

Introducing EP Evaluator[®] RELEASE 9

Essential Quality Assurance for the Clinical Laboratory

Upgrade Your Lab's Performance With The Industry Standard in Clinical Laboratory Quality Assurance Software

EP Evaluator[®]

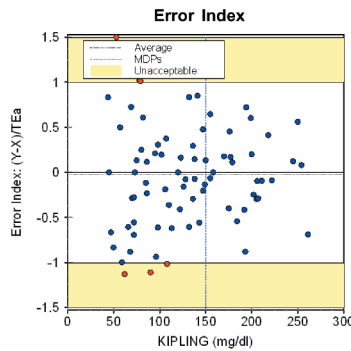
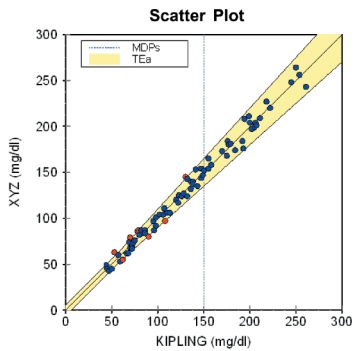
User's Manual -- Data Innovations, Inc.

EXAMPLE

Two Instrument Comparison

X Method: KIPLING

Y Method: XYZ



Evaluation of Results

EXAMPLE was analyzed by methods KIPLING and XYZ to determine whether the methods are equivalent within Allowable Total Error of 6 mg/dl or 10%. 80 specimens were compared over a range of 44 to 261 mg/dl. The test FAILED. The difference between the two methods was within allowable error for 72 of 80 specimens (90.0%). The average Error Index (Y-X)/TEa was -0.02, with a range of -1.13 to 1.67. The largest Error Index occurred at a concentration of 53 mg/dl.

Key Statistics:

Average Error Index -0.02
 Error Index Range -1.13 to 1.67
 Coverage Ratio --

Deming Regression Statistics:

$Y = \text{Slope} * X + \text{Intercept}$
 Correlation Coeff (R) 0.9930
 Slope 1.009 (0.982 to 1.036)
 Intercept -1.4 (-5.2 to 2.4)
 Std. Err of Estimate 6.8
 N 80 of 80

Evaluation Criteria:

Allowable Total Error 6 mg/dl or 10%
 Reportable Range --

Experiment Description

	X Method	Y Method
Expt Date:	01 Jun 2000	01 Jun 2000
Result Ranges:	44 to 261	43 to 264
Mean ± SD:	129.3 ± 56.8	129.2 ± 57.3
Units:	mg/dl	mg/dl
Analyst:	InezDoe	InezDoe
Comment:	Kipling comment	XYZ comment

Accepted by: _____

Signature

Date

EP Evaluator 9.0.0.337

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Major Features:

- Ten or 32 statistical modules so the user can meet all CLIA '88 and CAP requirements for validating and evaluating methods.
- Three Lab Management modules.
- Well-designed and easy to understand, professional reports ready to sign and file.
- Plots results in real time display as they are entered.
- Different versions provide the features needed for each of many types of labs. Get only the features you need.
- Implements many productivity features including import of data from spreadsheets, connectivity and many more.
- Network competent. Elegant network support. Installation takes only minutes.
- Designed by a clinical chemist for the clinical laboratory.



David G. Rhoads Associates
 A Data Innovations, Inc. brand
 Developing Software for the Quality-Driven
 Clinical Laboratory Since 1983

The features you need—at a very reasonable price.

History

EP Evaluator[®] has been a tremendous aid to laboratorians since the original version was first offered in 1991. The many labs which purchased this first release found that what previously took hours with pencil, calculator and graph paper was now quick and easy. At last, professional quality reports were simple to produce.

EP Evaluator[®], Releases 4 (2001), 5 (2002), 6 (2003) 7 (2005) and 8 (2007) had 15, 17, 20, 23 and 27 modules respectively. Productivity, project management, network security, lab management and data capture features were added in these releases.

“EP Evaluator[®] is a powerful and indispensable tool in my daily practice of clinical laboratory medicine. Since I began using the initial release of this software in 1991, it has been steadily improved and useful new modules have been added with every revision.”

Salvador F. Sena, Ph.D., DABCC

Dir. Clinical Chemistry, Danbury Hospital, Danbury, CT

New Features in Release EE9

Modules

Competency Assessment is our fourth lab management module. It will provide for assessing competency through asking questions and tracking various measures of competency assessment for individuals.

