



MiPAL Guide for Site Laboratories

Version 1.0

Developed by the IMPAACT Network Laboratory Center
Last Updated: 01 MARCH 2018

Table of Contents

Section 1: Overview of MiLab Central	2
Section 2: MiLab Central Administrative Account	2
Section 2.1 – Admin Account Features:	2
Section 2.2 - Requesting an Administrative Account (Admin).....	3
Section 2.3 - Navigating the Web Portal: Site Administration.....	4
Section 2.4 - User Management Module	5
Section 2.5 - PAL Assignment Module	6
Section 3: MiLab Central Laboratory User Account.....	8
Section 3.1 – Lab User Account Features	8
Section 3.2 - Requesting Lab User Accounts.....	8
Section 4: Managing Essential Documents	9
Section 4.1 – Purpose of Essential Documents Module	9
Section 4.2 – Submitting a New Essential Document	10
Section 5: MiPAL Workflow	11
Section 5.1 – Accessing MiPAL.....	11
Section 5.2 - MiPAL Basics	12
Section 5.3 - Adding a NEW Instrument or Method	14
Section 5.4 - Uploading Study-Specific Documents in MiPAL.....	15
Section 5.5 - MiPAL Completion and Ready for Internal Lab Review	15
Section 5.6 - Internal Review of the MiPAL	16
Section 5.7 - Network Laboratory Center Review and MiPAL Queries	17
Section 6: Supply Management	17

Section 1: Overview of MiLab Central

MiLab Central is a secure online web portal customized for use by network sites and laboratories to easily manage laboratory requirements for participation in network studies. The main features of MiLab Central include access to study specific Protocol Analyte Lists (**MiPAL**), management of required laboratory documents, and non-standard reagent and supply order management.

Refer to the relevant sections outlined in the Table of Contents for information and instructions on how to use the features and tools of MiLab Central.

The MiLab Central web portal requires an internet connection and a MiLab Central username/password. An account must be created for each person at the site and/or laboratory that will need to access the tools and information on MiLab Central. Refer to the following sections on how to create an account.

MiLab Central Web Portal can be accessed at <http://www.milabcentral.org>

Note: MiLab Central supports the following web browsers: Internet Explorer (IE), Safari, and Chrome

Section 2: MiLab Central Administrative Account

Section 2.1 – Admin Account Features:

- ✓ Request additional accounts to be created
- ✓ Deactivated old accounts
- ✓ View pending MiPALs for the network site's participating studies
- ✓ Assign lab staff to complete MiPAL, as needed
- ✓ Assign one Reviewer for each MiPAL to review and submit to Network Laboratory Center

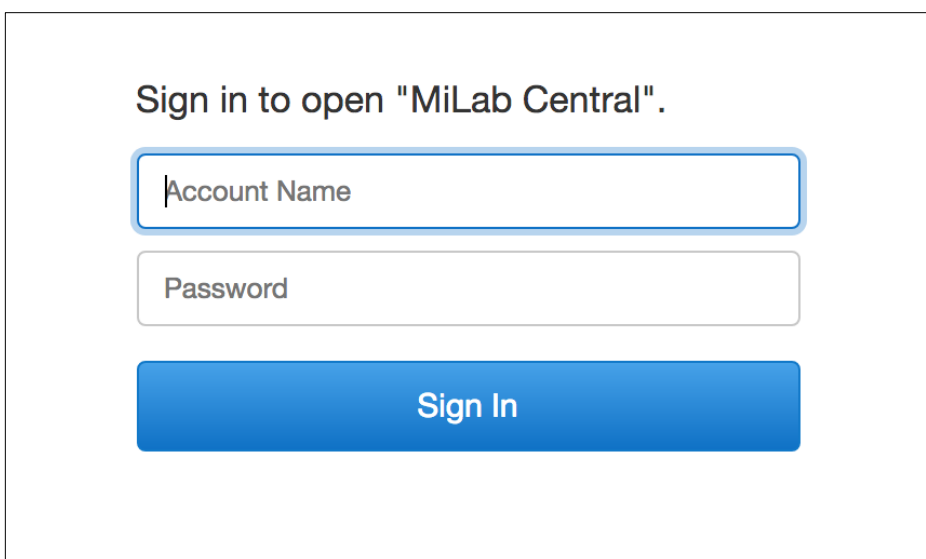
Each network site will need to determine at least one person to be the site's MiLab Central Administrative Account (also referred to as an "Admin" or "Admin Account"). A MiLab Central Administrative Account has the highest level privileges and control with regard to account management (requesting or deactivating accounts), access to testing information of associated testing laboratories (either site affiliated or contract labs), as well as assigning PALs to lab staff through the MiLab Central Web Portal.

