

EP Evaluator meets Instrument Manager

Using ODBC to capture your data



Carol R Lee
Data Innovations, Implementation Consultant

EP Evaluator meets Instrument Manager

- EE organizes and analyzes the testing needed to satisfy your quality assurance regulatory requirements.
- IM manages your patient results in the production setting.

ODBC Query into IM

- ODBC – Open Database Connectivity
- Download data for multiple analyzers and multiple analytes into almost all of the Statistical Modules.
 - Linearity
 - Method comparison
 - Reference intervals, ROC plots
 - CLSI EP5 Precision using your daily QC
 - 99 and 95th percentile Histograms on thousands of patient results

Streamline the quality assurance process

- With IM and EE, save hours or even days in data reduction and reporting of thousands of results
- Data in IM Specimen Management transfers easily to EE using the simple built in query with 4 filters
 - Date
 - Instrument ID
 - Analyte name
 - Specimen ID
- Create many experiments in just a few minutes
- Eliminate the need for intermediate worksheets
- Eliminate the potential for transcription errors



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Live Demo

EE and IM Requirements:

- **IM version 8.08 to 8.13**
 - Specimen Management license
 - ODBC license.
- **EE Revisions EE 9.2 to EE 11.2**
 - Standard plus Data capture versions, or higher

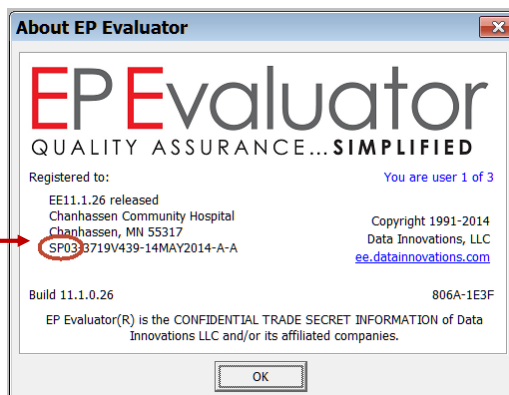
* EE and IM do not have to be on the same computer, EE just needs to be able to communicate to the IM server IP address.

Computer requirements

- **Computer:**
 - Windows XP or Win7 32 or 64 bit
 - User permissions
 - Full read/write/delete access to the EE folder, all underlying folders, the user's Application Data folder, and some registry folders
 - EE users must belong to the IM ODBC user group on IM
 - ODBC driver on **every EE workstation, PC, or server in the data capture pathway.**
- **Documentation:**
 - EE10 Users Guide: chapter 37
 - ODBC User's Guide for Instrument Manager: (ODBC UG). Chapter 1

EP Evaluator Data Capture Versions

- Standard + (Q)
 - 30 Statistical and 4 Lab Management Modules
 - Data Capture
- Professional Version (P)
 - Everything plus User security and audit trail
- Available as single user, or upgrade to multiple user networks
- Part # EE-D-xxxx



One time setup Steps for successful Data Capture

- On the EE computer or server:
 - Verify Read/Write File permissions
 - Install ODBC driver from IM Cache installation disk
 - Create ODBC data source name (DSN) in control panel
- On Instrument manager:
 - Ensure your experiment data goes into specimen management
 - Ensure the purge setting is long enough to retrieve your data.
 - Ensure the EE user is a member of the ODBC user group.
- On EP Evaluator -
 - Create a Master project policy definition for your instruments and analytes using IM codes
- On your Analyzers:
 - Plan appropriate specimen IDs for each EE experiment, i.e.,
 - set up barcodes to match linearity kits in EE Master policy

Summary of Setup steps

Where	What	Reference
1. EE Computer	Install ODBC driver	Intersystems ODBC driver in the: <ul style="list-style-type: none"> • IM Cache CD or • IM 8.12 or 8.13 system CD
	Set up ODBC connection in control Panel	IM ODBC Users guide
2. EE Program	Create Master policy definition	EE manual & HELP
3. Instrument Manager	Ensure data goes to SM	Review IM suppression rules
	Review purge length	IM Purge configuration
4. Analyzer	Use appropriate specIDs for EE policy	Instrument Manual and EE Master policy

Create experiments in EE and review reports in <5 min

8 am - the longest process

- 10 am

- 10:05

Prepare and run linearity studies on XYZ and ABC analyzers. LIN linearity set. Open the bottles, pour into tubes or cups with barcodes, put on analyzer, go get a cup of coffee.

