Pfizer Limited The Capital, 1802/1901, Plot No. C - 70, G Block, Bandra Kurla Complex, Bandra (East), Mumbai 400 051. Tel : +91 22 6693 2000 Fax : +91 22 2654 0274



To Whom It May Concern

This is to certify that Mr. Ashwin Balasubramanian has successfully completed his internship in Medical Affairs Team from January 17, 2022 to March 31, 2022.

During the internship period, he was found sincere, hardworking and diligent. He completed the assigned project with great deal of professionalism.

His association with us was fruitful and we wish Ashwin Balasubramanian all the best in his future endeavors.

For Pfizer Limited

DocuSigned by: Hitesh Muley A1C3E0120AB44AF

Authorized Signatory

March 31, 2022

CIN: L24231MH1950PLC008311 Email ID: contactus.india@pfizer.com Website: www.pfizerindia.com



Date: 7th July 2022

CERTIFICATE OF INTERNSHIP EXPERIENCE

This is to certify that **Dr. Harshit Zaveri** student Of MGM Medical College, Navi Mumbai has completed an Internship Project for the period of 8 weeks from 20th April 2022 till 20th June 2022 under the guidance of Gagandeep Momi – Medical Affairs Manager

Kindly note that the content of the project carried by the student is confidential and hence, we will not be able to share the details with the college.

During this tenure, we found the student having good conduct.

Mohammed Mansoor Hussain

Yours sincerely, for AstraZeneca Pharma India Limited

CORPORATE & REGD. OFFICE AstraZeneca Pharma India Ltd. P. B. No. 4525, Block N1, 12th Floor, Manyata Embassy Business Park, Rachenahalli, Outer Ring Road, Bangalore - 560 045, INDIA TEL:+91 80 6774 8000 FAX:+91 80 6774 8857 CIN:L24231KA1979PLC003563 WEB:www.astrazeneca.com/india FACTORY 12th Mile on Bellary Road Venkatala, Kattigenahalli Village Yelahanka Bangalore - 560 063 INDIA TEL:+91 80 6774 9000

FAX : +91 80 2846 2208 +91 80 6774 9628



File No. - EC/NEW/INST/2021/2255

Government of India Ministry of Health & Family Welfare Department of Health Research

> 2nd Floor, IRCS Building, New Delhi - 110001 Dated : 27-Jan-2022

Provisional Certificate

Subject: Provisional registration of the Ethics Committee relating to Biomedical and Health Research with the National Ethics Committee Registry for Biomedical and Health Research (NECRBHR), Department of Health Research (DHR).

In exercise of the powers conferred by sub-rule (3) of rule 17 of the New Drugs and Clinical Trials Rules, 2019, the designated authority in the Department of Health Research, Ministry of Health & Family Welfare, hereby provisionally registers and permits the following Ethics Committee to perform the duties of ethics committee as specified in Chapter–IV of the New Drugs and Clinical Trials Rules, 2019.

Name :	MGM Medical College Institutional Ethics Committee, Navi Mumbai,
Address :	MGM Medical College and Hospital, Navi Mumbai, Sector-1, Kamothe, Navi Mumbai, 410209., Navi Mumbai, Raigad, Maharashtra - 410209
Contact No: Fax :	022-27433404, 27437991, 27437992 022-27431094

2. The Ethics Committee shall observe all the conditions as stipulated in Chapter-IV of the aforesaid Rules, i.e., New Drugs and Clinical Trials Rules, 2019 and the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, specified by the Indian Council of Medical Research (ICMR).

3. The designated authority shall scrutinize the documents and information furnished with the application by the Ethics Committee for the issue of final registration certificate.

4. The above provisional registration shall be valid for a maximum period of two years from the date of its issue or till grant of final registration or rejection of provisional registration, whichever is earlier.

ANU Digitally signed by ANU NAGAR Date: NAGAR 2022.01.27 13:24:41 +05'30' (Anu Nagar) Joint Secretary Department of Health Research Designated Authority



INDIAN PHARMACOPOEIA COMMISSION National Coordination Centre - Pharmacovigilance Programme of India (PvPI) Ministry of Health & Family Welfare, Government of India

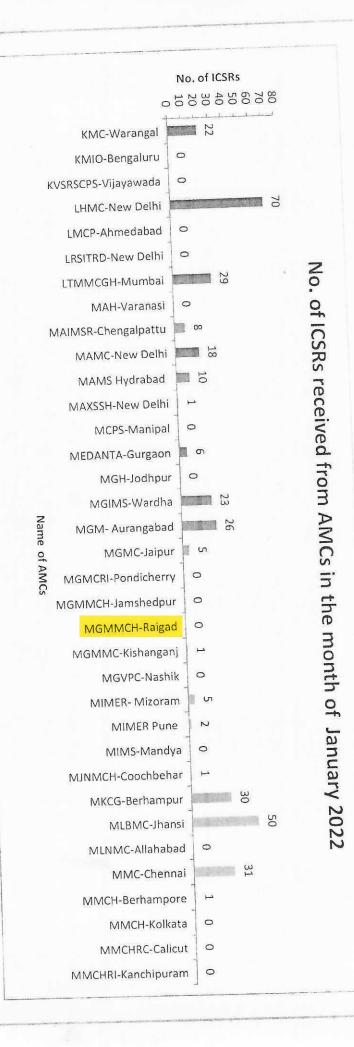
ADRs Reporting Status January-2022

The spontaneous ADRs reporting by the ADR Monitoring Centres (AMCs) under Pharmacovigilance Programme of India (PvPI), National Tuberculosis Elimination Programme (NTEP) & Anti-Retroviral Therapy (ART) centres under National Health Programmes, and Pharmaceutical Industries to National Coordination Centre-PvPI for the month of January-2022 has been compiled. During the month total 9561 ICSRs including follow-up ICSRs were reported to NCC-PvPI. The detail is given below-AMC/ADT/

AMC/ ART/RNTCP/NTEP MAH (Marketing Authorisation Holders)	5225	
	4	336
	Initial	Follow-up
	2998	1338

(I) The details are as follows:

Page 1 of 16



Page 8 of 16



File No. - EC/NEW/INST/2021/2255

Government of India Ministry of Health & Family Welfare Department of Health Research