Depending on the laboratory's association with the site (affiliated or contracted), and the preferred workflow for PAL completion and review, the Admin can be either site staff or laboratory staff. Each site should determine the best approach for their situation.

Section 2.2 – Requesting an Administrative Account (Admin)

Requests for an Administrative Account can only be granted by your site's Network Laboratory Center.

1. To Request an Admin Account, email your site's Network Laboratory Center. Include in your request:
 - The Site Name
 - Admin first name and surname
 - Admin Email address
2. Once the Network Laboratory Center has created an Admin Account, log-on information will be sent to the email address provided in the request. The email will contain:
 - Link to the web portal: www.milabcentral.org
 - Account username
 - Temporary password.
3. When accessing the MiLab Central Web Portal for the first time, enter the username (Account Name) and temporary password provided.



Sign in to open "MiLab Central".

Account Name

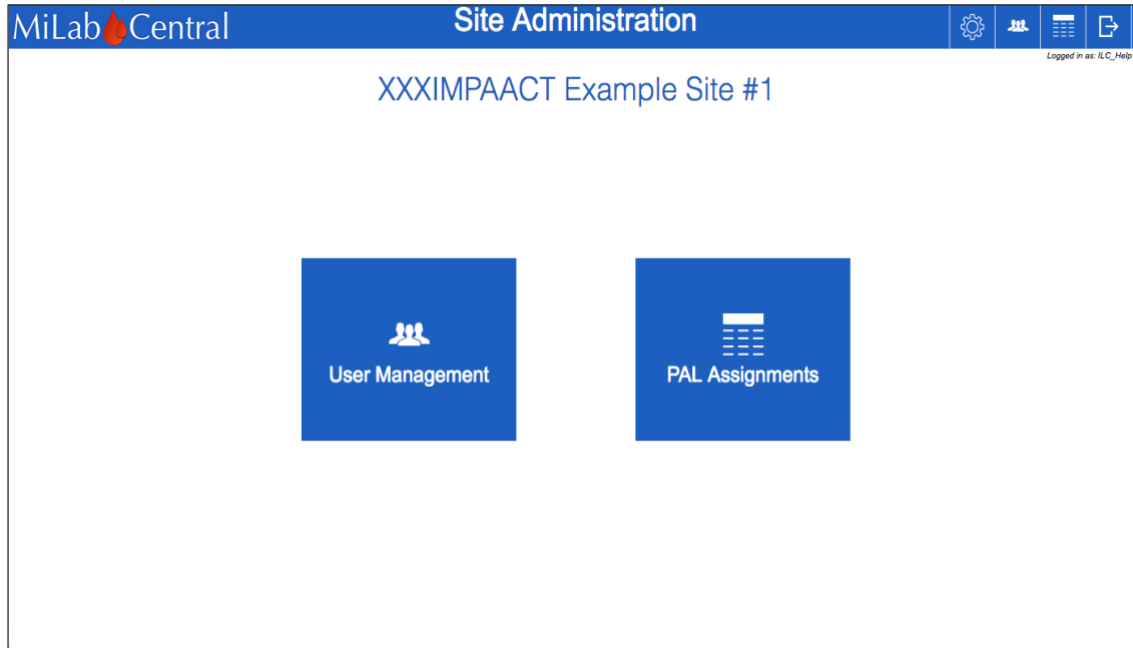
Password

Sign In

4. You will be prompted to create a new permanent password. Remember or write down your username and password and store in a secure place, as you will need this information each time you log in to the MiLab Central Web Portal.

Note: Please email your Network Laboratory Center if you need assistance with your username or password. If you forget your password, the Network Laboratory Center will have to reset it for you, therefore you should anticipate some delay in accessing MiLab Central web portal until your password reset request is completed.

