datainnovations.com

EP Evaluator Overview

Overview and Getting Started with New experiments

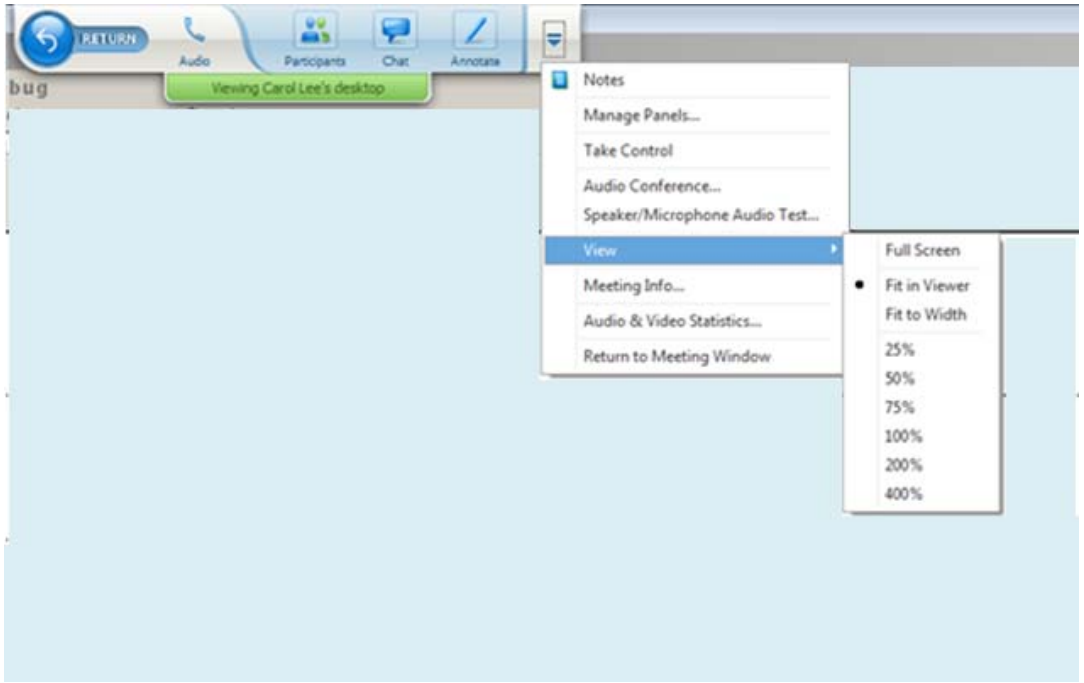
Carol R. Lee

Data Innovations Implementation Consultant

DATA INNOVATIONS
Simple Ideas, Better Solutions

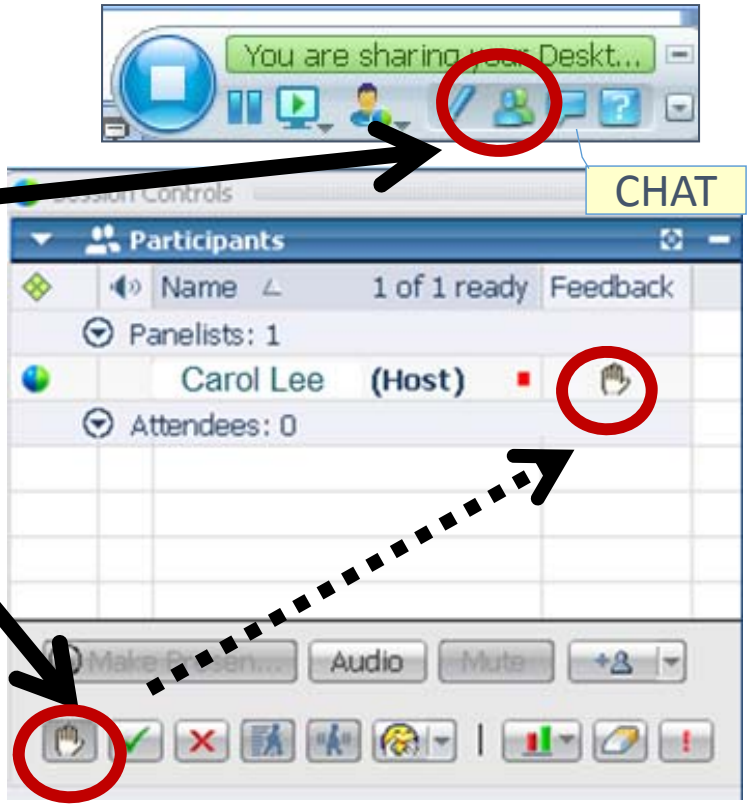
Viewing this presentation

- Webex taskbar
- Right side drop down
- View
- Choose your zoom



To ask a question …
Raise Your Hand Or Send A Chat

- **Phones are muted**
- **Click the participants icon** in the WebEx task bar
- **Click the hand** icon bottom left
- I'll unmute and call on you.
- Click the hand again to clear.
- Not on a phone or headset? Send a chat question to Michel



Session Objectives

- Create new experiments

- Enter data 2 of the 10 ways
  1. Manual entry
  2. Paste data into an experiment

- Print Reports

- Describe the STAT modules in EE 11.0
  - 30 for the standard version
  - 10 for the CLIA and COFRAC versions
  - We will review AMC, 2IC, MIC, QMC, LIN, SP

- Make and Manage Projects

FLOW

- Summary slides
- Features and flow chart
- Start EE
- Explore and create experiments
- Menu Bar & Preferences
- Projects
- RRE and copy/paste
- Rest of the Modules

What is EP Evaluator

- What is EP Evaluator and it's intended use for customers
  - EP Evaluator Software is Quality Assurance Software for the Laboratory. The purpose of the Statistical Modules is to provide reports based on specific laboratory experiments that meet CAP and CLIA '88 requirements for validating and evaluating methods. It satisfies all CLIA and CAP requirements for validation and verification of new methods being installed in a lab, and also for the ongoing quality assurance, calibration verification and harmonization of "equivalent " methods
- The Lab Management modules are intended as a bonus for lab managers.
  - Inventory management can be used to help manage laboratory supplies. It doesn't integrate with supply chain management or the instruments directly.
  - The" Incident tracking"module is part of the lab's QAPI process, and doesn't deal with instrument results per se,
  - The Incident Tracking Database represents the Error Identification phase of a laboratory QAPI program as defined in 2003, CMS final Rule 42 CFR 482, (2003) which: Requires a "Quality Assessment and Performance Improvement (QAPI) program. And is a Condition of participation in the Medicare reimbursement program.

Pulling data from Instrument Manager

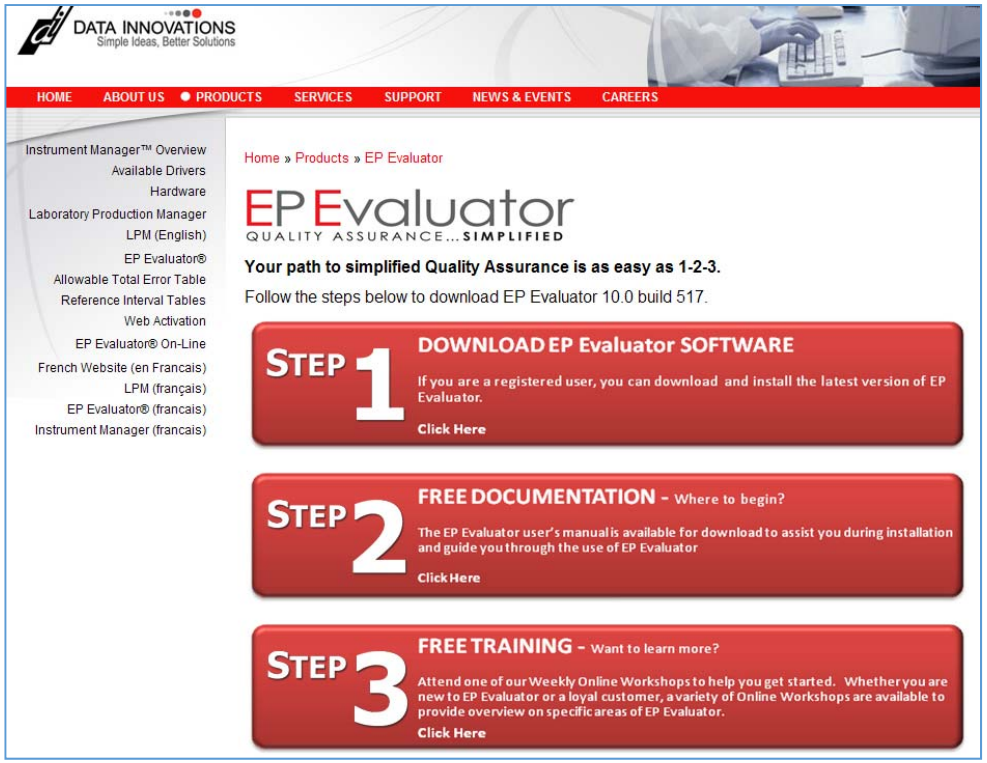
- How does it integrate with Middleware and what data does it pull?
  - o EP Evaluator can connect with Instrument manager via ODBC connectivity to download specified data directly into EP Evaluator to create the targeted module experiment.

- Is this only a feature in the Professional version?
  - This feature available in the data capture version, and the professional version.
- Is there any Patient Health Information contained in it?
  - EP Evaluator does not require or solicit PHI.

Documentation and Support

http://datainnovations.com/node/255

- the EE manual,
- Lab Stats Manual.
- the QuickStart Guide.
  - Download free to Subscription users or
  - PDFs in the physical disk set.
- Context sensitive HELP is part of the program.



EP Evaluator Features

- Clinical Laboratory Compliance Toolkit
  - Meets all CLIA '88 and CAP requirements for validating and evaluating methods. www.cms.hhs.gov/clia
  - New Method Validation / Verification
  - Ongoing Quality Assurance, Performance Verification, Harmonization
- 30 Statistical Modules including 8 CLSI documents
- 4 Lab Management Modules

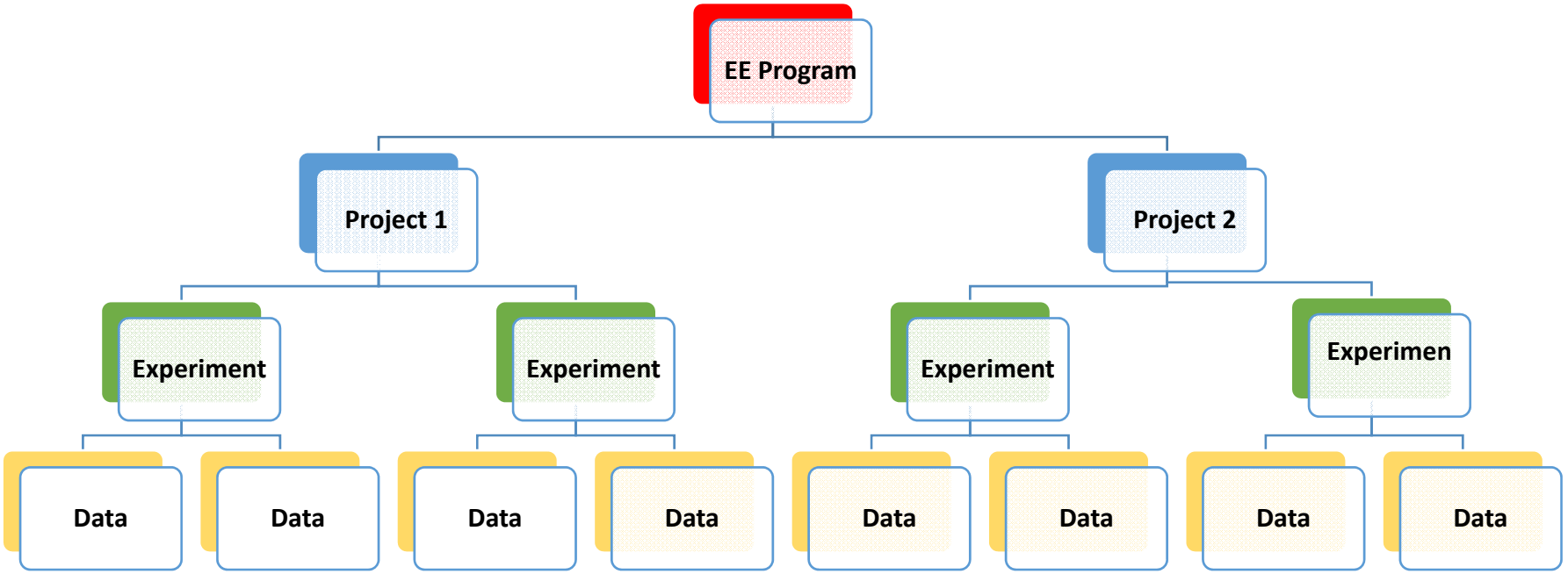
- **Vendor Tools**
  - FDA submissions
  - Reagent Quality Control
  - Customer Installations with instrument interfaces

- **Allowable error as pass/fail criteria**
  - Relates data quality to the lab's allowable error specification
  - TEA = 3*Random Err (Rea) + bias (SEa)
  - The +/- 3 SD model is used by CLIA, CAP, NYS and means that 99.7% of the data is within the TEA limit (error rate of 3 in 1000) A 3 sigma process

EP Evaluator Concepts

- **Statistical Module** – Does calculations and reports for a specific type of experiment - Like method comparison.
- **Project** – – a database folder containing a collection of Experiments from one or more Statistical Modules
- **Experiment** – one set of data collected for a specific purpose for one analyte
- **Instrument** = method (think outside the box!)
- (**RRE) Rapid Results Entry** – mechanisms to efficiently enter data into EE
- **"Policies" = Policy Definitions –** A MASTER template of parameters used in RRE. Policy definitions in a project autofill the key parameters needed to define the experiment.

EE Hierarchy

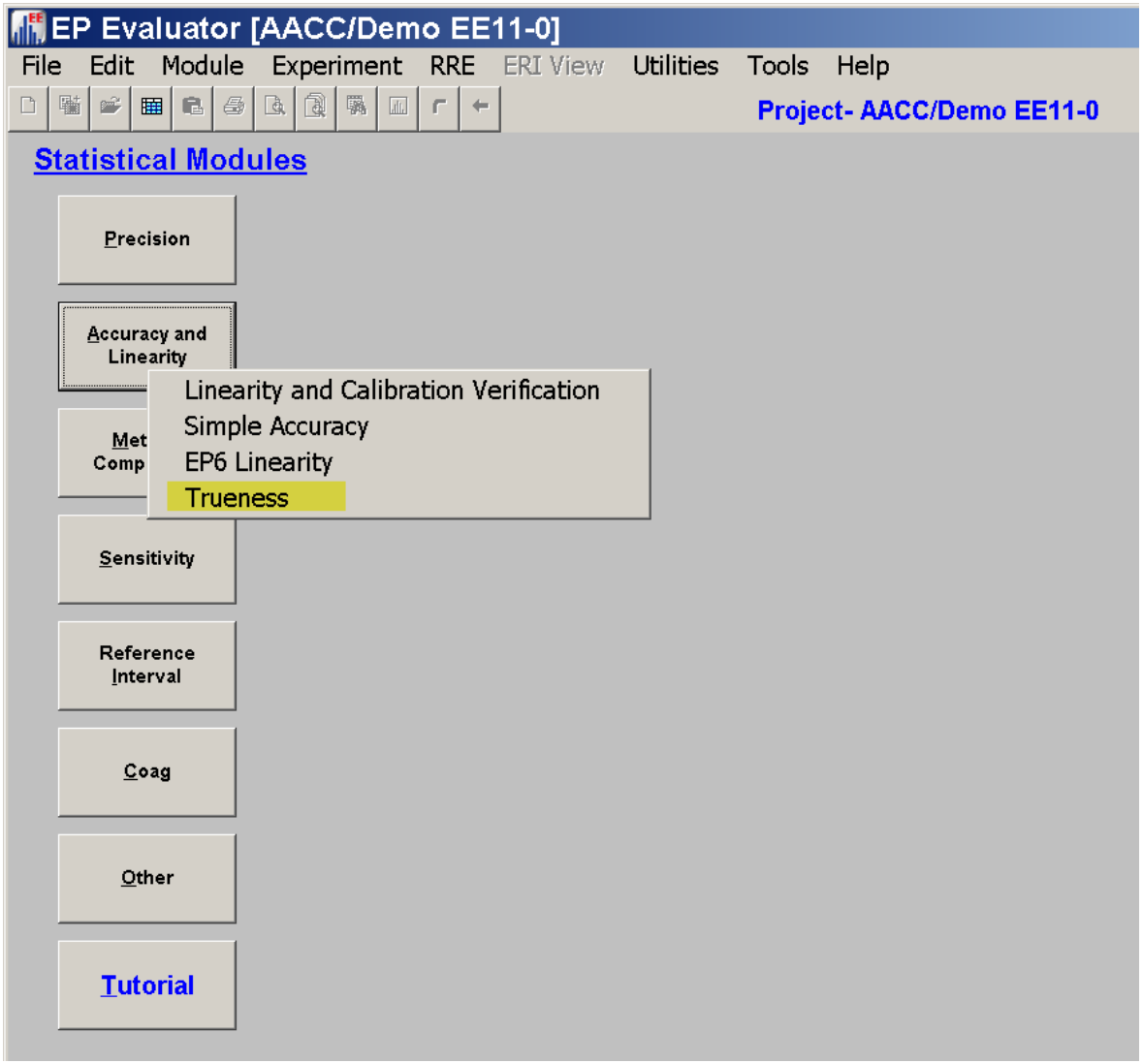


EP Evaluator Pass / Fail criteria

- **Some modules grade the results as Pass/Fail**
- **Allowable error as pass/fail criteria**
  - Relates observed data quality to the lab's allowable error specification
  - TEA = 3*Random Err (Rea) + bias (SEa)
  - The +/- 3 SD model is used by CLIA, CAP, NYS and means that 99.7% of the data is within the TEA limit
    - (error rate of 3 in 1000)
    - A 3 sigma process

Statistical Module Screen

- Main screen
- 34 modules (10 in CLIA and COFRAC versions)
- Tutorial - a very basic overview –



30 Statistical Modules

- Precision (2)
- Accuracy and Linearity (4)
- Method Comparison (7)
- Sensitivity (2)
- Reference Intervals, ROC (3)
- COAG (4)
- Carryover
- Interference
- Stability
- Other (6)

What module to use - 1

- New method Validation Verification V/V
  - AMC: Alternate Method Comparison AMC
    - Accuracy vs older method
    - Verify agreement at Medical Decision points – verify old reference intervals can be used for new method
  - 2IC
    - Harmonization of “equivalent” methods
    - Lot to lot verification
  - Simple Precision (SP)
    - Repeatability within run
  - * Complex Precision (CLSI EP05 and EP15) *Not in EE CLIA version
    - Reproducibility within Instrument / between run / between day
  - LIN: Calibration Verification LIN - CalVer
    - Calibration Verification (accuracy and Reportable range compared to a set of at least 3 true value standards)
    - Linearity of related materials

What module to use - 2

- New method Validation Verification V/V
  - QMC
    - Method comparison of qualitative / semi quant methods
    - Repeatability of Qualitative methods
  - * MIC – Multiple Instrument Comparison
    - Harmonization of up to 30 methods, e.g. POCT devices
- Reference intervals or cutoff points
  - VRI – Verify that new method ref interval is statistically the same as old
  - * ERI - When VRI fails, Establish Ref Interval for analyte
  - * ROC – establish clinical cutoff points
  - INR Geo mean & VRI verify new lots of PT reagent

    - * Not in EE CLIA version

EP Evaluator Features : Clinical Chemistry concepts not in generic SW packages

- Beyond p, “t”, Chi2 and R2
- Allowable error (TEA)
  - Clinical linearity
  - Accuracy, reportable range
- Method comparisons
  - Error boundaries TEA, conf limits, binomial
  - OLS, Passing Bablok or Deming regressions
  - Bias and Bland Altman Plots
- Trueness and Uncertainty
- Sensitivity / specificity
  - LOQ Functional sensitivity
  - LOB Analytical sensitivity
  - Truth tables in HMC and QMC
- Carryover
- Reference Intervals and ROC plots

- CLSI protocols and algorithms - 8
  - EP5 A2 Precision
  - EP6 Linearity
  - EP7 Interference (partial)
  - EP9 A2 Method Comparison
  - EP10 Preliminary Evaluation of Methods
  - EP12 Qualitative Method Comparison
  - C28a Establishment of Reference Intervals
  - GP10 ROC Curves

Performance Evaluation Goals

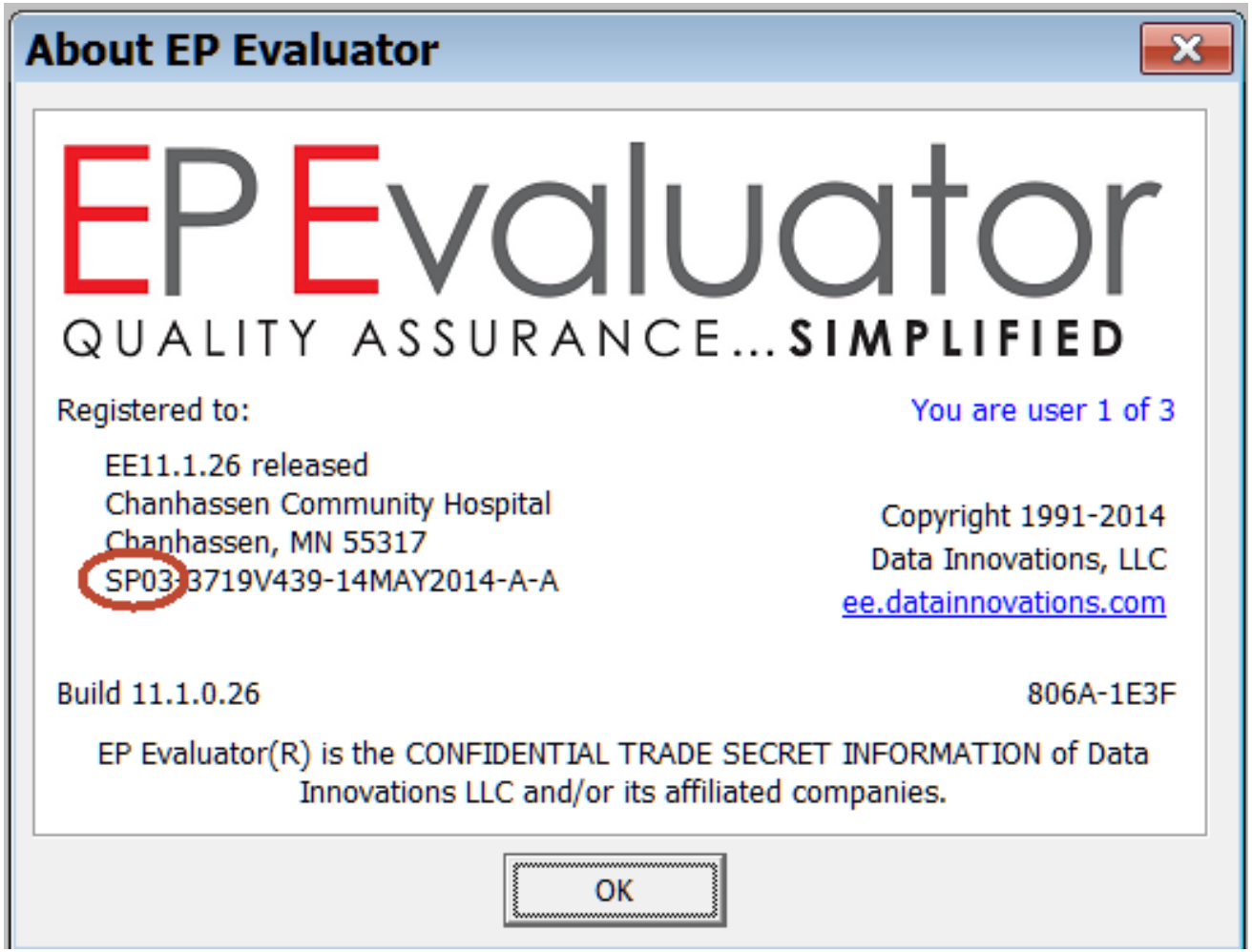
- **To compare the experimental data to *performance goals*.**
  - Proficiency testing (PT) limits aka:
    - **Total Allowable Error (TEa)**
  - Lab's stricter pass/fail criteria
- To be able to make a statement about the results of a single patient specimen submitted for testing.
  - **"This glucose test result is expected to be within 6 mg/dL or 10% of the true result 99.7% of the time"**

datainnovations.com

Starting EP Evaluator

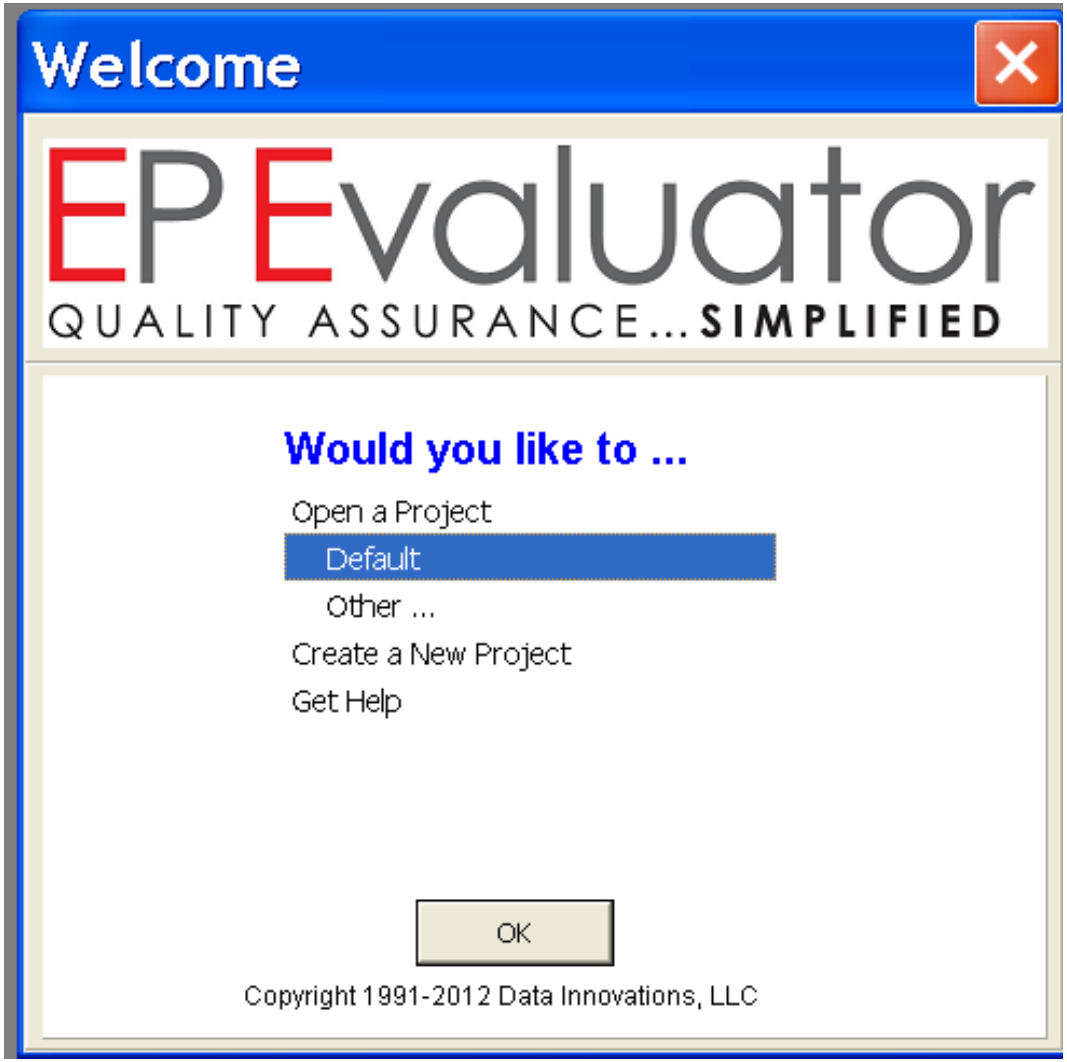
DATA INNOVATIONS
Simple Ideas, Better Solutions

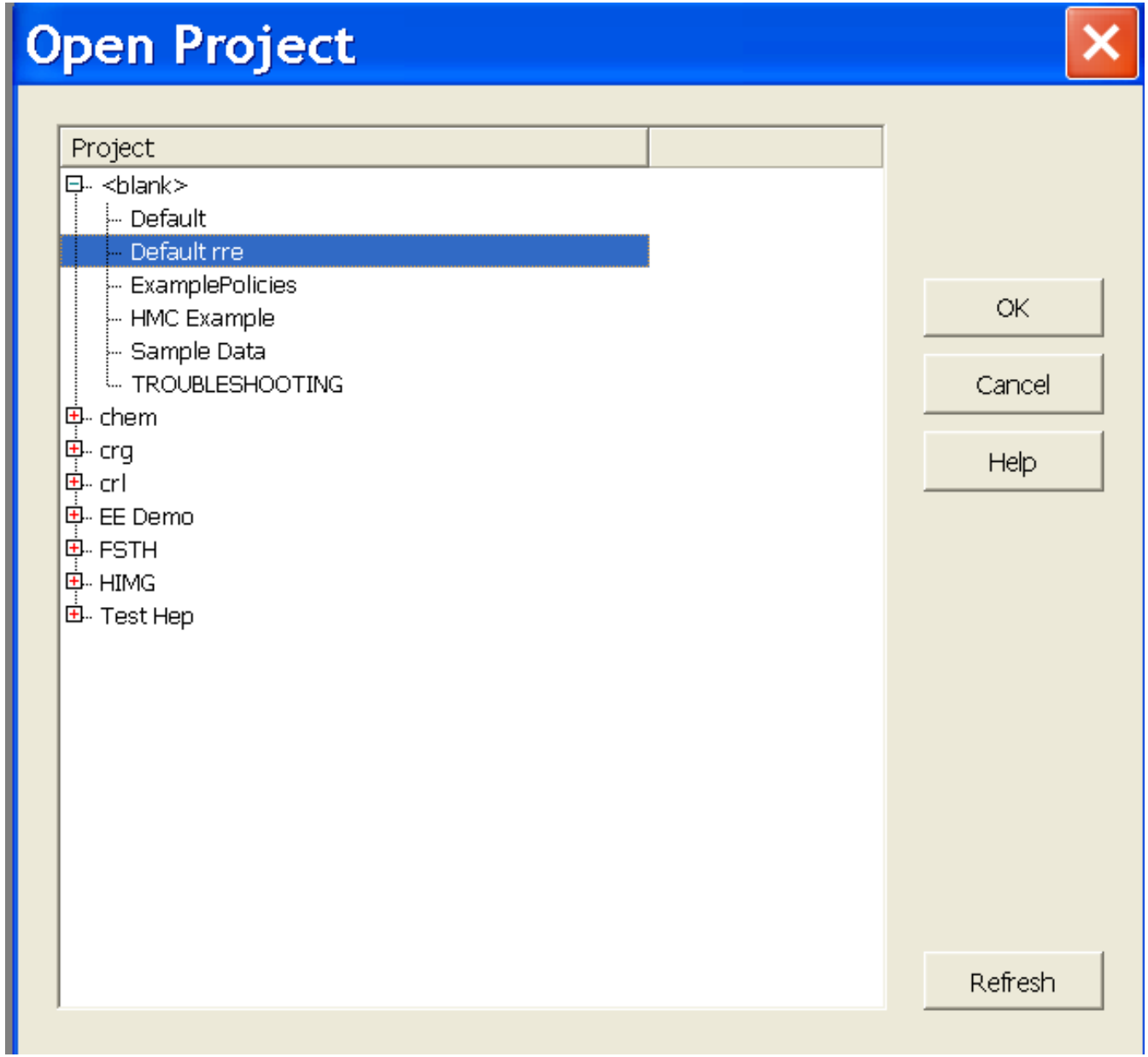
The About screen



Go to HELP\About to get back to this screen at any time

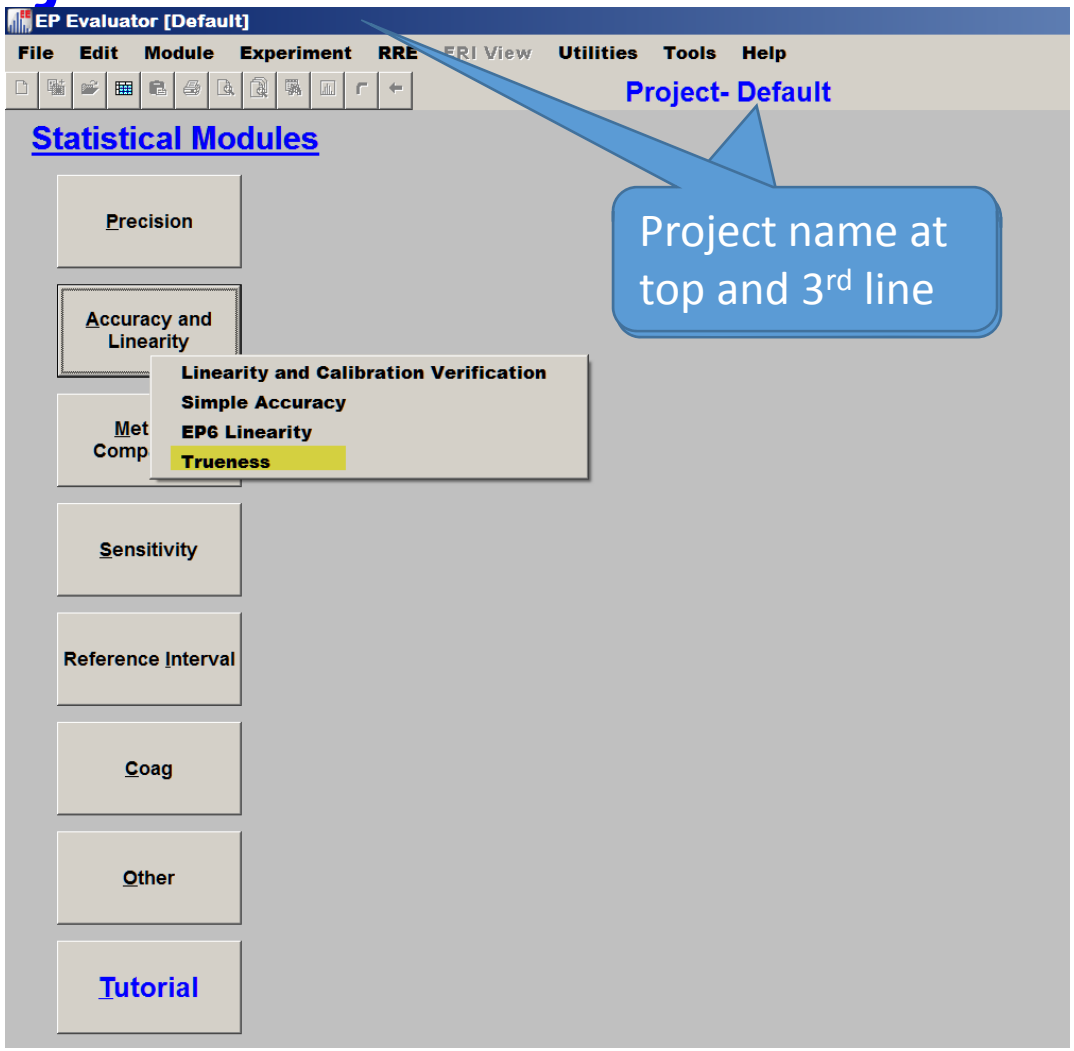
The Welcome Screen




Open Project
Project
<blank>
Default
Default rre
ExamplePolicies
HMC Example
Sample Data
TROUBLESHOOTING
chem
crg
crl
EE Demo
FSTH
HIMG
Test Hep
OK
Cancel
Help
Refresh

Project Name

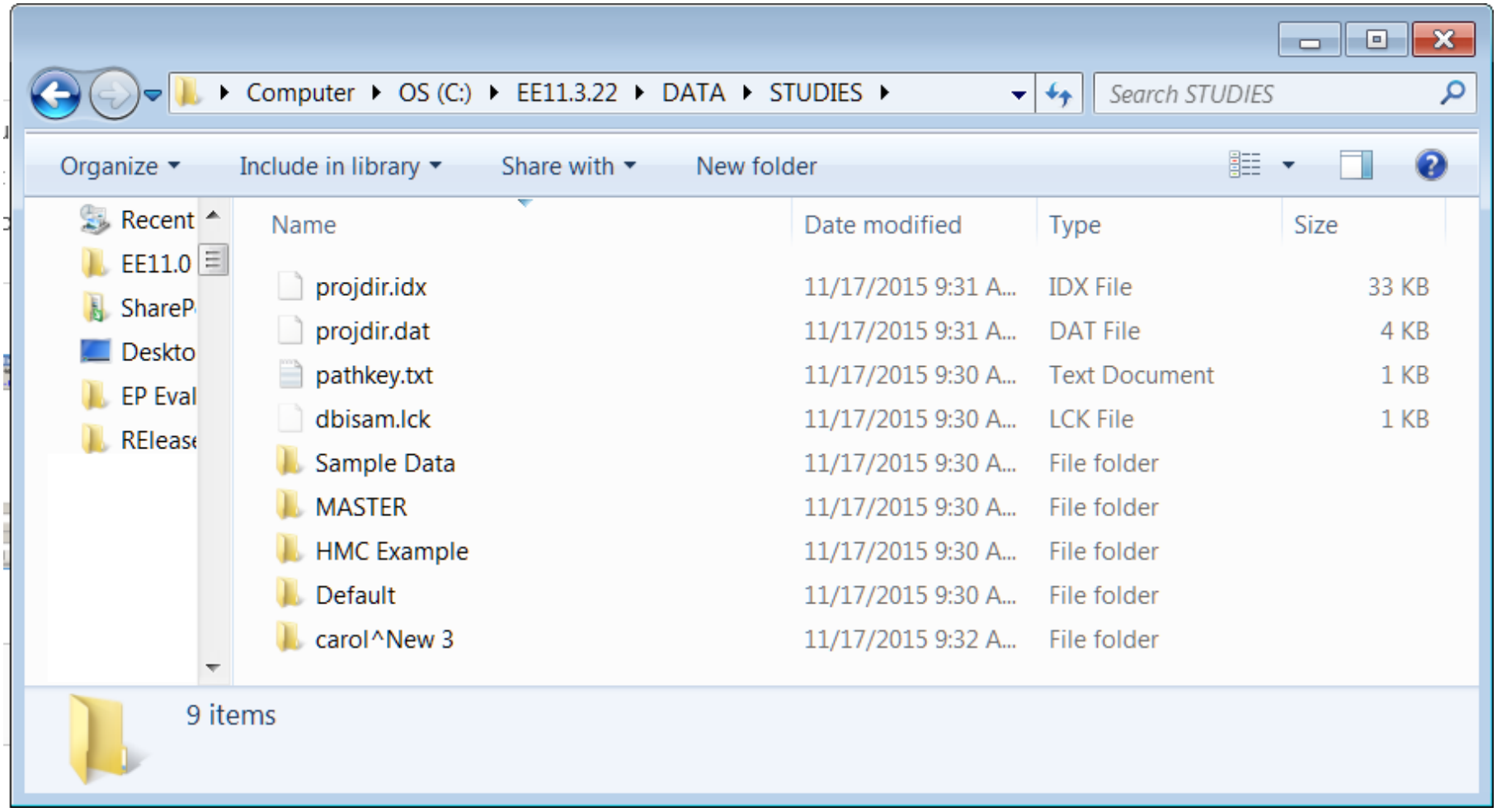
- Main screen
- Project name at top and 3rd lline



