EP Evaluator®

Quality Assurance for the Clinical Laboratory

Simplified process, powerful results

"While we (clinical labs) are but a **small component** of the total healthcare system, our data controls a large majority of **the critical decisions**."

David Rhoads PhD
Creator of EP Evaluator®

DATA INNOVATIONS
Simple Ideas, Better Solutions

RHOADS
a brand of DATA INNOVATIONS

Upgrade Your Lab's Performance with the Simple Elegance of EP Evaluator®

Your lab is busy; you need quality results quickly and reports that are ready to sign and deliver. And, you need it at a reasonable price that won't break your operating budget. **You need EP Evaluator®.**

Dr. David G. Rhoads, a board-certified clinical chemist developed the first EP Evaluator® in 1991, to help leverage the dollars coming into the lab in the most efficient way possible. With more than 30 years of experience in the clinical laboratory, Dr. Rhoads is a nationally recognized expert on quality assurance issues.

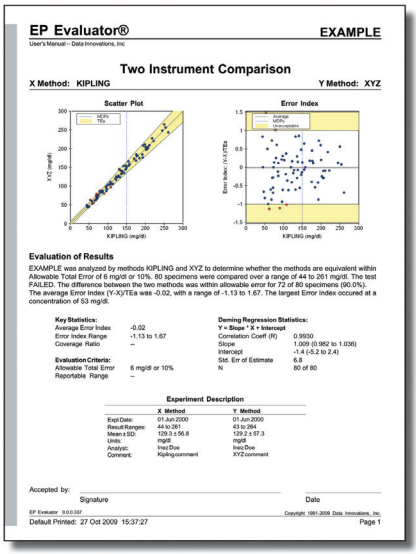
"EP Evaluator® is so simple to use and provides us with reliable information about our instruments."

Diane Davis, MT(ASCP)SH
Clinical Laboratory Specialist

Through the years, Data Innovations, in partnership with Dr. Rhoads, has continued to develop technology for the clinical laboratory and is now happy to introduce the latest version of our cutting-edge Quality Assurance Software: **EP Evaluator® Release 11**.

What Makes EP Evaluator® Release 11 Different from Other Software Products?

A board-certified **clinical chemist** with software expertise designed the **first EP Evaluator® in 1991** specifically for the clinical laboratory. The early adopters of the software program found that what previously took hours to accomplish with pencil, calculator and graph paper was now quick and easy. At last, professional quality reports were simple to produce! What was true then is true today.


EP Evaluator®
EXAMPLE
Two Instrument Comparison
X Method: KIPLING
Y Method: XYZ
Scatter Plot
Error Index
Evaluation of Results
Key Statistics:
Deming Regression Statistics:
Y = Slope * X + Intercept
Evaluation Criteria:
Experiment Description
Accepted by:
Signature
Date
Default Printed: 27 Oct 2009 15:37:27
Page 1

EP Evaluator® Release 11 produces reports that are:

- Well designed
- Easy to understand
- Inspector-ready reports are ready to sign and file

EP Evaluator® Release 11 leads with the following features:

- Up to 34 statistical modules depending on version, meeting all CAP and CLIA '88 requirements for validating and evaluating methods. You choose the version you need based on only the features your lab needs. See table on page 4 for feature list.
- Four Lab Management modules.
- 21 CFR Part 11 (Audit trail) compliance
- Definition of user groups to control access to specific projects. For example, chemistry users at site A will not be able to access hematology data at site B. Access may be password-controlled.
- Built-in backup and restore
- Copy data to and from spreadsheets
- Many ways to capture data from instruments so you can import your data without having to enter it manually.

Productivity Tools

- Perform calculations for 100 or more experiments at one time.
- Organization of results so you can see instantly those that passed and failed.
- Acquire data for instruments via middleware connectivity, files generated from instrument or files generated from LIS systems allowing you to import thousands of results into almost any statistical module and generate reports in a few minutes.
- Importing data directly from laboratory instruments or from files generated by laboratory instruments.
- Composite reports function allows you to combine reports from all statistical modules into one consolidated file for easy access and retention.

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

Salvador F. Sena, Ph.D., D.A.B.C.C.,
Education Director, Clinical Chemistry
Danbury Hospital
Danbury CT

A relatively **small percentage** of a hospital or clinic budget is devoted to the clinical lab, yet **more than 90%** of the objective data contributing to patient care comes **from the laboratory**.

Three major additions to EP Evaluator® Release 11 include:

1. Trueness module that can assist laboratories which participate in External Quality Control (EQC) or External Quality Assurance (EQA) programs to quantify their bias compared to their peer group. The Trueness module also evaluates uncertainty using available bias and precision components. EE 11.1 also includes a Sigma calculation to determine if a method conforms to a Six-Sigma™ standard of performance.

2. A scaled version called EP Evaluator COFRAC that will provide laboratories with the appropriate statistical modules need to seek or maintain accreditations with the Comité Français d'Accréditation (COFRAC)

3. Enhanced data acquisition utility to import data directly from external middleware and/or LIS systems

"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 is trouble free ... and for producing a quality application."

William D. (Dave) Gray
Albuquerque, NM

Support and Training

When you purchase EP Evaluator® Release 11 you get more than a software product, you get the full service you expect from the "go to" source for the clinical laboratory. Along with its well-staffed customer support division, Data Innovations LLC also provides regular 60-90 minute webcasts on select EP Evaluator® topics, providing a hands-on demonstration of how to work with EP Evaluator®.