- Open EE, create a new project and open linearity module
- Run ODBC data query and download data from ABC and XYZ analyzers .
 - Filter last 3 hours of data
 - Instruments ABC and XYZ
 - Test codes : Lin panel
 - Spec IDs LIN
- Review reports

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 or DXH**
 - 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

Analytes Edit

Analyte	Units	Max Decimal Places	Coag Flag*	For Inst Capture Only	
				InstCode	Factor
Estradiol	pg/mL	0		713	1
ETOH	mg/dL	1		2847	1
Fe	ug/dL	0		2360	
Ferritin	ng/mL	0		61	
Ferritin-Mul				2906	
Folate				685	
Free PSA				221	
FSH				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
...

Editing class: Architect

Callout 1: Either IM test codes or common name labels

Callout 2: IM test codes

Instruments

Names or Serial Numbers as defined in IM

Instruments

Name	Model	Serial No	MIC Abbrev
Architect	Generic	Generic	
Archie		123456	ARCh
Edith		78910	Edith

Buttons: F3 Add, F4 Delete, OK, Cancel, Help

Analyte settings depend on Modules / Options selected

Minimal

Most pass/fail options selected

Settings for all status modules EXCEPT Hematology Method Comparison.

Analyte	Medical Decision Points
	1 2 3 4 5
HA1c	6 6
In-TAGP	50 120
Al-AT	84 200
Acet	10 30
ACP	0 6
AlbG	3.5 5
AlbP	3.5 5
AlbF	40 150
ALT	0 55
Amikacin	5 25
Ammonia	18 72
AmpQ	1000
AmpSQ	1000
Amry	25 125
AmryU	1 17
Anti-CCP	5.0
Anti-HCV	0.8
Anti-TG	0 411
Anti-TPO	0 5.61
ApoA	95 223
ApoB	49 182

Settings for all status modules EXCEPT Hematology Method Comparison.

Analyte	Allowable Total Error	Pass	Fail	Flag	Pass/Fail		Low Priority Level	High Priority Level	Normal Range			Medical Decision Pt			
					Sec	Prn			Low	High	1	2	3	4	
HA1c	15	0	0	optional, depend on modules and options selected	50	10	4	8	4	6					
In-TAGP	16.2	50	50		50	10	50	120	50	120					
Al-AT	25	50	50		50	84	200	84	200						
Acet	25	50	25	3	377	50	10	30	10	30					
ACP	163	50	25	0.8	07.9	50	10	6	0	6					
AlbG	10	50	25	0.4	10.5	50	10	3.5	5	3.5	5				
AlbP	10	50	25	0.4	11.0	50	10	3.5	5	3.5	5				
AlbF	30	50	25	5	405	50	10	40	150	40	150				
ALT	20	50	25	6	413	50	10	0	55	0	55				
Amikacin	14	50	25	1.0	50.0	50	10	5	25	5	25				
Ammonia	1	50	25	4.70	107.0	50	10	18	72	18	72				
AmpQ	30	50	25			50	10								

Linearity sets

The prefix for the specIDs when run on the analyzer

Kit/Material*	Mode	InstCode	% or Ind.
<input type="checkbox"/> ALKP-ENZ	% Split	ALP-ENZ	
<input type="checkbox"/> ALT-ENZ	% Split	ALT-ENZ	
<input type="checkbox"/> AMY-ENZ	% Split	AMY-ENZ	
<input type="checkbox"/> AST-ENZ	% Split	AST-ENZ	
<input type="checkbox"/> AUDIT	Pre-Assign	AUDIT	
<input type="checkbox"/> 01*			
<input type="checkbox"/> 02*			
<input type="checkbox"/> 03*			
<input type="checkbox"/> 05*			
<input type="checkbox"/> CAL			
<input type="checkbox"/> GGT-ENZ			
<input type="checkbox"/> Kit			
<input type="checkbox"/> LD-ENZ			
<input type="checkbox"/> VERI%			
<input type="checkbox"/> VERICHE			

