect".

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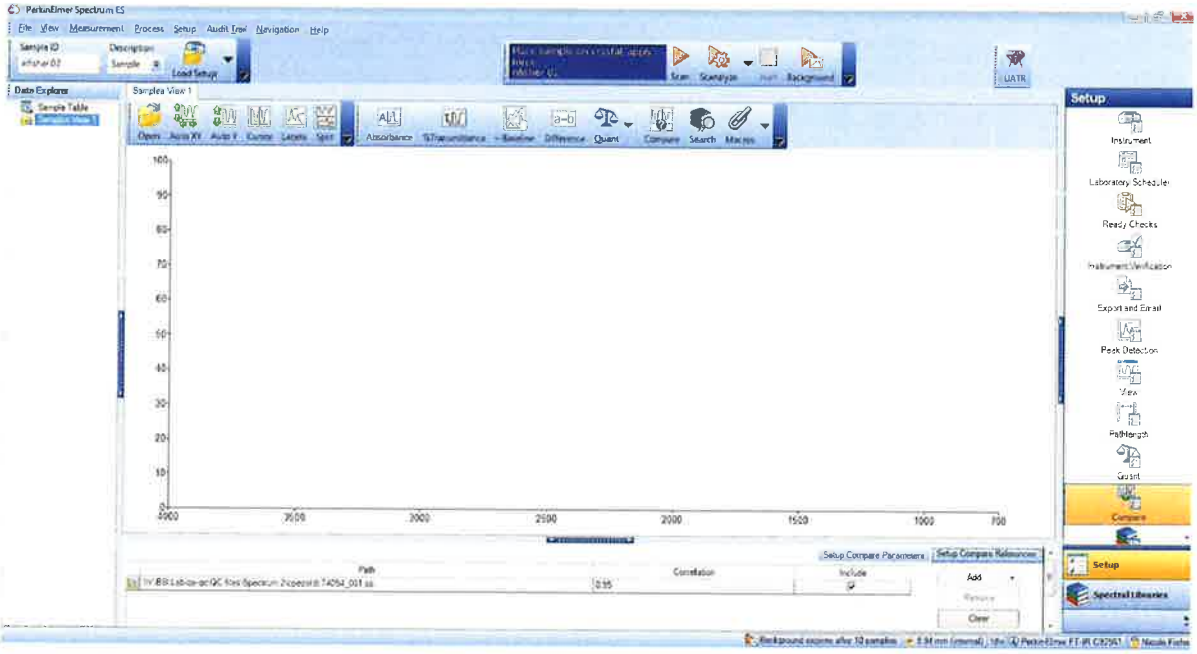
8.2.4.1. **NEVER check the box for the "Always Connect to this Instrument" option. If this happens, contact your supervisor to correct your user settings.**

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



8.2.6.

8.3. Perform a background scan prior to use each day and after every ten samples.

8.3.1. Remove the plastic cover and clean the UATR crystal using methanol and a KimWipe.

8.3.2. With the swinging arm to the side, click Background at the top of the screen.

8.4. Each analyst must run a Reference Standard prior to analyzing a product. A Reference Standard may be compared to multiple lots of the corresponding product on that day.

8.4.1. Note: If a reference standard is unavailable it is acceptable to refer to historical scans of reference standards. It should be noted in the appropriate documentation that the standard was unavailable at the time of use.

8.4.2. Enter the Lot Number, Expiration Date, date of analysis, and analyst initials in the Sample ID.

8.4.3. Place the Reference Standard on the UATR crystal using a static free scoop.

8.4.4. Align the swinging arm with the crystal and apply force by turning the green arm clockwise.

8.4.5. Press "Scan" on the top Toolbar. The program will preview the sample. Turn the green arm until the Force Gauge is approximately 125, or until the noise has subsided.

