

EP Evaluator Overview

Overview and Getting Started with New experiments

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Viewing this presentation

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

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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 <u>http://datainnovations.com/node/255</u>

- 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. <u>www.cms.hhs.gov/clia</u>
 - 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 <u>collection of</u> <u>Experiments</u> from one or more Statistical Modules
- Experiment one set of data collected for a specific purpose for <u>one analyte</u>
- 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.



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 –

	EP Eva	aluator	[AACC/Dem	no EE11-0]			
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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"



Starting EP Evaluator



The About screen



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



The Welcome Screen

Welcome 🛛
QUALITY ASSURANCESIMPLIFIED
Would you like to
Open a Project
Other
Create a New Project
Get Help
OK Copyright 1991-2012 Data Innovations, LLC

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Project Default Default rre ExamplePolicies HMC Example Sample Data TROUBLESHOOTING B- chem B- cril B- EE Demo B- FSTH B- HIMG B- Test Hep
F

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Project Name

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

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File	Edit	Module	Experiment	RRE ERI View	Utilities	Tools	Help		
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Project

- A database folder containing your <u>collection</u> 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

	▶ Computer ▶ OS (C:) ▶ EE11.3.22	2 ► DATA ► STUDIES ► -	Search STUDIES	
Organize •	Include in library Share with	▼ New folder		·] 0
💈 🔝 Recent	▲ Name	Date modified	Туре	Size
LEE11.0 LShareP Deskto LEP Eval	 projdir.idx projdir.dat pathkey.txt dbisam.lck Sample Data MASTER 	11/17/2015 9:31 A 11/17/2015 9:31 A 11/17/2015 9:30 A 11/17/2015 9:30 A 11/17/2015 9:30 A 11/17/2015 9:30 A	IDX File DAT File Text Document LCK File File folder File folder	33 KB 4 KB 1 KB 1 KB
	 HMC Example Default carol^New 3 	11/17/2015 9:30 A 11/17/2015 9:30 A 11/17/2015 9:32 A	File folder File folder File folder	
S S	9 items			



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Creating a New Project



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

👫 EP Evaluator Release 8 [Pol	icyTest1]
File Edit Module Experiment RR	E ERI View
New Project	
Open Project	Project 🛛 🔀
Re-open Recent Project 🔸 👥	Prefig:
Project Inventory	
	Project Marrier
	Project Name.
	For Client
	Institution My Local Hospital Prenared for: Chemistry - My Local Hospital
	By: Clinical Laboratory Kennett Community Hospital
	UK Cancel Help

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)

Project 🛛 🔀
Prefix:
CHEM
Project Name:
Method comparison DXC 4562 to DXC 4875 July 2010
I▼ For Client
Department
Institution
🦳 No Audit Trail
OK Cancel Help

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

lilli	Project	t- Default			×
ſ	L 🔇 🛛				
	Module	Experiment Description	status		~
Đ	SP	ANALYZER / BUN / Medium	•		-
	СР	XYZ / GLUCOSE / HIGH	•]	
Ð	LIN	ASSAYER / AMMONIA maine st	•]	
	SA	Eximer 250 / Glucose	•	1	
œ	EP6	Eximer 250 / CO2	•]	
Đ	AMC	KIPLING / XYZ / EXAMPLE	•	1	
	2IC	METH1 / METH2 / DEFAULT	•	1	
	EP9	KIPLING / XYZ / EXAMPLE	•	1	
Đ	QMC	Chem Assay / Analyzer / Example	•	1	
Đ	POC	xMeth / yMeth / GLU2	•	1	
Đ	MIC	MIC-Q4-2000 / Glucose	•	1	
Ð	LOB	IMMUNOASSAYER / ALT	0	1	
	LOQ	ImmunoAssayer / TSH	•	1	
Ð	VRI	Analyzer / DHEAS	•	1	
€	INR-MC	XMeth / Y / PT	0	1	
	INR-Geo	Assayer / Protime	•	1	
	INR-Ck	Eximer 400 / PT / XYZ-2002	•	1	
	AON	Assayer / Glucose	•	1	
	со	Analyzer / HCG	•	1	
Ð	IF	Analyzer / AST / High / Hemoglobin	•	1	
	PSTD	Eximer 500 / Glucose	•	1	
	EP10	BUN ANALYZER / BUN	•	1	
Ŀ	ств	Evimer / ALT / 1234	0	1	×
27	' modules, 60	experiments			

HELP!