Project

- A database folder containing your collection of Experiments for one or more Statistical Modules
  - Every experiment belongs to a project.
  - Projects can **only** be opened in EE.
- EP Evaluator comes with:
  - 3 projects with sample data:
    - "Default", "Sample Data" and "HMC example"
  - 2 projects with RRE examples
    - "Example Policies and "HMC Example"
- You can make many new projects *
  - Exception: CLIA version users can only use Default and sample data. Not allowed to create new projects
- Projects stored in folders on your network or hard drive.
  - Active projects EE\data\studies
  - Archived projects EE\data\backups

Studies directory for Active projects



datainnovations.com

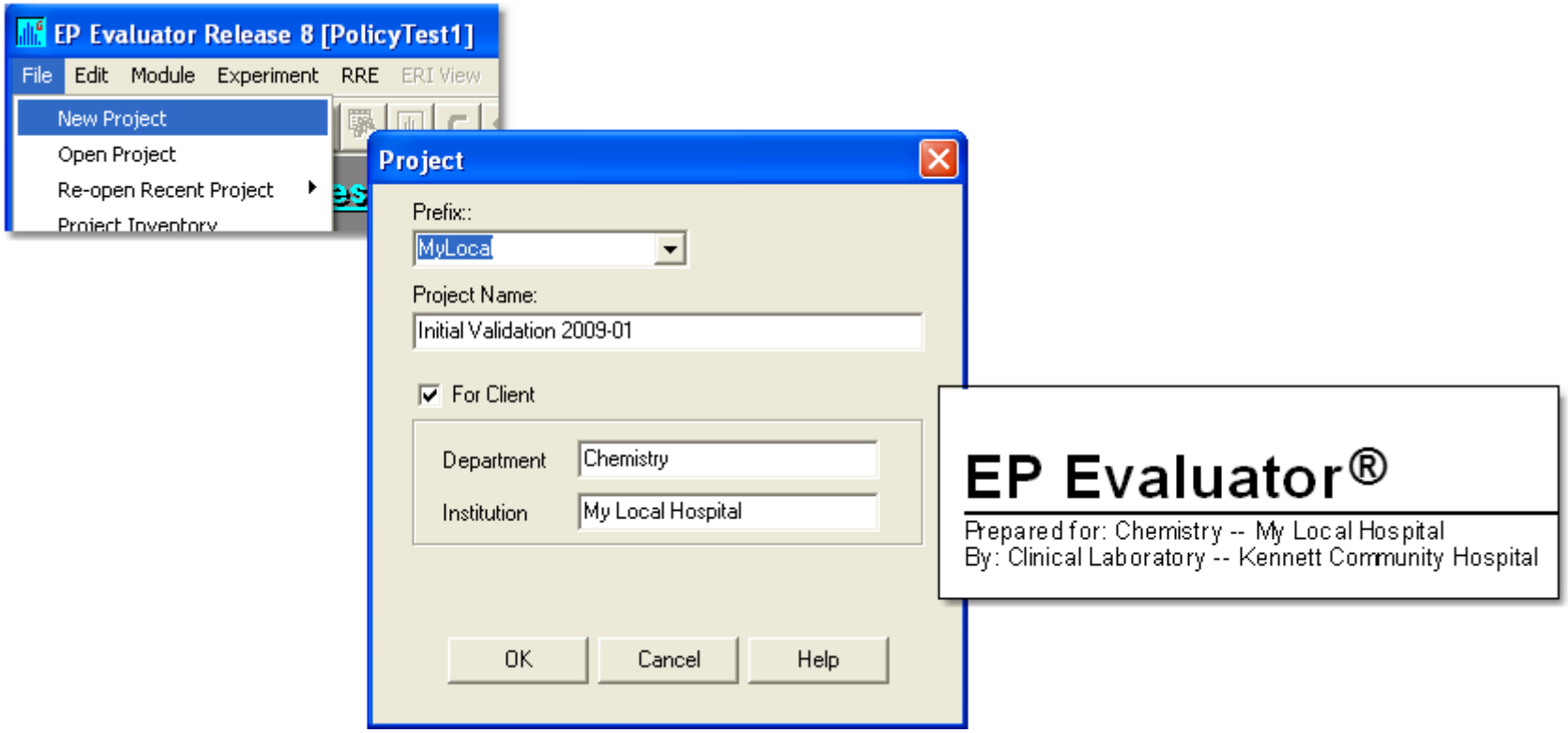
Creating a New Project

DATA INNOVATIONS
Simple Ideas, Better Solutions

Projects

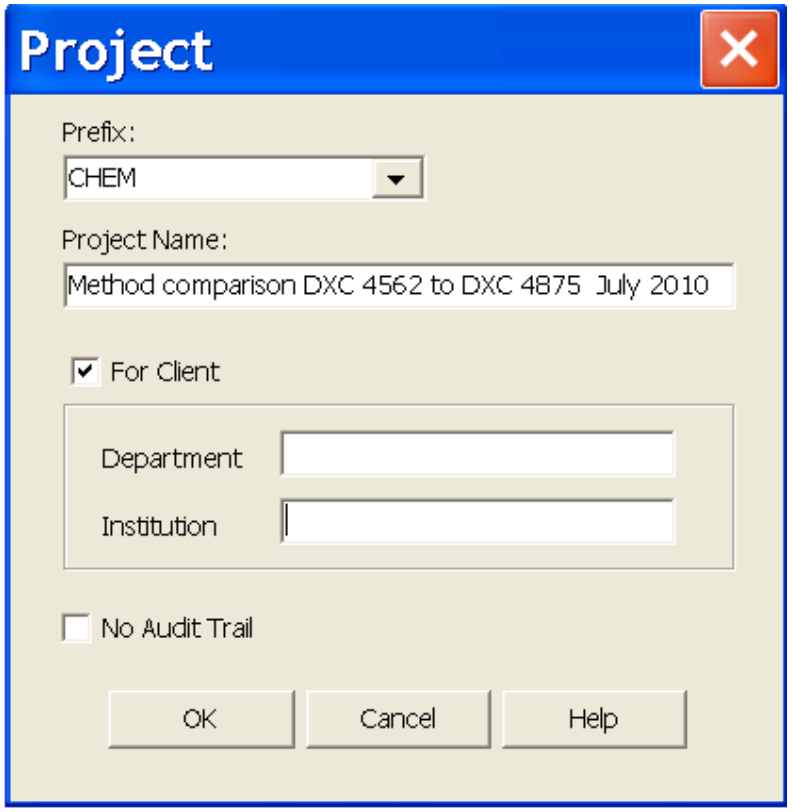
- **Projects must be unique – a 2 part name**
- **Prefix ^ unique name**
  - **Chem^"Validation for city Med Center – June 2009"**
- **The prefix serves as a folder name**
  - **Can Add more projects under the same prefix**
- **Organized in the EE file menu by prefix.**

Creating a New Project



Naming your project:

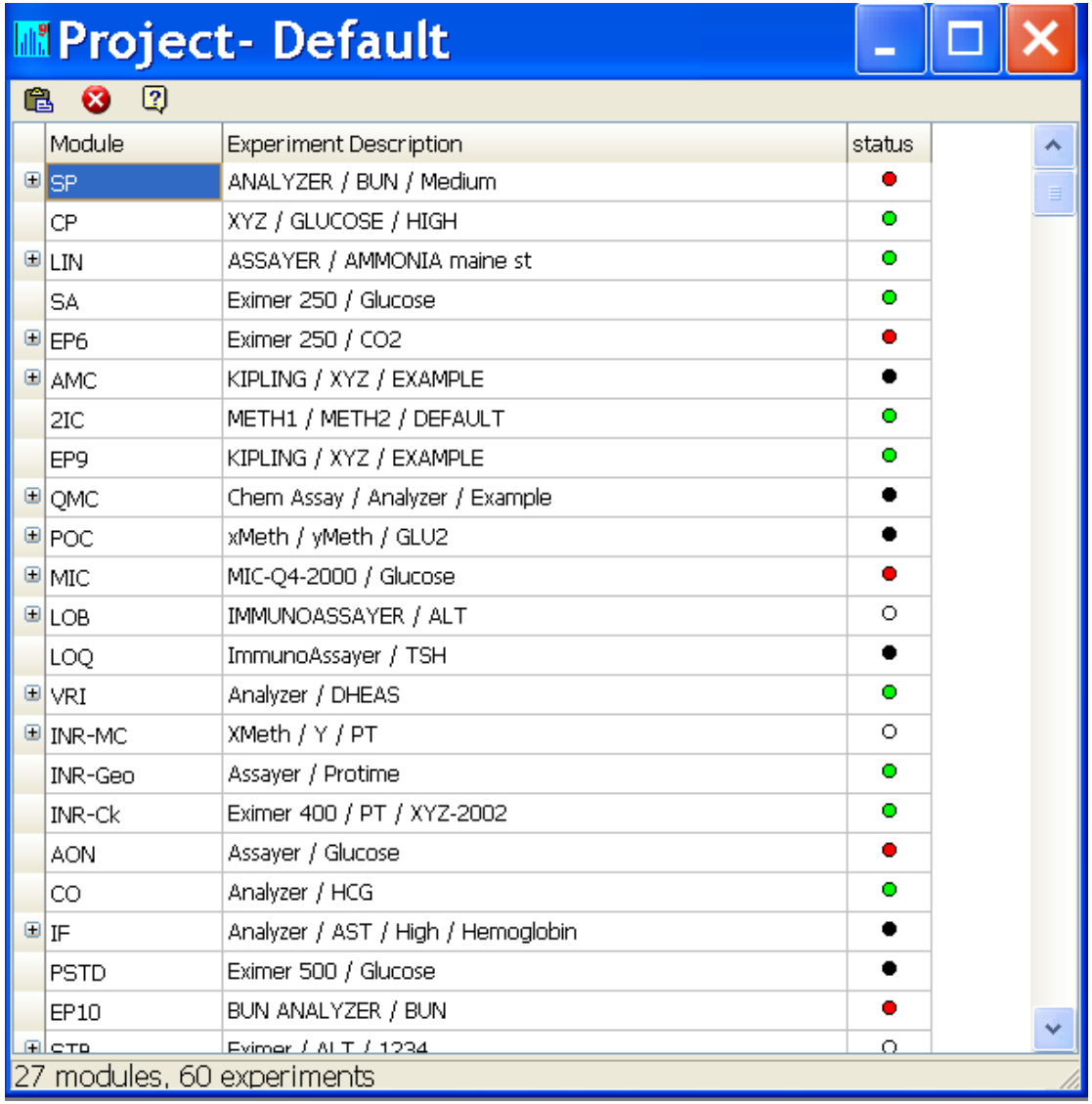
- Prefix – 12 chars:
  - User's initials or department name
- Project name - 80 char
  - Describe the activity
    - i.e., validations
    - Method comparison
    - Linearity
  - Include a date
- For Client (Optional)



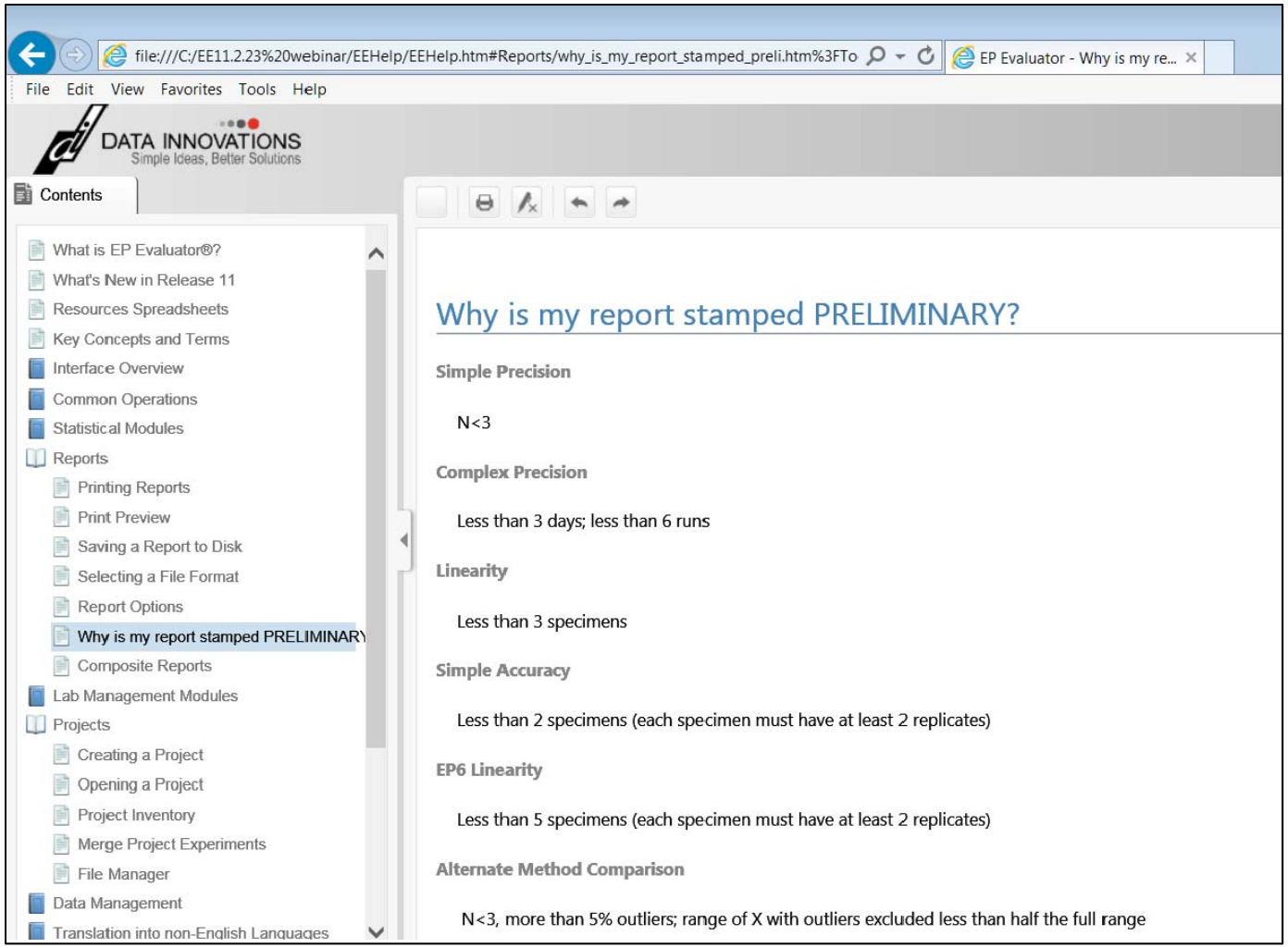
30 Statistical Modules

- Precision (2)
- Accuracy and Linearity (4)
- Method Comparison (7)
- Sensitivity (2)
- Reference Intervals, ROC (3)
- COAG (4)
- Carryover
- Interference
- Stability
- Other (6)

Inventory


Project- Default
Module
Experiment Description
status
SP
ANALYZER / BUN / Medium
CP
XYZ / GLUCOSE / HIGH
LIN
ASSAYER / AMMONIA maine st
SA
Eximer 250 / Glucose
EP6
Eximer 250 / CO2
AMC
KIPLING / XYZ / EXAMPLE
2IC
METH1 / METH2 / DEFAULT
EP9
KIPLING / XYZ / EXAMPLE
QMC
Chem Assay / Analyzer / Example
POC
xMeth / yMeth / GLU2
MIC
MIC-Q4-2000 / Glucose
LOB
IMMUNOASSAYER / ALT
LOQ
ImmunoAssayer / TSH
VRI
Analyzer / DHEAS
INR-MC
XMeth / Y / PT
INR-Geo
Assayer / Protime
INR-Ck
Eximer 400 / PT / XYZ-2002
AON
Assayer / Glucose
CO
Analyzer / HCG
IF
Analyzer / AST / High / Hemoglobin
PSTD
Eximer 500 / Glucose
EP10
BUN ANALYZER / BUN
27 modules, 60 experiments

HELP!



datainnovations.com

Exploring Experiments

Starting with Alternate Method Comparison - AMC

DATA INNOVATIONS
Simple Ideas, Better Solutions

datainnovations.com

Creating New Experiments

Starting with Alternate Method Comparison - AMC

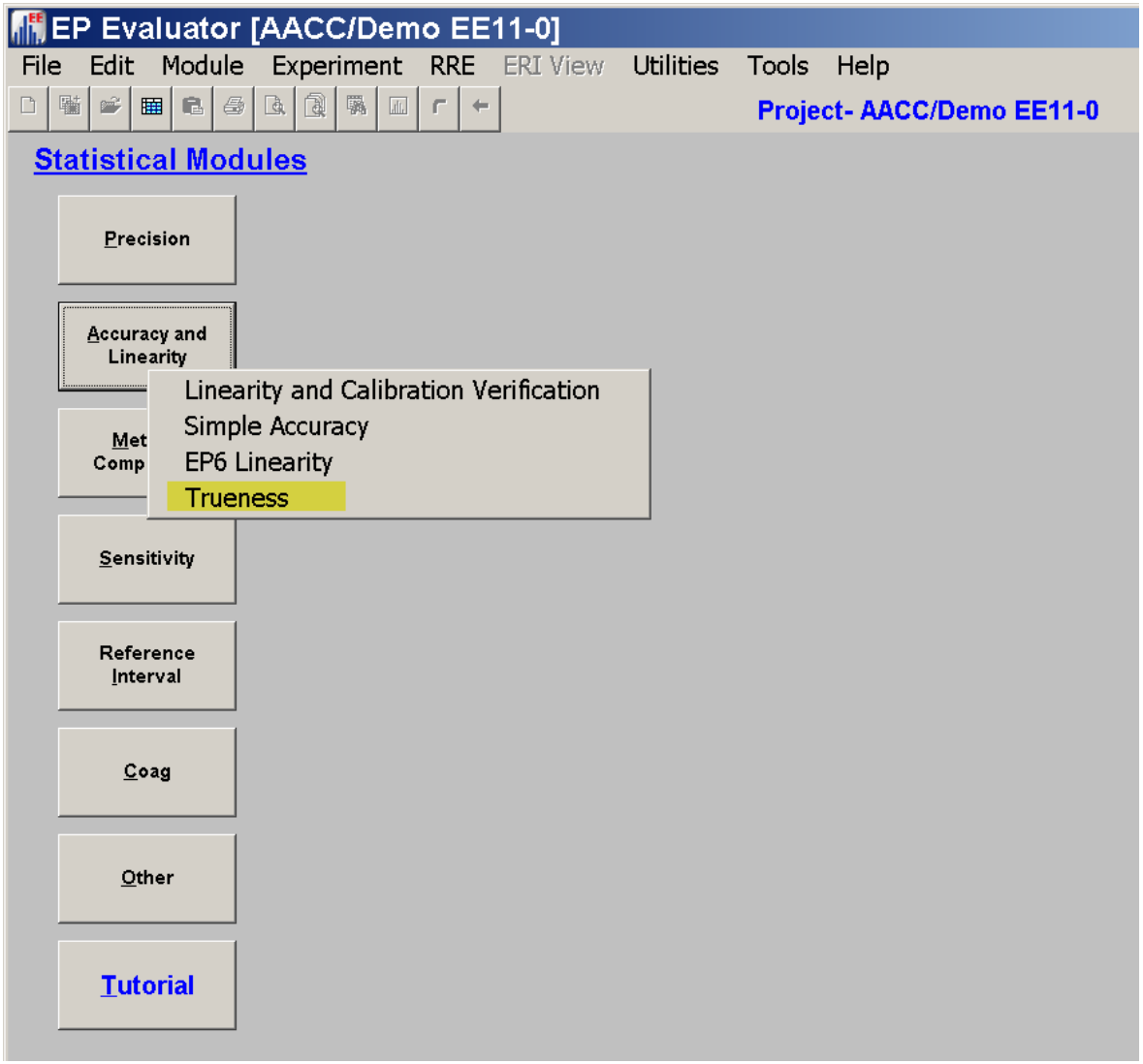
DATA INNOVATIONS
Simple Ideas, Better Solutions

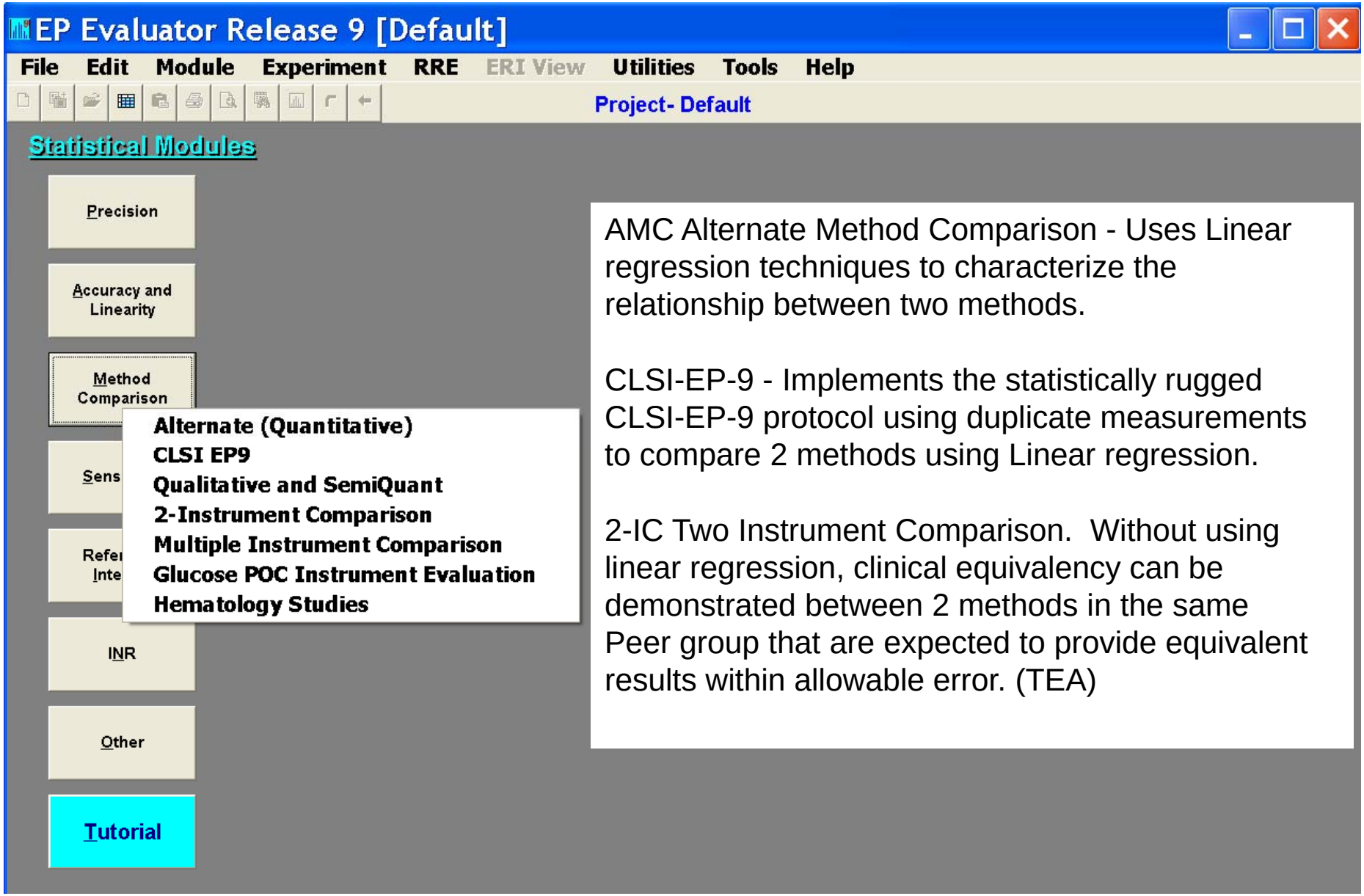
Key Screens

- **Statistical Module screen** main screen
- **Module Overview Screen** – the main entry screen for each module- summary of all current experiments in a project
- **Parameter screen** – customizes the options for each experiment, when creating the experiment initially or modifying later.
- **Experiment Detail screen** – data entry and experiment statistics.

Statistical Module Screen

- Main screen
- 34 modules (10 in CLIA and COFRAC versions)
- Tutorial - a very basic overview –





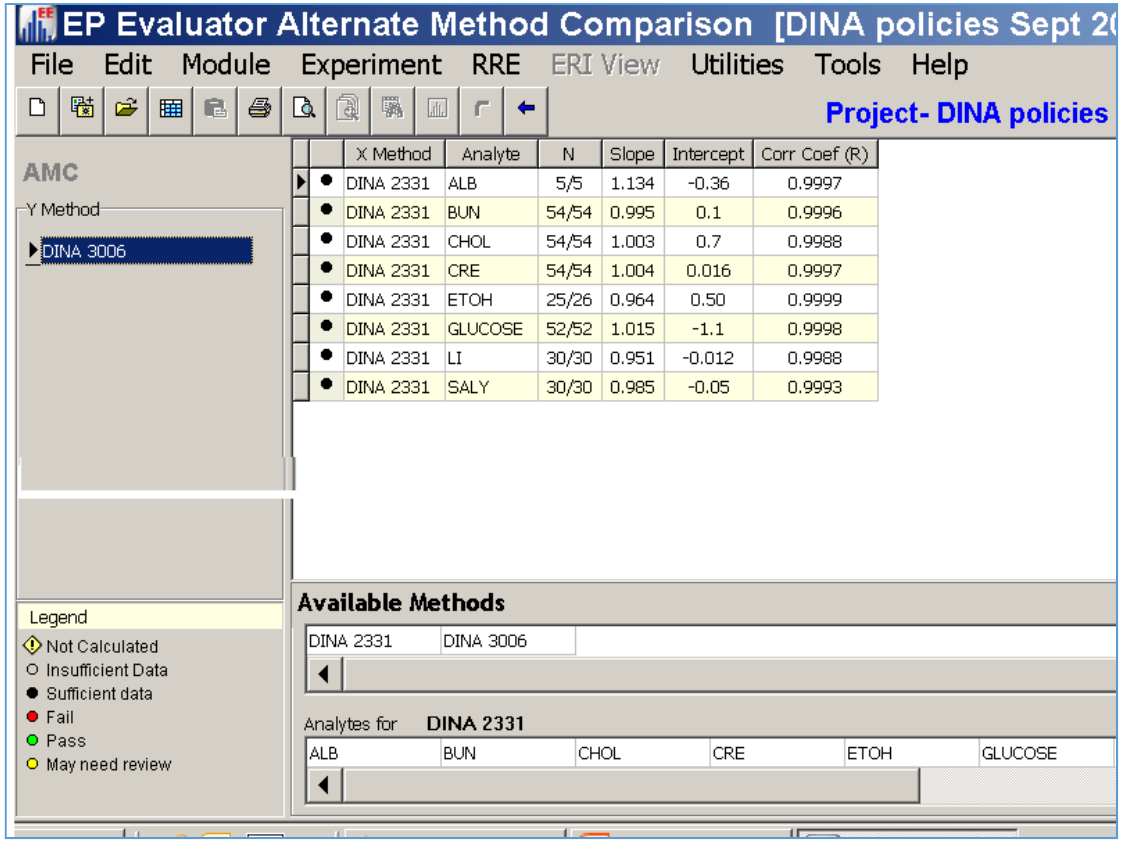
AMC Alternate Method Comparison - Uses Linear regression techniques to characterize the relationship between two methods.

CLSI-EP-9 - Implements the statistically rugged CLSI-EP-9 protocol using duplicate measurements to compare 2 methods using Linear regression.

2-IC Two Instrument Comparison. Without using linear regression, clinical equivalency can be demonstrated between 2 methods in the same Peer group that are expected to provide equivalent results within allowable error. (TEA)

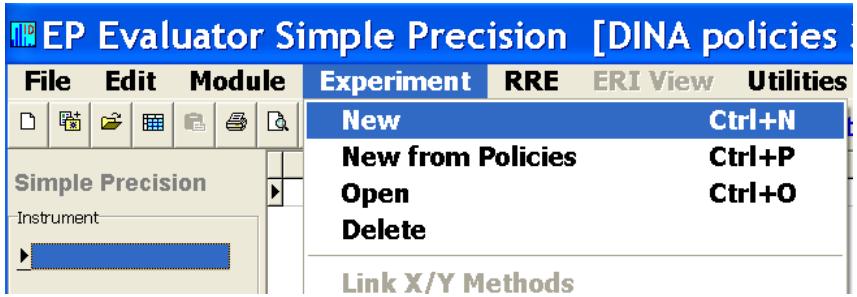
Module Overview Screen

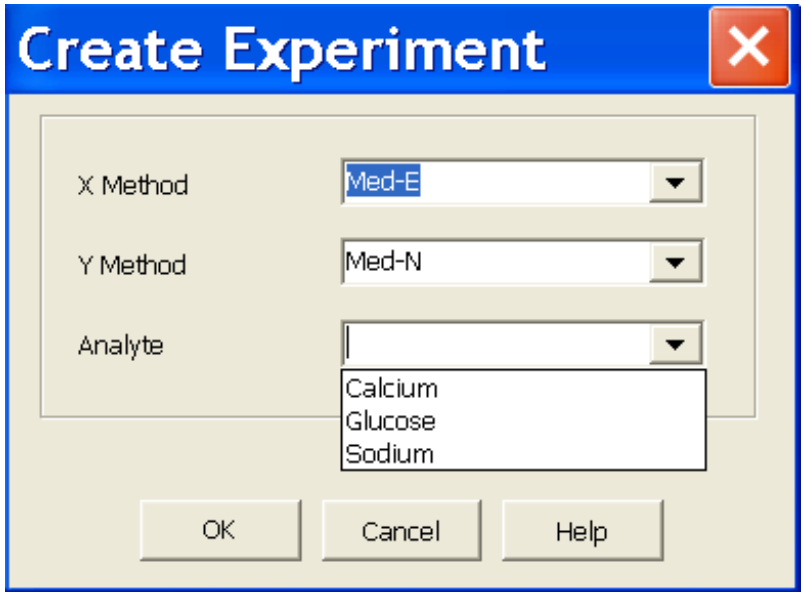
- Gray Table of contents
  - Module name
  - All instruments with experiments
- White grid:
  - For each instrument Lists all experiments with basic stats. their status: pass, fail, not calculated, etc.
- Experiment: one analyte
- Double click experiment to open it



Creating a new experiment

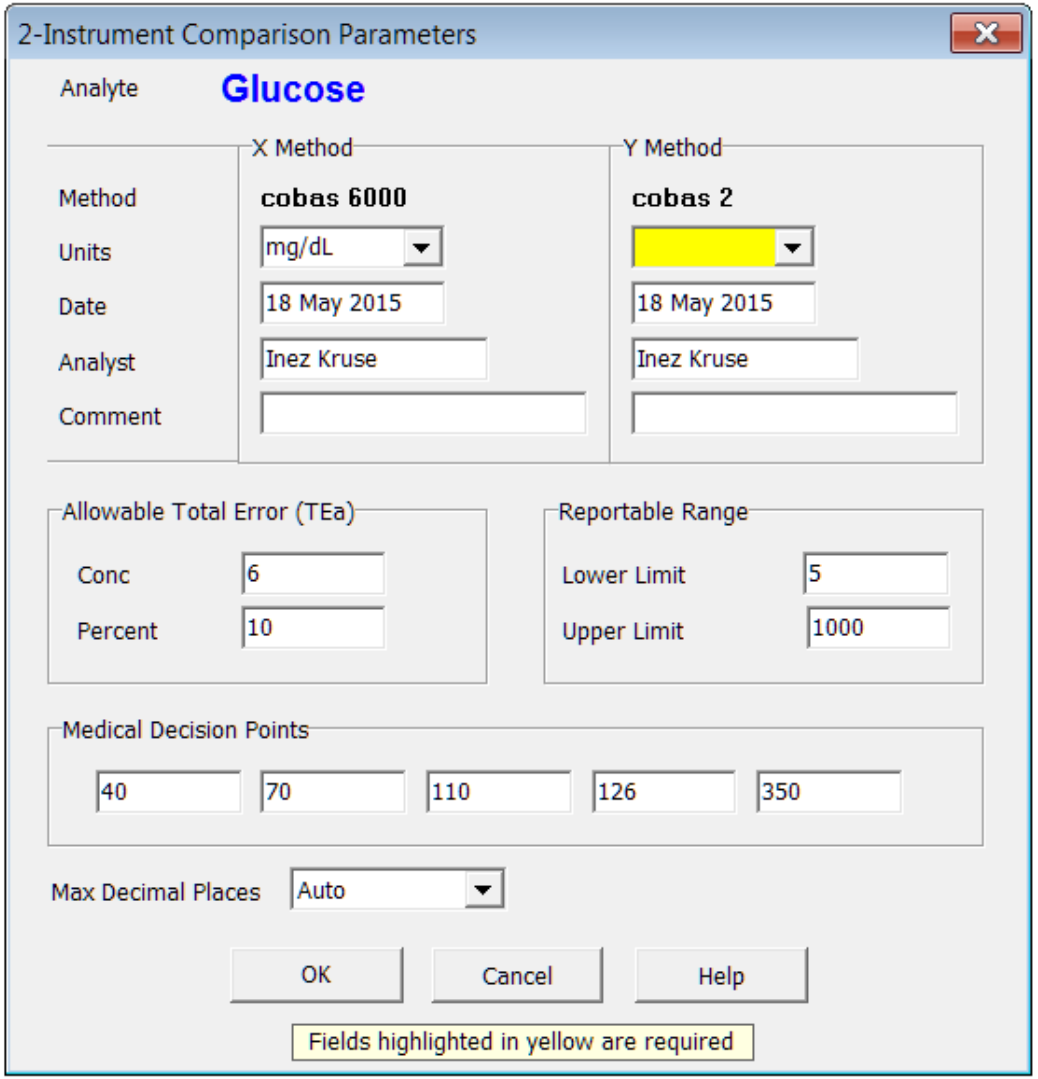
- Click the New Experiment icon , or choose Experiment / New from the Experiment Menu.
- Name the new experiment
  - Method or instrument name
  - Analyte name
  - For precision experiments enter the Sample Name
  - Method comparison experiments need two instrument or method names
    - Method X (reference)
    - Method Y (test)
  - Names entered previously appear in the drop-down items
  - Click OK to go to the Parameters screen





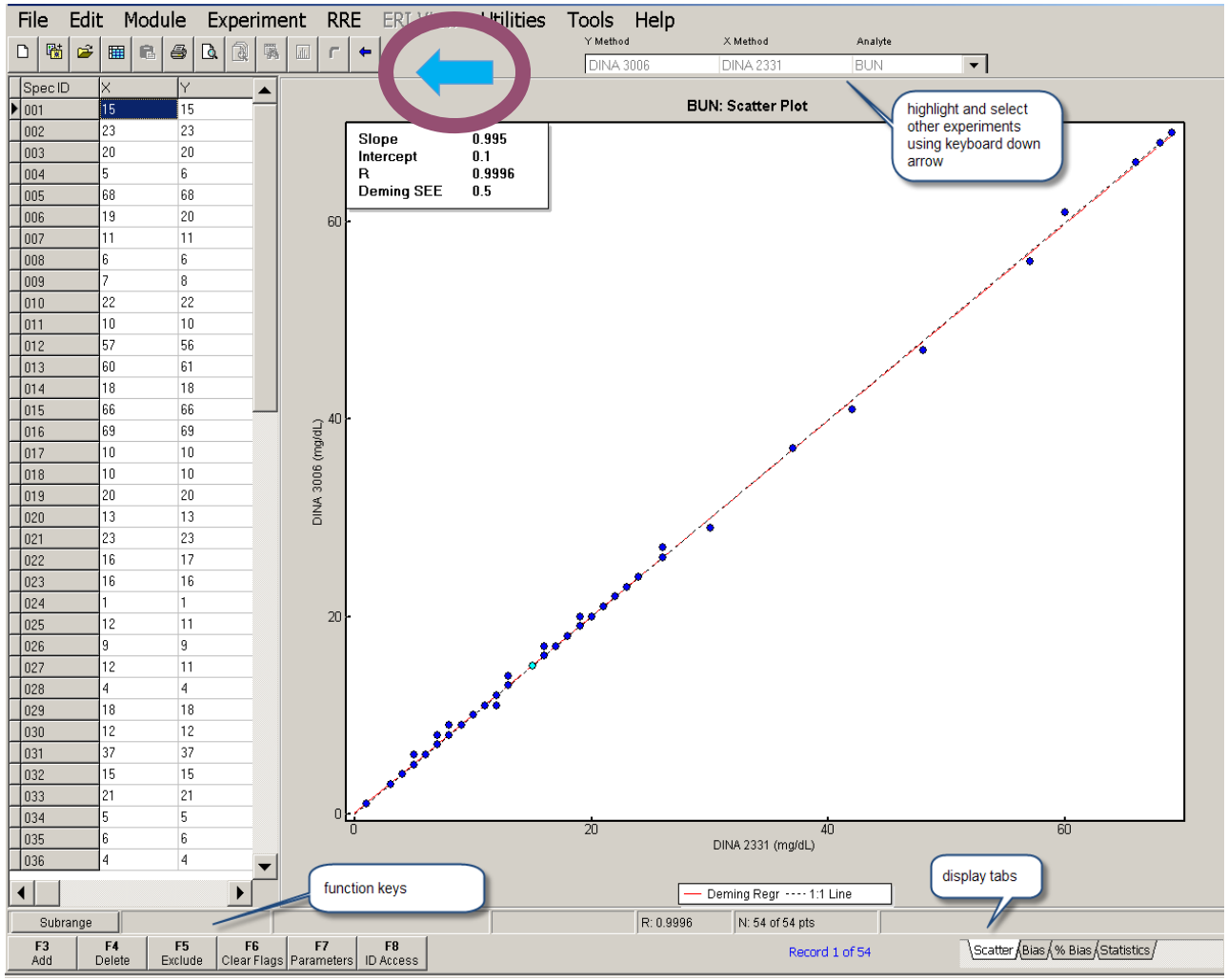
The Parameters Screen

- The parameters screen is where you customize your experiment.
- Define Evaluation criteria like Allowable Error.
- Enter units, analyst name, decimal places, lot numbers, etc.



