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# EP Evaluator Overview

Overview and Getting Started with New experiments

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# 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

# EE Documentation

- 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.

**DATA INNOVATIONS**  
Simple Ideas, Better Solutions

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Instrument Manager™ Overview  
Laboratory Production Manager  
JResultNet®  
**EP Evaluator®**  
Allowable Total Error Table  
Reference Interval Tables  
Web Activation  
French Website (en Français)

Home » Products

## EP Evaluator

QUALITY ASSURANCE... SIMPLIFIED

**Release 11** - The Standard for Quality Assurance software designed to evaluate and measure the clinical laboratory performance and provide clear, concise, 'inspector-ready' reports to meet all CLIA '88, CAP, JCAHO and COFRAC requirements. EP Evaluator® was designed by a board-certified clinical chemist specifically to meet the needs of the clinical laboratory and is used by more laboratories and more invitro diagnostics (IVD) companies than any other software of its kind.

Additional Information

Brochure Buy Software Trial Software  
Sample Reports Version History **Documentation**

Version Comparisons	Regulatory Requirements				EP Evaluator® Versions			
	CLIA '88	CAP	TJC	COFRAC	EE CLIA	EE COFRAC	EE Stnd	EE Pro
<b>Accuracy and Linearity</b>								
Clinical Linearity, Calibration Verification and Reportable Range	✓	✓	✓	○	●		●	●
Simple Accuracy ?	✓	✓			●		●	●
CLSI EP6 Linearity ?						●	●	●
<b>Trueness</b> ?						●	●	●
<b>Method Comparison</b>								
Alternate (Routine Quantitative) ?	✓	✓	✓	✓	●	●	●	●
CLSI EP9 Method Comparison ?							●	●
Two Instrument Comparison ?		✓	✓	✓	●	●	●	●

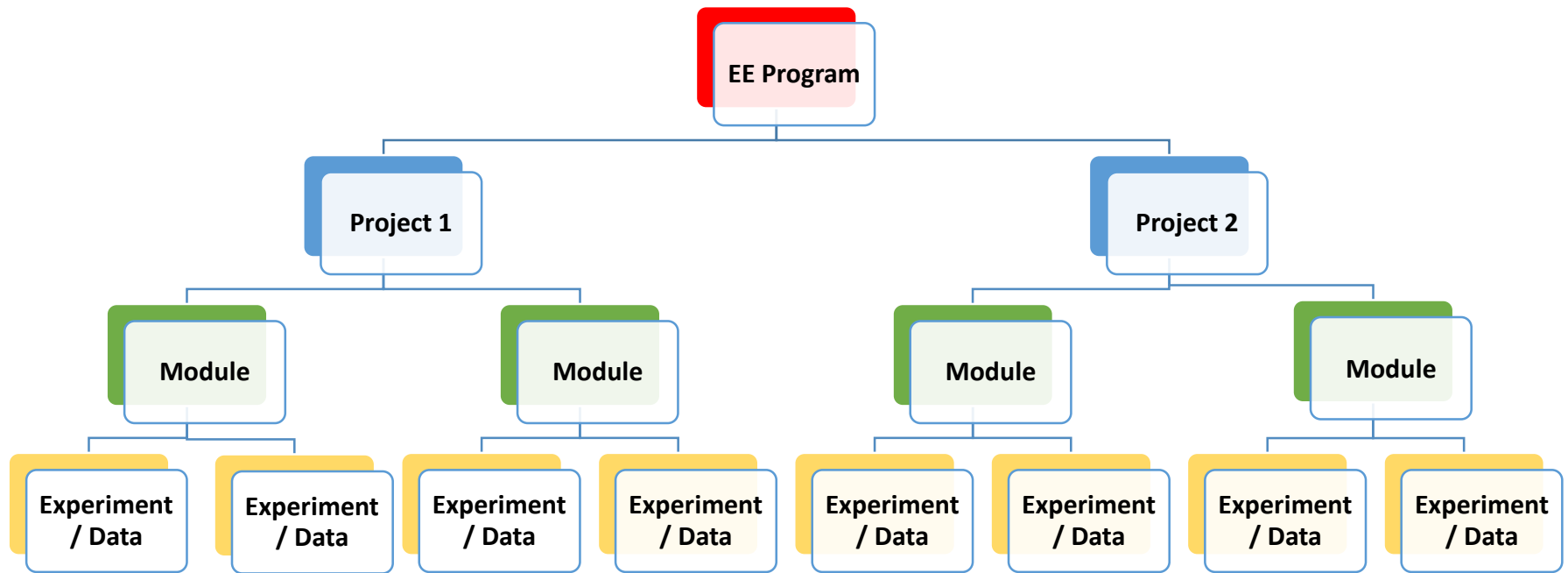
# EP Evaluator Features

- **Clinical Laboratory Compliance Toolkit**
  - Meets all CLIA '88 and CAP requirements for validating and evaluating methods. [www.cms.hhs.gov/clia](http://www.cms.hhs.gov/clia)
  - New Method Validation / Verification
  - Ongoing Quality Assurance, Performance Verification, Harmonization
- 30 Statistical Modules including 9 CLSI documents
- 4 Lab Management Modules
- **Vendor Tools**
  - FDA submissions
  - Reagent Quality Control
  - Customer Installations with instrument interfaces

# EP Evaluator Concepts

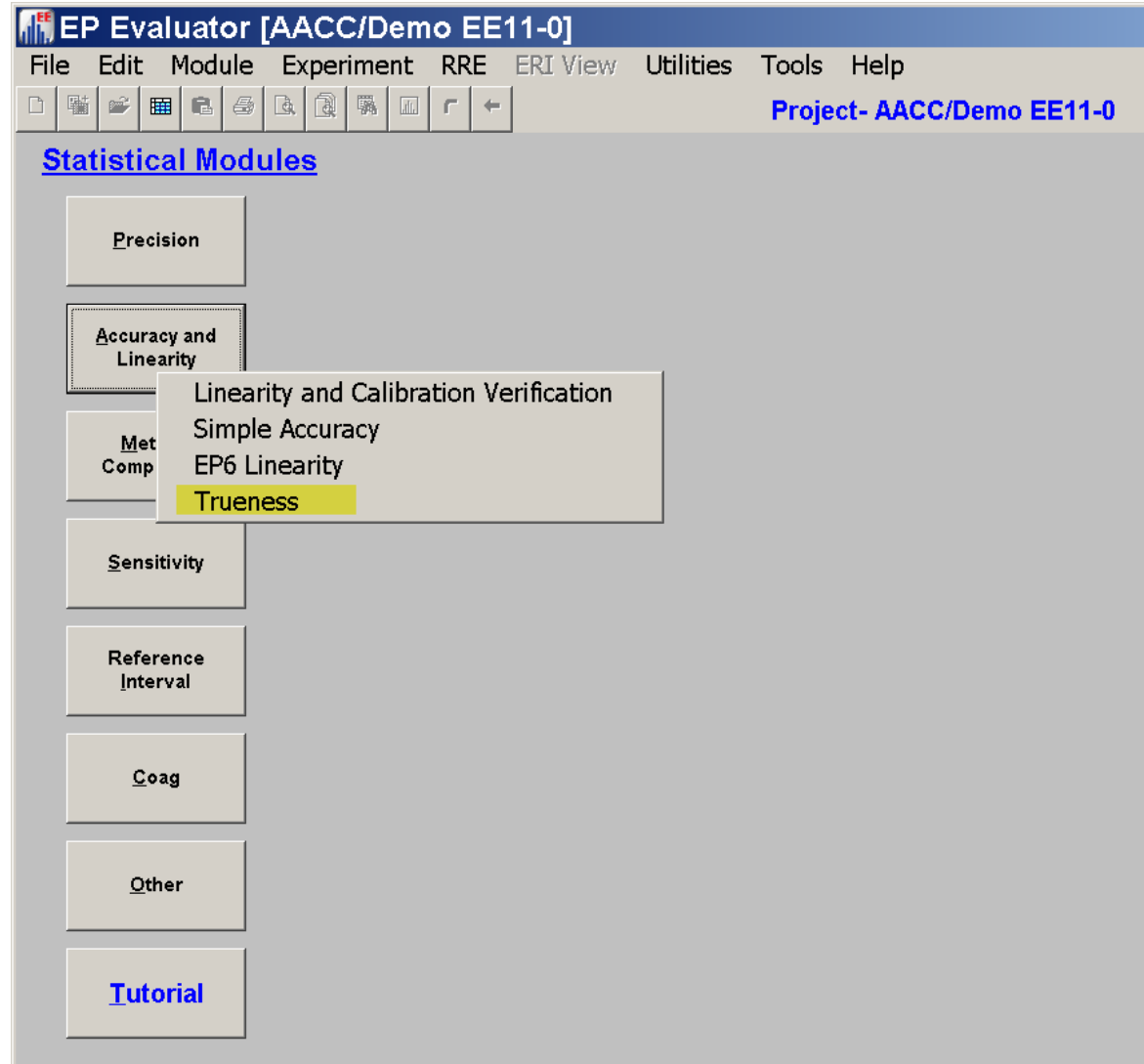
- **Statistical Module** – Does calculations and reports for a specific type of experiment - Like method comparison.
- **Project** – – a database folder containing a collection of Experiments from one or more Statistical Modules
- **Experiment** – one set of data collected for a specific purpose for 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



# 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)



# 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 performance limits (allowable error specification)
  - $TEA = 3 * \text{Random Err (Rea)} + \text{bias (SEa)}$
  - 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

# Performance limits

- Per CLIA, your laboratory is responsible for defining a policy or *specification* for the amount of **Total Allowable Error (TEa)** medically or administratively acceptable for your methods
- Allowable error examples can be found:
  - **Official CLIA limits table** from the EE Tools menu
  - **“Rhoads Suggested Performance Standards.pdf”** in EE\Resources
  - **Allowable Total Error Tables** on our DI website <http://www.datainnovations.com/products/ep-evaluator/allowable-total-error-table>

# 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

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**

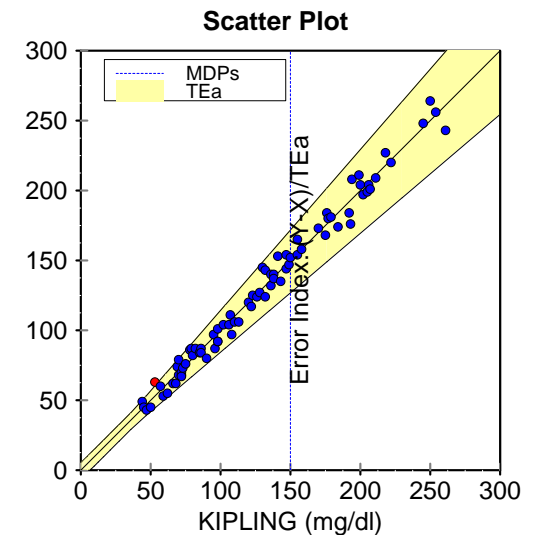
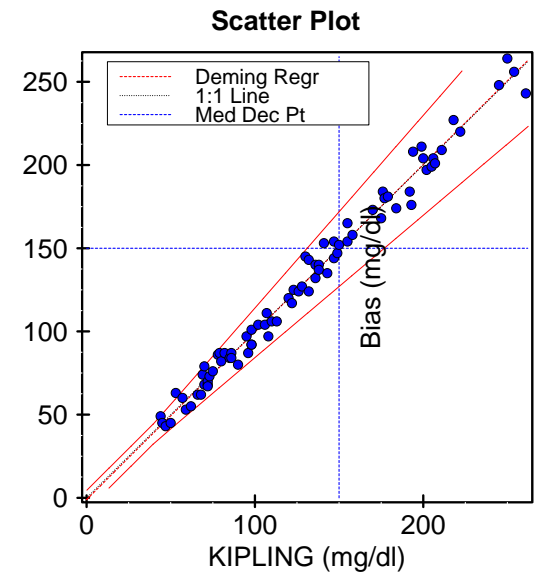
AMC Alternate Method Comparison - Uses Linear regression techniques to characterize the relationship between two methods.