Simple Accuracy determines accuracy for those systems where the specimen concentrations are specified as a range.

Stability assesses the stability of a storage condition for reagents or specimens over time.

CLSI EP6 Linearity implements the CLSI Linearity document.

Histogram and Descriptive Stats calculates many statistical parameters for systems where the mean (or central tendency) and SD (dispersion) are appropriate.

Extraction of Data from Middleware allows the user to extract data directly from middleware for import directly into many EE modules.

Productivity Features

Connectivity—Provides capability of direct communication of EE9 with instruments.

Policy Definitions—provides for standardization of test descriptors such as names, units and reportable ranges. These descriptions are stored in a data base so they can be easily used when importing data and creating new experiments.

Rapid Results Entry—Includes importing of results from spreadsheets as well as capture of results directly from instruments. Such input may be for more than 100 tests on a single specimen.

System Requirements

32 bit Windows—Works with Windows 98 and higher, including Vista. Most EE9 features (except serial data capture) will work on Intel Macs if the Crossover program is used.

Processor (CPU) speed: 300 MHz or greater.

Hard disk space requirements: The size of the application before data has been entered is about 30 MB.

Printer output may go to any local or network device supported by an appropriate Windows printer driver.

Networks: Both the executables and the database are installed on the server under the same folder. Access is provided via an icon on user's desktop. The database engine is included in the executable.

One of the tasks I perform is testing software. This morning I {received} EP Evaluator[®] and I just completed my testing. The software installed perfectly and I tested it using a variety of accounts with no problems whatsoever. Thanks for delivering a product that was trouble free...and for producing a quality application.

William D. (Dave) Gray

Consultant

Albuquerque, NM

Modules in EP Evaluator® Release 9

10* 32*Modules	Brief Description
<ul style="list-style-type: none"> • • Linearity • • Simple Accuracy • • CLSI EP6 Linearity 	<p>Includes linearity, accuracy, reportable range, precision and calibration verification.</p> <p>Checks that specimen results are within a defined range. <i>(New in EE9)</i></p> <p>Linearity according to the CLSI model. <i>(New in EE9)</i></p>
<ul style="list-style-type: none"> • • Precision - Simple • • Precision - Complex 	<p>Calculates simple mean, SD and related statistics. Optionally detects outliers.</p> <p>Implements CLSI EP5. A statistically rugged algorithm for calculating within-run, between-run, between-day and total precision.</p>
<ul style="list-style-type: none"> • • Sensitivity - Limits of Blank • • Sensitivity - Limits of Quantitation 	<p>Calculates lowest concentration significantly different from zero.</p> <p>Calculates lowest concentration which is quantitatively reliable.</p>
<ul style="list-style-type: none"> • • Reference Interval - Verification • • Reference Interval - Establishes • • Reference Interval - ROC Plots 	<p>Verifies normal range.</p> <p>Uses 2 or 3 different approaches to calculate a normal range (central 95% interval). Includes CLSI C28-A.</p> <p>From test results and gold-standard diagnosis, calculates cut-off values for tests like Troponin. Determines diagnostic effectiveness of test. Implements CLSI GP10.</p>
<ul style="list-style-type: none"> • • Method Comparison - Alternate (Quantitative) • • Method Comparison - CLSI EP9 • • Method Comparison - Qualitative • • Method Comparison - POC Glucose • • Multiple Instrument Comparison • • Two Instrument Comparison • • Hematology Studies 	<p>Elegant but simple computation using regular and Deming Regression. Also estimates medical decision points.</p> <p>Implements CLSI EP9A. A statistically rugged procedure often used for submissions to regulatory agencies.</p> <p>Performs both Qualitative and Semi-Quantitative analysis of methods. Also converts quantitative data into semi-quantitative groups.</p> <p>Compares POC glucose results to those from a laboratory instrument. Implements both Clarke and Consensus diagrams.</p> <p>Easy comparison of 3 to 30 instruments without using linear regression.</p> <p>Compares two instruments without using linear regression. Specifically designed for semi-annual instrument harmonization process.</p> <p>Compares both CBC and Diff parameters for multiple instruments. Optionally may assess clinical sensitivity.</p>
<ul style="list-style-type: none"> • • Carryover • • Performance Standards • • Interference • • Preliminary Evaluation of Methods • • Histograms and Descriptive Stats • • Six Sigma Analysis • • Average of Normals • • Stability 	<p>Calculates specimen to specimen carryover.</p> <p>Calculates total allowable error from several different criteria.</p> <p>Determines maximum concentration of interferent which allows reporting of a clinically acceptable result.</p> <p>Implements CLSI EP10. With 50 results assayed over 5 days, this procedure determines linearity, precision, accuracy, carryover and drift.</p> <p>Calculates several types of means and displays data in a histogram. <i>(New in EE9)</i></p> <p>Shows if method meets criteria for Six Sigma performance from bias and precision statistics.</p> <p>Tracks median value of all patient results in order to detect changes in method bias.</p> <p>Check stability of a reagent or specimen. <i>(New in EE9)</i></p>
<ul style="list-style-type: none"> • • INR - Manual Check • • INR - Geometric mean and VRI • • INR - Method Comparison • • Inventory Management 	<p>Validates the INR calculation.</p> <p>Calculates geometric mean and verifies reference interval for PT and INR results.</p> <p>Compares both PT and INR for two methods.</p> <p>Provides for tracking receipt and dispensation of laboratory supplies.</p>
<ul style="list-style-type: none"> • • Incident Tracking • • Cost Per Test • • Competency Assessment 	<p>Tracks lab errors and incidents for quality improvement reasons.</p> <p>Calculates cost per test based on costs of supplies, labor, equipment, etc.</p> <p>Supports both stock and facility-definable questions. <i>(New in EE9)</i></p>

