Network Laboratory Working Instructions for Submission of Instrument and Method Validation Documentation via MiLab Central

I. SCOPE:

In an effort to ensure appropriate and efficient review of instrument and method validations required to be approved for IMPAACT or ACTG network studies, the IMPAACT/ACTG Laboratory Center at UCLA has implemented an electronic validation submission system within MiLab Central.

Laboratories will use the MiLab Validation Submission system to facilitate pSMILE review of all new assay validations relevant to network studies.

The Laboratory Center will review the associated instrument and methods details for relevance to the laboratory's active or anticipated study participation and facilitate pSMILE validation review.

pSMILE will only review and provide sign-off of validation documentation received through the MiLab Central Portal. Email requests for validation review received by either the Laboratory Center or pSMILE will be rejected until they have been properly submitted within the MiLab system using the instructions below.

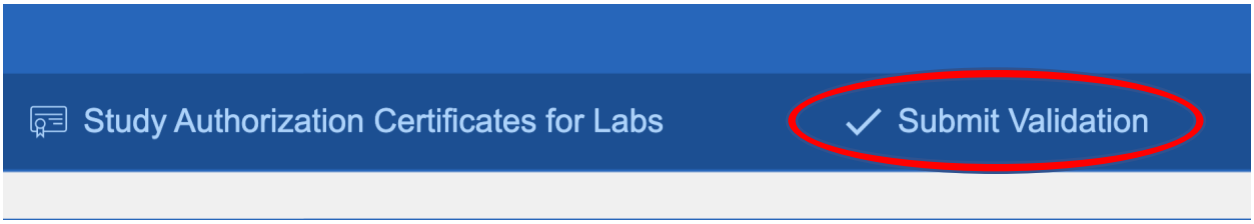
II. VALIDATION SUBMISSION INSTRUCTIONS:

1. Information you will need available prior to submission:
    a. Instrument and Method name
    b. Instrument and Method Manufacturer
    c. Instrument Serial number
    d. Method product code (reference code used for ordering reagents/kits)
    e. US FDA approved/cleared status
    f. CE marked status, if not U.S. FDA approved
    g. Sample types validated (e.g. plasma, whole blood, sputum, etc.)
    h. Copy of completed validation summary signed and dated by Lab Director
    i. Copy of manufacturer's package insert(s)

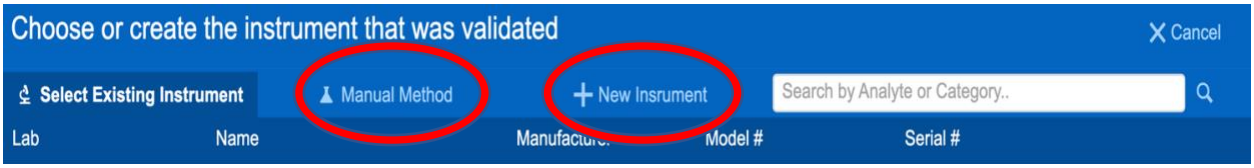
2. Laboratory Staff responsible for validation submissions should ensure they have a MiLab Central account. If you have an account, no additional credentials are needed. To request a new MiLab Central account, please send an email to actg.labcenter@fstrf.org or impact.qaqc@fstrf.org.