> 2nd Floor, IRCS Building, New Delhi - 110001 Dated : 27-Jan-2022

Provisional Certificate

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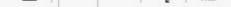
Name :	MGM Medical College Institutional Ethics Committee, Navi Mumbai,
Address :	MGM Medical College and Hospital, Navi Mumbai, Sector-1, Kamothe, Navi Mumbai, 410209., Navi Mumbai, Raigad, Maharashtra - 410209
Contact No: Fax :	022-27433404, 27437991, 27437992 022-27431094

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ANU Digitally signed by ANU NAGAR Date: NAGAR 2022.01.27 13:24:41 +05'30' (Anu Nagar) Joint Secretary Department of Health Research Designated Authority





MGM Medical College and hospital, Navi Mumbai, Panvel, Raigad

is certified as



as per guidelines established by Food Safety and Standards Authority of India



Excellent

Shri Arun Singhal Chief Executive Officer FSSAI

Auditing Parmer FSATO INSPECTION SERVICES Training Partner Parikshan Implementation Parmer FDA Maharashtra - Raigad

Valid up to: 17 February 2024

No: 25/355/2009-AWD Government of India Ministry of Fisheries, Animal Husbandry and Dairying Department of Animal Husbandry and Dairying O/o Committee for the purpose of Control and Supervision of Experiments on Animals (CPCSEA) *****

Delhi Milk Scheme Complex, Shadipur, Delhi – 110008 Date: 03.03.2022

To,

Dr. Prakash Khandelwal, Chairman, IAEC Mahatma Gandhi Mission's Medical College Sector - 18, Kamothe, Navi Mumbai - 410209, Maharashtra Email:drkhandelwalpn@gmail.com Mobile: 9822072226

Subject: Renewal of Registration and Reconstitution of Institutional Animals Ethics Committee (IAEC)- regarding

Sir,

The registration of Animal House Facility of your establishment with CPCSEA has been renewed for a period of five years from the date of issue of this letter.

2. The new registration number of Animal House Facility of your establishment is **303/PO/Re/S/2000/CPCSEA for Research for Education purpose on small animals**. Henceforth, the new registration number may kindly be quoted in all your future correspondence with this office.

3. The CPCSEA has accepted the following members recommended by the establishment.

Name of the IAEC Members	Designation in IAEC
1) Dr. Prakash Khandelwal	Biological Scientist, Chairperson
2) Dr. Ipseeta Ray	Scientist from different biological discipline,
	Member Secretary
3) Dr. Yashoda Kattimani	Scientist from different biological discipline
4) Dr. G S Narshetty	Scientist In charge of Animal House Facility
5) Dr. Krutika Khiratkar	Veterinarian

4. CPCSEA hereby nominates the following members to the Institutional Animals Ethics Committee (IAEC) of your establishment:

Details of Nominee(s)	Nominated as	
1) Dr. K. Pani Prasad	Main Nominee	
Principal Scientist, ICAR - Central Institute		h
of Fisheries Education, Yari Raod, Panch		Y
Marg, Varsova, Mumbai – 400061,		
Maharashtra		
Contact No :9867241101		
Email : kpaniprasad@cife.edu.in		
2) Dr. Arvind Ingle	Link Nominee	
Scientific Officer 'F', Tata Memorial Centre,		6
ACTREC, Navi Mumbai- 410210, MS		
Contact No :09969855176		
Email : aingle@actrec.gov.in	Contd	

Contd..

3) Dr. Prabhakar S. Ukale	Scientist from outside the Institute
Veterinarian, Animal House Facility,	
Institute of Chemical Technology, Nathalal	
Parekh Marg, Matunga East, Mumbai -	
400019, Maharashtra	
Contact No :9029938325, 7021420723	
Email : prabhukale@gmail.com	
4) Shri Sharad Bhagat	Socially Aware Nominee
Technical Officer – A, ICMR National	
Institute for Research in Reproductive Health	
Department of Biochemistry & Virology, J	
M Street, Parel, Mumbai – 400012,	
Maharashtra	
Contact No :9869748756	
Email :sharadbiotech@gmail.com	

(Please note that any change in IAEC members can be made only with prior approval of CPCSEA.)

5. The IAEC is valid for a period of five years and is coterminous with renewed period of registration. IAEC is required to be reconstituted at the time of renewal of registration as per CPCSEA guidelines.

6. You are requested to convene the meeting of the re-constituted IAEC within a period of 30 days and upload the same on the website of the CPCSEA.

7. It is stated that only above approved IAEC members shall sign, with date, on the attendance sheet of the IAEC meetings, and decisions will be taken only in meetings where quorum is complete. The quorum for holding IAEC meeting is six (6), and Main Nominee, Scientist from outside the Institute and Socially Aware Nominee must be present in such meetings. Link Nominee can attend in case main nominee conveys his unavailability in writing to the chairman IAEC. However, Link Nominee should be invited once in a year to update him/ her about the activities of IAEC. Any decision taken in the meetings of IAEC without quorum shall be considered invalid.

8. It is also to inform you that before commencing any research on large animals you are required to send research protocols with due recommendation of IAEC to CPCSEA for further approval (procedure for submission of Research Protocols is available on the website of CPCSEA).

Yours sincerely,

(Dr. S. K. Dutta) Member Secretary (CPCSEA)

Copy for necessary action to: Nominees of CPCSEA.

The Main Nominee is requested to ensure that the IAEC meetings are held regularly as stipulated in the SOP of CPCSEA and submit the Annual Inspection Reports of the Animal House Facility regularly on the Website of CPCSEA.

The Main Nominee is requested to conduct the Inspection of Animal House Facility within a period of 30 days and submit the Inspection Report on the Website of CPCSEA



MEMORANDUM OF UNDERSTANDING

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M.G.M. Medical College & Hospital

Kamothe, Navi Mumbai - 410209

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Tuberculosis Officer

Dr. Kiran Patil (I.A.S.)

Chairman District Integrated Health &

Chief Executive Officer

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Raigad-Alibag

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Chief Executive Officer, Zilla Parishad, Alibag, District-Raigad& District National Tuberculosis Elimination Programme Society, Alibag, District-Raigad.