(<) (<) (<) file:///C:/EE11.2.23%20webinar/E	EHelp/EEHelp.htm#Reports/why_is_my_report_stamped_preli.htm%3FTo 🔎 🚽 🙋 🩋 EP Evaluator - Why is my re 🗙
File Edit View Favorites Tools Help	
DATA INNOVATIONS Simple Ideas, Better Solutions	
Contents	
What is EP Evaluator®?	∧
What's New in Release 11	
Resources Spreadsheets	Why is my report stamped PRFLIMINARY?
Key Concepts and Terms	
Interface Overview	Simple Precision
Common Operations	
Statistical Modules	N<3
II Reports	Complex Precision
Printing Reports	complex Precision
Print Preview	Less than 3 days; less than 6 runs
Saving a Report to Disk	•
Selecting a File Format	Linearity
Report Options	Less than 3 specimens
Why is my report stamped PRELIMINAR	n
Composite Reports	Simple Accuracy
Lab Management Modules	
Projects	Less than 2 specimens (each specimen must have at least 2 replicates)
📄 Creating a Project	FP6 Linearity
Opening a Project	al o antonny
Project Inventory	Less than 5 specimens (each specimen must have at least 2 replicates)
Merge Project Experiments	
File Manager	Alternate Method Comparison
Data Management	N < 3 more than 5% outliers: range of X with outliers excluded less than half the full range
Translation into non-English Languages	V Investment 3/2 outliers, range of A wat outliers excluded less than han the full fallye



Exploring Experiments

Starting with Alternate Method Comparison - AMC





Creating New Experiments

Starting with Alternate Method Comparison - AMC





- 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 –

	EP Eva	aluator	[AACC/Dem	no EE11-0]			
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EP Evaluator Release 9 [Default]							
--	---						
File Edit Module Experiment RRE ERI View	Utilities Tools Help						
	Project- Default						
Statistical Modules							
Precision Accuracy and Linearity	AMC Alternate Method Comparison - Uses Linear regression techniques to characterize the relationship between two methods.						
Method Comparison	CLSI-EP-9 - Implements the statistically rugged						
Alternate (Quantitative) CLSI EP9 Sens Qualitative and SemiQuant	to compare 2 methods using Linear regression.						
2-Instrument Comparison Reference Interenc	2-IC Two Instrument Comparison. Without using linear regression, clinical equivalency can be demonstrated between 2 methods in the same						
INR	Peer group that are expected to provide equivalent results within allowable error. (TEA)						
<u>O</u> ther							
<u>T</u> utorial							

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

In EP Evaluator /	Alternate N	lethod	l Co	mpa	rison	[DINA	policies S	Sept 2(
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4140	X Method	Analyte	N	Slope	Intercept	Corr Coef (R)		
AIMC	• DINA 2331	ALB	5/5	1.134	-0.36	0.9997		
-Y Method	DINA 2331	BUN	54/54	0.995	0.1	0.9996		
DINA 3006	 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		
Legend	Available Me	thods						
Not Calculated O Insufficient Data		DINA 2000						
Sufficient data Fail Ress	Analytes for D	INA 2331						
 Pass May need review 	ALB	BUN	СНО	DL	CRE	ETO		OSE
						(

Creating a new experiment

- Click the New Experiment icon, o 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

EP Evaluator S	[DINA policies	
File Edit Module	Experiment RRE	ERI View Utilities
D 😼 🛎 🖩 🙃 🚳 🖪	New	Ctrl+N
	New from Policies	Ctrl+P
Simple Precision	Open	Ctrl+O
Instrument	Delete	
	Link X/Y Methods	

Create Experiment							
X Method	Med-E						
Y Method Analyte	Calcium						
	Glucose Sodium						
UK	Cancel Help						

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.

Analyte	Glucose		
	Chacose		
	X Method	Y Method	
Method	cobas 6000	cobas 2	
Units	mg/dL 💌	▼	
Date	18 May 2015	18 May 2015	
Analyst	Inez Kruse	Inez Kruse	
Comment			
Allowable Tot	al Error (TEa)	Reportable Range	
Conc	6	Lower Limit 5	
Percent	10	Upper Limit 10	00
Medical Decis	ion Points		
40	70 110	126 350	
1.0	1		
Max Docimal P	lacos Auto	1	
Max Declinal F		1	
	ок с	Cancel Help	

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.

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	SF	PEC3		30		32				
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	SF	PEC5		50		48				
	SF	PEC6		60		56	i			

EP	Eval	uator A	MC [Defau	ılt			
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▶	Pas	te with Po	olicies	•			
Delete All Results							

EE Resources Folder

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

							×
Computer 🕨 🤇	OS (C:)	► EE11.2.23 webinar ► Resources ►		-	 ✓ ✓ Search R 	esources	Q
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laces 😓 Recent Places		🗏 e9Res-InvMan-Materials-Oct2007.pdf	11/20/2010 12:42	Adobe Acrobat D	62 KB		
👢 EE11.0		\rm e9Res-LISFormats.pdf	11/20/2010 12:42	Adobe Acrobat D	92 KB		
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👢 Gala 2014		HMC example.xls	3/19/2014 9:54 AM	Microsoft Excel 97	234 KB		
		ResteERIList.xls	6/28/2012 2:41 PM	Microsoft Excel 97	166 KB		
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Documents		ResteParmsInSS.xls	3/12/2015 10:21 A	Microsoft Excel 97	237 KB		
🕹 Music		PasteWithPoliciesList.xls	3/9/2015 12:29 PM	Microsoft Excel 97	269 KB		
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🚴 Carol R. Lee		💷 TEASim.exe	10/29/2006 10:43	Application	2,156 KB		
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📴 All Control Panel Items							
Note: Appearance and Persona	liz 👻						
10 itoms							

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.





