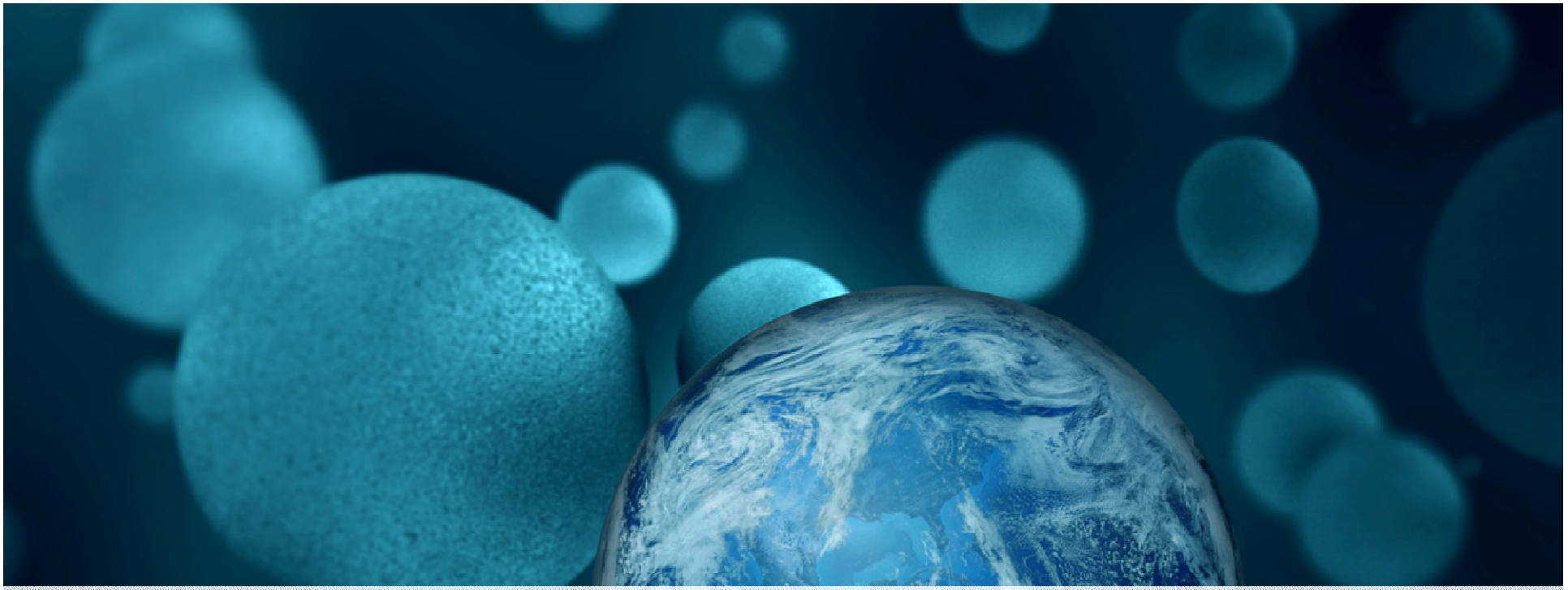


ThermoFisher SCIENTIFIC

Sharing Information & Achieving Secure and Compliant Data Management

Maarten van As
Account Manager Informatics

The World Leader in Serving Science

Global Scale

- 50,000 employees in 50 countries
- $17 billion in annual revenues
- Unparalleled commercial reach
- 10,000 employees working with customers every day

Unmatched Depth

- Innovative technologies
- Applications expertise
- Lab productivity partner

Premier Brands

life technologies

Thermo SCIENTIFIC

Fisher Scientific

Unity Lab Services

ThermoFisher SCIENTIFIC

Thermo Fisher Scientific Informatics

Unparalleled Industry Expertise

- Informatics provider for over 32 years
- Over 300 dedicated employees with 100 in-house services personnel
- Second to none LIMS, SDMS, spectral & integration capabilities
- Over 1500 LIMS implementations
- Strategic partnerships with hardware & software vendors
- ISO 9001:2008 compliant QMS for global Development, Sales Services & Support
- Integration & paperless lab specialists

Thermo Scientific CONNECTS™

The Leader in Laboratory Productivity

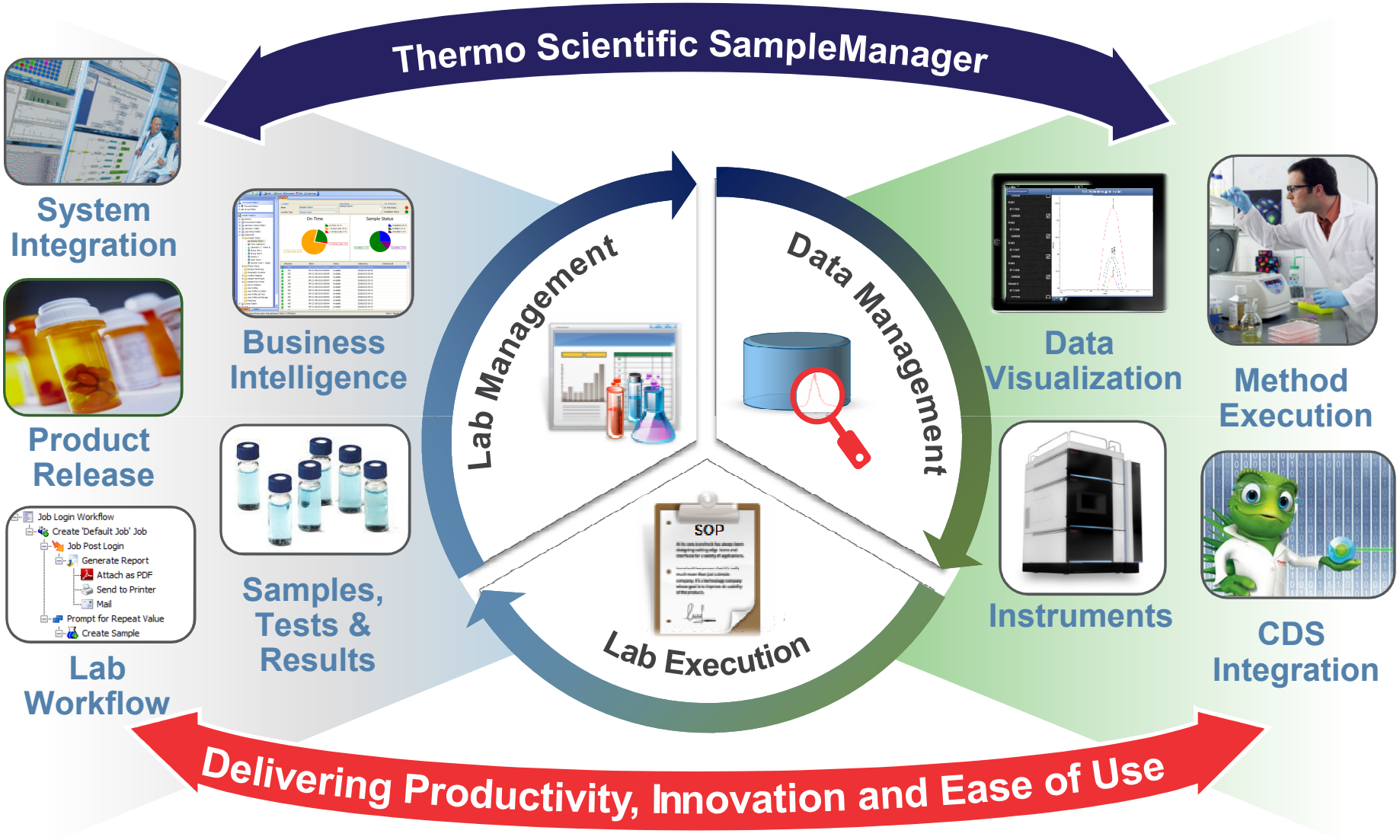
Global Presence

Local Reach

- UK & NL Based Support Desk
- NL Based Implementation services
- Partner network
- Local Account Management.

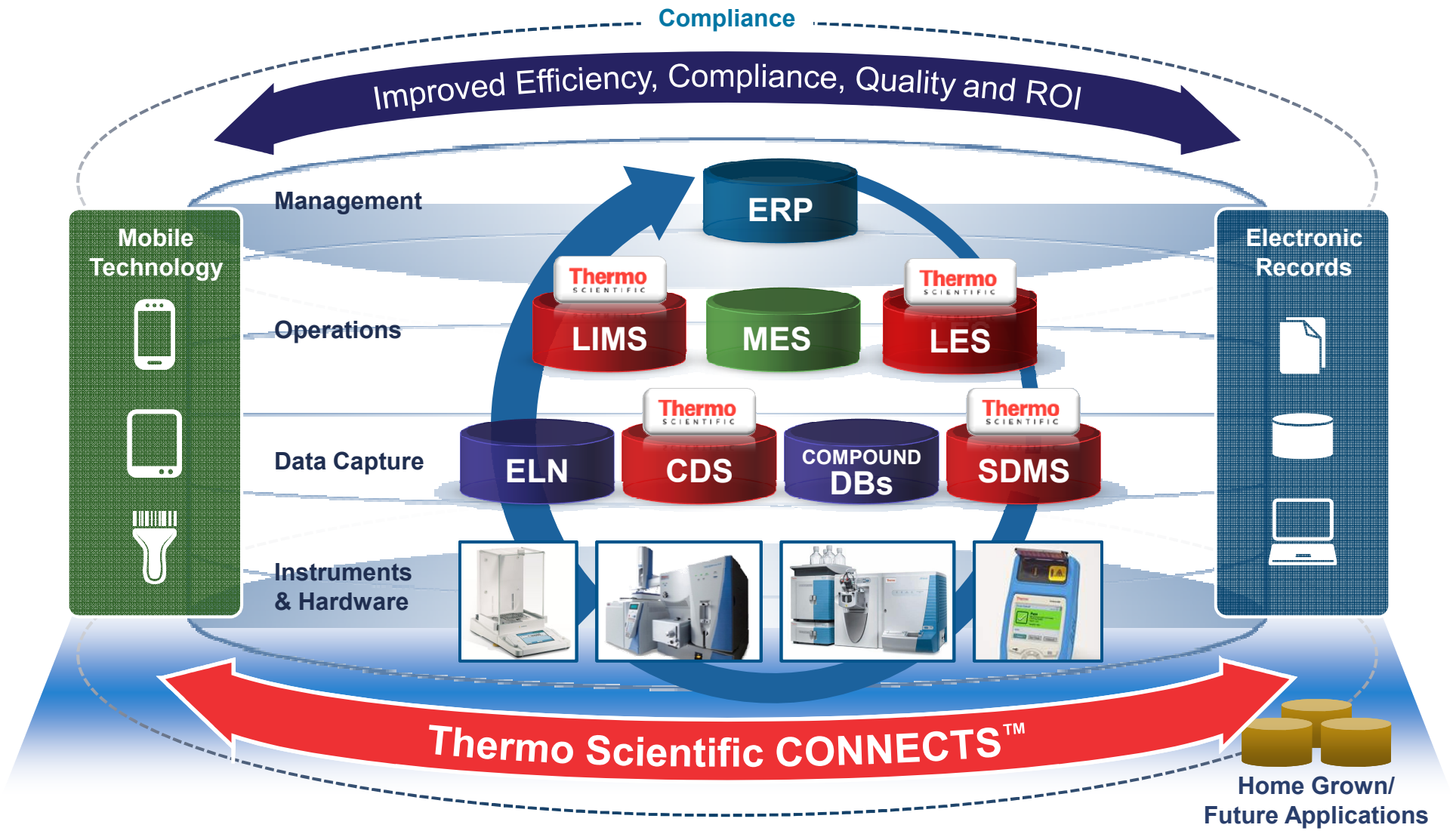
ThermoFisher SCIENTIFIC

Integrated Laboratory Informatics Solution



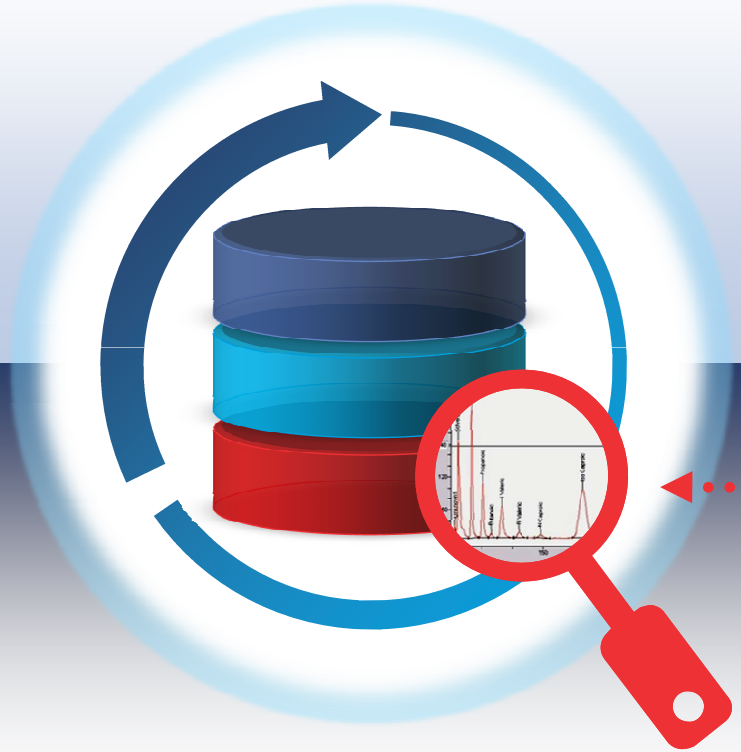
ThermoFisher SCIENTIFIC

Improve Quality
Delivering The Paperless Lab Environment



ThermoFisher SCIENTIFIC

Data Management
Thermo Scientific Data Manager



Real-time raw data access
anytime, anywhere, any format

Data Management
The problem faced by scientists across the globe

- Laboratories produce vast amounts of data from a number of different scientific instruments
  - MS, ICP, FTIR, UV, AA, LC, GC, SEM.....
- Some questions.....

How do you make sure you can access the original raw data?

How do you centralise this data?

How do you collect all these different data types from each instrument efficiently?

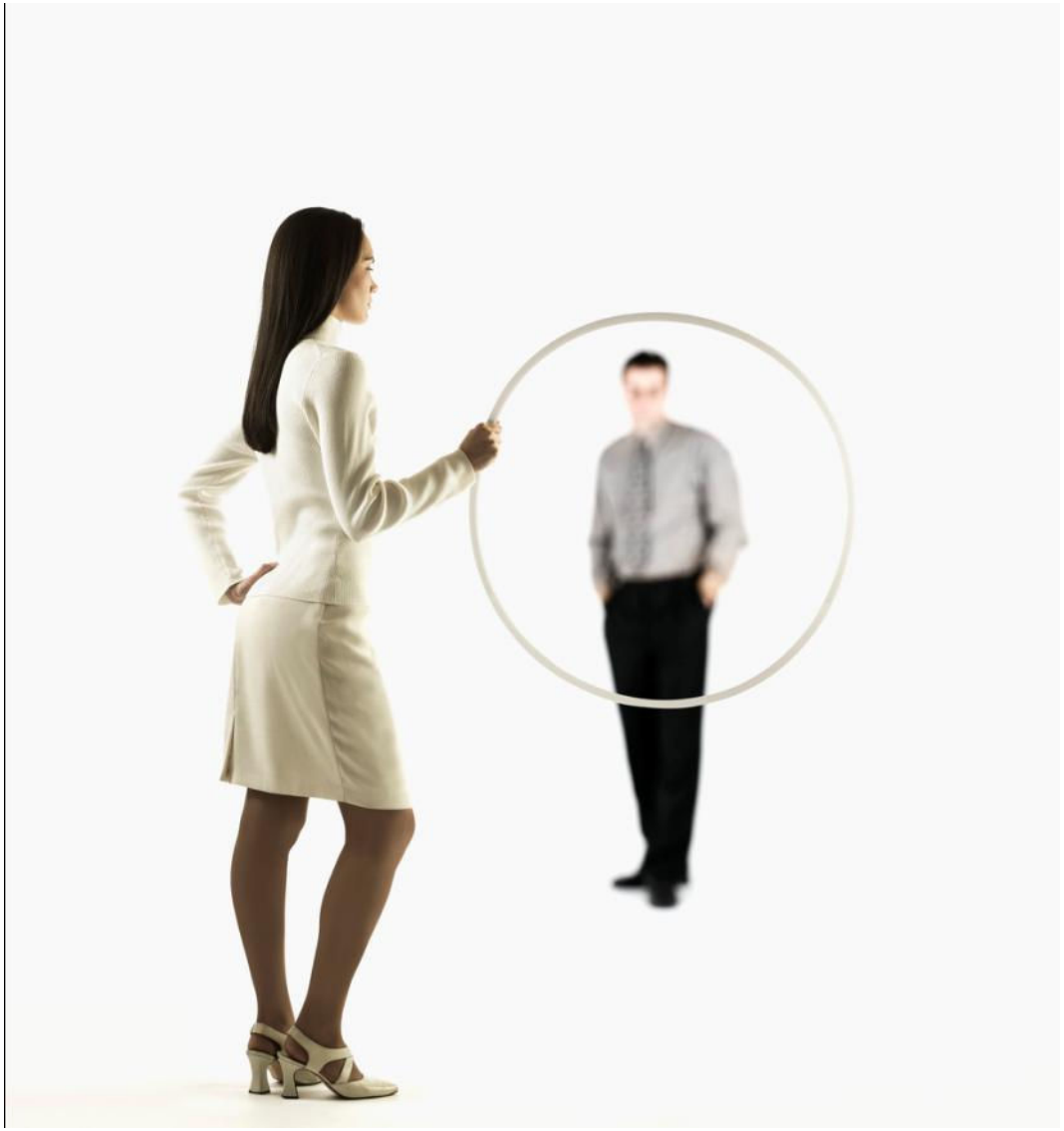
How do you share this data?

How do you search all this data?

How do you future proof this data?

The regulatory drivers to manage data?

- Food and Drugs Administration
- Drinking Water Inspectorate or country specific bodies
- UKAS
- ISO 17025
- Patent Practices



US Food and Drugs Administration

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Silver Spring MD 20993

Warning Letter

VIA UPS MAIL

WL: 320-12-08

February 23, 2012

Dr. Ayman Sahli
Chief Executive Officer
Gulf Pharmaceutical Industries
P.O. Box 997
Airport Road, Digdaga Area
Ras al Khaimah, UAE

Dear Dr. Ayman Sahli:

During our September 25 to October 3, 2011 inspection of your pharmaceutical manufacturing facility, Gulf Pharmaceutical Industries, located at Airport Road, Digdaga Area Ras Al Khaimah, United Arab Emirates, investigators from the U.S. Food and Drug Administration (FDA) identified significant violations of Current Good Manufacturing Practice (CGMP), Title 21, Code of Federal Regulations, Parts 210 and 211. These violations cause your drug product(s) to be adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 351(a)(2)(B)] in that the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with, CGMP.

We have reviewed your firm's response of October 28, 2011, and note that it lacks sufficient corrective actions.

Specific violations observed during the inspection include, but are not limited to, the following:

US Food and Drugs Administration

4. Your firm has not established appropriate controls over computer or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel. Your firm also fails to maintain a backup file of data entered into the computer or related system [21 CFR § 211.68(b)].

For example,

a) There is no system in place to ensure that all electronic raw data from the laboratory is backed up and/or retained.

During the inspection, you informed our investigators that electronic raw data would not exist for most HPLC assays over two years old because data is not backed up and storage space is limited.

Data is deleted to make space for the most recent test results. You also informed our investigators that printed copies of HPLC test results are treated as raw data.

Printed copies of HPLC test results from your firm's systems do not contain all of the analytical metadata (for example: instrument conditions, integration parameters) that i considered part of the raw data. We acknowledge that your response indicates that you have created a procedure in order to implement the back-up and retention of HPLC data. This electronic HPLC data supports testing, disposition, and other significant quality control decisions, and it is essential that you maintain this information for each batch. In your response, please provide a detailed update on your firm's implementation of this correction. Also describe your firm's policy for retaining HPLC raw electroni data associated with pending applications.

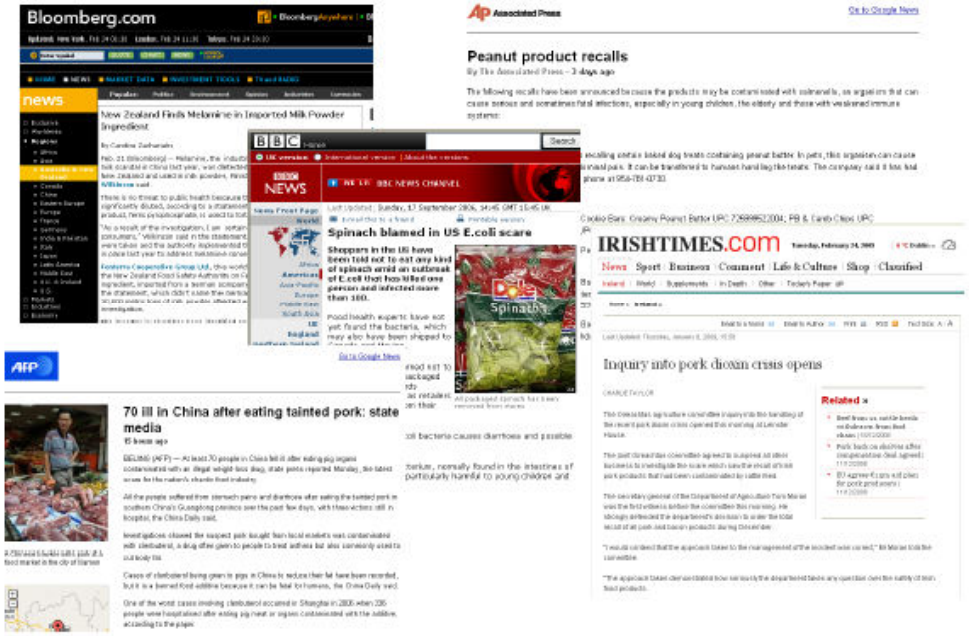
US Food and Drugs Administration

a) There is no system in place to ensure that all electronic raw data from the laboratory is backed up and/or retained.