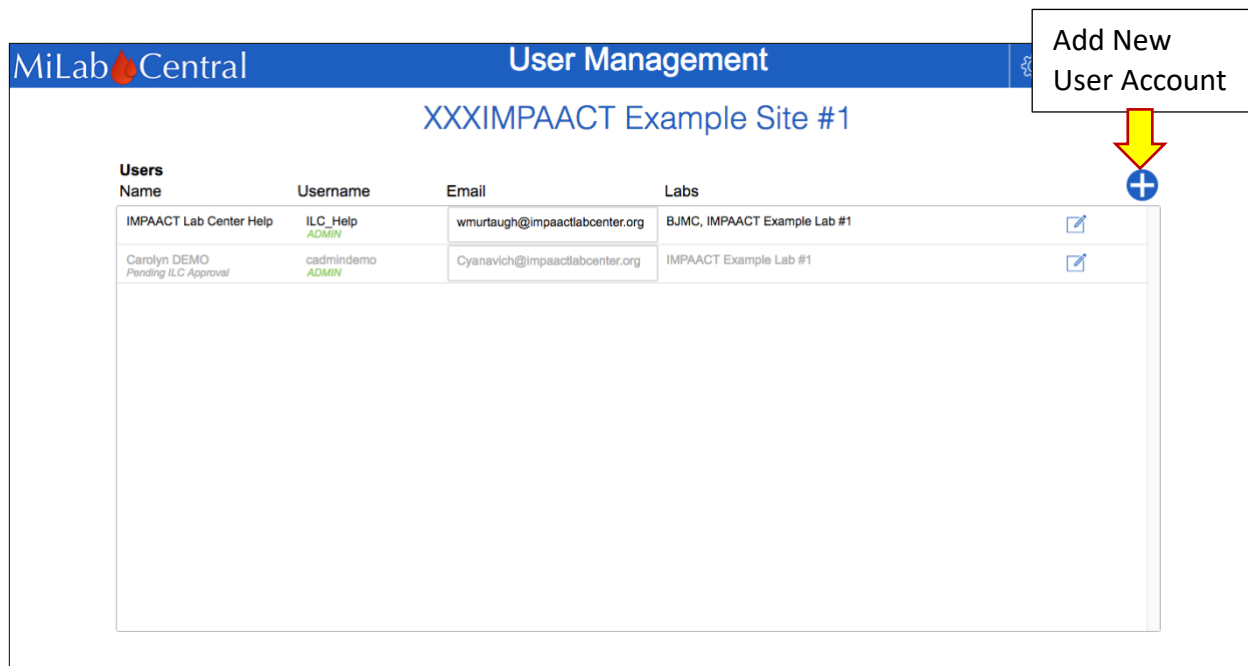
Section 2.3 – Navigating the Web Portal: Site Administration



In addition to accessing the standard panel of tools and features, the Admin will have access to the Site Administration homepage to manage (request/remove) Laboratory User Accounts through the User Management Module and will be responsible for assigning appropriate staff to complete and review MiPALs through the PAL Assignments Module.

Section 2.4 – User Management Module

Entering the User Management Module will bring you to the page where you can add new user accounts and view/manage the user information for all active and pending accounts (refer to example below).



MiLab Central **User Management**

XXXIMPAACT Example Site #1

Users Name	Username	Email	Labs
IMPAACT Lab Center Help	ILC_Help ADMIN	wmurtaugh@impaactlabcenter.org	BJMC, IMPAACT Example Lab #1
Carolyn DEMO Pending ILC Approval	cadmindemo ADMIN	Cyanavich@impaactlabcenter.org	IMPAACT Example Lab #1

Add New User Account

Admins are responsible for ensuring that the appropriate laboratory staff have access to the MiLab Central web portal by requesting additional Laboratory User accounts. Additional accounts can be requested by clicking on the Add (+) button in the top right corner. Selecting this button will take you to the “Create New User” screen. Complete the required fields for each Lab User, including the affiliated laboratories (Refer to the example below). Users can only be assigned by the Admin to a laboratory associated with the site (affiliated lab or contract lab), and therefore will only have access to the laboratory documents and testing information of the laboratory to which they are assigned. Additionally, each network lab will only be able to see the sites they are associated with and the aligned protocols.

The screenshot shows the 'Create New User' form in the MiLab Central web portal. The form is set against a light gray background with a blue header bar at the top containing the 'MiLab Central' logo. The form fields are arranged vertically on the left side. Each field is labeled with an asterisk indicating it is required. The fields are: 'First Name' with a placeholder 'Example First Name', 'Last Name' with a placeholder 'Example Last Name', 'Email' with a placeholder 'sample@email.com', 'Username' with a placeholder 'Example Username', and 'Labs' with a dropdown menu showing 'IMPACT Example Lab #1'. Below the fields, there is a small text note '* = Required Field'. At the bottom of the form, there are two buttons: a blue 'Submit' button and a red 'Cancel' button.