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 Harmonization

- 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



Statistical Modules

Precision

**Simple  
Complex (incl CLSI EP5)**

Accuracy  
Linearity

Method  
Comparison

Sensitivity

Reference  
Interval

INR

Other

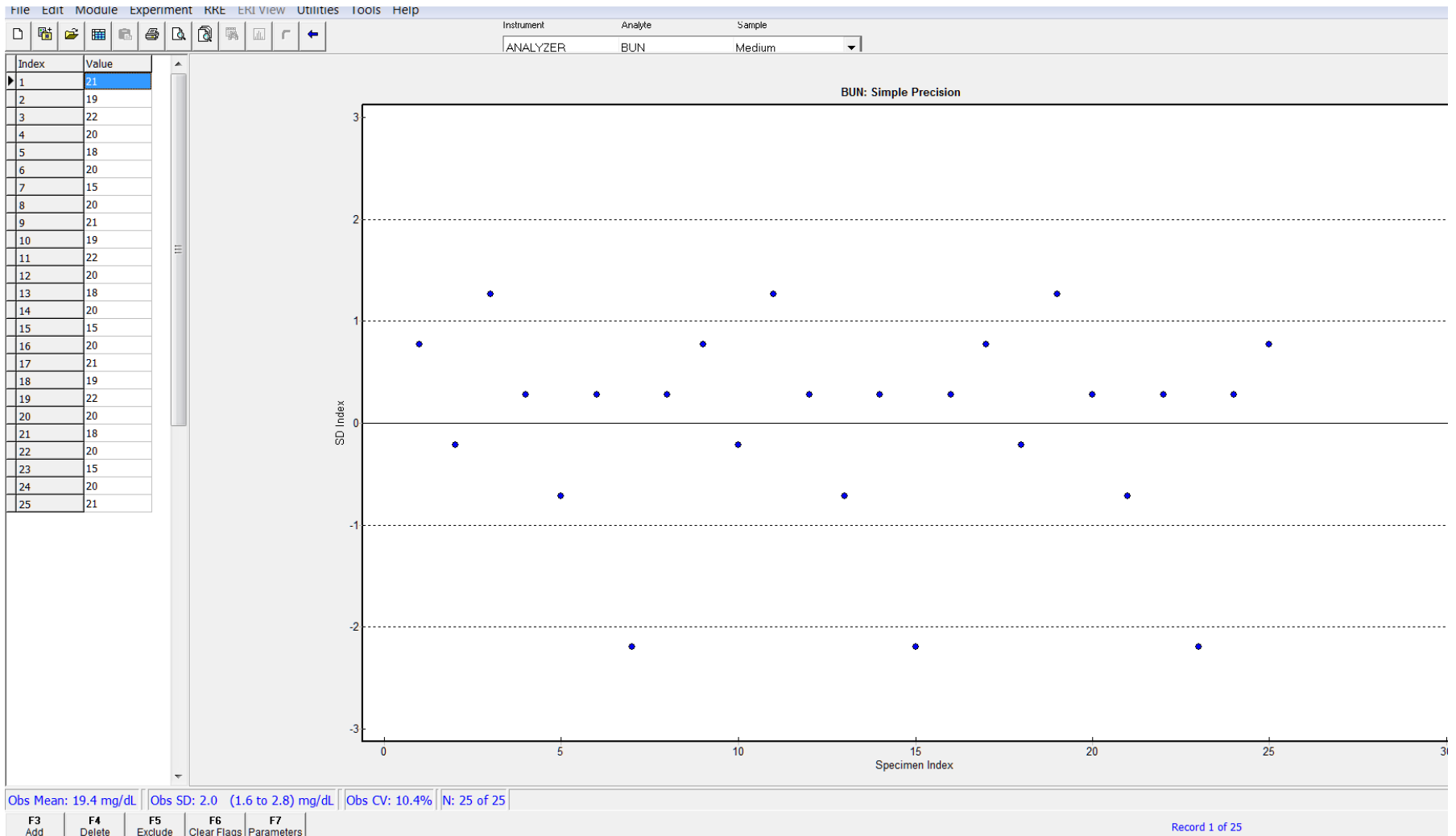
**Tutorial**

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



## Statistical Modules

Precision

Accuracy and  
LinearityMet  
CompLinearity and Calibration Verification  
Simple Accuracy  
EP6 Linearity  
Trueness

Sensitivity

Reference  
Interval

Coag

Other

Tutorial

## 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

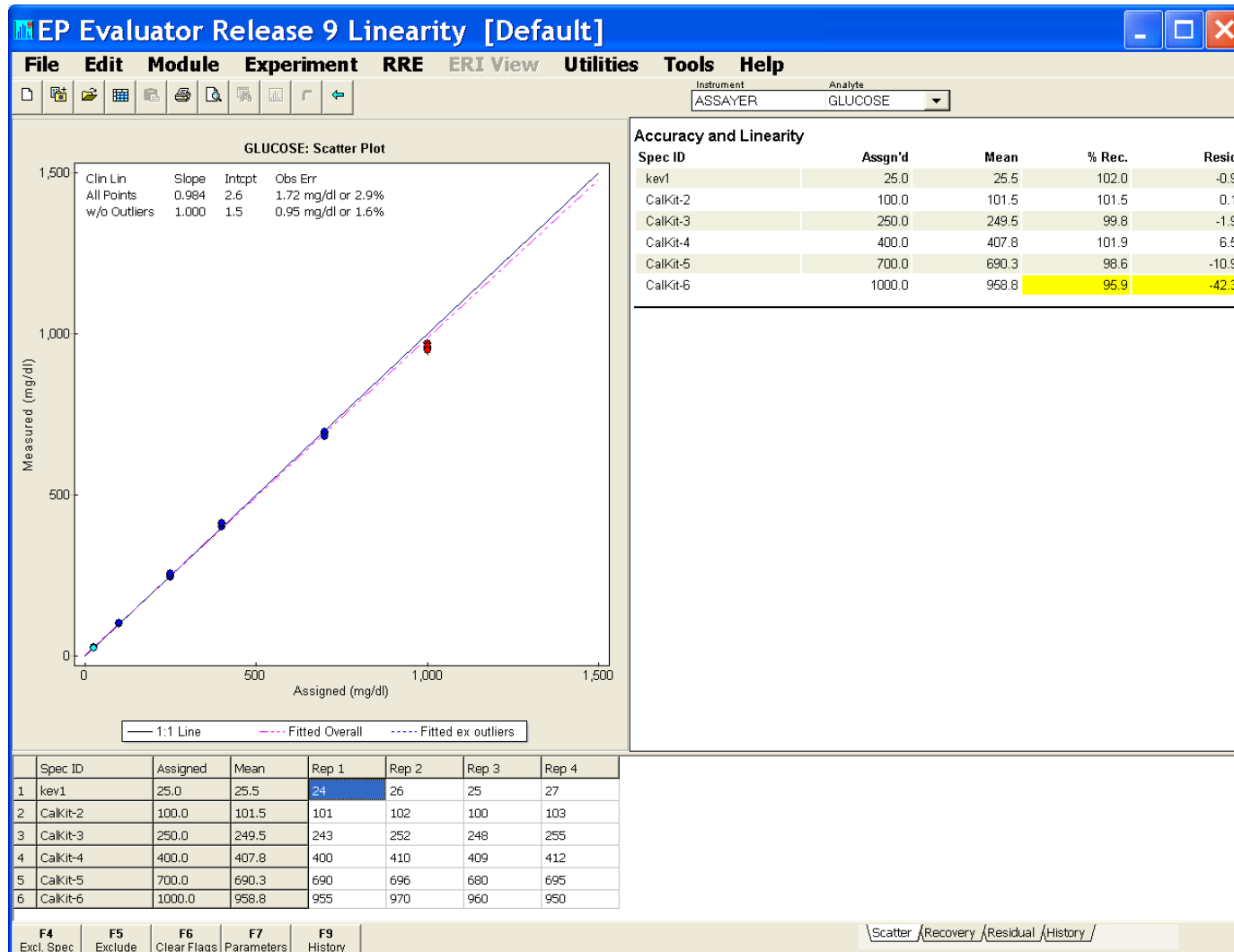
**Trueness:** satisfies the French COFRAC requirement, and the ISO 15819 recommendation to assess Trueness and Uncertainty



# 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

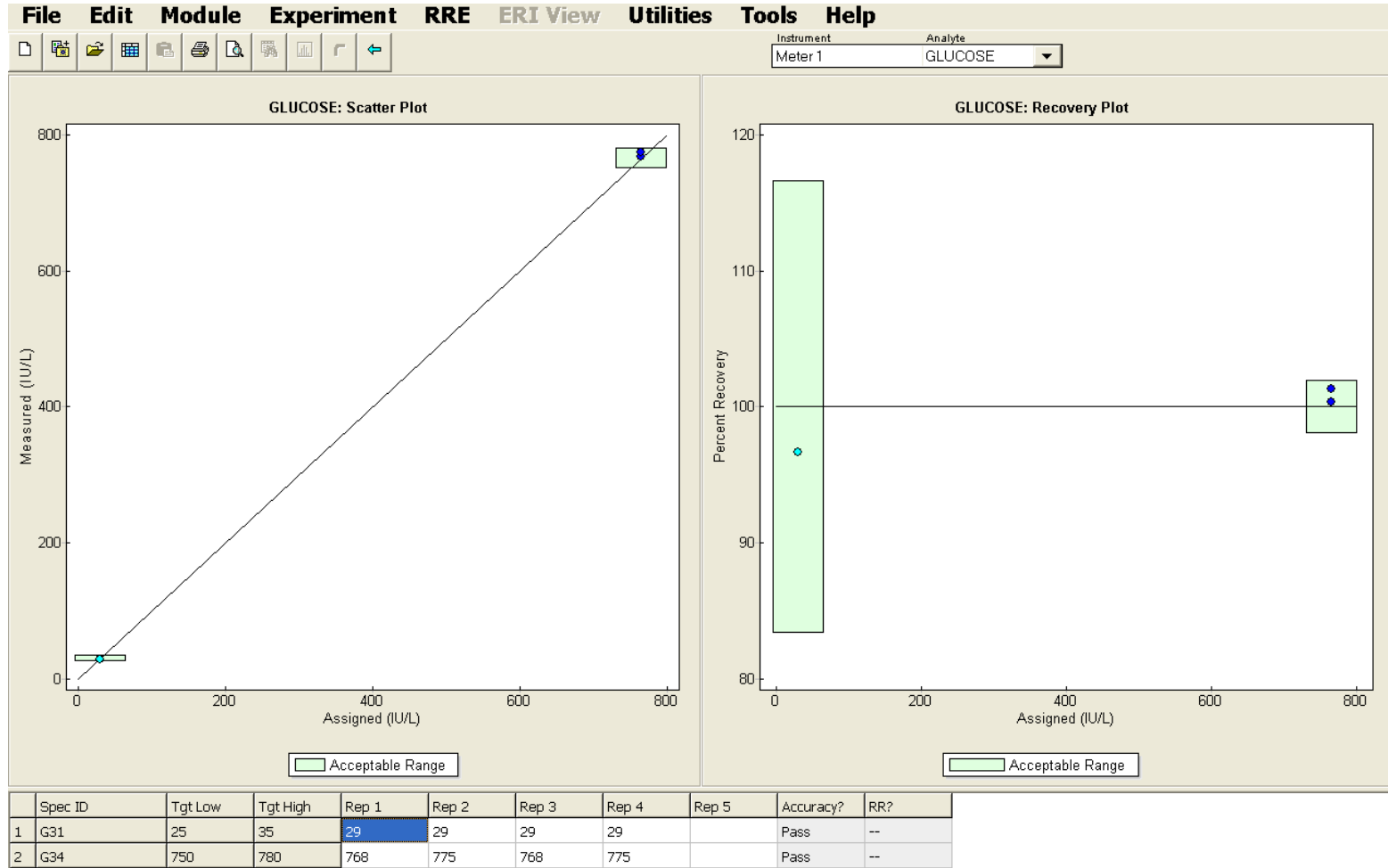
# A typical Linearity Experiment



# 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



# Set up Target ranges.

The image shows a software interface for setting accuracy parameters. The main window is titled "Simple Accuracy Parameters" and contains the following information:

- Instrument: **Eximer 250**
- Analyte: **Glucose**
- Units: **mg/dL**
- Analyst: **mki**
- Date: **16 Jul 2009**
- Max decimal places: **Auto**
- Confirm Reportable Range
- Reportable Range:
  - Low Limit: **20**
  - High Limit: **625**
- Proximity Limits:
  - Conc: **50**
  - Pct: **10**

The "Specimens and Assigned Values" sub-dialog is open, showing a table of specimen data:

Spec ID	Tgt Low	Tgt High
L1	28.2	35.6
L2	281.1	297.5
L3	578.6	612.2

The "Edit" button in the sub-dialog is circled in red. The main dialog also has "OK", "Cancel", and "Help" buttons at the bottom.