Analyte	01	02	03	04	05
1 %Alc	4.0	8.0	12.4	16.6	21.2
2 Acet	0	47	95	142	190
3 AlbG	1.5	2.6	3.8	4.9	6.0
4 AlbP	1.5	2.6	3.8	4.9	6.0
5 Ammonia	28	174	321	467	613
6 ApoA	10	346	643	1000	1299
7 ApoB	0	134	274	378	487
8 ASO	20	544	853	1276	1828
9 BilO	0.1	3.0	5.9	8.8	11.7
10 BilT	0.1	5.7	11.3	16.8	22.4
11 BilT	0.1	5.7	11.3	16.8	22.4
12 Ca	1.6	5.1	8.6	12.1	15.6
13 CA 15-3	16	283	550	817	1084
14 CaC	1.6	5.1	8.6	12.1	15.6
15 CEA	9.3	399	789	1179	1569

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

Keys to success with IM Download

- Set up a RRE policy for your instruments, using instrument names and test names or test codes already in IM. If you are not sure what they are, you can
 - Do a dry run to capture data that will reveal those names. Copy the test code names from the final query display screen.
- Standardize your specimen IDs for your QA experiments so you can find them in IM. i.e.
 - LIN, SA: instrument codes for linearity sets: Lin-01, lin-02, etc
 - SP: one or 2 “prefix” letters
- For method comparisons, note the range of spec IDs
 - In the RRE wizard, “force Spec ID length” lets you trim or add leading zeros to make it easier to match “barcode” spec ids to a manually entered method.
- Set the purge on IM to at least the time needed to gather your data

QC or not QC

- Modules
 - SP simple precision,
 - CP complex precision,
 - MIC Multiple Instrument comparison.
- All data for EE needs to be present in specimen management,
 - Allow QC data to go into specimen management for the study duration, or
 - Run special QC specimens with defined Spec IDs as though they are patients.

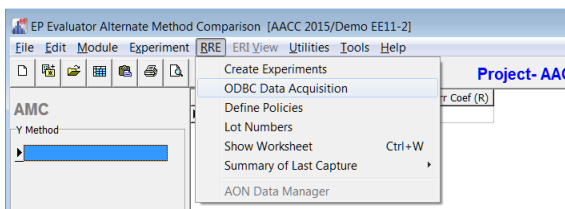
You are ready to capture your Data!

8/6/2015

The screenshot shows the 'EP Evaluator Release 9 [Default]' application window. The menu bar includes File, Edit, Module, Experiment, RRE, ERI View, Utilities, Tools, and Help. The toolbar contains various icons for file operations. The main window title is 'Project-Default'. Under the 'Statistical Modules' section, several options are listed: Precision, Accuracy and Linearity, Method Comparison, Sens, Refer Inte, INR, and Other. A 'Tutorial' button is at the bottom left. A callout box for 'Method Comparison' lists: Alternate (Quantitative), CLSI EP9, Qualitative and SemiQuant, 2-Instrument Comparison, Multiple Instrument Comparison, Glucose POC Instrument Evaluation, and Hematology Studies. A light blue callout box says 'Let's Create an experiment by Capturing some data from Instrument Manager!'. A pink callout box explains 'AMC Alternate Method Comparison - Uses Linear regression techniques to characterize the relationship between two methods.' The footer contains 'datainnovations.com', 'Copyright Data Innovations, LLC 2014', and the page number '20'.

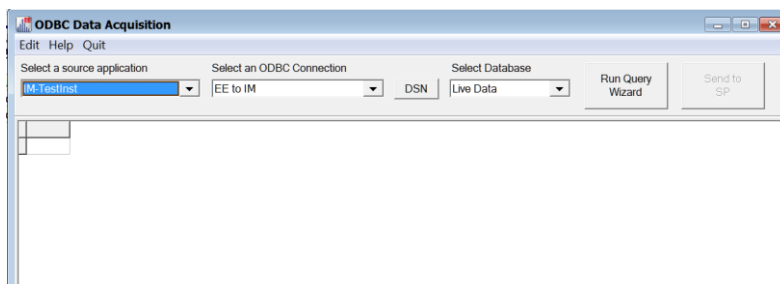
RRE : Connect to Instrument Manager

- Open EE and the AMC Module.
- From the AMC module Overview screen, go to RRE and Select
 - Connect to Instrument Manager (EE9 and EE10)
 - ODBC Data Acquisition (EE11)