Once submitted, the Network Laboratory Center will be notified of the new account request and must approve each request before the account becomes activated. Activation of a new user can take up to 2 business days. Therefore, it is recommended that you establish MiLab Central User accounts.

Refer to the Lab User Account Section to learn about additional tools and features for Laboratory Users.

Section 2.5 – PAL Assignment Module

The web-based Protocol Analyte List (called **MiPAL**) for all new Network studies will be completed and submitted through the MiLab Central web portal. The MiPAL replaces the former MS-Excel spreadsheet.

The site and laboratory will be notified by their Network Laboratory Center representative when a new study specific MiPAL is available.

1. When a new MiPAL is available, the Admin must log in to MiLab Central, and enter the PAL Assignments Module.
2. Select a MiPAL from the “Available PALs” list in the left panel.
NOTE: For every MiPAL, the Admin will always be included by default in the “Assigned to” list in order for the Admin to access the MiPAL, determine which lab staff are most appropriate to complete it, and view the progress of pending MiPALs.
3. In the “Assigned to” panel on the right, select the Lab User who will be primarily responsible for filling out and completing the MiPAL, then check the “Primary User” box.
4. To give additional staff access to the MiPAL, select the Add (+) button and select a name from the available accounts. You may assign as many staff as needed to complete the MiPAL.
5. As with the previous PAL format, once the MiPAL has been filled out it must be thoroughly reviewed by one additional site or laboratory staff member prior to submission to the Network Laboratory Center for DCLOT approval. Under the “Review Assigned to” dropdown list, select the person that will be responsible for final review and submission to the Network Laboratory Center. Note: This person cannot be the same as the “Primary User”.

Each user will be notified via an automatically generated email once they have been assigned to a MiPAL. At any time before the MiPAL is submitted, the Admin can add or remove users from the PAL Assignment list. Optionally, by selecting the “Email Alert” button, the Admin can send an email to each Lab User reminding them they have a MiPAL pending.

Section 3: MiLab Central Laboratory User Account

Section 3.1 – Lab User Account Features

MiLab Central Laboratory User Accounts (Lab Users) features include:

- ✓ Complete MiPALs as assigned by the Admin
- ✓ Review and Submit MiPALs as assigned by the Admin
- ✓ Upload and access study-specific lab related documents for your laboratory (e.g. HIV algorithms, Specimen Flowcharts)
- ✓ Upload and access your laboratory's Essential Documents (Refer to section 4.1)
- ✓ Order applicable non-standard reagents/supplies based on study needs.

Section 3.2 – Requesting Lab User Accounts

As described in Section 3, the Laboratory User accounts are requested by the site's Admin and approved by the Network Laboratory Center. The Admin will assign each Lab User to one or more site associated laboratories, as appropriate, allowing the Lab User to securely view testing information only for their laboratory. Often, sites will utilize multiple laboratories to meet all of the testing requirements of the study, therefore the site may need to assign a Lab User from each associated laboratory to work on the MiPAL.

Once the Network Laboratory Center has approved the Admin's request for a new Lab User Account, log-on information will be sent to the Lab User email address provided in the request. The email will contain:

