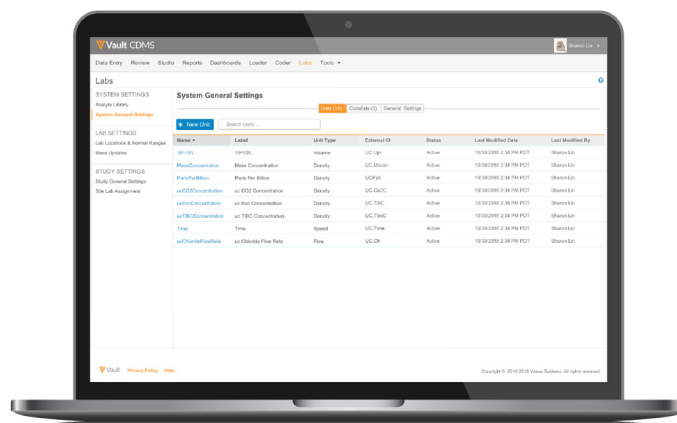


Veeva Vault CDMS - Local Labs Module

Managing Reference Ranges and Units Across All Your Studies

Laboratory reference ranges for any test or analyte are unique to each lab. Working with one or more labs at each site creates a burden on the sites and data managers to collect and manage the reference ranges and correlated units for every study. There is an additional burden on data managers to standardize the data and units across the study for reporting and analysis purposes.



Streamlining Work with Local Lab Data

Vault CDMS optimizes the site experience and data quality by creating a master list of units and range values for use across all your studies. Units of measure and laboratory normals are managed centrally in Vault CDMS. When entering results, sites simply select the lab location and Vault automatically loads the correct units and reference range. Sites only enter the collection date, time, and lab results - nothing else is required.

Business Benefits

Minimizes Data Entry

- Sites only enter the collection date, time, and lab results.
- Selecting the lab location auto-populates range values and associated units.

Maximizes Data Quality

- Manage lab reference ranges in one place for the entire organization. Ranges entered in the master list are available for every study.
- Updated range values are immediately available, minimizing the risk of making decisions on outdated information.

Features

Clean, Intuitive Interface

The modern UI is easy to navigate and use with little training needed. The local lab data is unified with Vault EDC administration, workflows, and case report forms.

Centralized Tracking of Reference Ranges

Enter lab normal information once and share it across all of your studies and sites.

Data-driven Normals Selection

Vault uses the patient demographic information such as age and gender to auto-populate the appropriate normal range data for that specific patient, laboratory, and analyte.

Manual Override

If authorized, sites may override the auto-populated range values for a particular analyte. Both sets of values are displayed.

Reference Range Effective Dates

Effective dates for lab normals ensure the correct ranges display for the given collection date.

Pre-defined Units

Vault automatically loads the appropriate units once sites designate the lab. No more selecting units from a dropdown list.

Background Unit Conversions

Vault maintains a library of unit conversion ratios and generates standardized results and units to accompany the original results and units in data extractions.

Visual Indicators

Visual icons indicate when results are outside of reference ranges. Sites can easily see which results need review for clinical significance.

Analyte Library

Vault provides a preloaded master list of all commonly used analytes.

LOINC Code Support

Comply with the FDA guidance to report LOINC codes with lab results by adding the appropriate LOINC codes within your analyte master list.

Rapid Setup

Upload lab locations and normal ranges from a spreadsheet template for easy deployment.

Changes to Lab Reference Ranges

Lab reference ranges will change due to a new testing method, a new analyzer, or a software update. With most EDCs, a site updates the normal range for an individual study, and every study and site using that lab needs to make the same update. Such a fragmented process introduces delays and increases the likelihood of error.

With Vault CDMS, the sponsor or CRO will update the lab reference range, including the effective date provided by the lab, and the new information is instantly available across all your studies. Vault then uses the effective date to generate a discrepancy report and flag impacted forms.

Test Code	Analyte	Gender	Lower Age	Upper Age	Lower Normal	Upper Normal	Units	Effective Begin Date	Effective End Date	Approved	In Use	Last Modified Date
2800717	Hemoglobin count	Male	4.6	6.0	10%NA		%	02/10/2009 12:00 AM EDT		No		07/07/2009 12:25 PM EDT
1300049	Hemoglobin count	Female	6.0	6.8	10%NA		%	02/10/2009 12:00 AM EDT		No		07/07/2009 12:25 PM EDT
0500024	Hematocrit	Male	40	54	%		%	02/10/2009 12:00 AM EDT		Yes	INUSE	07/07/2009 12:25 PM EDT
4872047	Hematocrit	Female	37	48	%		%	02/10/2009 12:00 AM EDT		Yes	INUSE	07/07/2009 12:25 PM EDT
6145006	Hemoglobin	Male	13.5	17	g/dL		g/dL	02/10/2009 12:00 AM EDT		No		07/07/2009 12:25 PM EDT
2307165	Hemoglobin	Female	12	15	g/dL		g/dL	02/10/2009 12:00 AM EDT		Yes	INUSE	07/07/2009 12:25 PM EDT
6400010	Creatinine	Male	18	85	Years	2	mg/dL	02/10/2009 12:00 AM EDT		Yes	INUSE	07/07/2009 12:25 PM EDT
1300049	Creatinine	Female	18	85	Years	0	mg/dL	02/10/2009 12:00 AM EDT		No		07/07/2009 12:25 PM EDT
3001002	White Blood Count	Both	4	10	10 ³ /mm ³		10 ³ /mm ³	02/10/2009 12:00 AM EDT	06/10/2009 12:00 AM EDT	Yes	INUSE	07/07/2009 12:25 PM EDT
0410072	Platelets	Both	150	300	10 ³ /mm ³		10 ³ /mm ³	02/10/2009 12:00 AM EDT		Yes	INUSE	07/07/2009 12:25 PM EDT
6400010	Erythrocytes	Both	137	147	mm ³		mm ³	02/10/2009 12:00 AM EDT		No		07/07/2009 12:25 PM EDT
2500719	Platelets	Both	5.4	5.3	mm ³		mm ³	02/10/2009 12:00 AM EDT		No		07/07/2009 12:25 PM EDT
0700010	Platelets	Both	200	104	mm ³		mm ³	02/10/2009 12:00 AM EDT		Yes	INUSE	07/07/2009 12:25 PM EDT