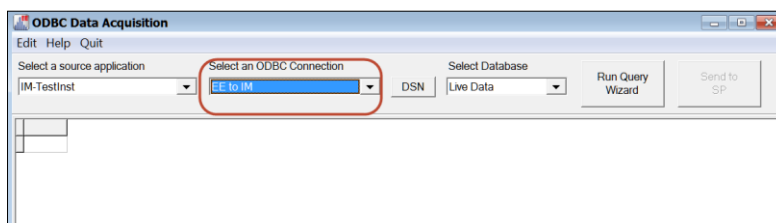
Select the type of connection

- **Test instrument ID** shows all instrument S/Ns in all active connections, i.e, Cobas, Architect, Vitros, DXC
 - use for method comparisons
- **Connection** shows all connections, but no test instrument IDs in a specific connection
- Live Data or Archived data



Select the ODBC database

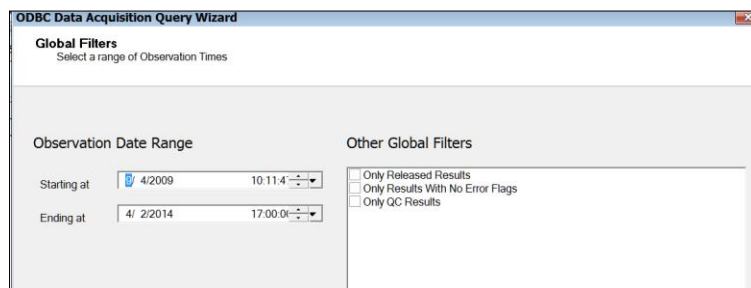
- Select the ODBC connection you set up for IM
- Click the Run Query Wizard button



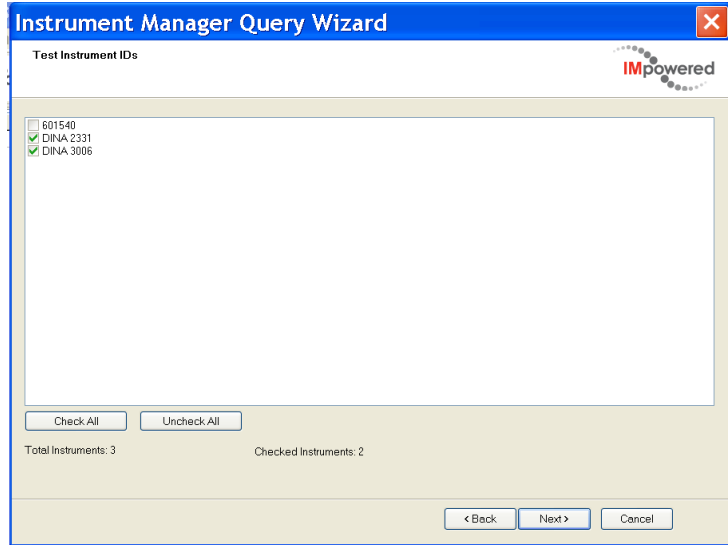
Tip: if the ODBC connection box is blank, the DSN button takes you to the correct control panel setup screen

Use the Date and Global filter

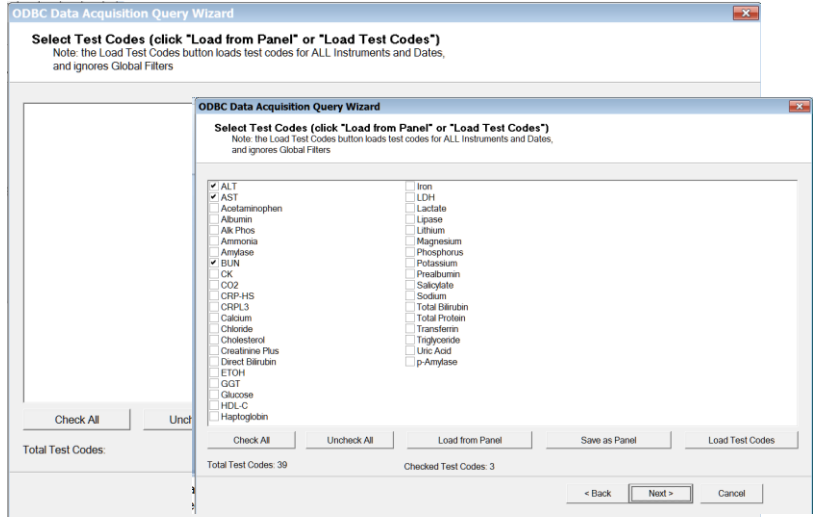
- Select the shortest date range possible for your data
- Define the global filter criteria, then click “Next”.



