

1. How to Submit a Validation in MiLab (Title Slide)

2. Topic Overview

This video tutorial covers the following topics:

- Validation Overview,
- Validation Document Preparation, and
- How to Submit Validation or Verification Documents for Review:
 - Including validations for manual methods that do not require separate instruments or analyzers, for example rapid or point of care testing, and
 - Submitting validation summaries that include testing of multiple analytes that use the same instrument, such as chemistry or hematology panels.

3. Validation Overview

One of the DAIDS GCLP requirements for all laboratories is documentation of appropriate validation or verification of all testing performed in support of the network studies. During your preparations for study laboratory approvals, the Laboratory Center may request validation documentation to verify against the primary instruments and methods listed on your MiPAL. Please be aware that validations completed for IQA and VQA qualification should be submitted directly to those programs and not through the MiLab validation process. Additionally, only instrument and method validations listed on your PAL as primary will be accepted for submission. In order for the Laboratory Center to track the status of your validation, allow for efficient review, and prevent documents getting missed or lost via email, the Laboratory Center has developed a process for submitting your laboratory validation documents via MiLab Central.

4. Validation Document Preparation

Before you begin the submission process, please ensure you have the following information available: the name, manufacturer, and serial number of the instrument that will be used for study testing. The name of the method and the product code, this is usually the manufacturer's reference code used for ordering purposes. The FDA approval or clearance status and the CE marked status if available. Please be aware that many tests are required by DAIDS to be FDA approved. So, please check with the Lab Center before submitting if you plan on using methods that do not have an FDA status. You will also need to know the specimen types that were used for the validation, for example, plasma, serum, whole blood, or sputum. The validation summary should be signed and dated by the Laboratory Director. You will also need a copy of the reagent or test kit package insert provided by the manufacturer.

5. How to Submit Validation or Verification Documents for Review

Once you have all the required information available, log onto the MiLab Central web portal. On the homepage, select the Submit Validation tab. This tab will allow you the flexibility to create, view, and manage any of your validation submissions.

To upload a new validation, first check if the applicable instrument has already been added to your inventory by clicking on Select Existing Instruments tab. If the instrument is not listed, identify if the validation is for a manual method or if it applies to a new instrument, not yet listed in your inventory. If this is for a manual method, simply select the Manual tab and you will be taken directly to the analyte and methods section. If the validation includes a new instrument, select the New Instrument tab, and complete the required fields. When you are finished, click Create.

If you have identified that the instrument is already in your inventory, there is no need to create a duplicate entry. Just begin by clicking Select, next to the appropriate instrument. Next, you will choose the analyte or analytes associated with your validation. You can scroll through the list, or you can type in a key word to search more quickly. You will want to select all the analytes that are included in your validation. Please do not create multiple submissions for method validations completed on the same instrument. This will create unnecessary work for you, and it may lead to rejection of your submission or delays in review.

For each analyte selected, you will be required to select the test method or reagent kit details that are already added to your inventory or submit new method details to your inventory by selecting Add Method. For each method, you will be required to indicate the specimen type, as well as the FDA or CE Marked status. Either Yes or No. Once complete, select Save and go back to analytes. You will need to repeat this step for each analyte included in your validation. To verify that all applicable analytes have been added to your submission, check the box Show selected only.

Once you have verified all analytes are accounted for, select the Documents tab. Here you will upload your validation summary documents and a copy of the package insert. Remember that the uploaded document files' names will not transfer, so you are required to complete the document name fields below before submission. If needed, you may add any additional supporting documents by selecting Add Document.

Finally, complete the remaining fields at the bottom of the window, including the validation type, the date the validation was performed, whether it's for primary or backup purposes (note that only primary submissions will be accepted), and then you can also indicate any notes for the Laboratory Center or pSMILE. Once you are done, click Submit.

You also have the option to save your progress and return in another session if you need to gather additional information prior to submission. At any time, you can also cancel and delete your submission.

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Once you click Submit, the Lab Center will be notified of your submission and will facilitate the formal review of your validation data by pSMILE. You will not be able to modify anything after submission, so if there is any incomplete or erroneous information, either pSMILE or the Lab Center can open up your submission for revision. pSMILE will reach out to the laboratory directly to address any issues. If everything is in order, they will sign off on the validation, and the Laboratory Center will provide an approval letter indicating that the instrument and method are acceptable for use on network studies. If you want to review the status of submitted validations, you can return to the Submit Validations tab and select, Existing Validations.

6. How to Submit a Validation in MiLab (End Slide)

This concludes the How to Submit a Validation in MiLab video tutorial. Additional information about using MiLab is available on the ACTG IMPAACT Laboratory Center website, which is available at www.actg-impact-lc.org.