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 Sigma (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 Image: Construment Compare Image: Construment Construment Construment Construment Compare	∲
OK	Cancel Help	

Generate Composite Report

EP Evaluator [Default]	Generate Composite Rep	ort
File Edit Module Experiment RRE New Project	ER: StatMod Lin (Linearity)	Creation Date/Time
Open Project Re-open Recent Project	2IC (2 Instrument Compare) SP (Simple Precision)	1/20/2012 8:17:56 AM 1/20/2012 8:17:46 AM
Project Inventory Import Export	INR-Chk (Coag-INR Manual Check) INR-Geo (Coag-INR Geometric Mean & VRI) INR-MC (Coag-INR Method Comparison)	1/20/2012 8:18:38 AM 1/20/2012 8:18:22 AM 1/20/2012 8:18:30 AM
Composite Report Setup Generate		
Print Print Preview CR Print Preview Printer Setup	Composite Report File Name C:\Documents and Settings\criee.DINA\My Document Display Composite Report PDF after generation	s\CLIA Verifications-29-Feb-2012-14-39-38.PC <mark>é</mark>
Preferences Security > Self Test	Generate	tel Help
Exit		

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 10.0.0.517 Default Printed: 29 Feb 2012 14:41:26 Copyright 1991-2012 Data Innovations, LLC

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EP Evaluator[®]

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INR-Geo (Coag-INR Geometric Mean & VRI)	24
INR-MC (Coag-INR Method Comparison)	26

Report headers, logo, etc.

Prepared for: Account 55081612 - West Penn Hospital By: WIN 7 54 bit -- Council Bluffs MC

- 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.

EP Evaluator 9.6.0.466 West Penn/West Penn cobas 6000s c

	Simple	e Precision			
	ſ	Preferences			
		1 Graphs 2 Reports	3 Interface 4 Calculation	ns <u>5</u> Other	
		Suppress Materials	summary reports ity Report ummary report	Change Report Headings	if blue lines don't print
	-	Suppress unmeasu Always show printe Report headings for cl Prepared for:	rred linearity levels from rep r selection <u>d</u> ialog ient reports	Prepared for: Prepared for: By: By:	spared for
		By:	Change OK	Defaults	OK Cancel
About EP Evaluator			Project		
. ⁹	EP Evaluator Release 9 Build 9.6.0.466		Prefix: West Penr Project Nar West Penr	me: n cobas 6000s core SNs 1-	4K9-09 & 14M1-01
	You are user 1 of 3		For Cli	ient	
Registered to: WIN 7 54 bit Council Bluffs MC	\supset		Departi	ion West Penn Hospi	2 tal
Council BLuffs, IA SQ03-9427G765-2 Copyright 1991-2012	24JAN2015			OK Cancel	Help
www.dgrhoads.com		ок		2/10/09	

Calcium

Instrument: c501-1 14E2-09

Sample Name: CC2

Menu Bar Options





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.

File	Edit	Module	Experiment	RR	
	New P	roject			
	Open Project				
	Re-open Recent Project				
	Project Inventory				
	Import				
	Export				
	Composite Report				
	Print				
	Print P	review		- 1	
	CR Print Preview				
	Printer	Setup			
	Prefere	ences			
	Securi	ty			
	Self Test				
_	Exit				

Preference Calculations

Preferences	X	
<u>1</u> Graphs <u>2</u> Reports <u>3</u> Interface <u>4</u> Calculations <u>5</u> Trueness	<u>6</u> Other	
AMC Passing-Bablok Type O None O Regression Method Comparison AMC Graph/MDP O Deming Passing-Bablok	Calculate QMC/ROC Conf Intervals using <u>S</u>core Method (CLSI recommended) <u>E</u>xact Binomial Method 	
Minimum R for estimating MDPs from Deming Regression (AMC only)	When computing 90% CI for non-parametric Reference Interval, use index numbers from:	
	CLSI Table Formula	
Simple Precision Verification	Show <u>T</u> Test for Aternate Method Comparison	
Pass/Fail Pass/Fail/Uncertain	 Allow limited amounts of missing MIC results Allow 1-step difference in QMC with 5+ lvls 	
OK Cancel	Help	

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	150.1-18	33.3 > 183.3
Percent	2%	98%	0%	0%	0%
Other Statistics					
Points (Plotted/Total)	296/297				
Outliers	Not Tested Description Deble all an able all hu				
SubRange Bounds	None	Fassi	ny bablock enable	eu by	
Corr Coef (R)	0.9862		preferences		
Bias	0.0 (0.0 %)		protoronooo		
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	Red	type indicates ide	al slo	ope of 1.0
Rep SD X	1				
Rep SD Y	1	OF I	ntercept of 0.0 is i	not w	ithin the
SD of differences	0.9		confidence int	orval	s
Paired T Test	0.95		confidence in	ei vai	13
T Probability	0.344				
Degrees of Freedom	294				