# 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

# Data Entry – Gold Standard

File Edit Module Experiment RRE ERI View Utilities Tools Help

Test Reference Analyte  
 NCCLSEx2 Immunochromatic ELISA

SpecID	Ref	Test
S00001	N	N
S00002	N	N
S00003	N	N
S00004	P	P
S00005	P	P
S00006	N	N
S00007	N	N
S00008	P	N
S00009	P	P
S00010	P	P
S00011	N	P
S00012	N	N
S00013	P	P
S00014	P	P
S00015	N	N
S00016	N	N
S00017	P	P
S00018	N	N
S00019	P	P
S00020	P	P
S00021	N	N
S00022	N	N
S00023	N	N
S00024	P	P
S00025	N	N
S00026	N	N
S00027	P	P
S00028	P	P
S00029	N	N
S00030	N	N
S00031	N	N
S00032	N	N

	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%)      Pos Agreement: 95.3%      Neg Agreement: 93.7%

Sensitivity: 95.3% (92.3 to 97.2%)      Pred. Value Pos: 95.0%      Pred. Value Neg: 94.1%

Specificity: 93.7% (89.8 to 96.1%)      Prevalence: 55.8%

Enter 2 state results

Gold standard

# 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

### Define Results Coding

# Levels  (2-6)

Define the levels in order from least positive to most positive. "Result Value" is the value as it appears in your Results Data. "Report Name" is the level description to print on the report. When using numeric results with cutoffs, the Result Value column contains the cutoff values. Click the **Help** button for examples.

Reference Method

Results format: Numeric, large are POSITIVE

Level	Cutoff Values	Report Names
1		Very Negative
2	100	lower than 0
3	200	Positive
4	300	Very Positive
5	400	WOW
6	500	Critical Value

Test Method

Results format: Numeric, large are POSITIVE

Level	Cutoff Values	Report Names
1		Very Negative
2	100	Negative
3	200	Positive
4	300	Very Positive
5	450	VVP
6	550	Critical Value

>> <<

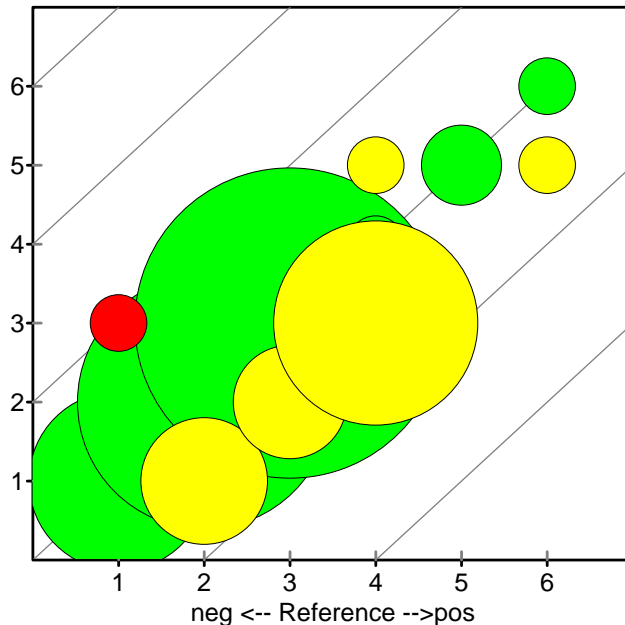
OK Cancel Help



# 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

Statistical Modules

Precision

Accuracy and Linearity

Method Comparison

Sensitivity

Reference Interval

**Verify Reference Interval  
Establish Reference Interval/ROC**

INR

Other

**Tutorial**

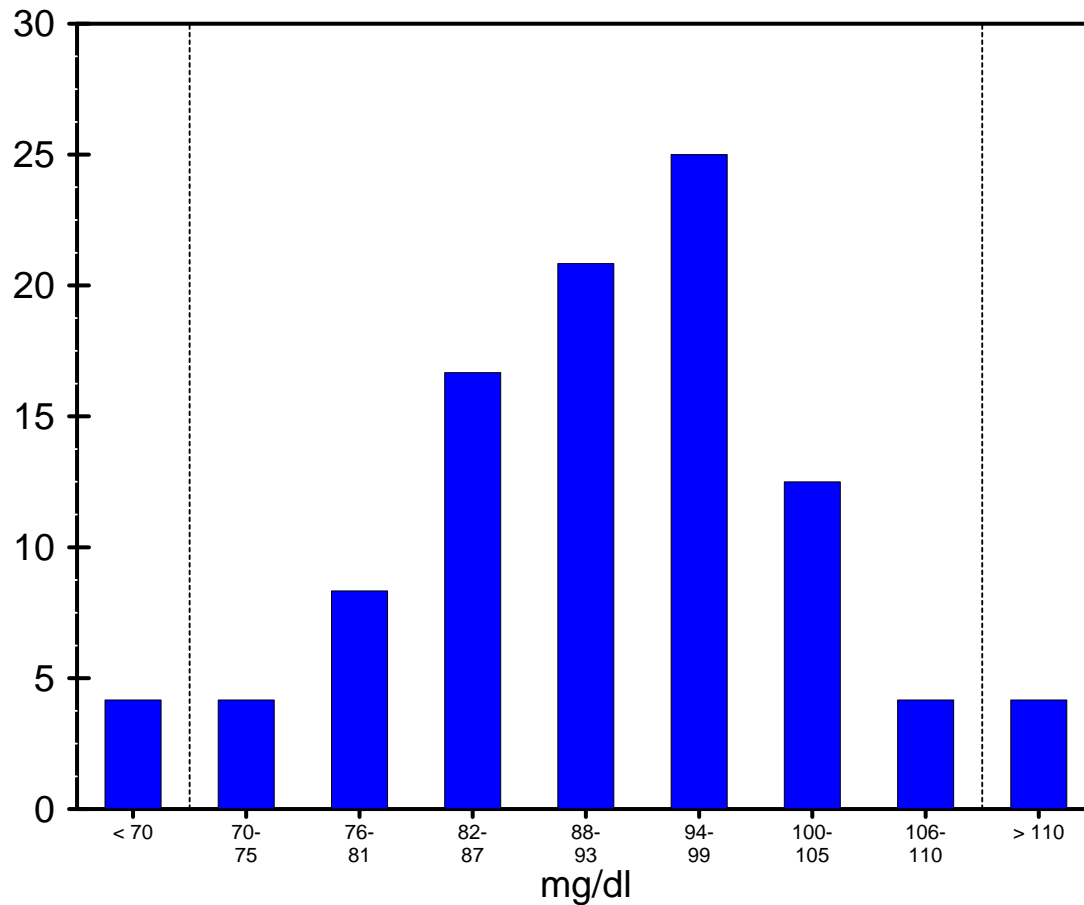
VRI - Verification of Reference Interval. Verifies that the reference range of a new method is statistically equivalent to a target reference range.

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.

# Verify Reference intervals

## Reference Interval Histogram

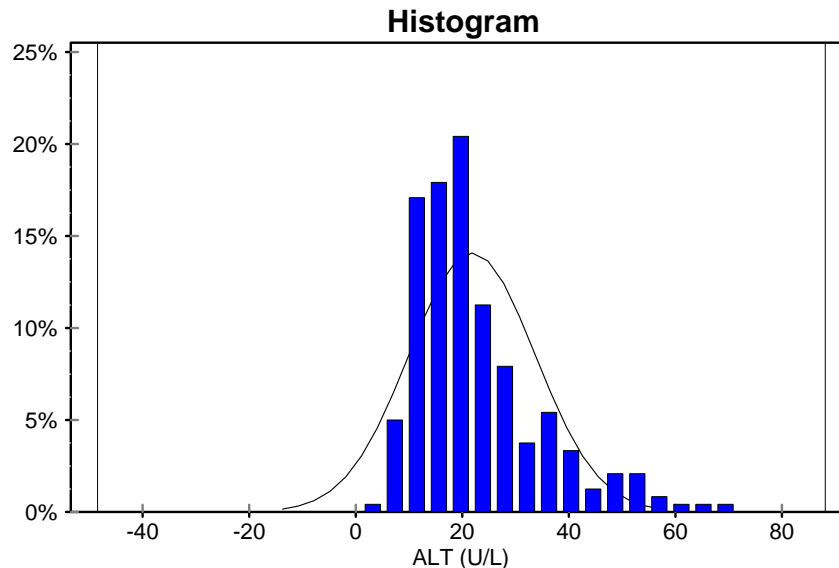


# Establish Reference Intervals - ERI

## Reference Interval Estimation: Combined

Central 95% Interval (N = 240)					
	Lower		Upper		Confidence Ratio
	Value	90% CI	Value	90% CI	
<b>Nonparametric (CLSI C28-A)</b>	<b>8</b>	<b>6 to 9</b>	<b>54</b>	<b>49 to 65</b>	<b>0.21</b>
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 Features : Clinical Chemistry concepts not in generic SW packages

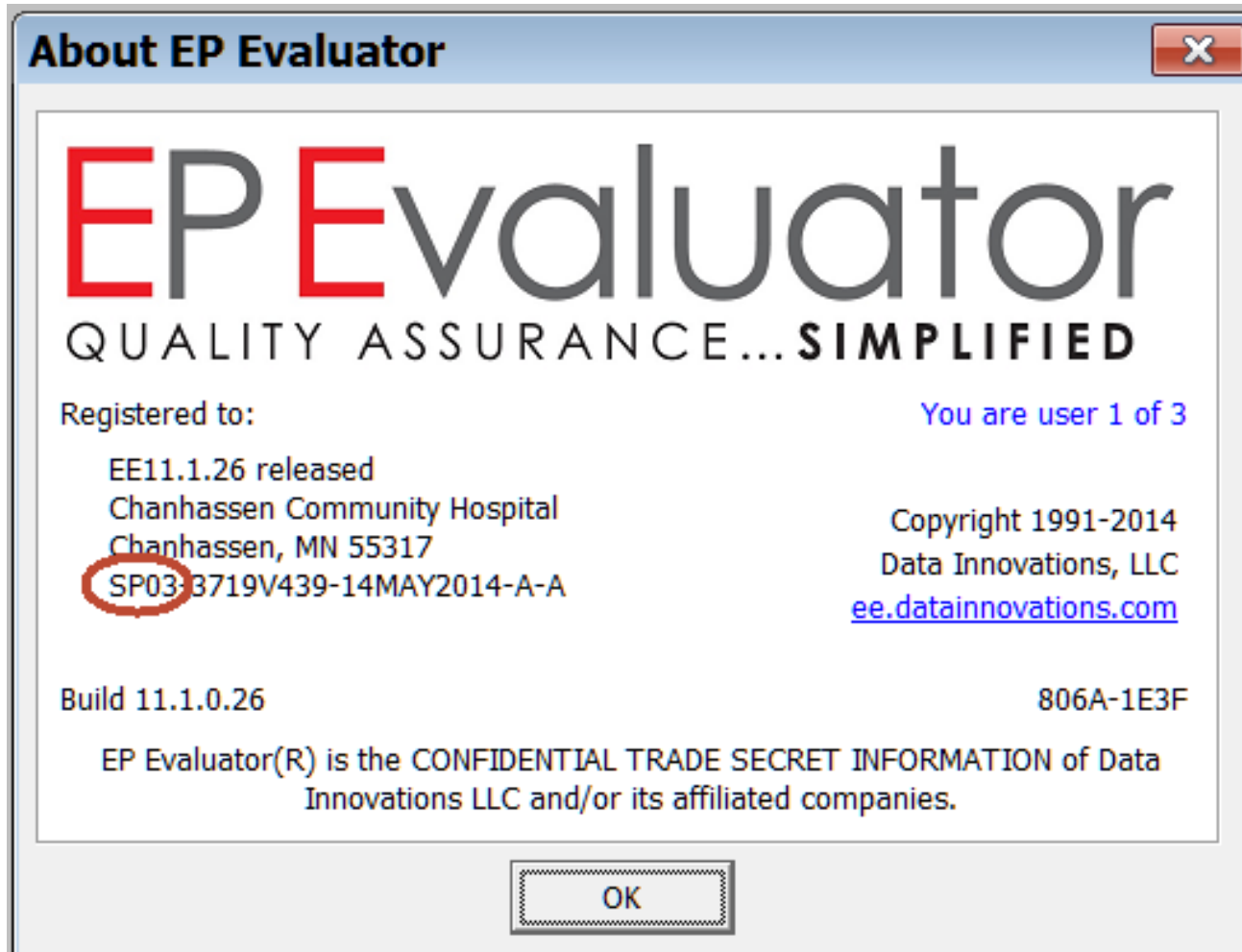
- Beyond p, “t”, Chi2 and R2
- Allowable error (TEA)
  - Clinical linearity
  - Accuracy, reportable range
- Method comparisons
  - Error boundaries TEA, conf limits, binomial
  - OLS, Passing Bablok or Deming regressions
  - Bias and Bland Altman Plots
- Trueness and Uncertainty
- Sensitivity / specificity
  - LOQ Functional sensitivity
  - LOB Analytical sensitivity
  - Truth tables in HMC and QMC
- Carryover
- Reference Intervals and ROC plots
- CLSI protocols and algorithms - 9
  - 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
  - EP26 Lot-to-Lot Verification