Experiment Detail Screen

- One analyte
- Data Entry
  - Manual or
  - paste from Excel
- Blue Back arrow
- Function keys
- Observed statistics



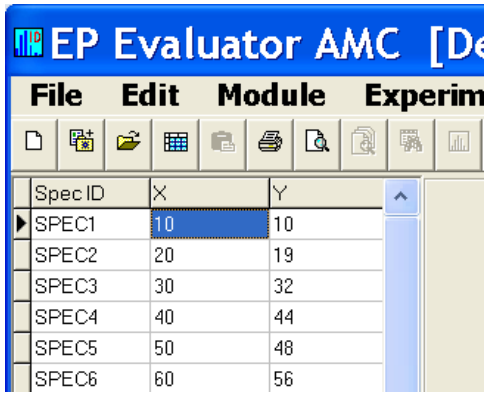
Demo of Method Comparison - AMC

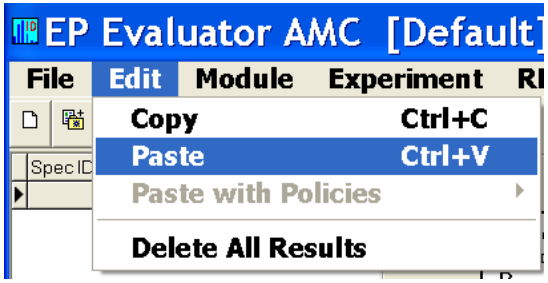
- Most modules are organized in a similar fashion
- Data Entry Area
- Plot / Graph / Table of Results
- Summary Statistics
- Function Keys

Entering Data

Here are 2 ways to enter data into the Experimental Detail Screen.

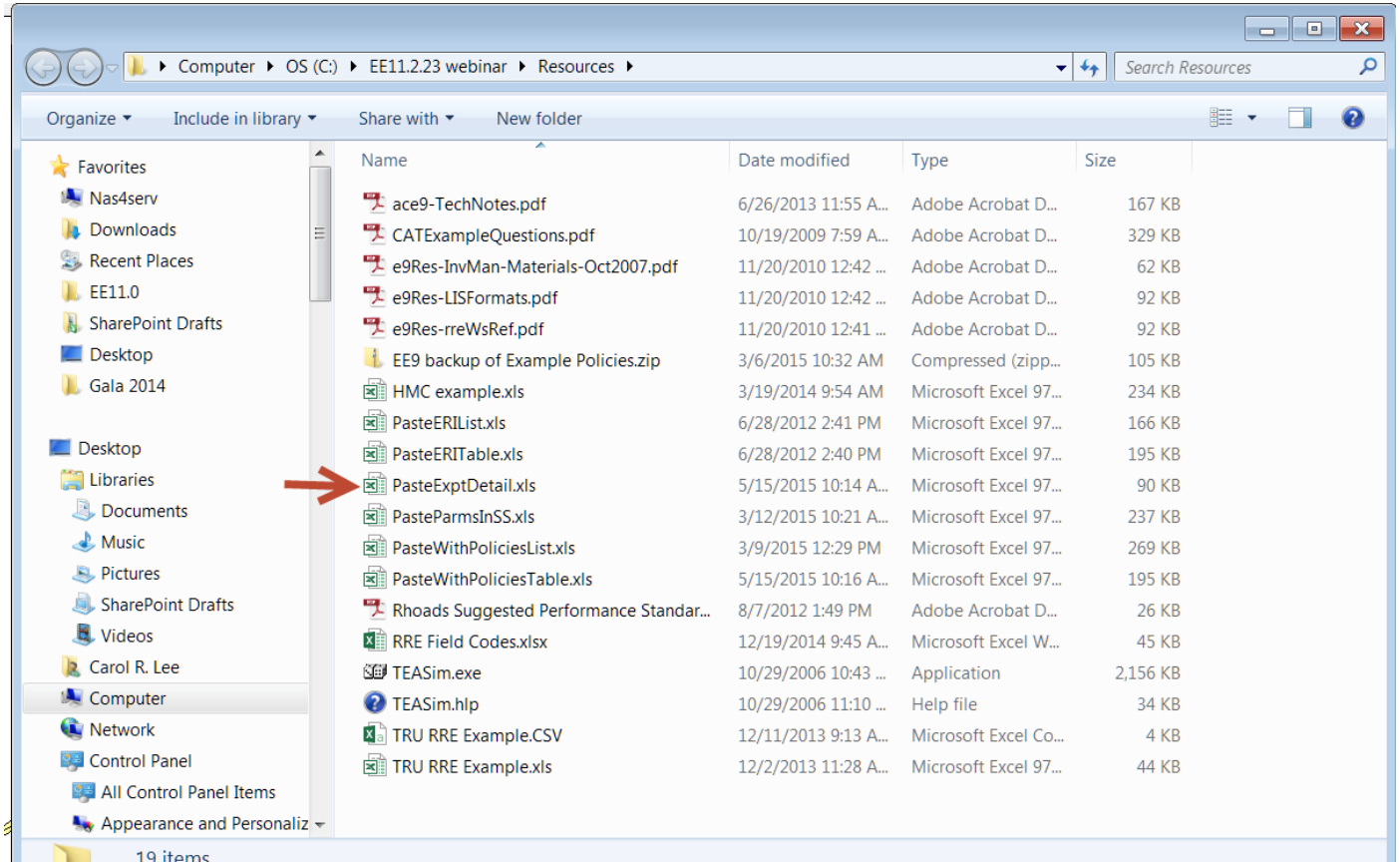
1. Type it into the highlighted cell.
2. You can paste data from a Microsoft® Excel spreadsheet.
   - The EE program folder on your computer or network contains a spreadsheet with examples of correct formats to paste data into the experimental detail screen for most modules. i.e., "**C:\EE11\Resources\PasteExptDetail.xls**"
   - Simply COPY the data from the spreadsheet and PASTE it into EE using the PASTE command in the EDIT menu.



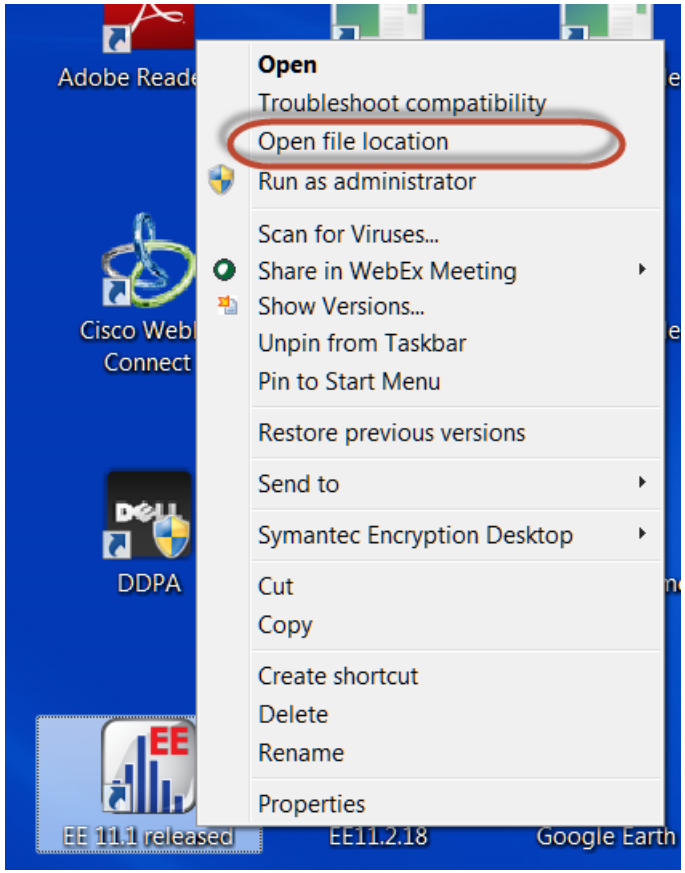


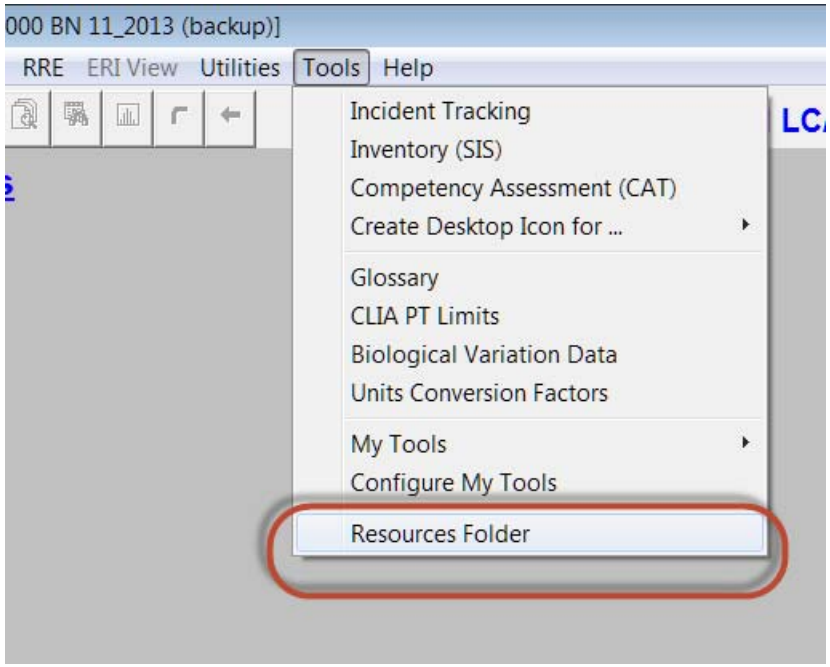
EE Resources Folder

Annotated examples for RRE techniques are available in your EE\Resources folder. Use with the project ExamplePolicies



Find your Resource folder





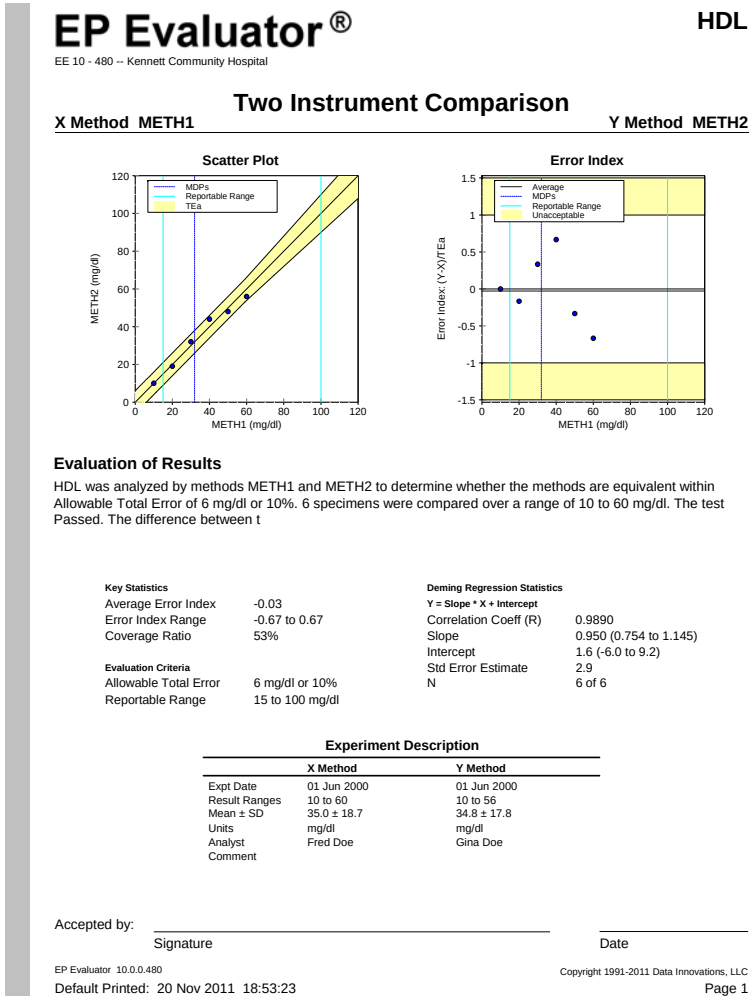
Specimen IDs

- Header = SPECID
- Method Comparison SPECID used to link the data pairs
- Linearity SPEC IDS needed for each level of “standards” Lin-01, Lin-02, Lin-03, etc
- SpecID is alphanumeric
- SPECID sort is alphanumeric, not numeric. 1, 10, 2, 20, 3, 30, …..
- Default SPECIDs for EE follow the format S00001

Printing a Report

- **Single Experiment Report.** To Print or Preview a single report from the Experimental detail screen, select Print (or Print Preview) from The FILE Menu. Or click the appropriate icon.

- **Reports with Multiple Experiments.** To print reports and a Summary page for multiple experiments, you must be in the OVERVIEW screen. Again, select Print or Print Preview from the File Menu, or click the appropriate icon.



EP Evaluator®

HDL

EE 10 - 480 -- Kennett Community Hospital

Two Instrument Comparison

X Method METH1 Y Method METH2

Scatter Plot

Error Index

Evaluation of Results

HDL was analyzed by methods METH1 and METH2 to determine whether the methods are equivalent within Allowable Total Error of 6 mg/dl or 10%. 6 specimens were compared over a range of 10 to 60 mg/dl. The test Passed. The difference between t

Key Statistics	
Average Error Index	-0.03
Error Index Range	-0.67 to 0.67
Coverage Ratio	53%
Evaluation Criteria	
Allowable Total Error	6 mg/dl or 10%
Reportable Range	15 to 100 mg/dl

Deming Regression Statistics	
Y = Slope * X + Intercept	
Correlation Coeff (R)	0.9890
Slope	0.950 (0.754 to 1.145)
Intercept	1.6 (-6.0 to 9.2)
Std Error Estimate	2.9
N	6 of 6

Experiment Description

	X Method	Y Method
Expt Date	01 Jun 2000	01 Jun 2000
Result Ranges	10 to 60	10 to 56
Mean ± SD	35.0 ± 18.7	34.8 ± 17.8
Units	mg/dl	mg/dl
Analyst	Fred Doe	Gina Doe
Comment		

Accepted by: _____ _____

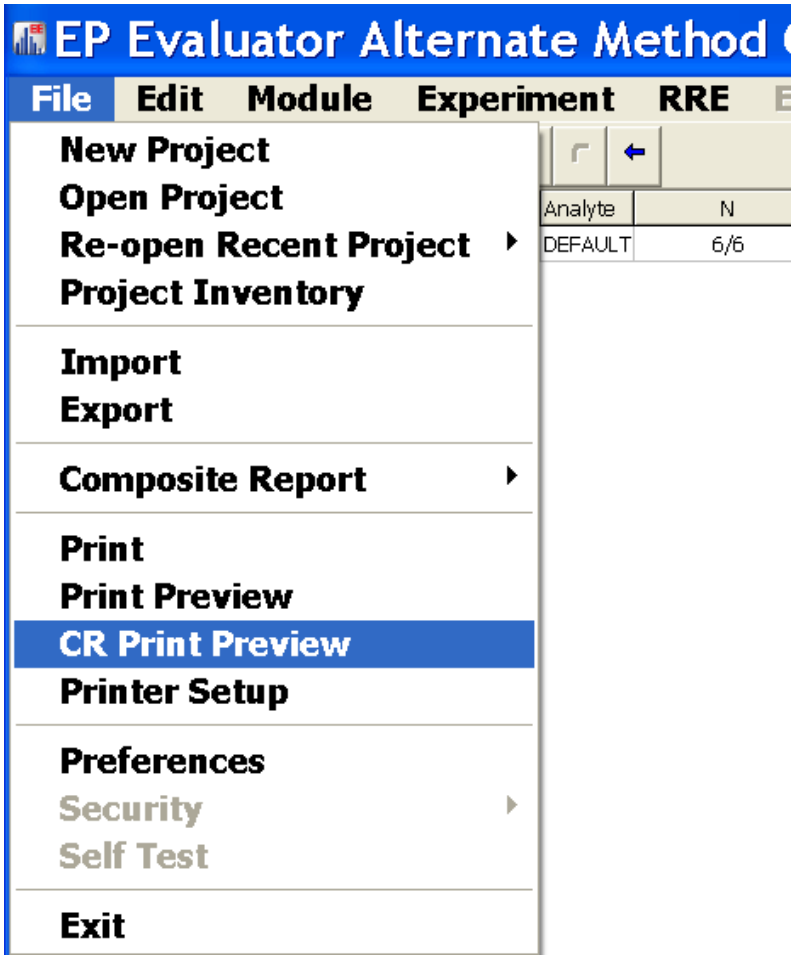
Signature Date

EP Evaluator 10.0.0.480

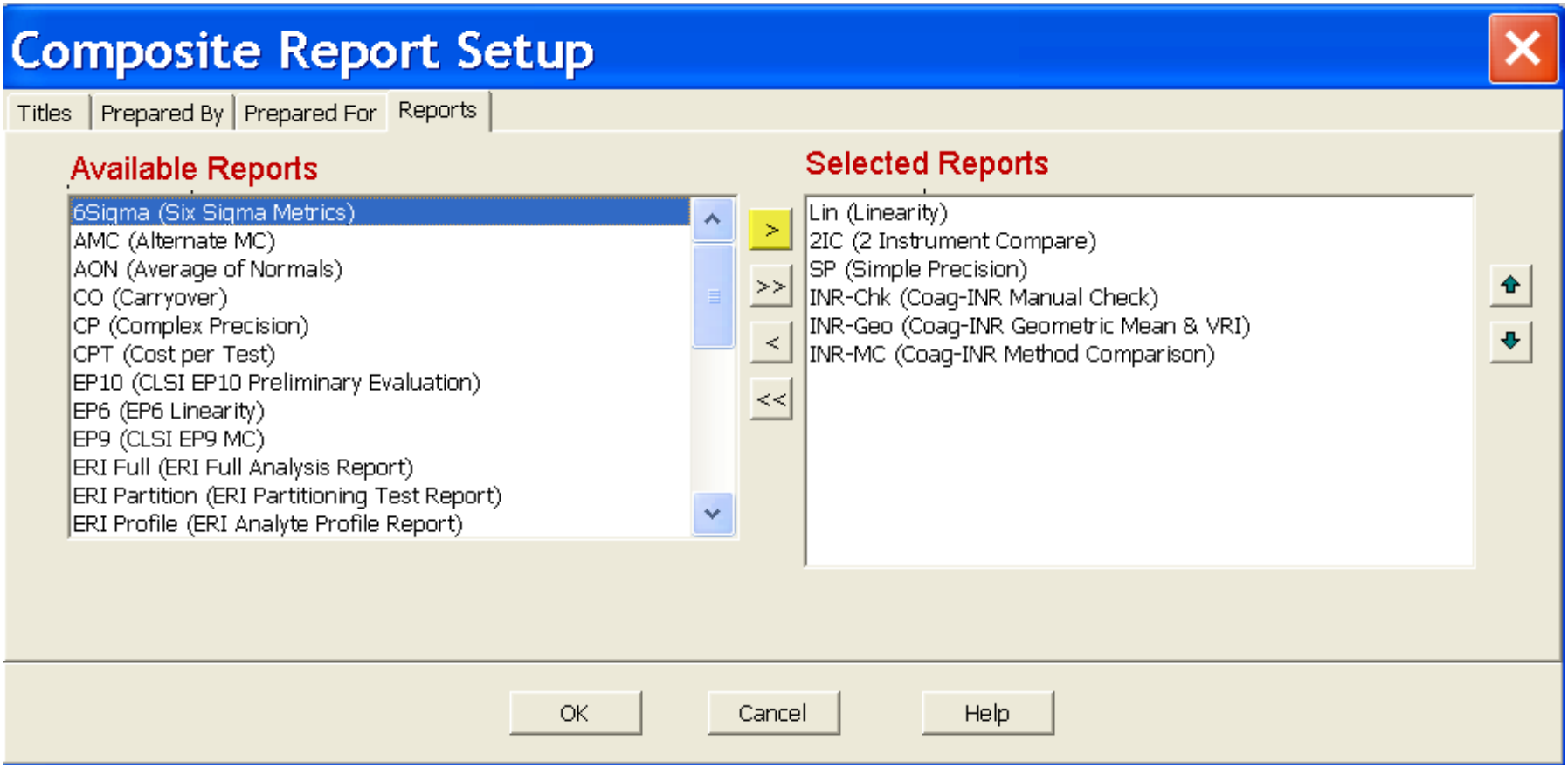
Default Printed: 20 Nov 2011 18:53:23

Composite Reports

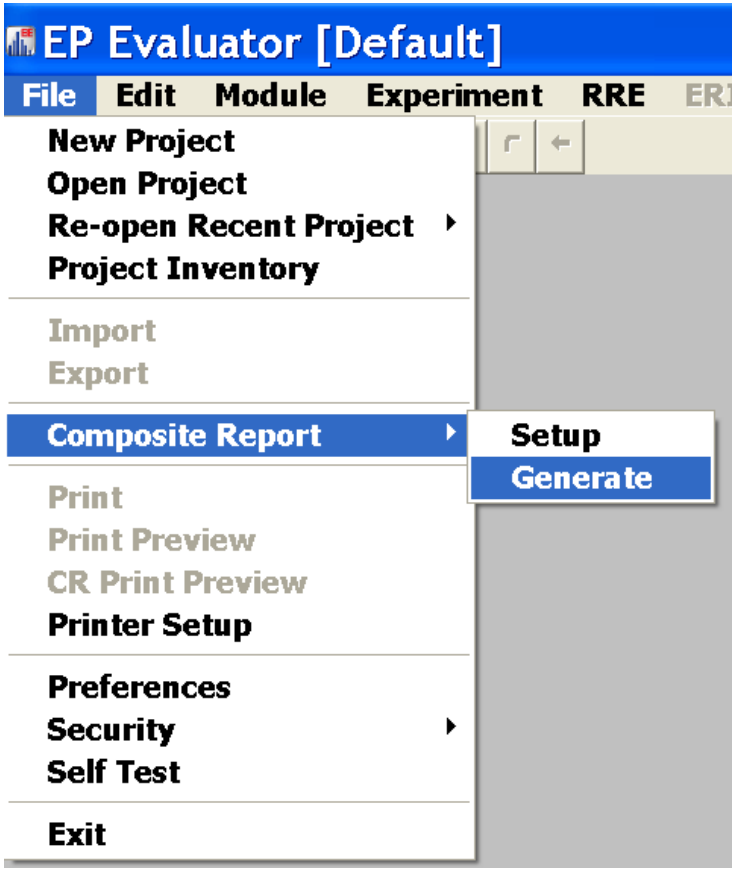
- Create Composite Reports for Multiple Experiments in Multiple Modules.
  - Set up the Composite Report (CR) from the File Menu
  - When an experiment is ready to report, select CR Print Preview (or click the icon) to add the report to the composite report list.
  - Generate the Report from the File Menu.

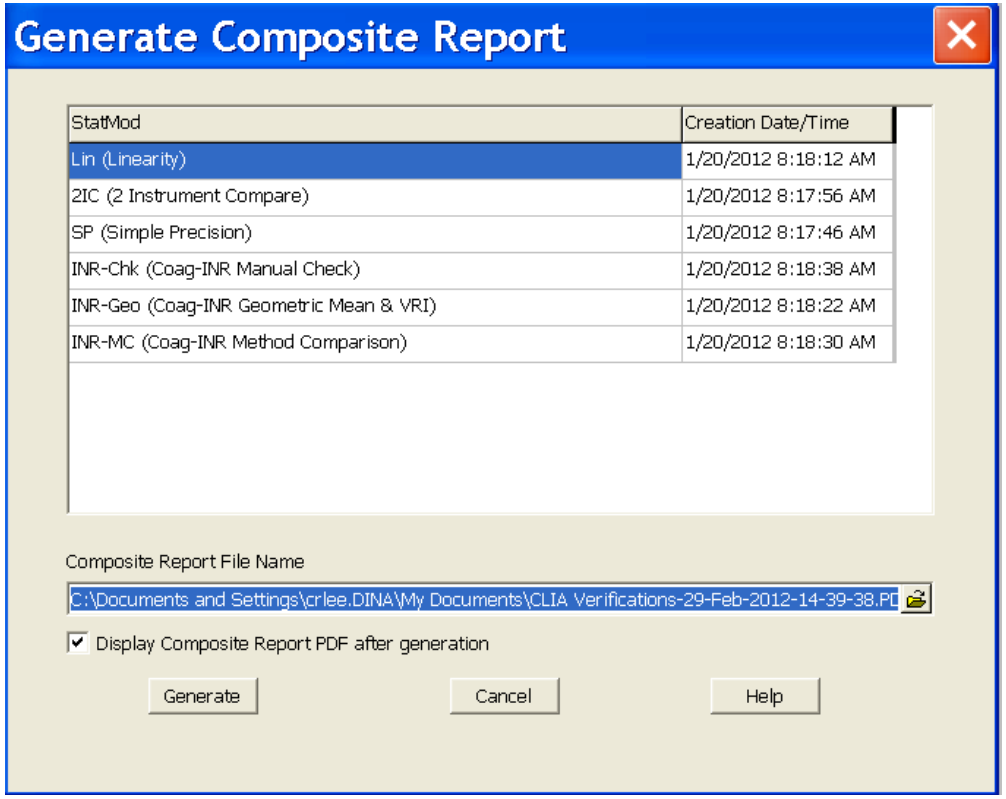


Composite Report Setup



Generate Composite Report





EP Evaluator®

CLIA Verifications

Semi-Annual

2/29/2012

Prepared for

Carl Commissioner
Regularatory Commission
123 Commission Drive
Anytown, XX, 12345

Prepared by

Dr. Mark Mainstay
Clinical Laboratory
Kennett Community Hospital
Kennett Square, PA 19348

Accepted by

Signature

Name / Title

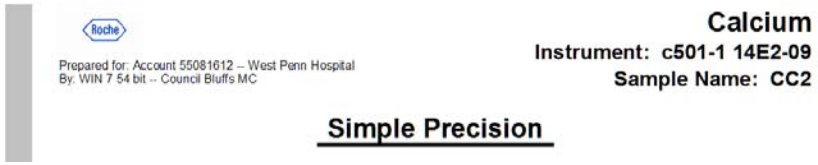
Date

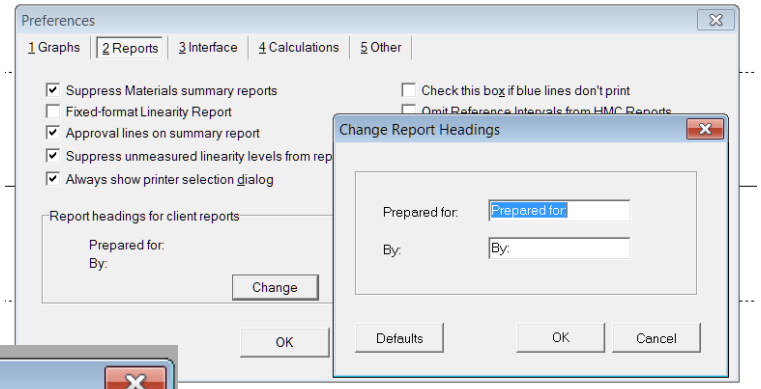
EP Evaluator®

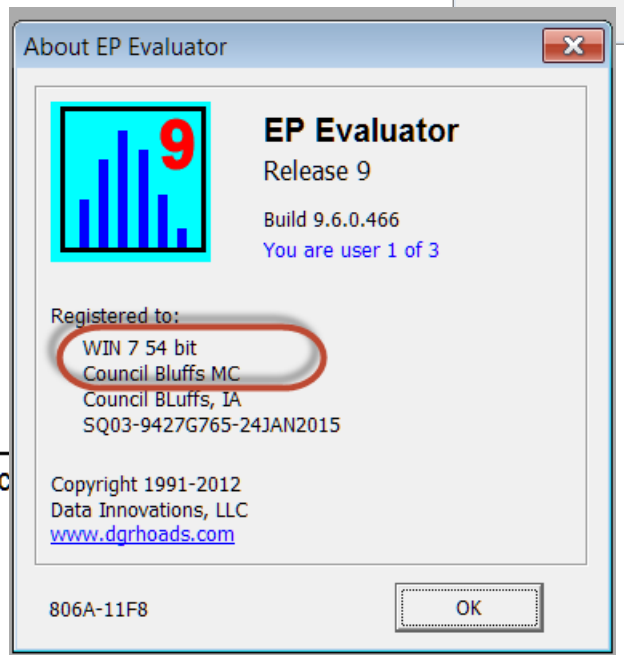
Table of Contents

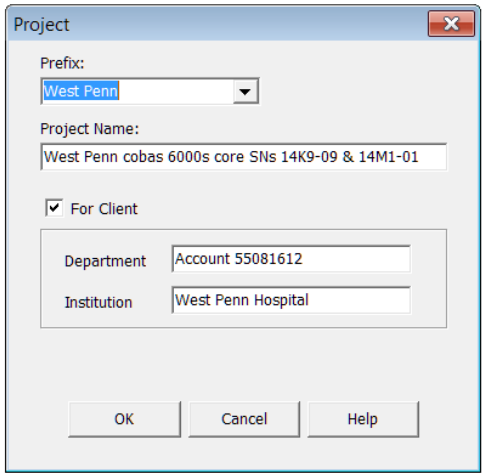
Report headers, logo, etc.

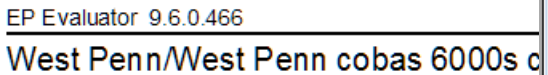
- Verbiage on each report all appears in UPPER left corner
  - "Prepared for / By " labels can be changed in Preferences.
  - "By" Verbiage from UNLOCK screen (Specialists should keep this short) 1st 2 lines only
  - **"For" is Client information** as entered from Project NAME
- Roche_logo resides in EE11:\forms
- Site project name and EP Evaluator Version # appear at lower left of report.





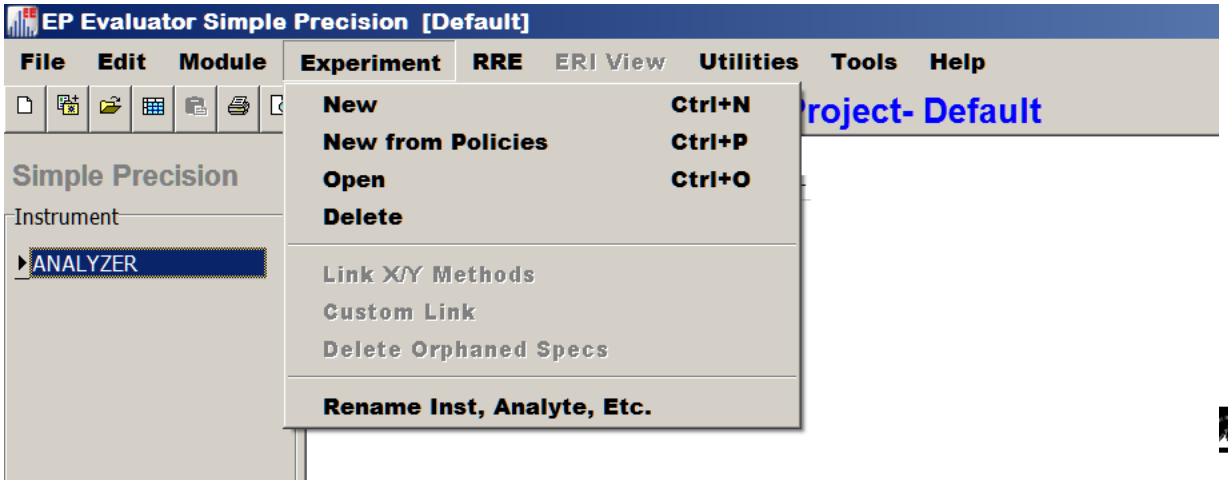






Menu Bar Options

datainnovations.com



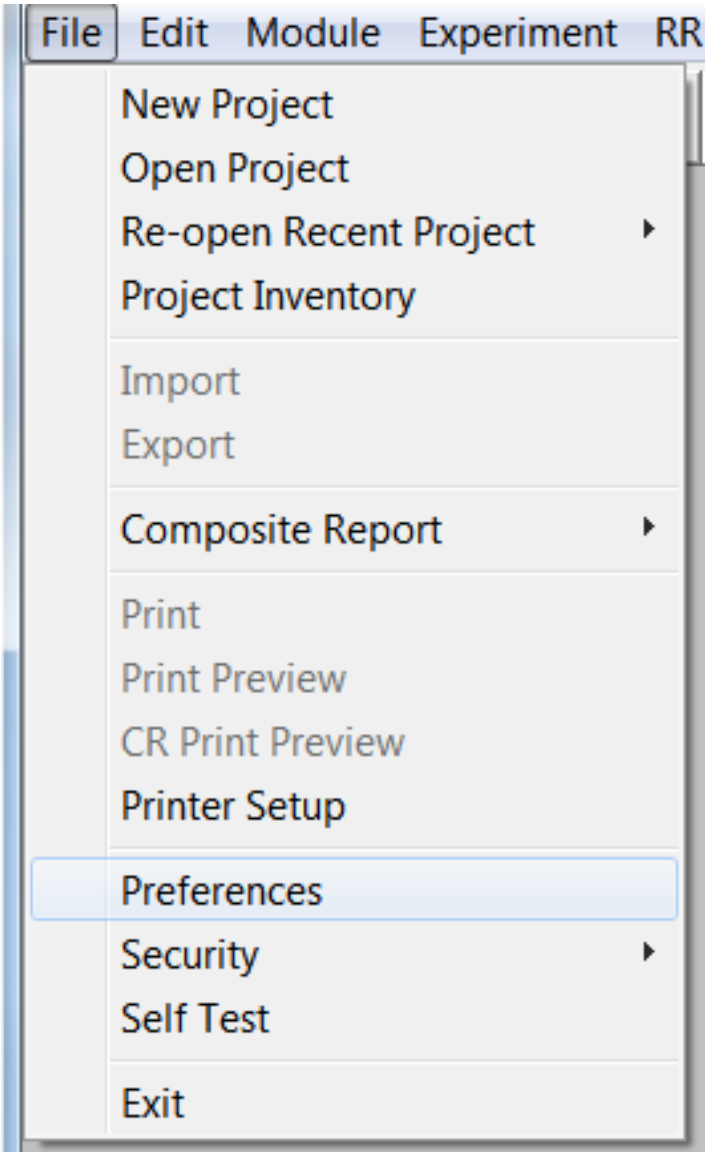
DATA INNOVATIONS
Simple Ideas, Better Solutions

Key Menu Bar options * 1

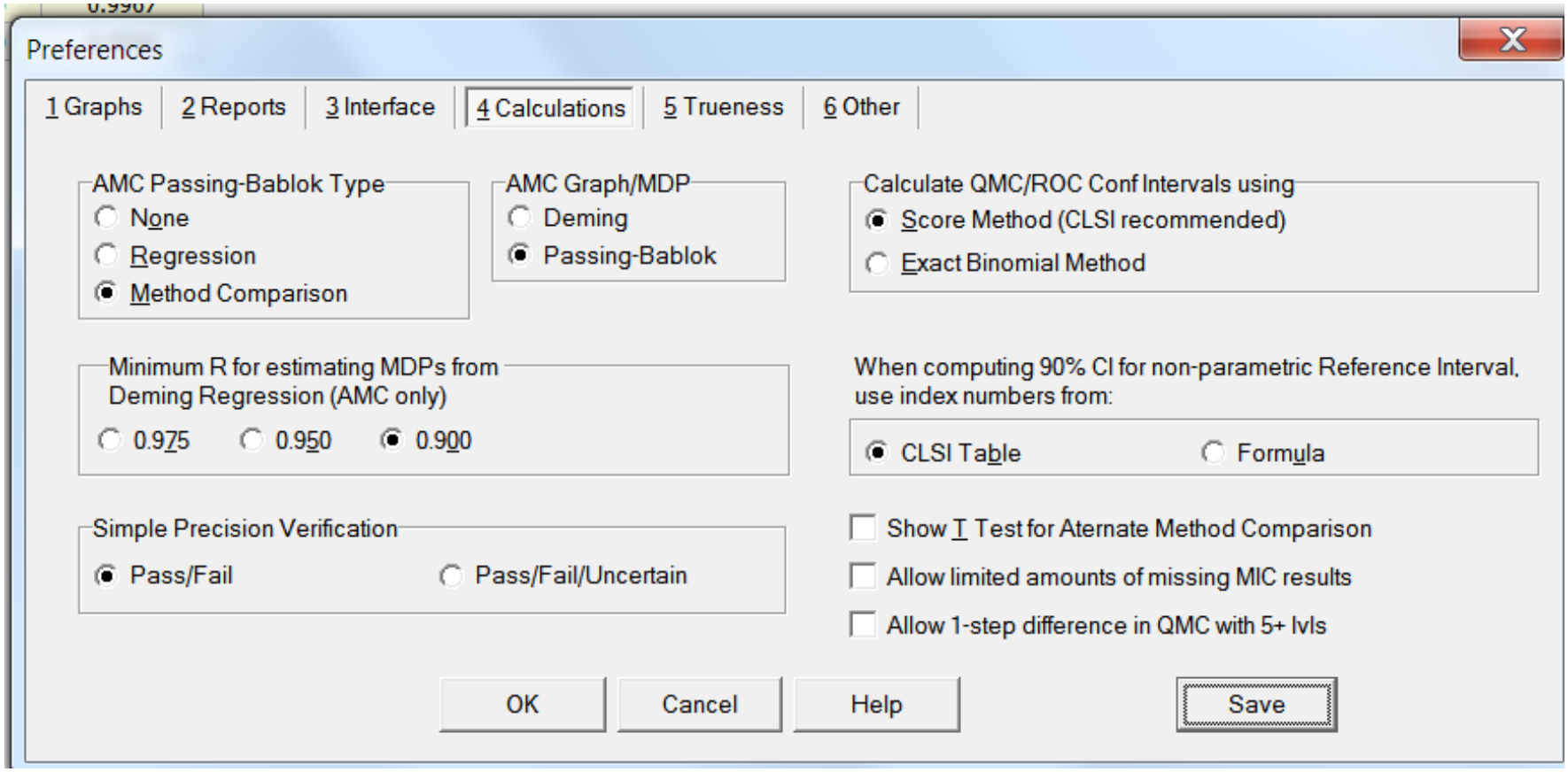
- **File**
  - New and Open projects
  - Import export: transfer projects and experiments
  - Preferences: set up special options for several modules.
  - Project inventory
  - Print / Print Preview / Print Setup
  - User Security – Professional version
- **Edit:** copy/paste / delete data
- **Module:**
  - shortcuts to the modules from any location.
  - Recalculate statistics. Or Clear Overview statistics
  - Summarize to History for Linearity or MIC modules
  - Batch Edit the lot numbers

Preferences

- View Preferences in File \ Preferences
- Within a project, Preferences apply to all existing and future experiments
- Prior to EE11.0, you could change preferences in a project, but when you closed the program and returned, the original preferences came back
- In EE 11.0, you can save preferences as prefernces.ini file that will apply to **all** projects on the local machine.