3. Once you have all of the information in Step 1 above, Log in to www.milabcentral.org

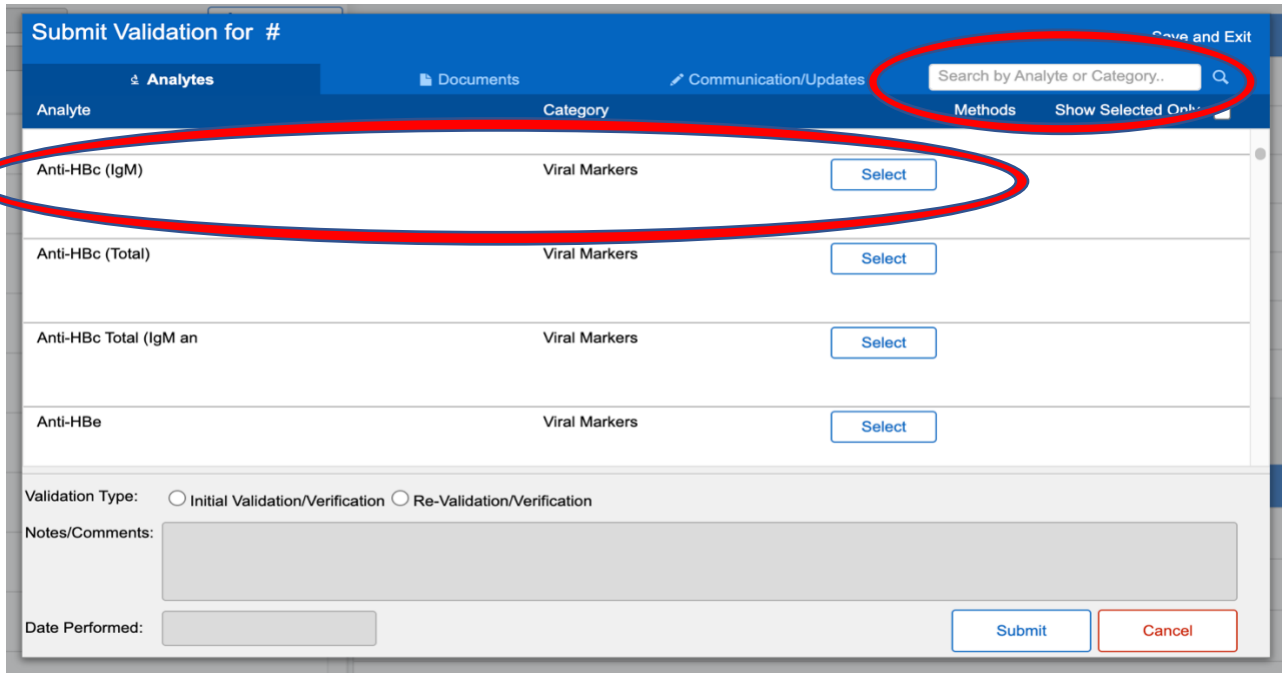
4. On the top menu of your MiLab homepage, select “Submit Validation”



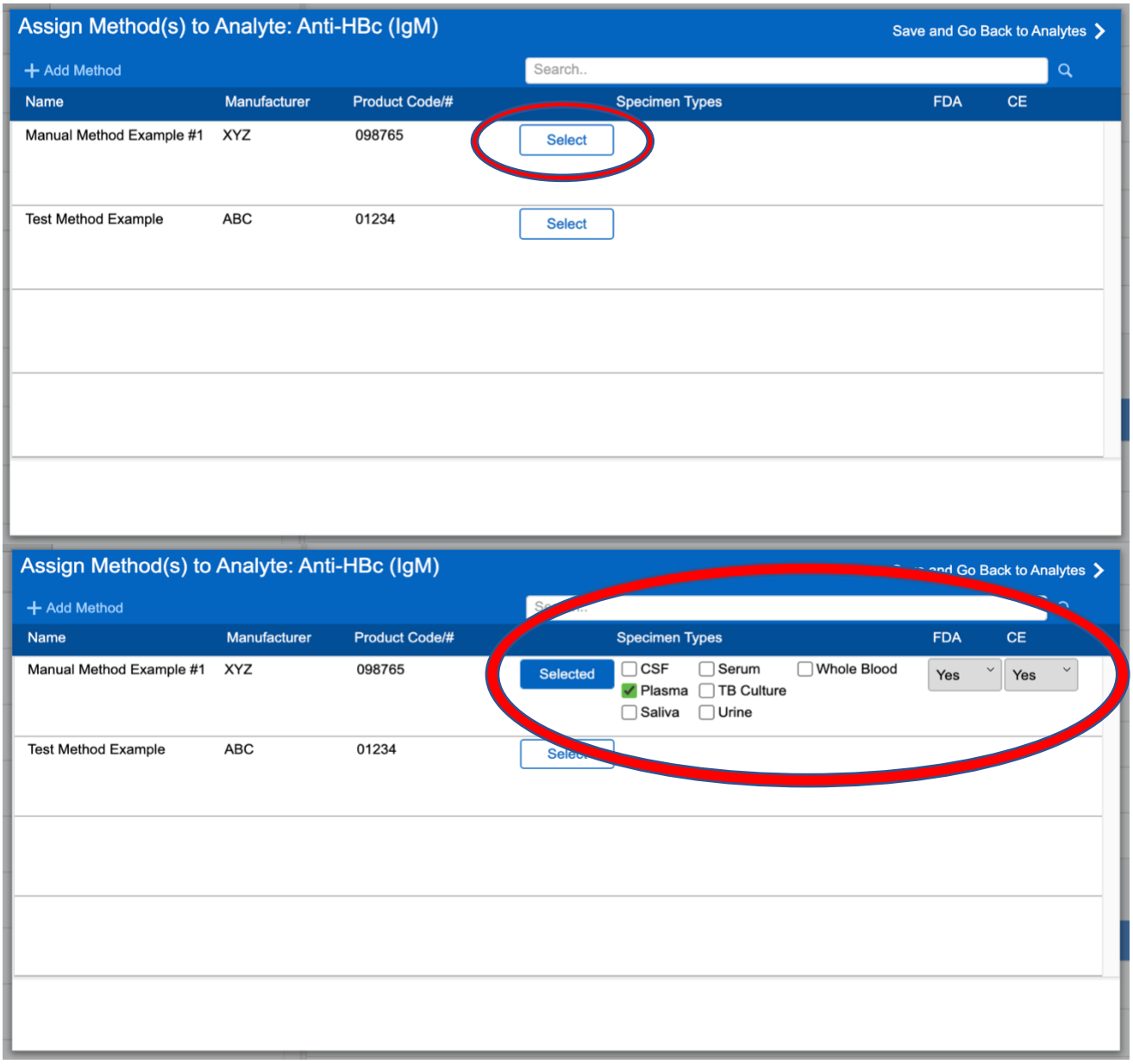
5. Select the instrument that was validated from your current inventory list.
    a. If the instrument has not yet been added to your inventory list, you can add it to your inventory by selecting “ + New Instrument”
    b. If it is a manual method with no associated instrument, select the Manual Method tab and select the analyte that applies to the method (e.g. urine, hcg). This information will stand in for the required instrument details.