US Food and Drugs Administration

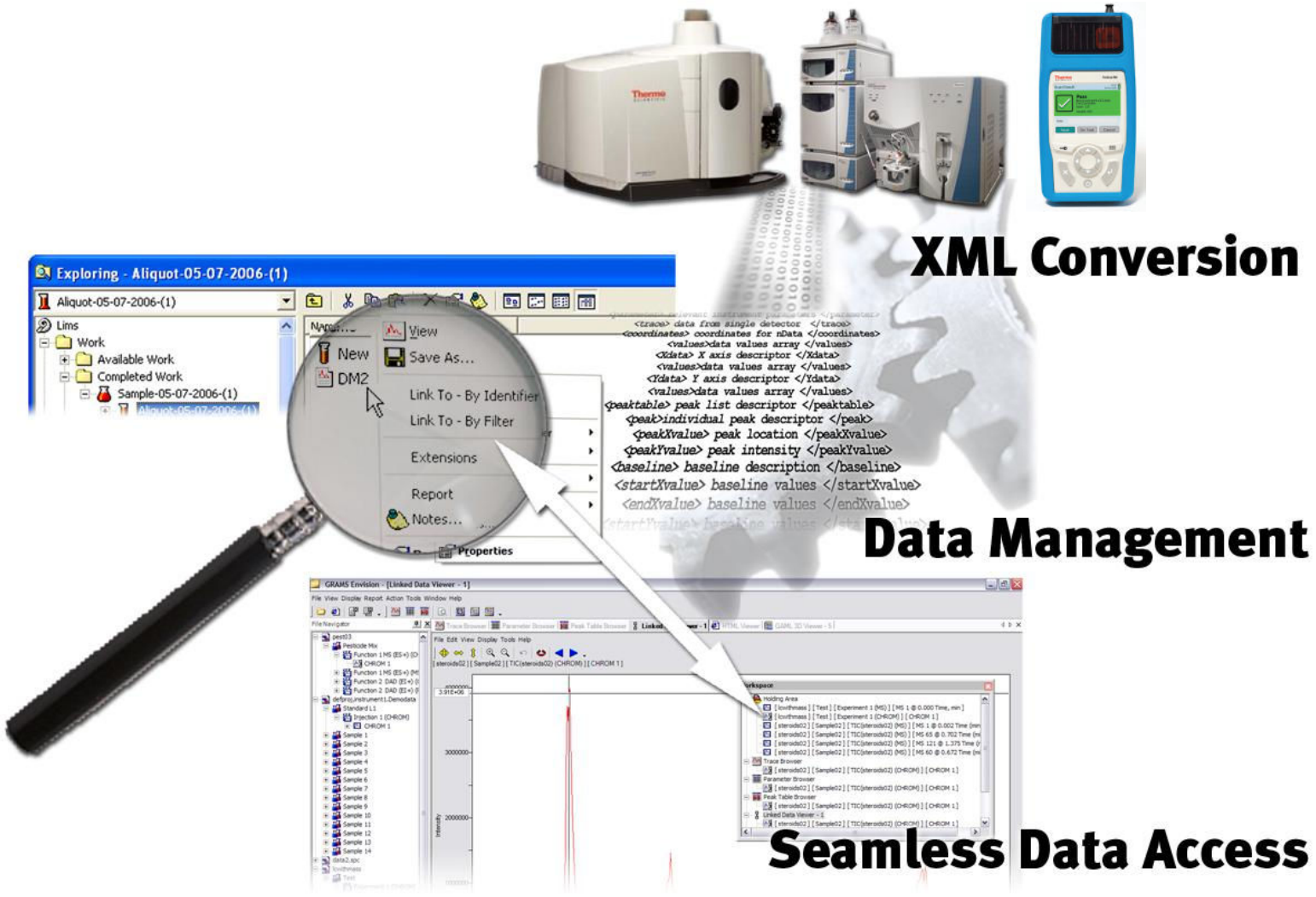
Printed copies of HPLC test results from your firm's systems do not contain all of the analytical metadata (for example: instrument conditions, integration parameters) that is considered part of the raw data.

Food Safety testing – increasing regulatory scrutiny



ThermoFisher SCIENTIFIC

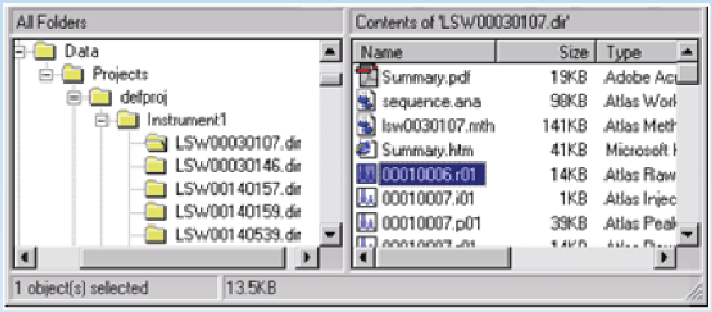
What is Data Manager?



ThermoFisher SCIENTIFIC

Data Capture, Storage and Indexing

Manual via PC

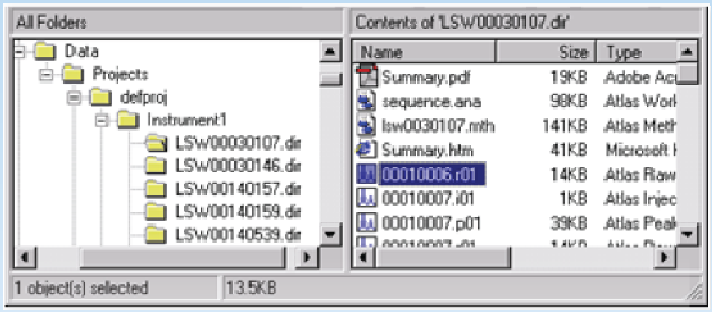


Automated using
Packaging Agents

ThermoFisher SCIENTIFIC

Data Capture, Storage and Indexing

Manual via PC



Automated using Packaging Agents

Data Manager

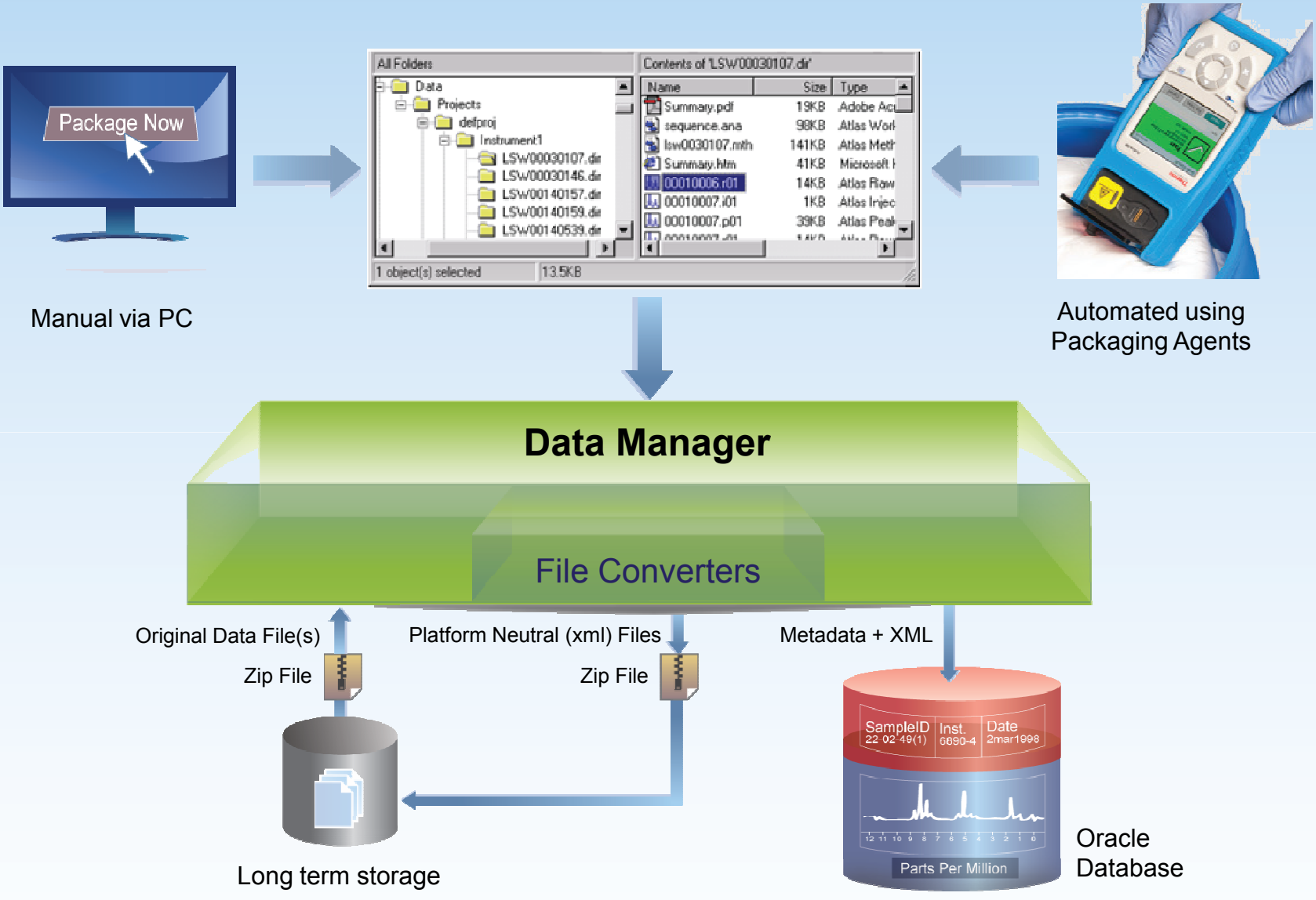
Original Data File(s)

Zip File

Long term storage

ThermoFisher SCIENTIFIC

Data Capture, Storage and Indexing



ThermoFisher SCIENTIFIC

180 Supported Instrument Formats

Acton Research SpectraSense
Agilent ChemStation LC/GC/PDA/MS*
Agilent HP LAS GC/LC Chromatography*
Agilent/HP 1040 Diode Array (PAWS)
Agilent/HP 1090 Diode Array (PAWS)
Agilent/HP 8452/8453 UV-Vis
Agilent/HP ChemStation GC/LC/MS/PDA
Agilent/HP IRD ChemStation GC-IR (DOS)
Alton Instruments LS2000
Amersham Biosciences Unicorn Chromatography*
Analect Instruments FT-IR
Analytical Spectral Devices FieldSpec
Analytical Spectral Devices LabSpec
Analytical Spectral Devices PSII UV-Vis
AnDI/netCDF Chromatography
AnDI/netCDF FT-IR
AnDI/netCDF Mass Spectrometry
Ando Instruments AQ 6312B
Applied Automation Optichrom Advance
Applied Biosystems/MDS Sciex Analyst
ASCII XY - Constant X Spacing
ASCII XY - High Precision X
ASCII XY - Variable X Spacing
ASCII Y-only (Single column)
ASI ReactIR
AVIV UV-Vis/CD

Beckman - All UV-Vis/Fluorescence
Beckman 32 Karat Chromatography*
Beckman DU60 UV-Vis (ASCII)
Beckman FT1000/2000 FT-IR
Beckman Gold Chromatography
Bio-Rad BioDimensions PDA
Bio-Rad Digilab 3200 FT-IR
Bio-Rad Digilab IMX FT-IR
Bio-Rad Sadtler
Bio-Tek Instruments Kroma System 3000*
Brimrose NIR
Bruins Instruments Omega Series UV-Vis/NIR
Bruker AMX/X32 Series NMR

Dilor Microdil 28/Z24 Raman (V1)
Dionex-Lee Scientific 600 Chromatography

EG&G PAR CCD
EG&G PAR OMA88
EG&G PAR ProcessVision
EG&G Spectrum Master MAESTRO II

Finnigan ITDS GC-MS
Finnigan Xcalibur GC/LC/MS/PDA
Foss NIRSystems NSAS NIR
Foss NIRSystems Vision NIR

GBC Spectral UV-Vis
GE Nicolet NMR
GE OMEGA NMR
Gilson Unipoint Chromatography
Groton Technology PF1 PDA
Groton Technology SoloNET PDA
Guided Wave NIR

Hamilton Sundstrand AnaGRAMS
Hamilton Sundstrand Analect FT-IR
Hamilton Sundstrand PIONIR
Hitachi D7000 HSM Chromatography
Hitachi R-1200/1100 NMR
Hitachi R-1500 NMR
Hitachi-GRAMS 3400 UV-Vis
Horiba FT-IR

IBM 9420 UV-Vis
IBM IR30 FT-IR
Interspectrum/Spectrolab PFS2000

Jasco J-600 CD
Jasco J-700 CD
Jasco Spectrum Manager IR/UV/FL/Raman/CD
J-CAMP DX (V4.24)
JEOL Delta NMR (Generic format)
JEOL GX/EX NMR
JEOL WinSpec FT-IR
JMBS Diamir*
JY Horiba DataMax
JY Horiba ISA PRISM Raman
JY Horiba ISA SpectraMax Raman (DOS)
JY Horiba SpectraMax (Windows)
JY Horiba Spex Raman

Kontron DS450 Chromatogram

Ocean Optics OOBase32 UV-Vis
Optical Solutions PS-1/PS-E Spectrometer
Otsuka UV-Vis DAD

PE Sciex Analyst*
Perkin Elmer Access* Chrom*
Perkin Elmer TurboChrom*
PerkinElmer 7000 Series FT-IR
PerkinElmer FL DataManager
PerkinElmer FL Winlab
PerkinElmer IR AutoIMAGE
PerkinElmer IR DataManager FT-IR
PerkinElmer Nelson 2600 Chromatography
PerkinElmer Nelson Access* Chrom
PerkinElmer PC137 SAM
PerkinElmer PEGRAMS 1000/1600/2000
PerkinElmer PIONIR NIR
PerkinElmer Spectrum IR
PerkinElmer TravelIR FTIR
PerkinElmer Turbochrom (up to V3.3)
PerkinElmer TurboMass GC/LC/MS
PerkinElmer UV DataManager
PerkinElmer UV Winlab
Perseptive Biosystems Voyager TOF-MS
Perten GRAMS
Perten PerCon NIR
Pharmacia LKB GelscanXL
Phillips IR/40 FT-IR
Polymer Laboratories Cirrus GPC*
Polymer Labs Cirrus GPC/SEC
Prolab Resources/Teknivent GC-MS V1

Radiomatic FLO-1
Renishaw WiRE Raman
Roper Scientific Princeton Instruments CCD

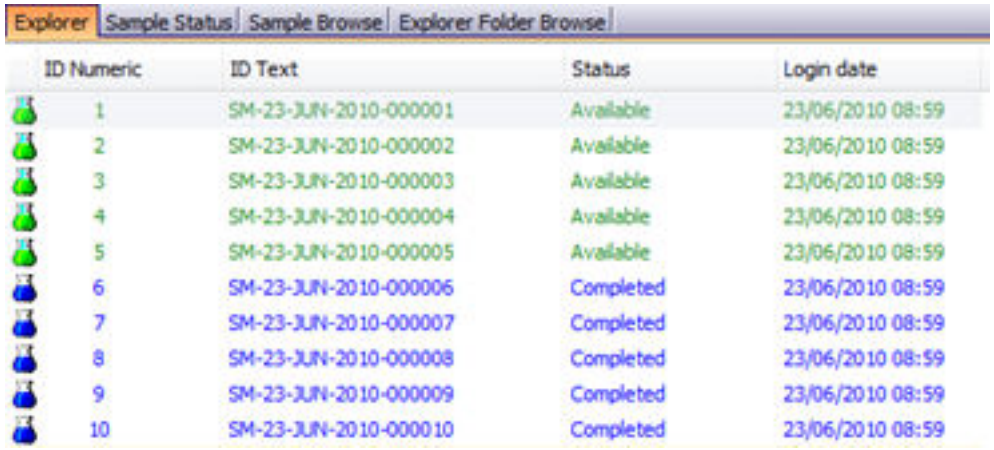
Scientific Software, Inc. EZ Chrom Elite™Chromatography*
SensIR - All FT-IRs
Shimadzu Class-VP*
Shimadzu Hyper-IR
Shimadzu Hyper-UV
Shimadzu QP5000 GC-MS
Shimadzu UV160/265
Siemens DIFFRAC/DIFFRA

Thermo Scientific Elemental VG PlasmaQuad ICP-MS
Thermo Scientific Xcalibur GC/LC/MS/PDA
Thermo Scientific Atlas Chromatography*
Thermo Scientific Finnigan ChromQuest*
Thermo Scientific Finnigan Masslab*
Thermo Scientific Finnigan Xcalibur Chromatography System*
Thermo Scientific Multichrom*
Thermo Scientific Nicolet Omnic IRDATA & GROUP Files*
Thermo Scientific Nicolet Omnic Series Files*
Thermo Scientific Solaar*
Thermo Scientific Spectronic Helios UV-Vis*
Thermo Scientific Thru-Put Target Chromatography*
Thermo Scientific SPC (GRAMS)
Thermo Scientific ICON FT-IR
Thermo ScientificWinFIRST FT-IR
Thermo Scientific OMNIC Atlus FT-IR
Thermo Scientific OMNIC FT-IR
Thermo Scientific OMNIC Series FT-IR
Thermo Scientific PC-IR FT-IR
Thermo Scientific RESULT FT-IR
Thermo Scientific SX/DX FT-IR
Thermo Scientific InstaSpec
Thermo Scientific RUNNES II
Thermo Scientific Aminco-Bowman 2
Thermo Scientific SLM 3000 UV-Vis
Thermo Scientific SLM Universal UV & FL
Tracor Northern TN-6500
Tracor Northern TN-6600

Varian Cary UV-Vis (OS/2)
Varian Cary WinUV*
Varian Cary-GRAMS UV-Vis
Varian Galaxie*
Varian Saturn 3 GC-MS
Varian Saturn 5 GC-MS
Varian Star GC Chromatography
Varian VNMR
Varian XL/XR/Gemini NMR
Varian/Chemagnetics SpinSight NMR

ThermoFisher SCIENTIFIC

Allows you to view actionable raw data directly from the sample



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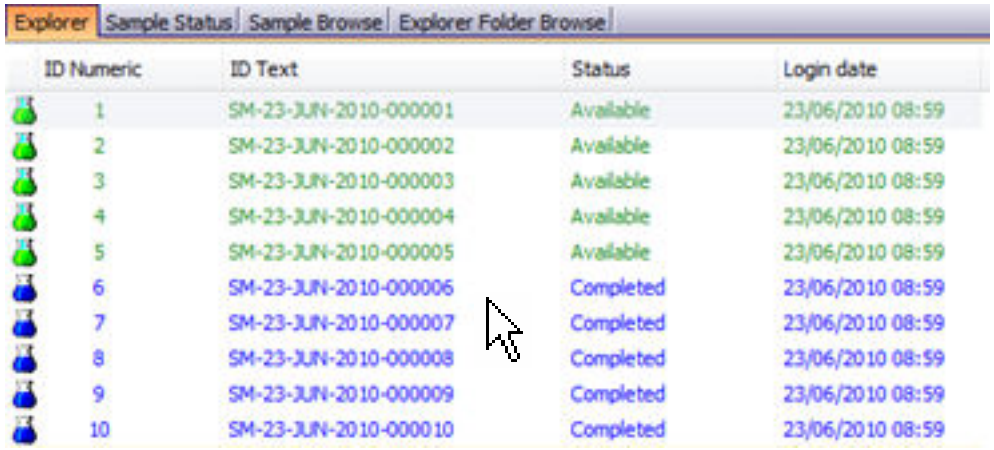
3	SM-23-JUN-2010-000003	Available	23/06/2010 08:59
4	SM-23-JUN-2010-000004	Available	23/06/2010 08:59
5	SM-23-JUN-2010-000005	Available	23/06/2010 08:59
6	SM-23-JUN-2010-000006	Completed	23/06/2010 08:59
7	SM-23-JUN-2010-000007	Completed	23/06/2010 08:59
8	SM-23-JUN-2010-000008	Completed	23/06/2010 08:59
9	SM-23-JUN-2010-000009	Completed	23/06/2010 08:59
10	SM-23-JUN-2010-000010	Completed	23/06/2010 08:59