Preference Calculations



AMC Statistics Tab

Regression Analysis	Deming	Passing-Bablok	Regular
Slope	1.036 (1.017 to 1.056)	1.000 (1.000 to 1.000)	1.021 (1.002 to 1.041)
Intercept	-3.7 (-5.7 to -1.6)	0.0 (0.0 to 0.0)	-2.2 (-4.2 to -0.1)
Std Err Est	0.9	--	0.9
SMAD	0.6	0.0	0.7

Distribution of Results					
Range	<= 83.3	83.4-116.7	116.8-150.0	150.1-183.3	> 183.3
Percent	2%	98%	0%	0%	0%

Other Statistics	
Points (Plotted/Total)	296/297
Outliers	Not Tested
SubRange Bounds	None
Corr Coef (R)	0.9862
Bias	0.0 (0.0 %)
X Range	79 to 113 (1X)
Y Range	79 to 113 (1X)
X Mean ± SD	102.8 ± 5.0
Y Mean ± SD	102.8 ± 5.1
Rep SD X	1
Rep SD Y	1
SD of differences	0.9
Paired T Test	0.95
T Probability	0.344
Degrees of Freedom	294

Passing Bablock enabled by preferences

Red type indicates ideal slope of 1.0 or intercept of 0.0 is not within the confidence intervals

Confidence intervals calculated per CLSI EP09-A2

Key Menu Bar options - 2

- **Experiment**
  - New experiments from scratch CNTRL N
  - New experiments using policy definitions CNTRL P
  - Open a specific experiment CNTRL O
  - Link X and Y methods
  - Custom Link data with dissimilar names
  - Delete orphaned specs (AMC POC EP9 or 2IC)
  - Rename / delete experiments

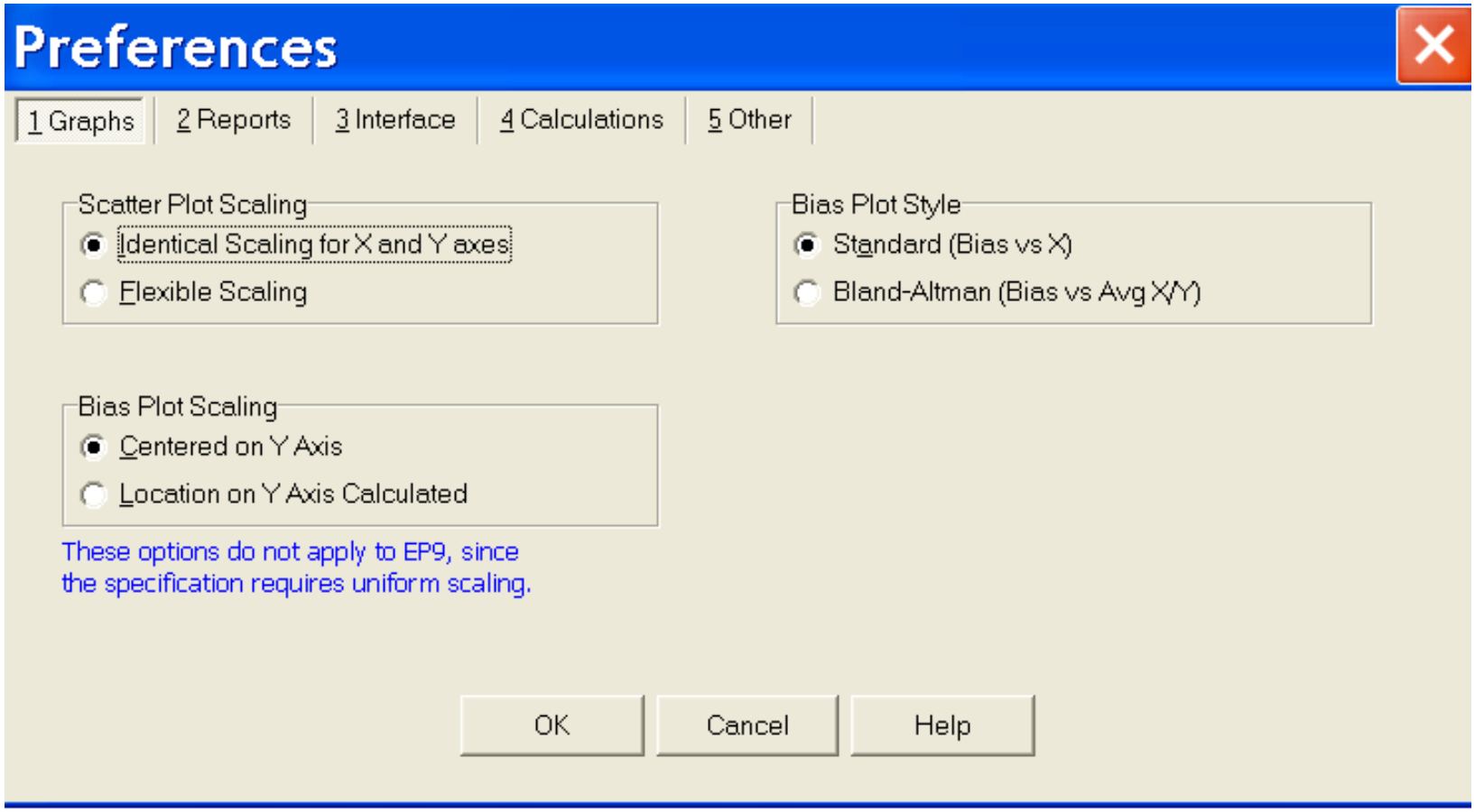
Key Menu Bar options - 3

- RRE
  - Create experiments for multiple analytes using
    - instrument capture
    - Keyboard entry from instrument printouts
  - Capture Data from Instrument Manager
  - Define policy definitions to re-use over and over
  - Define global lot numbers
  - Open last or saved RRE worksheets
  - AON Data Manager.

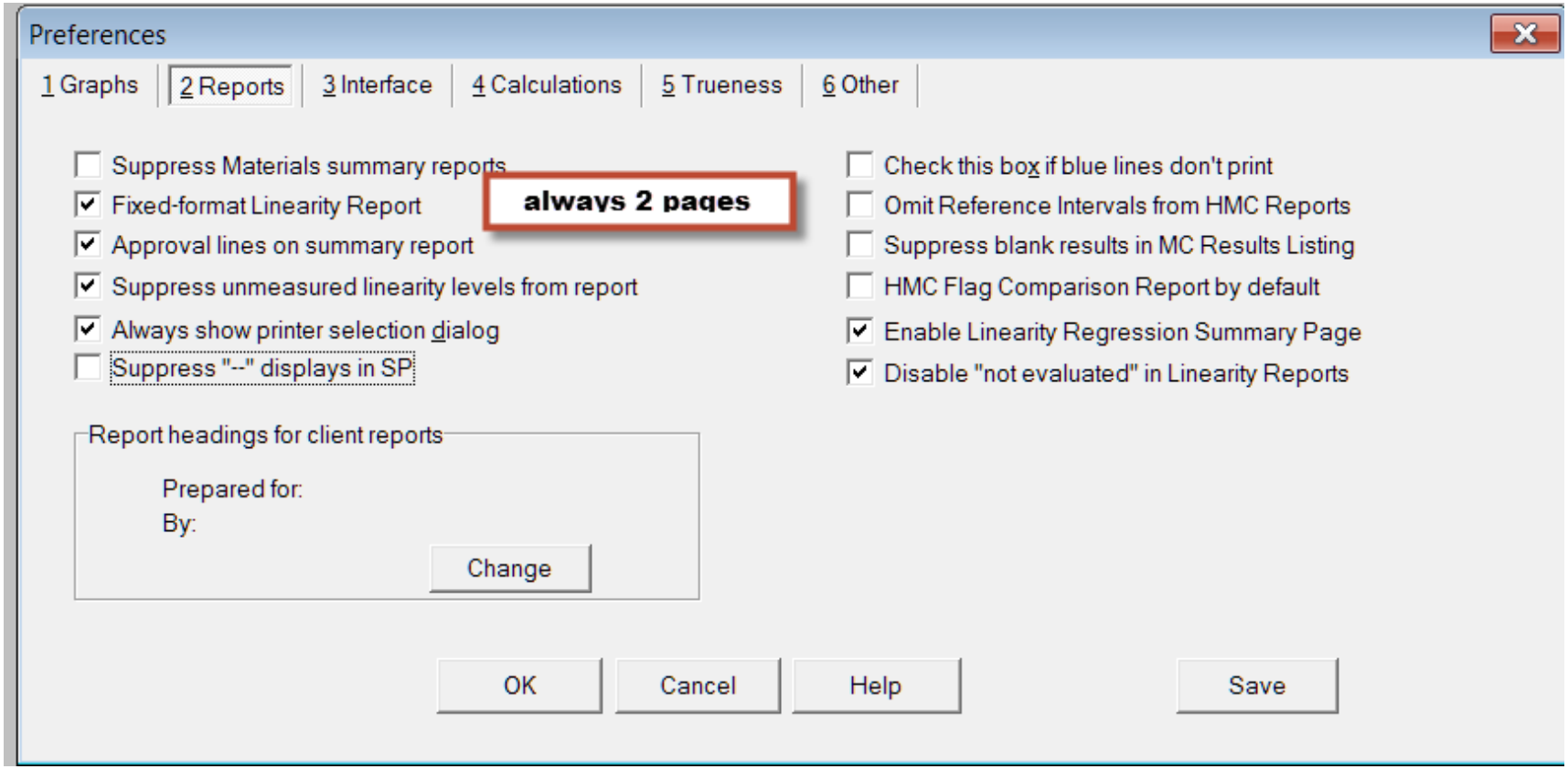
Useful Menu Bar Options – Misc.

- **Utilities**
  - File Manager – manages your projects, backup files, view inventory on all projects
  - Typing Help History Editor – edit items in the dropdowns
  - Update Wizard - brings all active projects into new major version
- **Tools**
  - Open the 3 lab management modules and create their icons
  - CLIA PT limits table
  - Glossary of terms
- **Help**
  - Indexed and Searchable help
  - Send a bug report
  - Check for a newer major or minor version: automatic update as prompted
  - Renew subscription

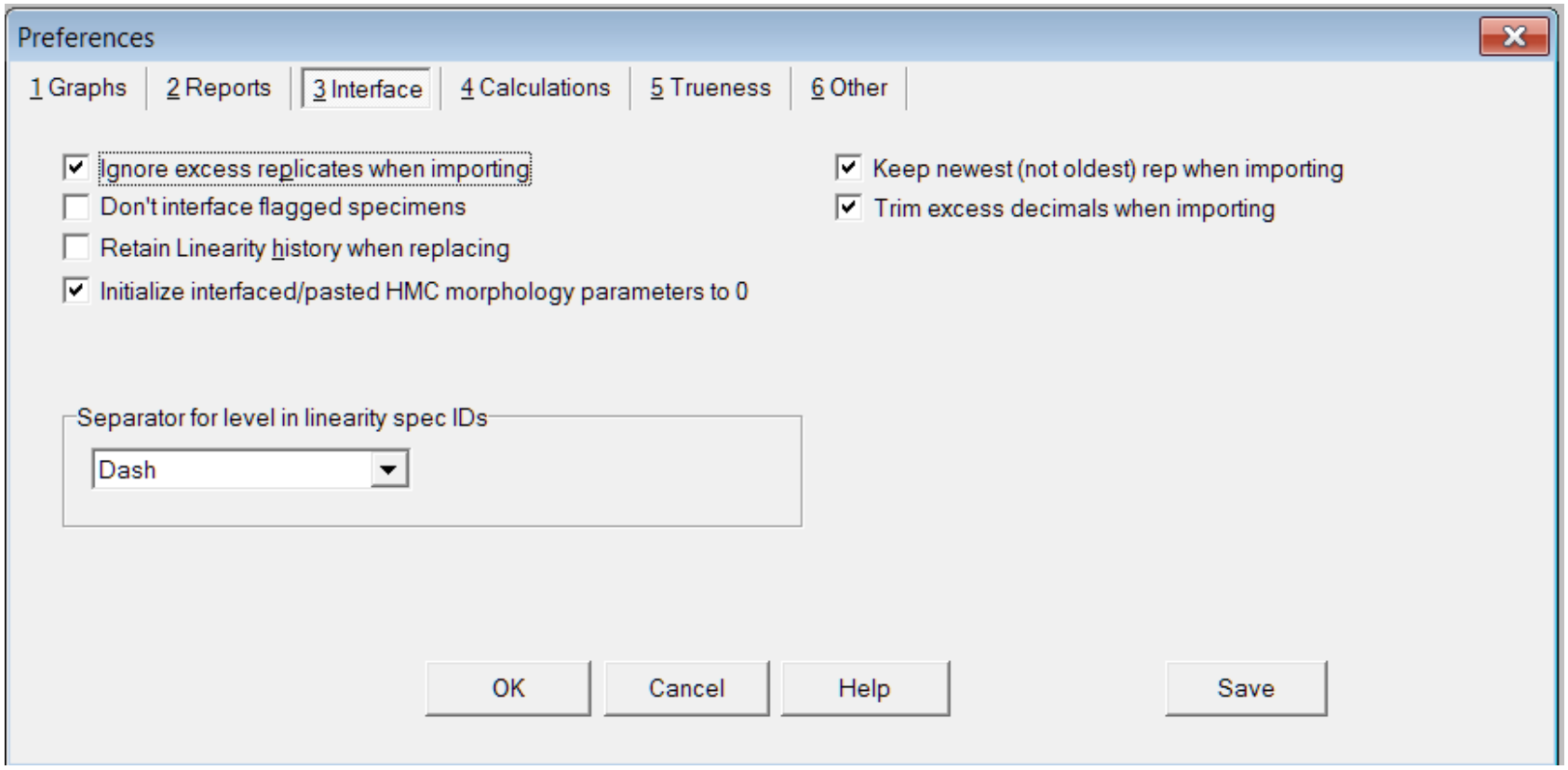
Preferences for Regression Graphs



Preferences Affecting Linearity Reports



Preferences affecting Interfacing or copy/paste



datainnovations.com

Projects

Open a project

Create a new project

Inventory

Manage your projects

DATA INNOVATIONS
Simple Ideas, Better Solutions

datainnovations.com

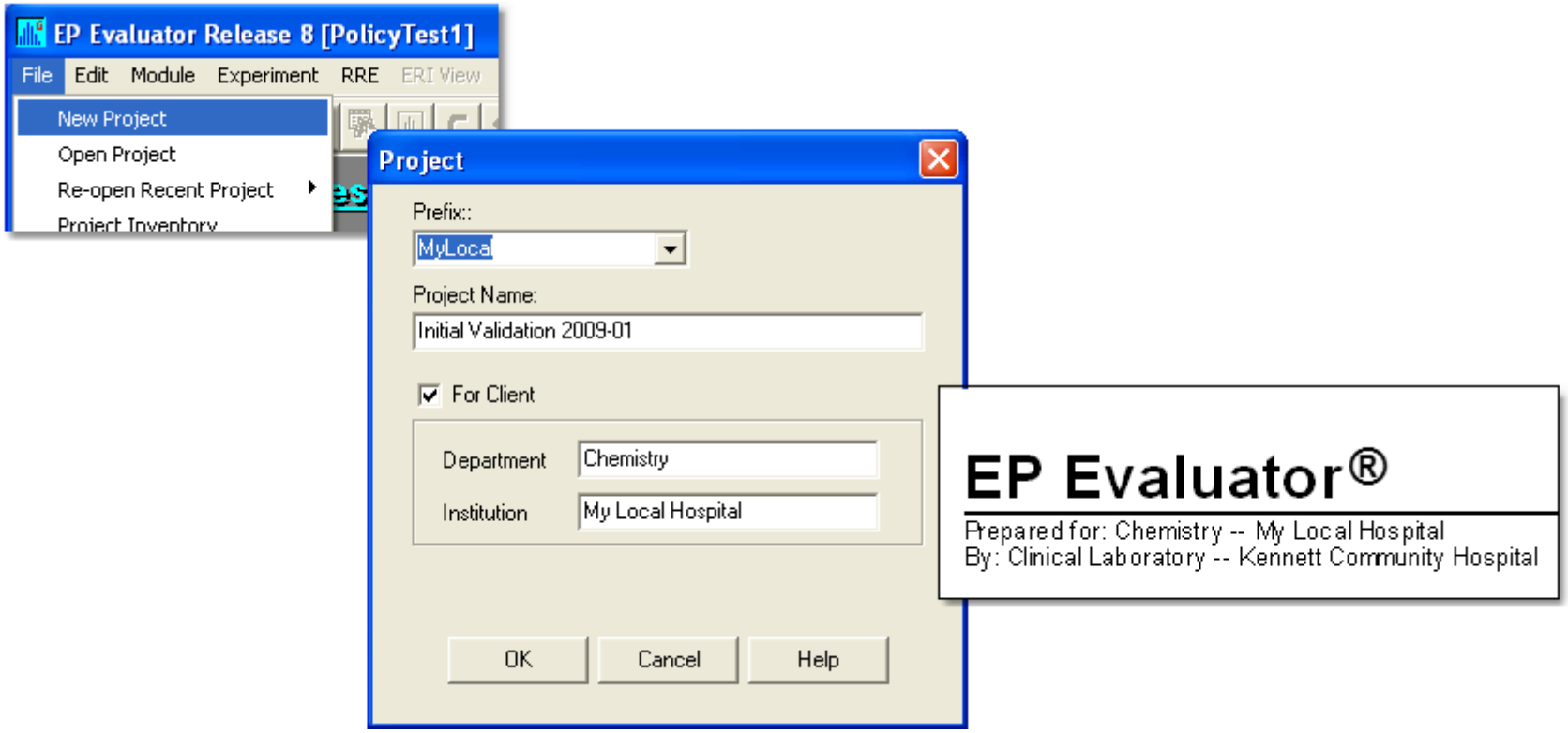
Creating a New Project

DATA INNOVATIONS
Simple Ideas, Better Solutions

Projects

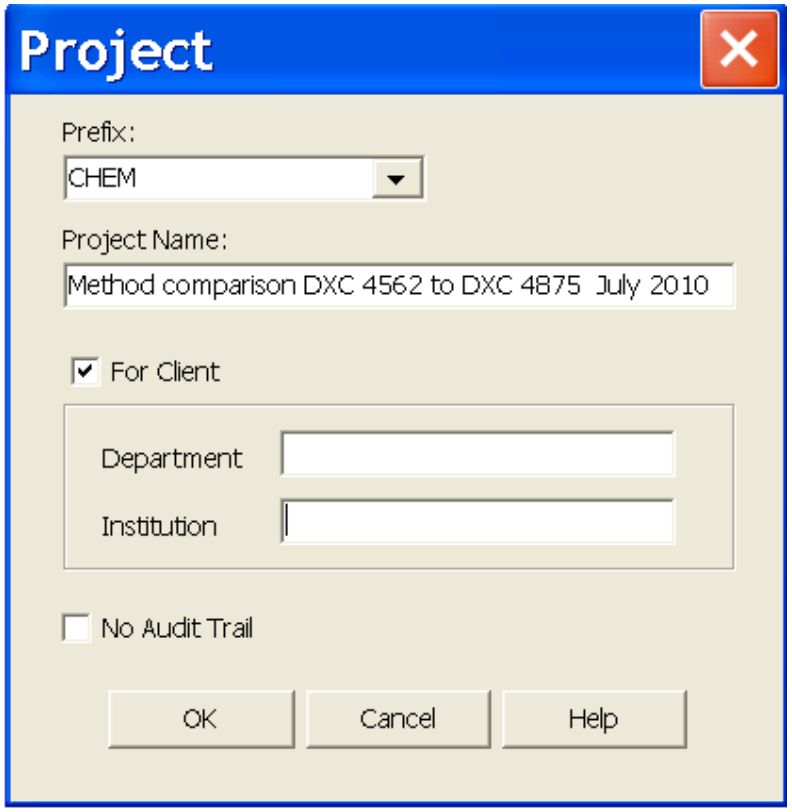
- **Projects must be unique – a 2 part name**
- **Prefix ^ unique name**
  - **Chem^"Validation for city Med Center – June 2009"**
- **The prefix serves as a folder name**
  - **Can Add more projects under the same prefix**
- **Organized in the EE file menu by prefix.**

Creating a New Project



Naming your project:

- Prefix – 12 chars:
  - User's initials or department name
- Project name - 80 char
  - Describe the activity
    - i.e., validations
    - Method comparison
    - Linearity
  - Include a date
- For Client (Optional)



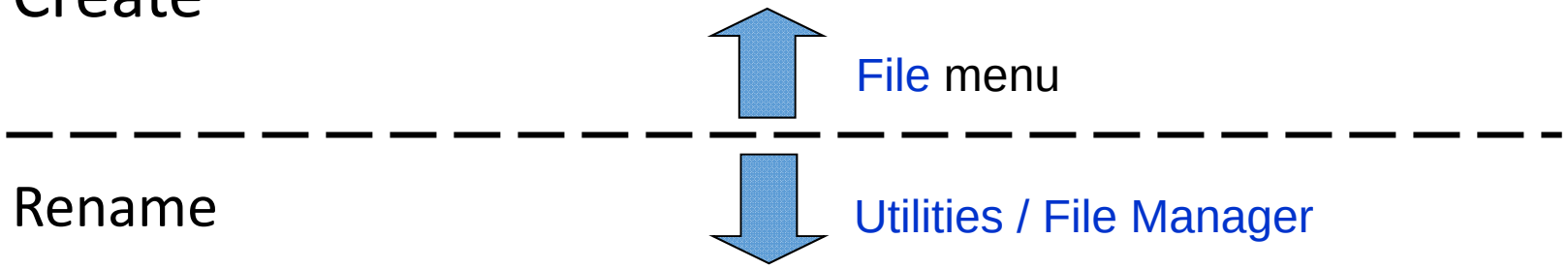
datainnovations.com

Managing Projects

DATA INNOVATIONS
Simple Ideas, Better Solutions

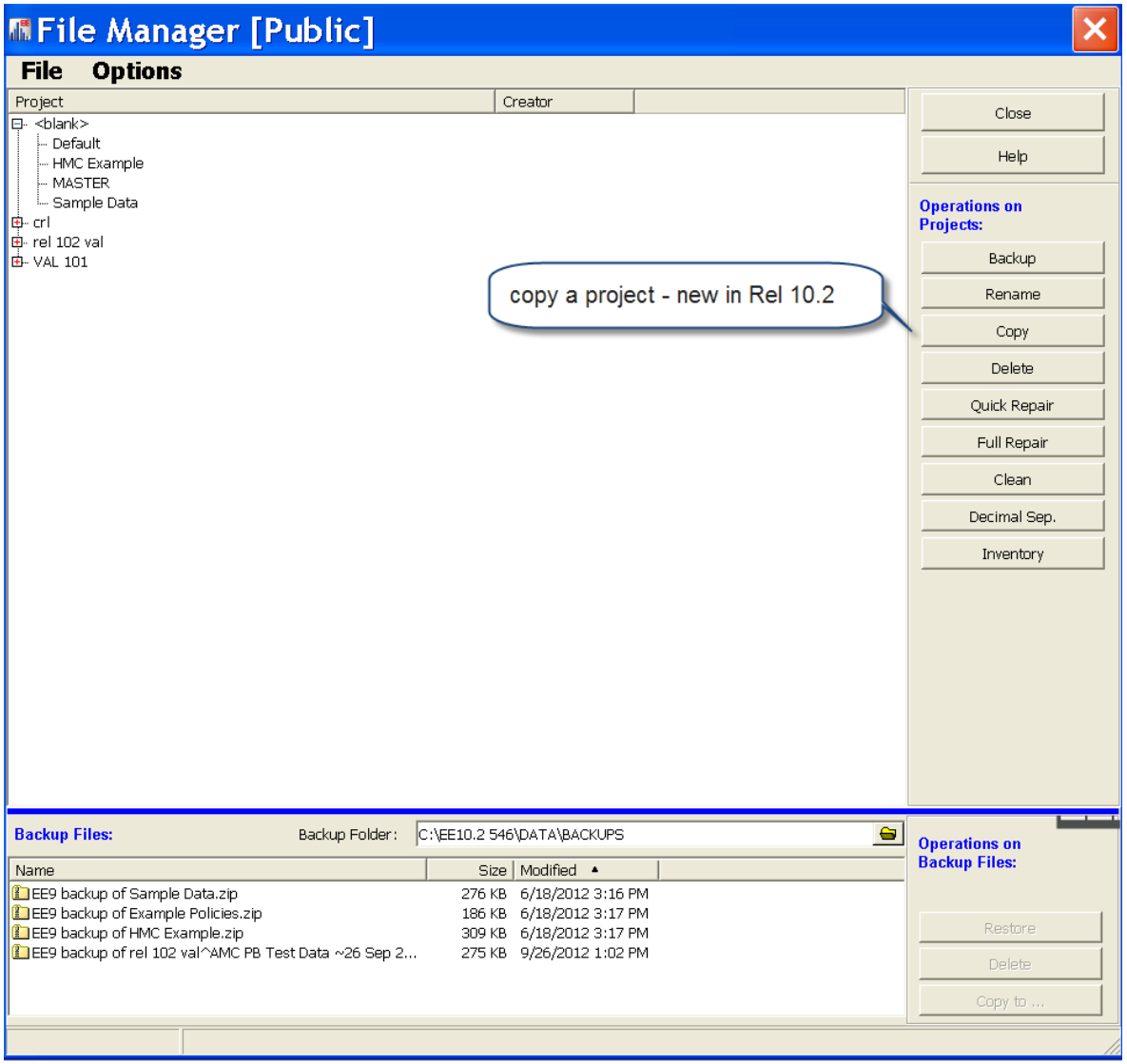
Active Project Management Functions

- Open/Reopen
- Create



- Rename
- Delete
- Backup
- Restore
- Inventory (see what experiments a project contains)
- Repair (fix database errors)
- Move out of EP Evaluator® (e.g., offsite storage)

The File Manager (Utilities\File Manager)



Project Backups:
A way to Share Data

- A EP Evaluator "project" contains all the data, policy definitions, experiments with data, and reports for a specific work assignment.
- Projects are portable only by using the backup function.
- To create a backup (archive) file for your project:
  - From the Main Statistical Module screen
  - Open Utilities\file Manager
  - Select the P**roject Name** in the top half of the screen
  - Click on Backup to create a zipped file archived to date and time.
    - Default folder is c:\EE\data\backups
    - Can "copy to" any folder or travel drive. Email to your colleagues.
- Restore when needed, or in EP Evaluator on another computer.

MASTER Project

- Created using Policy Definitions
- Cannot be opened or viewed in the File Open menu
- Cannot be renamed, deleted,
- Contains no inventory
- Can be backed up and restored using the Utilities File Manager.
- New Projects inherit policy definitions from the “Master Project”,
- Policy definitions from a current project can be copied to the Master project for future “new projects”

datainnovations.com

What's new in EE 11.1?

You asked for it!!

DATA INNOVATIONS
Simple Ideas, Better Solutions

Overall Project

- **Preferences**
  - The user can disable the notification of a new available **Update.**
  - **Option for a Regression Summary** page for Linearity reports: slope, intercept, R
  - Preferences can be saved to a file
- **Each time EE starts**, it verifies that the permissions are correct for writing files and writing to the registry
- **Most EE screens can be resized** and positioned to suit the user. The **Print Preview** screen will continue to appear full screen.
- **Method Comparisons**
  - 2IC, AMC, CLSI EP9, POC, and QMC Data entered can be viewed either in **SpecID** order or in the order that the data was originally entered.

Highlights of EE 11.1

EE11.1.26 released April 2014

- Added the Sigma Calculation to the Trueness Module, EQC data
- Added optional **Regression Summary** page to Linearity reports with slope, intercept, corr. coeff. Switch on with a new **Preference**
- Added new **Preference** that allows the user to disable the feature notifying the user when a new **Update** is available
- Added the **Merge Project** command to the **File** menu, so the user can copy experiments from a selected project into the currently open project. **Merge Project** does not copy **HMC** experiments.
- The Factor Sensitivity module now allows users to select curve fit regressions of logarithmic, or 1st, 2nd, or 3rd order polynomial.
- Method comparison modules 2IC, AMC, CLSI EP9, POC, and QMC Data entered can be viewed either in **SpecID** order or in the order that the data was originally entered.

Highlights of EE11.2

1. Carryover adds new user defined calculations for Error Limit..
2. Simple Precision supports 3 levels of “Sample Name” in policies and a new vendor SD claim based on conc or Percent or both.
3. Can now paste Data for ERI directly into the studies data grid.
4. The EE Professional version allows control over which statistical modules are enabled and which are not.
5. HMC users can change the regression plot default from no to yes after the study is created.
6. A precision study in the LIN module requires between 10 – 20 replicates (not *only* 10 replicates)
7. A new button on the ODBC screen filters matched spec IDS from multiple instruments to be downloaded to a Method comparison experiment
8. RRE is now supported for the stability muddle
9. Go to the Resources folder from the TOOLS menu
10. SIS module tracks the costs of inventory items
11. Project Merge now includes HMC studies

EE11.2 Simple Precision changes

- 3 levels of Controls or specimens
- Add a Vendor precision goal that is allowable error based. Within run SD, CV% or both This would be controlled in modules and options and be class specific (not analyte specific).
- Add a preference to suppress all occurrences of /”__”. In the overview screen or the report summary page. E.g., when target mean is not entered or target CV% can’t be calculated.

Carry over changes

- Before EE11.2 the calculated error limit depended on the maximum number of decimal places in the data. If there was a 0.0 in the data, the error limit was 1.
- Now the user can use either
  - classic calculated error limit
  - A user defined concentration
  - A user defined percent of the low mean
- This error limit model is more comparable to the carryover experimental design recommended in *Tietz - Fundamentals of Clinical Chemistry.*

RRE, Policies, and Projects

- RRE and project management
  - **RRE\Lot number database** is now both searchable and

  can be sorted by lot #, expiration data, source and comment,
  - **RRE edit\paste and import export** will correctly paste data from csv files that have been modified in MS Excel
  - **"Merge Project"** has been added to the File menu to copy experiments from a selected project into the current open project. (does not apply to HMC experiments)
- Policies
  - Error messages will display when truncations occur while **Pasting** data into the **Policy** forms.
  - The Equivalency Test Code feature (inside **RRE > Define Policies > Interface > Combine/Discard**) has improved flexibility to be able to accept incoming analyte names up to 24 characters to be mapped to a 16 character user defined analyte name .

“Misc”

- **HMC**
  - scatter plots show false negatives and false positives in yellow and red colors.
  - An error message now appears if the user attempts to exclude an **HMC** parameter that is used to compute another **HMC** parameter.
- **QMC**
  - Users can control the visibility of three statistics (Agreement, McNemar's Test, and Cohen's Kappa) in the QMC reports.
  - The defaults are set in **Policies\Modules & Options** (initial default is Y)
  - Checkboxes in the **Parameters** screen can also customize each **QMC** experiment.
- Stability
  - Stability experiments can now be transferred from older releases of EE using the Update Wizard.
- Trueness
  - The Trueness StatMod was updated to calculate Sigma in EQC mode experiments.
- Tutorial Files
  - A bug was fixed that prevented Tutorial files from being accessed if the Language in Preferences was set to ‘None’.

Factor sensitivity*

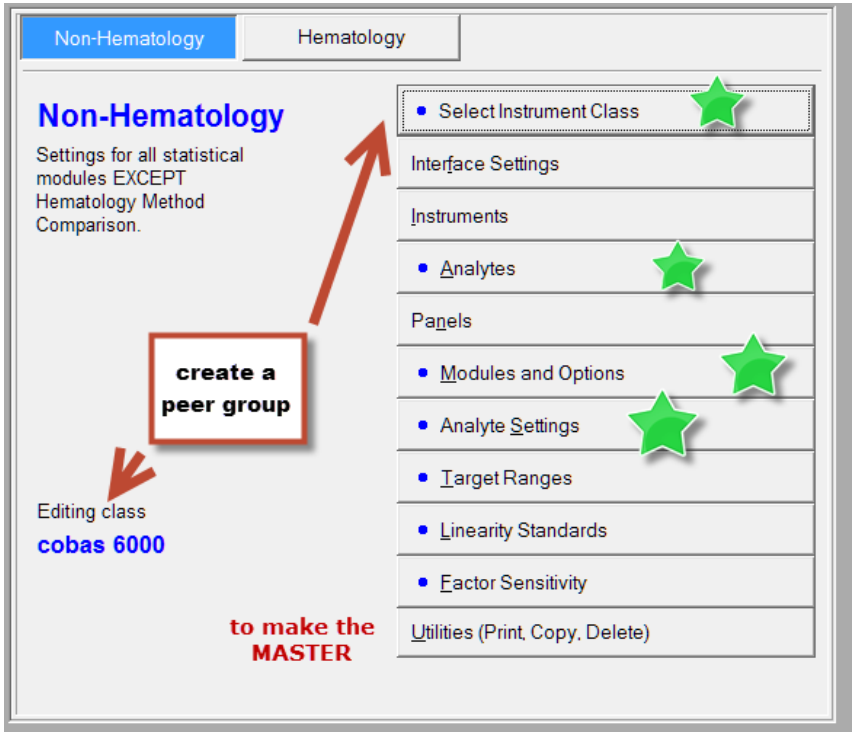
- The user can manually select regression polynomials of degree 1, 2, or 3, or a logarithmic curve fit.
- The regression degree, regression polynomial equation, R-squared value, and SEE is present on both the Experiment Detail screen and the report.
- **A new "Regression Limits" option** in the parameters screen lets users choose the actual Dilutions to be used in the regression plot.
- **Dilutions:**
  - The maximum dilution is now 100% rather than 99%, and decimal points are allowed.
  - Theoretical Dilutions are now sorted numerically
  - Added a column to reveal the computed Actual Dilutions in the Experiment Detail screen.
  - "Edit \ Paste with Policies – List" now honors decimals found in the dilution portion of the specimen ID.
  - The number of decimal digits in the computed Actual Dilutions is now the same as the maximum number of decimal digits in the Theoretical Dilutions.
- *See the Factor Sensitivity topics in EP Evaluator Help for more detail regarding these changes.