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		×
1 Graphs 2 Reports 3 Interface 4 Calculati	tions <u>5</u> Other	
Scatter Plot Scaling Identical Scaling for X and Y axes <u>Flexible Scaling</u>	Bias Plot Style	
Bias Plot Scaling © <u>C</u> entered on Y Axis © <u>L</u> ocation on Y Axis Calculated		
These options do not apply to EP9, since the specification requires uniform scaling.		
ОК	Cancel Help	

Preferences Affecting Linearity Reports

Preferences	
<u>1</u> Graphs <u>2</u> Reports <u>3</u> Interface <u>4</u> Calculations <u>5</u> Trueness	<u>6</u> Other
Suppress Materials summary reports	Check this box if blue lines don't print
Fixed-format Linearity Report always 2 pages	Omit Reference Intervals from HMC Reports
Approval lines on summary report	Suppress blank results in MC Results Listing
Suppress unmeasured linearity levels from report	HMC Flag Comparison Report by default
Always show printer selection <u>d</u> ialog	Enable Linearity Regression Summary Page
Suppress "" displays in SP	Disable "not evaluated" in Linearity Reports
Report headings for client reports Prepared for:	
Dy. Change	
OK Cancel	Help Save

Preferences affecting Interfacing or copy/paste

Preferences				
<u>1</u> Graphs <u>2</u> Reports <u>3</u> Interface <u>4</u> Calculations <u>5</u> Trueness	<u>6</u> Other			
 ✓ Ignore excess replicates when importing ✓ Don't interface flagged specimens ✓ Retain Linearity history when replacing ✓ Initialize interfaced/pasted HMC morphology parameters to 0 				
Separator for level in linearity spec IDs Dash				
OK Cancel	Help Save			



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Projects

Open a project

Create a new project

Inventory

Manage your projects





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Creating a New Project



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

👫 EP Evaluator Release 8 [Pol	icyTest1]
File Edit Module Experiment RR	E ERI View
New Project	
Open Project	Project 🛛 🔀
Re-open Recent Project 🔸 👥	Prefig:
Project Inventory	
	Project Marrier
	Project Name.
	For Client
	Institution My Local Hospital Prenared for: Chemistry - My Local Hospital
	By: Clinical Laboratory Kennett Community Hospital
	UK Cancel Help

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)

Project 🛛 🛛 🛛
Prefix:
CHEM
Project Name:
Method comparison DXC 4562 to DXC 4875 July 2010
✓ For Client
Department
Institution
🔲 No Audit Trail
OK Cancel Help



Managing Projects



Active Project Management Functions

- Open/Reopen
- Create



- 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)

File Manager [Public]			×
File Options			
Project ⊡- <blank></blank>	Creator		Close
Default HMC Example			Help
Sample Data			Operations on Projects:
⊕, rel 102 val ⊕, VAL 101			Backup
	copy a proje	ect - new in Rel 10.2	Rename
			Сору
			Delete
			Quick Repair
			Full Repair
			Clean
			Decimal Sep.
			Inventory
Backup Files: Backup Folder:	C:\EE10.2 546\DATA\BACKUPS	6	Operations on
Name	Size Modified 🔺		Backup Files:
🚺 EE9 backup of Sample Data.zip	276 KB 6/18/2012 3:16 F	M	
EE9 backup of Example Policies.zip	186 KB 6/18/2012 3:17 F	PM	Rectore
III EE9 backup of HMC Example.zip	309 KB 6/18/2012 3:17 F 275 KB 9/26/2012 1:02 F	۲۷I M	
	2,0,00 9/20/2012 1.021		Delete
			Copy to

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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 Project 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"



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What's new in EE 11.1?

You asked for it!!



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



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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

Non-Hematology	Hematol	ogy						
Non-Hemato Settings for all statisti modules EXCEPT Hematology Method Comparison.	ology cal	Select Inst Inter <u>f</u> ace Setti Instruments	trument Class	3				
An	alytes	·						×
E	dit							
Π	Analyte	Units	Max Decimal	Coag Flag*	For li	nst Cap	ture Only	
	/ and yte	011113	Places	oodg i idg	InstCod	e	Factor	
	Estradiol	pg/mL	0		713	1		
	ЕТОН	mg/dL	1		2847	1		
Editing class	Fe	ug/dL	0		2960	~~		
Architect	Ferritin	ng/mL	0		61	IM tes	st 📃	
L	Ferritin-Mul				2906	codes	s	
	Folate El	ther IM test code	es or comm	on	685			
	Free PSA	ame labels			221			
	FSH	mice	۷.		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		