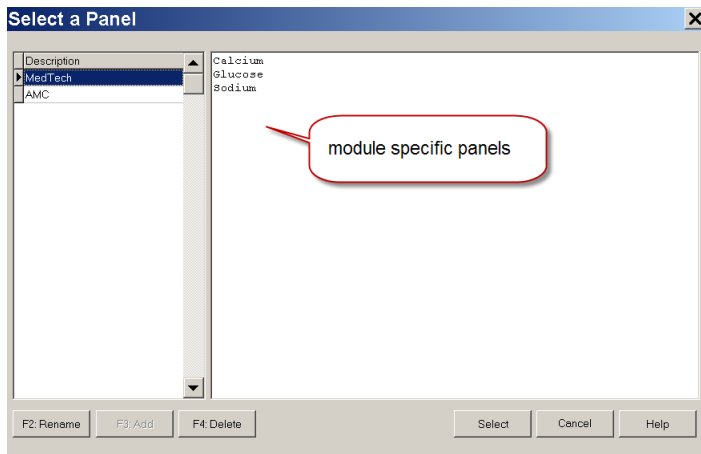
Select your instruments



Select your IM test codes

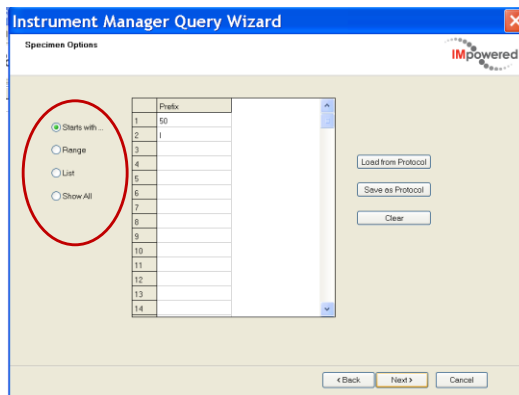


Save a TEST ID Panel

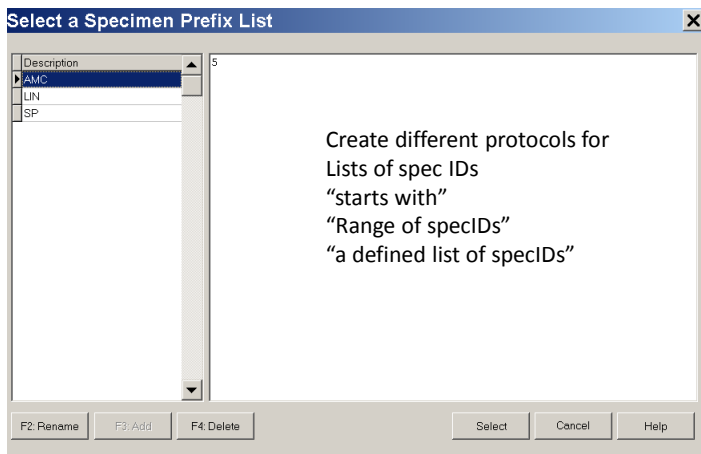


Filter the SpecIDs you want

- Use the “selection buttons” to filter the specimen IDs for these experiments,
- Save a “protocol” for your specific specIDs