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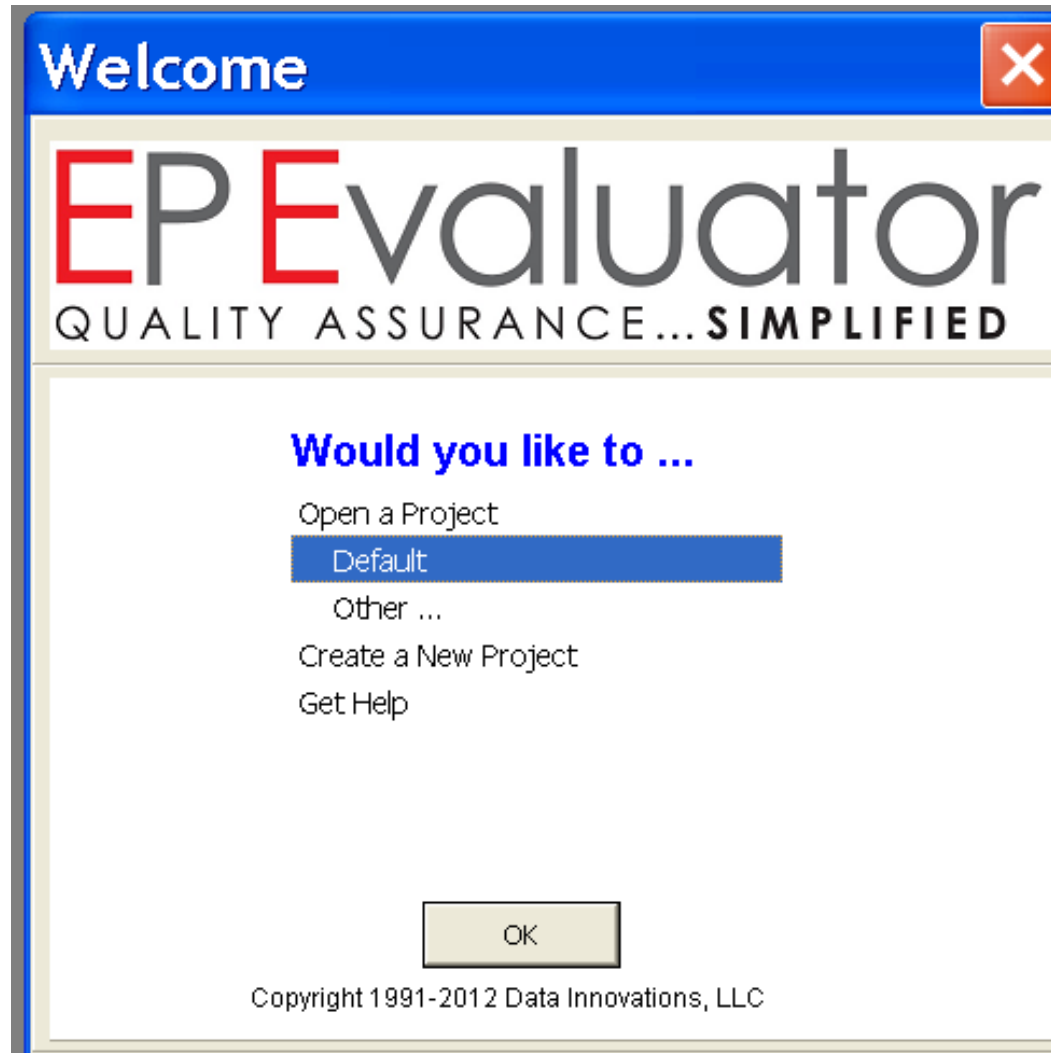
# Starting EP Evaluator

# The About screen



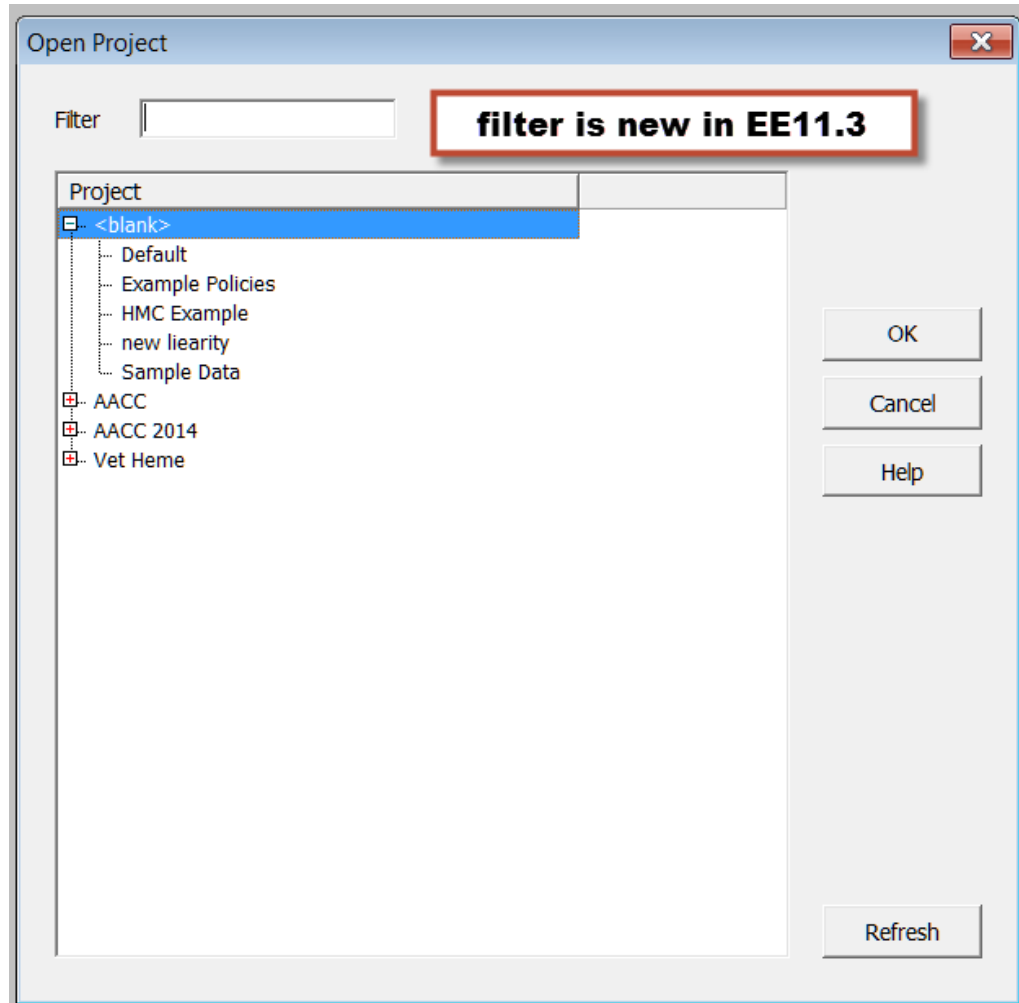
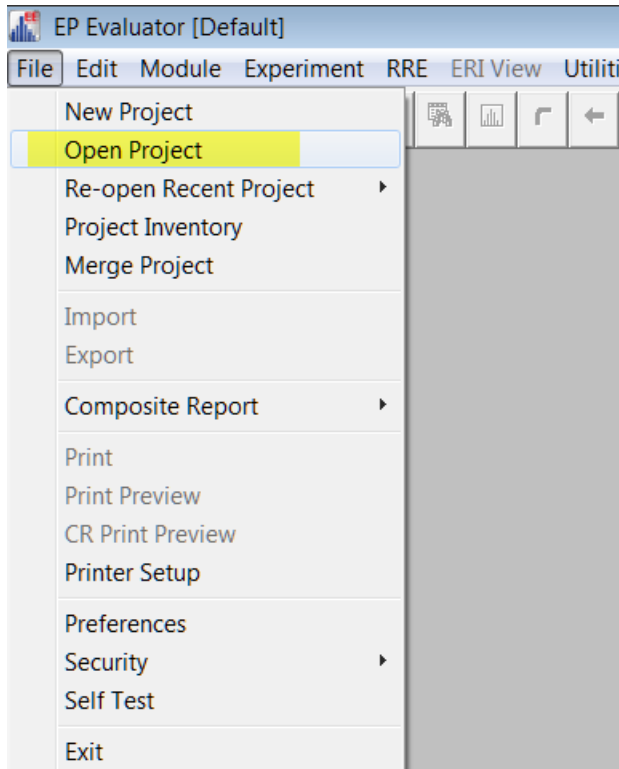
Go to HELP>About to get back to this screen at any time

# The Welcome Screen



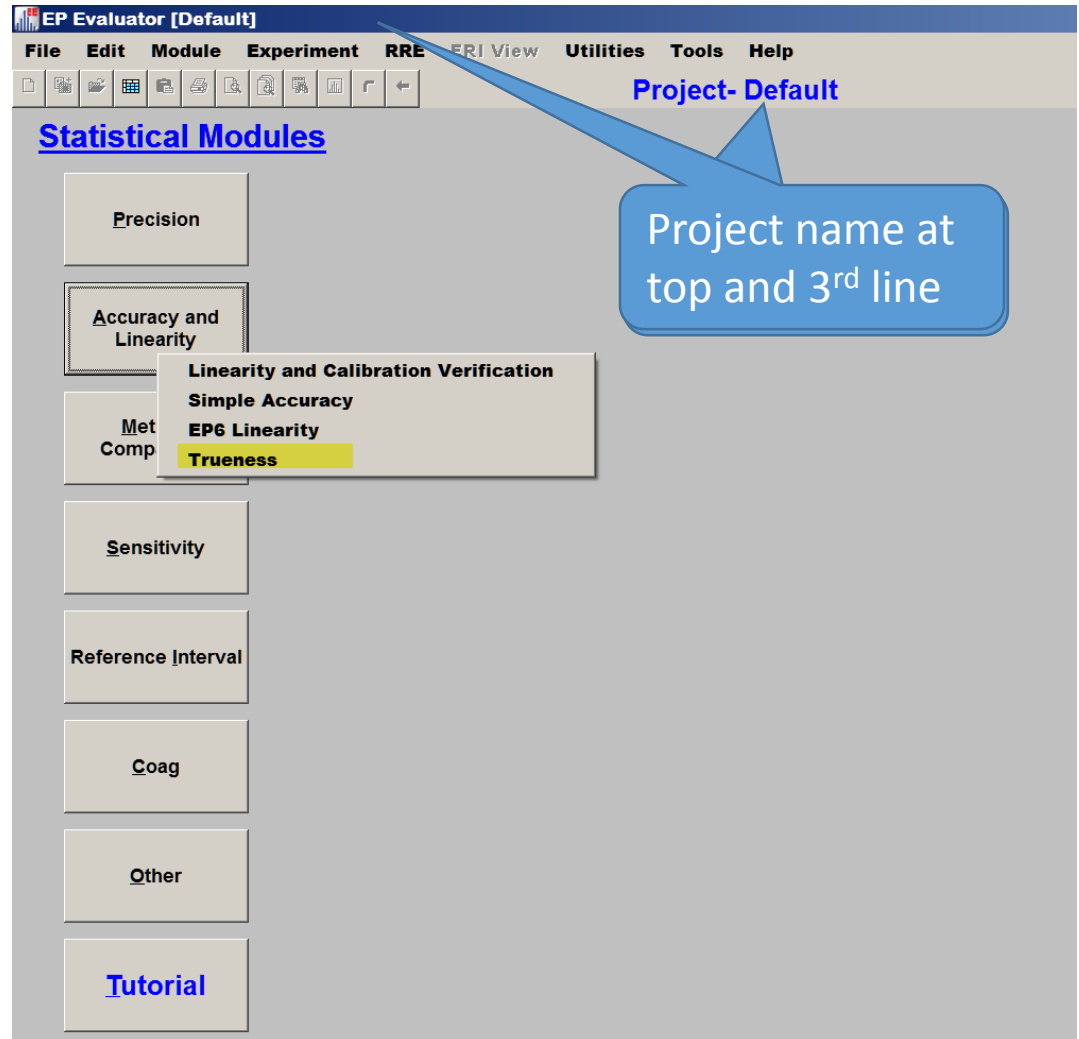


# Open a Project



# What Project Are You In?

- Main screen
- Project name on 1<sup>st</sup> and 3<sup>rd</sup> lines



# Inventory

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	●
STR	Eximer / ALT / 1234	○