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Instruments

Names or Serial Numbers as defined in IM

Non-Hematology Hem	atology				
Non-Hematology Settings for all statistical modules EXCEPT Hematology Method Comparison.	Select Ins Interface Sett Instruments	trument Class			
Editing class Architect	Instrument Architect Archie Edith	S Model Generic	Serial No Generic 123456 78910	MIC Abbre ARch Edith	
	F3 Add	F4 Delete	ок	Cancel	Help

Analyte settings depend on Modules / Options selected

Minimal

Non-Hematology		Hema	atology	/			
Non-Hemat		Analy	∕te ∣	Para	amet	ers	- K
Settings for all statis	-	Edit					
Hematology Method		A 1 - 4 -	1	vledica	l Decisi	on Poin	ts
Comparison.		Analyte	1	2	3	4	5
	Þ	%A1c	4	6			
	1	A-1-AGP	50	120			
		A1-AT	84	200			
		Acet	10	30			
		ACP	0	6			
		AlbG	3.5	5			
		AlbP	3.5	5			
		AlkP	40	150			
Editing class		ALT	0	55			
Architect		Amikacin	5	25			
		Ammonia	18	72			
		AmpQ		1000			
		AmpSQ		1000			
		Amy	25	125			
		Amy-U	1	17			
		Anti-CCP		5.0			
		Anti-HCV		0.8			
		Anti-TG	0	4.11			
		Anti-TPO	0	5.61			
		АроА	95	223			
		АроВ	49	182			
	٦	Key					

Most pass/fail options selected

Non-Hematology		Hema	atology																
Non-Hemato	!	Analy	∕te I	Para	ım	ete	ers -	Key	/										
Settings for all statis		Edit			1														
modules EXCEP1 Hematology Method Comparison.	Γ	Analyte	Allov Tota	vable I Error		En		Rep	ortable	Pro	.ow ximity imit	Hi Prox Li	gh simity mit	No Ra	rmal inge	4	/ledical	Decisio	on Po
			Conc	Pct	1	op	tional, d	epend	on	onc	Pct	Conc	Pct	Low	High	1	2	3	4
	▶	%A1c	1.0	25	51	mo se	odules a lected	ina opt	ions		50		10	4	6	4	6		
	Γ	A-1-AGP		16.2	50						50		10	50	120	50	120		
	Γ	A1-AT		20	50		20	20	000.0		50		10	84	200	84	200		
	Γ	Acet		25	50		25	3	377		50		10	10	30	10	30		
	Γ	ACP		10.3	50		25	0.8	87.9		50		10	0	6	0	6		
	E	AlbG		10	50		25	0.4	10.5		50		10	3.5	5	3.5	5		
Editing close		AlbP		10	50		25	0.4	11.0		50		10	3.5	5	3.5	5		
		AlkP		30	50		25	5	4555		50		10	40	150	40	150		
Architect		ALT		20	50		25	6	4113		50		10	0	55	0	55		
	Γ	Amikacin		14	50		25	1.0	50.0		50		10	5	25	5	25		
		Ammonia	3	10	50		25	4.70	997.90		50		10	18	72	18	72		
	Γ	AmpQ		30	50		25				50		10				1000		
	IT.	La		20	0.0		00	100	0000		50		10				1000		