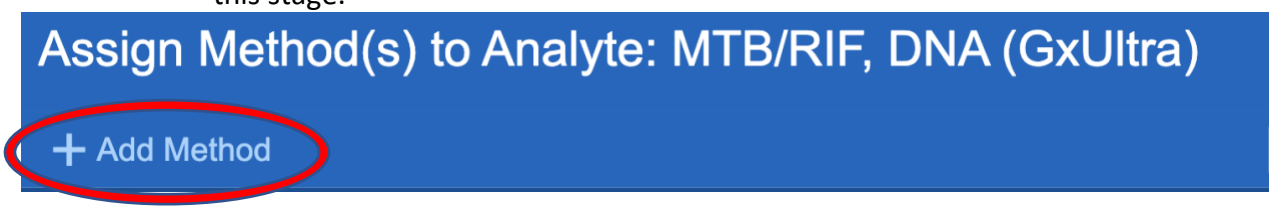
6. After you have selected the applicable instrument or manual method, select the analyte from the list. You can also do a quick search using the search bar in the upper right corner.

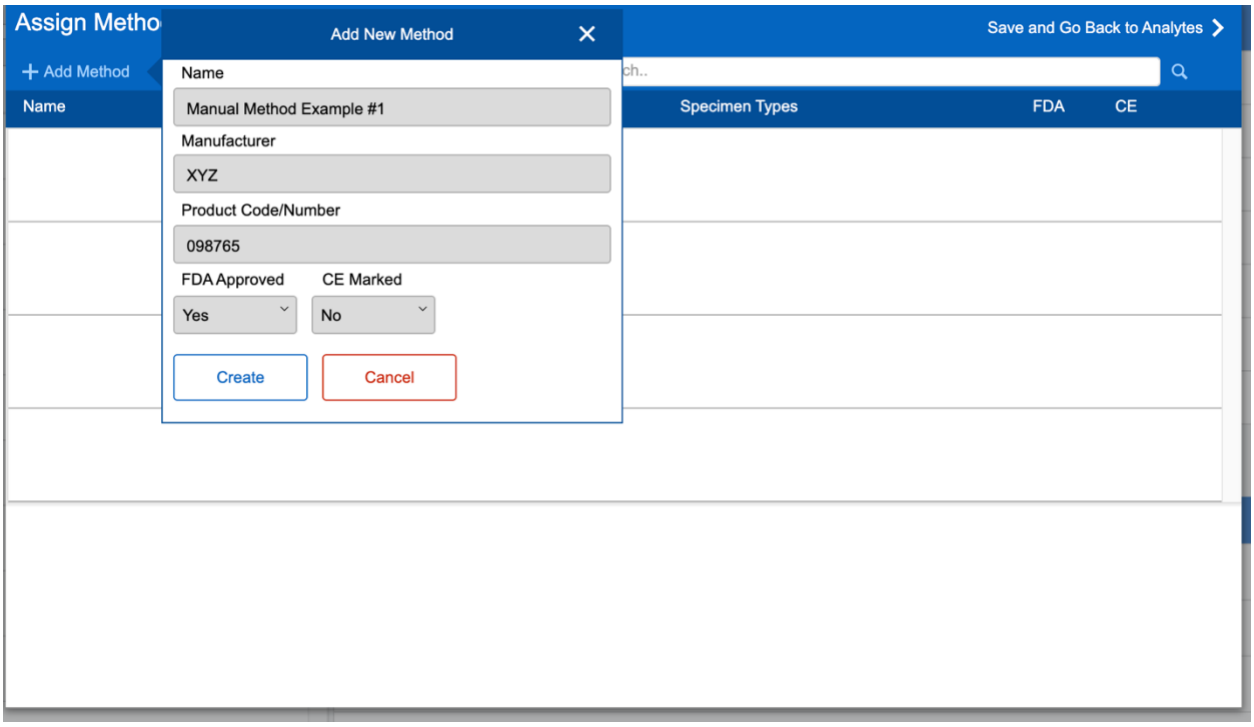


7. For each analyte selected, choose the applicable method product and kit details from your inventory list, including specimen type(s) validated and the US FDA and CE marked status of the assay.



   a. If the method is not yet in your inventory list, you can add it as a new method at this stage.

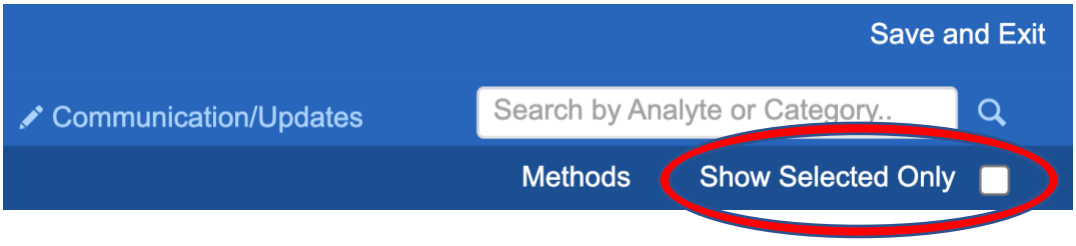


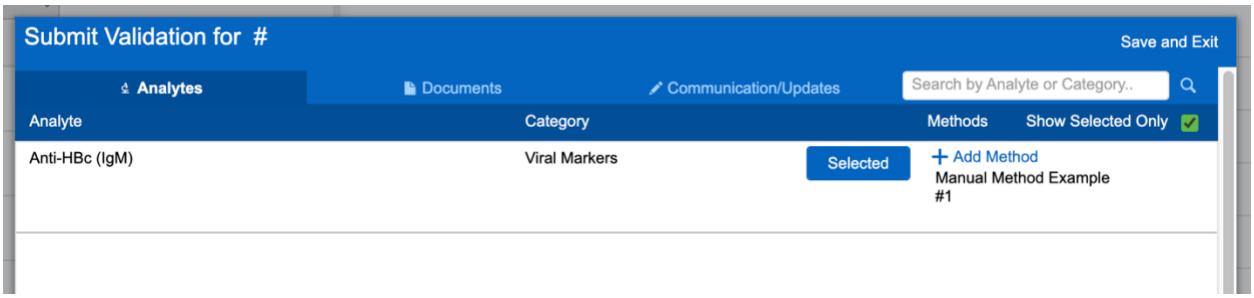


b. Once you have completed the method section, select "Save and Go Back to Analytes"