AND

MGM Medical College & Hospital, Kamothe, Tal- Panvel, District- Raigad

This MOU is executed on 1st April 2021 between CHIEF EXECUTIVE OFFICER, ZILLA PARISHAD, ALIBAG, DISTRICT-RAIGAD & DISTRICT NATIONAL TUBERCULOSIS ELIMINATION PROGRAMME SOCIETY, ALIBAG, DISTRICT-RAIGAD having its office at Parijat Society, Raiwadi Complex, Plot No.14, Shribag, Tal Alibag, Dist. Raigad Pin 402201 (Hereinafter called "the Grantor, which expression shall unless exclude by or repugnant to the context include its successors in-interest, executors, administrators and legal representatives) And MGM MEDICAL COLLEGE & HOSPITAL, KAMOTHE, TAL PANVEL, DIST. **RAIGAD** hence forth referred to as PPP Partner, having its office at Plot No.1and 2, Sector-1, Kamothe, Tal Panvel, Dist. Raigad acting through its Hereinafter called "the Grantee", which expression shall unless excluded by or repugnant

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NEW MUMBA to the context include its successors it, interest, executors, administrators and legal representatives).

WHEREAS the Grantor plans to implement "NTEP (National Tuberculosis Elimination Programme) i.e.District DR. TB center with Indoor & Outdoor facilities through Grantee on partnership (PPP partner).

AND WHEREAS the Grantor has agreed to engage the services of the Grantee, subject to terms and as hereunder.

1. D.DR.TB center (under): The activities would be implemented in the District/s of **Raigad, Maharashtra** for performance of the following activities in accordance with NTEP policy;

2. Project Location

The PPP Partner would be providing the services as specified above at the following location/ (s) as decided in consultation with concerned CTO/DTO.

a. Urban/ Rural: Urban/ Rural.

b.District/TU/Block/(s): Whole Raigad District including Panvel Corporation

Area.

c. Urban Wards/ Panchayats covered: Yes.

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d. Population Covered: App. 30 lacs.

3. Period of Co-operation:

The PPP Partner agrees to perform all activities outlined in the guideline for partnerships in above mentioned area. The duration of cooperation will be fromday signing of MOU or the day of the starting the activity / function whichever is later.

Contract assigned for a period of three year 1st April 2021 to 31st March 2024, renewable as per the needs of the programme, subject to satisfactory performance. The contract should be renewed every year on 1st April. The Contract can be terminated by the District Health Society/ State Health Society or the PPP Partner any time with one month prior notice by either side.

4. Terms, conditions and specific services during the period of the MOU.

A. The District Health Society shall (please strike out whichever is not applicable)

i. Provide financial and material support to the PPP for carrying out the activities as mentioned in the partnership guideline.

ii. Provide relevant copy of technical guidelines, updates, manuals & circulars, etc.)

iii. Provide NTEP drugs, logistics and laboratory consumables for use as per NTEP policy as outlined the partnership guideline.

iv. Periodically review the performance and activities being undertaken by the PP Partner

B. MGM will: -

i. Perform all activities as agreed upon and signed under the partnership as mentioned below.

- 1. Institute should be tertiary care hospital with the pulmonologist will be available round the clock.
- 2. Separate designated clinic for MDR TB patients management should be available and comply with the National Guidelines for Air -borne infection control for outpatient settings
- 3. Relevant specialists like Pulmonologist, Physician, Psychiatrist, Dermatologist & gynecologist etc should be available.
- 4. D.DR.TB center Committee to be formed with the above group of doctors.
- 5. To renovate (in keeping with the National Airborne Infection Control Guidelines and National Guidelines for Programmatic Management of Drug Resistant TB (PMDT) provided for the purpose) and designate a special clinic area designated for MDR TB out patient service with earmarked well ventilated preferably open air waiting area separate from other waiting areas, away from clinics managing immune suppressed and vulnerable cases where the patients who will be eligible to avail D.DR.TB services under NTEP will be fast tracked, segregated and counseled in accordance with NTEP guidelines.
- 6. Doctors and Nursing staff should be available from institute round the clock consultation services made available, if required by the patients.
- 7. Management of adverse drug reactions (ADRs) as per National PMDT Guidelines.

Indoor D. DR. TB'Center scheme :

The terms and condition are as follows.

- 1. To designate a special ward compliant with national AIC guidelines and at least 10 beds earmarked for indoor management of DRTB patients according to National PMDT Guidelines.
- 2. Routine clinical laboratory investigation facility to be made available for pretreatment evaluation and monitoring.
- 3. Doctors and Nursing staff should be available from institute round the clock to the DRTB patients.
- Ancillary drugs should be provided by MGM Hospital as per DR TB center Committee's advised services / facilities to diagnose and manage adverse drug reaction (ARDs) as per National PMDT Guidelines.
 Services / facilities to diagnose and manage the service of the ser
- 5. Services / facilities to diagnose and manage the comorbid condition 6. Records and reports to be maintained for PMDT
- 5. Records and reports to be maintained for PMDT registration, follow up, referral and transfer (if required) \of patients as per guidelines update the same on the day basis using Nikshay.
- 7. Quarterly reports to be submitted electronically.

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Dist. Tuberculosis Officer Raigad-Alibag

Dr. Killan Patil (I.A.S.) Chairman District Integrated Health & Family Welfare Society, Raigad Chief Executive Officer Raigad Zilla Parishad, Albert

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- 8. All doctors in the hospital should be following Standards for TB care in India and notify all TB cases through Nikshay.
- 9. Ensure coordination with implementing District officers and staff as well as laboratory for proper follow up of patients till outcome.
- 10. The Drug Resistant Tuberculosis Patients seeking treatment at DRTB Centre of MGMIHS will not be charged for any & all complications related to the tuberculosis (e.g. Pneumothorax, Hemoptysis, Respiratory Failure)

However any emergency not connected / related to tuberculosis requiring intervention (e.g. stroke, acute myocardial infarction, acute kidney injury, D.K.A., Dialysis). The expenses should be borne by patient.

