Purpose: The purpose of this manual is to provide the information about the immunophenotyping module of Chimera Proficiency Testing (CPT) program to the participants.

Scope: This document applies for all the existing as well as potential participants of the program.

Procedure: This instruction manual is applicable for the existing as well as potential participants to know about the terms/information required for participation in the program. It includes the detailed instruction on the following:

- How to apply
- Payment details
- Details for submission of sample confirmation
- Eligibility Criteria for participants
- Sample related information
- Details of program scope
- Procedure to submit the result
- Subcontracting activities
- Contact details

How to apply:

- a. To participate in the Chimera proficiency testing (CPT) program the interested laboratory have to first, fill an online subscription cum registration form available on Chimera web portal https://chimera-pt.webflow.io
- b. After successful submission of online form, you will get a confirmation mail in registered mail Id. You have to confirm your subscription by clicking the link. This will confirm your registration.

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- c. After registration participant laboratory have to submit participation charges.
- d. After successful payment evaluation will be done by the chimera management to ensure all the information for approval for participation.
- e. Once all the criteria are full filled the participant are provided a unique code, the code is communicated to the participant(s), via portal.

2.Payment details:

Total annual cost of participation in this service is –

Annual registration fee=5000

Immunophenotyping= 5000 per test in scope

GST (GST number - 07AAGCV2511C1ZT) = 18%

Total Amount = Registration fees + Participation fees +GST

The fees can be paid using the following account details -

Yes bank Ltd.

Account Number- 005561900005925

IFSC Code - YESB00000555

To- Chimera Translational Research Fraternity Pvt. Ltd

A/2A Ground Floor, Green Park

New Delhi-110016

3. Sample handling and processing information

a. Upon receiving the samples, go to the Chimera PT Web Portal and fill the sample receiving details in the given format/Inform Chimera about the sample details by mail.

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- **b.** The sample will be transported at room temperature (12-18 $\pm 2^0$ C) and test must be performed within 24 hours of sample receiving
- c. The sample must be stored at room temperature $12-18^0$ C $\pm 2^0$ C in sterile condition immediately after receiving. So that these samples remain unaffected from contamination.
- **d.** Upon receiving the samples perform the viability test to check the viability of sample by using your own standardizes method of testing.
- **e.** Please check the microscopic slide image updated on portal in resource section to decide the panel of antibodies to put up the test.
- **f.** Perform the test according to the manufacturer protocol.
- **g.** Please maintain the record of sample receiving date, time and temperature upon which the sample was received along with the sample processing date.
- **h.** You will find test specific worksheet in the resource section which helps you to note down the result.
- i. Results have to be analyzed as per the standard of the participating lab.
- **j.** After completion of the test, the results need to be submitted in Chimera web Portal by using your own login credentials within 5-10 working days.
- **k.** We try our best to provide contamination-free sample to our participants.

4. Chimera Proficiency Testing Program Schedule

S.No	Test	Schedule
1.	Leukemia	Thrice in a year
2.	Lymphoma	Thrice in a year
3.	CD 34 stem cell enumeration	Thrice in a year
4.	PNH (Paroxysmal Nocturnal	Thrice in a year
	Haemoglobinuria)	

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- **5.** All PT sample need to be tested as per the standard operating procedure (SOP) of the participating laboratory.
- **6.** Once the sample is received we request all the participants to submit the date, time, temperature and volume of sample received on format available on portal.

7. Details for submission of sample conformation:

- a. Upon receiving the sample at your laboratory, log in to the portal by using your credentials. After login you will land up on home page.
- b.On home page you will found the link for sample receiving confirmation.
- c. Fill the information and click on submit button to confirm the information.

8. Details of test in scope:

Sample type	Sample Volume	Parameter used	Test method used
Whole Blood (Heparin)	1 ml	Acute Leukemia	Immunophenotyping
Whole Blood (Heparin)	1ml	Lymphoma	Immunophenotyping
Whole Blood (Heparin)	1ml	CD 34+ Stem cell enumeration	Immunophenotyping
Whole Blood (Heparin)	1ml	PNH (Paroxysmal Nocturnal Haemoglobinuria	Immunophenotyping

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- **9.** All the guidelines are followed for preparing, packaging and dispatch of PT sample to minimize the chance of any contamination. However, it is requested to treat them as clinical/ infectious samples and care must be taken in their handling and disposal as per common biomedical waste treatment guideline.
- **10. Mode of reporting of result:** All the participants have to submit their result on the template available on web portal by using your own login credentials.

11. Procedure to submit the result:

- a. Once you are ready with the results, login to your account on the portal.
- b. Go to the submit tab. In submit tab you will find the options for result submission for immunophenotyping.
- c. Submit the result in the format available (For any queries kindly write to us)
- d. Upon uploading the data click on the submit button.
- 12. No results from participants would be accepted after deadline given with the samples.
- **13.** All participants are requested to maintain the confidentiality of the report and don't compare results with any other participating laboratory.
- **14.** If the sample would not receive within defined time frame or if received any contaminated sample, participating laboratory have to intimate us within 48 hours via mail or call.
- **15.** In case of loss or damage to the PT item in transit, the courier company would be asked to pay for the lost sample.
- **16.** For Immunophenotyping we are not able to provide additional sample.
- 17. The evaluation sheet will be available on web portal after 15 days of the result submission deadline. Participants can download it from the website by using their login. No hard copy of evaluation sheet will be send to any participant.
- **18.** Any complaint regarding error in assessment sheet must be reported within 10 days.

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19. Eligibility Criteria for participants:

- Legally identified.
- Either accredited or planning to get accreditation.
- All clinical laboratories those with purely research or industrial roles, manufacturers
 of diagnostic instruments and reagents, and other laboratories are welcome to
 participate
- The participants have to sign the Non-Disclosure Agreement for maintaining the confidentiality at the time of subscription.
- All the participants have to fill the feedback form after the completion of one round of proficiency testing. The feedback form is available in your personal page after log in.

20. Subcontracting activities:

S.No.	Subcontractor	Subcontracting Activities
1.	Chimera Transplant	Sample procurement (HLA & PRA)
	Research Foundation	Screening)
		Sample preparation.
		Homogeneity and stability testing.
		Sample Storage.

21. Contact details:

Sneha Kumari

Contact address: 209-C 2nd and 3rd floor, Masjid Moth South extension part –II

Email: ctrf.info@gmail.com
Contact number: 9507432062

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22. Note: The enrolment of participants can be done at any time during the calendar year for any test in the scope. One time enrolment will continue until the participants submit the request for cancellation of participation.

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