Allows you to view actionable raw data directly from the sample



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4	SM-23-JUN-2010-000004	Available	23/06/2010 08:59
5	SM-23-JUN-2010-000005	Available	23/06/2010 08:59
6	SM-23-JUN-2010-000006	Completed	23/06/2010 08:59
7	SM-23-JUN-2010-000007	Completed	23/06/2010 08:59
8	SM-23-JUN-2010-000008	Completed	23/06/2010 08:59
9	SM-23-JUN-2010-000009	Completed	23/06/2010 08:59
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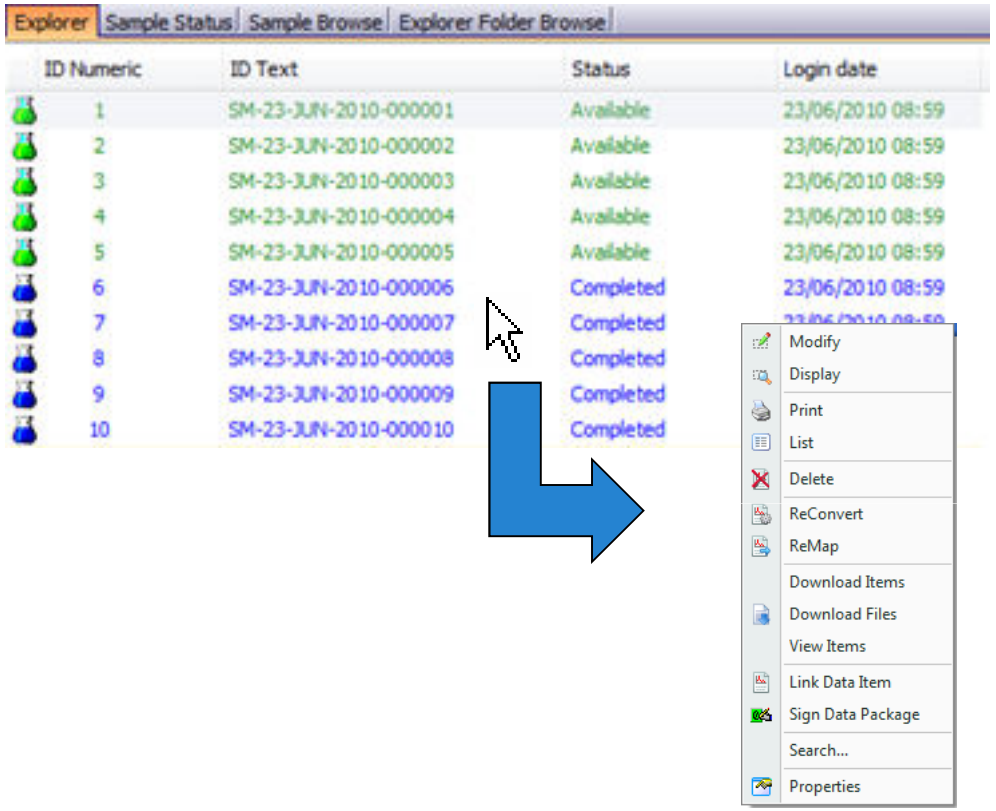
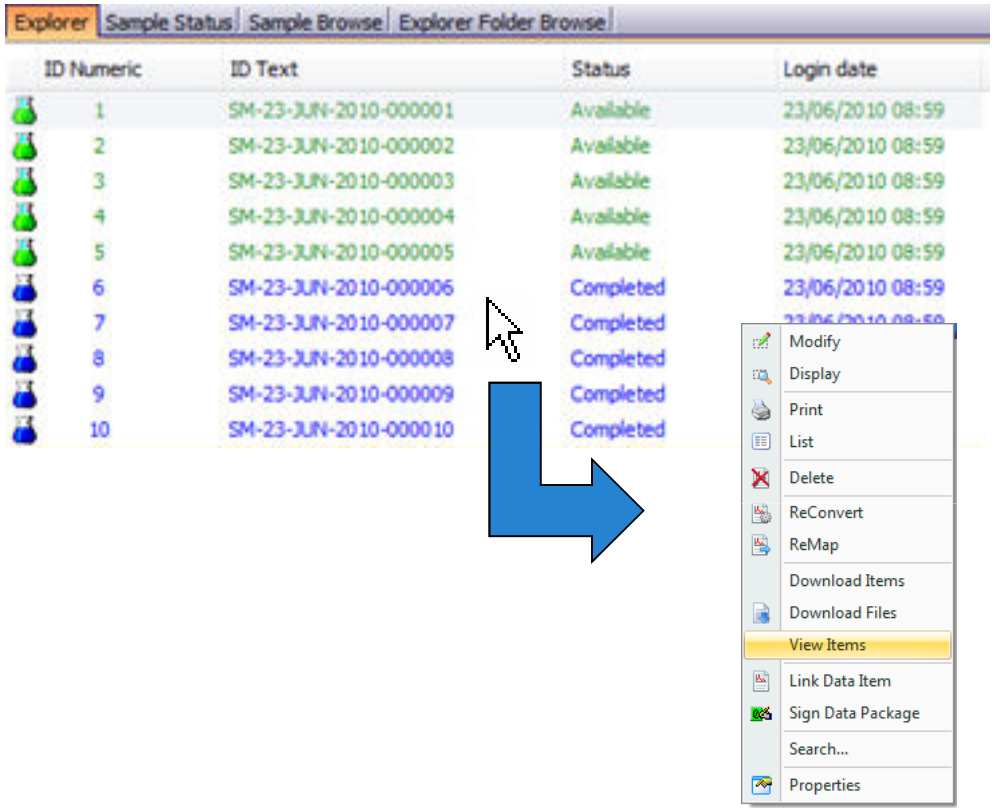
Allows you to view actionable raw data directly from the sample



ThermoFisher SCIENTIFIC

Allows you to view actionable raw data directly from the sample



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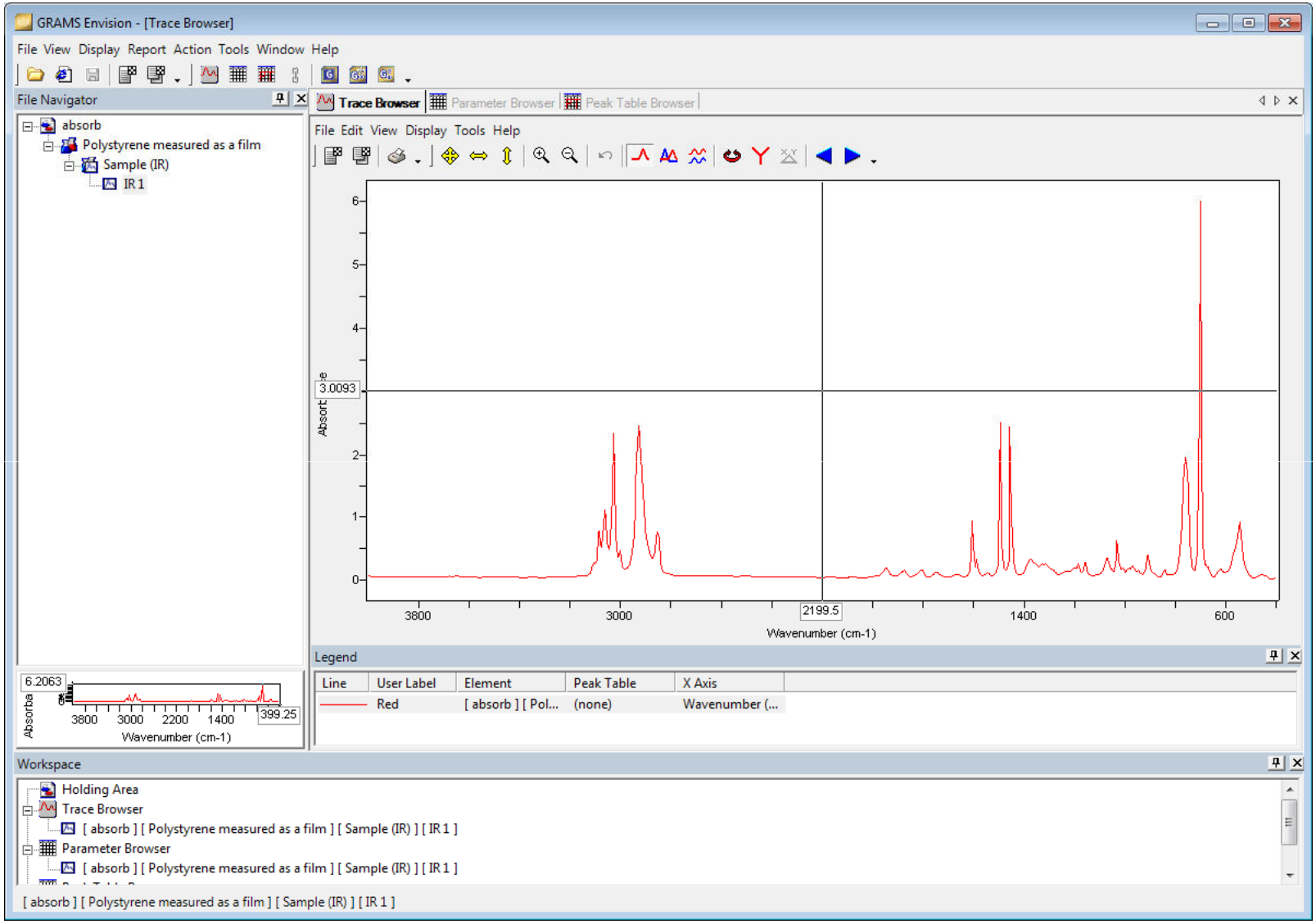
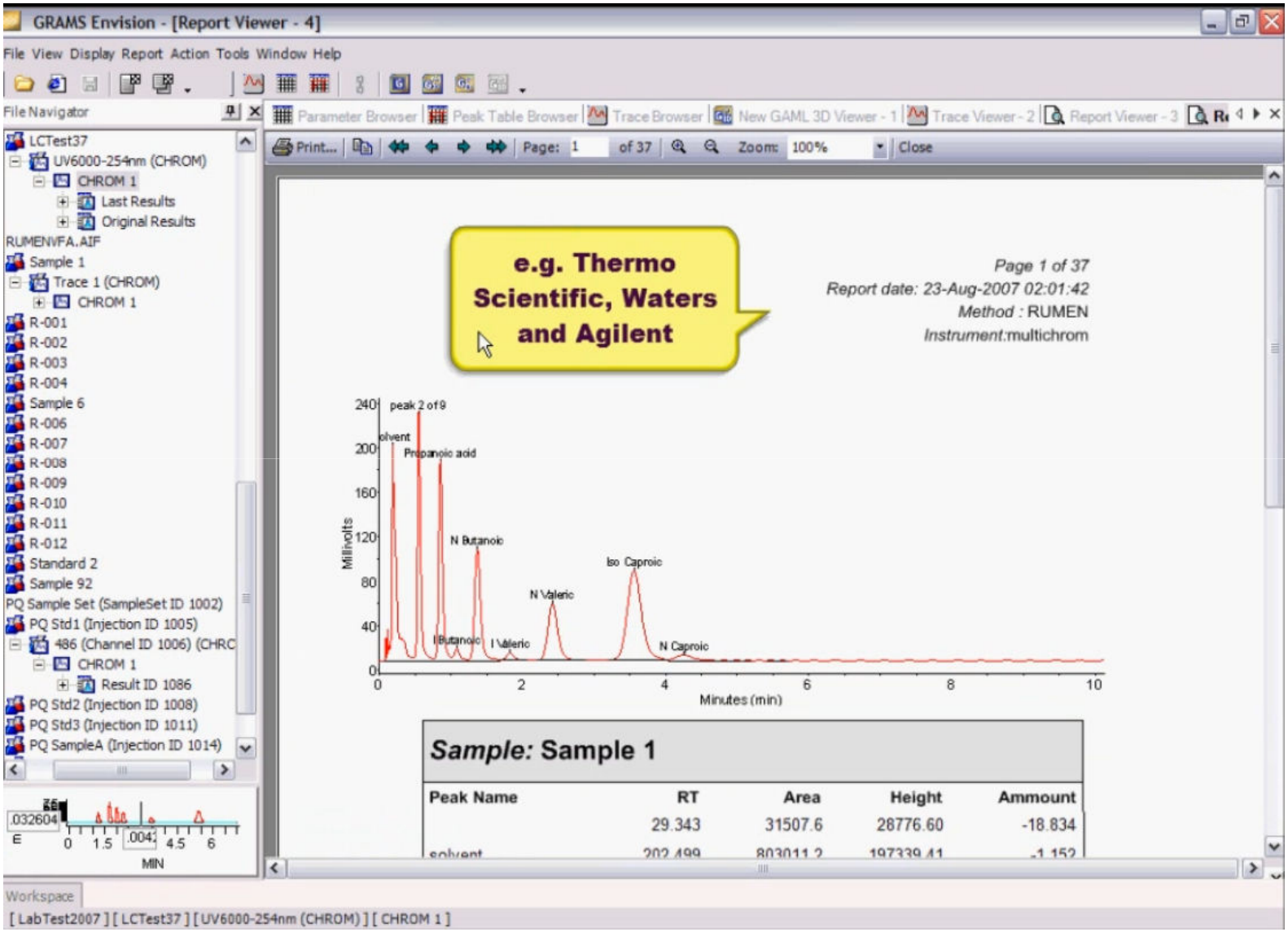


ThermoFisher SCIENTIFIC

And also allows cross vendor reporting ...



ThermoFisher SCIENTIFIC

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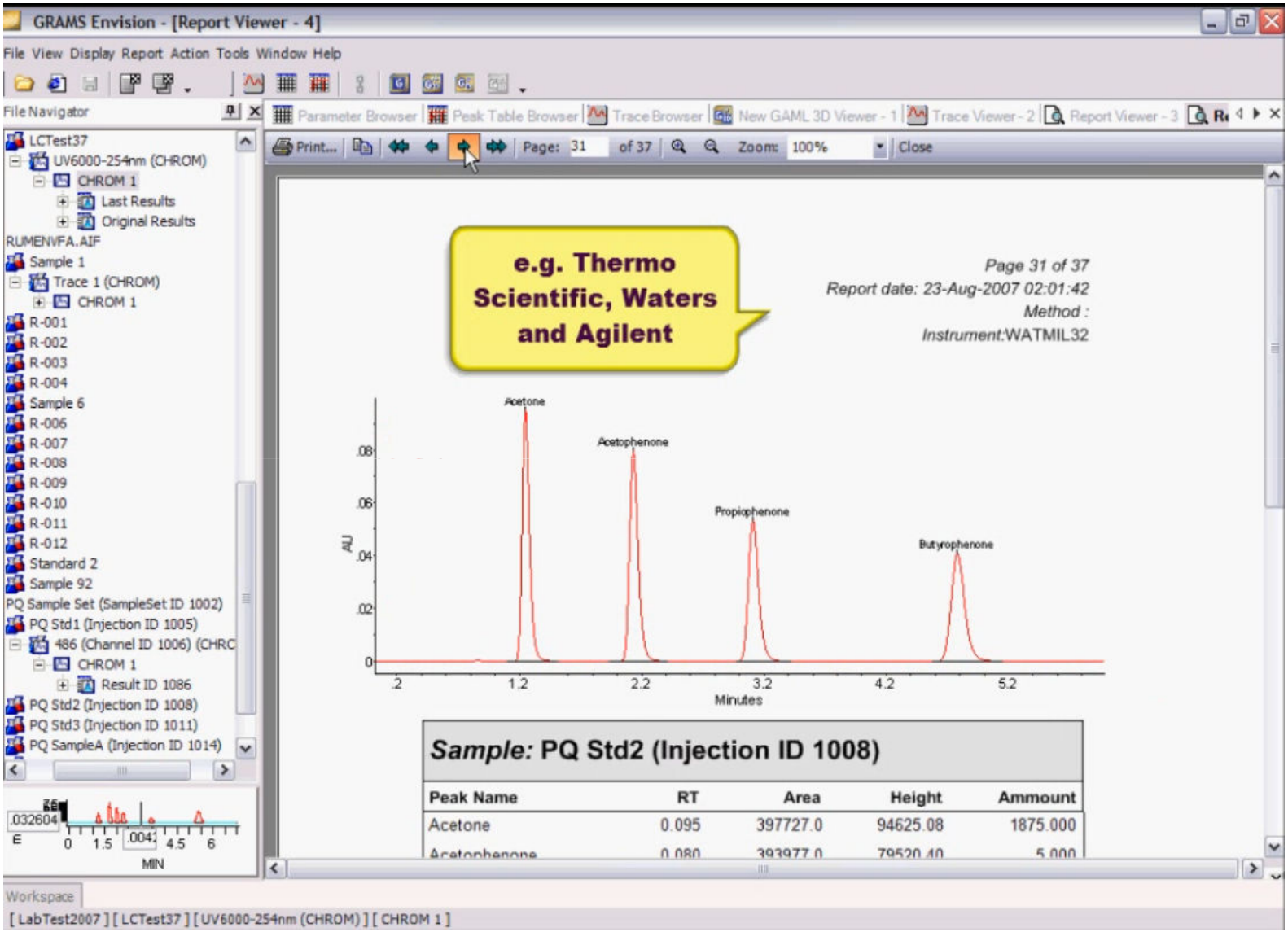

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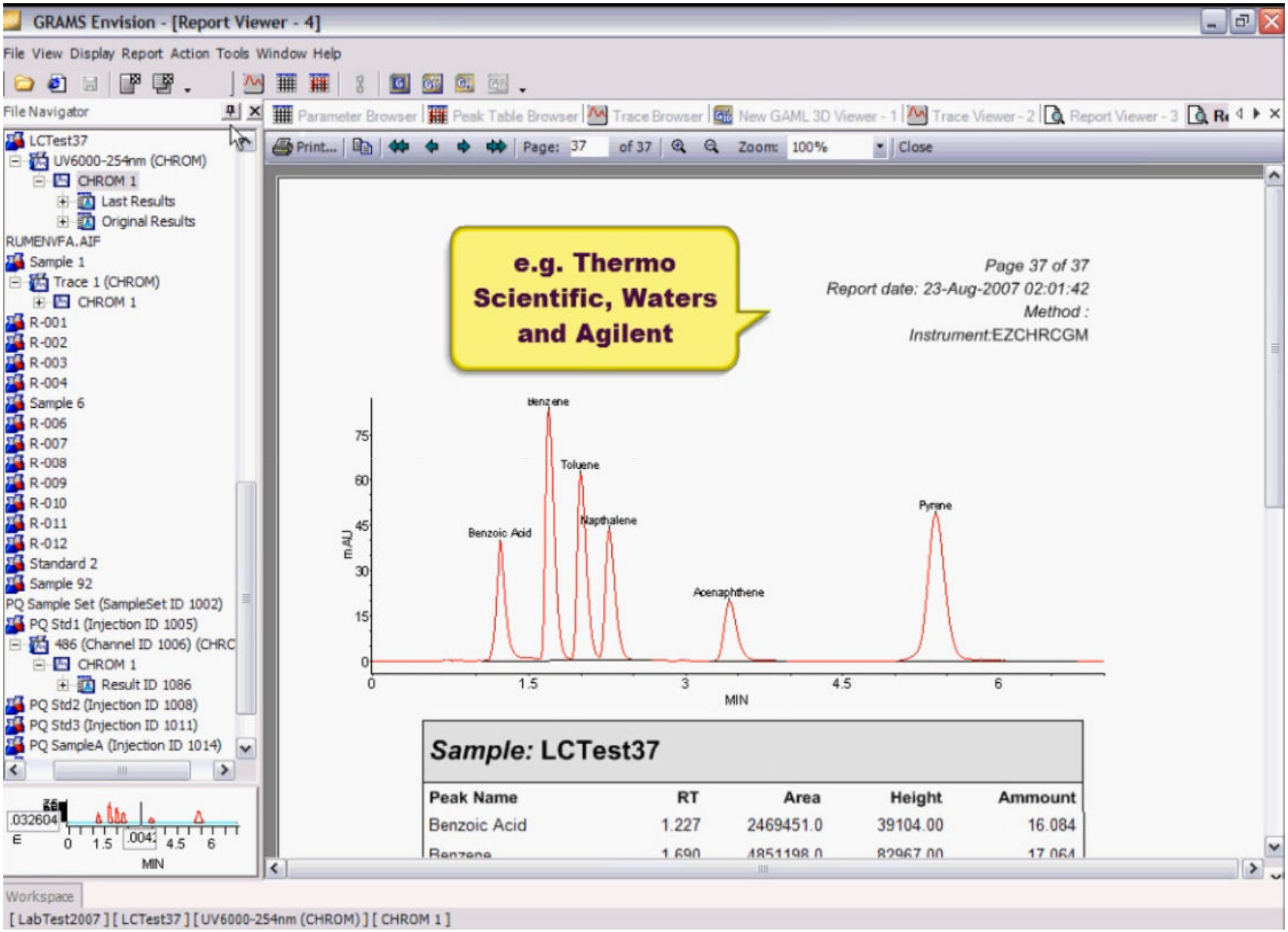
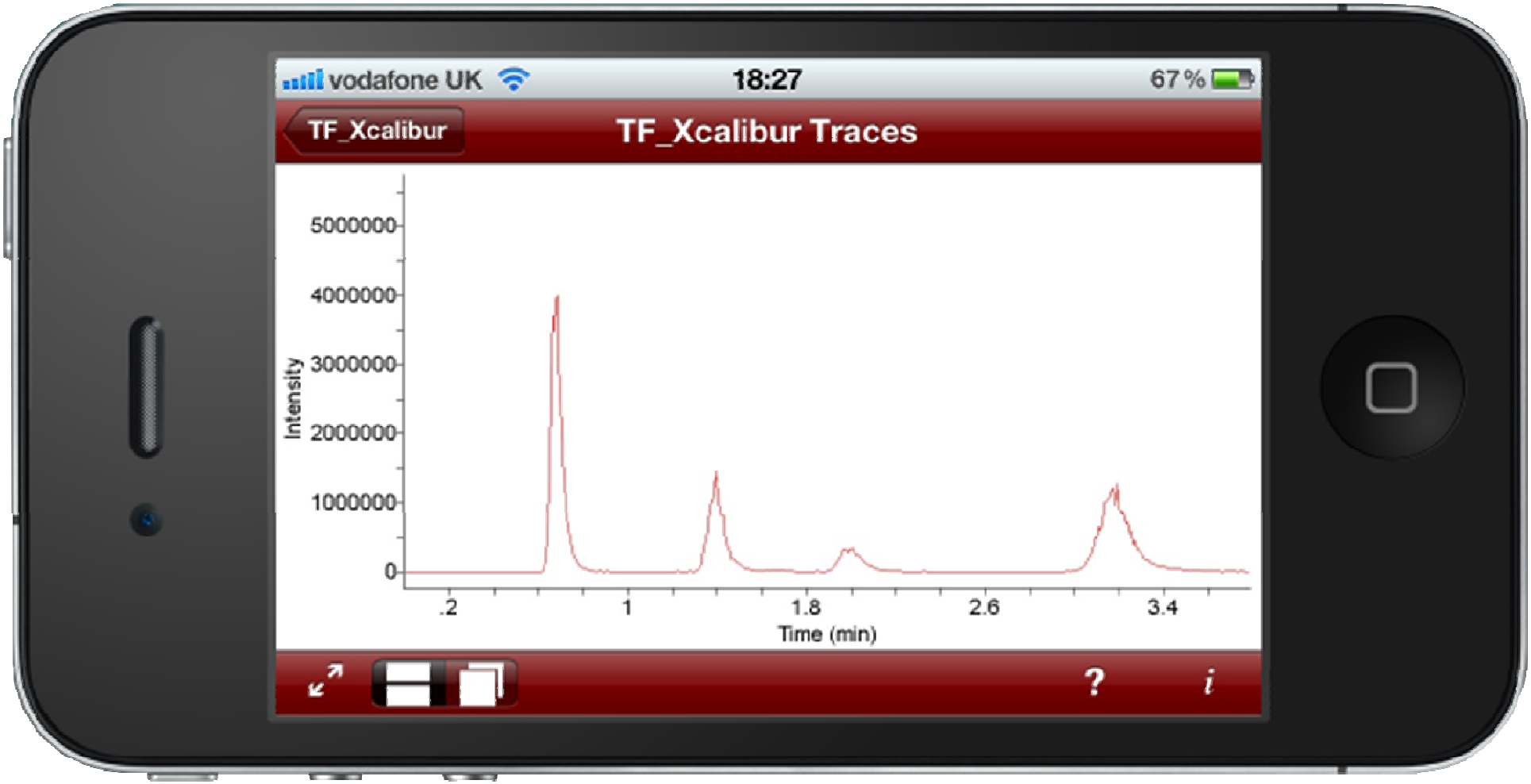