11. The diagnostics services to be provided by the partner organization would include at least.

Sr. No.	Investigations of times test		Rate for tests (In Rs.)
1	Complete Blood Count (CBC)	1	138
2	Blood Sugar (RBS)	1	25
3	LFT. (SGOT/SGPT/Billirubin)	1	275
4	Blood Urea Nitrogen (BUN)	1	55
5	Serum Creatinine	1	56
6	TSH	6	125
7	Urine Routine & Microscopy	1	39
8	Urinary Pregnancy Test (UPT)	1	69
9	Chest X-Ray	3	70
10	ECG	1	100
11	Sr. Electrolytes	1	365
12	Audiometry (PTA)	1	120
13	ESR	1	65
14	Sr. Uric Acid	1	70
15	Urea	1	105
16	HIV	1	75
17	HBSAG	1	130
18	HCV	1	275
19	Sr. Magnesium	1	300
20	USG-Abdomen & Pelvis	1	265
21	Sr. Calcium	1	70
22	Renal Function Test (RFT) With Electrolyte	1	440
23	Indoor stay for maximumdays	7days	
24	Bed Charges, Meals, Breakfast etc.	Included.	
25	Ancillary drugs for management \of adverse drug reaction and co morbidities	As required	

- 12. The DR TB Centre cannot deny services to any eligible patient from the geographical area assign to the centre.
- 13. This does not restrict the DR TB Centre from extending any further services to the patients, if clinically deemed necessary.

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Dist. Tuberculosis Officer Raigad-Alibag

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- 14. DR TB Centre committee doctors will have to be trained in PMDT at National Level.
- 15. Management of MRD/XRD TB patients is to be done as per NTEP Guidelines second line anti TB drugs will be provided from NTEP.
- 16. The performance review of the PPM partner would be done bi annually and in case lack of satisfactory performance the contract may be terminated by either party with one month written notice.

5. Grant-in-Aid

The reimbursement of bills of indoor DRTB patients will be done by the District National Tuberculosis Elimination Program society, Raigad under NHM District Health Society after submission of monthly bills of indoor patient by the MGM Medical College Hospital, Kamothe, Tal Panvel, Dist. Raigad to the Office of District Tuberculosis Officer, Raigad (Parijat Society, Raiwadi Complex, Plot No.14, Chendhare, Shreebag No.2, Alibag, Dist. Raigad.

Sr.	Service Name	Rates per day	Remarks
No.			
1)	Consultation Charges OPD	Rs.200/- One	For Consultation (One
		Time per patient	Time)
2)	IPD Specialist Visit Charges	Rs.250/- per day	For Specialist Visit
	(Consultation Charges)	per patient	(Consultation Charges)
3)	Indoor Charges Package Cost	Rs.1000/- per	Include Pre-Treatment
•	Per day	day per patient	Evaluation (As per List)
			Bed Charges, Meals,
	•	a tree water and the	Breakfast and Ancillary
			drugs etc.
	Total Rate for one patient for	Rs.1450/- per	Patient should not be
	one day	day per patient	charged at any cost for
	1. 200 million		MDR TB Indoor treatment

Note:-1) From 2nd day onwards charge will not exceed Rs.1250/- per day per Indoor patient.

- Indoor Charges Package Cost per day (if Pre-treatment evaluation done outside) is Rs.800/- per day per patient.
- Package cost per day for admitted MDR-TB Patients will be Rs.1000/including pre-treatment evaluation (as per above list), bed charges, meals, breakfast and all necessary ancillary drugs etc.
- 2. In house Specialist Consultation charges would be applicable at Rs.250/day/per patient for indoor patients.
- 3. Rs.800/- per day if pre treatment investigation is done at the district level or outside and patient is admitted to the ward hospital.
- 4. To provide Training, formats and registers for PMDT.
- 5. To Provide access & training to NIKSHAY for online data management and patient tracking.



Dist. Tuberculosis Office Raigad-Alibag

Dr. Kill n Path (L Chairman District Integrated Health & Family Welfare Society, Raigad Chief Executive Officer Raigad Zilla Parishad, Alibag

M.G.M. Medical College & Hospital Kamothe, Navi Mumbai - 410209

6. Fund Management.

Funds under this MOU shall be placed at the disposal of the Grantee in separate account opened by it, subject to its furnishing to the Grantor a letter of commitment containing such conditions as may be approved by the Grantor from the bank that the bank shall not exercise a lien over the said account or may right to set off or adjust any amount due to payable under any loan or credit arrangement which the Grantee may be having or may have with the bank against the amounts standing to the credit of the Grantee in the said amount.

The Grantee shall install and maintain separate books of accounts on cash basis accounting along with proper vouchers for expenditure incurred and with details of outstanding liabilities, if any. The Grantor shall have the right to inspect by its authorized officers of independent agencies the books of accounts and other records relating to the project fund kept by the Grantee any time during the agreement period or thereafter.

7. Grievance Redressal Mechanism

All grievances will be addressed within a period of thirty days by DTOof the concerned district. Final decision will rest with district Health Societies. Annual review would be a platform for addressing grievance of PPM partners.

8. Right over Information/data

All documents, information, statistics and data collected by the Grantee in the discharge of the obligation under the MOU incidental or related to it (whether or not submitted to the Grantor) shall be the joint property of the Grantor, and the Grantee.

9. Indemnity

The Grantee hereby agrees to always keep the Grantor indemnified and harmless from all claims /demands / action and proceedings which may arise by reason of any activity undertaken by Grantee if the activity is not in accordance with the approved guidelines.

This MOU shall be enforceable in courts situated at [Mumbai, Maharashtra]; any suit or application for enforcement of the above shall be filed in the competent court at Mumbai and no other district of Maharashtra or outside Maharashtra shall have any Jurisdiction in the matter.

10. Termination Mechanism

The partnership may be terminated by either side through written notice of one month. In case services of PPM partner are discontinued, unspent balance, if any will be refunded by the partner.

If the Grantor at any stage decides that the Grantee has misutilised the amounts (or any part thereof) already received from the Grantor or has fraudulently claimed any covenants, stipulation or obligations hereunder a commits a breach of any of the terms, conditions or provision of this MOU on its part to be observed and performed, or it at any stage reasonable ground exist to apprehend the breach of

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Dr. Kiran Patil (I.A Chairman District Integrated Health & a Society Rain

the terms and condition of the MOU in future or that the continuance of this project may be prejudiced or be in jeopardy he/she may revoke this MOU wholly or partially and ask the Grantee to refund the amount received till then along with interest accrues, if any after giving at least fifteen days' notice and an opportunity of being heard to the Grantee.