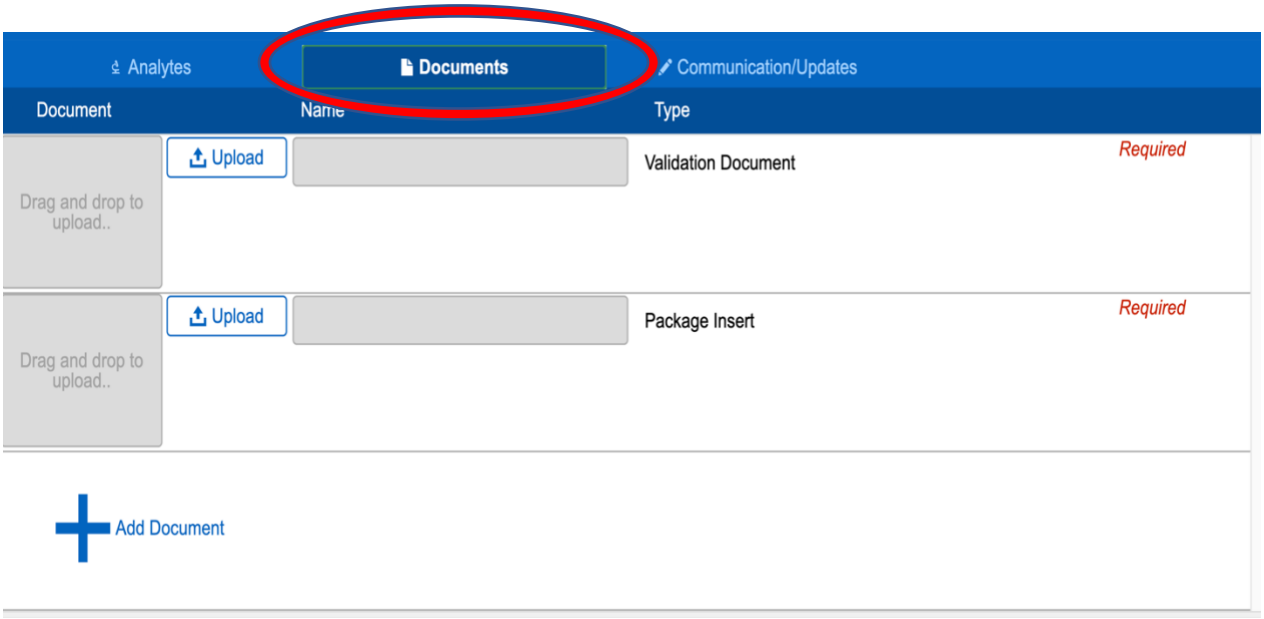
8. If necessary, Repeat Step 7 above for any additional analytes that apply to your validation.

9. To filter the Analyte list to show only the selected analytes, check the box "show selected analytes". Double check that this list includes all analytes that apply to your validation.





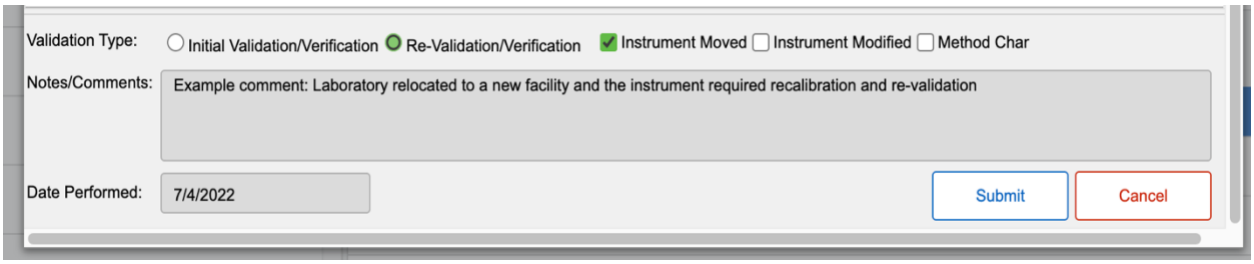
10. Next, you will need to upload the completed validation documents. Begin by selecting the documents tab.



