

The Design and Implementation of an Electronic Laboratory Specimen Tracking System as a Tool in Collaborative Clinical Research and Multicenter Clinical Trials

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Background

- This RhoLAB™ system was developed as part of the study “An Extended Phase II Study of Decitabine in Subjects with High Risk Sickle Cell Disease.”
- The objective of the study is to examine in a multi-center setting whether long-term administration of decitabine over a period of 18 months can produce sustained elevations in HbF in subjects who remain at high risk of early mortality and morbidity despite hydroxyurea (HU) therapy or in patients who are intolerant of HU therapy.
- Safety and efficacy evaluations of decitabine include a number of assays that will be performed among five central laboratories on specimens collected as often as every 2 weeks.
- This complex study design generated the need for a system that could accurately and efficiently track specimens and report results for up to 50 subjects across 10 U.S. sites and five central laboratories.

RhoLAB™

What is RhoLAB™? (What does it do?)

- RhoLAB™ is a laboratory specimen tracking system that facilitates the timely collection, transportation, and processing of samples, and notifies clinical sites and the statistics and data management center (SDMC) when results are available.
- **How? (The RhoLAB™ Interface)**
- Accessible through a secure website for use by sites, labs, and the SDMC
- Additional RhoLAB™ secure log-in page to access the system

Features

Enrolling Subjects

- Information automatically populates to RhoLAB™ once a subject has been entered into the Electronic Data Capture (EDC) system, minimizing the amount of data that must be manually entered by site study coordinators.



• However, subjects can also be entered manually if necessary (e.g. if a subject must be entered into RhoLAB™ before they are entered into EDC).

• Subjects are enrolled and identified by their CSCC ID number, thus protecting their confidentiality



Adding Specimens

- The RhoLAB™ system defaults to the expected number of specimen tubes in order to minimize manual entry, but this information can be modified to reflect the actual number of collected specimens.
- Barcode scanners are used to scan in each unique Specimen ID number, eliminating incorrect data entry.
- Bar code labels listing the study name and specimen number are provided for specimen tubes as well as subject research files, making record-keeping more accurate and efficient.



• Each specimen is associated with the secure Subject ID number within the RhoLAB™ system, allowing labels to be de-identified, showing only the specimen number.

• Central Lab investigators have access to the RhoLAB™ system, however, they can view only completely de-identified subject data. They do not have access to any data that can link the specimen to the subject (i.e. gender, date of birth, medical record numbers).



- RhoLAB™ provides a comments field when adding specimens, which allows coordinators to comment on any specimen abnormalities. Thus the system accurately reflects the condition of the specimens before they are shipped.
- A Specimen Summary page provides coordinators with a summary of the specimens entered.

Shipping Specimens

- Coordinators can select specimens to include in a shipment.
- Each shipment has a unique ID, and viewing the details of each shipment allows users to see the sender, the recipient, the date the shipment was sent, the date it was received, and the specimens numbers for all specimens included in the shipment.
- RhoLAB™ provides a printable packing list, which lists the sender, recipient, and specimen numbers for all specimens included in the shipment.
- Additionally, shipments can be tracked through the mail courier's website.



RhoLAB™ Automated Email Notifications

- Upon shipment from a site, email notifications are sent to Lab A (VDJ Laboratory) and SDMC Coordinators.
- Upon shipment from the Lab A (VDJ Laboratory), email notifications sent to Lab E (Reticulocyte Laboratory) and to SDMC Coordinators.
- When analyses are performed, the system provides notifications of clinical and safety endpoints.

Customized User Roles

• The RhoLAB™ system of user roles enables control over exactly what each user is authorized to see, add, and/or edit.

Site Study Coordinator Role

- Enrolls subjects in RhoLAB™
- Adds specimens
- Creates shipments
- Ability to view specimen info from his or her site only

Lab Role

- Receives email notification of shipments from sites
- Confirms receipt of shipments in RhoLAB™
- Ability to check the condition in which specimens arrive
- Creates shipments to send to other labs

RhoLAB™ Administrator Role

- Role for SDMC staff
- Receives email notifications of shipments
- Ability to add users, facilities, roles...
- Ability to view subjects, specimens, and shipments

Summary

- The RhoLAB system allows sites to track and ship blood specimens, and sends electronic notifications to investigators when results are available.
- RhoLAB provides detailed information to central laboratory investigators about specimen collection and shipment.
- Recent upgrades to the RhoLAB system allow central laboratory investigators to ship and track specimens from one central laboratory to another.
- Additional features provide investigators with detailed information about shipments, including the laboratory or site from which a specimen originated.
- These capabilities, combined with the use of customized laboratory collection kits, bar code scanners, and specimen labels, provide for maximum accuracy in entering data and tracking specimens for the duration of the trial.