


Chimera Translational Research Fraternity Pvt. Ltd.			
	<b>General Instructions</b>	<b>Doc No.</b>	<b>CTRF/PT/DOC/03</b>
		<b>Revision No.</b>	<b>01</b>
		<b>Date</b>	<b>20/03/2020</b>
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**Purpose:** The purpose of this manual is to provide the information about the 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
- 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.
- 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.

<b>Prepared By:</b>	<b>Approved By:</b>
<b>Quality Manager</b>	<b>Program Director</b>

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## 2. Payment details:

Total annual cost of participation in this service is -

Registration fees = 5000 INR

Participation fees -

1. HLA Typing (Low Resolution)= 6000 INR
2. Luminex PRA Screening= 8000 INR
3. CDC Cross Match= 4500
4. Flow Cytometer Cross Match= 5500

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. Chimera Proficiency testing Program Schedule

<b>S.No</b>	<b>Test</b>	<b>Schedule</b>
1.	HLA Typing & PRA Screening	Thrice in a year
2.	CDC & FCXM	Twice in a year

4. All PT sample need to be tested as per the standard operating procedure (SOP) of the participating laboratory.

5. 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.

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**6. 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 find the link for sample receiving confirmation.
- c. Fill the information and click on submit button to confirm the information.

**7. Details of our scope:**


<b>Sample type</b>	<b>Parameter used</b>	<b>Test method used</b>
Whole Blood	HLA Typing	SSO/ SSP
Serum	Anti-HLA antibody identification	Luminex PRA Screening
Buffy Coat & Serum	Donor Specific Anti- HLA Antibody Identification	Flow Cytometer Cross match
Buffy Coat & Serum	Donor Specific Anti- HLA Antibody Identification	Complement Dependent Cytotoxicity Cross match

**8.** 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.

**9.** All the samples need to be stored at 4-8<sup>0</sup> C in sterile condition so that it can remain unaffected from any contamination. Records of temperature need to be maintained.

**10.** The test (**CDC and FCXM**) must be performed within 24 hours of sample receiving. Please maintain the record of sample receiving date and time, temperature upon which sample was received along with sample processing date.

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**11.** Rest of the test need to be performed as per the laboratory turnaround time after the sample receipt and submit the results within 5-10 days.

**12. 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.

**13. 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 different test. For ex: if you have to submit results for HLA Typing click on HLA typing format and upload the result.
- c. Upon uploading the data click on the submit button.

**14.** No results from participants would be accepted after deadline given with the samples.

**15.** All participants are requested to maintain the confidentiality of the report and don't compare results with any other participating laboratory.


**16.** Provided PT sample would be stable for a longer duration of time. 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.

**17.** In case of loss or damage to the PT item in transit, the courier company would be asked to pay for the lost sample.

**18.** After receiving intimation from participant following remedies are taken:

S.No.	Sample Type	Remedies
1.	HLA Typing	Participants are requested to intimate us within 48 hours of receiving of sample. The fresh sample is provided to them and the deadline is increased for 2 days.
2.	PRA Screening	Participants are requested to intimate us within 48 hours of receiving of sample. The

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		fresh sample is provided to them and the deadline is increased for 2 days.
3.	CDC cross match	The sample(s) will not be provided to the participants. Participant(s) are requested to participate in the next round.
4.	Flow Cytometry cross match	The sample(s) will not be provided to the participants. Participant(s) are requested to participate in the next round.

**19.** 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.

**20.** Any complaint regarding error in assessment sheet must be reported within 10 days.


**21. Eligibility Criteria for participants:**

- Legally identified.
- Either accredited or planning to get accreditation.
- The participating lab should be working in the field of transplant immunology/molecular genetics.
- 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.

**22. Subcontracting activities:**

S.No.	Subcontractor	Subcontracting Activities
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<b>1.</b>	Chimera Transplant Research Foundation	<ul style="list-style-type: none"> <li>• Sample procurement (HLA &amp; PRA Screening)</li> <li>• Sample preparation.</li> <li>• Homogeneity and stability testing.</li> <li>• Sample Storage.</li> </ul>
<b>2.</b>	Medanta- The Medicity	<ul style="list-style-type: none"> <li>• Sample procurement (CDC &amp; FCXM)</li> </ul>

**23. Contact details:**

Sneha Kumari

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

Email: [ctrf.info@gmail.com](mailto:ctrf.info@gmail.com)

Contact number: 9507432062

**24. 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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