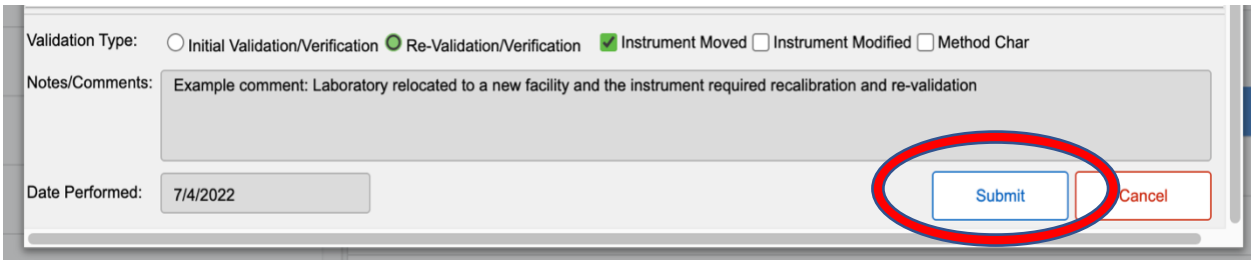
11. Upload, at minimum, the completed validation document and manufacturer's package insert. You can drag and drop the document files or click "Upload" and select the documents from your local files. If needed, you may upload additional documents by selecting "+ Add document"

12. Type a name for each document submitted that clearly describes the document (eg. Validation of Instrument XXX for Hematology testing).

13. Select whether the validation is an initial validation or a re-validation. If Re-validation, you will be required to enter a reason for the re-validation. In the "Date Performed" field, enter the date the validation was signed off by the Lab Director.



14. Once all fields have been completed, select "Submit". If any information is missing, an error message will appear indicating the missing fields and you must correct the missing fields before you will be allowed to submit. Upon successful submission, a pop-up window will appear indicating that the validation has been successfully submitted to the Laboratory Center. The Laboratory Center will be automatically notified of the submission.



15. The Laboratory Center will review the submitted information for accuracy and relevance to required network testing. Once verified, the submission will be made available to the laboratory's pSMILE coordinators for documentation review.

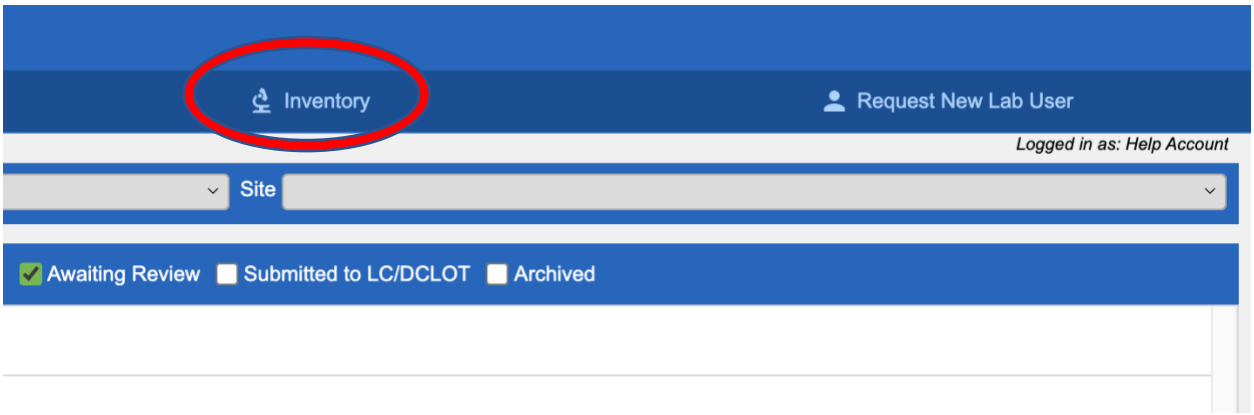
a. The Laboratory Center will reject any submissions that are incomplete, and the laboratory will receive a notification explaining why the submission was rejected. The laboratory staff will then have an opportunity to edit the submission details through MiLab Central and resubmit.

16. pSMILE may reach out to the site as needed via email to communicate questions or concerns. However, any changes or modifications needed to the validation submission must be re-submitted to the Laboratory through the MiLab system.