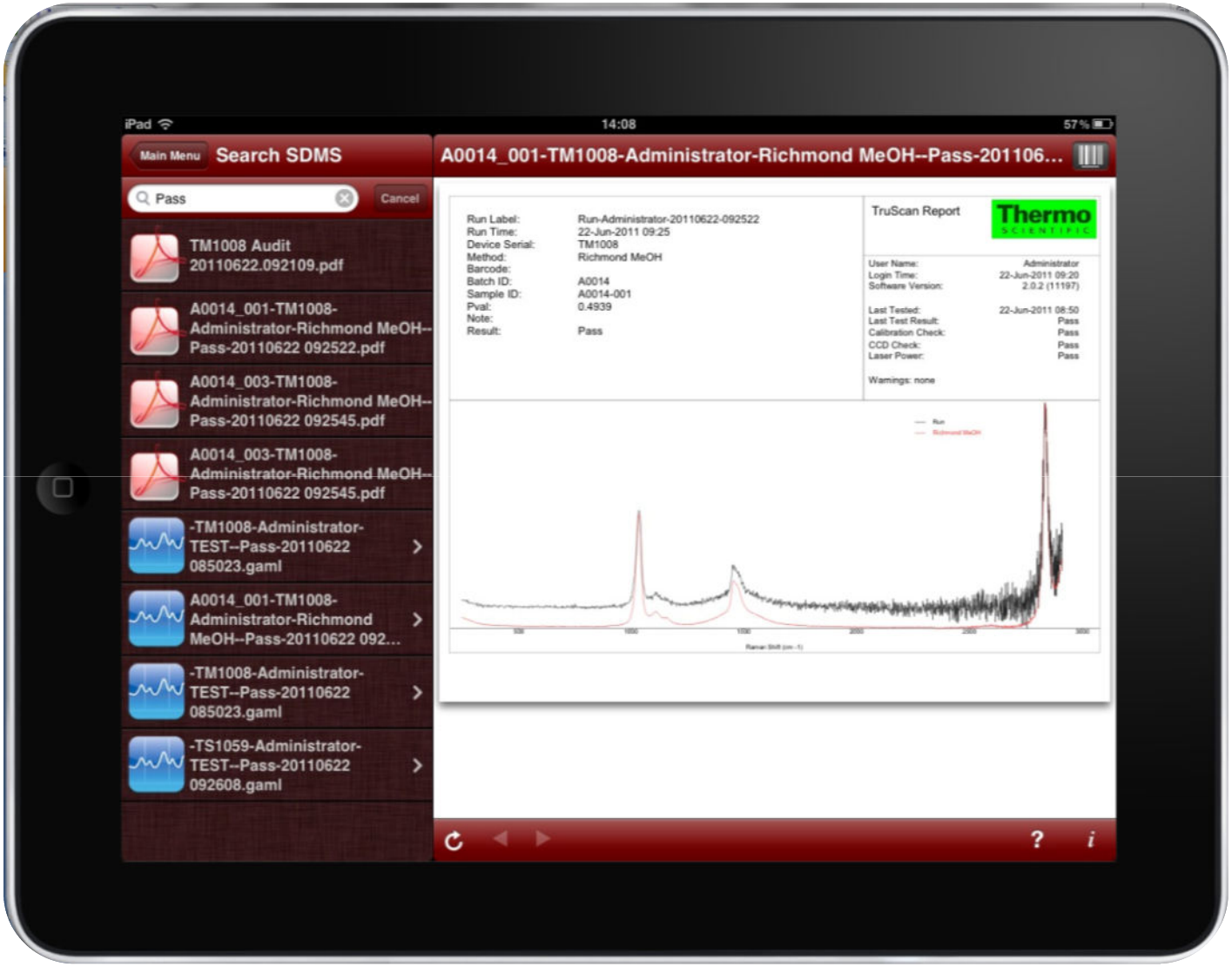
ThermoFisher SCIENTIFIC

Mobile Data Access

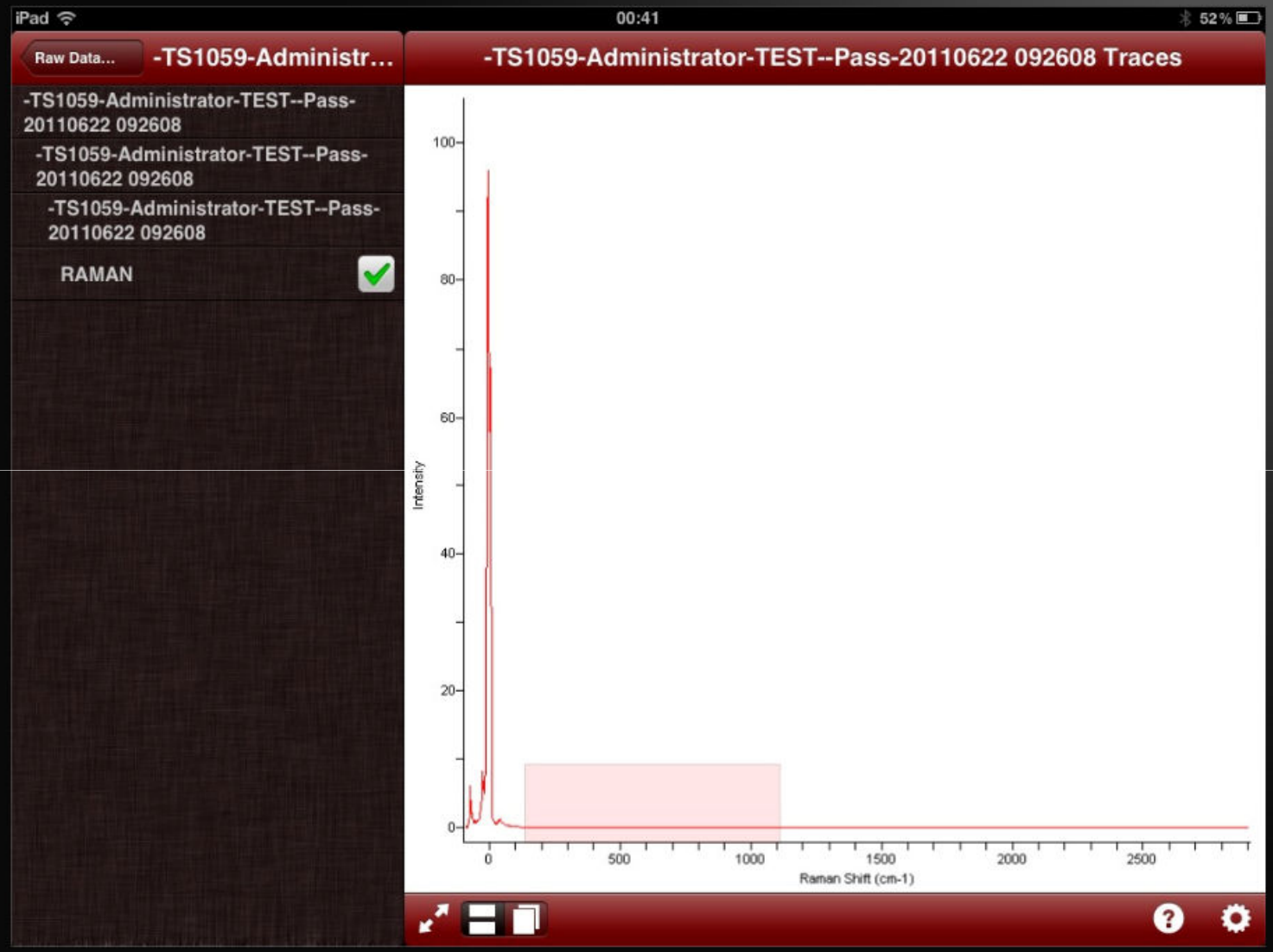


ThermoFisher SCIENTIFIC

..Search..



