



LOCAL LAB NORMALIZATION

LabConnect provides an integrated solution to the new world of clinical trials — as your needs evolve, we’re evolving the technology to support them.

KEY FEATURES

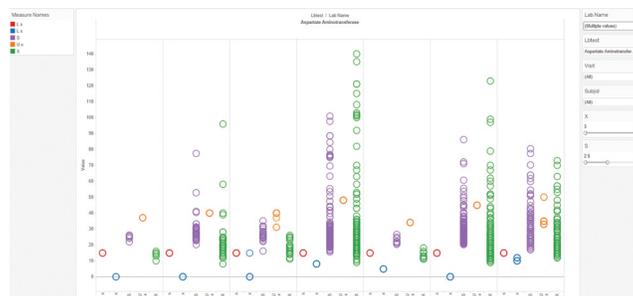
- Easy fax or scan solution for sites
- Flexible requisition form to identify subject demographics, visit details, patient status and site comments
- Rapid double-data entry processing, including translation service where needed
- Central web portal for local laboratory results
- Regular transmission of electronic datasets of local lab results
- Availability of normalized local lab results within LabConnect’s data visualization portal
- One button export of normalized data to Excel
- Easy identification of trends, patterns, outliers and variability within the normalized results data
- Ability to accept non-protocol required testing, retest visits, unscheduled visits and lab comments

Working with local lab reports can present many challenges for sites and sponsors. The ability to capture local lab data quickly, accurately and cost-effectively is critical, as is the ability to compile this data reliably within a validated CDISC-compliant clinical laboratory database.

Test Type	Ref. Range	Units	C0029 27-Feb-2018(Fri)	C0101 31-Jan-2018(Thu)	C0209 18-Jan-2018(Fri)	UNSCHED 09-Jan-2018(Fri)	C0218 02-Jan-2018(Fri)
GLUCOSE	70 - 140	mg/dL	81	89	91	94	97
NA (SODIUM)	135 - 145	mmol/L	141	137	135	141	143
K (POTASSIUM)	3.5 - 5.2	mmol/L	4.1	4.3	4.5	4.7	4.3
CL (CHLORIDE)	98 - 107	mmol/L	106	104	102	103	107
CO2 (CARBON DIOXIDE)	23 - 29	mmol/L	24	20	20	23	25
BUN (BLOOD UREA NITROGEN)	8 - 24	mg/dL	23	22	25	22	19
CREATININE	0.74 - 1.35	mg/dL	1.30	1.48	1.83	1.43	1.38
CA (CALCIUM)	8.5 - 10.2	mg/dL	8.5	8.9	8.8	9.3	9.2
PHOSPHORUS	2.5 - 4.5	mg/dL	3.4	3.1	3.0	3.9	3.3
URIC ACID	3.7 - 8	mg/dL	3.5	3.1	3.4	3.4	3.2
PROTEIN TOTAL	6.3 - 7.9	g/dL	6.4	6.5	6.4	6.8	6.4

LabConnect has developed a solution to address local laboratory data collection, which reduces demands on sites while ensuring that the data is available to sponsors in near real time. Local laboratory reports are de-identified and sent to LabConnect.

Using appropriate statistical models, results for the individual local laboratory tests are normalized based upon an established reference. The reference ranges for the normalization may be those used by one of the participating local laboratories, LabConnect’s established harmonized reference ranges, or an established reference range provided by a reliable source.



Normalized data can then be visualized and analyzed within the data visualization portal.

LOCAL LAB NORMALIZATION (cont.)

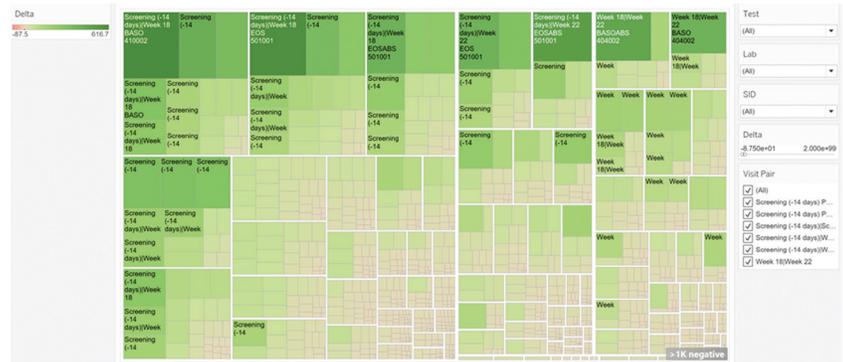
METHODOLOGY

Reliable statistical modeling of laboratory results to a consistent reference range for each analyte permits reliable result normalization for gender, age and ethnicity.

NORMALIZED DATA REVIEW

- Powerful data analytics dashboards allow easy identification of outliers, patterns, trends, inconsistencies and omissions
- Each dashboard provides a filterable graphical presentation of the selected data:
 - PCA plots
 - Bar charts
 - Heatmaps
 - Point plots
 - Tables with conditional formatting
- Generate hundreds of unique graphs and plots of normalized local lab data
- Easy delta analytics
- Conversion of local laboratory reference ranges to SI and conventional units

Normalized local laboratory data is available for easy assessment within our secure local lab analytics portal. Simply select the dashboard for the presentation desired and filter the data as needed.



Tree maps of the normalized results provide an easy way to identify those parameters that show movement between visits (shown above). On-screen filtering of data allows rapid assessment by test, subject, visit, laboratory and degree of delta.

Other available dashboards include principle component analysis, bar charts, delta plots and more. All of the data supporting each dashboard is easily exportable to Excel with one button click.

To arrange a demonstration of LabConnect's local laboratory data collection and normalization services, please contact your local LabConnect representative or request a demonstration at www.labconnectllc.com/locallabnormalization.

ABOUT LABCONNECT

Founded in 2002, LabConnect provides global central laboratory services including routine and esoteric laboratory testing, kit building, sample management, biorepository and scientific support services for biopharmaceutical and CRO clients. LabConnect's unique combination of state-of-the-art technology, world-class laboratories, easy access to emerging markets and extensive specialized testing expertise means the drug development industry can rely on a single provider for all of their central laboratory service needs.



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