*10 and 32 refer to the number of statistical modules in a given version. 10 in the CLIA and Vendor versions. 32 in the Standard, POC and Professional versions.

Available Versions and Licenses

Version	Num Modules	Projects	Connectivity	Network Security and Audit Trail	Purchase/ Subscription
• CLIA	10	-	-	-	P/S
• Vendor	10	Y	Y	-	S
• Standard	32	Y	-	-	P/S
• Standard + Data Capture	32	Y	Y	-	P/S
• Professional	32	Y	Y	Y	P/S
License	Description				
• Single PC	Allows the user to install the software on one PC at a time.				
• Site	<i>Available only to hospitals and academic institutions in the US and Canada.</i> User may install the software on an unlimited number of PCs at a single street address. Each user has access to only data on their own PC.				
• Network	Allows the user to install the software on a network server. Data for each project can be accessed by any authorized user on the network. The number of concurrent users (i.e. those using the program at the same time) may be 1, 5, 10 or more.				

Support

Purchase Plan	Subscription Plan
<ul style="list-style-type: none"> • Unlimited free telephone support for 60 days. • Updates only to fix software bugs. • Annual support plan for unlimited free telephone support and automatic free upgrades available. 	<ul style="list-style-type: none"> • Unlimited free telephone support throughout subscription period. • Software updates to next version of EE and to fix software bugs.

ORDER INFORMATION

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 (800) 786-2622 • (802) 658-1955 • (802) 658-2782 (fax)

**Download a complete program trial version of
 EP Evaluator[®] Release 9 software from our website:
dgrhoads.com**



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Developing Software for the Quality-Driven Clinical Laboratory Since 1983

EP Evaluator® , Release 9

Pricing for Subscription Plans

Subscription Plans (per year)

Single user	\$250 (E9C-RY)	\$750 (E9S-RY)	\$1000 (E9D-RY)	\$1250 (E9P-RY)
Network - 1 concurrent user	\$495 (E9C-N1-RY)	\$1500 (E9S-N1-RY)	\$2000 (E9D-N1-RY)	\$2500 (E9P-N1-RY)
Network - 3 or more users price per user (1)	n/a	\$750 (E9S-N3M-RY)	\$1000 (E9D-N3M-RY)	\$1250 (E9P-N3M-RY)

(1) For networks of 3 or more concurrent users, price is the number of concurrent users * price for each user.

- ◆ Quantity discounts available
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Other Products

Simple Inventory System Starter Kit \$450
 Contains three barcode scanners and
 box of Avery labels (100 sheets)

The following set of two books are available electronically for EP Evaluator®. Hard copies in addition to what each license type is entitled are:

Lab Statistics, Fun and Easy, 4th Edition \$50
EP Evaluator®, Release 9 User's Manual \$75
If both books are purchased together \$100

Available from:

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