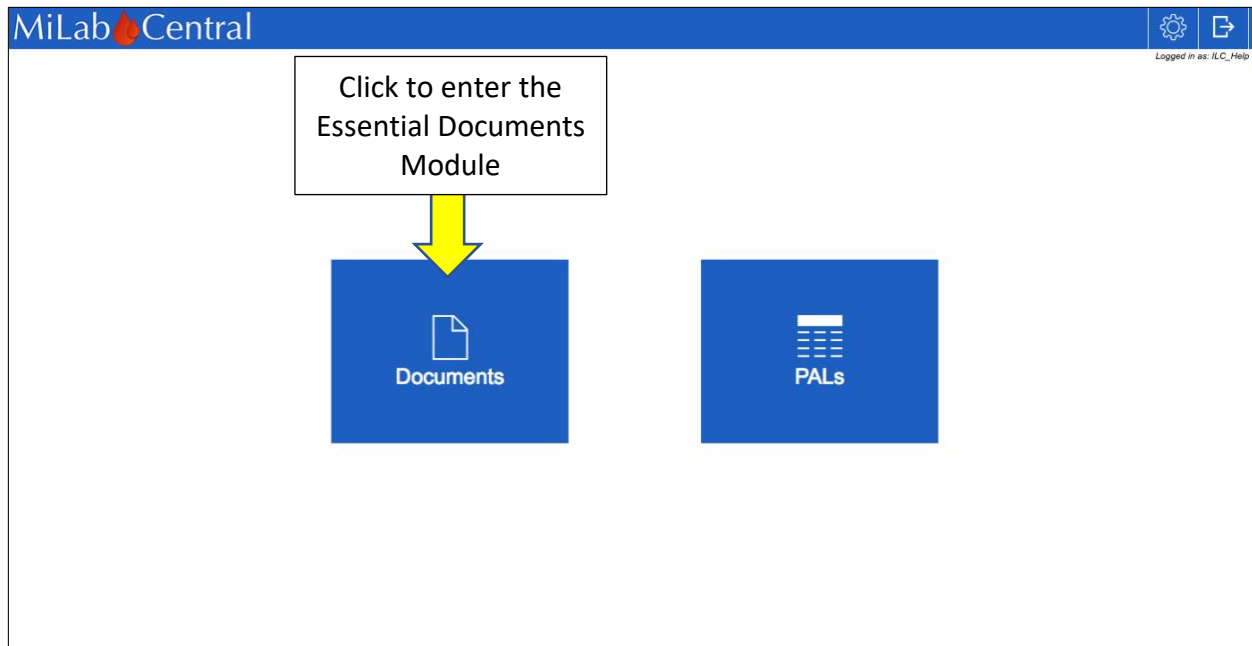
- Link to the web portal: www.milabcentral.org
- Account username
- Temporary password.

When accessing the MiLab Central Web Portal for the first time, enter the username and temporary password provided.

You will be prompted to create a new permanent password. Remember or write down your username and password and store in a secure place, as you will need this information each time you log in to the MiLab Central Web Portal.

Note: Please contact the Network Laboratory Center if you need assistance with your username or password.

Section 4: Managing Essential Documents



Section 4.1 – Purpose of Essential Documents Module

As part of the laboratory readiness process for participation in all network studies, laboratories must produce current copies of routine laboratory documents, referred to as Essential Documents. The documents below are examples of common requirements for approval of laboratory readiness for study activation, but other documents may be required as requested by DCLOT or your network laboratory center.

Essential Documents include, but are not limited to:

- Lab Director CV
- CAP, CLIA, SANSA, ISO or other accreditation certificates as applicable
- Current age appropriate Normal Ranges for all assays
- IATA or Dangerous Goods Shipping training certificates
- SOP lists or SOPs (upon specific request of the Network Lab Center)

MiLab Central

Documents Library Show Lab Current Only ☐

Type **Document Name** **Number** **Effective Date** **Expiration Date** **Submit New**

CLIA Certification

Reference Ranges - Adult

Reference Ranges - Ped

IATA Certification

Example Lab #1

Type	Document Name	Number	Effective Date	Expiration Date
Director CV	Test document	IMPAACT Example Lab #1	12/13/2017	12/13/2017
SOPs	Test Document #2	IMPAACT Example Lab #1	12/13/2017	12/13/2017

From the main screen, click the “Documents” module on the left. The Documents module allows Lab Users to upload and manage all of their laboratory’s Essential Documents in one Documents Library. Once uploaded, these documents remain easily accessible to both the laboratory and the Network Laboratory Center as needed to meet laboratory requirements for study activation. If desired, users can sort and access documents by type and current version.