Rapid Results Entry (RRE)

- Describes several different efficient data-entry techniques:
  - Pasting experimental results from Excel into experiment detail screen
  - Paste with Policies into overview screen
  - Efficient keyboard entry of results on printouts for multiple analytes
  - Data Acquisition from Instrument Manager
- EE Users Guide Chapters 35, 36, 37
- Help Topics are available for most all of the setup screens

Step 1 – Instrument Class, Analytes, and Units

- Go to Statistical Modules Screen
- Select RRE / Define Policies from the menu; select the Non-Hematology Tab

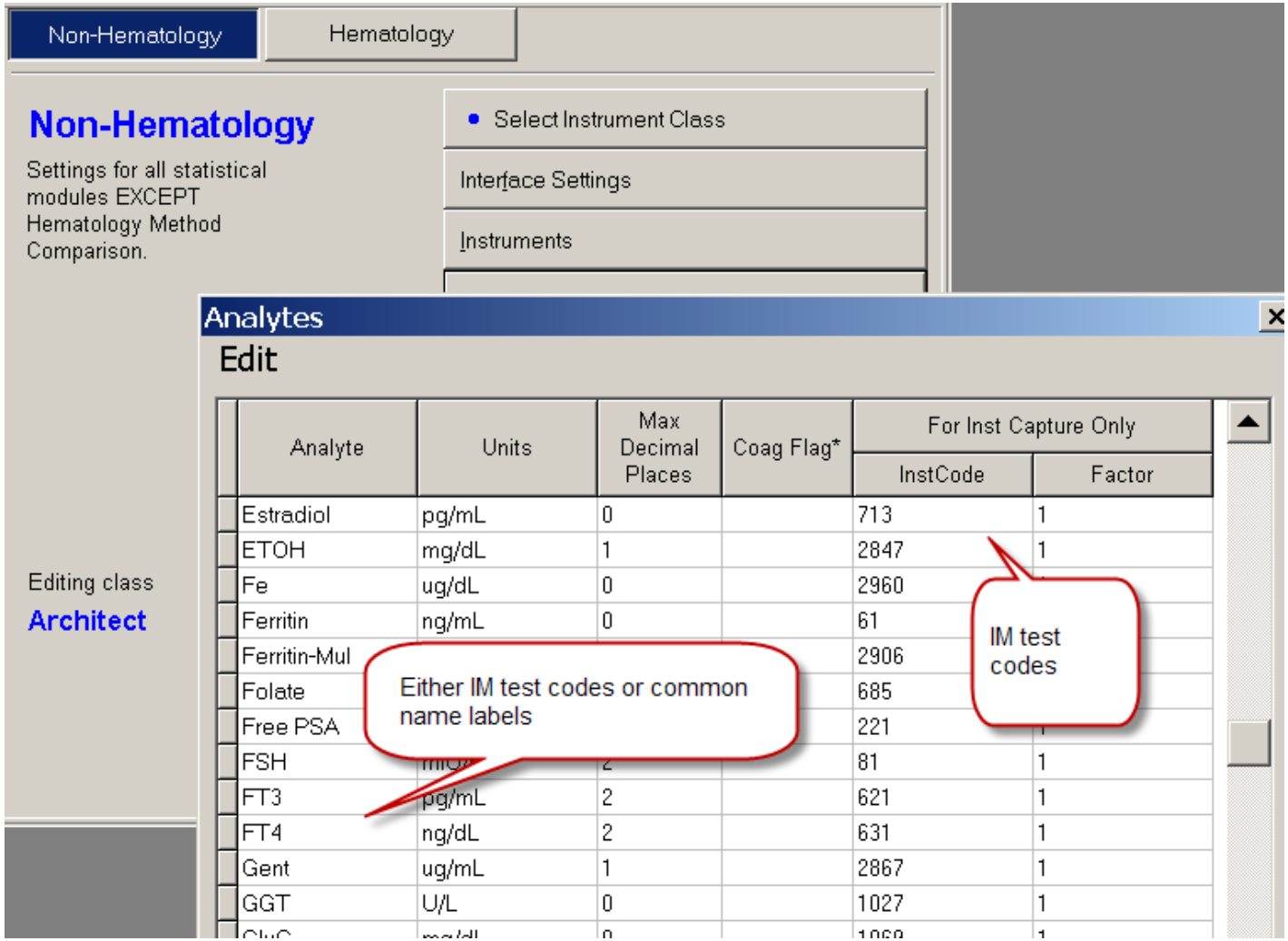


RRE – Rapid Results Entry
Policy Definitions

- Set up a RRE "Policy Definition" Master Policy template to store frequently used method characteristics.
  - **Peer Group Classes * – like COBAS 6000 or Architect**
  - **Instrument serial numbers * Fred 1, Fred 2, Cobas75678**
  - **Analyte names and units and test codes * Glu BUN 1021**
  - **Default module settings * (decimal points, reps expected)**
  - Allowable errors - TEa
  - Reportable ranges, reference intervals, and more

- BOLDED * Items are needed for ODBC download
- Use the analyte names or test codes mapped in IM
- Use the instrument Names mapped in IM

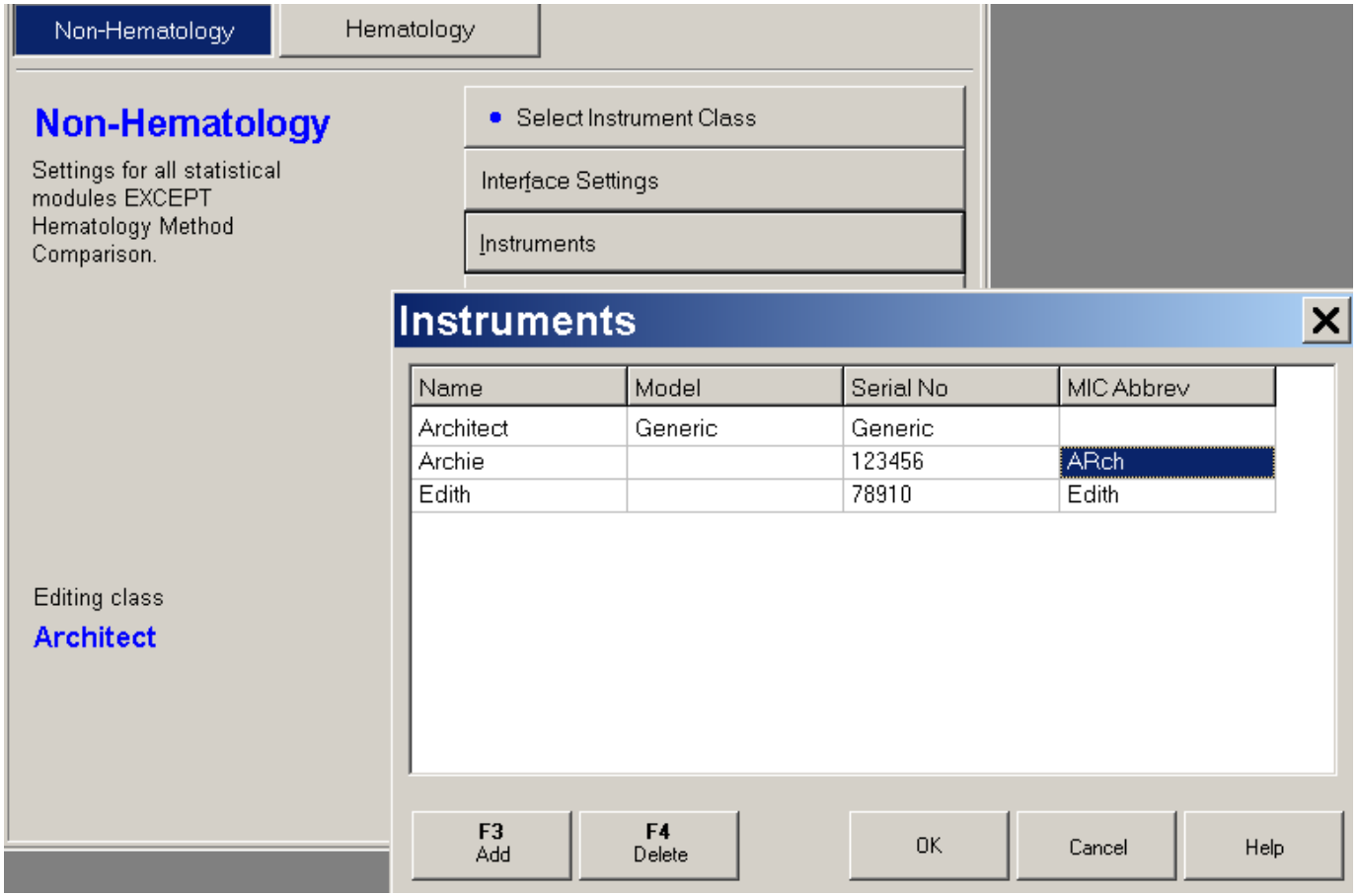
Policy Definition Analytes



Analyte	Units	Max Decimal Places	Coag Flag*	For Inst Capture Only	
				InstCode	Factor
Estradiol	pg/mL	0		713	1
ETOH	mg/dL	1		2847	1
Fe	ug/dL	0		2960	
Ferritin	ng/mL	0		61	
Ferritin-Mul				2906	
Folate				685	
Free PSA				221	
FSH		2		81	1
FT3	pg/mL	2		621	1
FT4	ng/dL	2		631	1
Gent	ug/mL	1		2867	1
GGT	U/L	0		1027	1

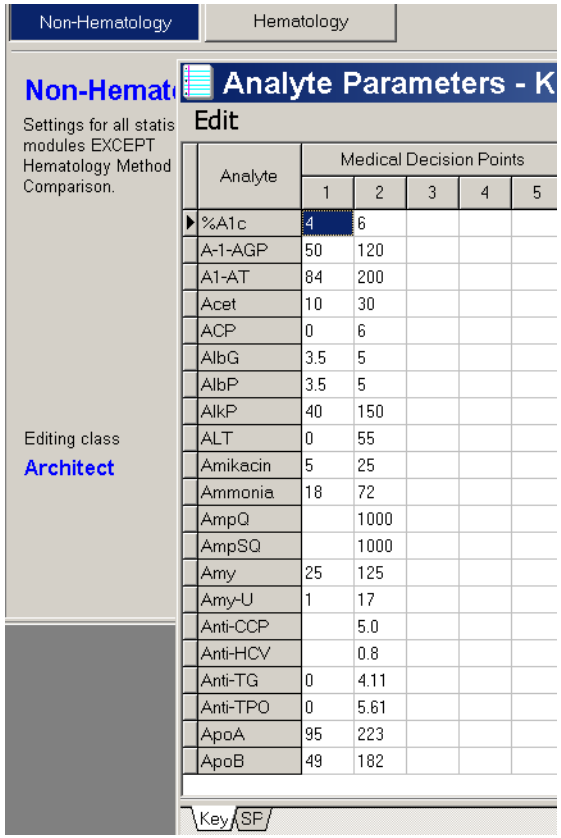
Instruments

Names or Serial Numbers as defined in IM

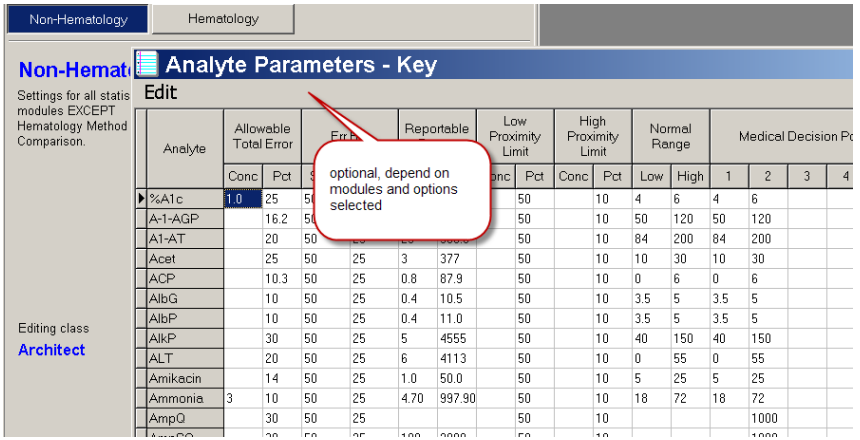


Analyte settings depend on Modules / Options selected

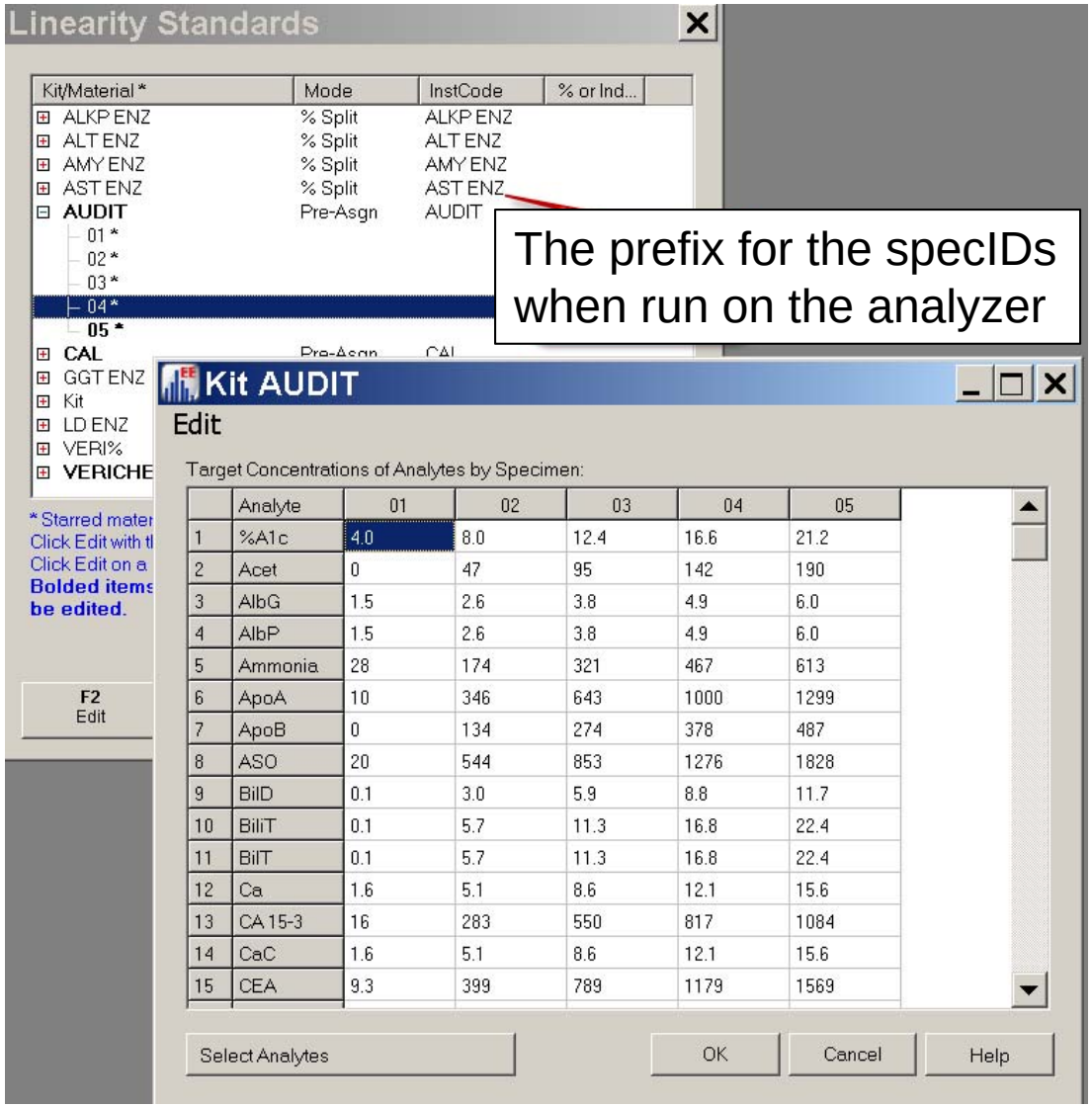
Minimal



Most pass/fail options selected



Linearity sets

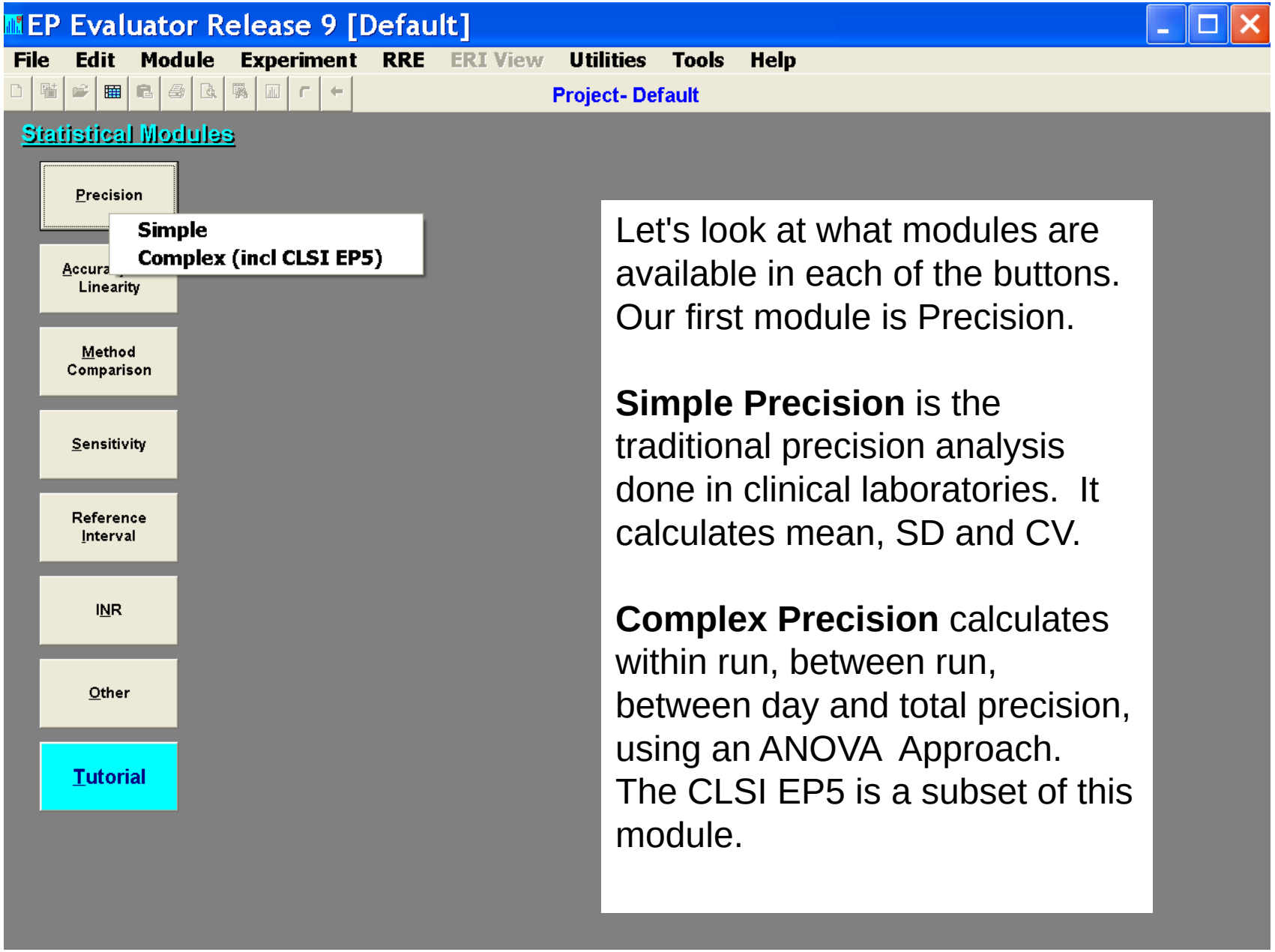


Audit-01
Audit-02
Audit-03
Audit-04

datainnovations.com

Exploring the Modules

DATA INNOVATIONS
Simple Ideas, Better Solutions



Let's look at what modules are available in each of the buttons. Our first module is Precision.

Simple Precision is the traditional precision analysis done in clinical laboratories. It calculates mean, SD and CV.

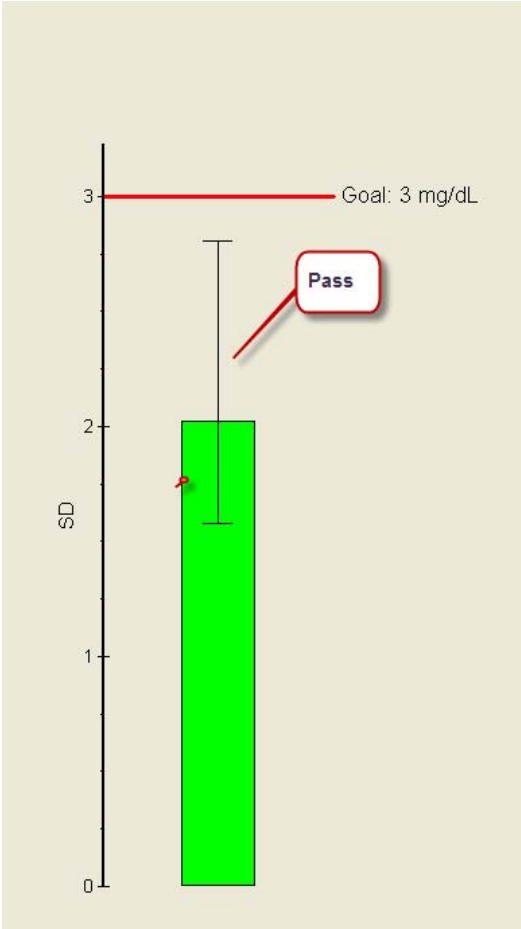
Complex Precision calculates within run, between run, between day and total precision, using an ANOVA Approach. The CLSI EP5 is a subset of this module.

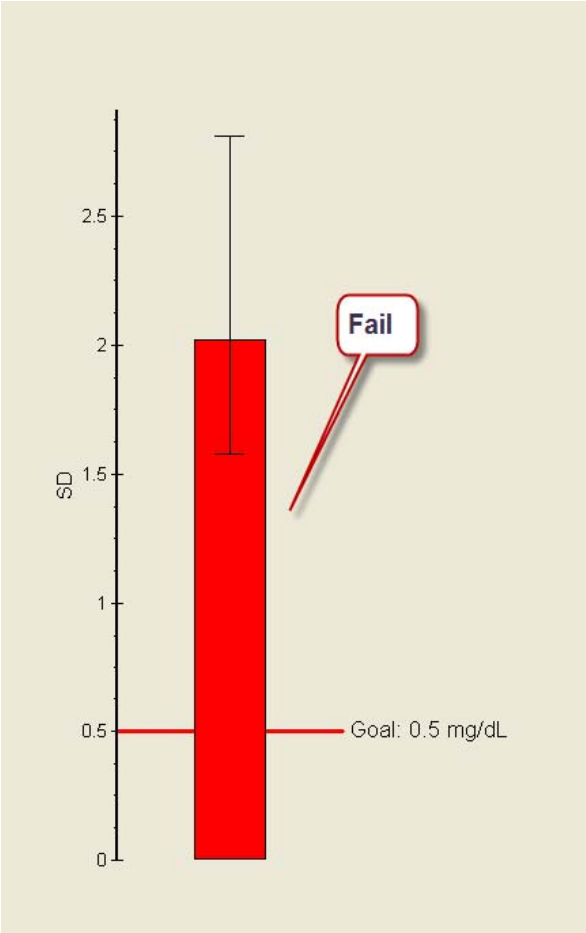
Simple Precision Enhancements implemented in EE10.1

- A preference option changes Pass/Fail reporting to Pass/Fail/Uncertain.
  - The uncertainty of the accuracy of the SD is described by the 95% confidence limits. The uncertainty becomes smaller as the number of values in the experiment increases.
  - the experiment will be designated “uncertain” if the SD goal is within the 95% Confidence Interval (CI) around the observed SD.

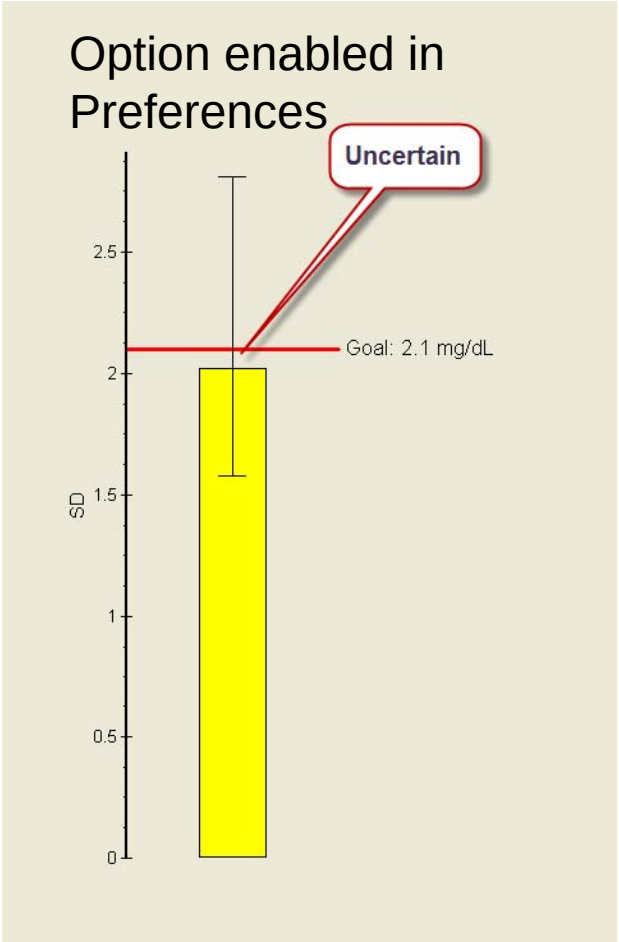
- Two features that will help verify new control lot ranges.
  - User defined target mean as well as a target SD goal,
  - Enable a histogram to display the range of observed data relative to the observed or target mean.

Pass / Fail / Uncertain

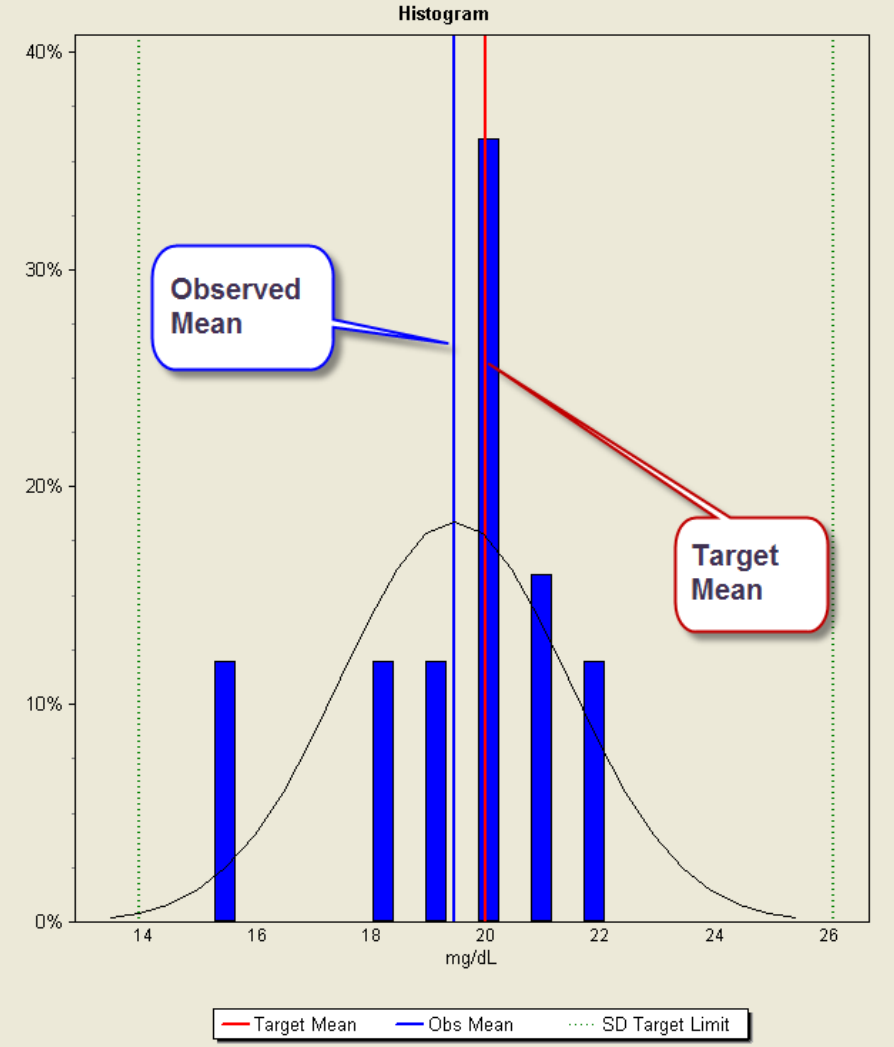




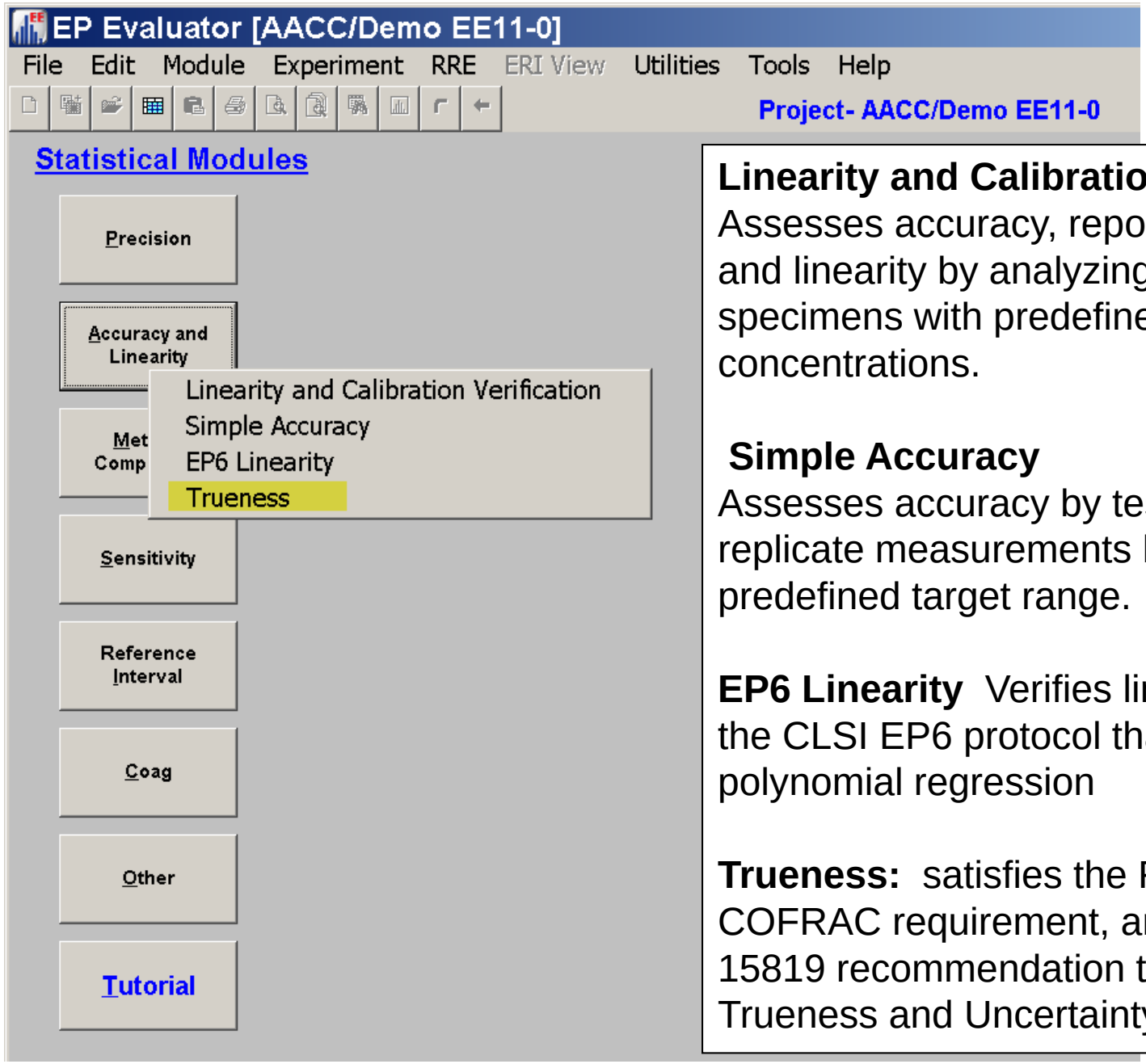
Option enabled in Preferences



Histogram of Precision data



Obs Mean	19.4 mg/dL
Target Mean	20
Obs SD	2.0 (1.6 to 2.8) mg/dL
SD Goal	--
Bias	0.6 mg/dL (2.8%)
Target Range	+/- 3.0 SD
Precision Verification Goal	None



Linearity and Calibration Verification
Assesses accuracy, reportable range, and linearity by analyzing more than 3 specimens with predefined concentrations.

Simple Accuracy
Assesses accuracy by testing whether replicate measurements lie within a predefined target range.

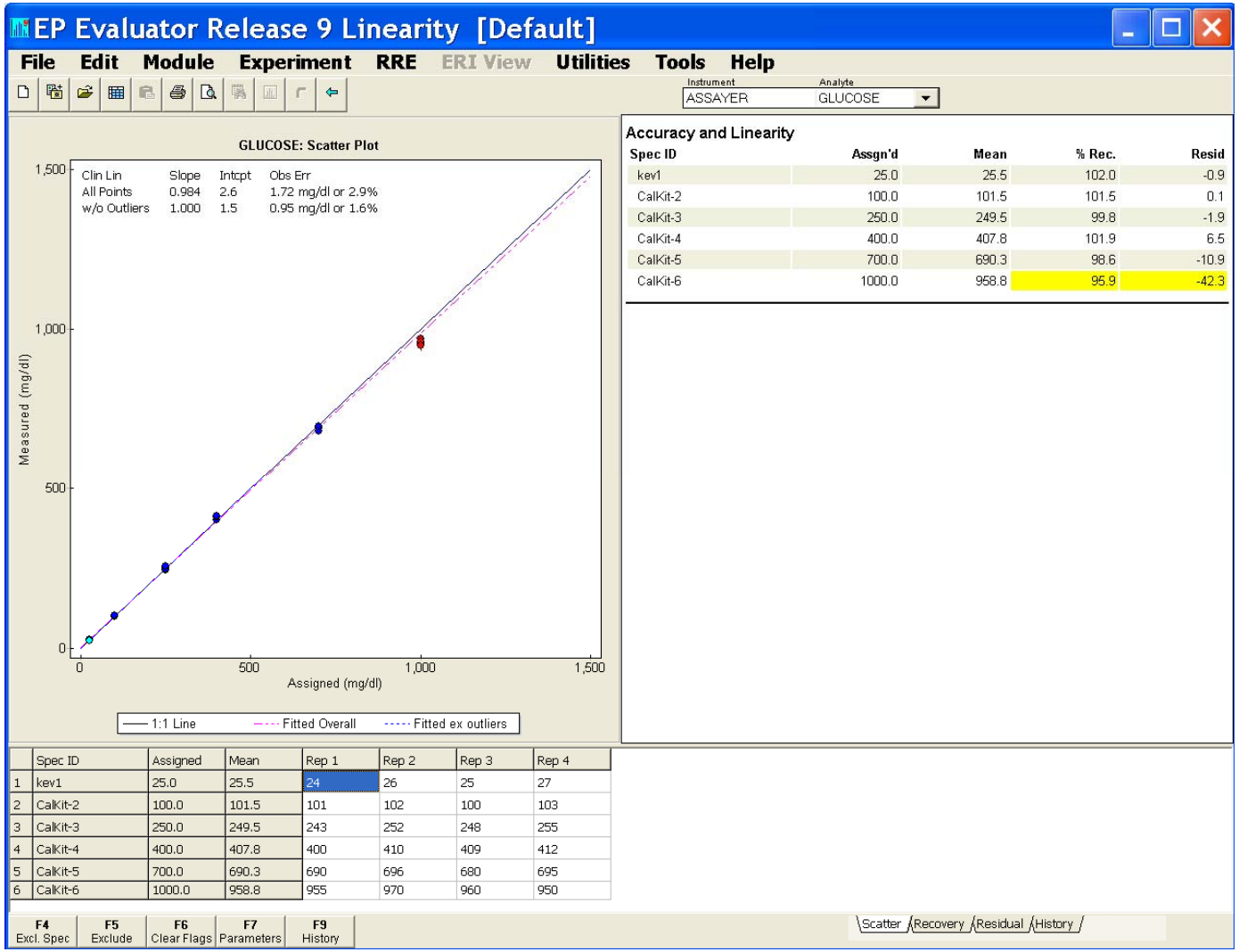
EP6 Linearity Verifies linearity using the CLSI EP6 protocol that offers polynomial regression

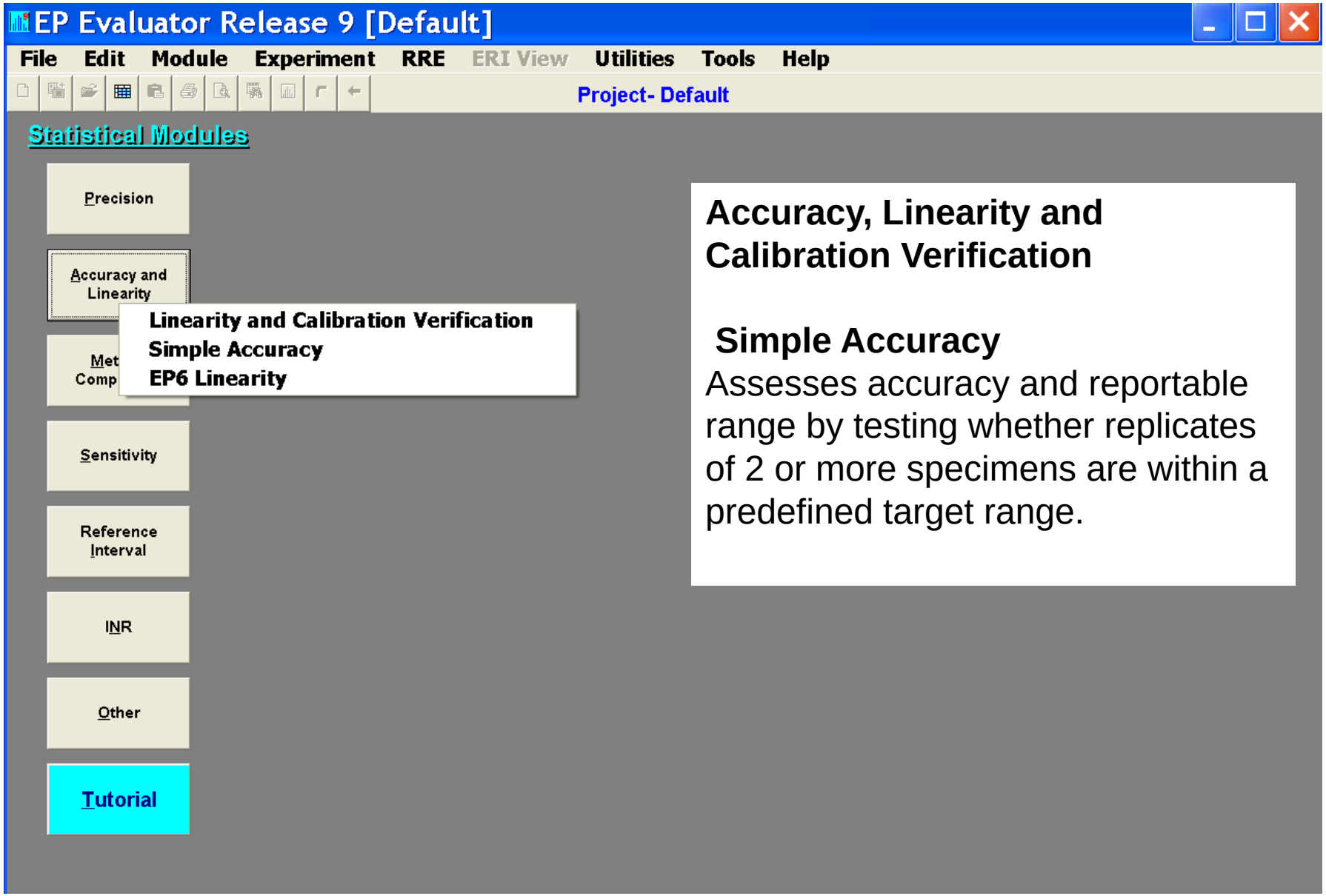
Trueness: satisfies the French COFRAC requirement, and the ISO 15819 recommendation to assess Trueness and Uncertainty

Linearity, Calibration Verification Module

- Satisfies all CLIA requirements –
- Uses Total error (TEA) and SEA (bias) for pass/fail criteria
  - TEA may need a conc component if testing low values
- Report Options
  - Calibration verification.
    - Includes accuracy, reportable range
  - Accuracy
    - Accuracy Passes if all levels (mean value – assigned) less than SEA
  - Clinical Linearity (an EP Evaluator exclusive)
    - Linearity PASSES if: a straight line can be drawn through the SEA error bars around each measured mean value.
  - Reportable range fails if
    - low or high mean recovery fails accuracy test
    - Assigned values not within proximity limits
    - Can choose linearity, accuracy reportable range separately

A typical Linearity Experiment





Accuracy, Linearity and Calibration Verification

Simple Accuracy

Assesses accuracy and reportable range by testing whether replicates of 2 or more specimens are within a predefined target range.

Accuracy linearity Group

- Simple Accuracy –
  - Only need 2 controls or standards
  - Specify a TARGET Range for acceptability.
  - Addresses needs of Coag and POCT departments

- CLSI EP6
  - Uses a polynomial best fit curve and compares to linear regression...
  - Used by IVD vendors to establish linearity claim.
  - Allows entry of allowable “deviation” from linearity as a Percent of TEA.