ThermoFisher SCIENTIFIC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00:41
52 %
Raw Data...
-TS1059-Administr...
-TS1059-Administrator-TEST--Pass-20110622 092608 Traces
-TS1059-Administrator-TEST--Pass-20110622 092608
-TS1059-Administrator-TEST--Pass-20110622 092608
-TS1059-Administrator-TEST--Pass-20110622 092608
RAMAN
Intensity
100
80
60
40
20
0
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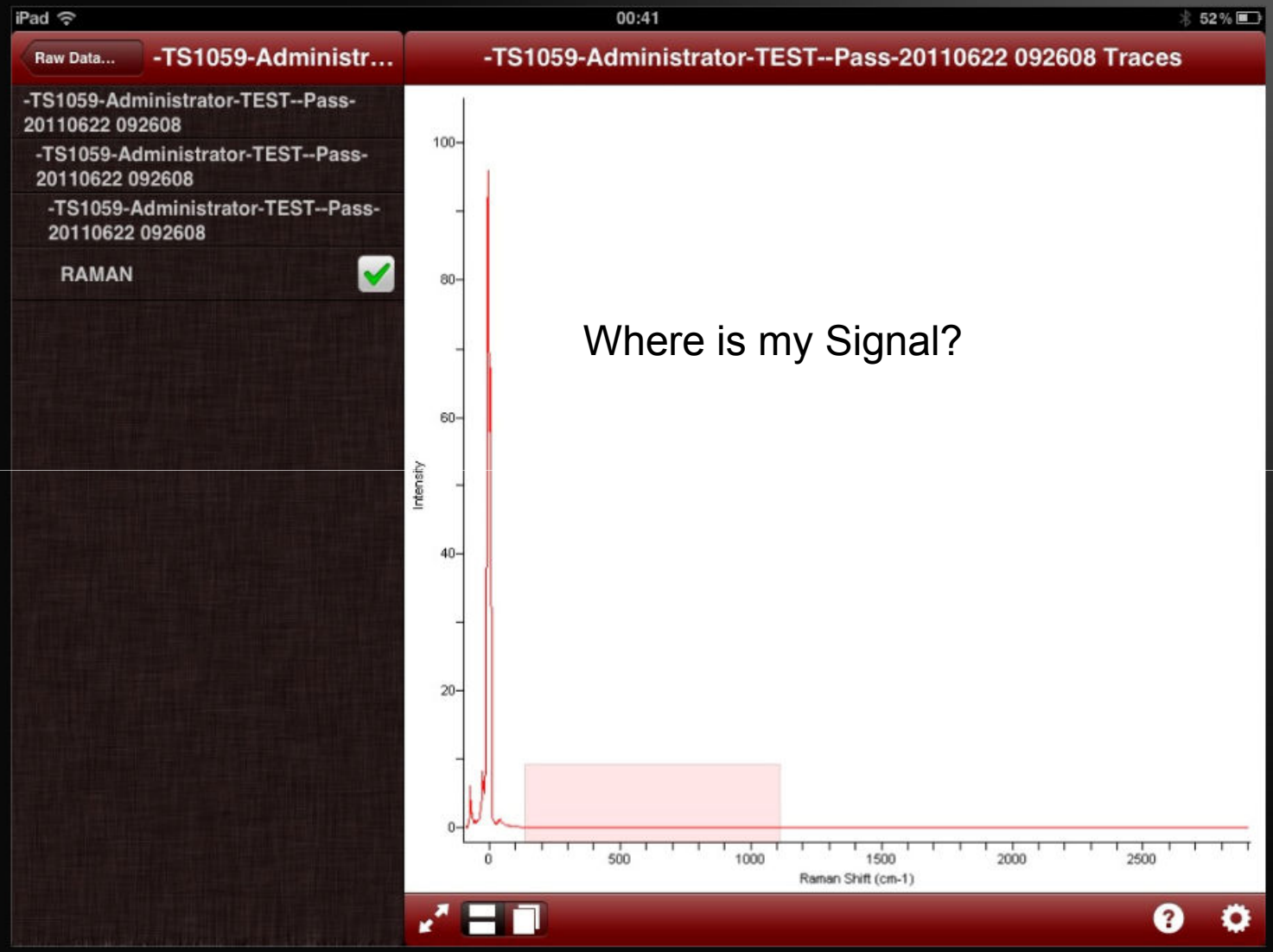
500
1000
1500
2000
2500
Raman Shift (cm-1)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-TS1059-Administrator-TEST--Pass-20110622 092608
RAMAN
Where is my Signal?
Intensity
100
80
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40
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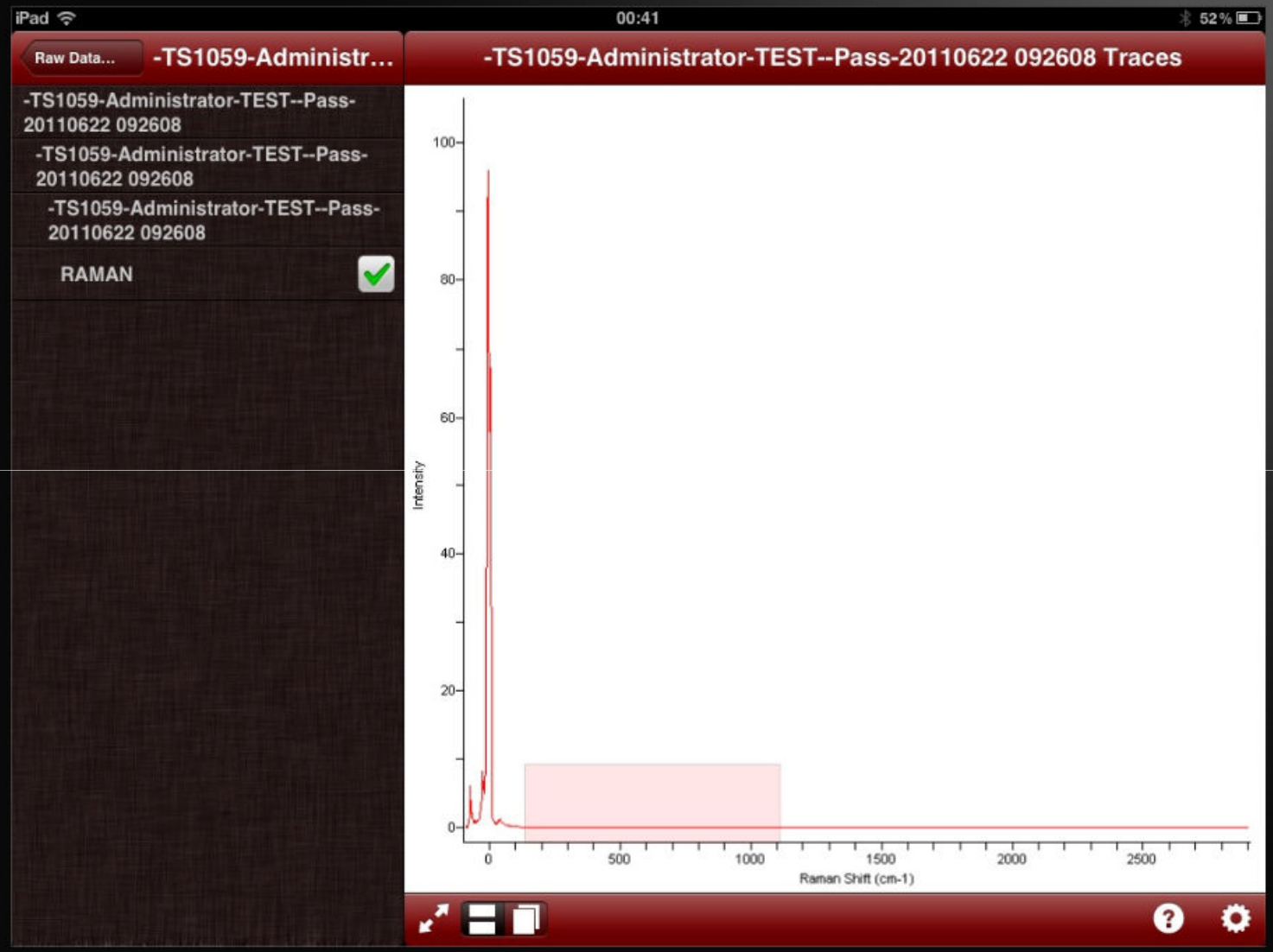
Raman Shift (cm-1)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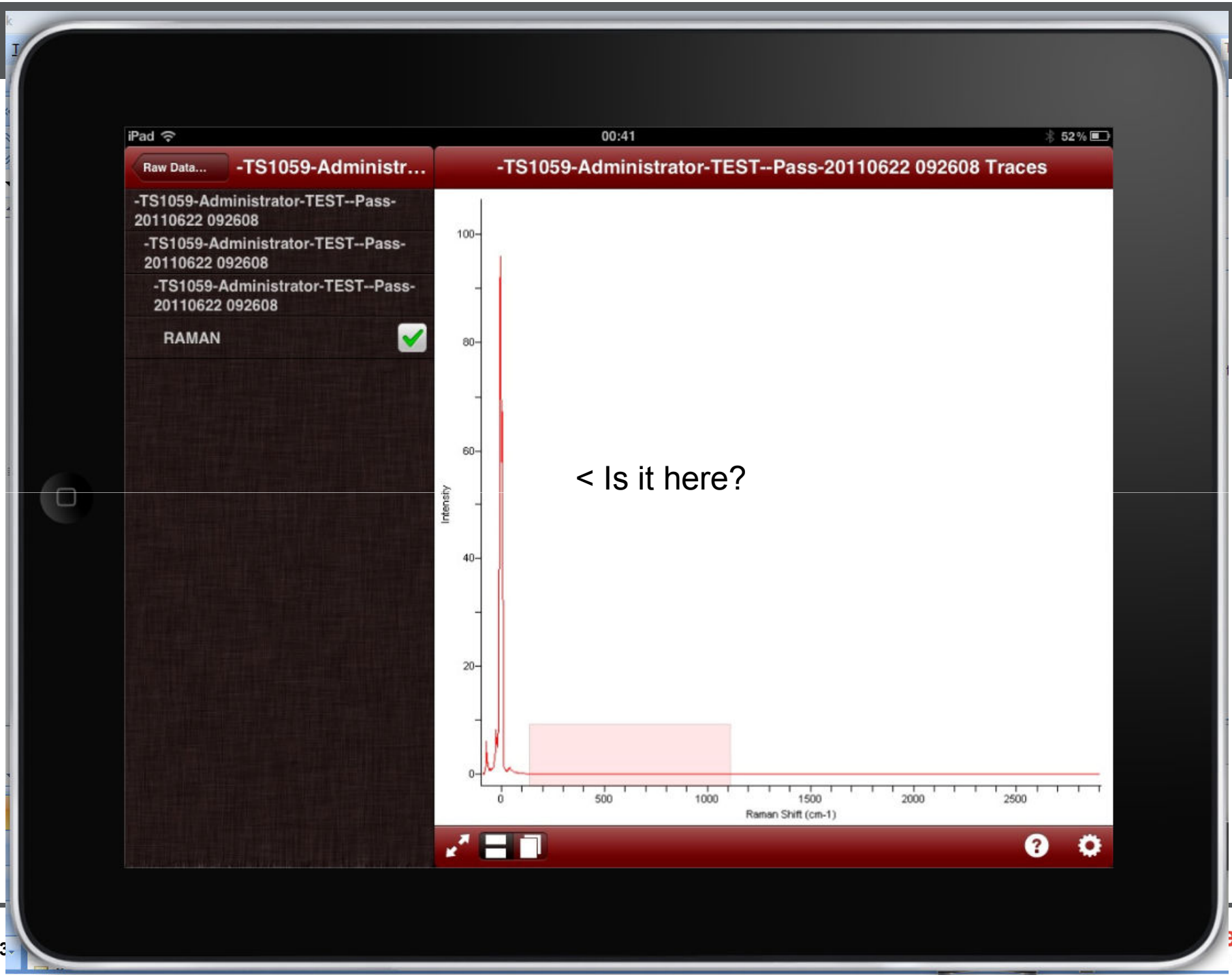
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RAMAN
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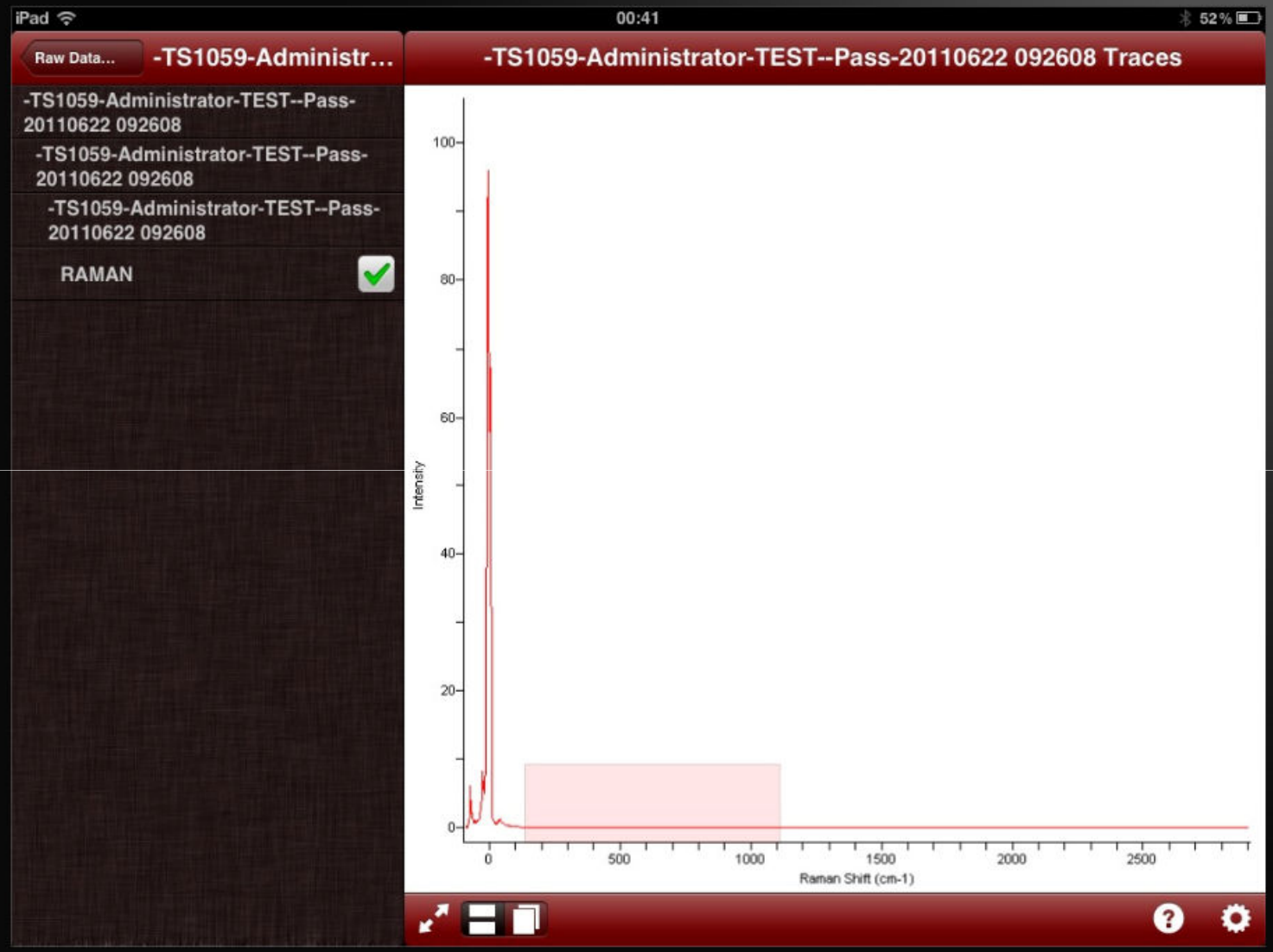
Raman Shift (cm-1)
< Is it here?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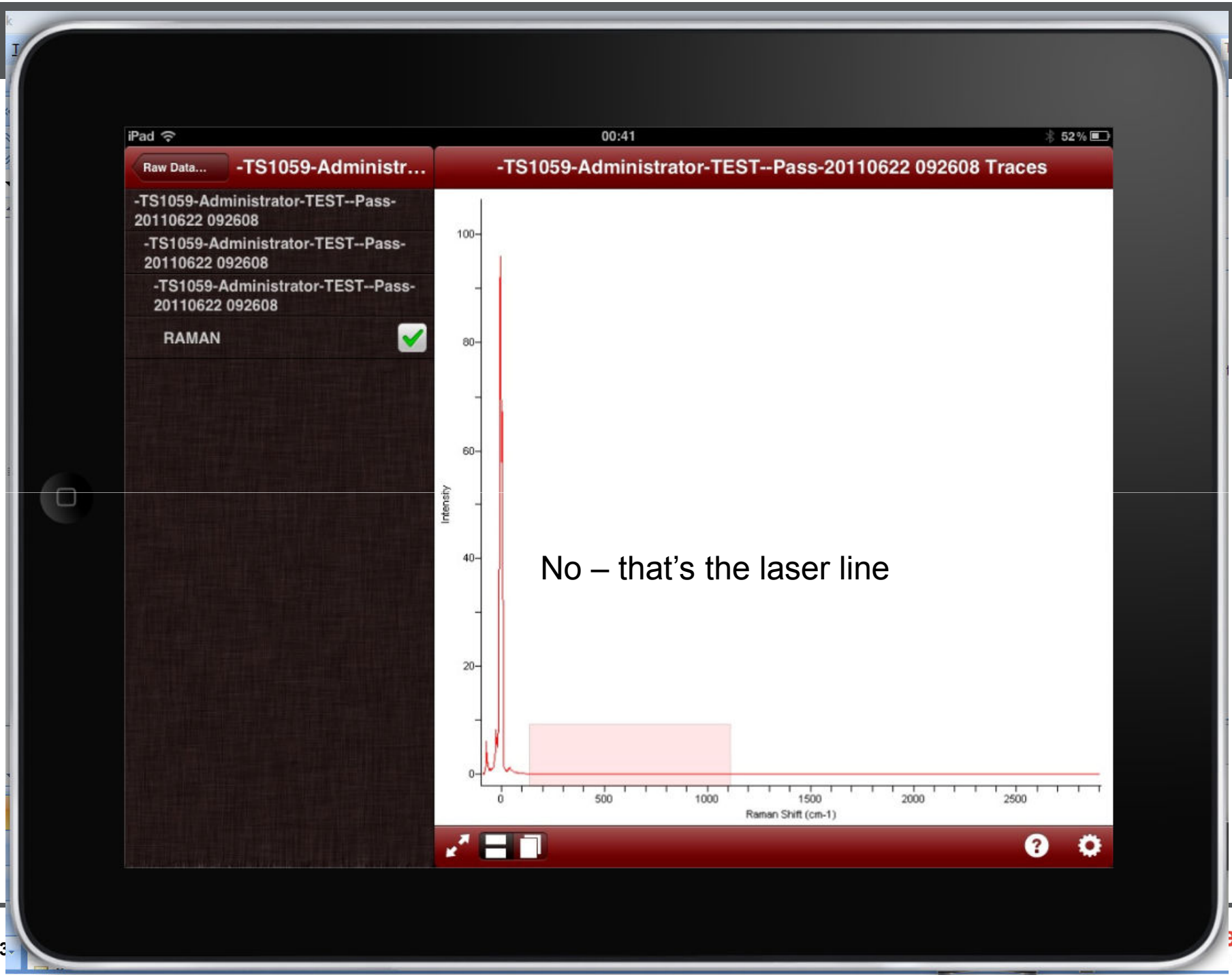
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-TS1059-Administrator-TEST--Pass-20110622 092608
RAMAN
Intensity
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40
20
0
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500
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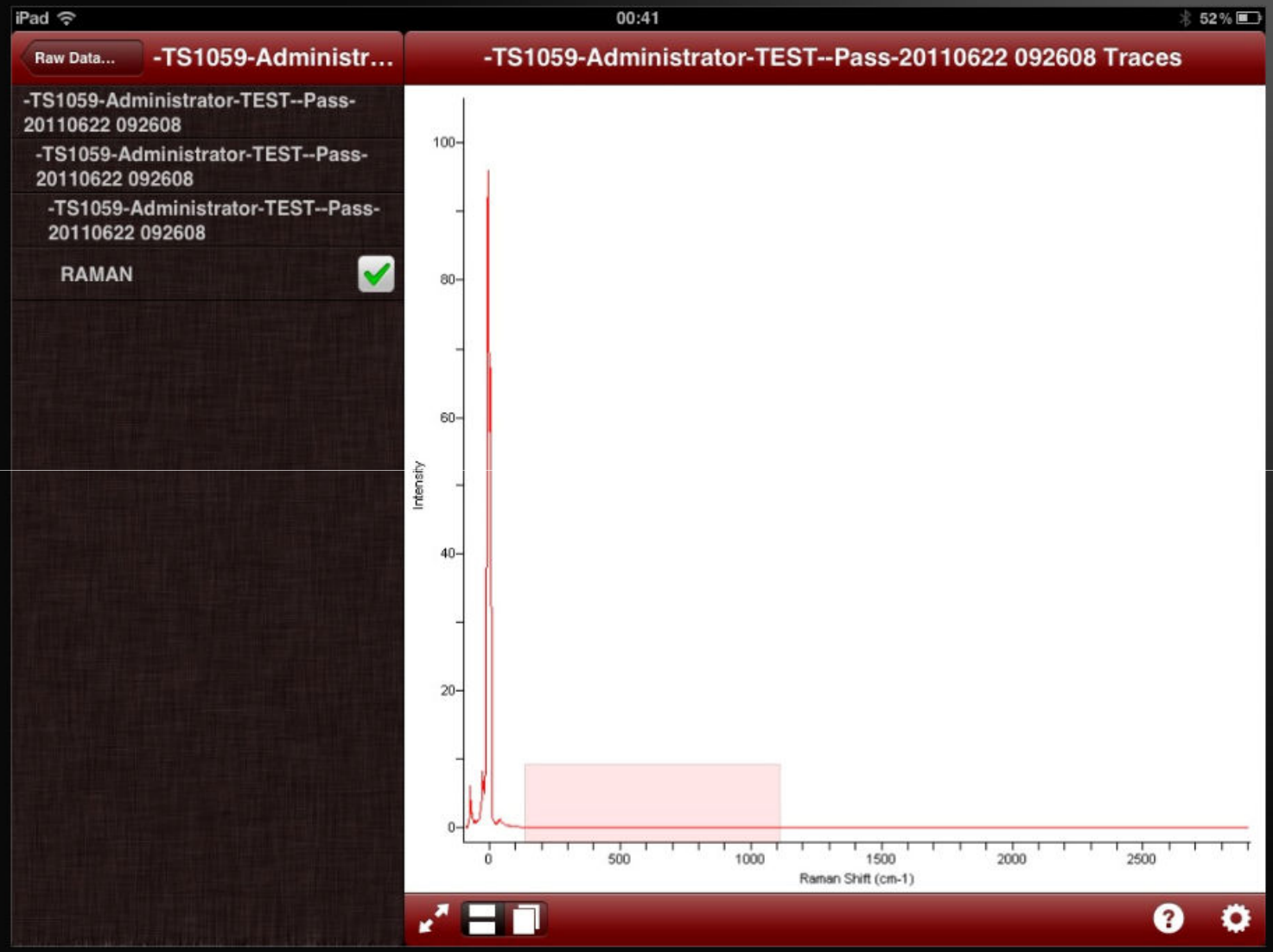
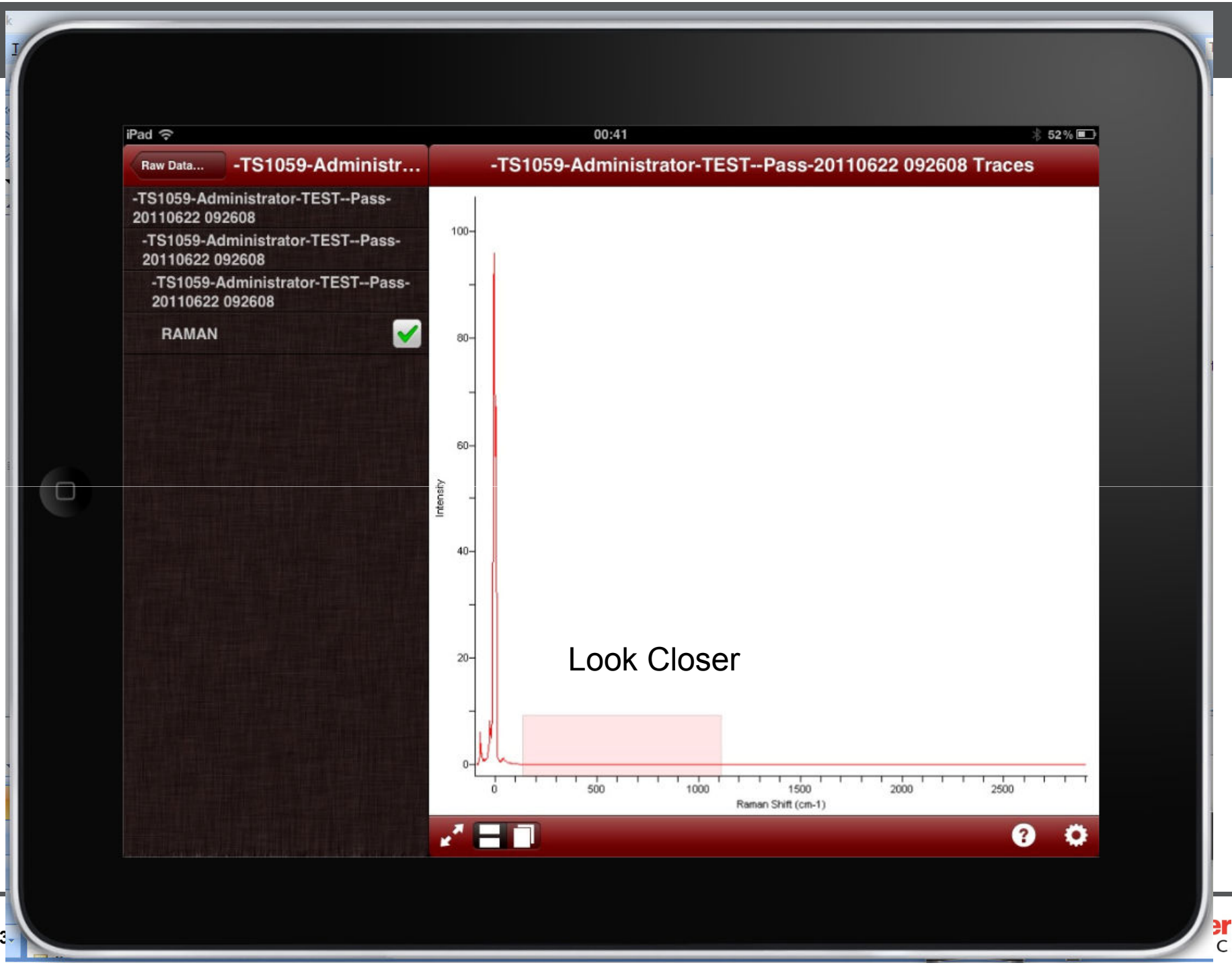
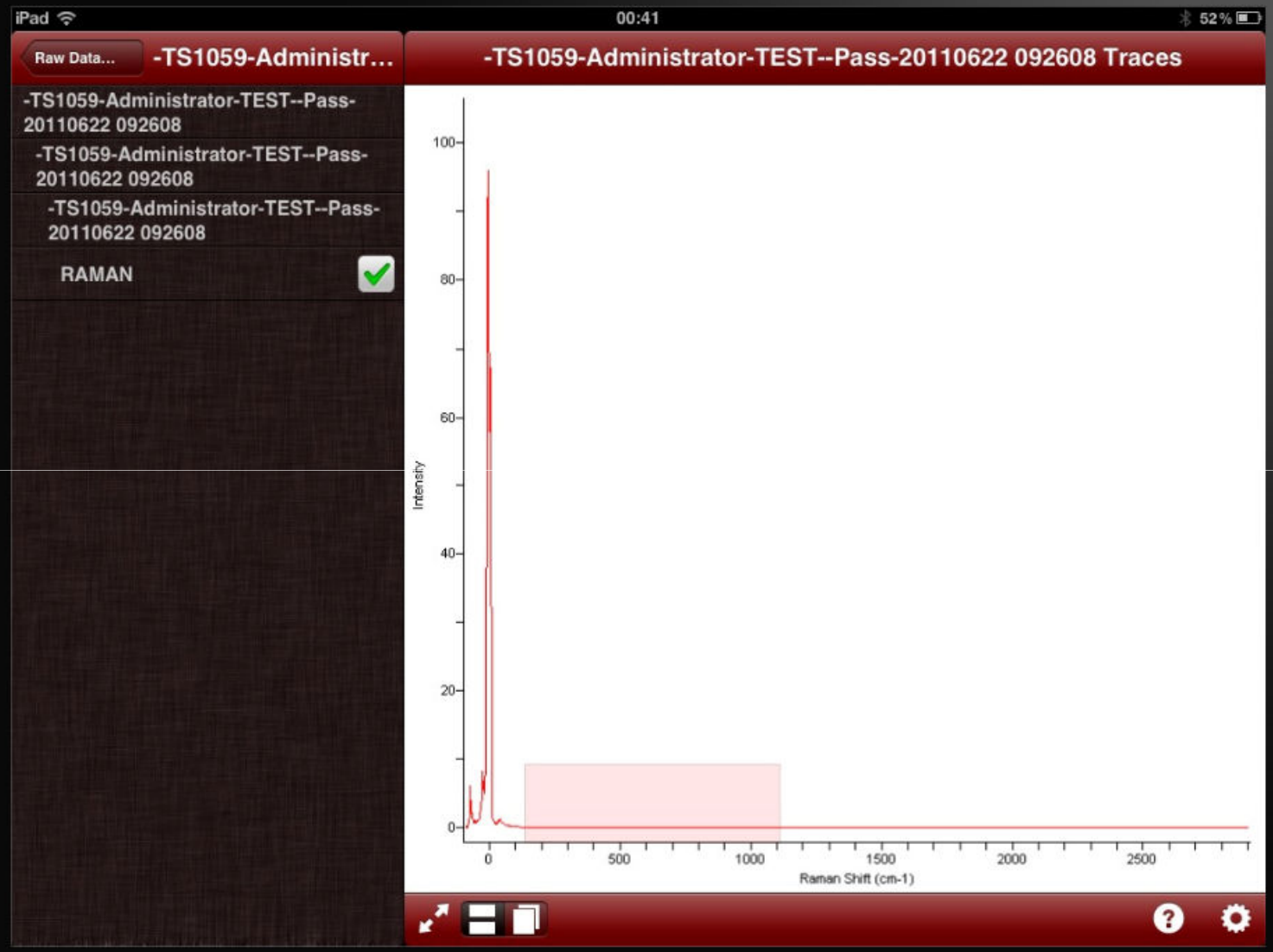
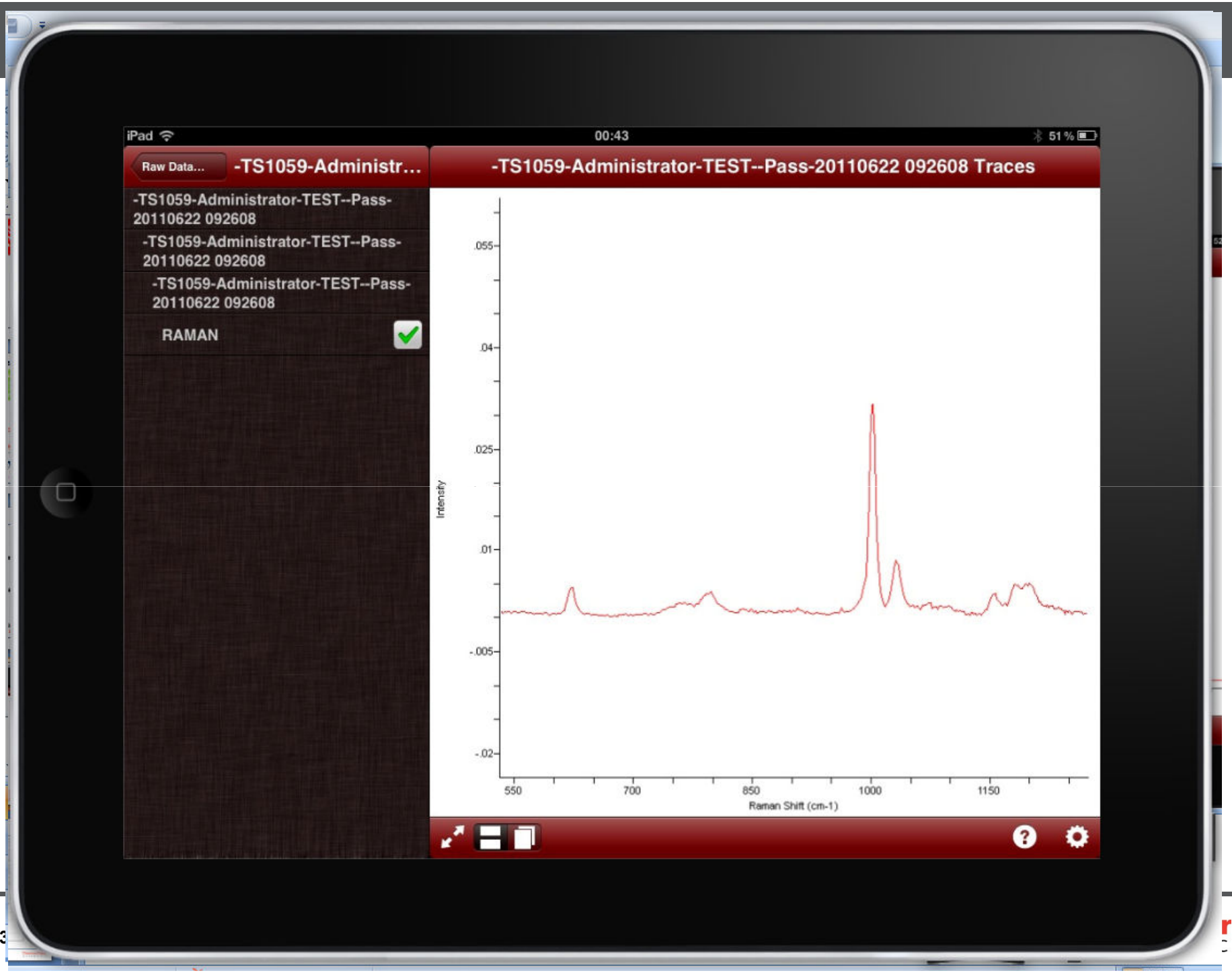
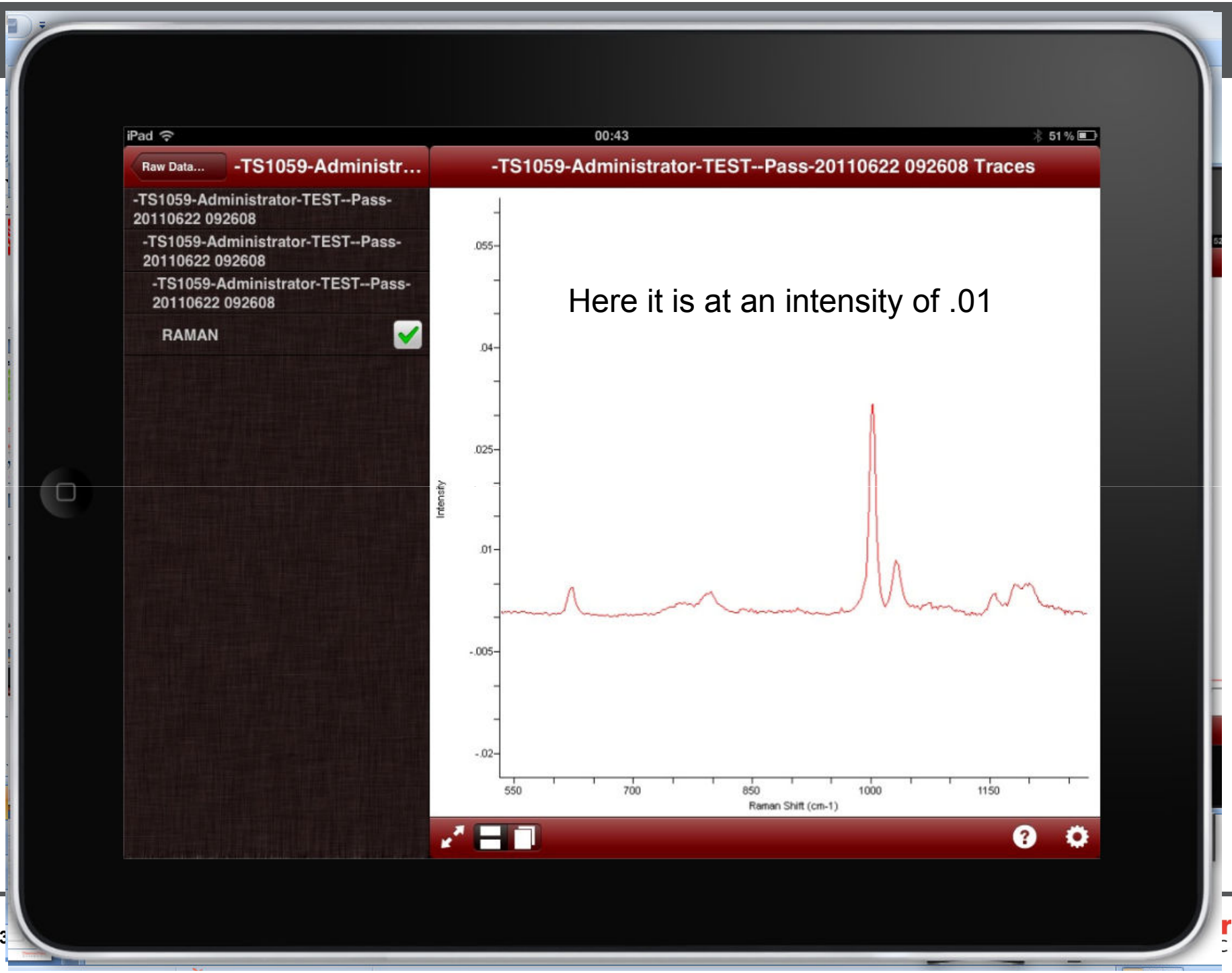
1500
2000
2500
Raman Shift (cm-1)
No – that's the laser line