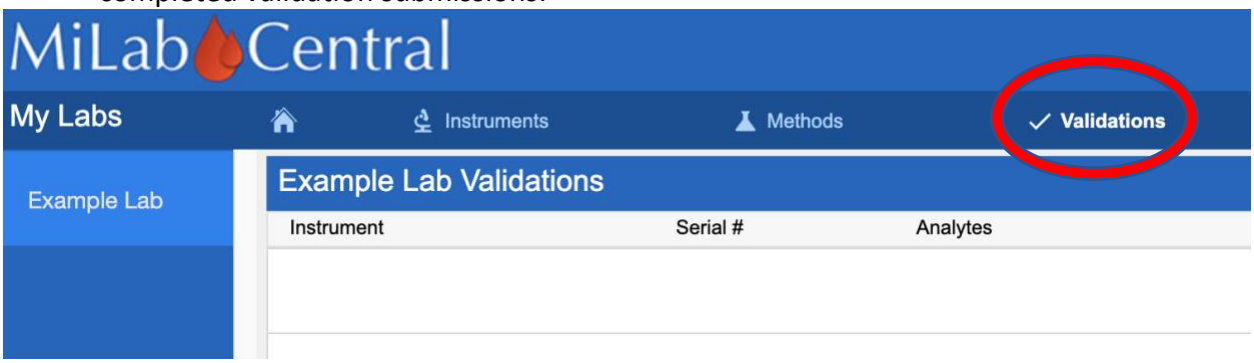
17. Once pSMILE has signed off on the validation summary via MiLab, the Lab Center will be automatically notified and will provide the laboratory with a formal network approval letter stating that the instrument and/or methods are cleared to be used on network studies.

III. CHECKING THE STATUS OF SUBMITTED VALIDATION REVIEW

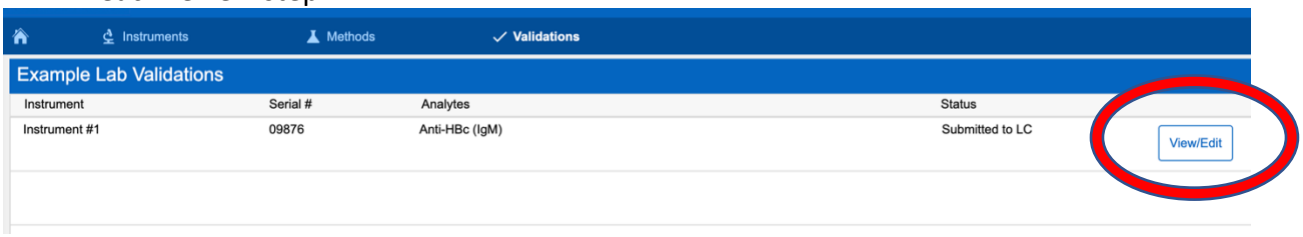
1. At any time, the laboratory may check the status and date of their submission within MiLab Central by selecting the "Inventory" Tab on the MiLab Central homepage.

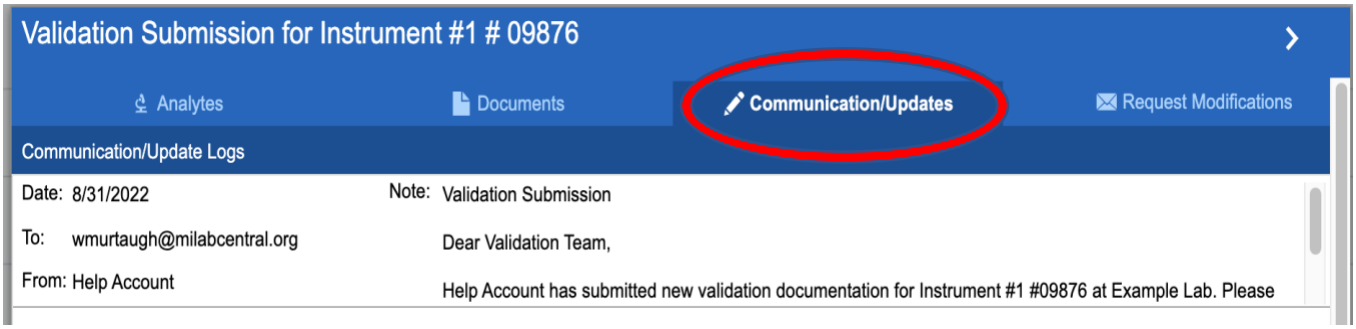


2. Once you are on the inventory Page, select "Validations" to see a list of all pending and completed validation submissions.



3. For any submission listed, select “View/Edit” to review the details of your submission. The “Communications/Updates” tab will provide dates and communications related to each review step.





4. If you have any questions or issues with completing your validation submissions through MiLab Central, please contact the IMPAACT and ACTG Laboratory Center Validations Team at lc.validations@fstrf.org