11. The programmatic and financial review of the partnership will be conducted every quarter.

12. Necessary approval of State Health Society has been obtained: Yes

NEW MUMBAI 410209 10

Signature of authorized signatory Dr G. S. Narshetty Dean, MGM Medical College & Hospital, Kamothe, Navi Mumbai.

Dean. SeeG.M. Medical College & Hospital Kamothe, Navi Mumbai - 410209

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Signature of authorized signatory Chief Executive Officer, Zilla Parishad Raigad & District National Tubersulosis Elimination Programme Society, Alibag, District Raigad

Jag, District Raigau

Seal

Dr. Kirah Patil (I.A.S.) Chairman District Integrated Health & Family Welfare Society, Raigad Chief Executive Officer Raigad Zilla Parishad, Aliboa

Dist. Tuberculosis Officer Raigad-Alibag

MOU

between

National AIDS Control Organisation, Ministry of Health and Family Welfare, Government of India

&

Mahatma Gandhi Mission's Medical College & Hospital, Kamothe, Navi Mumbai -410 209

This Agreement is made on <u>1</u> day of <u>December</u> 2018 by and between Ccompetent Authority, National AIDS Control Organisation, Ministry of Health and Family Welfare, Government of India, 9th Floor, Chandralok Building, 36, Janpath, New Delhi 110 001 (hereinafter referred to as "NACO (First Party)")

AND

Mahatma Gandhi Mission's, Medical College, Navi Mumbai (hereinafter referred to as ("Second Party"), run by Mahatma Gandhi Mission, a Public charitable Trust bearing registration number - F- 674(Nanded) having its registered office at - Nanded acting through Dean, MGM Medical College, Kamothe, Navi Mumbai - 410 209, the authorised signatory, hereinafter referred to as "Second Party", which expression shall, unless repugnant to the context, include its successor in business, administrators, liquidators and assigns or legal representatives.

- WHEREAS NACO (first Party) is providing first line antiretroviral treatment (hereinafter referred to as ART) to persons living With HIV/AIDS (hereinafter referred to as PLHAs) in India through designated public hospitals as per the guidelines issued by the NACO (first Party) from time to time:
- AND WHEREAS NACO (first Party) coordinates the aforementioned provision of ART at designated public hospitals by limiting the selection, procurement, distribution and rational use of drugs, including antiretroviral drugs, and prescribing guidelines for treatment of opportunistic infections and provision of ART;
- AND WHEREAS NACO (first Party) is desirous of extending the provision of ART to more PLHAs in collaboration with not-for-profit non-governmental organisations;

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- AND WHEREAS Mahatma Gandhi Mission's, Medical College, Navi Mumbai (hereinafter referred to as ("Second Party") an Organization registered under the MGM Trust Registration. It has established a centre to extend AIDS related treatment, care and other services to its employees and their families living with HIV/AIDS and to extend these services to PLHA's in the nearby areas as a part of their corporate social responsibility;
- AND WHEREAS the parties hereto had set up a collaborative ART project since <u>01/12/2018</u> (month & year) and hereby reduce the terms of the agreement to writing;

NOW THEREFORE THIS AGREEMENT WITNESSES AS FOLLOWS:

I. PURPOSE OF COLLABORATIVE ART PROJECT

The purpose of the present Agreement is to continue the collaborative ART project between NACO (first Party) and second Party that had been a model for high quality provision of ART and associated healthcare and medical management of PLHAs in Maharashtra, India.

- II. RESPONSIBILITIES OF NACO
- NACO (first Party) shall continue to organize refresher training or provide support for training of personnel of second Party involved in the collaborative ART project.
- NACO (first Party) shall provide to second Party regular updates on National ART guidelines from time to time as earlier.
- 3) NACO (first Party) and second party shall form a committee comprising of representative from NACO (first Party), Nodal Officer / Director of second Party, which shall supervise and monitor the collaborative ART project to ensure provision of quality services.
- 4) NACO/SACS will continue to provide drugs on a [three] monthly basis on receipt of a requisition/s from second party and certificate of utilization of drugs in a prescribed format supplied earlier.

III. RESPONSIBILITIES of second party

Second party had set up a centre at MGM Medical College & Hospital, Kamothe Navi Mumbai, Maharashtra State and has appointed Dr. Umakant Deshpande, as Nodal Officer for the official contact for the collaborative ART Project.

 Second party represents that it provides various health services to PLHAs, a description of which is set out at Schedule III to the present Agreement.

2) Second Party undertakes that it will comply with all the laws for the time being in force in India in the running of the ART centre as done earlier. Second Party has obtained all necessary government approvals and have appointed the necessary staff with the requisite technical qualifications.

3) Second Party strictly follows the National ART guidelines (drug regimen as well as physical standards) issued by NACO (first party) from time to time, follow the terms of reference for staff including qualifications as specified by NACO (first Party) and has ensured that mechanisms needed for good treatment adherence are in place.

4) Second party shall respect the autonomy and privacy of the patients, and to this end provides pre- and post-test counseling, obtains written informed consent from the patient prior to a test or treatment, and maintains confidentiality of the patients on the principle of shared confidentiality.

5) Second Party shall provide for data protection systems to ensure that the confidential records of the patients are computerized and are protected so that they are not accessible to any unauthorized person.

 Second Party shall provide a copy of all medical records to the patients on their request.

7) Second Party shall provide all health services related to provision of ART and treatment of opportunistic infections, including those listed in Schedule III, free of cost to patients who require treatment. Second Party shall not deny services to any person living with HIV on any ground. The ARV drugs used for community will be supplied by NACO/SACS.

 Second Party shall maintain all the registers and reporting formats as per NACO (first party) ART guidelines. They will send report of all adverse drug reactions to NACO (first party).

 Second Party shall use standard NACO (first Party) Monitoring and Evaluation tools.