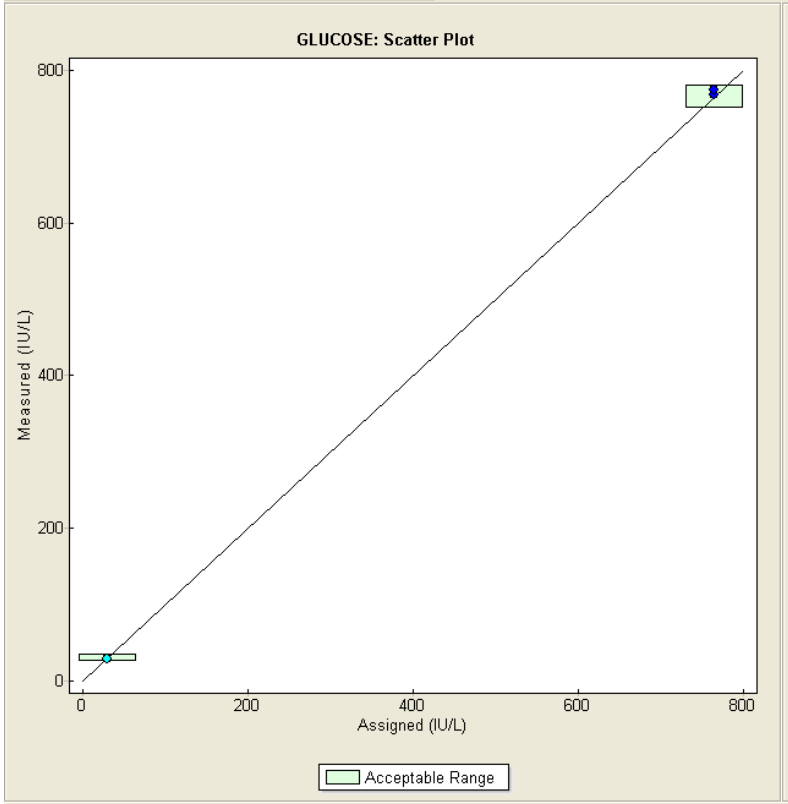
Simple Accuracy –

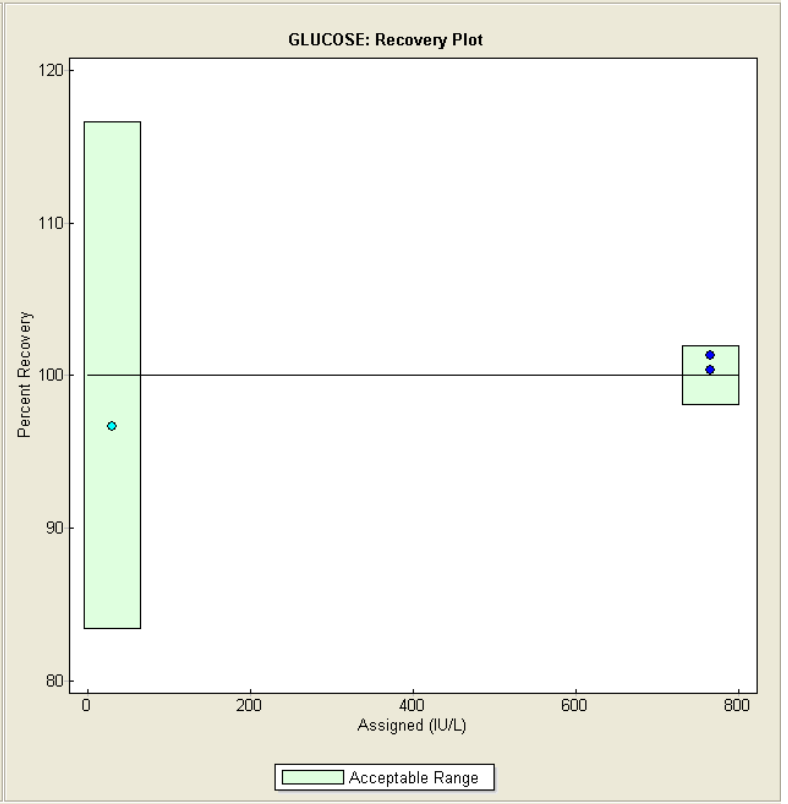
- Good for Coag and POCT departments
- Minimum of 2 controls or standards
- TARGET Ranges provided by Manufacturer define acceptability for accuracy and reportable range.
- Assesses Accuracy and Reportable Range
- PASS or FAIL

Simple Accuracy

File Edit Module Experiment RRE ERI View Utilities Tools Help

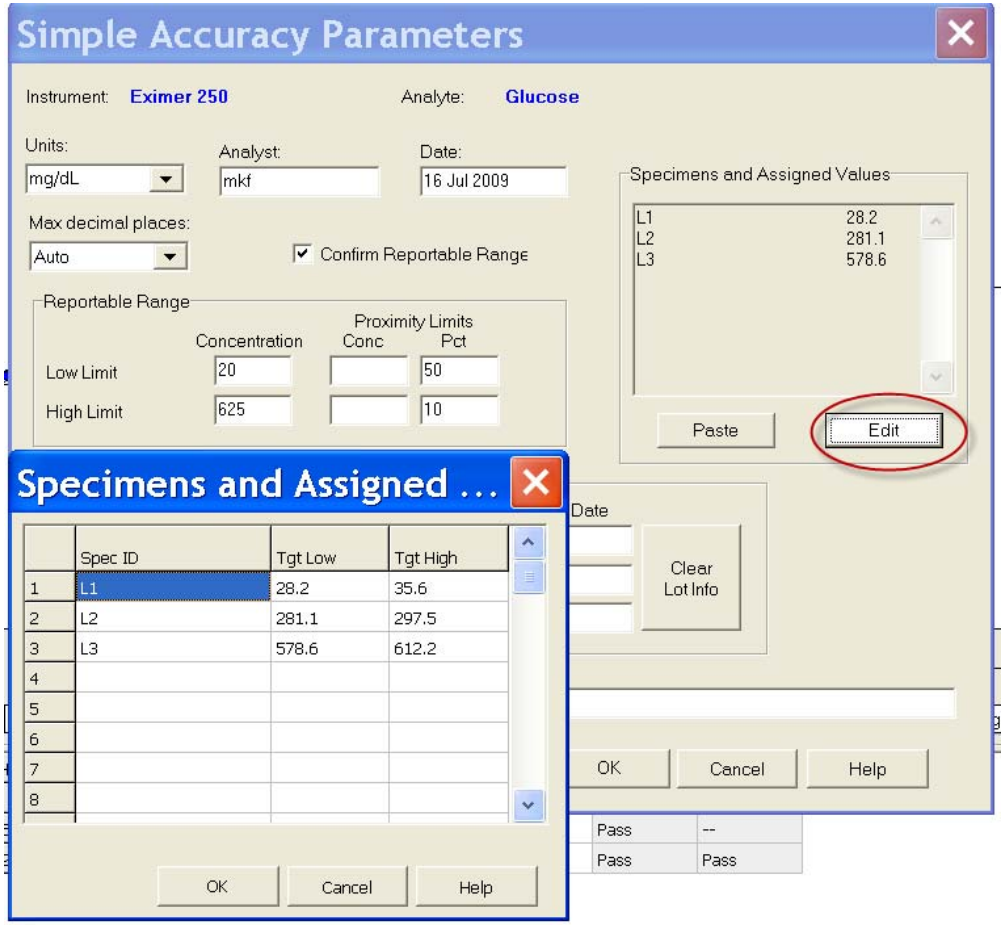
Instrument: Meter 1 Analyte: GLUCOSE





	Spec ID	Tgt Low	Tgt High	Rep 1	Rep 2	Rep 3	Rep 4	Rep 5	Accuracy?	RR?
1	G31	25	35	29	29	29	29		Pass	--
2	G34	750	780	768	775	768	775		Pass	--

Set up Target ranges.



Report Summary

EP Evaluator®

tsting EE 9.5(458) -- Holy Moly MC

Simple Accuracy Summary

Instrument	*Analyte*	*Range Tested*	*# Levels*	*Accuracy*	*Rpt. Range*	*Accept*
Meter 1	✘ GLUCOSE	30 to 765 IU/L	2	Pass	1 of 2 Fail	_____
Meter 10	✔ GLUCOSE	30 to 765 IU/L	2	Pass	Pass	_____
Meter 2	✘ GLUCOSE	30 to 765 IU/L	2	Pass	1 of 2 Fail	_____
Meter 3	✔ GLUCOSE	30 to 765 IU/L	2	Pass	Pass	_____
Meter 4	✔ GLUCOSE	30 to 765 IU/L	2	Pass	Pass	_____
Meter 5	✘ GLUCOSE	30 to 765 IU/L	2	Pass	1 of 2 Fail	_____
Meter 6	✔ GLUCOSE	30 to 765 IU/L	2	Pass	Pass	_____
Meter 7	✔ GLUCOSE	30 to 765 IU/L	2	Pass	Pass	_____
Meter 8	✔ GLUCOSE	30 to 765 IU/L	2	Pass	Pass	_____
Meter 9	✔ GLUCOSE	30 to 765 IU/L	2	Pass	Pass	_____

CLSI EP6

- Implements CLSI EP06-A
- Program picks the best poly fit
- Bartlett's test to check for consistent SD or CV%
- Scatter plot and residual plot

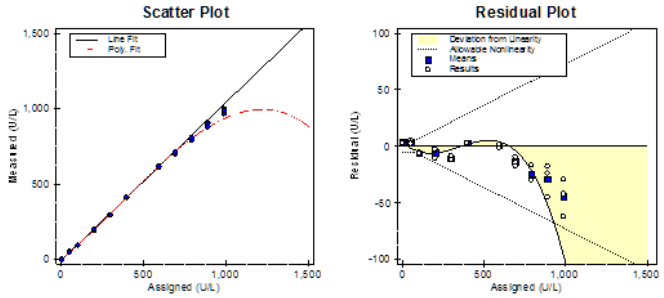
EP Evaluator®

EE 11.2.23 Webinar -- Community Hospital

GGT

Instrument Axcel 12

CLSI EP6 Linearity



Data IS NOT linear within allowable nonlinearity of 5 U/L (conc) or 7.0%

Fit of polynomial to data is poor (p<0.001)

Power of test to detect nonlinearity is poor (ratio=0.2)

Statistical Analysis

Specimen	Assigned Value	Mean	Poly. Fit	Line Fit	Deviation from Linearity	Deviation Percent	
0	0.3	0.3	0.3	-3.3	3.6	***	
1	49.6	52.3	46.8	48.4	-1.6	-3.3	
2	98.8	94.3	95.3	100.0	-4.7	-4.7	
3	197.2	198.0	197.2	203.1	-5.9	-2.9	
4	295.6	296.0	303.4	306.3	-2.9	-0.9	
5	394.1	412.7	411.2	409.6	1.7	0.4	
6	590.9	617.0	620.1	615.9	4.2	0.7	
7	689.4	705.7	715.7	719.2	-3.5	-0.5	
8	787.8	797.7	801.6	822.3	-20.7	-2.5	
9	886.2	897.0	875.2	925.5	-50.3	-5.4	
10	984.7	984.7	933.6	1028.8	-95.2	-9.3	O

***: Absolute value > 99% x: Excluded o: Exceeds allowable nonlinearity

Evaluation Criteria

Allowable Total Error (TEa)	10 U/L (conc) or 14.0%
% for Nonlinearity	50%
Allowable Nonlinearity	5 U/L (conc) or 7.0%
Use weighted regression?	If applicable

Supporting Data

Slope	1.048 (1.039 to 1.058)
Intercept	-3.6 (-6.1 to -1.1)
Analyst	DH/LP
Date	21 Oct 2011
Units	U/L
Value Mode	Pre-Assigned
Controls	--
Reagents	--
Calibrators	--
Comment	

CLSI EP06 pg 2

EP Evaluator®

EE 11.2.23 Webinar -- Community Hospital

GGT

Instrument Axcel 12

CLSI EP6 Linearity

Experimental Results

Specimen	Mean	SD	CV	Measured Concentrations		
0	0.3	0.6	173.2	1	0	0
1	52.3	1.5	2.9	54	52	51
2	94.3	0.6	0.6	95	94	94
3	198.0	4.4	2.2	200	193	201
4	296.0	1.7	0.6	298	295	295
5	412.7	0.6	0.1	413	412	413
6	617.0	1.7	0.3	618	615	618
7	705.7	4.0	0.6	705	702	710
8	797.7	7.2	0.9	794	793	806
9	897.0	14.2	1.6	881	908	902
10	984.7	16.6	1.7	967	1000	987
Pooled		**7.2**	**52.2**			
Degrees of Freedom		22	22			
Bartlett's p		0.000	0.000			
Accept equality hypothesis?		No	No			

x Excluded

Polynomial Fit Analysis

Polynomial	Coefficients and their T statistics				Std Error of Estimate	"Best" Polynomial
	Constant	X	X^2	X^3		
Line	-3.609 2.9	1.048 218.9			4.906	
2nd Order	-3.269 2.3	1.041 69.6	1.456E-005 0.5 (*)		4.966	
3rd Order	**0.05346** **0.1 (*)**	**0.9183** **56.1**	**0.0005089** **8.6**	**-4.861E-007** **8.6**	**2.673**	**Best**

Analysis based on weighted regression. Standard error expressed as a multiple of imprecision SD
(*) Statistically equivalent to zero

Trueness Module

- In the Linearity Accuracy Group
- Satisfies the Trueness, Accuracy and Uncertainty *requirements* for COFRAC certification in France.
- Satisfies the ISO 15189 *recommendation* to assess trueness and uncertainty of laboratory instruments performing analyses of biological fluids

Acronyms used in Trueness

- EQA – External Quality Assessment
  - Proficiency testing programs like CAP, New York State, EQAS.
- EQC – External Quality Control programs like Biorad Unity Realtime, MAS, …
- IQC: Internal Quality Control
  - The labs daily QC Overall mean
  - Typically at least 2 levels
  - Could be the same as the EQC material

ISO Definitions -

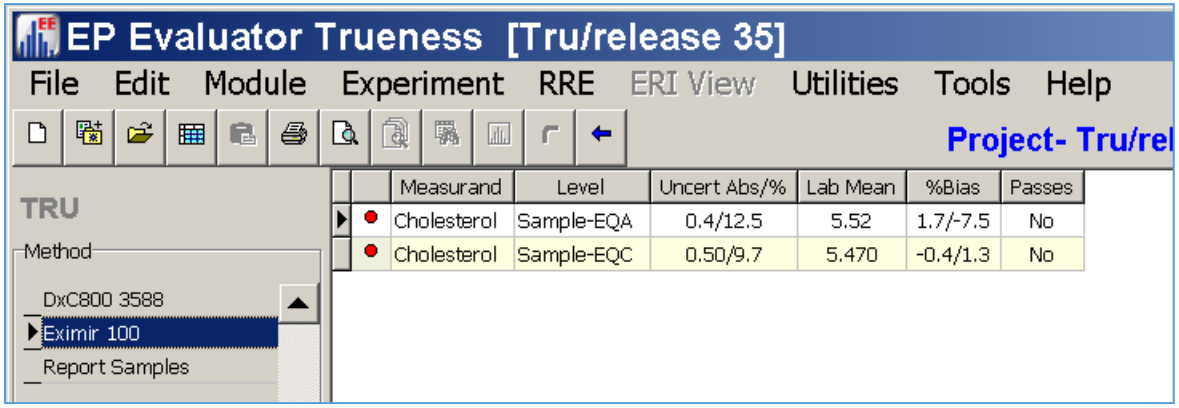
- Trueness
  - the closeness of agreement between the average value obtained from a **large** series of test results and an accepted reference value (also the mean of a huge set of data)
  - Data Source: EQC (like Biorad Unity) – monthly summary compared to peer or All method group mean.
  - Monthly summary expressed as mean +/- SD
- Accuracy
  - closeness of agreement between a (**single**) measured quantity value and a true quantity value of a measurand.
  - Data Source : EQA (PT surveys)
  - Single lab value compared to group mean (peer or All method)
  - Imprecision is embedded in the single lab result.

New Definitions

- Measurand:
  - The analyte in it's milieu - like fluid type
  - Urine glucose
  - Serum glucose
  - CSF glucose
- Uncertainty
  - Characterization of the dispersion of the values attributed to the measurand.
  - components of uncertainty might include precision, bias, drift, carryover. Calibration variation, etc.
  - EE only uses precision and bias.

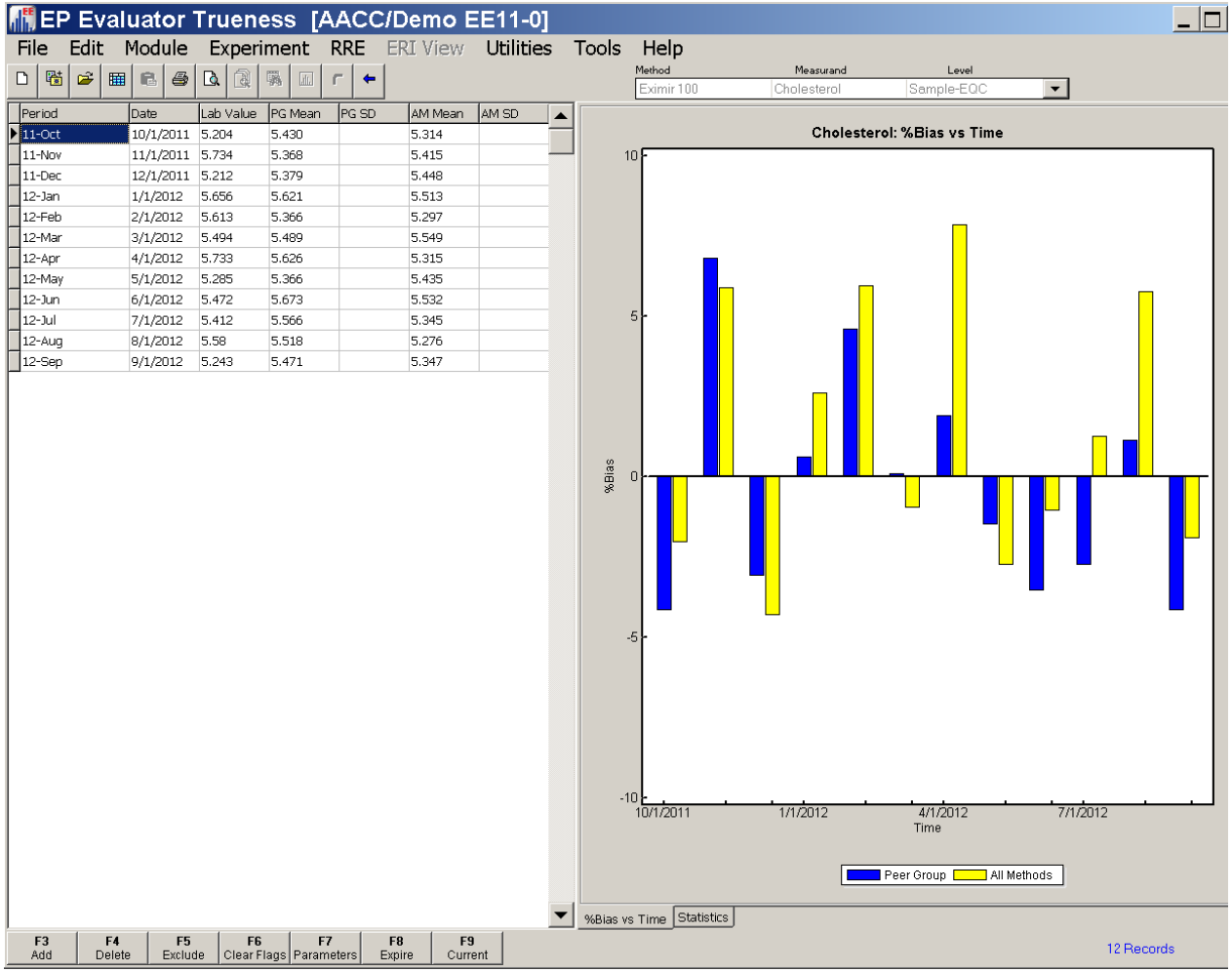
Module Overview Screen Trueness

- Gray column
  - Module name in Gray in upper left.
  - All methods with experiments are listed
- White grid:
  - For each method Lists all experiments with basic stats. their status: pass, fail, not calculated, etc.
- Experiment: one *Measurand*
- Double click experiment to open it



Experiment Detail Screen

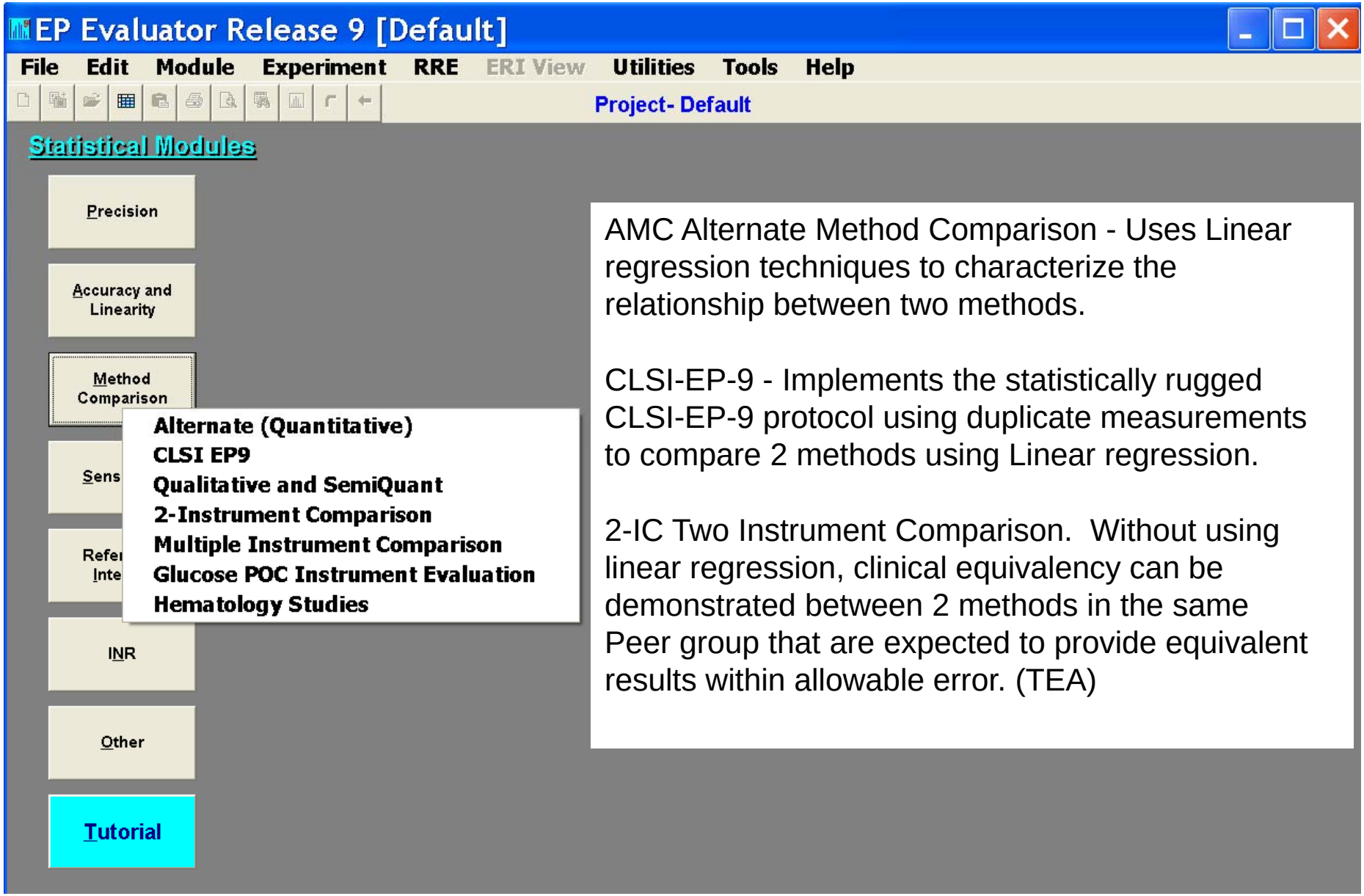
- One row for each comparative event
- Data Entry
  - SpecID
  - Date / period
  - Lab Value
  - Peer mean
  - Peer SD
  - All meth mean
  - All meth SD
- Observed statistics
- Tabs for Graphs, charts, statistics



Trueness Module Key Statistics

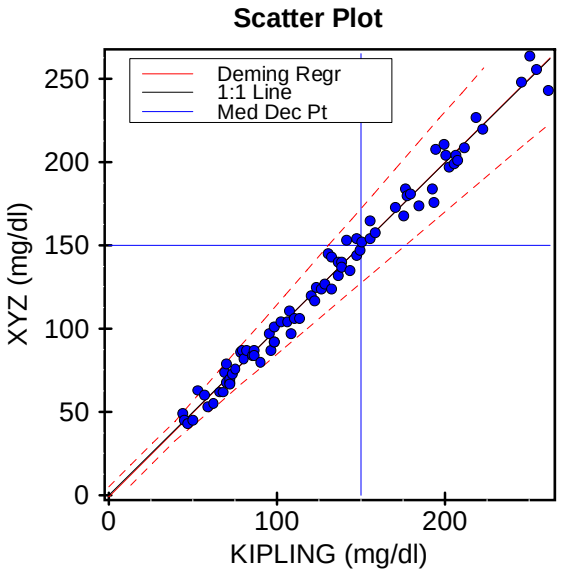
- Trueness Report using EQC Data
- A single level experiment
- Overall bias to peer or all method selected group
- Overall Uncertainty
- Specimen uncertainty if selected group reports SD
- %bias vs time for **both groups** when data available
- Sigma calculation of lab data

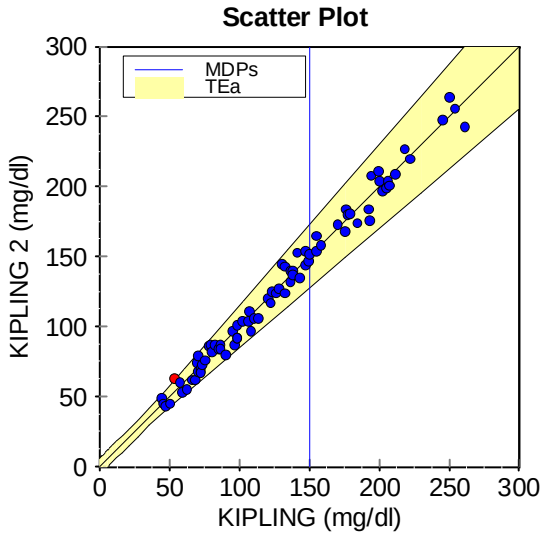
- Accuracy Report using EQA data
- Experiment can have multiple levels
- Overall bias to peer or all method selected group
- Overall Uncertainty
- Specimen uncertainty if selected group reports SD
- %bias vs selected group
- %bias vs time for selected group
- Scatter plot if multi-level experiment
- Uncertainty plot


EP Evaluator Release 9 [Default]
File
Edit
Module
Experiment
RRE
ERI View
Utilities
Tools
Help
Project- Default
Statistical Modules
Precision
Accuracy and Linearity
Method Comparison
Sens
Refer Inte
INR
Other
Tutorial
Alternate (Quantitative)
CLSI EP9
Qualitative and SemiQuant
2-Instrument Comparison
Multiple Instrument Comparison
Glucose POC Instrument Evaluation
Hematology Studies
AMC Alternate Method Comparison - Uses Linear regression techniques to characterize the relationship between two methods.
CLSI-EP-9 - Implements the statistically rugged CLSI-EP-9 protocol using duplicate measurements to compare 2 methods using Linear regression.
2-IC Two Instrument Comparison. Without using linear regression, clinical equivalency can be demonstrated between 2 methods in the same Peer group that are expected to provide equivalent results within allowable error. (TEA)

Method Comparison
Validation vs Harmoniza

- Method Validation
  - 2 methods not expected to be statistically identical
  - Relationship defined by regression line slope and intercept
  - Alternate Method Comparison - AMC
- Method Harmonization
  - Methods expected to be clinically identical
  - Relationship defined by agreement within allowable error (TEA)
  - 2 Instrument Comparison 2IC
  - Multiple instrument Comparison module – MIC

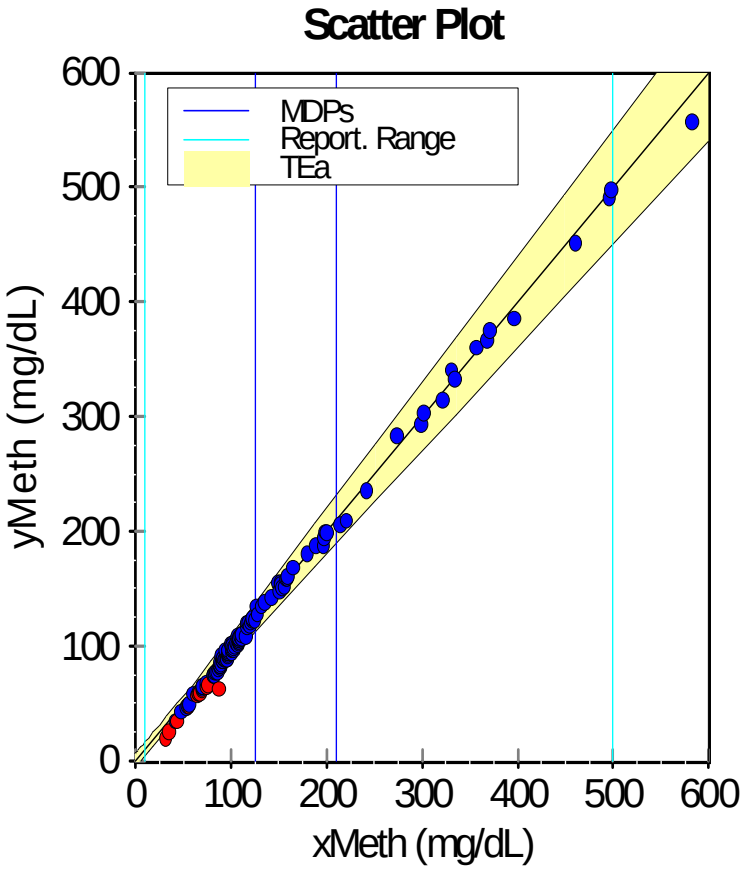


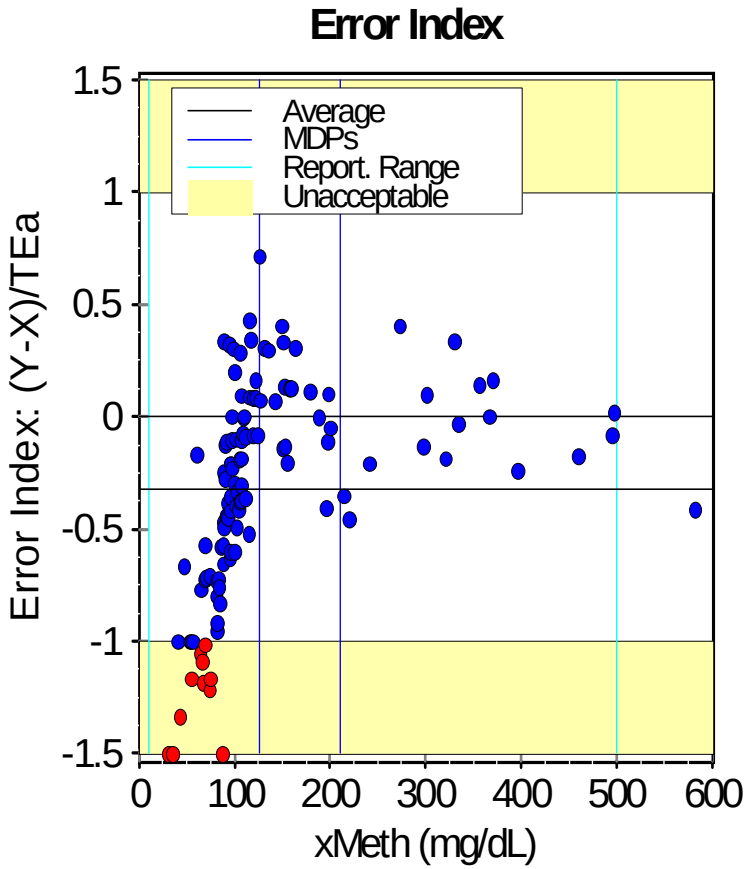


Method Comparison - Harmonization

- Semi-annual CLIA requirement
- Production methods for the same test on multiple instruments must produce clinically identical results.
- Simple Pass/Fail answer.
- Avoids issues with interpretation of slope, intercept and correlation coefficients.
- 2IC - for 2 Instrument Comparison
- MIC - for Multiple Instrument Comparison

Harmonization Plots

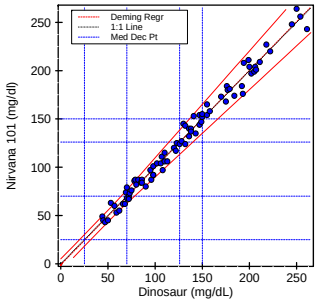




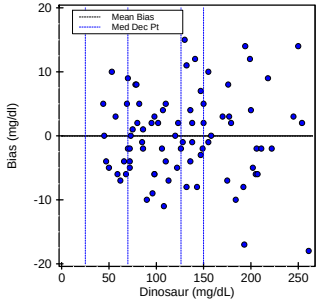
Alternate (Quantitative) Method Comparison

X Method: Dinosaur **Y Method: Nirvana 101**

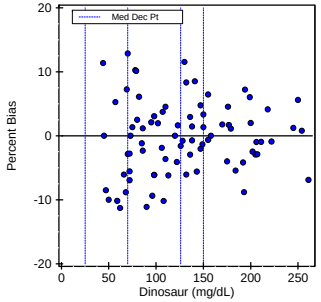
Scatter Plot



Bias



Percent Bias



Regression Analysis

	Deming	Regular
Slope:	1.007 (0.980 to 1.034)	1.002 (0.975 to 1.029)
Intercept:	-1.0 (-4.7 to 2.8)	-0.3 (-4.1 to 3.5)
Std Err Est:	6.8	6.8

95% Confidence Intervals are shown in parentheses

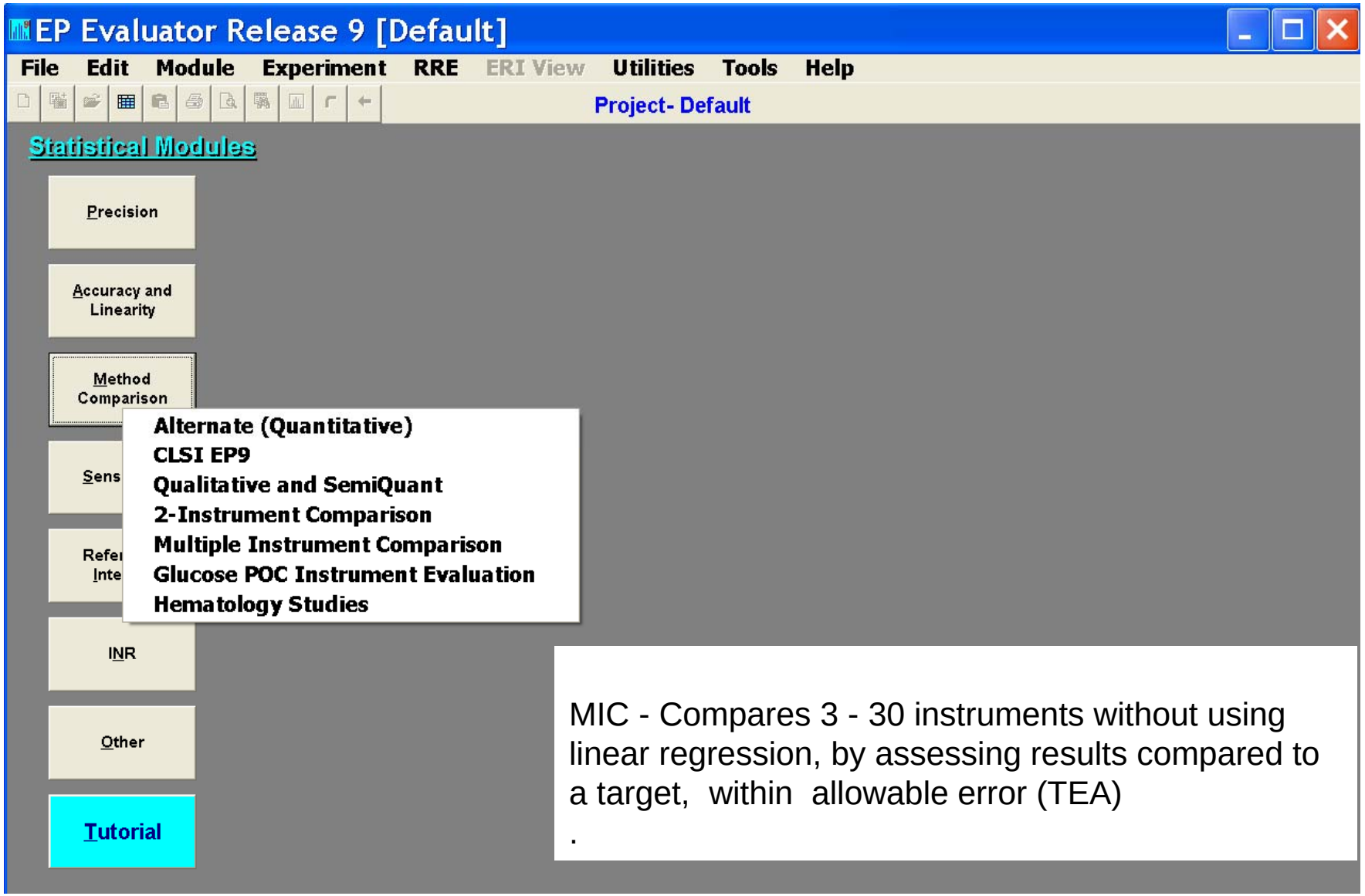
Medical Decision Point Analysis

Calculated by Deming Regression (R>=0.9)

X Method MDP	Y Method Pred. MDP	95% Conf. Limits Low	High
25	24.2	21.0	27.4
70	69.5	67.3	71.7
126	125.9	124.4	127.4
150	150.1	148.5	151.7
300	301.1	296.3	306.0

Supporting Statistics

Corr Coef (R):	0.9929	Std Dev Diffs:	6.7	Scatter Plot Bounds:	Allowable Error
Bias:	0.0	SubRange Bounds:	None		6.0 mg/dl or 10.0%
X Mean ± SD:	129.4 ± 56.1	Points (Plotted/Total):	82/82		
Y Mean ± SD:	129.3 ± 56.7	Outliers:	None		

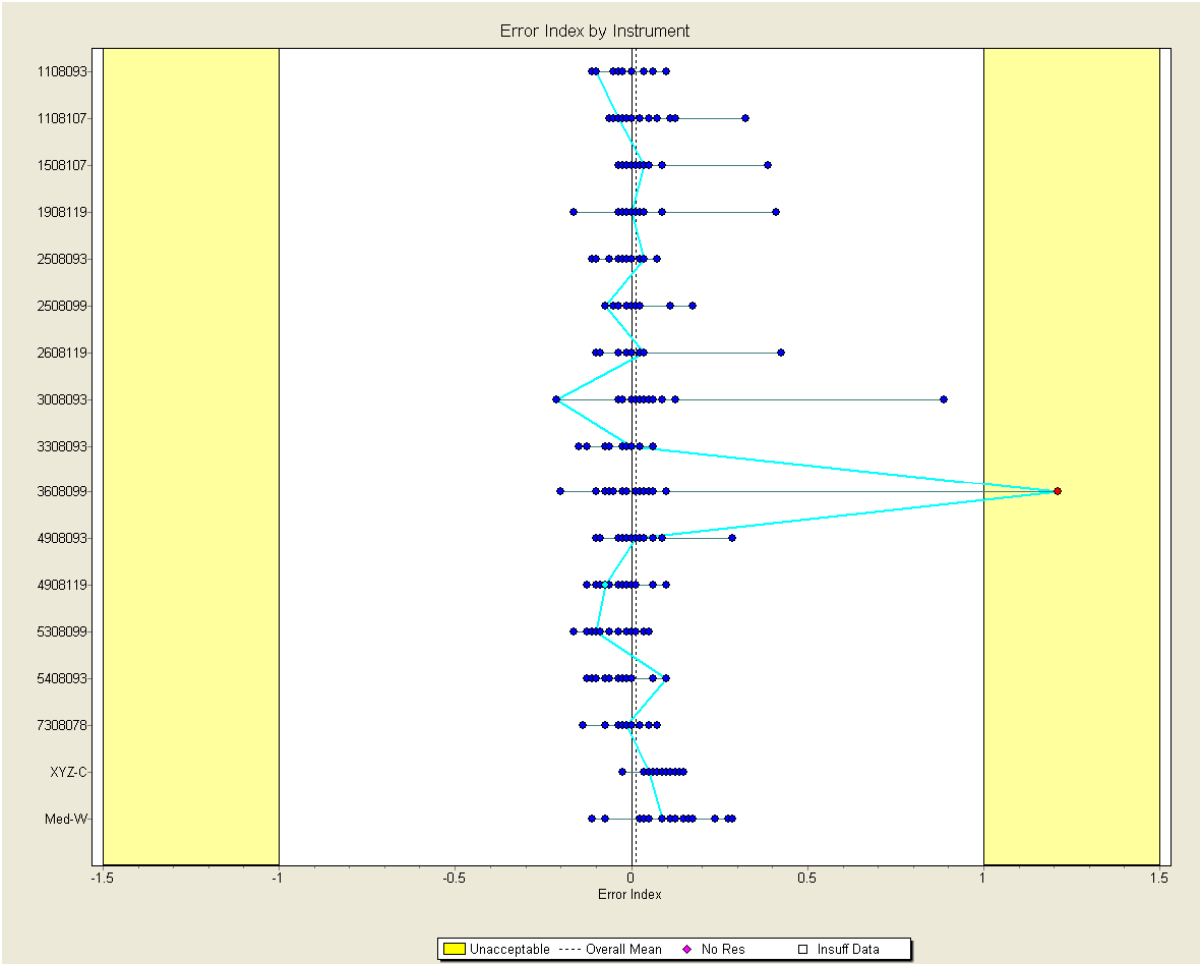


Method Comparison – MIC
Multiple Instrument Comparison

- One analyte
- 3 to 30 instruments* on a single page
- As few as 3 specimens
- Some missing results allowed
- Compare POC devices to Core lab, or each other
- Specimens pass if results within Allowable error
- See at a glance which devices may have issues

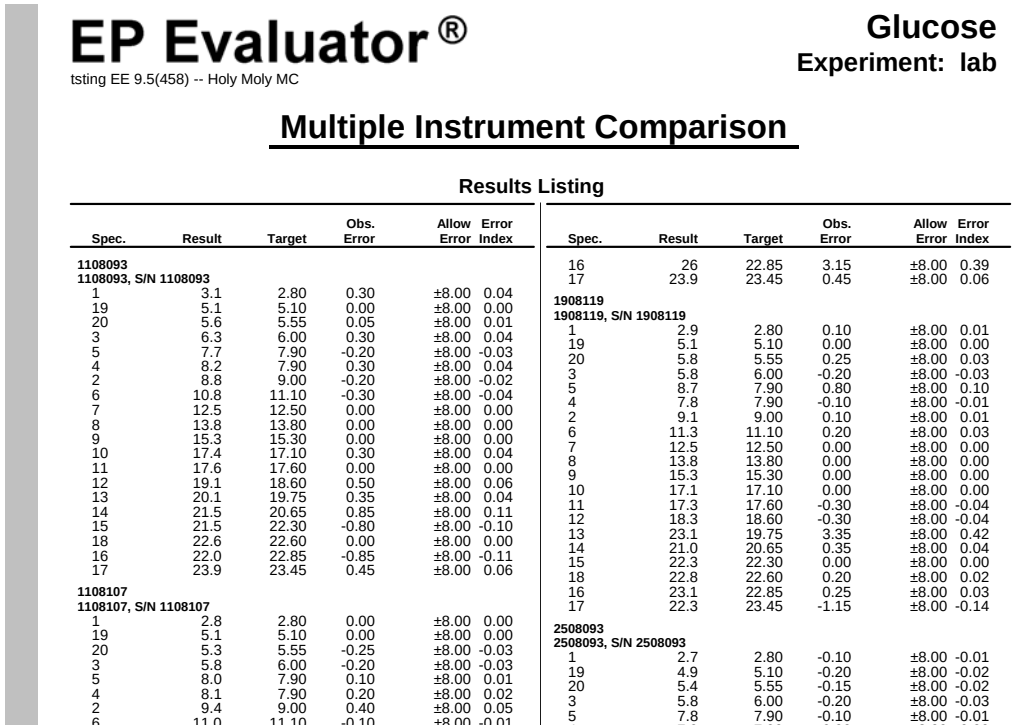
* TIP: You can compare instruments, methods, reagent lots, technologist performance, etc.