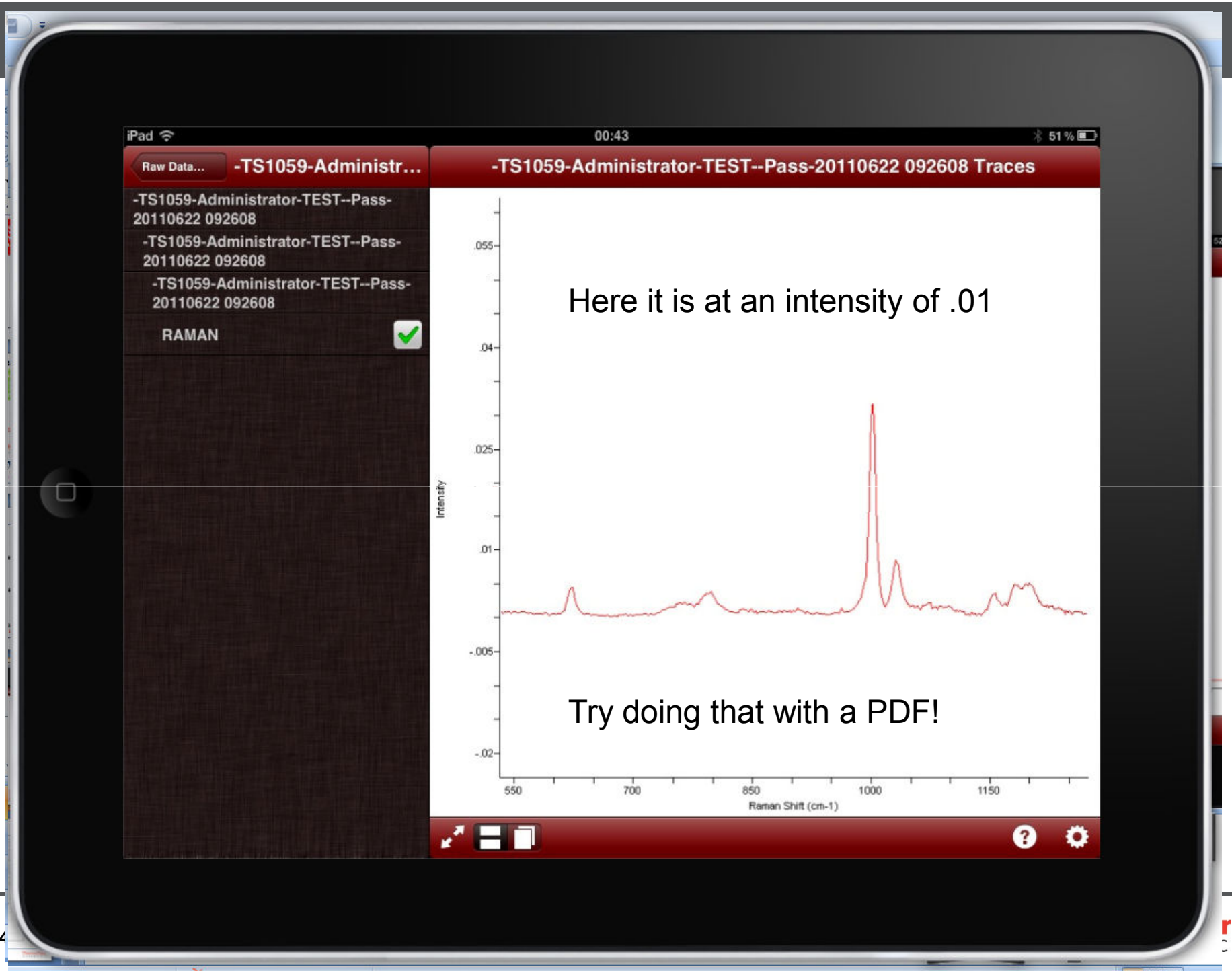

iPad
00:41
52 %
Raw Data...
-TS1059-Administr...
-TS1059-Administrator-TEST--Pass-20110622 092608 Traces
-TS1059-Administrator-TEST--Pass-20110622 092608
-TS1059-Administrator-TEST--Pass-20110622 092608
-TS1059-Administrator-TEST--Pass-20110622 092608
RAMAN
Intensity
100
80
60
40
20
0
0
500
1000
1500
2000
2500
Raman Shift (cm-1)


iPad
00:41
52%
Raw Data...
-TS1059-Administr...
-TS1059-Administrator-TEST--Pass-20110622 092608 Traces
-TS1059-Administrator-TEST--Pass-20110622 092608
-TS1059-Administrator-TEST--Pass-20110622 092608
-TS1059-Administrator-TEST--Pass-20110622 092608
RAMAN
Intensity
100
80
60
40
20
0
0
500
1000
1500
2000
2500
Raman Shift (cm-1)
Look Closer

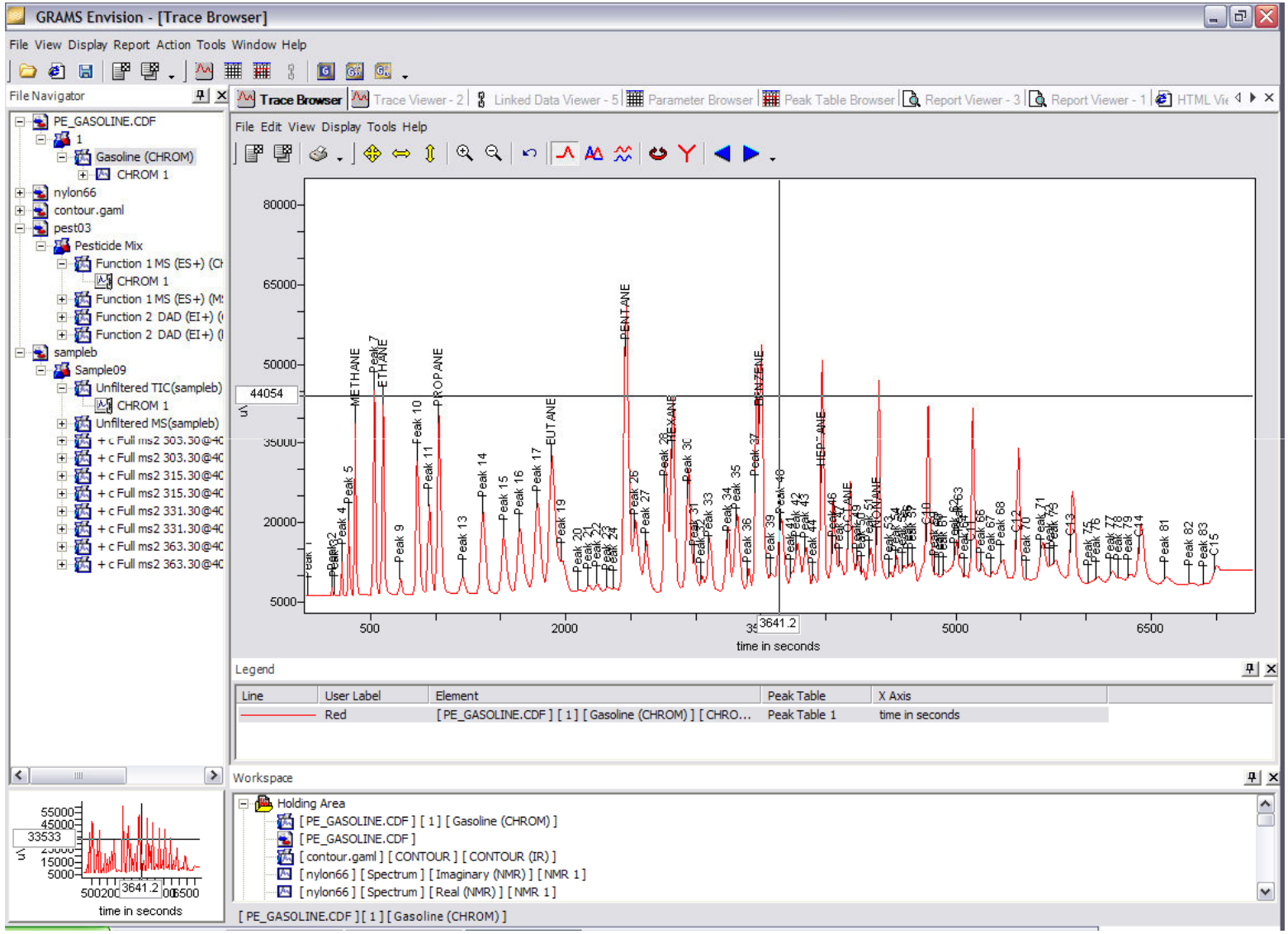

iPad
00:41
52 %
Raw Data...
-TS1059-Administr...
-TS1059-Administrator-TEST--Pass-20110622 092608 Traces
-TS1059-Administrator-TEST--Pass-20110622 092608
-TS1059-Administrator-TEST--Pass-20110622 092608
-TS1059-Administrator-TEST--Pass-20110622 092608
RAMAN
Intensity
100
80
60
40
20
0
0
500
1000
1500
2000
2500
Raman Shift (cm-1)


iPad
00:43
51 %
Raw Data...
-TS1059-Administr...
-TS1059-Administrator-TEST--Pass-20110622 092608 Traces
-TS1059-Administrator-TEST--Pass-20110622 092608
-TS1059-Administrator-TEST--Pass-20110622 092608
-TS1059-Administrator-TEST--Pass-20110622 092608
RAMAN
.055
.04
.025
.01
-.005
-.02
Intensity
550
700
850
1000
1150
Raman Shift (cm-1)


iPad
00:43
51 %
Raw Data...
-TS1059-Administr...
-TS1059-Administrator-TEST--Pass-20110622 092608 Traces
-TS1059-Administrator-TEST--Pass-20110622 092608
-TS1059-Administrator-TEST--Pass-20110622 092608
-TS1059-Administrator-TEST--Pass-20110622 092608
RAMAN
Here it is at an intensity of .01
Intensity
.055
.04
.025
.01
-.005
-.02
550
700
850
1000
1150
Raman Shift (cm-1)

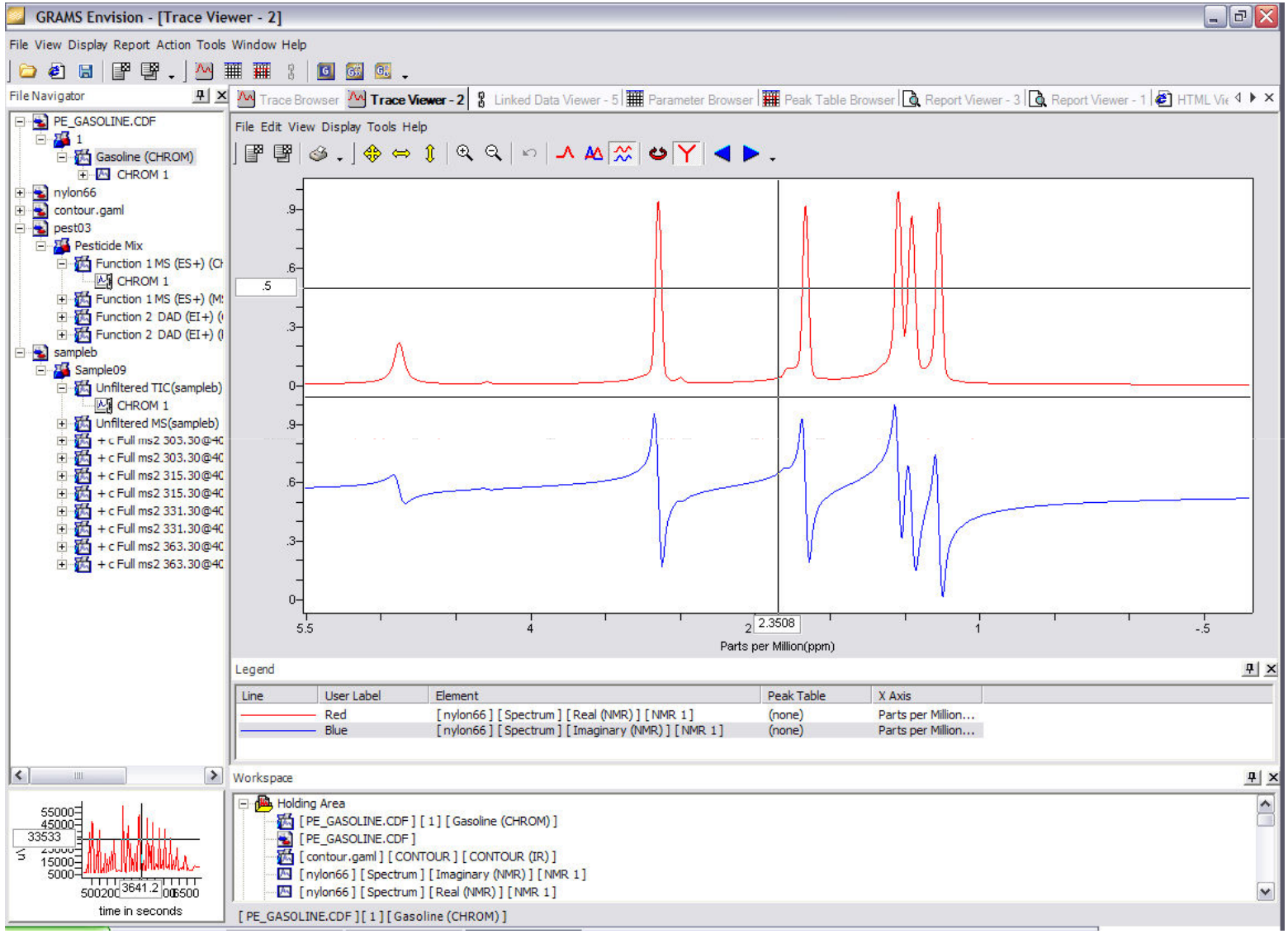

iPad
00:43
51 %
Raw Data...
-TS1059-Administr...
-TS1059-Administrator-TEST--Pass-20110622 092608 Traces
-TS1059-Administrator-TEST--Pass-20110622 092608
-TS1059-Administrator-TEST--Pass-20110622 092608
-TS1059-Administrator-TEST--Pass-20110622 092608
RAMAN
Here it is at an intensity of .01
Try doing that with a PDF!
Intensity
.055
.04
.025
.01
-.005
-.02
550
700
850
1000
1150
Raman Shift (cm-1)

..and Desktop Viewing of real raw data.