Section 4.2 – Submitting a New Essential Document

MiLab Central

Submit New Document

Upload Document*

Click icon to upload file

Document Type*

Document Name*

Lab*

Effective Date

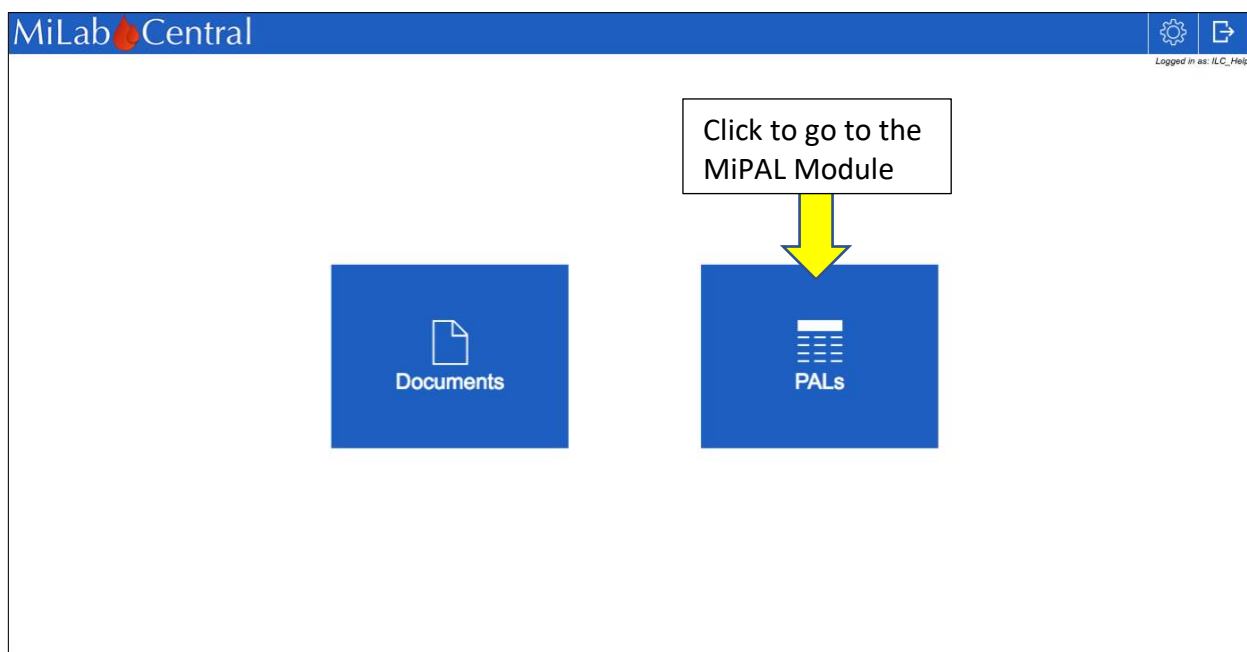
Expiration Date

* = Required Field

Submit **Cancel**

1. Within the Documents Module, click on the blue “Submit New” button in the upper right of the document list. You will be taken to a new page to complete document upload (refer to example below).
2. Click on the “upload” icon to add the appropriate document from your local drive. The file should be in Word or PDF format.
3. Complete the appropriate fields on the right and click “Submit”.
4. The Network Laboratory Center will be notified of each new document submission. They will review and confirm that the document is appropriate before it will be added and can be accessed in the Document Library. All pending submissions will appear in grey font until approved by the Network Laboratory Center.

Section 5: MiPAL Workflow



Section 5.1 – Accessing MiPAL

The Site’s Admin will assign laboratory staff to either complete or review a MiPAL. Refer to previous Section 2.5 for instructions on this process.

Once the Site Admin assigns the MiPAL, the Lab Users will receive an automated email indicating which study specific MiPAL is available, and if they have been assigned to complete or provide internal review of a completed MiPAL.

To access the MiPAL, log in to MiLab Central Web Portal and enter the PALs Module.

Within the PALs Module, MiPALs that have been assigned to be completed will appear in the **To Fill Out** list on the left.

For MiPAL Reviewers, PALs that have been completed and are awaiting internal review and submission to the Network Laboratory Center will be marked with the phrase “Ready for Review” and can be accessed from the **To Review** list on the right (refer to example screenshot below). MiPALs that have been submitted to the Network Laboratory Center and are pending approval will be marked with the phrase “Submitted”.

MiLab Central Available PALs

To Fill Out

Protocol Name Version	
XXXIMPAACT Example Site #1: XDemo2X Version: 1	Ready for Review Load
XXXIMPAACT Example Site #1: IMPAACT 2003B / A5300B (PHOENIX) Version: 0.33	Load

To Review

Protocol Name Version	
Version: 1.0	Submitted Review
	Review
	Review
XDemo2X Version: 1	Ready for Review Review

Section 5.2 – MiPAL Basics

In an effort to increase the efficiency and consistency of filling out PALs, for each analyte there are now fewer fields that need to be completed from a list of prepopulated and network approved options for both the primary and backup laboratories:

- ✓ Laboratory Name
- ✓ Instrument
- ✓ Test Method/Kit

New testing information can always be submitted, for example, as new methods and instruments are validated. Once approved by the Network Laboratory Center, this information will be added to your laboratory’s instrument and method lists. See below section on Adding New Instruments or Methods for details.