- 10) Second party shall provide standard, regular monthly reports of patient numbers and relevant details for the previous month to NACO (first party) by the 4th of each month in prescribed formats in accordance with the guidelines laid down by NACO (first Party) from time to time. NACO (first Party) will be free to use the data so sent to them in an anonymous manner.
- 11) Second party shall provide details of the ART team at their centre along with the names and technical qualifications of the staff in case of any change to NACO (tirst party) from time to time.
- 12) Second party shall entirely bear the costs related to the staff's salary (doctors, counselors, pharmacist, nurses, medical records officer and administrative staff) and the cost related to the infrastructure. Second party represents that it has enough funds to run the programme for the next three / five years. Second party will permit NACO (first party) to inspect its documents relating to the balance sheets, profit and loss accounts, grants and donors, financial and other documents so that NACO (first party) can verify the representation of sustainability of the collaborative ART project.
- 13) NACO/SACS will provide drugs for ART on receipt of a requisition/s from second party and certificate of utilization of drugs in a prescribed format supplied earlier.
- 14) Second party has already established a network with NGOs involved in HIV care and support as well as with the Indian Network for People Living With HIV/AIDS or PLHA groups in the area for increasing access to treatment and for follow-up support.
- 15) The designated representatives of second party shall continue to attend the coordination meeting with NACO (first party) at their own costs.
- 16) Second party shall not permit research or clinical trial, whether relating to the allopathic system of medicine or any alternate system of medicine or any combination thereof, at the designated ART centre, except with the approval of the Drugs Controller General of India for the conduct of such clinical trial. Further, in the event of an approved clinical trial, the Party of the Second Part will ensure that ethical protocols are complied with.
 - 17) Use of any data obtained by second party during the course of its collaborative ART project shall be done in an anonymised manner such that the identity of the patients enrolled at the collaborative ART project is not revealed in any manner.
 - 18) Second party shall maintain the records for a period of five years from the time that this Agreement is terminated or lapses by efflux of time.

- 19) Second party shall constitute a grievance redressal mechanism. [A model grievance redressed mechanism is annexed hereto.] Further, second party shall forward to NACO (first party) in an anonymised manner the nature of complaints received and action taken thereon on a monthly basis.
- 20) Second party shall continue to provide space, CD 4 machine and staff for the ART center.

IV. COMMENCEMENT

V.

 This Agreement shall become effective upon signature by both the Parties and It shall remain in full force from the last date of renewal till completing of 3 yrs of agreement.

RENEWAL OF AGREEMENT

- This Agreement is renewable at the option of NACO (first party) and second party.
- Six months prior to the expiry of the Agreement due to efflux of time NACO (first party) shall intimate second party if it intends to renew or not to renew the Agreement.
- 3) In the event that second party decides not to renew the Agreement, second party shall intimate three month in advance to NACO (first party) about its inability to continue to provide treatment free of charge to the patients enrolled. If second party fails to continue to provide treatment free of charge or expresses its inability to do so, they shall give notice to the patients and NACO (first party) about this and refer the patients to the nearest government hospital providing treatment for opportunistic infections and ART, as directed by NACO (first party). Further, upon such referral, second party shall forthwith forward a copy of all medical records of the patients to such hospital and to NACO (first party) or a person designated by NACO (first party) will be responsible for ensuring that the patients continue to receive the drugs.
- 4) In the event that NACO (first Party) desires to renew the Agreement, the terms and conditions of this Agreement, as may be amended, will apply *de novo*. It is made expressly clear that in that event, second party will have to re-apply for and re-obtain certification.

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5) Both parties shall ensure that there is no treatment interruption of the patients.

VI. TERMINATION OF AGREEMENT

- The second party shall ensure that the infrastructure and manpower at centre is provided as per operational guidelines and in event of any deficiencies / reduction/withdrawal of space or staff, NACO (first party) (GOI) will exercise its option to terminate the agreement unilaterally
- 2) Any party may terminate this Agreement without giving any reasons after giving three months notice to the other party at the address provided in this Agreement for correspondence or the address last communicated for the purpose and acknowledged in writing by the other party.
- 3) On such notice of termination being received by any party, second party shall intimate NACO (first party) about its inability to continue to provide treatment free of charge to the patients enrolled. If second party cannot continue to provide treatment free of charge, they shall give notice to the patients and NACO (first party) about this and refer the patients to the nearest government hospital providing treatment for opportunistic infections and ART, as directed by NACO (first party). Further, upon such referral, second party shall forthwith forward a copy of all medical records of the patients to such hospital and to NACO (first party) or a person designated by NACO (first party) to receive such medical records. Thereupon, NACO (first party) will be responsible for ensuring that the patients continue to receive the drugs.

VII. BREACH BY second party

- 1) In case second party is not able to provide services as per agreement or defaults on the provision of this Agreement or declines the patients to provide medication or directly or indirectly makes any charges for the treatment of opportunistic infections or ART or otherwise enters into any malpractices, it shall be liable for breach of agreement and breach of trust and other consequences which may include black listing with NACO (first party), MOHFW, Ministry of Home affairs and External Affairs. This action shall also be intimated to their parent/ International NGO also for necessary action by them.
 - If second party is found to have made any charges for the treatment which was to be given free of charge under this Agreement or to have not provided the medicines to the named patients or to have otherwise misappropriated the funds or goods released by NACO (first party) to second party, then without prejudice to any other right or consequence or mode of recovery, NACO (first party) may recover the amount thereof from second party and/or its office bearers as arrears of land revenue.

1)

2)

VIII. SETTLEMENT OF DISPUTES

- Any dispute or difference or question arising at any time between the parties hereto arising out of or in connection with or in relation to this Agreement shall be referred to and settled by arbitration under the provisions of the Arbitration and Conciliation Act, 1996 or any modification or replacement thereof as applicable for the time being in India.
- 2. The arbitration shall be referred to an arbitrator nominated by Secretary Department of Legal Affairs, Ministry of Law and Justice, Govt. of India Delhi. The Arbitrator may, if he so feels necessary, seek opinion of any health care personnel with experience of working in the field of HIV and care and treatment of PLHAs.
- 3. The place of arbitration shall be either New Delhi or the site of the collaborative ART project, which shall be decided by the arbitral tribunal bearing in mind the convenience of the parties.
- 4. The decision of the arbitrator shall be final and binding on both the parties.

LAW APPLICABLE.

This Agreement shall be construed and governed in accordance with the laws of India.