27 modules, 60 experiments

# HELP!

The screenshot shows a web browser window with the following details:

- Address Bar:** file:///C:/EE11.2.23%20webinar/EEHelp/EEHelp.htm#Reports/why\_is\_my\_report\_stamped\_preli.htm%3FTo
- Browser Tab:** EP Evaluator - Why is my re... x
- Menu Bar:** File Edit View Favorites Tools Help
- Logo:** DATA INNOVATIONS Simple Ideas, Better Solutions
- Left Sidebar (Contents):**
  - What is EP Evaluator®?
  - What's New in Release 11
  - Resources Spreadsheets
  - Key Concepts and Terms
  - Interface Overview
  - Common Operations
  - Statistical Modules
  - Reports
    - Printing Reports
    - Print Preview
    - Saving a Report to Disk
    - Selecting a File Format
    - Report Options
    - Why is my report stamped PRELIMINARY?**
    - Composite Reports
  - Lab Management Modules
  - Projects
    - Creating a Project
    - Opening a Project
    - Project Inventory
    - Merge Project Experiments
    - File Manager
  - Data Management
  - Translation into non-English Languages
- Main Content Area:**

## Why is my report stamped PRELIMINARY?

  - Simple Precision**
    - N<3
  - Complex Precision**
    - Less than 3 days; less than 6 runs
  - Linearity**
    - Less than 3 specimens
  - Simple Accuracy**
    - Less than 2 specimens (each specimen must have at least 2 replicates)
  - EP6 Linearity**
    - Less than 5 specimens (each specimen must have at least 2 replicates)
  - Alternate Method Comparison**
    - N<3, more than 5% outliers; range of X with outliers excluded less than half the full range



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# Creating New Experiments

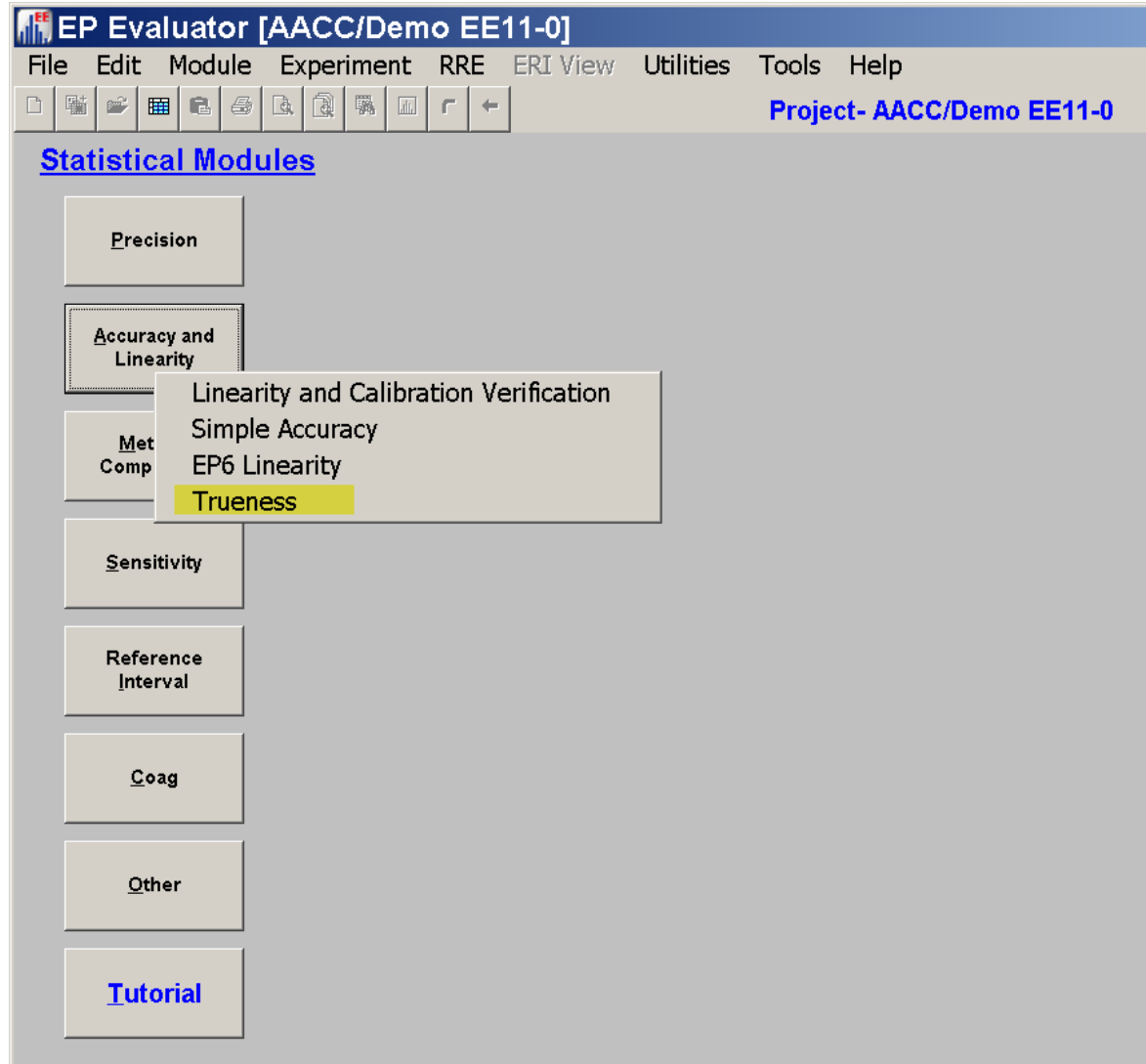
**Starting with Alternate Method Comparison - AMC**

# 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 –





Statistical Modules

Precision

Accuracy and Linearity

Method Comparison

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**Tutorial**

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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.

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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

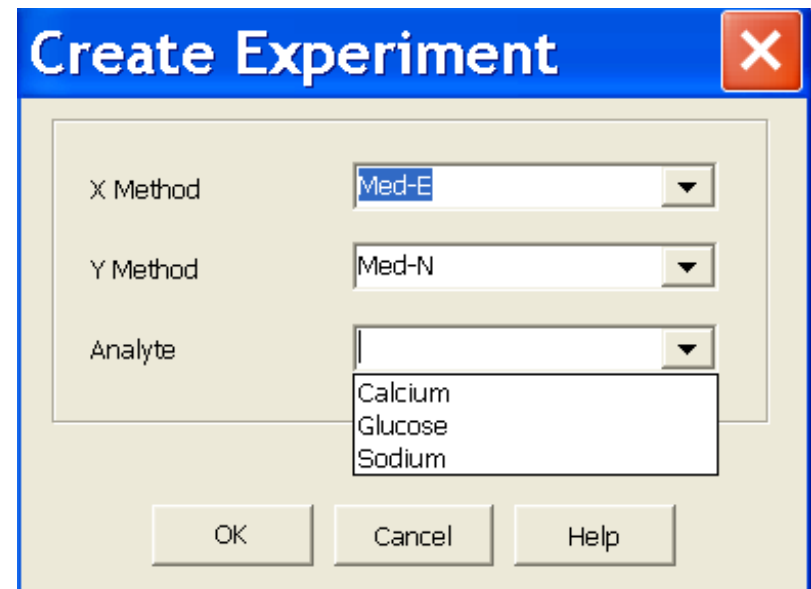
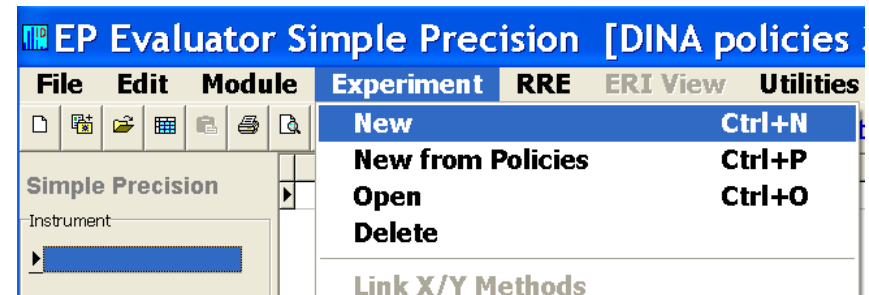
The screenshot shows the 'EP Evaluator Alternate Method Comparison' window for 'DINA policies Sept 20'. The interface includes a menu bar (File, Edit, Module, Experiment, RRE, ERI View, Utilities, Tools, Help) and a toolbar. The main area is divided into several sections:

- AMC (Alternate Method Comparison):** A table with columns: X Method, Analyte, N, Slope, Intercept, and Corr Coef (R). The table lists 8 experiments for DINA 2331 with various analytes.
- Y Method:** A list box containing 'DINA 3006'.
- Legend:** A section with icons and text: Not Calculated (yellow diamond), Insufficient Data (white circle), Sufficient data (black circle), Fail (red circle), Pass (green circle), and May need review (yellow circle).
- Available Methods:** A section with a dropdown menu showing 'DINA 2331' and 'DINA 3006'. Below it, a section titled 'Analytes for DINA 2331' shows a list of analytes: ALB, BUN, CHOL, CRE, ETOH, and GLUCOSE.

X Method	Analyte	N	Slope	Intercept	Corr Coef (R)
DINA 2331	ALB	5/5	1.134	-0.36	0.9997
DINA 2331	BUN	54/54	0.995	0.1	0.9996
DINA 2331	CHOL	54/54	1.003	0.7	0.9988
DINA 2331	CRE	54/54	1.004	0.016	0.9997
DINA 2331	ETOH	25/26	0.964	0.50	0.9999
DINA 2331	GLUCOSE	52/52	1.015	-1.1	0.9998
DINA 2331	LI	30/30	0.951	-0.012	0.9988
DINA 2331	SALY	30/30	0.985	-0.05	0.9993

# Creating a new experiment

- Click the New Experiment icon ,  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.

The screenshot shows a software window titled "2-Instrument Comparison Parameters" with a close button (X) in the top right corner. The window is for the analyte "Glucose" and the method "ZIC". It is divided into two columns for "X Method" (METH1) and "Y Method" (METH2). The Y Method column has a yellow highlight on its "Units" dropdown menu. Below the method columns are sections for "Allowable Total Error (TEa)", "Reportable Range", "Max Decimal Places", and "Medical Decision Points". The "Medical Decision Points" section has input fields for 60, 126, and 350. At the bottom, there are "OK", "Cancel", and "Help" buttons, and a note that "Fields highlighted in yellow are required".