NEW Format and Features:

- The Primary and Backup testing information are now stacked vertically for ease of viewing within the width of your screen.
- External Quality Assurance (EQA) information is already linked to the MiPAL analytes through the MiLab Central database and does not need to be entered by the laboratory. It will be automatically generated on the final MiPAL document.
- Following completion and finalization of the initial MiPAL, any subsequent changes (e.g. instrument changes, revisions needed because of a Protocol Version change, etc.) are automatically captured in a revision history at the end of the MiPAL.
- Primary and Backup information that are commonly used across studies for a particular analyte can be saved as the default configuration for all future MiPALs by selecting “Set Default” below the analyte name. When a new MiPAL is loaded, clicking “Autofill with Defaults” will populate the saved fields for all applicable analytes.
- Each Analyte has a text box that can be utilized for notes to either the internal reviewer or the Network Laboratory Center, as you deem appropriate. Feel free to use the free text field in any way that is most useful to your process.
- Your progress on the MiPAL is automatically saved, so you can exit and return as many times as needed to complete the process.

The screenshot displays the MiPAL interface for 'XDemo2X: XXXIMPAACT Example Site #1'. The interface includes a header with the MiPAL logo, site name, and version (PAL Version: 2). Below the header is a table with columns: Assay, Lab, Instrument, and Method/Kit Name. The table lists several analytes under the 'Rapid HIV' category, including 'Anti-HIV-1/2'. Callouts highlight key features: 'Set Default' (Save analyte information for future PALs), 'Add a note' (Add a note), and 'Autofill with Defaults' (Populate information from previously saved analytes).

Assay	Lab	Instrument	Method/Kit Name
Rapid HIV			
Anti-HIV-1/2	Primary	IMPAACT Example Lab #1	N/A
	Backup	N/A	N/A
		N/A	N/A
	Backup	N/A	N/A

1. Select Laboratory Name

First, select the site associated lab that will be performing the testing for a given analyte. Once the Lab is chosen, the available menu of instruments and methods linked to the selected laboratory will be populated in the drop-down list.

If the Lab that intends to perform the testing is not currently in the list of available options, contact your Network Laboratory Center to confirm the lab should be added to the list of network approved laboratories.

2. Select Instrument and Method

After you have selected the lab, clicking on the instrument or method/kit field will take you to a list of the laboratory's approved instruments or methods (refer to example below). To locate the instrument or method, you can type the name into the search bar, or scroll through the list. Once you have found the appropriate choice, simply click on it to add it to the MiPAL.

There may be analytes on the MiPAL in which an instrument or method is Not Applicable, such as for stored samples, rapid HIV testing, or when there are multiple analyte options (e.g. HIV algorithms). In such cases, DO NOT leave the fields blank. Select the field and click "Mark as N/A". Any fields left blank will prevent submission to your Network Laboratory Center.

Section 5.3 – Adding a NEW Instrument or Method

If you need to add a new instrument or method that is not listed:

1. Complete all of the fields at the bottom of the list, including Name of the instrument or method, the manufacturer, the serial number (for instruments) or the product code (for methods/kits), and the FDA approval status.
2. Click "Create New" to submit.
3. At this point a prompt will ask if you have validation data to upload. If this is the first time you will be using the instrument or method for network protocols, you are strongly encouraged to upload documentation of successful validation. Documentation of successful EQA performance for a new assay will be needed prior to final laboratory activation for a study.

NOTE: Every new instrument and method submission is required to be approved by the Network Laboratory Center. The approval process will be more efficient if validation documentation is included with the submission when appropriate.

4. When the Network Laboratory Center approves a new instrument or method submission it is automatically added to the laboratory's instrument or method list for use on future MiPALs. Submissions that are missing fields or are otherwise incomplete or are not accompanied by appropriate documentation when necessary may be rejected, which will result in the information being removed from the MiPAL field.

Select for fields that are Not Applicable. Do not leave fields blank.

Select Primary Method for ALT (SGPT)

Mark as N/A
☒ Show All

Can't find what you're looking for? Try searching

Name	Manufacturer	Model Number
Modified bromcresol green binding assay	Roche	07 3746 1
IFCC method without pyridoxal-5'-phosphate	Roche	07 6495 7
Enzymatic colorimetric method	Roche	07 5998 8
IFCC method without pyridoxal-5'-phosphate	Roche	07 6494 9
Diazo method	Roche	07 3748 8
Kinetic test with urease & glutamate dehydrogenase	Roche	07 6303 9
Enzymatic method with phosphoenolpyruvate & malate dehydrogenase	Roche	07 6676 3
Ion-selective electrodes using undiluted specimens	Roche	
Buffered kinetic Jaffe reaction without deproteinization	Roche	

Still Can't find what you're looking for? Add a new method.