IX. ADRESSES FOR CORRESPONDENCE

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In witness thereof, the parties herein have appended their respective signatures the day and the year above stated.

Signed For and on behalf of
Competent authority NACO
Signature Date In the presence of
Name and Signature
Date

[In case the contract is entered into by the President through the NACO, this needs to comply with the Rules of Business laid down in this behalf.] : Competent Authority, NACO

SCHEDULE 1

MODEL LIST OF DRUGS TO BE PROVIDED BY NACO TO Second Party

S.no	LIST OF ARV DRUGS		
	Adults		
1.	Zidovudine300mg + Lamivudine 150mg		
2	Zidovudine300+Lamivudine150+Nevirapin200		
3	Tenofovir 300 mg+ Lamivudine 300 mg+ Efavirenz 600 mg		
4	Tenofovir 300 mg+ Lamivudine 300 mg		
5	Nevirapine tablet/Suspension 200 mg/50 mg		
6	Efavirenz 200 mg, 600 mg		
7	Lopinavir 400 mg /ritonavir 100 mg		
8	Atazanavir 300 mg/ ritonovir 100mg		
	Paediatric		
9	Tablet.Zidovudine 60+ Stavudine 30		
10	Tablet.Zidovudine 60+ Stauvudine 30+Nevirapine		
11	Tablet.Abacavir 60+ Lamivudine30		
12	Tablet.Efavirenz 50 mg		
13	Lopinavir/ ritonovir 100/25 tablet		
14	Lopinavir / ritonovir syrup		

SCHEDULE II

MODEL FOR A ONE YEAR AGREEMENT

Year	Centre	Number of PLHAs for whose treatment stock is
		to be provided
2018-19		

SCHEDULE III

MODEL OF DESCRIPTION OF SERVICES PROVIDED PROPSOED TO BE

Address of site	Mahatma Gandhi Mission's, Medical College, Kamothe, Navi Mumbai
Outpatient	As per Statistics attached
Days	Monday to Saturday
Timings .	08.30 am to 03.30 pm(As per hospital timings)
Inpatient care	24 Hours
Number of patients registered	As per Statistics attached
Number of patients receiving ART	As per Statistics attached
Average number of patients attending OPD everyday	As per Statistics attached
Criteria followed in administering ARVs	As per NACO Guidelines
Treatment for OIs	As per NACO Guidelines
First line regimen	TLE/EFV
Description of follow-up of patients	As per NACO Guidelines As per NACO Guidelines for ART Center
Facilities available Personnel and their qualifications	As per NACO Guidelines for ART Center As per NACO Guidelines for ART Center

ANNEXURE

MODEL GRIEVANCE REDRESSAL MECHANISM

[Note: This portion has been taken from the draft law on HIV/AIDS and it would be advisable for MGM Medical College & Hospital, Navi Mumbai to constitute a grievance redressal mechanism at the outset.]

- (a) Second party shall appoint a person of senior rank, working full time in the organisation, as the Complaints Officer, who shall, on a day-to-day basis, deal with complaints received from an aggrieved person or an authorised representative of such person.
- (b) Every aggrieved person or an authorised representative of such person, who has a grievance against the second party about the services provided
 - or refused, has the right to approach the Complaints Officer to attend to such complaint and shall be informed of such rights by second party.
- (c) The Complaints Officer may inquire suo motu, and shall inquire, upon a complaint made by any aggrieved person or authorised representative of such person, into the complaint.
- (d) The Complaints Officer shall act in an objective and independent manner when inquiring into complaints made.
- (e) The Complaints Officer shall inquire into and decide a complaint promptly and, in any case, within seven working days. Provided that in cases of emergency, the Complaints Officer shall decide the complaint within one day.
- (f) The Complaints Officer, if satisfied that there has been an unfair/arbitrary refusal of services or deficiency in the services provided, shall (i) first direct second party to rectify the cause of the grievance, (ii) then counsel the person alleged to have committed the act and require such person to undergo training and social service. Upon subsequent violations by the same person, the Complaints Officer shall recommend to second party to, and the institution shall, initiate disciplinary action against such person.
- (g) The Complaints Officer shall inform the complainant of the action taken in relation to the complaint.

Assistance to ART Centres in various sectors under NACP

Public Health Sector Remarks Component Medical Colleges, Distt. Hosp. Available Land Under V Infrastructure Development NACP-III V Equipment (CD4 machine) . V Additional Human Resources 1 Diagnostic Kits (HIV/CD4) V ARV Drugs (First Line) Can be done as per cost effective/ Govt rates Drugs for Opportunistic Infections TA/DA by V sponsoring Training of key personnel agency V IEC material V **Operational** Costs



CERTIFICATE OF ACCREDITATION

MGM MEDICAL COLLEGE & HOSPITALS, CENTRAL LABORATORY

has been assessed and accredited in accordance with the standard

ISO 15189:2012

"Medical laboratories - Requirements for quality and competence"

for its facilities at

PLOT NO 1 & 2, NH4 JUNCTION, SION - PANVEL EXPRESS WAY, MUMBAI, MAHARASHTRA, INDIA

in the field of

Medical Testing

Certificate Number:

MC-2166

Issue Date:

26/04/2022

Valid Until:

25/04/2024

This certificate remains valid for the Scope of Accreditation as specified in the annexure subject to continued satisfactory compliance to the above standard & the relevant requirements of NABL. (To see the scope of accreditation of this laboratory, you may also visit NABL website www.mabl-india.org)

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Name of Legal Identity : Mahatma Gandhi Mission

Signed for and on behalf of NABL



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N. Venkateswaran Chief Executive Officer



भारतीय आयुर्विज्ञान अनुसंधान परिषद स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research Department of Health Research, Ministry of Health and Family Welfare, Government of India

Date: 13/06/2022

Total Operational (initiated independent testing) Laboratories reporting to ICMR:

Government laboratories : 1437 Private laboratories : 1952

-	Real-Time RT PCR for COVID-19	:	2282 (Govt: 803 + Private:1479)
	TrueNat Test for COVID-19	:	935 (Govt: 583+ Private: 352)
	CBNAAT Test for COVID-19	;	127 (Govt: 41 + Private: 86)
-	Other Molecular-Nucleic Acid (M-NA) Testing Platforms for COVID-19	;	45 (Govt: 10 + Private: 35)
	Note: Other Molecular-Nucleic Acid includes Abbott ID NOW, RT-LAMP, CRISPR-Cas9 and Accula™ Total No. of Labs		3389
	TOTAL (NO: OF Labs	•	5565

*CSIR/DB1/DST/DAE/ICAR/DRDO/MHRD/ISRO Laboratories.