Linearity sets

(it/Material* ALKP ENZ ALT ENZ AMY ENZ AST ENZ		Mo % S % S % S % S Pre-	de l plit / plit / plit / plit / Asan /	InstCode ALKP ENZ ALT ENZ AMY ENZ AST ENZ	% or Ind			
- 01* - 02* - 03* - 04* - 05*		Dra	Acces (T W	he pro	efix fo un on	or the s the ar	pecIDs alyzer
I GGT ENZ Kit LD ENZ VERI%	H K Edit Targ	it AUD	IT ions of Anal	ytes by Speci	men:			
Sterrod metor		Analyte	01	02	03	04	05	
ck Edit with t	1	%A1c	4.0	8.0	12.4	16.6	21.2	
k Edition a	1	Acet	0	47	05	1.40	100	
- Lancon a	14	INCEL	0	47	30	142	190	
ded items	3	AlbG	1.5	2.6	3.8	4.9	6.0	
ded items dited.	3	AlbG AlbP	1.5	2.6	3.8 3.8 3.8	4.9	6.0 6.0	
ded items adited.	2 3 4 5	AlbG AlbP Ammonia	1.5 1.5 28	2.6 2.6 174	3.8 3.8 3.8 321	4.9 4.9 467	6.0 6.0 613	
ded items adited.	2 3 4 5 6	AlbG AlbP Ammonia ApoA	1.5 1.5 28 10	2.6 2.6 174 346	3.8 3.8 3.8 321 643	4.9 4.9 467 1000	6.0 6.0 613 1299	
F2 Edit	2 3 4 5 6 7	AlbG AlbP Ammonia ApoA ApoB	1.5 1.5 28 10 0	2.6 2.6 174 346 134	35 3.8 3.8 321 643 274	142 4.9 4.9 467 1000 378	190 6.0 6.13 1299 487	
F2 Edit	2 3 4 5 6 7 8	AlbG AlbP Ammonia ApoA ApoB ASO	1.5 1.5 28 10 0 20	2.6 2.6 174 346 134 544	35 3.8 3.8 321 643 274 853	142 4.9 4.9 467 1000 378 1276	190 6.0 6.13 1299 487 1828	
F2 Edit	2 3 4 5 6 7 8 9	AlbG AlbP Ammonia ApoA ApoB ASO BilD	1.5 1.5 28 10 0 20 0.1	2.6 2.6 174 346 134 544 3.0	35 3.8 3.8 321 643 274 853 5.9	142 4.9 4.9 467 1000 378 1276 8.8	190 6.0 6.13 1299 487 1828 11.7	
F2 Edit	2 3 4 5 6 7 8 9 10	AlbG AlbP Ammonia ApoA ApoB ASO BilD BilIT	1.5 1.5 28 10 0 20 0.1 0.1	47 2.6 2.6 174 346 134 544 3.0 5.7	35 3.8 3.8 321 643 274 853 5.9 11.3	142 4.9 4.9 467 1000 378 1276 8.8 16.8	190 6.0 6.13 1299 487 1828 11.7 22.4	
F2 Edit	2 3 4 5 6 7 8 9 10 11	AlbG AlbP Ammonia ApoA ApoB ASO BilD BiliT BilT	1.5 1.5 28 10 0 20 0.1 0.1 0.1	47 2.6 2.6 174 346 134 544 3.0 5.7 5.7	35 3.8 3.8 321 643 274 853 5.9 11.3	142 4.9 467 1000 378 1276 8.8 16.8 16.8	190 6.0 6.13 1299 487 1828 11.7 22.4 22.4	
F2 Edit	2 3 4 5 6 7 8 9 10 11 12	AlbG AlbP Ammonia ApoA ApoB ASO BilD BilIT BilT Ca	1.5 1.5 28 10 0 20 0.1 0.1 0.1 0.1 1.6	47 2.6 2.6 174 346 134 544 3.0 5.7 5.7 5.7 5.1	35 3.8 3.1 643 274 853 5.9 11.3 11.3 8.6	142 4.9 4.9 467 1000 378 1276 8.8 16.8 16.8 12.1	190 6.0 6.13 1299 487 1828 11.7 22.4 22.4 15.6	
F2 Edit	2 3 4 5 6 7 8 9 10 11 12 13	AlbG AlbP Ammonia ApoA ApoB ASO BilD BilT Ca Ca CA 15-3	1.5 1.5 28 10 0 20 0.1 0.1 0.1 1.6 16	47 2.6 2.6 174 346 134 544 3.0 5.7 5.7 5.1 283	35 3.8 3.8 321 643 274 853 5.9 11.3 11.3 8.6 550	142 4.9 4.9 467 1000 378 1276 8.8 16.8 16.8 12.1 817	190 6.0 6.13 1299 487 1828 11.7 22.4 22.4 15.6 1084	
F2 Edit	2 3 4 5 6 7 8 9 10 11 12 13 14	AlbG AlbP Ammonia ApoA ApoB ASO BilD BilT BilT Ca Ca CA 15-3 CaC	1.5 1.5 28 10 0 20 0.1 0.1 1.6 16 1.6	47 2.6 2.6 174 346 134 544 3.0 5.7 5.7 5.1 283 5.1	35 3.8 321 643 274 853 5.9 11.3 8.6 550 8.6	142 4.9 4.9 467 1000 378 1276 8.8 16.8 12.1 817 12.1	190 6.0 6.13 1299 487 1828 11.7 22.4 25.6 1084 15.6	

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

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Exploring the Modules



EP Evaluator Release 9 [Default] Edit Module Experiment RRE ERI View File Utilities C 📲 🛩 🏛 🖻 🗁 🖪 🖏 🔟 🗂 **Project-Default** Statistical Modules Precision Simple Complex (incl CLSI EP5) Accura Linearity Method Comparison Sensitivity

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

Tools

Help

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.

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Reference

Interval

INR

Other

Tutorial

Confidential

-

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



Histogram of Precision data



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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