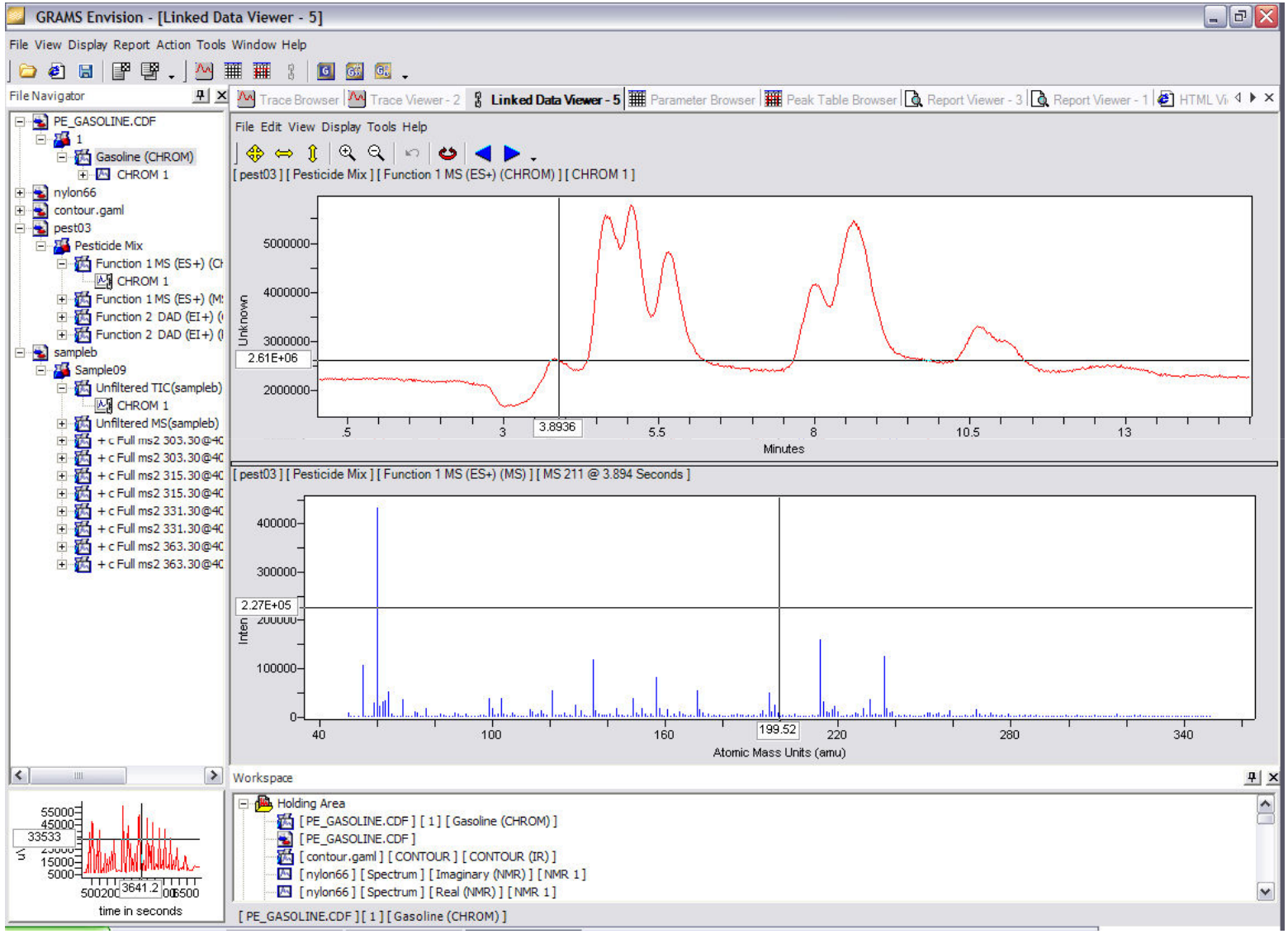
ThermoFisher SCIENTIFIC

..and Desktop Viewing of real raw data.



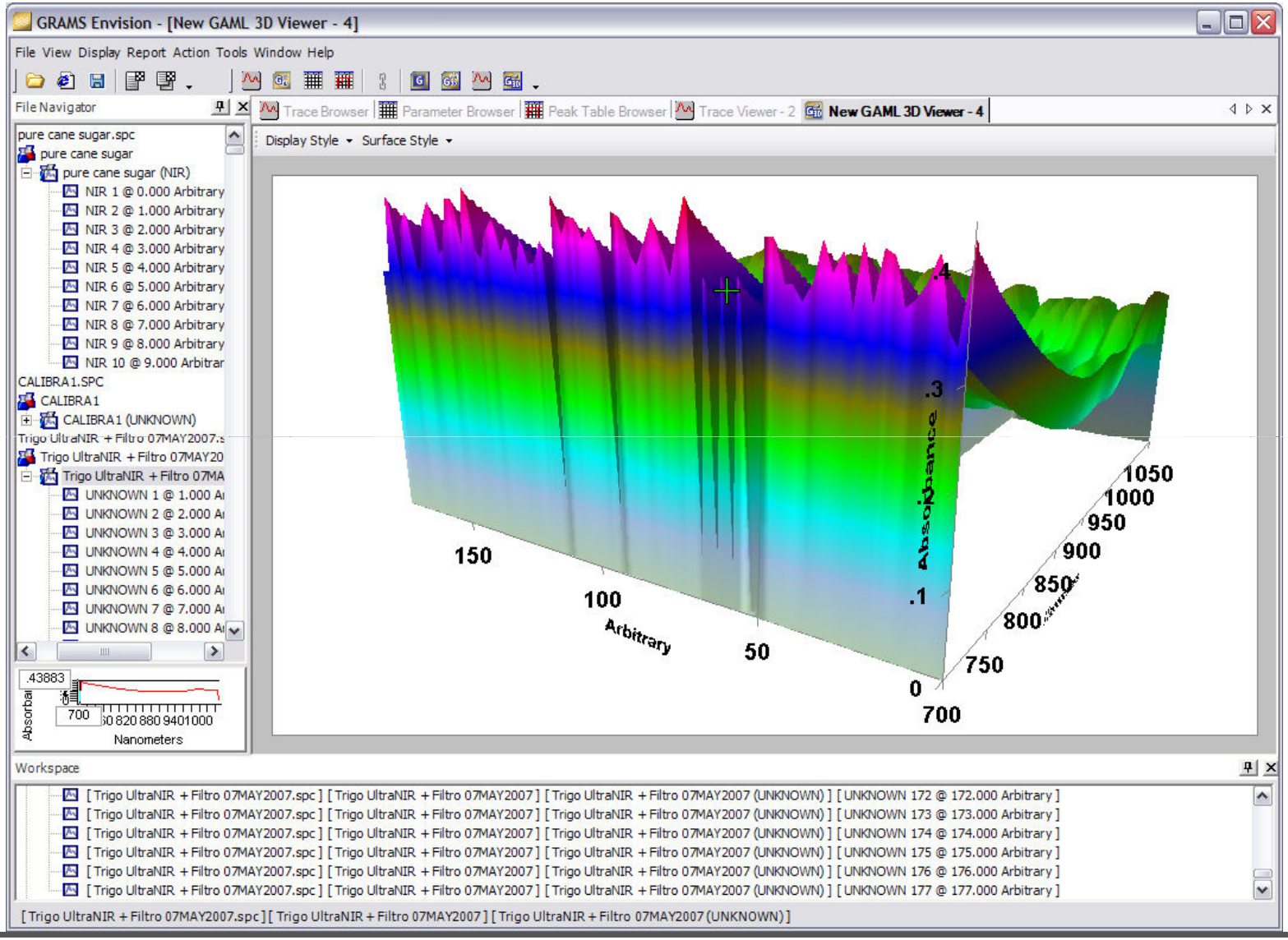
ThermoFisher SCIENTIFIC

..and Desktop Viewing of real raw data.



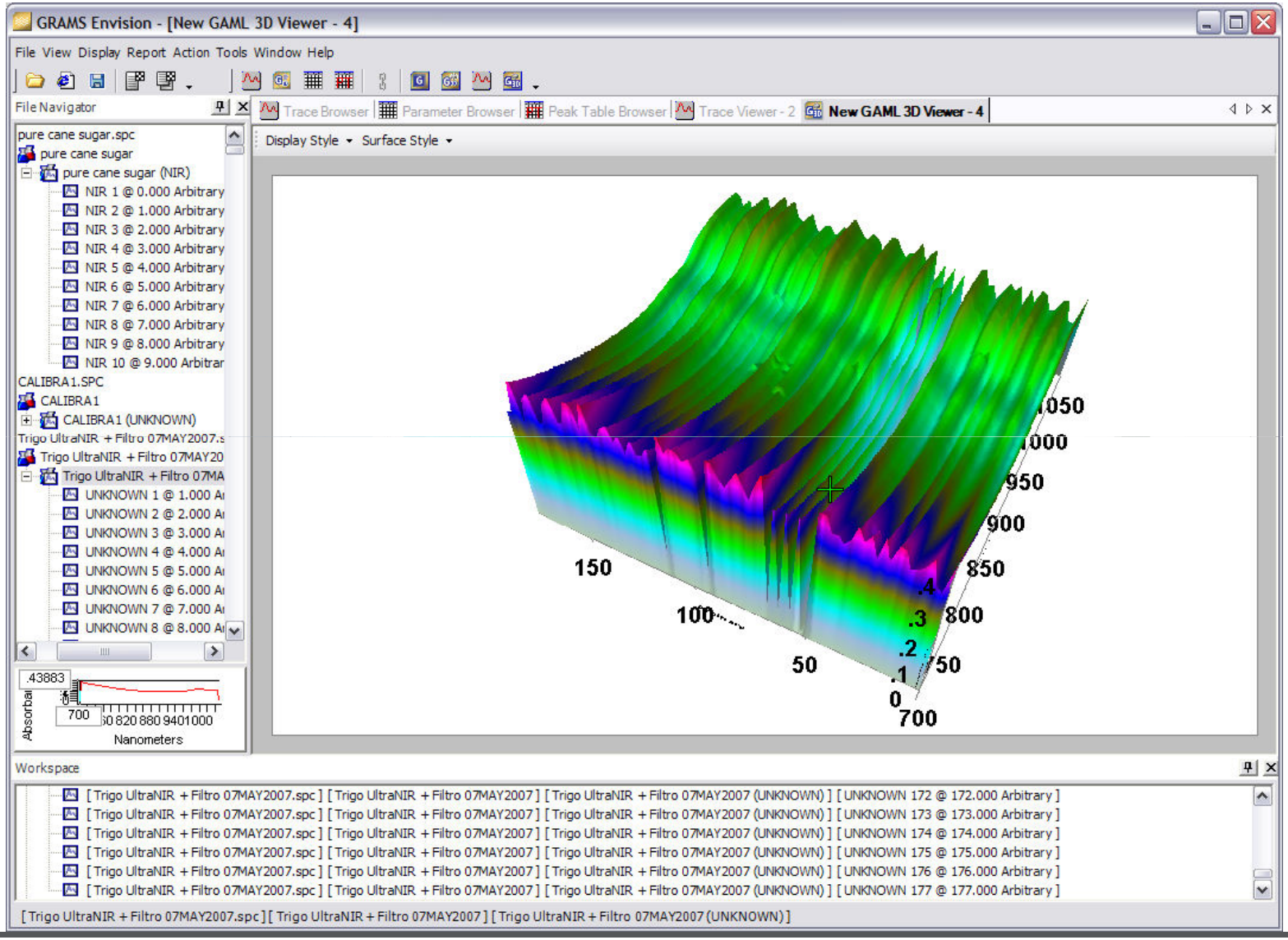
ThermoFisher SCIENTIFIC

..and Desktop Viewing of real raw data.



ThermoFisher SCIENTIFIC

..and Desktop Viewing of real raw data.



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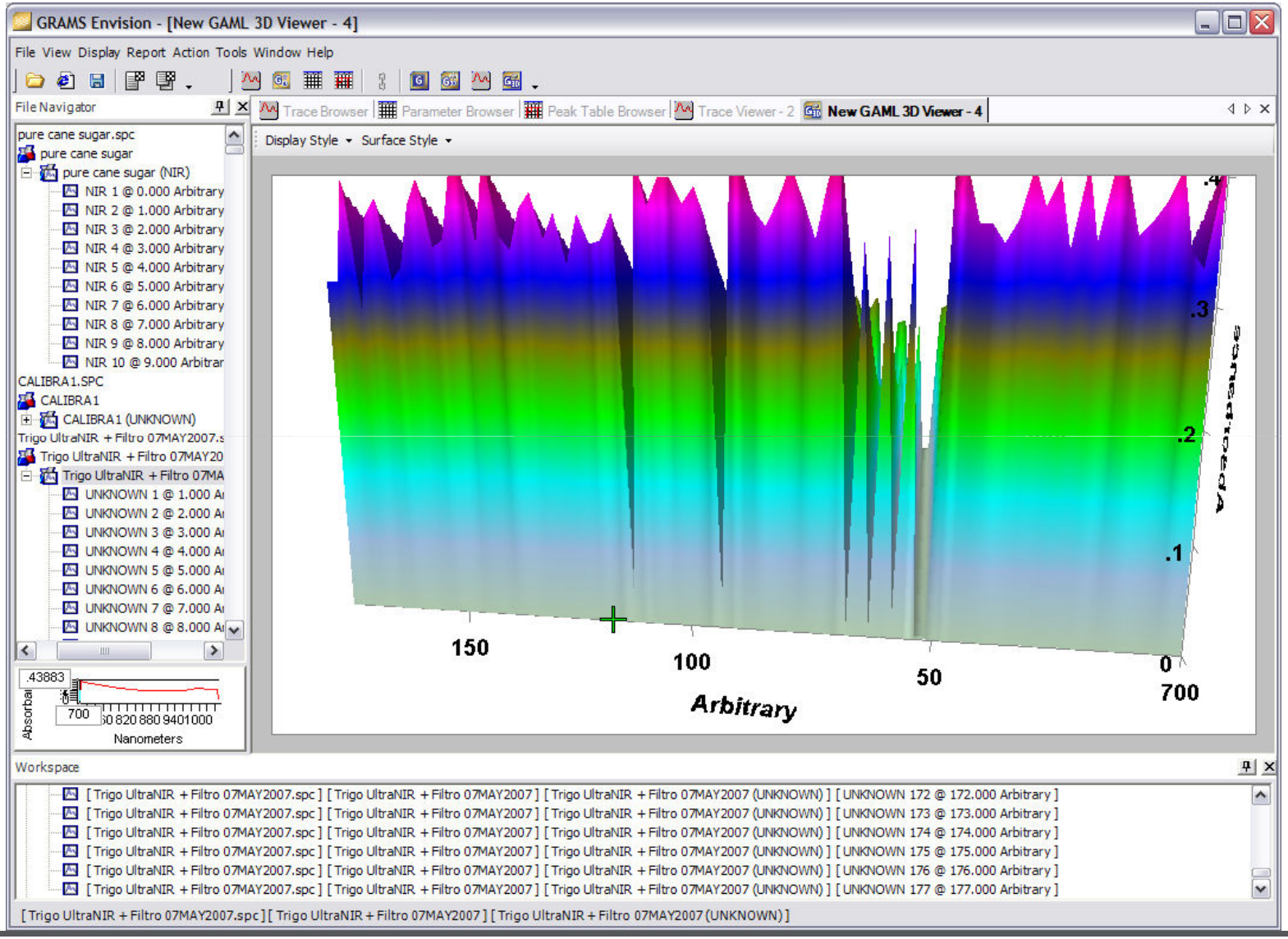
..and Desktop Viewing of real raw data.



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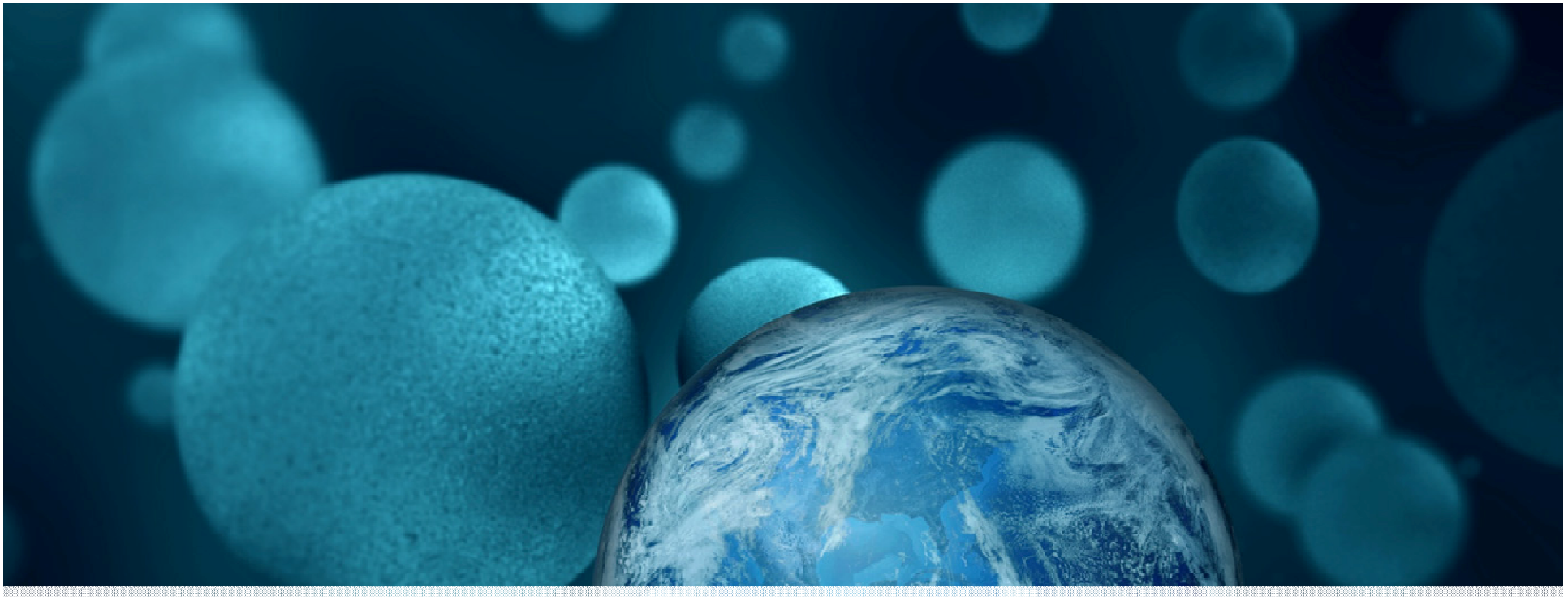
.....and not forgetting



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High Data Volume Sports Anti-Doping Case Study

The world leader in serving science

Customer Case Studies

- Sports Anti-Doping Laboratory
  - Collate data from many instruments from multiple vendors
  - Security primary focus
  - High volume of data

Sports Anti-Doping Requirements

- High visibility event
- Around 5,000 samples, average of 3 results per sample
  - Approximately 15,000 results
- Raw data has to be retained for 8 years
  - Secure
  - Future-proofed
  - Easy to retrieve if required

Many Instruments to Connect

- Connections to ≈ 21 different instrument types, ≈ 53 in total
  - 9 Thermo Scientific Exactive LC/MS
  - 10 GC/MS/MS, 5 GC/MS
  - 2 Thermo Scientific Orbitrap Velos HRMS; 1 Q-Exactive
  - 3 Thermo Scientific Delta V IRMS
  - 18 other instruments