All instruments on 1 page



Results Listing

- By instrument
- Observed error to target
- Allowable error
- Error index
- F = Failed point



EP Evaluator®

tsting EE 9.5(458) -- Holy Moly MC

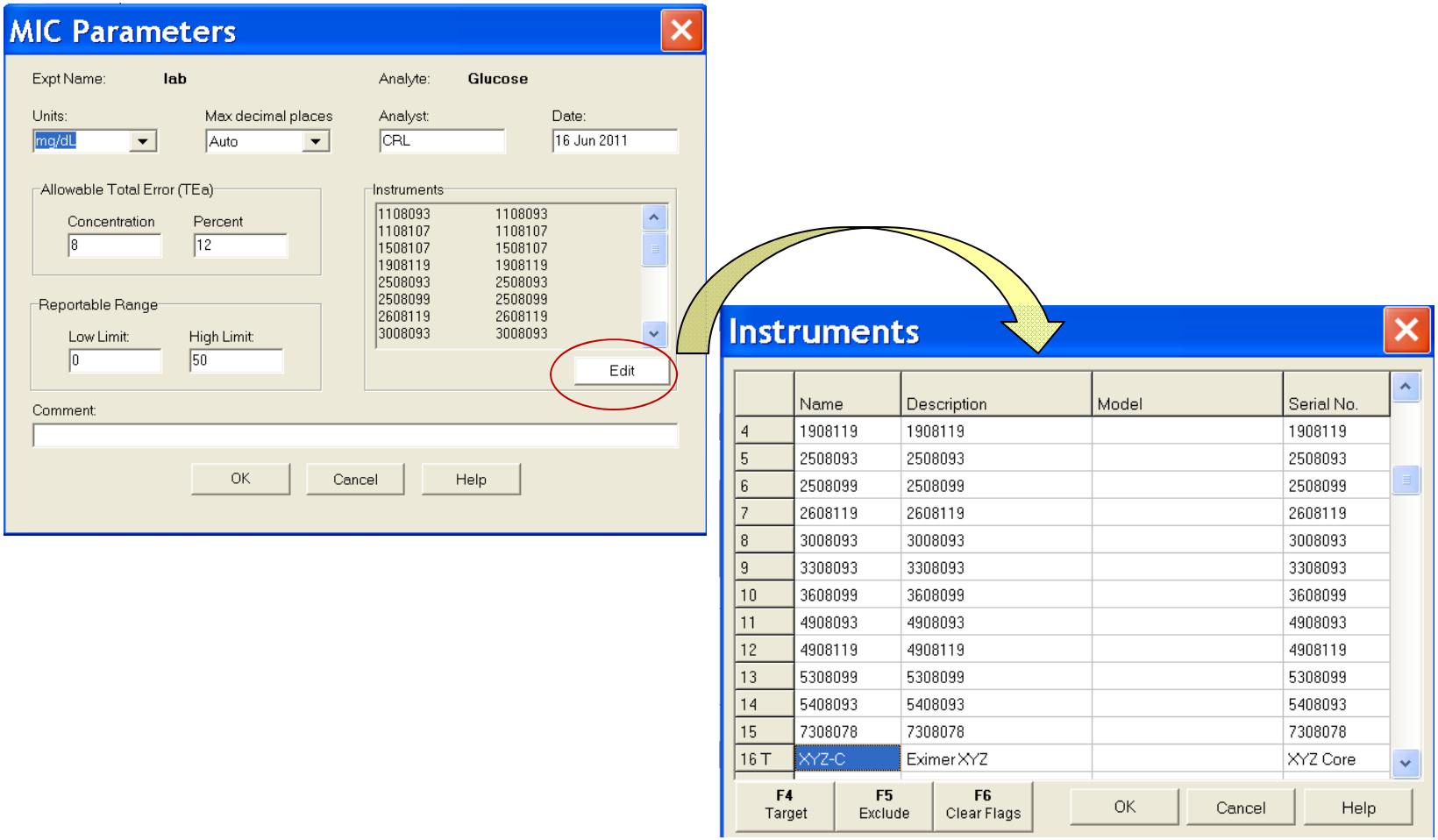
Glucose
Experiment: lab

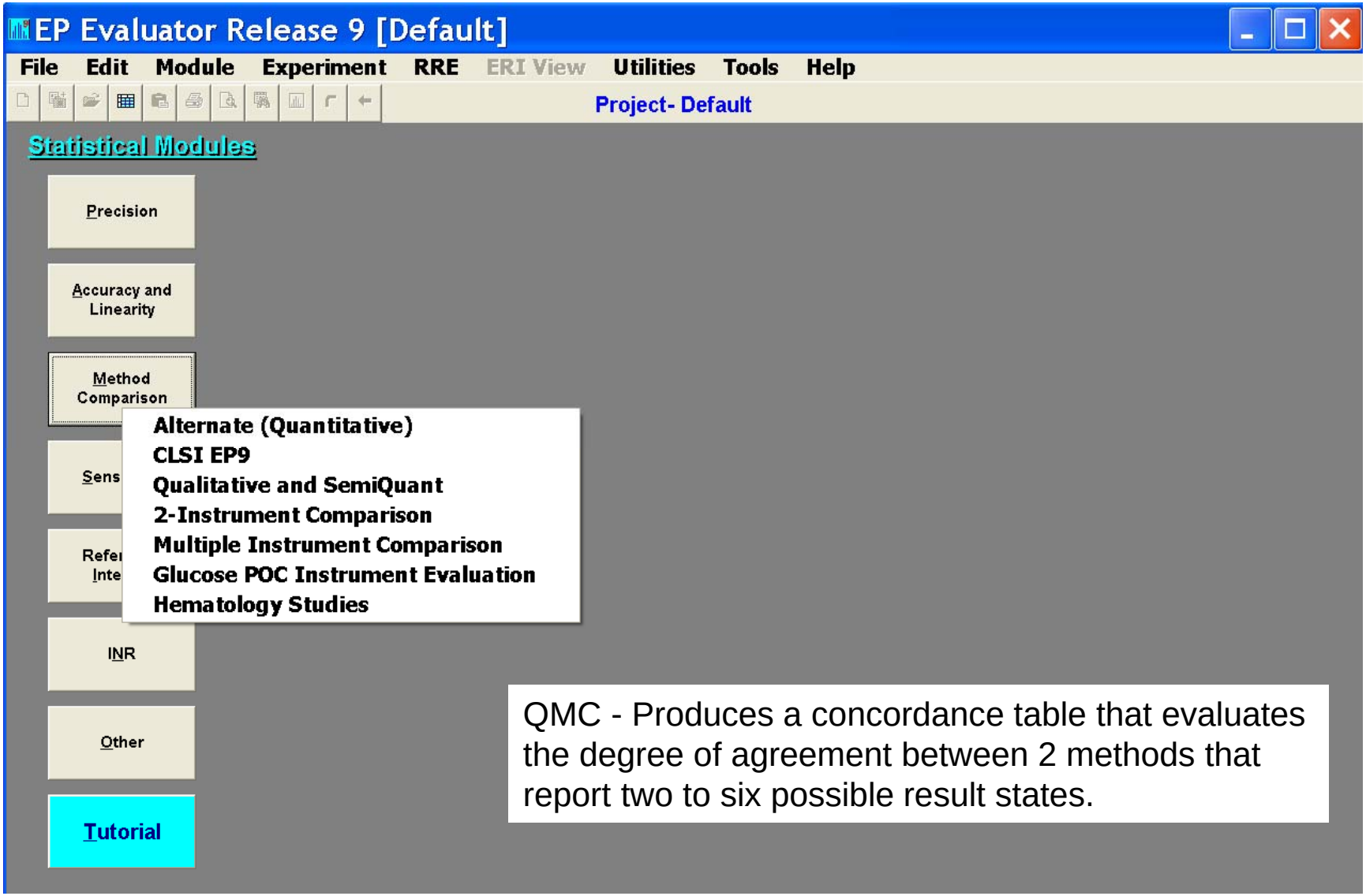
Multiple Instrument Comparison

Results Listing

Spec.	Result	Target	Obs. Error	Allow Error	Error Index
1108093					
1108093, S/N 1108093					
1	3.1	2.80	0.30	±8.00	0.04
19	5.1	5.10	0.00	±8.00	0.00
20	5.6	5.55	0.05	±8.00	0.01
3	6.3	6.00	0.30	±8.00	0.04
5	7.7	7.90	-0.20	±8.00	-0.03
4	8.2	7.90	0.30	±8.00	0.04
2	8.8	9.00	-0.20	±8.00	-0.02
6	10.8	11.10	-0.30	±8.00	-0.04
7	12.5	12.50	0.00	±8.00	0.00
8	13.8	13.80	0.00	±8.00	0.00
9	15.3	15.30	0.00	±8.00	0.00
10	17.4	17.10	0.30	±8.00	0.04
11	17.6	17.60	0.00	±8.00	0.00
12	19.1	18.60	0.50	±8.00	0.06
13	20.1	19.75	0.35	±8.00	0.04
14	21.5	20.65	0.85	±8.00	0.11
15	21.5	22.30	-0.80	±8.00	-0.10
18	22.6	22.60	0.00	±8.00	0.00
16	22.0	22.85	-0.85	±8.00	-0.11
17	23.9	23.45	0.45	±8.00	0.06
1108107					
1108107, S/N 1108107					
1	2.8	2.80	0.00	±8.00	0.00
19	5.1	5.10	0.00	±8.00	0.00
20	5.3	5.55	-0.25	±8.00	-0.03
3	5.8	6.00	-0.20	±8.00	-0.03
5	8.0	7.90	0.10	±8.00	0.01
4	8.1	7.90	0.20	±8.00	0.02
2	9.4	9.00	0.40	±8.00	0.05
6	11.0	11.10	-0.10	±8.00	-0.01
16	26	22.85	3.15	±8.00	0.39
17	23.9	23.45	0.45	±8.00	0.06
1908119					
1908119, S/N 1908119					
1	2.9	2.80	0.10	±8.00	0.01
19	5.1	5.10	0.00	±8.00	0.00
20	5.8	5.55	0.25	±8.00	0.03
3	5.8	6.00	-0.20	±8.00	-0.03
5	8.7	7.90	0.80	±8.00	0.10
4	7.8	7.90	-0.10	±8.00	-0.01
2	9.1	9.00	0.10	±8.00	0.01
6	11.3	11.10	0.20	±8.00	0.03
7	12.5	12.50	0.00	±8.00	0.00
8	13.8	13.80	0.00	±8.00	0.00
9	15.3	15.30	0.00	±8.00	0.00
10	17.1	17.10	0.00	±8.00	0.00
11	17.3	17.60	-0.30	±8.00	-0.04
12	18.3	18.60	-0.30	±8.00	-0.04
13	23.1	19.75	3.35	±8.00	0.42
14	21.0	20.65	0.35	±8.00	0.04
15	22.3	22.30	0.00	±8.00	0.00
18	22.8	22.60	0.20	±8.00	0.02
16	23.1	22.85	0.25	±8.00	0.03
17	22.3	23.45	-1.15	±8.00	-0.14
2508093					
2508093, S/N 2508093					
1	2.7	2.80	-0.10	±8.00	-0.01
19	4.9	5.10	-0.20	±8.00	-0.02
20	5.4	5.55	-0.15	±8.00	-0.02
3	5.8	6.00	-0.20	±8.00	-0.03
5	7.8	7.90	-0.10	±8.00	-0.01

Parameters Screen – Edit Instrument List



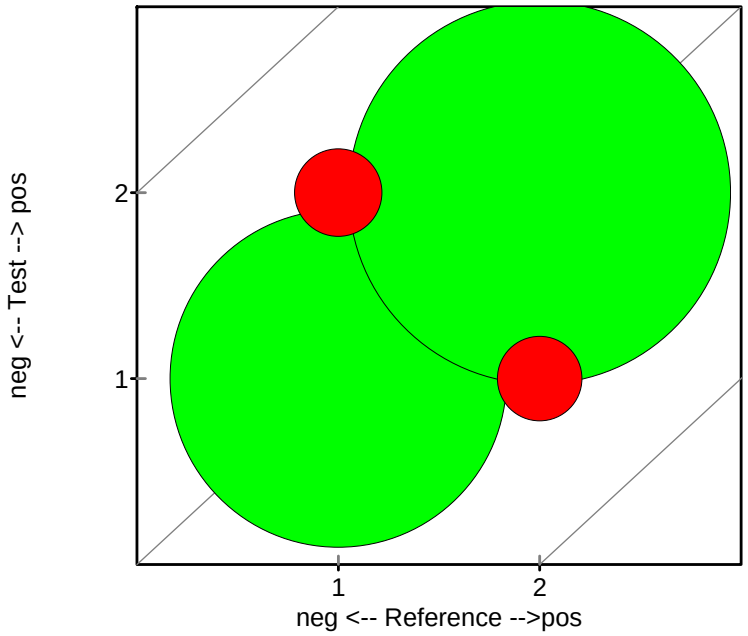


Method Comparison – Qualitative

- At least 20 specimens as 2 states
  - N or P is Default or
  - User defined labels
- Calculations
  - If One method is specified as a gold standard
    - specificity and sensitivity are calculated
  - If Neither method is a gold standard.
    - Only relationship of the two methods is calculated,
      - Degree of agreement - % positive, % negative
      - Probability of the differences being due to “chance”
      - Symmetry or “bias” of the disagreements

QMC – Qualitative Method Comparison

- Evaluates the degree of concordance between two qualitative or semi-quantitative methods.
- Includes CLSI EP12
- Colorful bubble chart – size of bubbles proportional to number of points
- Concordance or truth tables



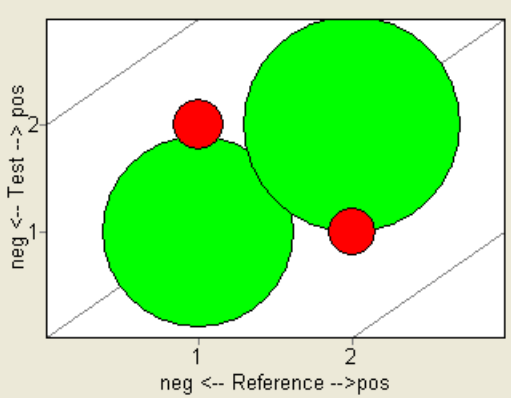
Statistical Summary

	Negative Reference	Positive Reference	Total
Negative Test	222	14	236
Positive Test	15	286	301
Total	237	300	537

Number excluded or missing: 0

Data Entry – Gold Standard

Not Gold Standard



	Reference	Test
1	Negative (N)	Negative (N)
2	Positive (P)	Positive (P)

Test	Reference		Total
	1 (neg)	2 (pos)	
1 (neg)	222	14	236
2 (pos)	15	285	300
Total	237	299	536

Number excluded or missing: 0

Agreement: 94.6% (92.3 to 96.2%)
Symmetry test PASSES (p = 0.853)
Kappa: 89.0% (85.1 to 92.9%)

Pos Agreement: 95.3%
Test < Ref: 14 (2.6%)

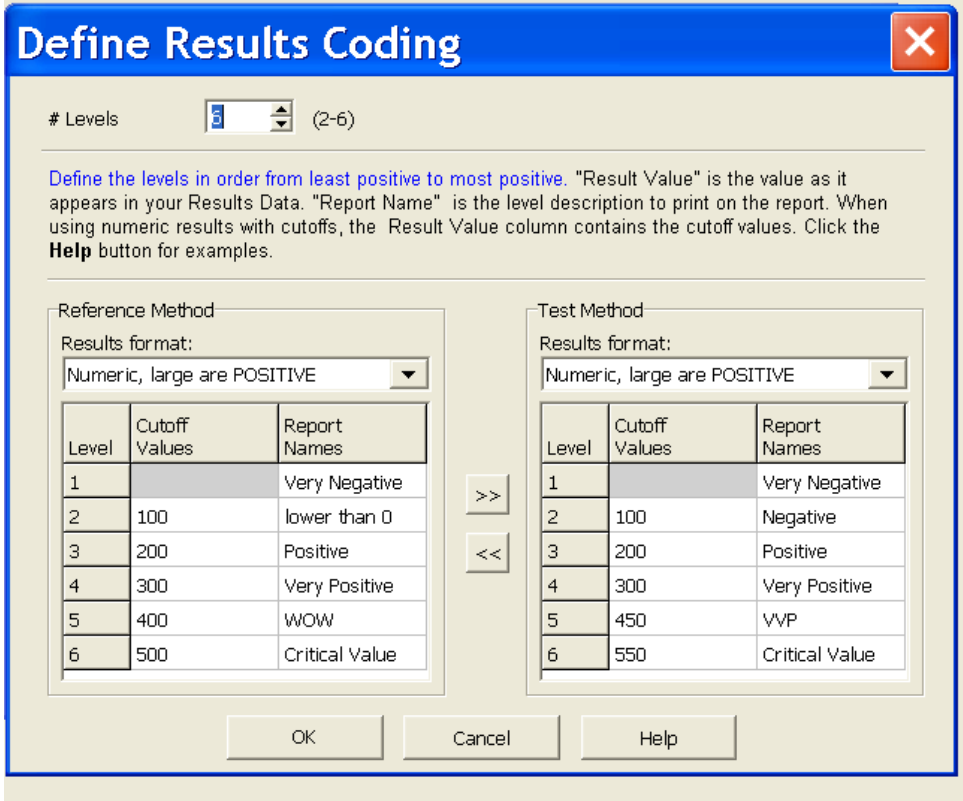
Neg Agreement: 93.7%
Test > Ref: 15 (2.8%)

Experimental Design
Semi-Quantitative

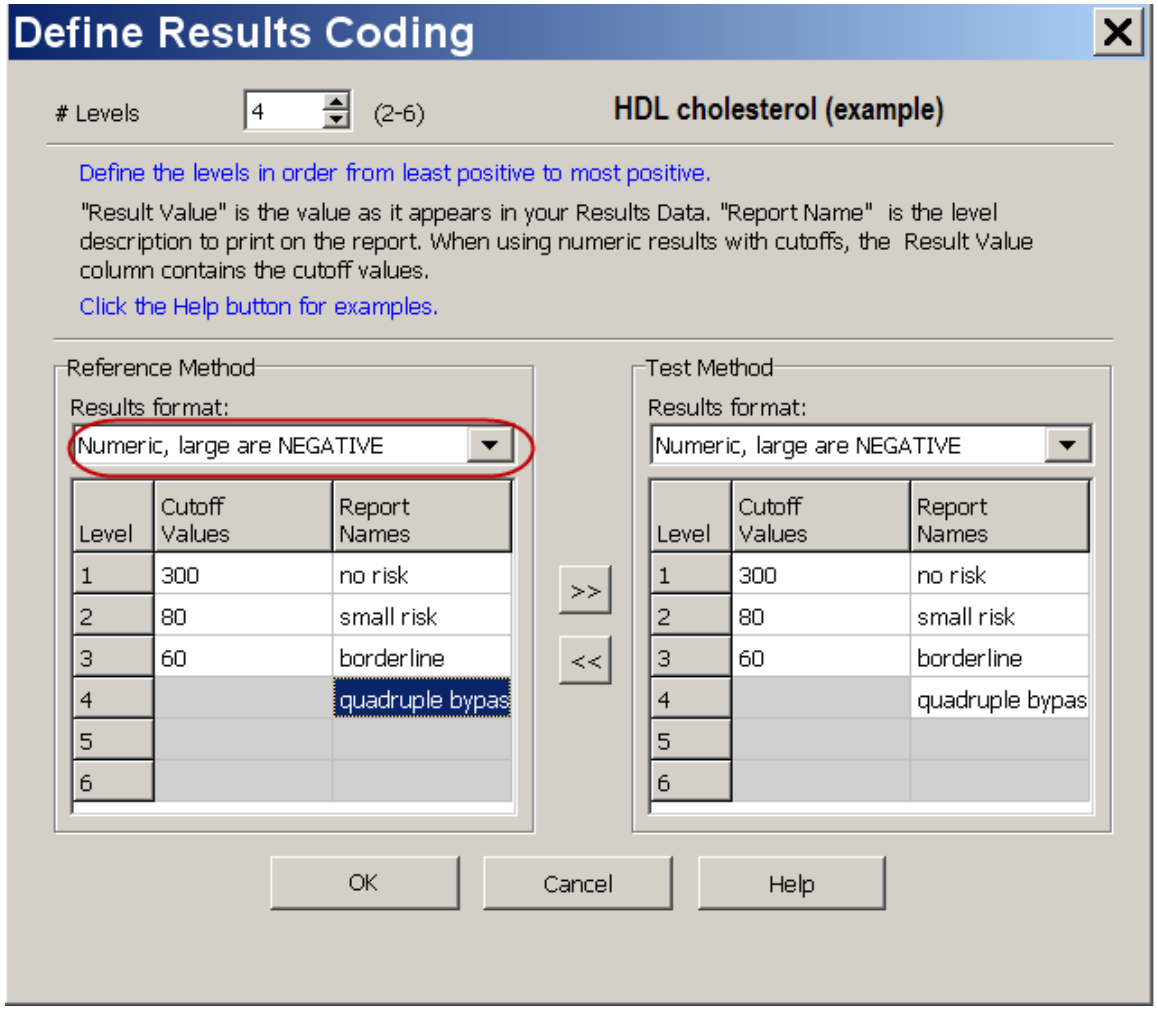
Custom Results Codes

- Up to 6 User defined ‘states”
  - Alphanumeric i.e., Equivocal, gray zone
  - Numeric cutoff values
- User defined Labels

	Reference	Test
1	<=100	<=100
2	101 to 200	101 to 200
3	201 to 300	201 to 300
4	301 to 400	301 to 450
5	401 to 500	451 to 550
6	>500	>550

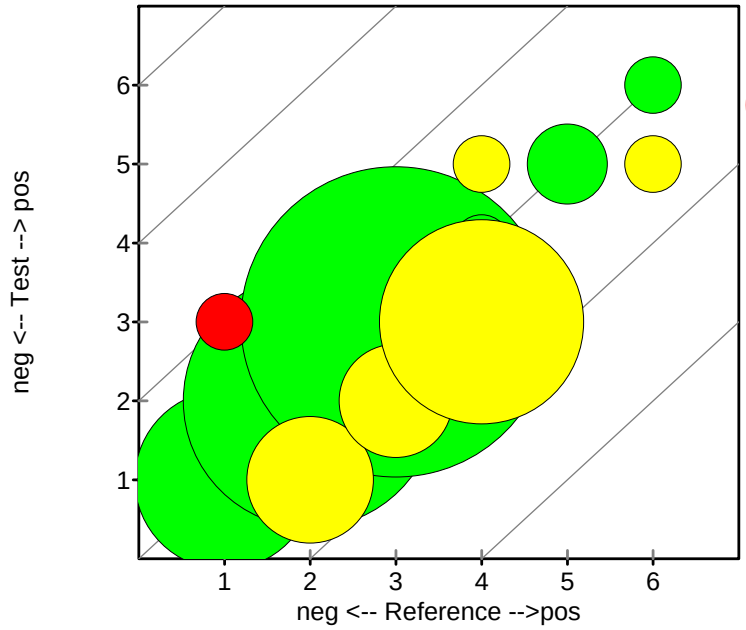


Example – large numbers are negative



Allow 1 step difference to accommodate “gray zones” *

Ref. Method: Chem Assay **Test Method: Analyzer**



Statistical Analysis
(Comparison of two Laboratory Methods)

Agreement	71.9% (61.8 to 80.2%)
Agreement within two	98.9% (93.9 to 99.8%)

95% confidence intervals calculated by the "Score" method.

McNemar Test for Symmetry:

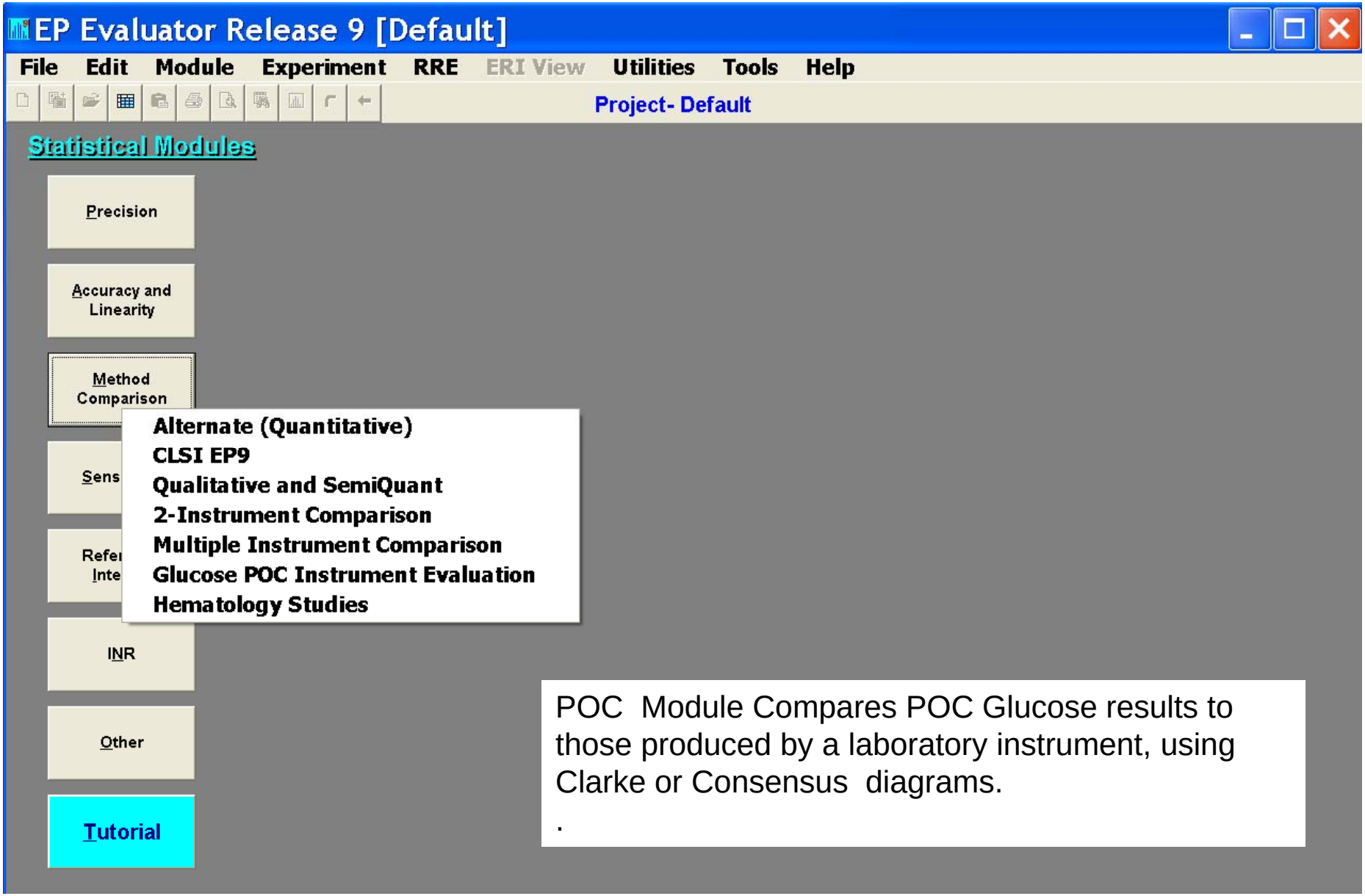
Test < Reference	23 (25.8%)
Test > Reference	2 (2.2%)
Symmetry test FAILS	p < 0.001 (ChiSq=17.640, 1 df)

A value of p<0.05 suggests that one method is consistently "larger".

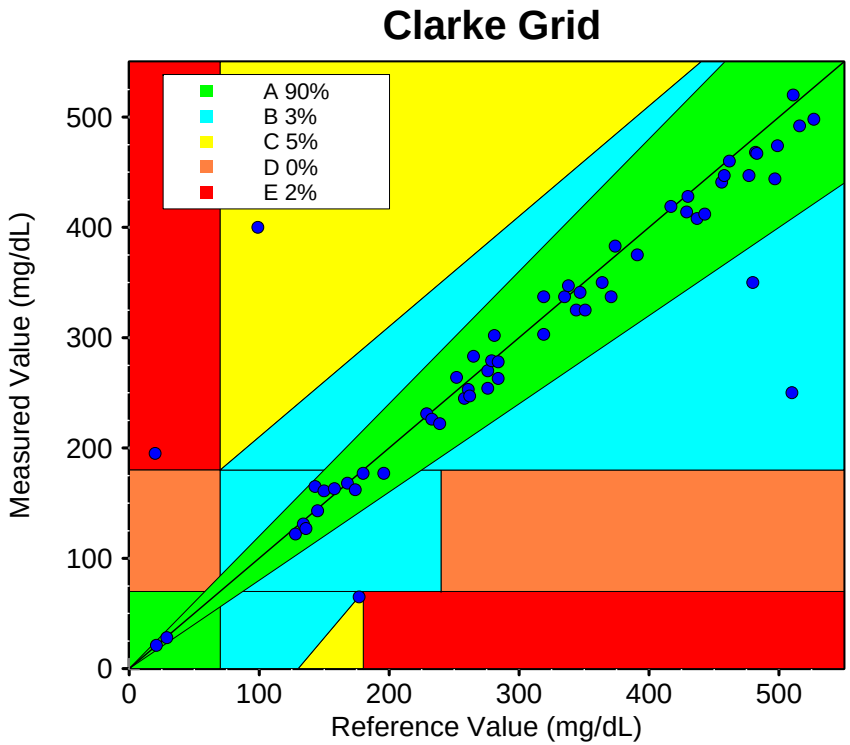
Cohen's Kappa 60.5% (47.4 to 73.6%)

Kappa is the proportion of agreement above what's expected by chance. Rule of thumb is Kappa>75% indicates "high" agreement. We would like to see VERY high (close to 100%) agreement.

* Enabled in preferences



POC Glucose
Zones of Clinical Impact



Region	Count	Percent	Cum Percent
A	54	90%	90%
B	2	3%	93%
C	***3***	***5%***	***98%***
D	0	0%	98%
E	***1***	***2%***	***100%***
Excluded	0		
Out/Bnds	0		
Total	60		

Report Interpretation Guide

Glucose POC Instrument Evaluation

Report Interpretation Guide

The Error Grid Analysis is a very specific form of method comparison that compares two Glucose methods using Clarke and Consensus diagrams.

Experimental results for this module are similar to those you would use in Alternate Method Comparison. One method is a reference method, presumed highly accurate. The second is a test method to be evaluated. Collect Glucose results for 20 or more specimens, measuring each specimen with each of the two methods. A larger number of specimens (50-100) is desirable. Units for both methods must be the same -- either mg/dL or mmol/L. Also results must be within the range 0-550 mg/dL or 0-30 mmol/L.

Key Statistics

The report shows a scatter plot, with the reference method on the X-axis and the test method on the Y-axis. The plot area is divided into five zones, A-E, which reflect the medical risk of the error:

Zone A: No effect on clinical action

Zone B: Altered clinical action, but little or no effect on clinical outcome

Zone C: Altered action, likely to affect the outcome

Zone D: Significant medical risk

Zone E: Could have dangerous consequences.

The zones are defined based on surveys of medical practitioners. The only difference between the Clarke Diagram and the Consensus Diagram is in how the zones are defined.

Preliminary Report

The word PRELIMINARY printed diagonally across the report indicates that the data is incomplete, and the report is not acceptable as a final report. Some or all of the statistics may be missing.

The Glucose-POC report is preliminary if there are less than 20 unexcluded data points.

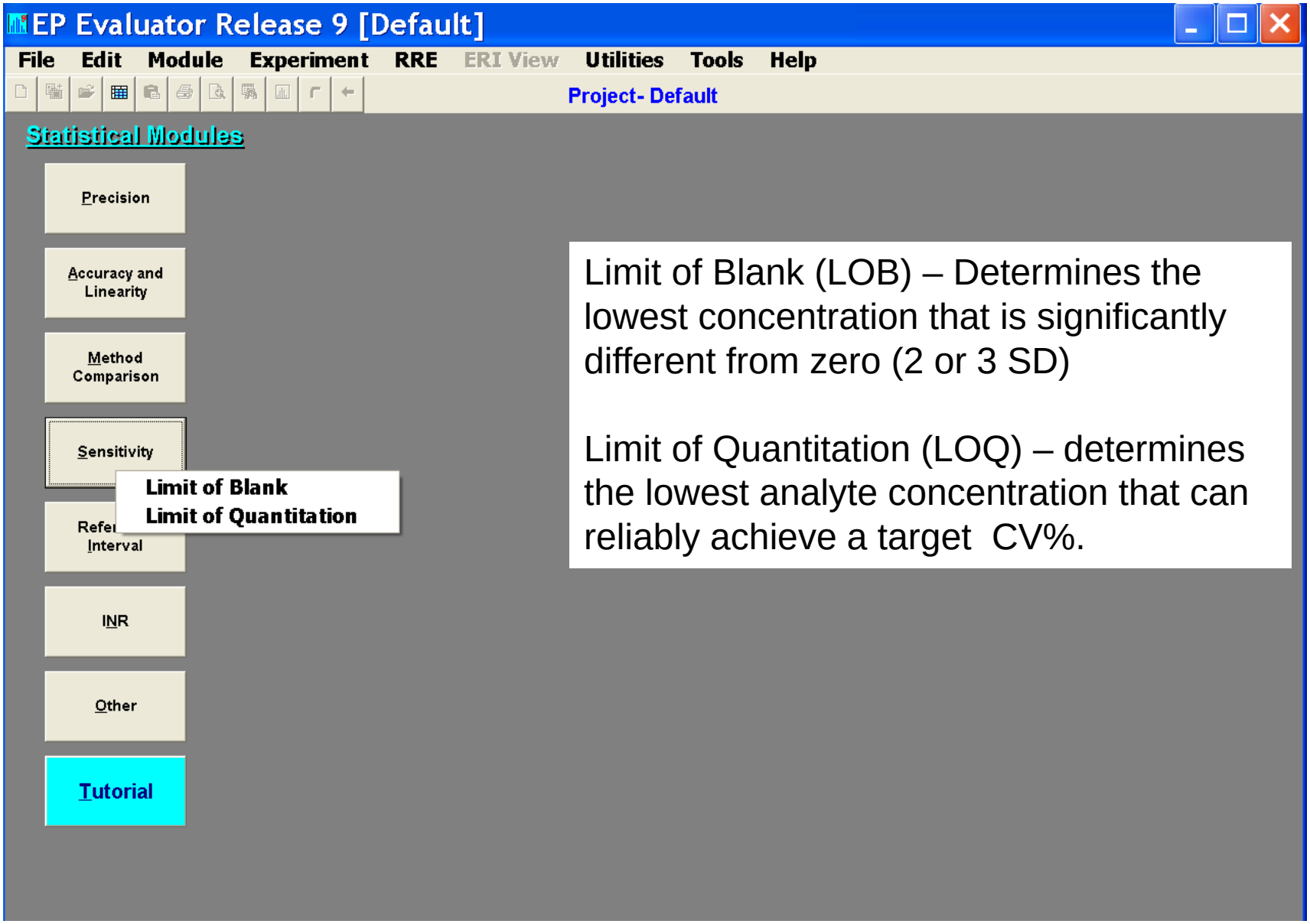
References

1. Parkes JL, Slatin SL, Pardo S, Ginsberg BH. *A New Consensus Error Grid to Evaluate the Clinical Significance of Inaccuracies in the Measurement of Blood Glucose.* Diabetes Care 23:1143-1148, 2000.