Name

Product Code

Manufacturer

FDA Approved?

Create New

Complete all fields and submit NEW instruments or methods

Section 5.4 – Uploading Study-Specific Documents in MiPAL

In addition to submission of a Protocol Analyte List, often the Network Laboratory Center will require study specific documents such as a specimen flowchart and maternal or infant HIV testing algorithms. You should refer to the study's Network Laboratory Center representative for specific documentation requirements. These documents can be uploaded in the MiPAL at any time prior to submission by selecting the "+" Add button (refer to example below). Documents should be in Word, Excel, or PDF format.

Section 5.5 – MiPAL Completion and Ready for Internal Lab Review

MiPAL submission is a two-step process. Once the MiPAL is completely filled out it is required to be reviewed internally by a person other than the designated Primary User. Your site's Admin has determined and assigned the Reviewer at the time the MiPAL was made available by the Network Laboratory Center. Checking the box "Ready for Internal Lab Review" will notify the Reviewer via an automated email that the MiPAL is pending their review.

Ready for Internal Lab Review ☐ Check this box when MiPAL is ready for internal reviewer.

Documents + Add upload study specific documents

Save & Exit

The submission process is NOT COMPLETE until the assigned *Reviewer* has submitted the MiPAL to the Network Laboratory Center. Refer to the next section 5.6 for MiPAL submission instructions.

Section 5.6 – Internal Review of the MiPAL

MiLab Central Available PALs

Logged in as: ILC_Help

To Fill Out

Protocol Name | Version

XXXIMPAACT Example Site #1: XDemo2X Version: 1	Ready for Review	Load
XXXIMPAACT Example Site #1: IMPAACT 2003B / A5300B (PHOENIX) Version: 0.33		Load

To Review

Protocol Name | Version

	Submitted	Review
		Review
		Review
XDemo2X Version: 1	Ready for Review	Review

Click here to review and submit the MiPAL

As previously described in the previous Section 5.1, all PALs pending internal review will be listed in the “To Review” section of the MiPAL Module. Click the “Review” button next to the MiPAL name to access the MiPAL.

Reviewers have the same privileges as the Primary User to make any changes needed to update and revise information entered into the MiPAL, view and enter additional notes, or upload additional study specific lab documents.

When the MiPAL is complete and ready for submission to the Network Laboratory Center, click “Submit to LC”. The Reviewer will be prompted to download a PDF of the submitted draft for

their reference, and the status will be changed to “Submitted” on the MiPAL Module homepage.

The screenshot shows the MiPAL interface with a table for assay data. The table has columns: Assay, Lab, Instrument, and Method/Kit Name. The first row is for 'HIV RNA' with 'Primary' as the Lab, 'IMPAACT Example Lab #1' as the Instrument, and 'N/A' as the Method/Kit Name. A 'Set Default' button is next to the 'HIV RNA' row. A 'Notes' pop-up window is open, showing 'Primary User: Please confirm Method name.' and 'Internal Review: Revised to N/A'. A yellow arrow points from the 'Submit to LC' button to a text box that says 'MiPAL is complete and ready for review by the Network Laboratory Center'.

Section 5.7 – Network Laboratory Center Review and MiPAL Queries

The Network Laboratory Center will be notified once the Reviewer has submitted the MiPAL. If there are no questions or issues that arise during Network Laboratory Center review, the MiPAL will be sent by the Network Laboratory Center to the DAIDS Clinical Laboratory Oversight Team (DCLOT) for review and sign-off.

Once checked by DCLOT, a final PDF version of the MiPAL that includes DCLOT name and sign-off date will be sent by the Network Laboratory Center to site and laboratory staff.

If at any point there are questions or issues raised by the Network Laboratory Center or DCLOT on the submitted MiPAL, the MiPAL will be de-submitted and can again be accessed via MiLab Central for revision and resubmission by the assigned lab users. The lab users assigned to complete and review the PAL will be notified via an automated email that the Network Laboratory Center has requested revision of the MiPAL.

Section 6: Supply Management

If your laboratory will be participating in a study that requires study specific central supply orders, your laboratory will receive dedicated instructions for utilizing the Supply Module from the Network Laboratory Center.