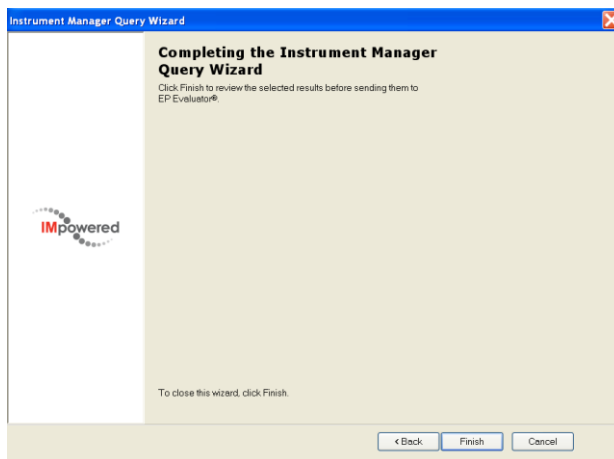


SpecID protocol



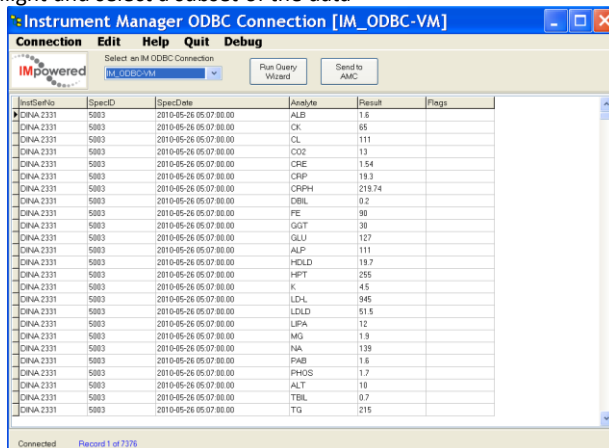
EP Evaluator and Instrument Manager

- Click "Finish"



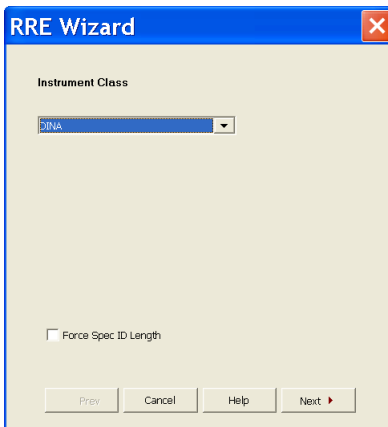
Send your data to the Module to create experiments

- EE result data that was sent from Instrument Manager.
- Click "Send to AMC" to send this data to the AMC module
- Can highlight and select a subset of the data



The second phase – EE’s RRE Wizard

- Choose the correct instrument class previously defined in RRE Policy Definitions and click "Next"



Reagents and Calibrators – optional for most modules

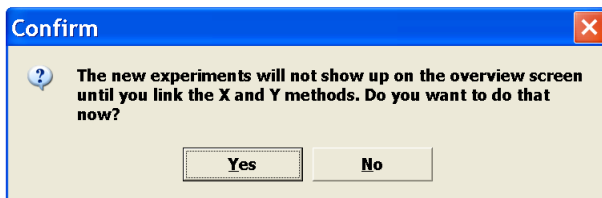
Tip: the complex precision module requires reagent and calibrator lots. Set up a lot number called “Any” to smoothly create all the experiments. Modify in the Parameters screen later.

EP Evaluator and Instrument Manager

- Click “Finish”

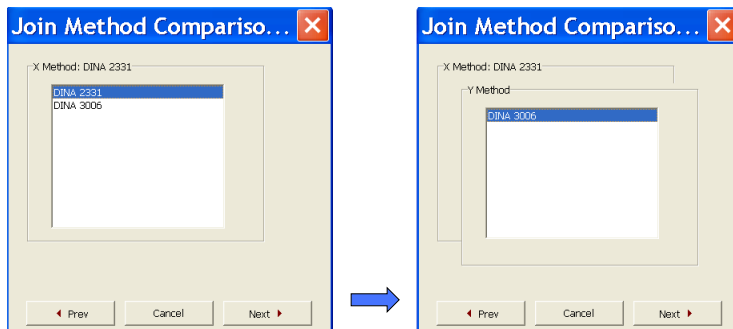
Creating the experiments

- An Activity Log displays the progress of the download from instrument Manager.
- Duplicate specimen IDs are ignored.
- For method comparison modules, click yes to Confirm “Link the X and Y methods”