Ing E	P Evalu	ator R	lelease	e 9 Lii	neari	ty [Def	fault]						
Fil	e Edit	Module	Exper	iment	RRE	ERI View	Utiliti	es Tools	Help				
								Instrum	nent	Analyte			
			1998 IIII					ASSA	AYER	GLUCOSE			
								Accuracy an	d Linearity				
			GLUCOSE	: Scatter Plo	ot			Spec ID		Assgn'd	Mean	% Rec.	Resid
1	500 Clin Lin	Slope	Intept Obs I	Err			1.	kev1		25.0	25.5	102.0	-0.9
	All Points	0.984	2.6 1.72	mg/dl or 2.99	16		11	CalKit-2		100.0	101.5	101.5	0.1
	w/o Outlier	s 1.UUU	1.5 0.95	mg/dl or 1.6%	10		1.	CalKit-3		250.0	249.5	99.8	-1.9
						1.		CalKit-4		400.0	407.8	101.9	6.5
						1.		CalKit-5		700.0	690.3	98.6	-10.9
						1		CalKit-6		1000.0	958.8	95.9	-42.3
Measured (mg/dl)	500 -	- 1:1 Line Assigned	500 A Fit	ssigned (mg/d ted Overall Rep 1	1,000 JI) Fitto	ed ex outliers	1,500 Rep 4						
	pec iD	25.0	25.5	24	26	25	27	1					
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	ainit'z	100.0	240.5	101	102	240	103						
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4 (0	ankit-4	400.0	407.8	400	410	409	412						
5 0	aikit-5 5//it-6	1000.0	690.3	055	696 070	680	050						
	aint 'U	1000.0	530.0	120	970	900	530						
F- Excl.	F5 Spec Exclude	F6 Clear Flags	F7 Parameters	F9 History							ery (Residual)	History /	

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

Set up Target ranges.

nsuu			Analyte.	Glucos				
Jnits	5:	Analyst:	Date:		_			
ng/o	dL 🗾	mkf	16 Jul 20	009	Speci	mens and Assi	igned Values	
Aax Auto	decimal places:	🔽 Confir	m Reportable R	lange	L1 L2 L3		28.2 281.1 578.6	~
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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	X 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	X 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	X 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

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)

Specimen	Assigned Value	Mean	Poly. Fit	Line Fit	Deviation from Linearity	Deviatio 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

Evaluation Criteria	
Allowable Total Error (TEa) % for Nonlinearity	10 U/L (conc) or 14.0%

5 U/L (conc) or 7.0%

If applicable

Allowable Nonlinearity

Use weighted regression?

 Supporting Data

 Slope
 1.048 (1.039 to 1.058)

 Intercept
 -3.8 (-8.1 to -1.1)

 Analyst
 DH/LP

 Date
 21 Oct 2011

 Units
 U/L

 Value Mode
 Pre-Assigned

 Controls

 Reagents

Comment

CLSI EP06 pg 2

EPEV E 11.2.23 Webinar - Co	alua mmunity Hosp		D r ® Clsi	EP6 l	.inea	rity	Instrument	GC t Axcel
			Expe	erimenta	l Result	ts		
Specimen	Mean	SD	cv	Measu	ed Concen	trations		
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	7.0	0.0	794	793	806		
9	897.0	14.2	1.6	881	908	902		
10	984.7	16.6	1.7	967	1000	987		
Pooled		72	52.2					
Degrees of Freedom		22	22					
Bartlett's n		0 000	0 000					
Accept equality hypot	hesis?	No	No					
				x Exd	uded			
		Coef	Polyne ficients and	omial Fi	t Analy	sis	Std Error	"Best"
Polynomial	Constant		X	X^:	2	X^3	of Estimate	Polynomi
Line	-3.609 2.9		1.048 218.9				4.908	
2nd Order	-3.269 2.3		1.041 69.6	1.456E 0.57	-005		4.968	
3rd Order	0.05346		0.9183	0.0008	i089	-4.861E-007	2.673	Best

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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

III EP Evaluator 1	٢r	ue	eness	Tru/re	ele	ease 35]				
File Edit Module	E	xŗ	periment	RRE	E	RI View	Utilities	Tool	s He	elp
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			Measurand	Level		Uncert Abs/%	Lab Mean	%Bias	Passes	
IRU		٠	Cholesterol	Sample-EQ	A	0.4/12.5	5.52	1.7/-7.5	No	
Method		٠	Cholesterol	Sample-EQ	С	0.50/9.7	5.470	-0.4/1.3	No	
DxC800 3588										

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



Method Compariso 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



0

0

50

100 150 200

KIPLING (mg/dl)

300

250

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



	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	Y Method	95% Conf. Limits		
MDP	Pred. MDP	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		

EP Evaluator Release 9 [Default]	
File Edit Module Experiment RRE ERI Vi	ew Utilities Tools Help
	Project- Default
Statistical Modules Precision Accuracy and Linearity Method Comparison	
Alternate (Quantitative) CLSI EP9 Qualitative and SemiQuant 2-Instrument Comparison Refer Inte Inte Glucose POC Instrument Evaluation Hematology Studies	
I <u>N</u> R Other Tutorial	MIC - Compares 3 - 30 instruments without using linear regression, by assessing results compared to a target, within allowable error (TEA)