8.4.6. Once the Force Gauge is adjusted, press "Scan".

8.4.7. Once the scan is complete, release the swinging arm by turning it counterclockwise.

8.4.8. Clean the UATR crystal and the swinging arm with methanol and a KimWipe.

8.5. A sample can be analyzed by following steps 8.4.1 through 8.4.8.

8.5.1. The LOD sample must be used for Finished Goods and Stability, unless the product does not require LOD analysis.

8.5.2. Raw Material samples: analyze As-is.

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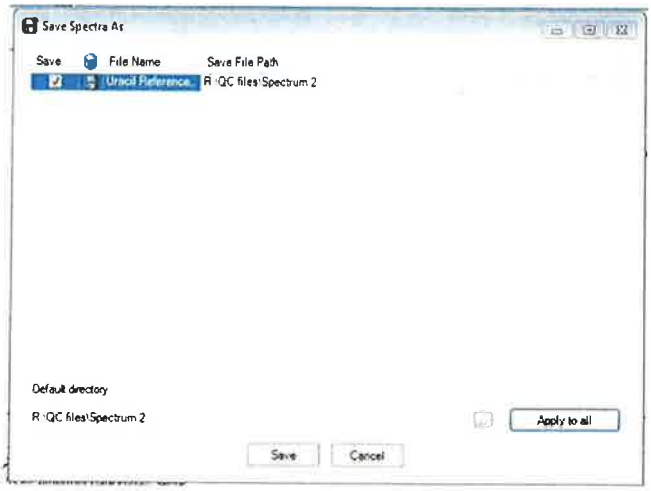
8.5.3. Wet Crystal samples should be analyzed As-is. If the appropriate correlation is not met due to water interference, the sample may be dried and analyzed as per the LOD analysis for that product.

8.6. Save all scans by choosing "File" then "Save As". The following screen will appear:



8.7.8.

8.7.1. Select "Apply to all" and "Save".

8.8. In the "Setup" pane on the right hand side, choose "Compare". On the bottom pane click the "Setup Compare References" tab.

8.9. Click "Clear" to remove any previous Reference Scans. Click "Add" then "Single Spectrum". Select the Reference Standard from step 8.4 in the Spectrum 2 folder.

8.10. Change the Correlation to 0.95. The "Setup Compare References" tab should appear as shown below.

8.11.

8.12. Select the sample being analyzed in the left hand pane.

8.13. In the top left toolbar select "Measurement" then "Compare". The Reference Standard and sample will be overlaid on the same spectrum and compared with a Correlation coefficient.

8.13.1. If the correlation is above 0.95, the comparison will be reported with Pass as the result.

8.13.2. If the correlation is below 0.95, the comparison will be reported as Fails and are subject to visual inspection by the QC Manager or qualified designee.

8.14. Print the report by clicking "File" then "Print". When the report is printed, initial 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.

9. CALIBRATION:

9.1. If the UATR attachment is removed, the functionality of the attachment must be tested prior to its next use.

9.1.1. Choose "Measurement", then "Instrument Checks", then "Ready Checks", then "Run Selected". All tests must pass in order to use the attachment.

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9.2. The Instrument Verification will be performed on a monthly basis to ensure that the instrument is still within calibration.
  9.2.1. To run Instrument Verification choose "Measurement", "Instrument Checks", then "Instrument Verification".
  9.2.2. The following tests will be completed:
    9.2.2.1. Abscissa Check
    9.2.2.2. Noise Check
    9.2.2.3. Ordinate Check
9.3. Once all tests are performed print the report by choosing "File" then "Print".
  9.3.1. 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.
9.4. If any tests report "Fails", notify a supervisor immediately.
9.5. Calibration and Instrument Verification documentation will be stored in the QC Laboratory in the UATR Two binder.
9.6. Document in the appropriate instrument notebook that the calibration has been performed.
  9.6.1. The reference on the instrument calibration sticker should be to the binder that the data is located in.
9.7. Calibration is performed annually by a certified PerkinElmer Service Technician. This calibration data will also be kept in the UATR Two Documentation binder. PerkinElmer will place an additional calibration sticker on the instrument.
  9.7.1. 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.

10. ANALYSIS OF UNKNOWN MATERIALS:

10.1. Ensure there is enough material for analysis.
  10.1.1. If there is not enough material for analysis contact the sample owner (the individual that submitted the sample) to increase the amount submitted.
10.2. Analysis of unknown materials will follow steps 8.4.1. to 8.4.8.
10.3. Since a formal lot identification may not be established for items submitted to the Quality Control laboratory for investigation or research purposes the sample should include a unique description. This may be a physical description and then a date or time for example.
10.4. Setup the appropriate compare library and compare the spectra through appropriate data bases, internal or external.
10.5. Report the best match.