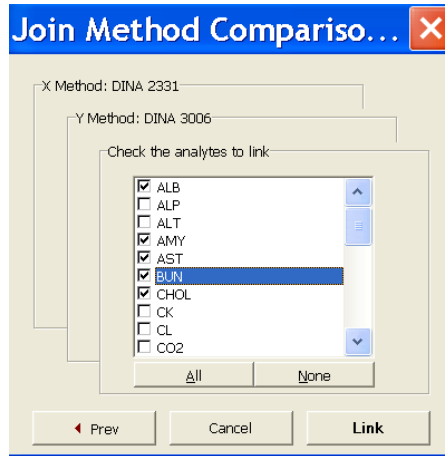
EP Evaluator and Instrument Manager

- Method Comparison
- Choose the X and Y axes



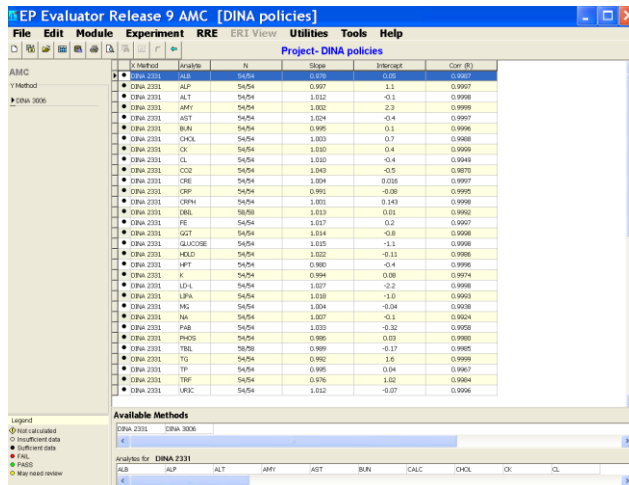
EP Evaluator and Instrument Manager

- Check the analytes to link



EP Evaluator and Instrument Manager

- The experiments are added to the Overview Screen immediately



EP Evaluator and Instrument Manager

- Print Preview displays the report.

EP Evaluator[®]
Clinical Laboratory -- Our Lady of Perpetual Motion

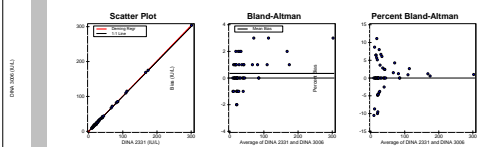
Alternate Method Comparison Summary

Y Method	X Method	Analyte	N	Slope	Intercept	Corr (R)	Accept
DINA 3006	✓ DINA 2331	ALB	54/54	0.978	0.05	0.9987	_____
	✓ DINA 2331	ALP	54/54	0.997	1.1	0.9997	_____
	✓ DINA 2331	ALT	54/54	1.012	-0.1	0.9998	_____
	✓ DINA 2331	AMY	54/54	1.002	2.3	0.9999	_____
	✓ DINA 2331	AST	54/54	1.024	-0.4	0.9997	_____
	✓ DINA 2331	BUN	54/54	0.995	0.1	0.9996	_____
	✓ DINA 2331	CHOL	54/54	1.003	0.7	0.9988	_____
	✓ DINA 2331	CK	54/54	1.010	0.4	0.9999	_____
	✓ DINA 2331	CL	54/54	1.010	-0.4	0.9949	_____
	✓ DINA 2331	CO2	54/54	1.043	-0.5	0.9870	_____
	✓ DINA 2331	CRE	54/54	1.004	0.016	0.9997	_____
	✓ DINA 2331	CRP	54/54	0.991	-0.68	0.9995	_____
	✓ DINA 2331	CRPH	54/54	1.001	0.143	0.9998	_____
	✓ DINA 2331	DBIL	58/58	1.013	0.01	0.9992	_____
	✓ DINA 2331	FE	54/54	1.017	0.2	0.9997	_____
	✓ DINA 2331	GGT	54/54	1.014	-0.8	0.9998	_____
	✓ DINA 2331	GLUCOSE	54/54	1.015	-1.1	0.9998	_____
	✓ DINA 2331	HDL	54/54	1.022	-0.11	0.9996	_____
	DINA 2331	HPT	54/54	0.960	-0.4	0.9995	_____
	DINA 2331	K	54/54	0.994	0.08	0.9974	_____
	DINA 2331	LD-L	54/54	1.027	-2.2	0.9998	_____
	DINA 2331	LIPA	54/54	1.018	-1.0	0.9993	_____
	DINA 2331	MG	54/54	1.004	-0.04	0.9938	_____
	DINA 2331	NA	54/54	1.007	-0.1	0.9924	_____
	DINA 2331	PAB	54/54	1.033	-0.32	0.9958	_____
	DINA 2331	PHOS	54/54	0.986	0.03	0.9980	_____