2. Clarke WL, Cox D, Gonder-Frederick LA, Carter W, Pohl SL. *Evaluating clinical accuracy of systems for self-monitoring of blood glucose.* Diabetes Care. 10:622-628, 1987

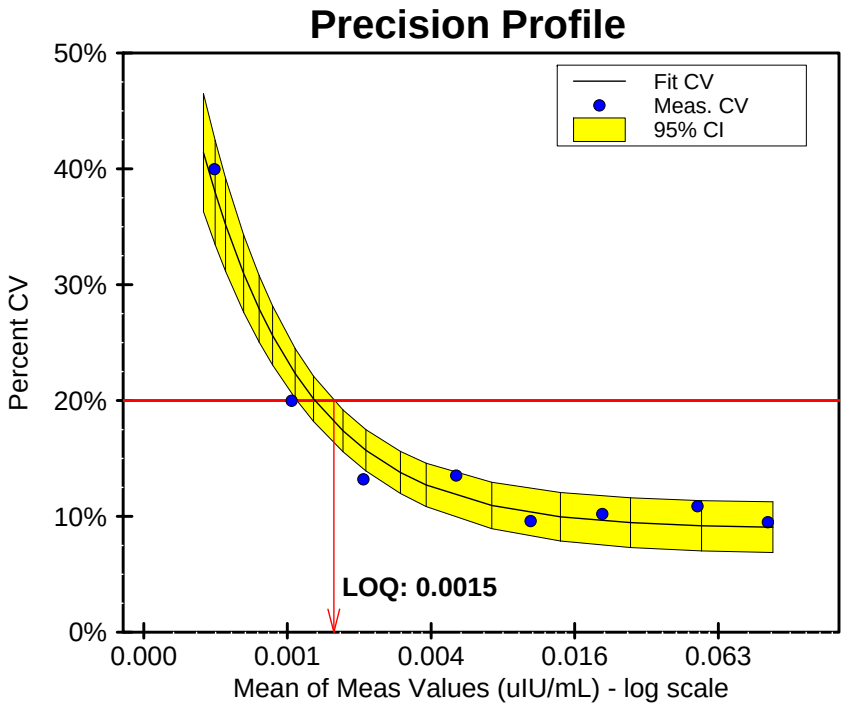
3. Cox DJ, Richards FE, Gonder-Frederick LA, Julian DM, Carter WR, Clarke WL. *Clarification of error-grid analysis.* Diabetes Care 12:235-236, 1989

4. Cox DJ, Gonder-Frederick LA, Kovatchev BP, Julian DM, Clarke WL. *Understanding error grid analysis.* Diabetes Care 20:911-912, 1997


EP Evaluator Release 9 [Default]
File
Edit
Module
Experiment
RRE
ERI View
Utilities
Tools
Help
Project- Default
Statistical Modules
Precision
Accuracy and Linearity
Method Comparison
Sensitivity
Limit of Blank
Limit of Quantitation
Refer Interval
INR
Other
Tutorial
Limit of Blank (LOB) – Determines the lowest concentration that is significantly different from zero (2 or 3 SD)
Limit of Quantitation (LOQ) – determines the lowest analyte concentration that can reliably achieve a target CV%.

LOQ Report Excerpt

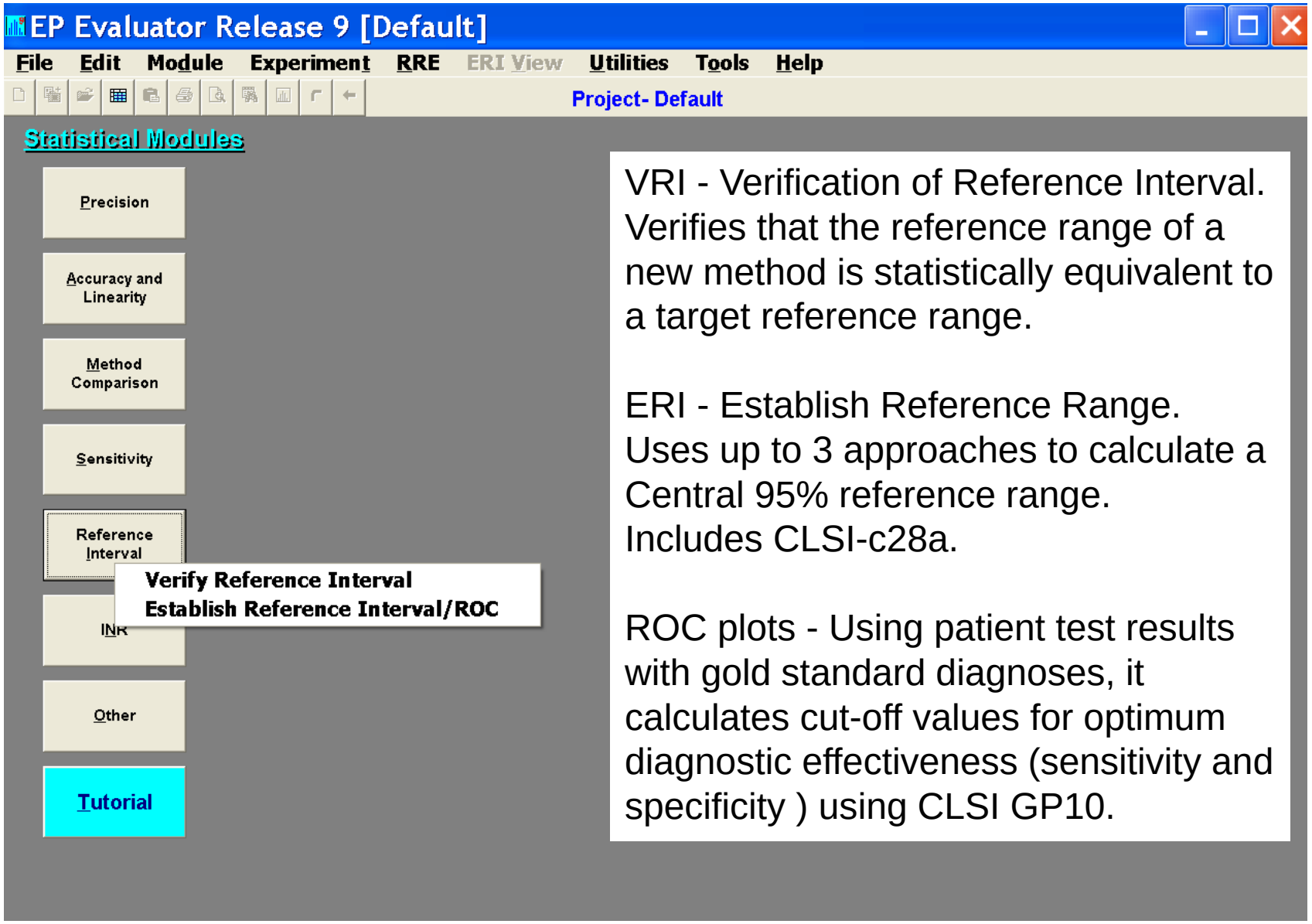
Sensitivity-Limit of Quantitation



Evaluation of Results

TSH was analyzed by ImmunoAssayer to determine the LOQ (lowest concentration for which CV is less than a target of 20%).

Specimens with mean measured concentration ranging from 0.00048 to 0.10078 uIU/mL were assayed. A curve was fit to estimate the relationship between Mean and CV. Based on the fitted model, the LOQ is 0.0015 uIU/mL. This is the point where the upper 95% confidence interval for the curve has a CV of 20%.



VRI - Verification of Reference Interval. Verifies that the reference range of a new method is statistically equivalent to a target reference range.

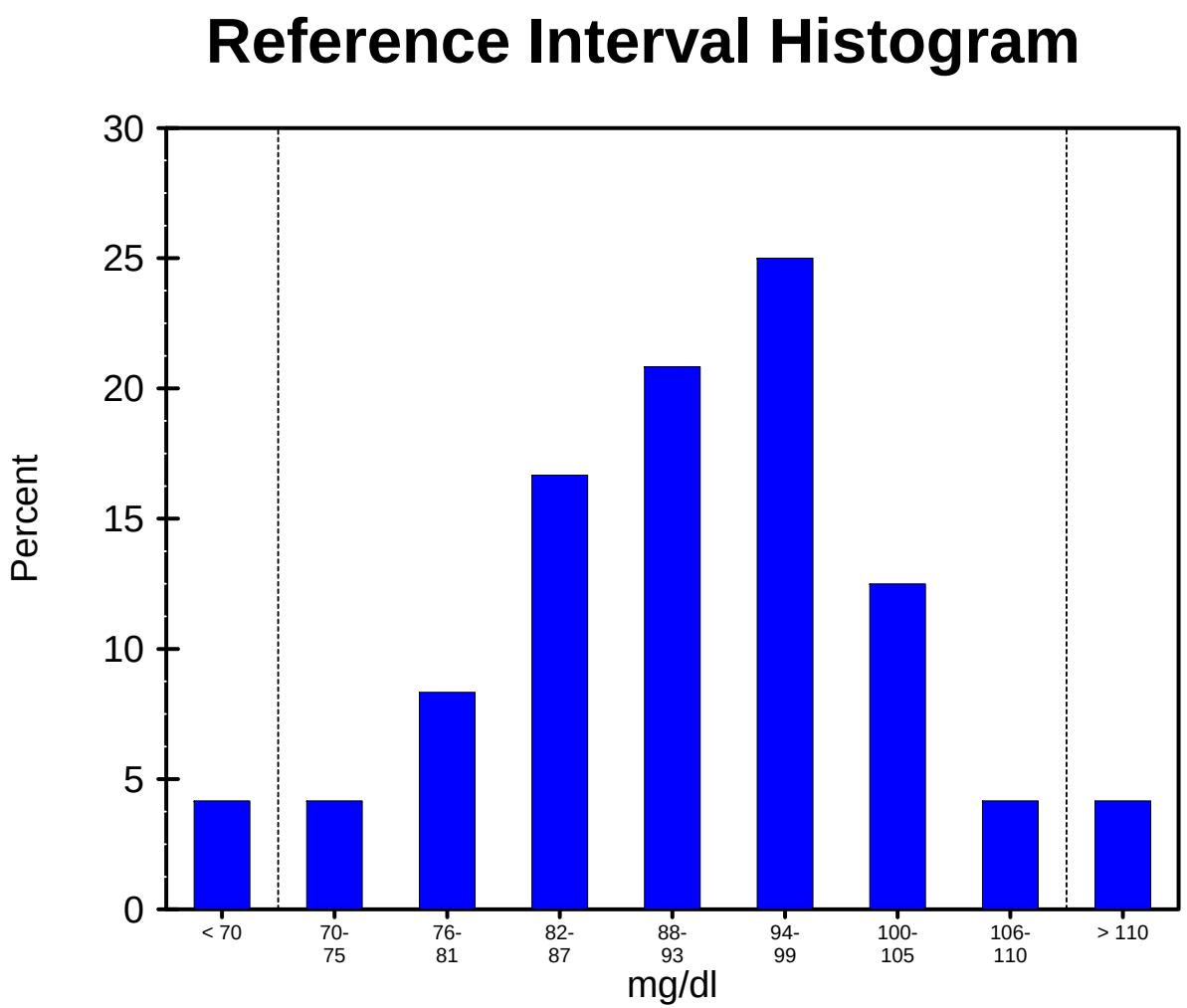
ERI - Establish Reference Range. Uses up to 3 approaches to calculate a Central 95% reference range. Includes CLSI-c28a.

ROC plots - Using patient test results with gold standard diagnoses, it calculates cut-off values for optimum diagnostic effectiveness (sensitivity and specificity) using CLSI GP10.

Reference intervals

- **Verify Ref interval – VRI**
  - As few as 20 points
  - Verify proposed ref interval is statistically same as old
  - Up to 10% of points can be outside
- **Establish Ref interval - ERI**
  - CLSI EP-28-a
  - Data is entered in a special way
  - Calculate partitions gender, smokers, age, etc.
  - Data is evaluated. upper and lower limits are proposed.
    - Parametric – data fits a bell shaped (normal) distribution
    - Non-parametric – top and bottom 2.5% are excluded.
    - Transformed to parametric : data undergoes an exponential transformation to convert the data to the Gaussian model by evaluating a probability plot of result vs. SDI (std dev index)

Verify Reference intervals



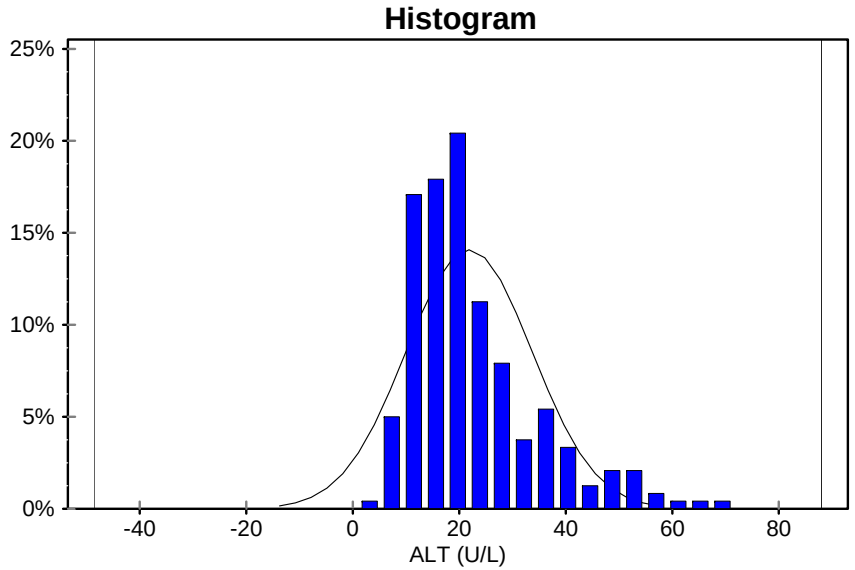
Establish Reference Intervals - ERI

Reference Interval Estimation: Combined

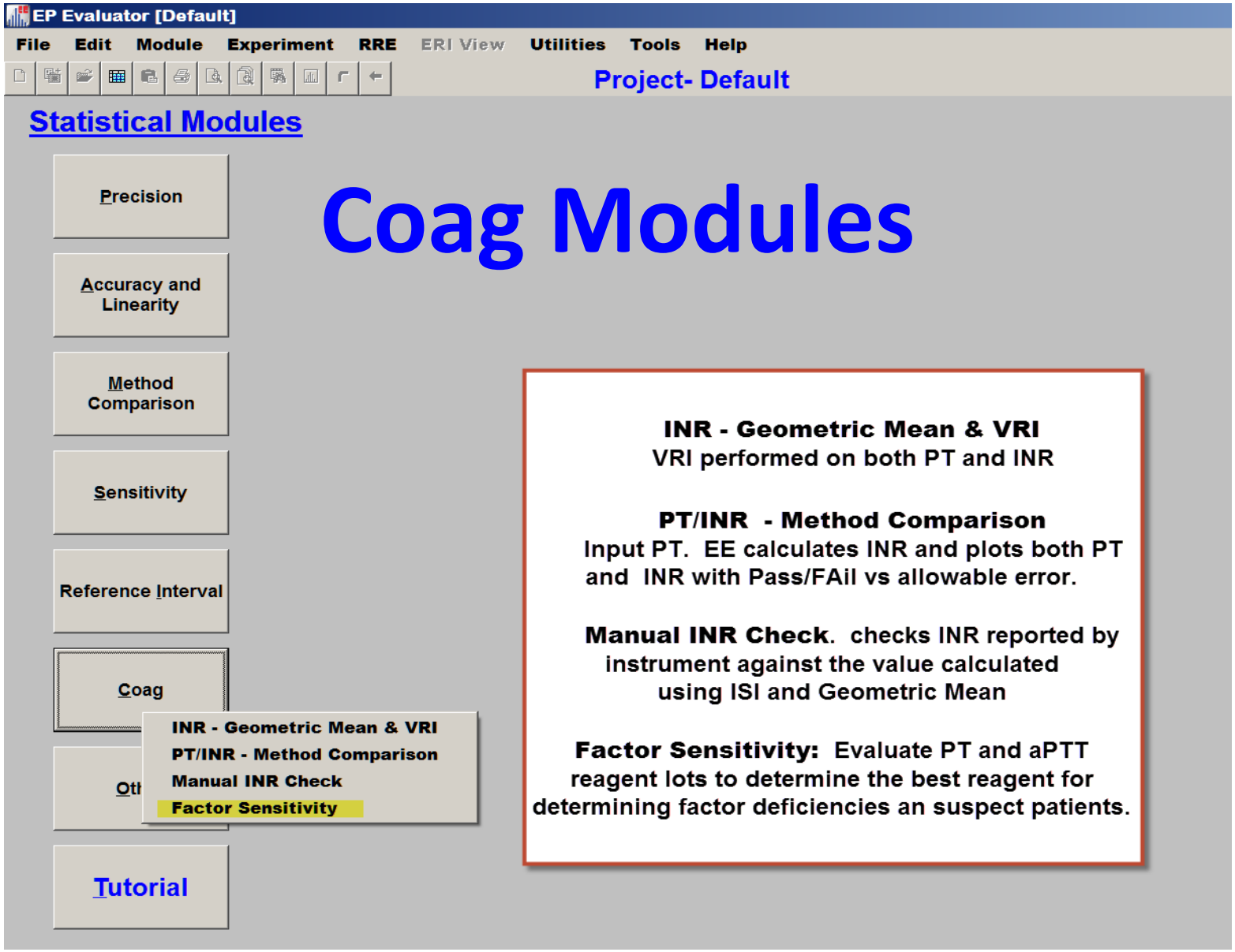
Central 95% Interval
(N = 240)

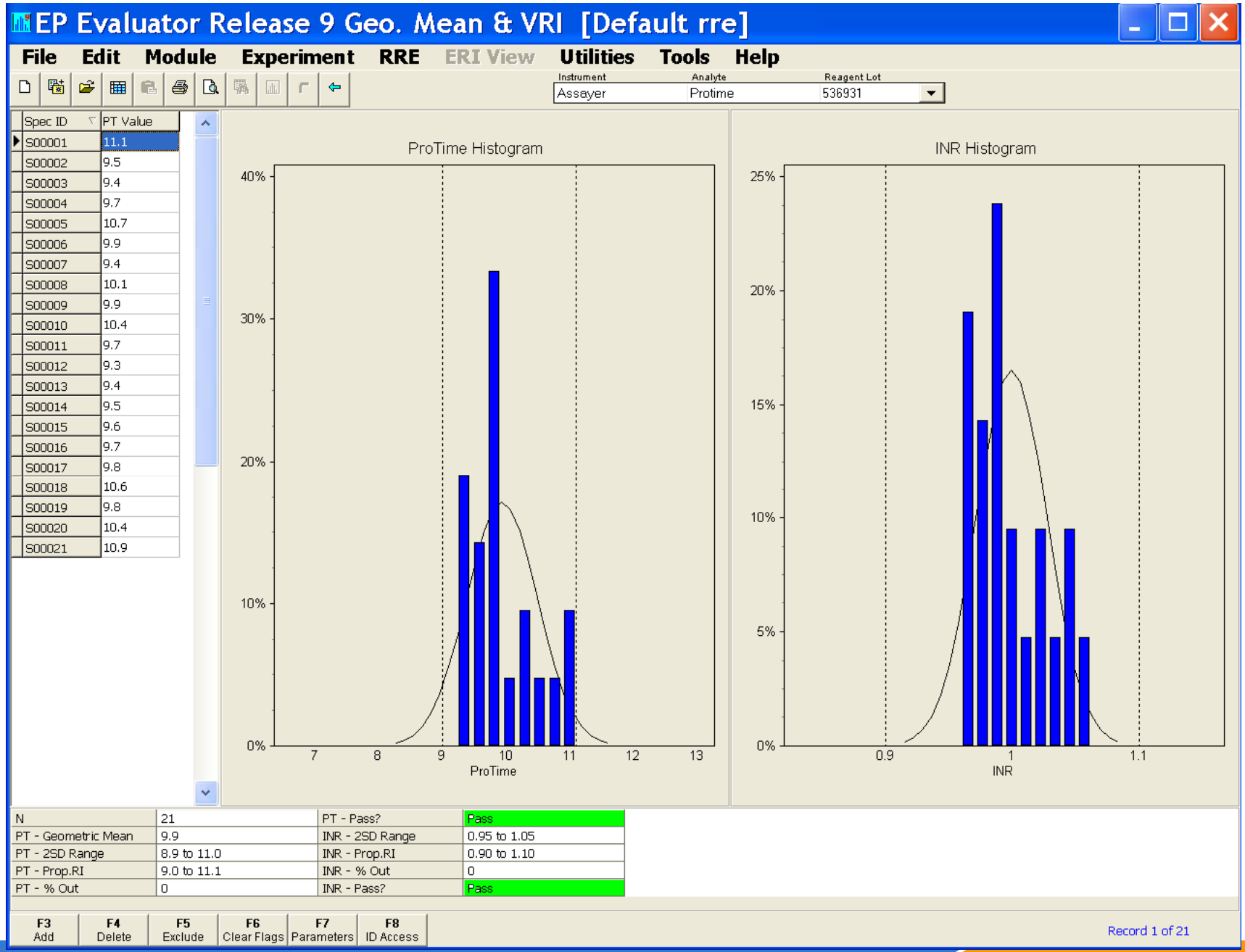
	Lower		*Upper*		*Confidence*
	Value	*90% CI*	*Value*	*90% CI*	*Ratio*
Nonparametric (CLSI C28-A)	**8**	**6 to 9**	**54**	**49 to 65**	**0.21**
Alternatives:					
Transformed Parametric	8	7 to 8	52	48 to 57	0.12
Parametric	-1	-3 to 1	46	44 to 48	0.09

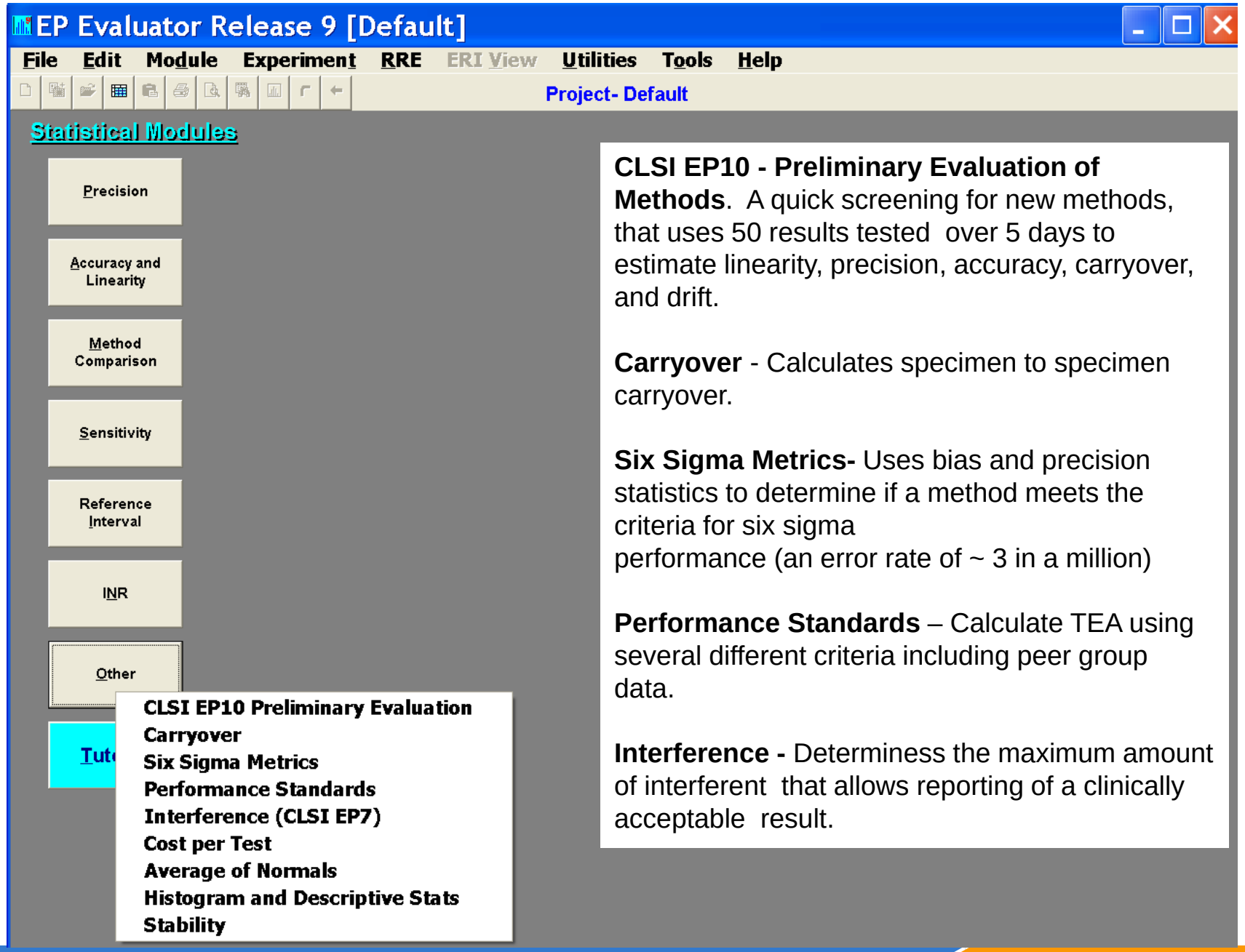
Confidence Limits for Nonparametric CLSI C-28A method computed from C28-A Table 8.



Selection Criteria:	
Bounds	None
Filter	None
Statistics:	
Mean	22.5 U/L
SD	11.9
Median	19.5
Range	5 to 69
N	240 of 240
Distinct values	50
Zeroes	0
Central 95% Index	6.0 to 235.0
Analyst	mkf
Expt. Date	13 Apr 2000




EP Evaluator Release 9 Geo. Mean & VRI [Default rre]
File Edit Module Experiment RRE ERI View Utilities Tools Help
Instrument Analyte Reagent Lot
Assayer Protime 536931
Spec ID PT Value
S00001 11.1
S00002 9.5
S00003 9.4
S00004 9.7
S00005 10.7
S00006 9.9
S00007 9.4
S00008 10.1
S00009 9.9
S00010 10.4
S00011 9.7
S00012 9.3
S00013 9.4
S00014 9.5
S00015 9.6
S00016 9.7
S00017 9.8
S00018 10.6
S00019 9.8
S00020 10.4
S00021 10.9
ProTime Histogram
40%
30%
20%
10%
0%
7 8 9 10 11 12 13
ProTime
INR Histogram
25%
20%
15%
10%
5%
0%
0.9 1 1.1
INR
N 21 PT - Pass? Pass
PT - Geometric Mean 9.9 INR - 2SD Range 0.95 to 1.05
PT - 2SD Range 8.9 to 11.0 INR - Prop.RI 0.90 to 1.10
PT - Prop.RI 9.0 to 11.1 INR - % Out 0
PT - % Out 0 INR - Pass? Pass
F3 Add
F4 Delete
F5 Exclude
F6 Clear Flags
F7 Parameters
F8 ID Access
Record 1 of 21



CLSI EP10 - Preliminary Evaluation of Methods. A quick screening for new methods, that uses 50 results tested over 5 days to estimate linearity, precision, accuracy, carryover, and drift.

Carryover - Calculates specimen to specimen carryover.

Six Sigma Metrics- Uses bias and precision statistics to determine if a method meets the criteria for six sigma performance (an error rate of ~ 3 in a million)

Performance Standards – Calculate TEA using several different criteria including peer group data.

Interference - Determiness the maximum amount of interferent that allows reporting of a clinically acceptable result.

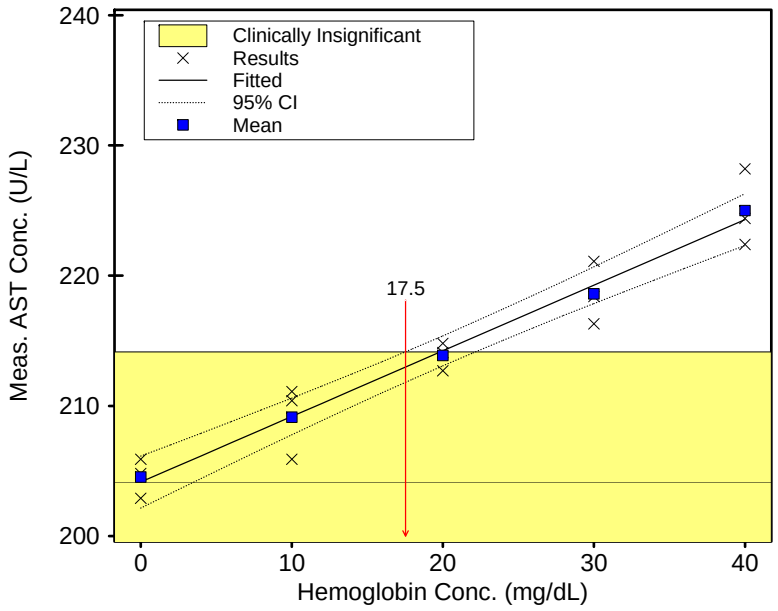
EP Evaluator®

Prepared for: chemistry Dept -- Holy Name hospital
By: Clinical Laboratory -- Our Lady of Perpetual Motion

AST
Instrument: Analyzer
Sample: High
Interferent: Hemoglobin

Interference Dose Response

Dose Response Curve



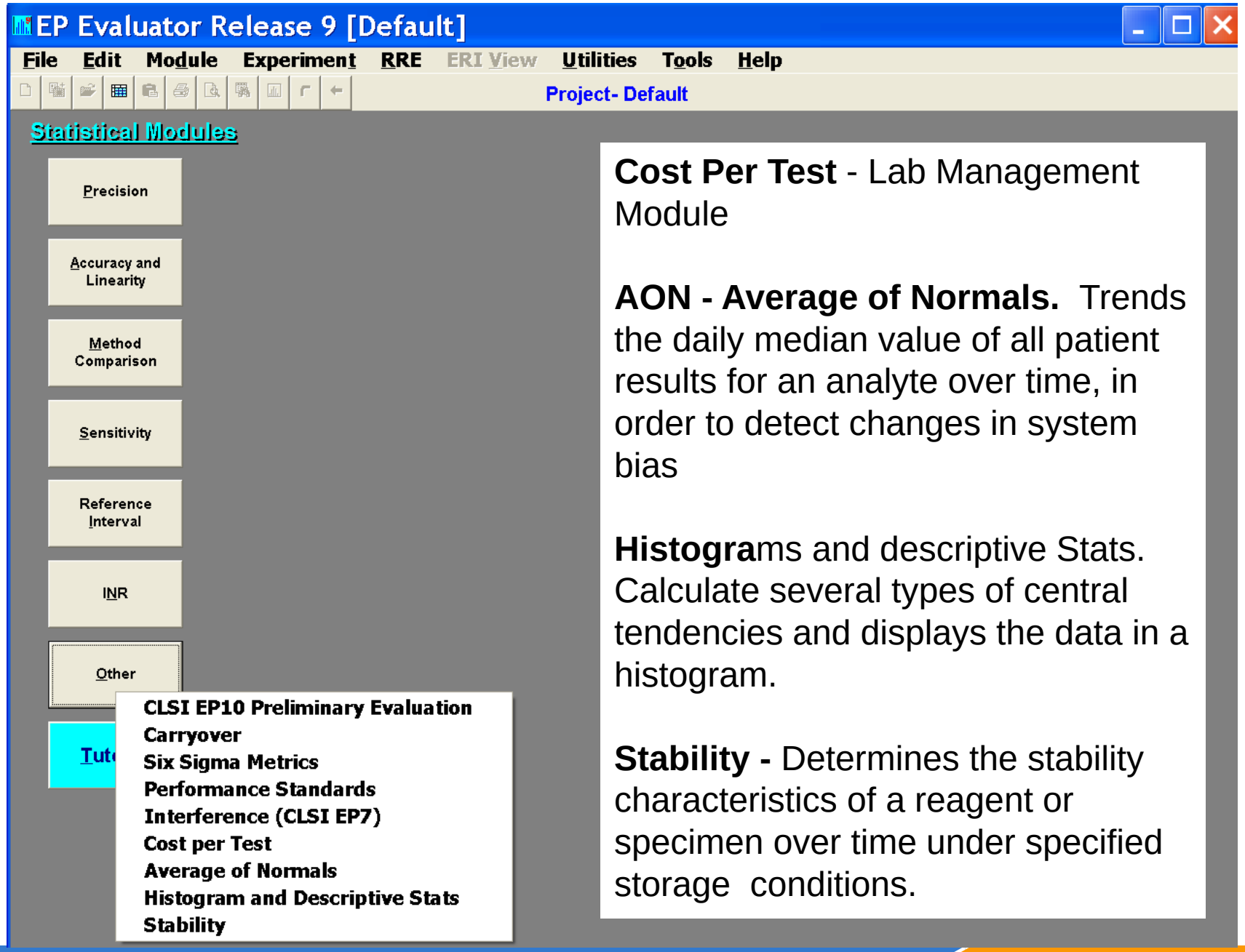
Evaluation of Results

AST at a concentration of 204.53 U/L was evaluated for interference on Analyzer according to CLSI document EP7-A. Bias exceeding 10 U/L is considered clinically significant.

The interference of Hemoglobin up to 40 mg/dL was tested. Over this range, the bias can be approximated from the relationship

Fitted Y = 204.1 + (0.504) X

with a standard error of 2.06 mg/dL. Bias at interference level X is the difference between the Fitted Value at X and the Fitted Value at zero. At Hemoglobin concentrations less than 17.5 mg/dL, the upper 95% confidence limit for predicted bias is not clinically significant.



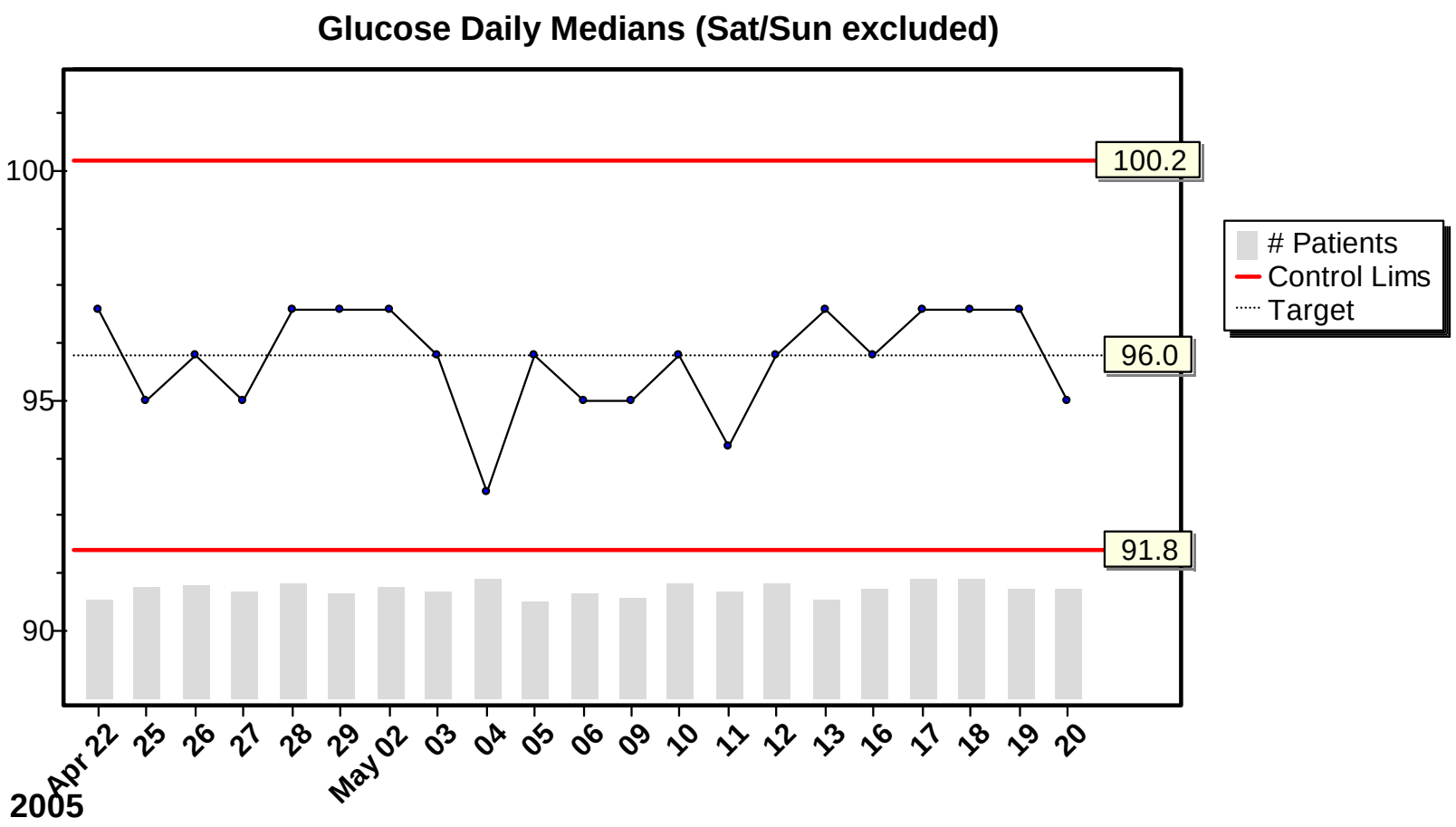
Cost Per Test - Lab Management Module

AON - Average of Normals. Trends the daily median value of all patient results for an analyte over time, in order to detect changes in system bias

Histograms and descriptive Stats. Calculate several types of central tendencies and displays the data in a histogram.

Stability - Determines the stability characteristics of a reagent or specimen over time under specified storage conditions.

Average of Normals



Questions and Discussion white board

Contact us

- North America Telephone Support (802)-658-1955
  - Northamerica-support@datainnovations.com
- Europe telephone support +32 2 332 24 13
  - Europe-support@datainnovations.com
- Asia Telephone Support 852-2398-3182
  - asia-support@datainnovations.com

datainnovations.com

Thank You!

DATA INNOVATIONS
Simple Ideas, Better Solutions