Parameter	X Method (METH1)	Y Method (METH2)
Method	METH1	METH2
Units	mg/dl	[Yellow Highlight]
Date	31 Jan 2016	31 Jan 2016
Analyst	Inez Doe	Inez Doe
Comment		
Reagent Lot	1256894	589612
Reagent Source	Eximer	dina
Reagent Exp Date	12/31/2018	12/31/2018

Allowable Total Error (TEa)

Conc	6
Percent	10

Reportable Range

Lower Limit	0
Upper Limit	600

Max Decimal Places: Auto

Medical Decision Points

60	126	350		
----	-----	-----	--	--

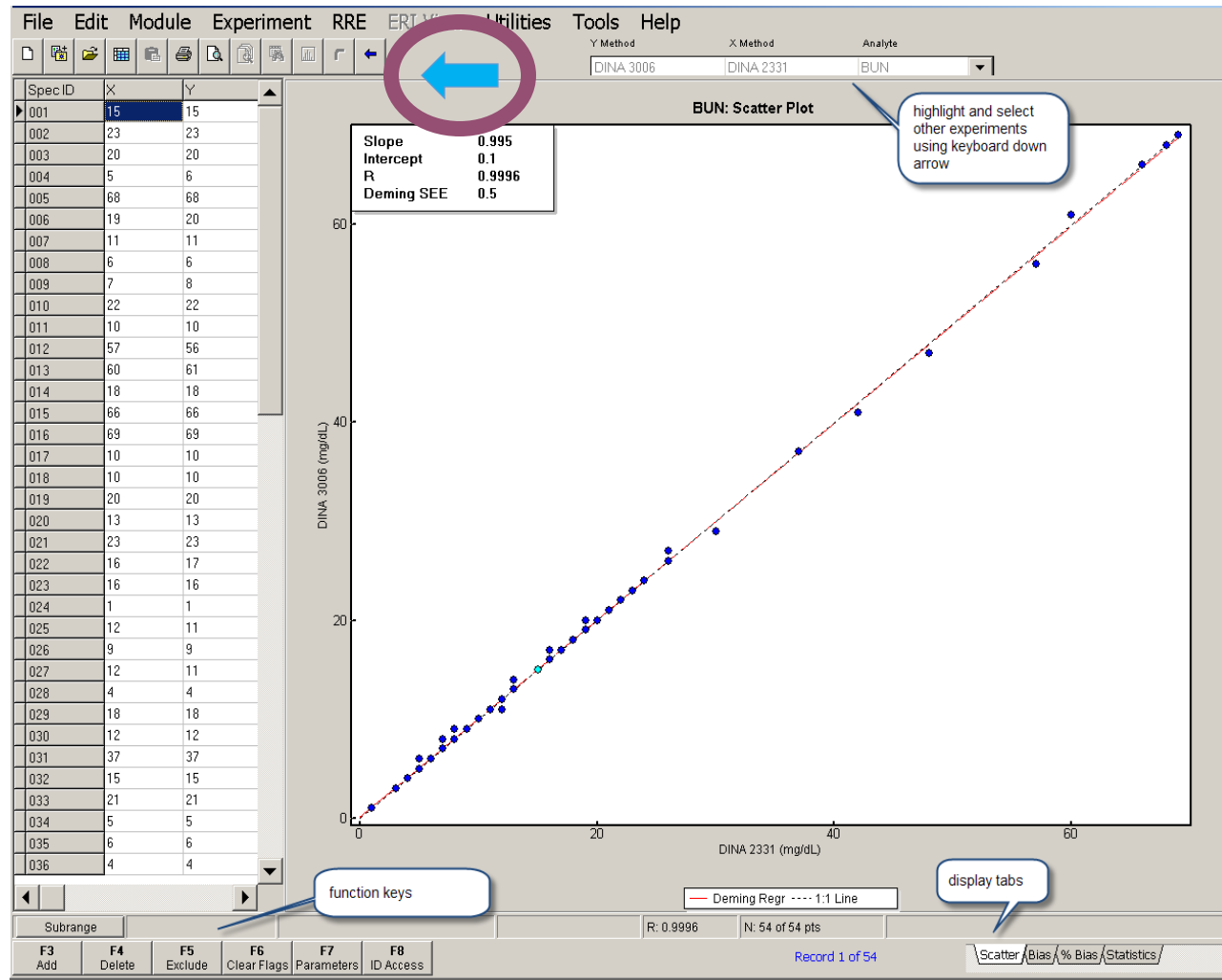
EP26 lot-to-lot validation

OK Cancel Help

Fields highlighted in yellow are required

# Experiment Detail Screen

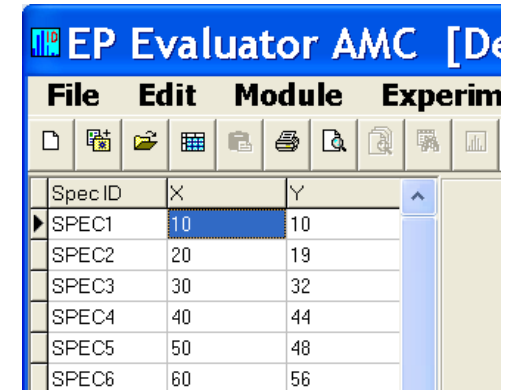
- One analyte
- Data Entry
  - Manual or
  - paste from Excel
- Blue Back arrow
- Function keys
- Observed statistics



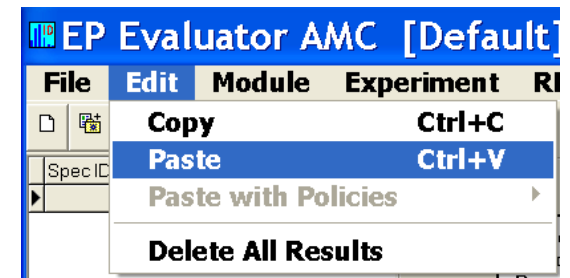
# Entering Data

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

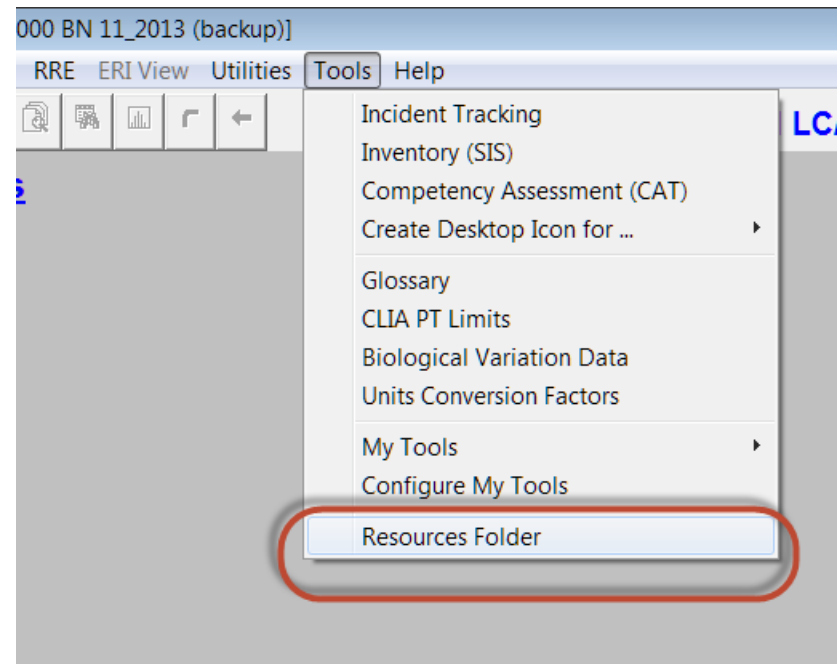
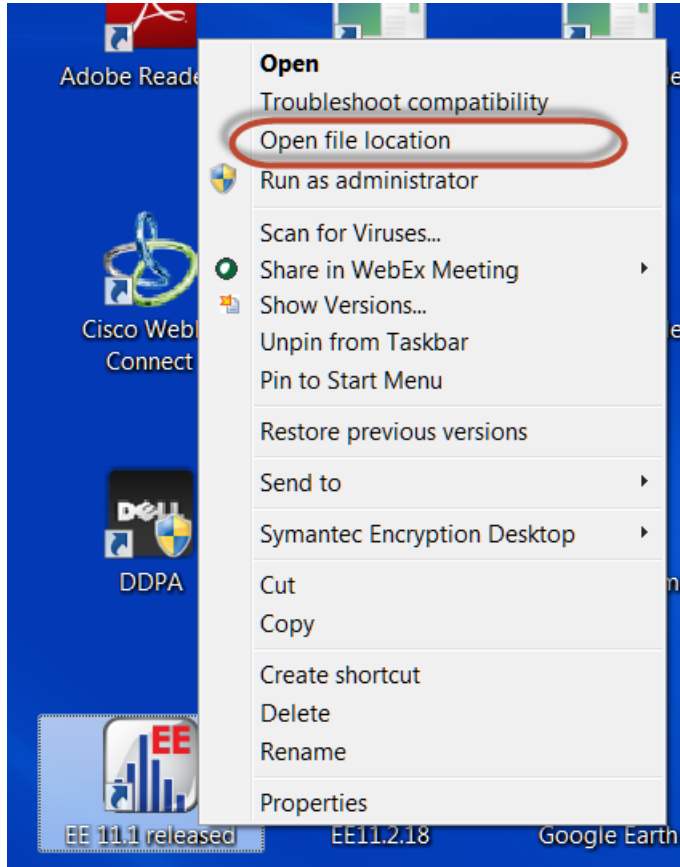
1. Type it into the highlighted cell.
2. You can paste data from a Microsoft<sup>®</sup> Excel spreadsheet.
  - The EE program folder on your computer or network contains a spreadsheet with examples of correct formats to paste data into the experimental detail screen for most modules. i.e., **"C:\EE11\Resources\PasteExptDetail.xls"**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



SpecID	X	Y
SPEC1	10	10
SPEC2	20	19
SPEC3	30	32
SPEC4	40	44
SPEC5	50	48
SPEC6	60	56

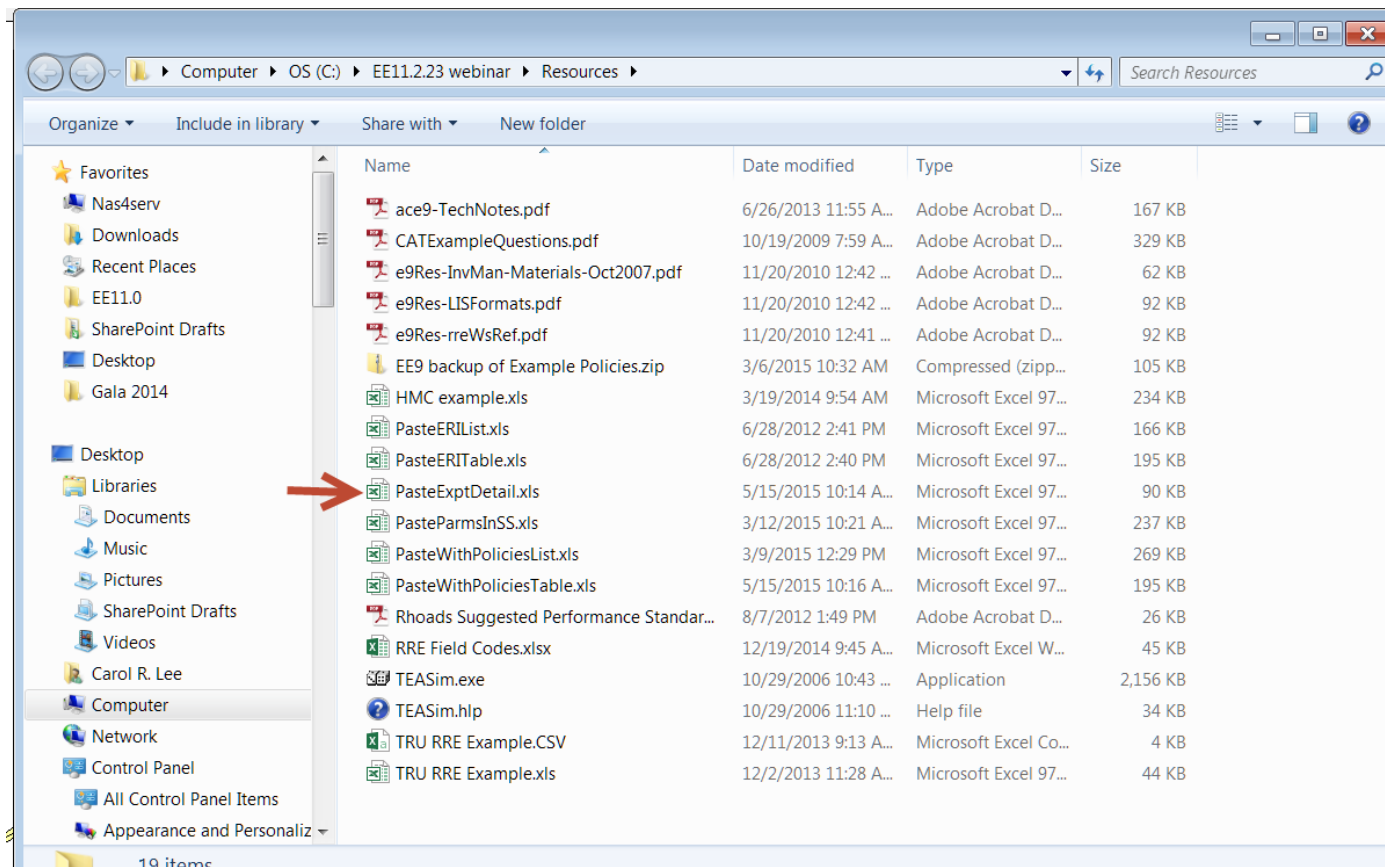


# Find your Resource folder



# EE Resources Folder

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



# Paste into Experiment Detail Screen

- Create an experiment as if you were going to type the results ...
  - Experiment – New
  - Experiment – New from Policies
- Then paste the results instead of typing them
- Paste just the numbers – not column headings or Sample IDs.
  