- Also interface to the reporting system

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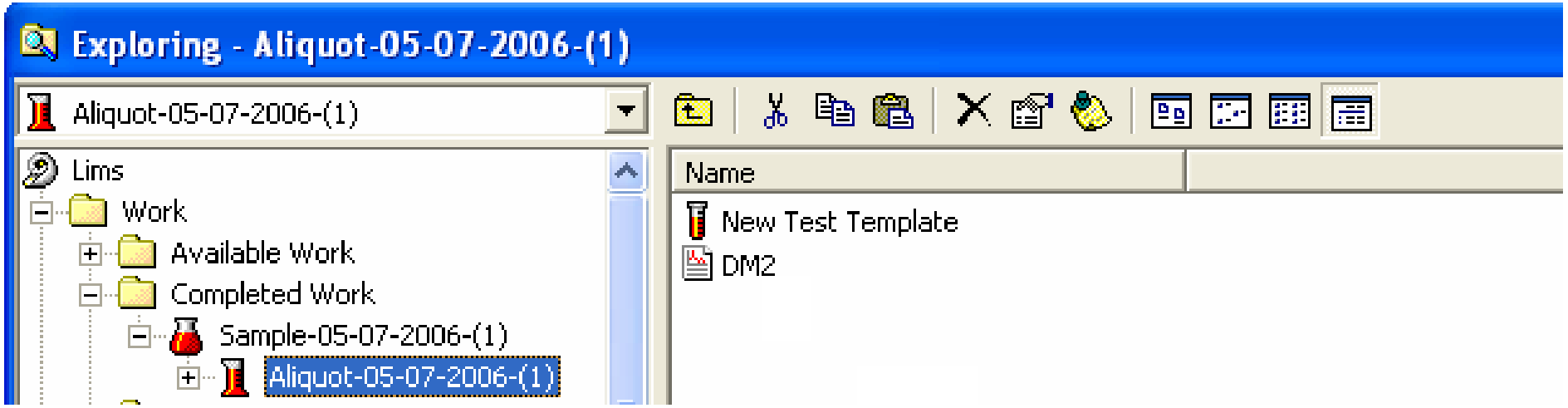
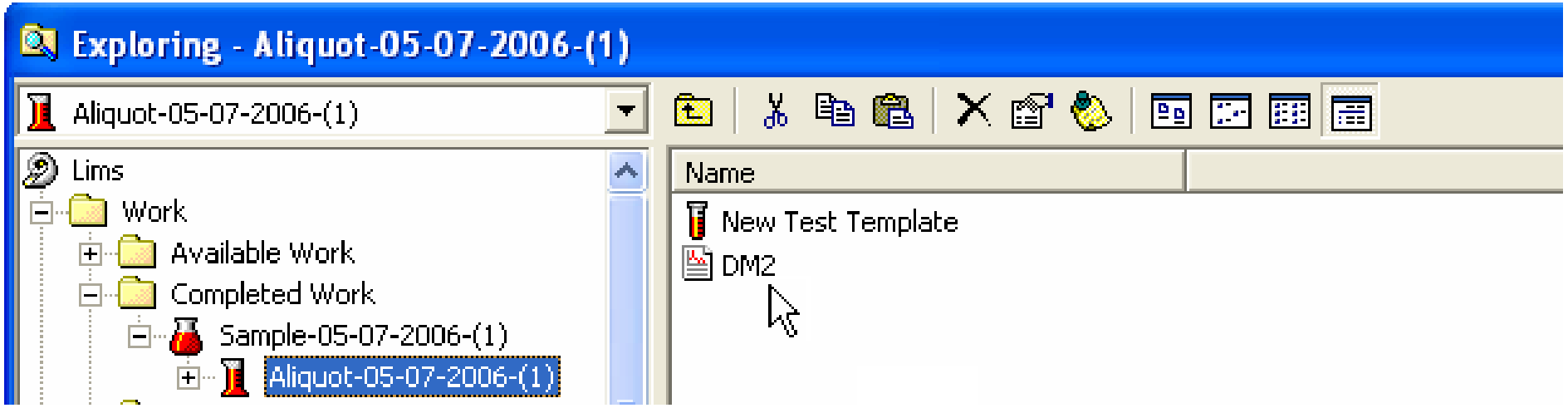
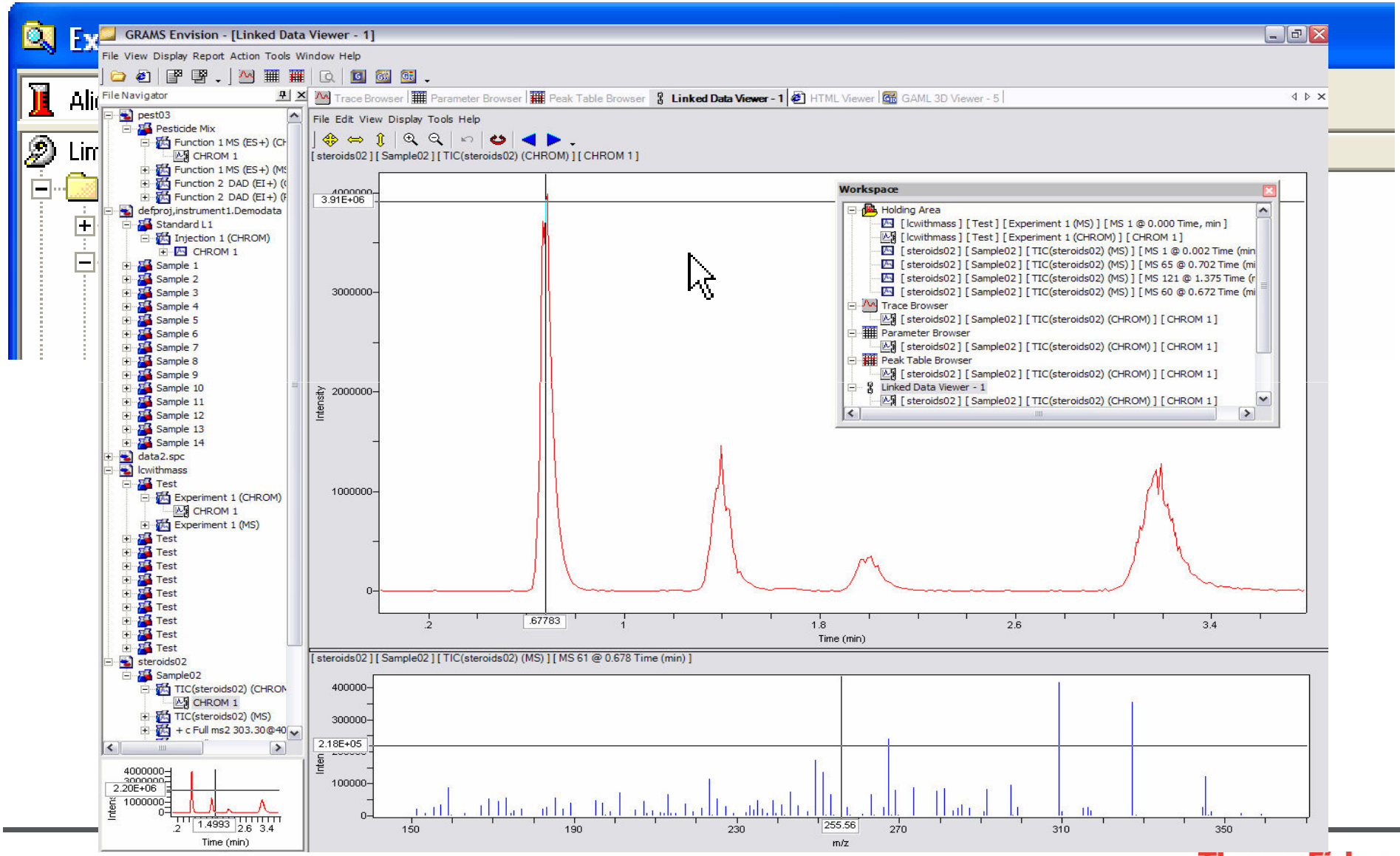
Reviewing Data from within LIMS



Reviewing Data from within LIMS



Reviewing Data from within LIMS



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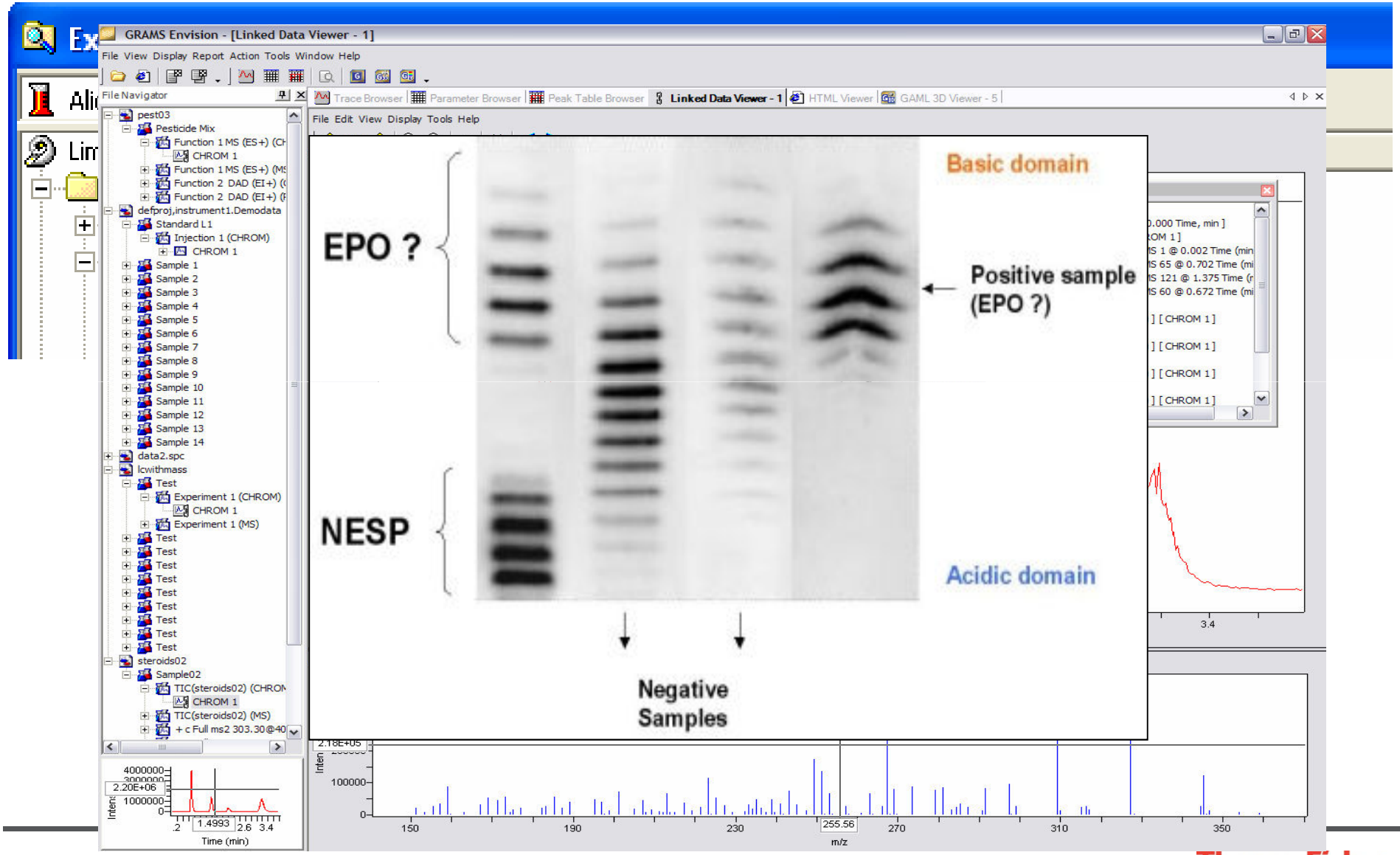
Reviewing Data from within LIMS



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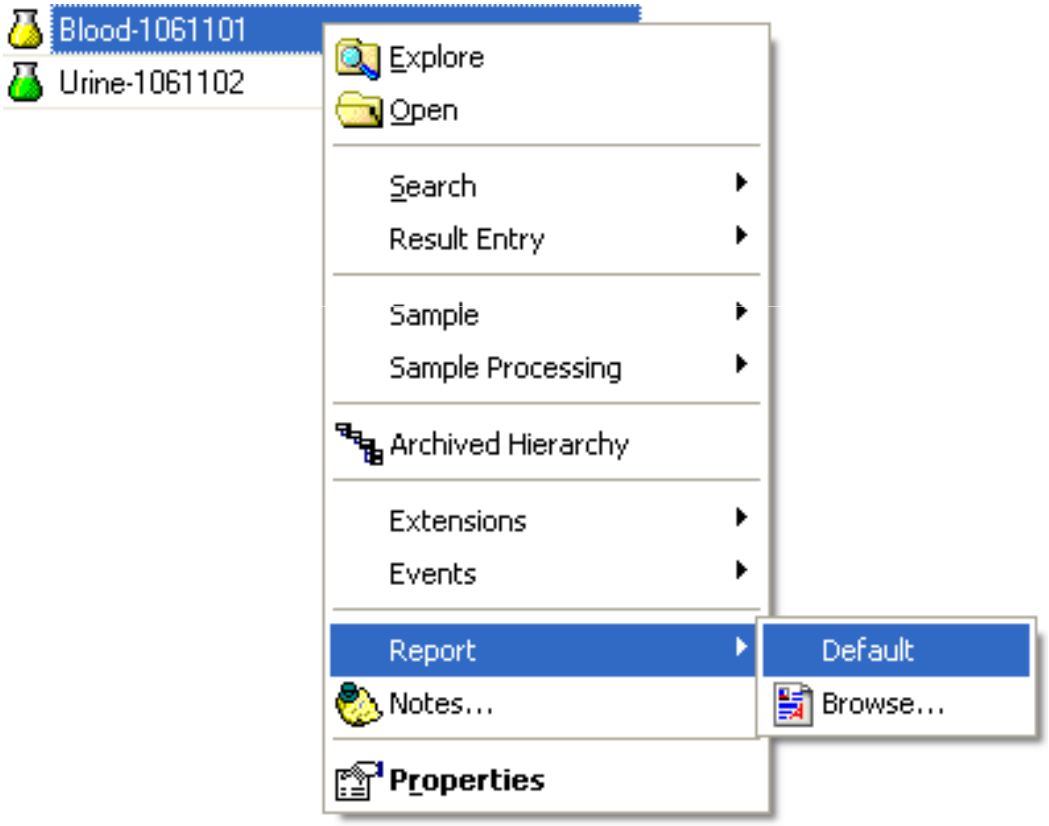
Linking Reports for Positives (...and Negatives)

- Built-in reporting as standard, using configurable templates



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Linking Reports for Positives (...and Negatives)

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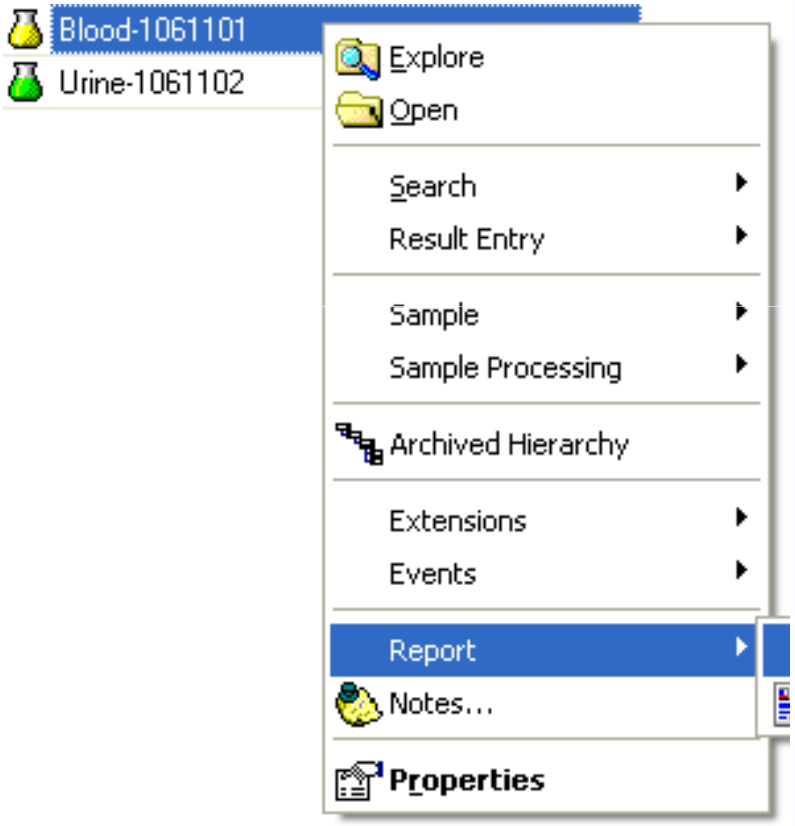

[redacted]ratory Address GSK Harlow
Tel 123456 Fax 123456
ISO/IEC 17025 Certificate No.: 123

[redacted]
King's College London

Test Report
Confidential
No. 12093

Page 1 of 1
19.09.2010

Sample ID	Urine-(Sep 18,2010)-011
Laboratory ID	[redacted]ab ID
Test Mission Code	7[redacted]
Type of Test	IC
Name of Competition	2012 [redacted] Games
Sport/Discipline	RU
Collection Date	18.09.2010 09:34:00
Collection Site	London, UK
Date of Receipt	18.09.2010 14:12:00
Sample Type	Urine
Gender	M

The sample above was analysed using Methods GC-MS/MS, LC-MS/MS, and Isoelectric Focusing.

Results

The analysis of the sample idientified above by the Laboratory method has shown the presence of 5α-androstane-3α,17β-diol.

Authorised by

Mike Manager
Laboratory Director

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Thermo Scientific Informatics Delivers!

- Full support for end to end sample and results workflow
  - UKAS / World Anti-Doping Agency (WADA) accredited environment
- Reported 75% of results in 24 hours, 90% in 26 hours
- Captured 1.4 million data files from 53 instruments
  - Available for subsequent ‘expert review’
  - Securely archived (min 8 years)
  - 1.2 TB data
- Supported 24 x 7 :
  - 240 scientists & staff from around the world
  - No unplanned interruption of operations throughout event

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  - No unplanned interruption of operations throughout event
- Already Booked for a similar event in 2016

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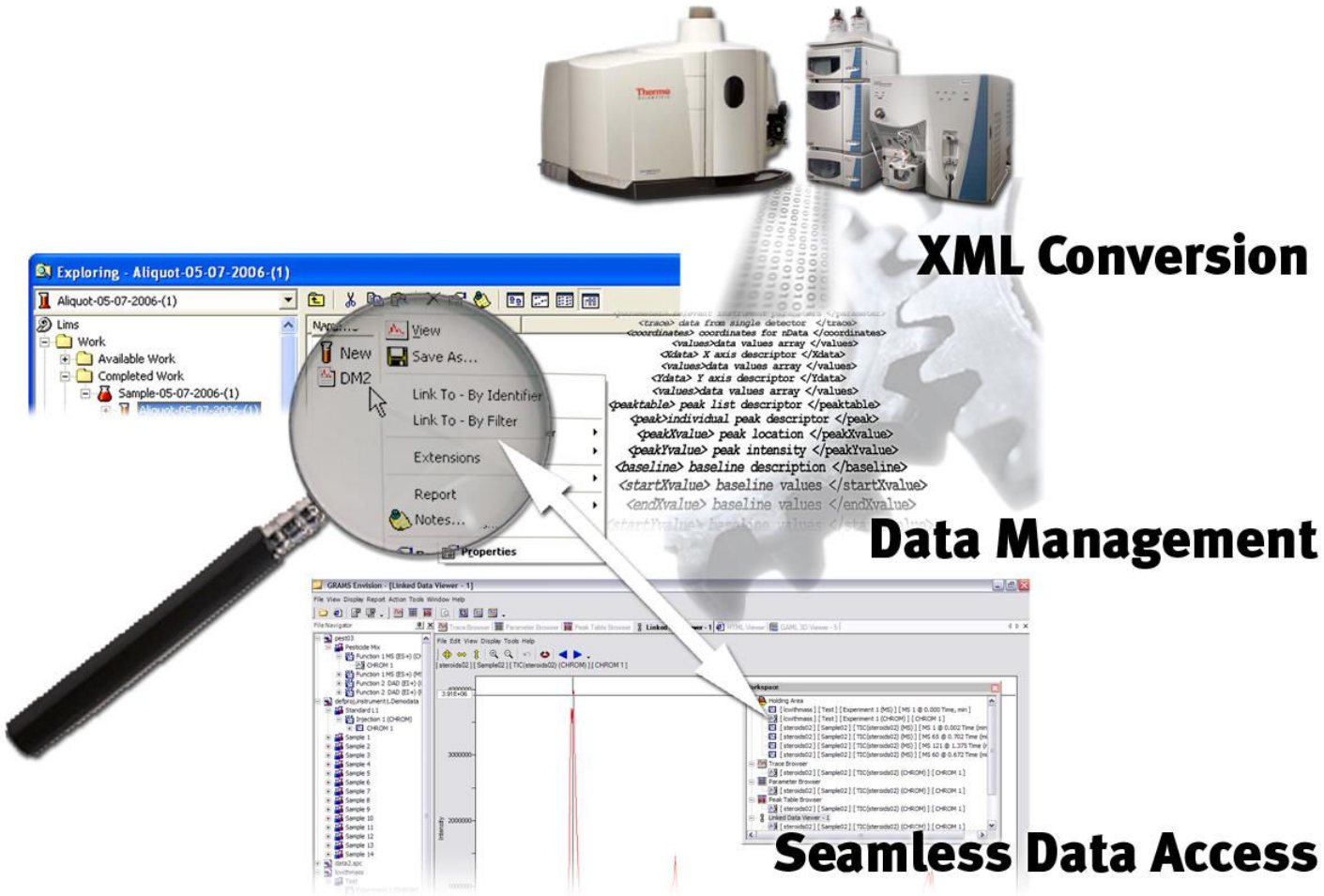
Thank you



www.thermoscientific.com/paperlesslab

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