 $\boldsymbol{<}$

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



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Results Listing

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



Glucose Experiment: lab

Multiple Instrument Comparison

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

Parameters Screen – Edit Instrument List

MIC Parameters	×						
Expt Name: Iab	Analyte: Glucose						
Units: Max decimal places mg/dL Auto	Analyst: Date: CRL 16 Jun 2011						
Allowable Total Error (TEa) Concentration Percent 8 12 Reportable Range Low Limit High Limit	Instruments 1108093 1108093 1108107 108107 1508107 1508107 1908119 1908119 2508093 2508093 2608119 2608119 3008093 3008093	Inst	rument	ts			×
Comment	Edit		Name	Description	Model	Serial No.	
		4	1908119	1908119		1908119	
		5	2508093	2508093		2508093	
		6	2508099	2508099		2508099	
		7	2608119	2608119		2608119	_
		8	3008093	3008093		3008093	_
		9	3308093	3308093		3308093	_
		10	3608099	3608099		3608099	_
		11	4908093	4908093		4908093	_
		12	4908119	4908119		4908119	-
		13	5308099	5308099		5308099	_
		14	5408093	5408093		5408093	_
		15	7308078	7308078		7308078	_
		16 T	XYZ-C	Eximer XYZ		XYZ Core	×
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	Refe	Multip	e Instrument (Compariso	n					
	Inte	Hemat	e POC Instrum ploav Studies	ent Evalua	tion					
	I <u>N</u> R		57							
	<u>O</u> ther	QMC - Produces a concordance table that evaluate the degree of agreement between 2 methods that report two to six possible result states.				ates t				
	Tutori	al								

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

Number excluded or missing: O



Data Entry – Gold Standard



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Not Gold Standard



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

	Refer			
Test	1 (neg)	2 (pos)	Total	
1 (neg)	222	14	236	
2 (pos)	15	285	300	
Total	237	299	536	
	Number exc	cluded or missing: 0		
Agreement: 94.6% (92.3 to 96.2%	b Pos Agree	ement: 95.3%	Neg Agreement: 93.7%	
Symmetry test PASSES (p = 0.8	53) Test < Re	f: 14 (2.6%)	Test > Ref: 15 (2.8%)	

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Kappa: 89.0% (85.1 to 92.9%)

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.

Numeric, large are POSITIVE				Numer	ic, large are f	POSITIVE
Level	Cutoff Values	Report Names		Level	Cutoff Values	Report Names
1		Very Negative	>>	1		Very Negative
2	100	lower than 0		2	100	Negative
3	200	Positive		<<	3 200 Pos	Positive
4	300	Very Positive		4	300	Very Positive
5	400	WOW		5	450	VVP
6	500	Critical Value		6	550	Critical Value
				· · · · ·		

Example – large numbers are negative

fine	Result	s Coding					
Levels	4	€ (2-6)	н	DL cho	lesterol (ex	ample)	
Define "Result descrip column Click th	the levels in : Value" is the otion to print o o contains the ne Help buttor	order from least posi e value as it appears on the report. When e cutoff values. n for examples.	itive to most p in your Result using numeria	oositive. ts Data. ' : results	'Report Name with cutoffs, 1	" is the level the Result Value	
Referen Results Numer	ce Method format: ic, large are M	NEGATIVE 💌		Test Me Results	thod format: ic, large are f	NEGATIVE	-
Level	Cutoff Values	Report Names		Level	Cutoff Values	Report Names	
1	300	no risk		1	300	no risk	
2	80	small risk		2	80	small risk	
з	60	borderline		3	60	borderline	
4		quadruple bypa		4	-	quadruple bypa	as
5			_	5	-		
0				<u>в</u>			
		ок	Cancel		Help		

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Allow 1 step difference to accommodate "gray zones" *

Ref. Method: Chem Assay

Test Method: Analyzer



* Enabled in preferences



POC Glucose Zones of Clinical Impact

Clarke Grid



Cum

Percent

90%

93%

98%

98%

100%

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



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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%.



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

Reference Interval Histogram



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Establish Reference Intervals - ERI

Reference Interval Estimation: Combined

	Centra	al 95% Interva (N = 240)	1		
	Lower		U	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.



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

Selection Criterio

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EP Evaluator Release 9 [Default]					
File Edit Module Experiment RRE ERI Vie	w <u>U</u> tilities T <u>o</u> ols <u>H</u> elp				
□ ■ ■ ■ ■ □ □ □ ► Project- Default ■ ■ □ □ ► ■					
Statistical Modules					
Precision Accuracy and	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,				
<u>M</u> ethod Comparison	and drift. Carryover - Calculates specimen to specimen				
<u>S</u> ensitivity	carryover. Six Sigma Metrics- Uses bias and precision				
Reference Interval	statistics to determine if a method meets the criteria for six sigma performance (an error rate of ~ 3 in a million)				
I <u>N</u> R Other	Performance Standards – Calculate TEA using several different criteria including peer group data				
CLSI EP10 Preliminary Evaluation Carryover <u>Tut</u> Six Sigma Metrics Performance Standards	Interference - Determiness the maximum amount of interferent that allows reporting of a clinically				
Interference (CLSI EP7) Cost per Test Average of Normals Histogram and Descriptive Stats	acceptable result.				
Stability	Confidential 14				

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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.




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Average of Normals

Average of Normals

Glucose Daily Medians (Sat/Sun excluded)



Questions and Discussion white board

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Thank You!