EP Evaluator[®] ALT

Alternate (Quantitative) Method Comparison

X Method: DINA 2331 Y Method: DINA 3006



Regression Analysis

	Deming	Passing-Bablok	Regular
Slope:	1.012 (1.006 to 1.017)	1.006 (1.000 to 1.015)	1.011 (1.006 to 1.017)
Intercept:	-0.1 (-0.5 to 0.2)	-0.1 (-0.3 to 0.0)	-0.1 (-0.5 to 0.2)
Std Err Est:	1.0	—	1.0

95% Confidence Intervals are shown in parenthesis

Supporting Statistics

Corr Coef (R): 0.9998	SubRange Bounds: None
Bias: 0.4	Points (P) Outliers: None
X Mean ± SD: 42.4 ± 50.4	Scatter Plot Bounds: None
Y Mean ± SD: 42.7 ± 51.0	
Std Dev Diff: 1.2	

Experiment Description

	X Method	Y Method
Event Date:	11 Mar 2011	11 Mar 2011
Rep. SD:	1	1
Range Ranges:	9 to 301	9 to 304
Units:	IU/L	IU/L
Reagent:	—	—
Calibrators:	—	—
Analyst:	carol	carol
Comment:		

Accepted by: _____ Date: _____
Signature _____ Date _____

EP Evaluator: 0.3.0.461 Copyright 1999-2010 Data Innovations, LLC
DINA policies Printed: 11 Mar 2011 22:04:20 Page 1

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EE Program	Create Master policy definition	EE manual & HELP
Instrument Manager	Ensure data goes to SM	Review IM suppression rules
	Review purge length	IM Purge configuration
Analyzer	Use appropriate specIDs for EE policy	Instrument Manual and EE Master policy

For more information about EE ...

- For more information, call us:
 - (sales) (802) 658-2850 or
 - Email northamerica-sales@datainnovations.com
 - (support): (802)-658-1955 or
 - Email northamerica-support@datainnovations.com
 - (fax) (802) 658-2782

- our website ee.datainnovations.com
 - Brochure and price list,
 - EE Users guides PDFs
 - Registration links for EP Evaluator training webinars
 - Download the current build of EE for a free 14 day trial.

- Context sensitive HELP in the EE program

Questions and Discussion



Q & A

- **Q: Can the single user version be installed on more than one PC or would you need to get the single user network version?**
 - **A: No, the single user license can only be installed on one computer (although multiple people could use it). To use multiple workstations, you need the network version with one or more concurrent users.**
- **Q: Some instruments can't use the same specID for multiple replicates How could you manage several replicates on this kind of instrument?**
 - **Answers:**
 - **Name the specimen IDs to start with the same characters.**
 - For linearity, use specimen IDs called LIN-01a, LIN-01b, LIN-01c; LIN-02a, LIN-02b, LIN-02c; etc. (where LIN is the "instrument specID code" as defined in the Linearity kit RRE setup.
 - For precision, make sure all replicates "start with" the same characters.
 - QC level 1 might be QC11, QC12, QC13, etc
 - QC level2 might be QC21, QC22, QC23, etc
 - **In the ODBC specID query, choose the "Starts with" option**
 - **After sending the data to the module, the first step of the RRE wizard allows you to "Force specID length"**
 - For linearity trim the right-most (or last) last distinguishing character from the spec ID so that you end up with LIN-01, LIN-02, etc.
 - For precision, trim the right hand characters so that the same levels are groupd together.
 - **If you are using barcodes for linearity and the Spec IDs in the IM database are all different and inconsistent with the EE conventions, then**
 - You can use the combine discard tables in the RRE\policy definition\interface button to create "specID equivalency" table so that all the incoming spec IDs are mapped to the prefix and level defined in the Linearity kit.