	Regulatory Requirements				EP Evaluator® Versions	
	CLIA '88	CAP	TJC	COFRAC	Stnd	Pro
Accuracy and Linearity						
Clinical Linearity, Calibration Verification and Reportable Range	✔	✔	✔	○	●	●
Simple Accuracy	✔	✔			●	●
Trueness					●	●
CLSI EP6 Linearity					●	●
Method Comparison						
Alternate (Routine Quantitative)	✔	✔	✔	○	●	●
CLSI EP9 Method Comparison					●	●
Two Instrument Comparison		✔	✔	✔	●	●
Multiple Instrument Comparison		✔	✔	✔	●	●
Qualitative / Semi-Quantitative	✔	✔	✔	○	●	●
POC Glucose					●	●
Hematology Studies		✔	✔		●	●
Precision						
Simple Precision	✔	✔	✔	✔	●	●
CLSI EP5 Precision					●	●
Reference Interval						
Establish	✔	✔	✔	✔	●	●
Verify	✔	✔	✔	✔	●	●
ROC Plots					●	●
Sensitivity						
Limits of Blank (Analytical) *	✔		✔	○	●	●
Limits of Quantitation (Functional)*				○	●	●
Lab Management						
Cost Per Test					●	●
Incident Tracking					●	●
Inventory Management					●	●
Competency Assessment					●	●
Coagulation						
Geometric Mean and VRI		✔	✔		●	●
PT/INR Method Comparison		✔	✔		●	●
Manual INR Check		✔			●	●
Factor Sensitivity (FS)					●	●
Other						
Performance Standards (TEa)					●	●
Carryover		✔		✔	●	●
CLSI EP10 - Preliminary Evaluation	✔	✔	✔		●	●
Interference (CLSI EP7) *	✔	✔	✔	○	●	●
Six Sigma Metrics					●	●
Average of Normals					●	●
Stability					●	●
Histogram and Descriptive Stats					●	●
Additional Features						
Composite Reporting					●	●
Data Acquisition from Middleware						●
Project Management					●	●
Audit Trail and Network Security						●

✔ Addresses requirements by regulatory legislation or organization

Items in red indicate changes in EE release 11

* Evidence can be provided from vendor or laboratory

SYSTEM REQUIREMENTS FOR EP EVALUATOR®

Operating Systems	Windows XP (32-bit) Windows 7 (32-bit and 64-bit) Windows Server 2008 (64-bit)
Memory Specifications	A minimum of 128 MB of RAM for the application
Hard Disk Specifications	Minimum of 200 MB for non-network, single-user implementation Minimum of 1 GB for networked, multi-user implementation
Other	Monitor (1024 x 768 minimum resolution), Keyboard, Mouse and local or networked Printer Adobe Reader or compatible program

SYSTEM REQUIREMENTS FOR DATA ACQUISITION FROM MIDDLEWARE

EP Evaluator®	EP Evaluator® 9 or later of Standard+Data Capture or Professional version
Instrument Manager™	Instrument Manager™, version 8.08 or later with Specimen Manager and ODBC
Laboratory Process Manager	Laboratory Process Manager (LPM) version 5.6.2 or later Microsoft ODBC driver for Oracle 2.575.1117.00 or later

SUPPORT AND MAINTENANCE

Subscription Plan – Free software updates for the version to which you subscribe along with any new releases that are introduced during your subscription period. Access to technical support via email or phone Monday through Friday, excluding holidays from 9 am to 8 pm EST/EDT.

PRODUCT TRAINING

Interactive Webinars and Advanced Workshops on selected EP Evaluator® topics are available. Consult training.datainnovations.com for further information and schedules.

ORDER INFORMATION

Data Innovations LLC

120 Kimball Avenue, Suite 100, South Burlington, VT 05403

802-264-3470 (sales) 802-658-2782 (fax)

or contact our regional Sales & Marketing Departments.

Download a free 14-day trial version of EP Evaluator® Release 11 software from our website: ee.datainnovations.com

RHOADS
a brand of DATA INNOVATIONS

Document ID: 1275 I Version 6.0

Let the quality assurance of EP Evaluator® go to work for you.
Download a free 14-day trial version of
EP Evaluator® Release 11 software from our website:
ee.datainnovations.com

North America
120 Kimball Avenue
Suite 100
South Burlington, Vermont
05403
Sales Tel: 802-658-2850
Technical support
Tel: 802-658-1955

Europe
34 av. Jacques Brel
1200 Brussels, Belgium
Sales Tel: +32 2 332 24 13
+32 2 770 62 22
Technical support
Tel: +32 2 332 24 13

S.D.L.M
Tour Egée
9, 11 Allée de l'Arche
La Défense
92671 Courbevoie Cedex
+33 1 76 63 74 20
+32 2 770 62 22

P.G.P. (UK) Ltd.
2nd Floor, 3 Brindley Place
Birmingham
B1 2JB
+44 1543 410 996

Latin America
Rua Cotoxó, 303 Cj 71
Perdizes Tower II
São Paulo, Brasil 05021-000
Sales Tel: 55-11-38013283
Technical support
Tel: 55-11-38013283

Asia
Room 3709, 37/F.,
118 Connaught Road West
Hong Kong
Sales Tel: 852-2398-3182
Technical support
Tel: 852-2398-3182

DATA INNOVATIONS
Simple Ideas, Better Solutions