- Note: This technique doesn't work for all statistical modules

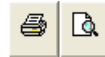


# Specimen IDs

- Header = SPECID
- Method Comparison SPECID used to link the data pairs
- Linearity SPEC IDS convention for each level of “standards” Lin-01, Lin-02, Lin-03, etc. The dash is configurable in Preferences.
- 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<sup>®</sup>

EE 10 - 480 - Kennett Community Hospital

HDL

### Two Instrument Comparison

X Method METH1      Y Method METH2

#### Scatter Plot

Scatter Plot showing METH2 (mg/dl) vs METH1 (mg/dl). The plot includes a regression line, MDPs (Mean Difference Percent), Reportable Range, TEa (Total Error Allowable), and Error Index:  $(Y-X)/\bar{X}$ .

#### Error Index

Error Index plot showing Average MDPs, Reportable Range, and Unacceptable range.

**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**

$Y = \text{Slope} \cdot X + \text{Intercept}$

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

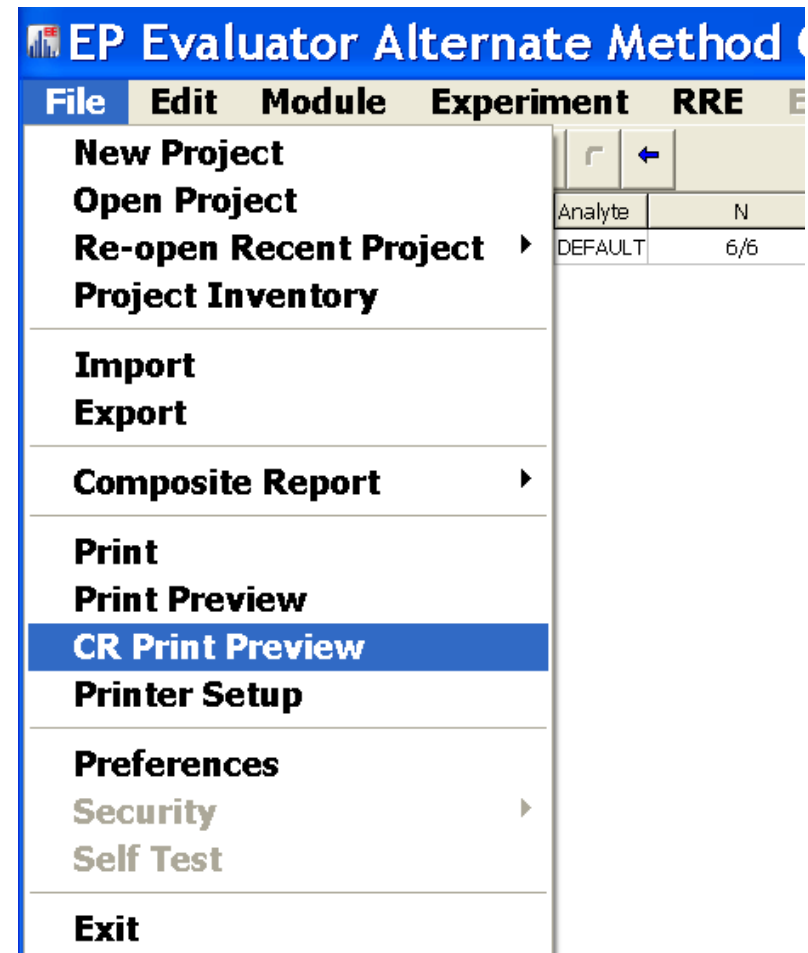
Date

EP Evaluator 10.0.0.480  
Default Printed: 20 Nov 2011 18:53:23

Copyright 1991-2011 Data Innovations, LLC  
Page 1

# 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

**Composite Report Setup**

Titles | Prepared By | Prepared For | Reports

**Available Reports**

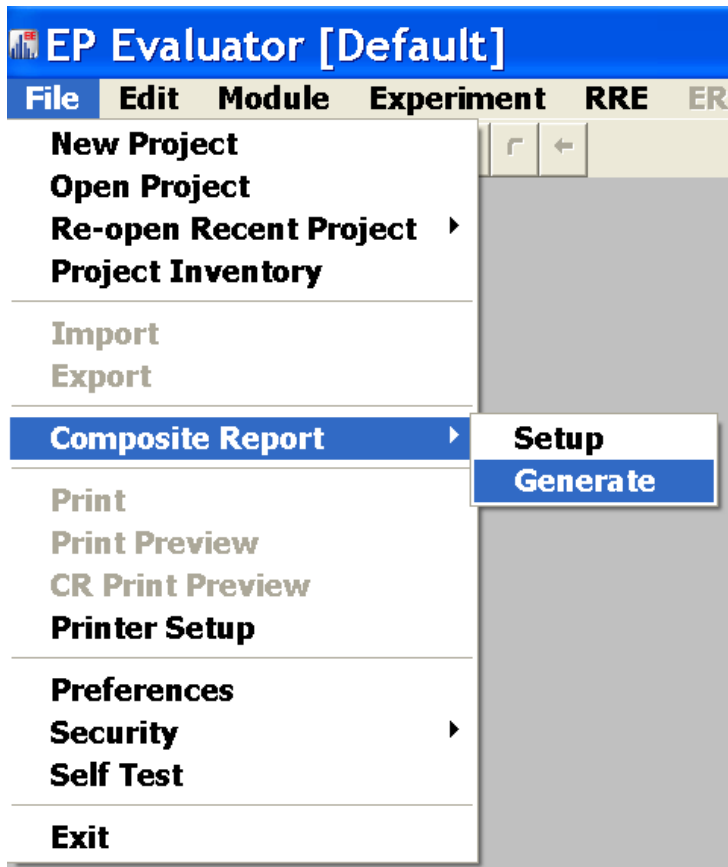
- 6Sigma (Six Sigma Metrics)
- AMC (Alternate MC)
- AON (Average of Normals)
- CO (Carryover)
- CP (Complex Precision)
- CPT (Cost per Test)
- EP10 (CLSI EP10 Preliminary Evaluation)
- EP6 (EP6 Linearity)
- EP9 (CLSI EP9 MC)
- ERI Full (ERI Full Analysis Report)
- ERI Partition (ERI Partitioning Test Report)
- ERI Profile (ERI Analyte Profile Report)

**Selected Reports**

- Lin (Linearity)
- 2IC (2 Instrument Compare)
- SP (Simple Precision)
- INR-Chk (Coag-INR Manual Check)
- INR-Geo (Coag-INR Geometric Mean & VRI)
- INR-MC (Coag-INR Method Comparison)

OK Cancel Help

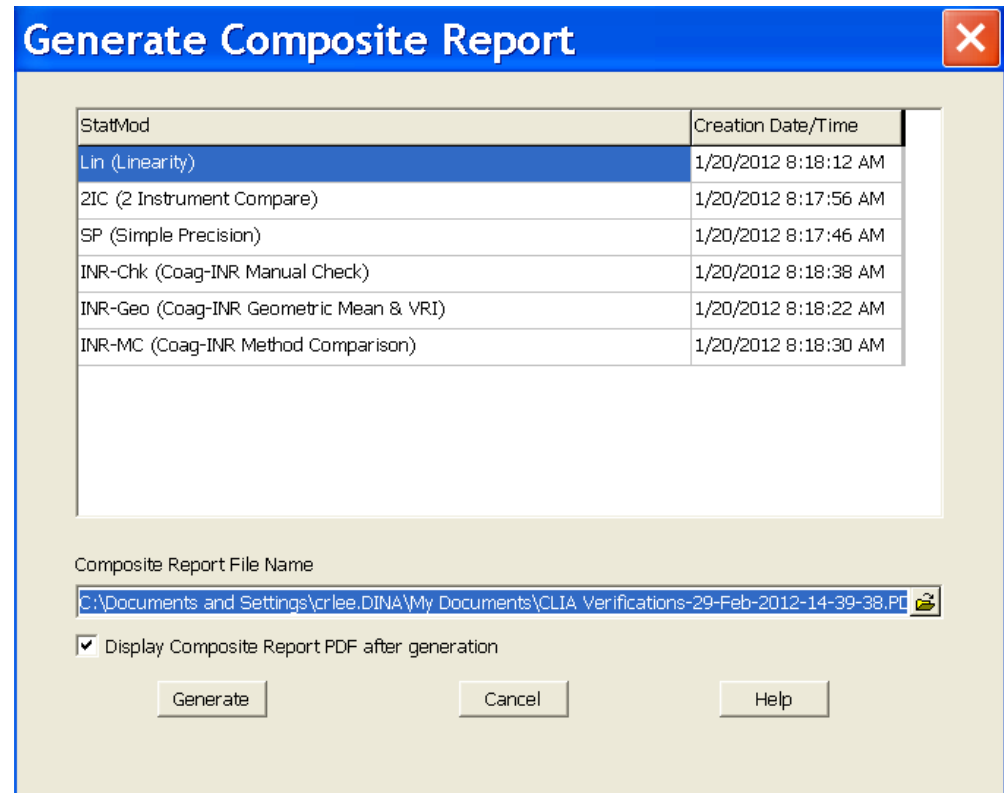
# Generate Composite Report



EP Evaluator [Default]

File Edit Module Experiment RRE ER

- New Project
- Open Project
- Re-open Recent Project ▶
- Project Inventory
- Import
- Export
- Composite Report ▶**
  - Setup**
  - Generate**
- Print
- Print Preview
- CR Print Preview
- Printer Setup
- Preferences
- Security ▶
- Self Test
- Exit



Generate Composite Report

StatMod	Creation Date/Time
Lin (Linearity)	1/20/2012 8:18:12 AM
ZIC (2 Instrument Compare)	1/20/2012 8:17:56 AM
SP (Simple Precision)	1/20/2012 8:17:46 AM
INR-Chk (Coag-INR Manual Check)	1/20/2012 8:18:38 AM
INR-Geo (Coag-INR Geometric Mean & VRI)	1/20/2012 8:18:22 AM
INR-MC (Coag-INR Method Comparison)	1/20/2012 8:18:30 AM

Composite Report File Name  
C:\Documents and Settings\crllee.DINA\My Documents\CLIA Verifications-29-Feb-2012-14-39-38.PDF

Display Composite Report PDF after generation

Generate Cancel Help

# EP Evaluator®

## CLIA Verifications

### Semi-Annual

2/29/2012

#### Prepared for

Carl Commissioner  
Regulatory 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

<i>Module</i>	<i>Page</i>
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INR-Geo (Coag-INR Geometric Mean & VRI)	24
INR-MC (Coag-INR Method Comparison)	26

# Menu Bar Options

[datainnovations.com](http://datainnovations.com)

The screenshot displays the 'EP Evaluator Simple Precision [Default]' application window. The menu bar includes 'File', 'Edit', 'Module', 'Experiment', 'RRE', 'ERI View', 'Utilities', 'Tools', and 'Help'. The 'Experiment' menu is open, showing the following options:

- New (Ctrl+N)
- New from Policies (Ctrl+P)
- Open (Ctrl+O)
- Delete
- Link X/Y Methods
- Custom Link
- Delete Orphaned Specs
- Rename Inst, Analyte, Etc.

The 'Simple Precision' sidebar on the left shows 'ANALYZER' selected under the 'Instrument' section. A blue banner at the top of the screenshot contains the text 'Project- Default'.

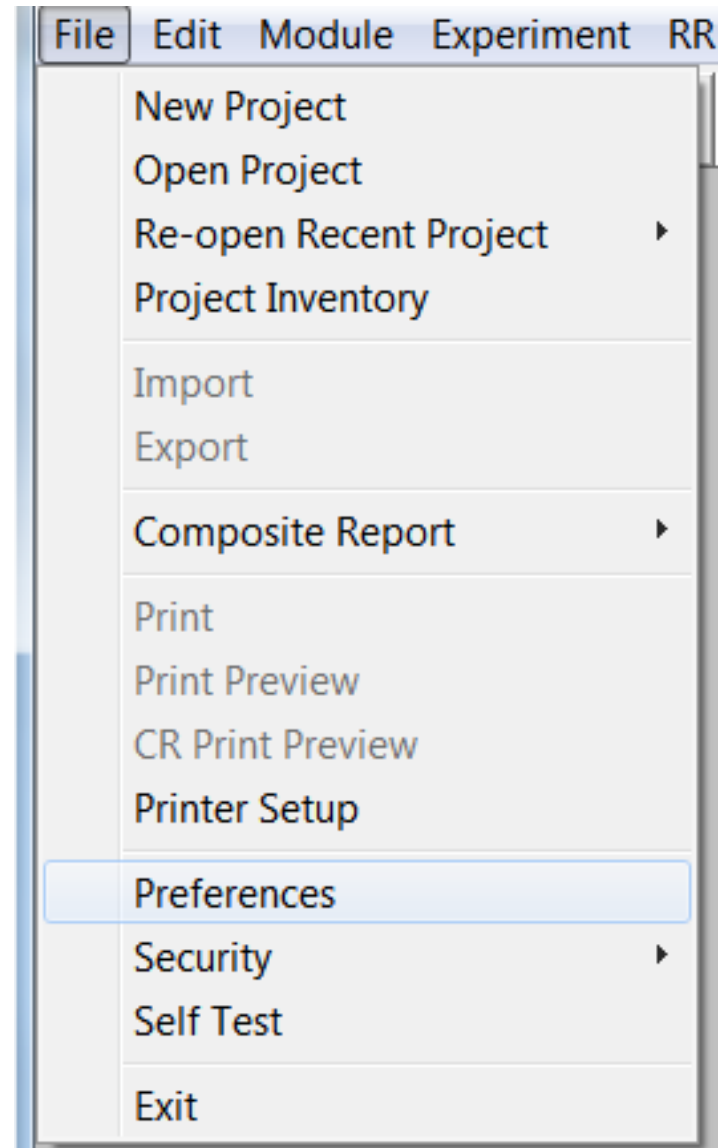


# Key Menu Bar options \* 1

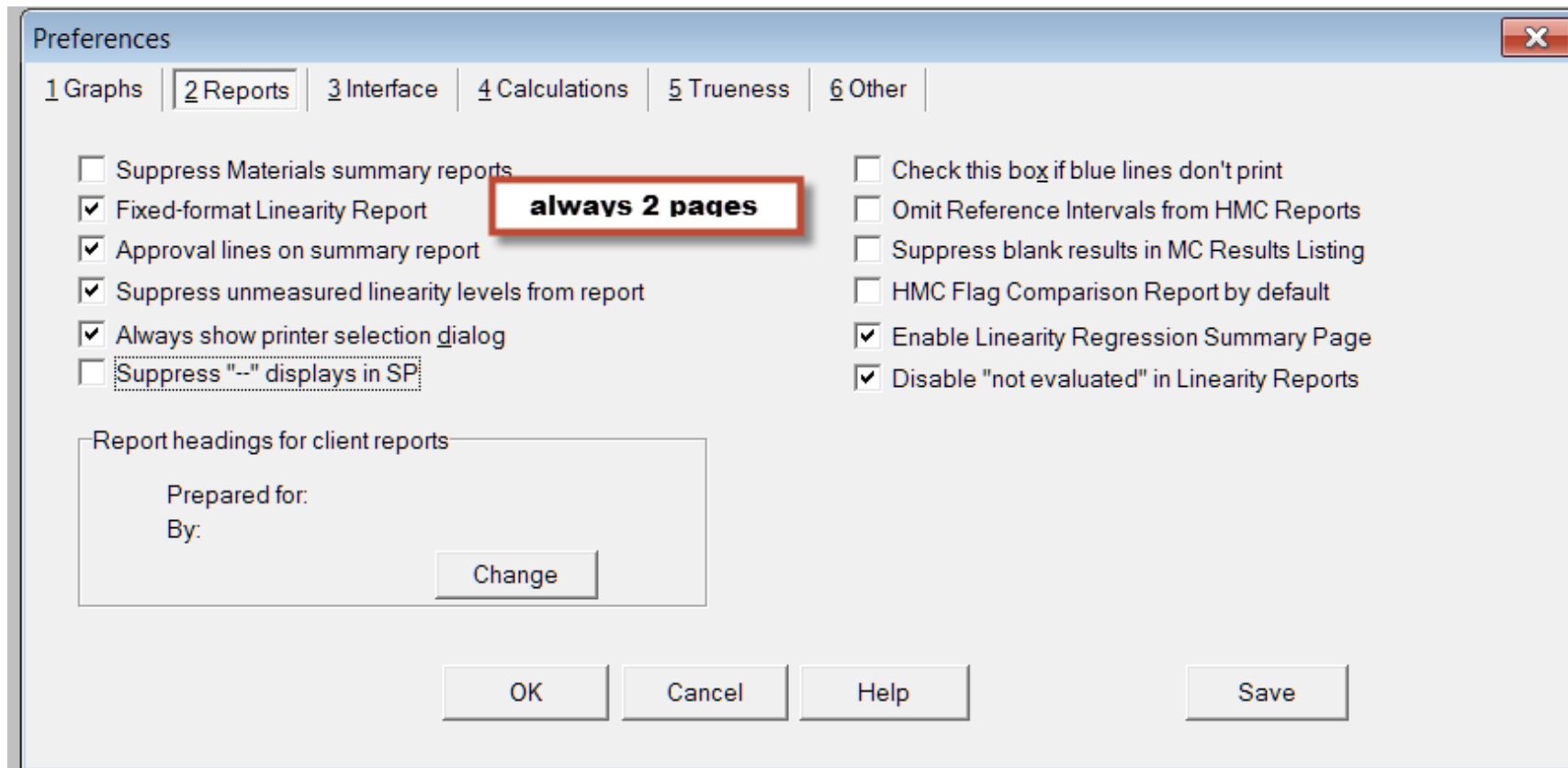
- **File**
  - New and Open projects
  - Import export: transfer projects and experiments
  - Preferences: set up special options for several modules.
  - Project inventory
  - Print / Print Preview / Print Setup
  - User Security – Professional version
- **Edit:** copy/paste / delete data
- **Module:**
  - 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 preferences.ini file that will apply to **all** projects on the local machine.



# Preferences Affecting Linearity Reports



# Preferences for Regression Graphs

**Preferences** [X]

1 Graphs | 2 Reports | 3 Interface | 4 Calculations | 5 Other

Scatter Plot Scaling

- Identical Scaling for X and Y axes
- Flexible Scaling

Bias Plot Style

- Standard (Bias vs X)
- Bland-Altman (Bias vs Avg X/Y)

Bias Plot Scaling

- Centered on Y Axis
- Location on Y Axis Calculated

These options do not apply to EP9, since the specification requires uniform scaling.

OK Cancel Help

# Preference Calculations

0.9907

Preferences X

1 Graphs | 2 Reports | 3 Interface | **4 Calculations** | 5 Trueness | 6 Other

AMC Passing-Bablok Type

None

Regression

Method Comparison

AMC Graph/MDP

Deming

Passing-Bablok

Calculate QMC/ROC Conf Intervals using

Score Method (CLSI recommended)

Exact Binomial Method

Minimum R for estimating MDPs from Deming Regression (AMC only)

0.975    0.950    0.900

When computing 90% CI for non-parametric Reference Interval, use index numbers from:

CLSI Table    Formula

Simple Precision Verification

Pass/Fail    Pass/Fail/Uncertain

Show I Test for Alternate Method Comparison

Allow limited amounts of missing MIC results

Allow 1-step difference in QMC with 5+ lvls

OK   Cancel   Help   Save

# 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		
<b>Distribution of Results</b>					
Range	<= 83.3	83.4-116.7	116.8-150.0	150.1-183.3	> 183.3
Percent	2%	98%	0%	0%	0%
<b>Other Statistics</b>					
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**

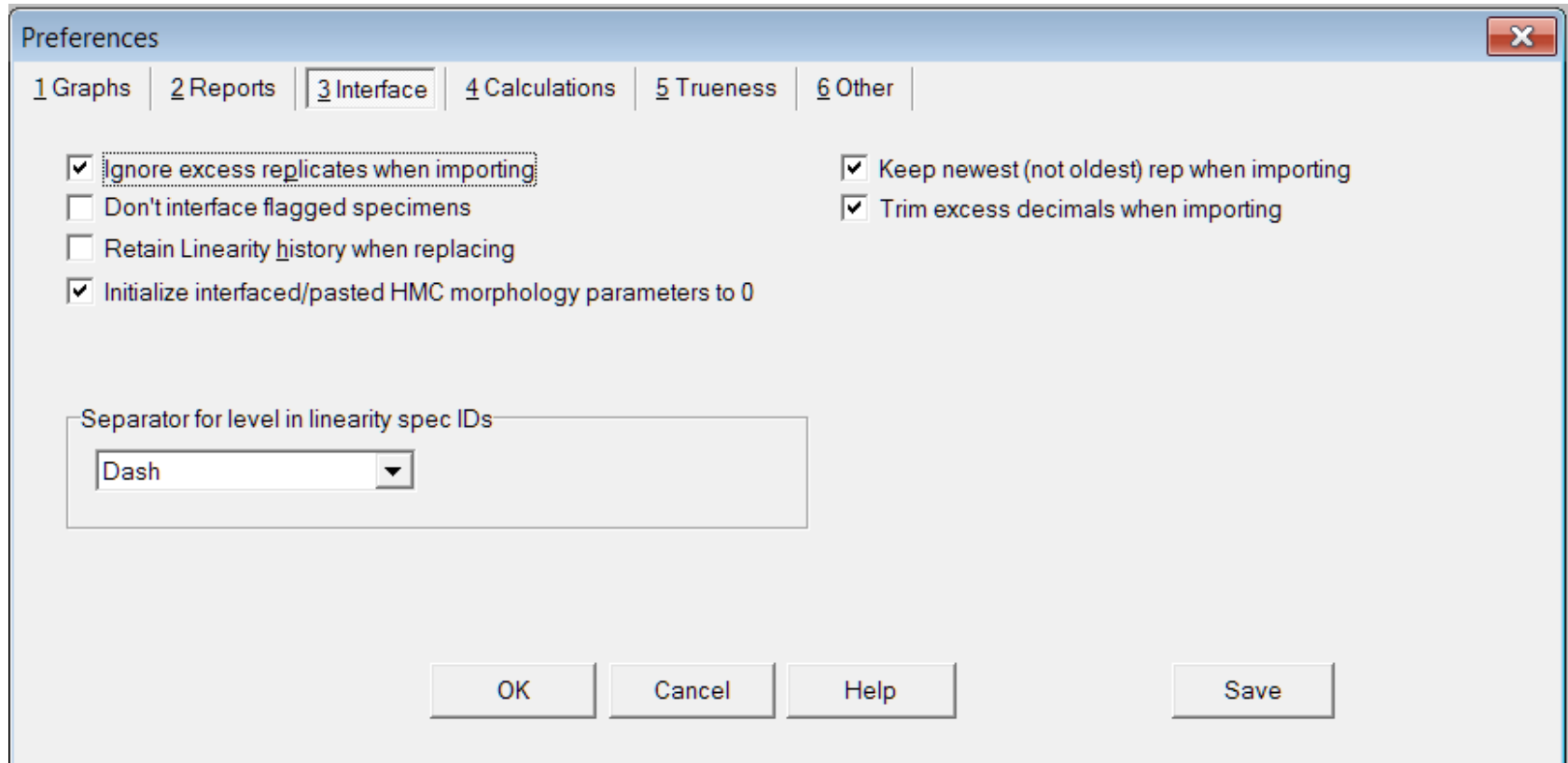
- Open the 3 lab management modules and create their icons
- CLIA PT limits table
- Glossary of terms

- **Help**

- Indexed and Searchable help
- Send a bug report
- Check for a newer major or minor version: automatic update as prompted
- Renew subscription



# Preferences affecting Interfacing or copy/paste



# For EE Support

- North America Telephone Support (802)-658-1955
  - [Northamerica-support@datainnovations.com](mailto:Northamerica-support@datainnovations.com)
- Europe telephone support +32 2 332 24 13
  - [Europe-support@datainnovations.com](mailto:Europe-support@datainnovations.com)
- Asia Telephone Support 852-2398-3182
  - [asia-support@datainnovations.com](mailto:asia-support@datainnovations.com)
- Latin America telephone support 55-11-38013283
  - [latinamerica-support@datainnovations.com](mailto:latinamerica-support@datainnovations.com)

# Additional Training & Services

- Visit the DI website for information on free training.  
<http://datainnovations.com/services/training/ep-evaluator-training-programs>
  - Overview and Getting Started with EP Evaluator
  - Project Management
  - RRE and Policy Definitions
  - Hematology Method Comparison
  - Determining Performance standards
  - Inventory Management
- For more in-depth training or consultation
  - Contact the DI Sales organization for a quote
    - 802-658-2050
    - [Northamerica-sales@datainnovations.com](mailto:Northamerica-sales@datainnovations.com)



[datainnovations.com](http://datainnovations.com)

# Thank You!