#Laboratories approved for both Real-Time RT-PCR and TrueNat/CBNAAT

\$Laboratories approved for both TrueNAT and CBNAAT

¥ Laboratories approved for Abbott ID NOW alone or in combination with any other testing platforms @Laboratories approved for RT-LAMP alone or in combination with any other testing platforms

€ Laboratories approved for CRISPR-Cas9 alone or in combination with any other testing platforms

δ Laboratories approved for Accula[™] alone or in combination with any other testing platforms

P: Provisional

 Δ Pvt. Laboratories acquired by Govt.

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INDIAN COU MEDICAL RE Gerving the mathe	NCIL OF BEARCH a view 191
Names of States	Test Names of Government Institutes Names of Private Institutes
	668. Sant Gadge Baba Amravati University, 830. Lab Services, Ayugen Biosciences Pvt Ltd, 562
	Amravati Shivajinagar, Pune
for the second	669. #RCSM Govt. Medical College, Kolhapur 831. MCM Multice 200 Billige and Thospital Navi Multibater
1 Stationer	670. Model Rural Health Research Unit 832. # Ruby Hall Clinic, Dept of Laboratory, Grant Med
	(MRHRU), Sub District Hospital, Agar, Foundation, 40, Sassoon Road, Pune
	Dahanu, Palghar 833. D. Y. Patil Medical College, Kolhapur
	671. *Indian Institute of Science Education and 834. Molecular Diagnostic Laboratory, Department
.*	Rescarch (IISER), Pune Pathology, LMMF's Deenanath Mangeshkar Hospital 672. Govt. Medical College, Jalgaon Research Center, Erandwane, Pune
1	
	673. District General Hospital, Ahmednagar 674. #Government Medical College, Baramati Nashik
	675. #Govt. Medical College, Chandrapur 836. Apoorva Diagnostic and Health C
	676. #Govt. Medical College, Yavatmal BhaktivedantaHospital and Research Instit
	677. Swami Ramanand Bhaktivedanta Swami MArg, Sector 1, Mira Bhayanda
1	TeerthRuralGovernmentMedicalCollege, 837. Dr. DY Patil Medical College Hospital and Resea
	Ambajogai Centre, Pimpri, Pune
	678. Government Medical College, Gondia 838. Molecular Laboratory, Jaslok Hospital and Resea
	679. *Agharkar Research Institute, Pune Centre, 15, Dr Deshmukh Marg, Peddar Road, Mumba
	680. District General Hospital, Ratnagiri 839. NM Medical, Harchandrai House, Above Axis Bank,
	681. Dr. Shankarrao Chavan Govt. Medical Floor, Maharshi Karve Road, Marine Lines (E), Mumbr
	College, Nanded 840. Bharati Vidyapeeth (Deemed to be University) Med
	682. YCM Hospital, Pimpri College, Pune
	683. Babasaheb Ambedkar Marathwada 841. ¥Lifecare Diagnostic & Research Centre Pvt. Ltd. 2
	University, Aurangabad Cosmos Plaza, J P Road, Andheri West, Mumbai



CMCVIROEQAS

(Under the aegis of Indian Association of Medical Microbiologists)

Department of Clinical Virology Christian Medical College, Vellore

Certificate of Participation

This is to certify that, LAB ID V0835

Department of Microbiology, MGM Medical College and Hospital, Navi Mumbai, Maharashtra



has participated in the Virology External Quality Assessment Scheme during the year 2023 for the following panels:



Blood Borne Virus Serology
 Dengue Serology

Dr. Rajesh Kannangai Coordinator



The Department of Clinical Microbiology, Christian Medical College, Vellore - 632 004.

This is to certify that

Department of Microbiology

MGM Medical College & Hospital, Navi Mumbai

LAB CODE NO : M0959

Participated in the Microbiology External Quality Assessment Scheme

Basic Bacteriology and Serology: Tier 1 under the aegis of

Indian Association of Medical Microbiologists (IAMM) for the year 2023.

U. Z. W Balaji Veeraraghavan, MD., Ph.D., FRCP., Microbiology EOAS Coordinator





भारतीय आयुर्विज्ञान अनुसंधान परिषद स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research Department of Health Research, Ministry of Health and Family Welfare, Government of India

Date: 11/06/2020

Total Operational (initiated independent testing) Laboratories reporting to ICMR:

Government laboratories : 637 Private laboratories : 240

- Real-Time RT PCR for COVID-19 : 524 (Govt: 343 + Private: 181)
 TrueNat Test for COVID-19 : 283 (Govt: 269 + Private: 14)
- - TrueNat Test for COVID-19
 : 283 (Govt: 269 + Private: 1

 - CBNAAT Test for COVID-19
 : 70 (Govt: 25 + Private: 45)

Total No. of Labs : 877

*CSIR/DBT/DST/DAE/ICAR/DRDO Laboratories. #Laboratories approved for both Real-Time RT-PCR and TrueNat/CBNAAT \$Laboratories approved for both TrueNAT and CBNAAT

S.	Names of States	Test Category		Names of Government Institutes Names of Private Institutes
1.	Andhra Pradesh (58)	RT-PCR	1.	Sri Venkateswara Institute of Medical1. Manipal Hospital, Tadepalli, GunturSciences, Tirupati2. PathGene Health Care Pvt Ltd#2nd Floor,
	Govt: 53		2.	Sri Venkateswara Medical College, Srinivasapuram, Tiruchanoor Road, Opp LV Tirupati kayanamandapam, Tirupathi

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	Test Category	Names of Government Institutes	Names of Private Institutes
	298.	*Tata Memorial Centre ACTREC, Mumbai	117. Genepath Diagnostics India Pvt Ltd, 4th Floor, Above Phadke Hospital, Pune
	299.	*Tata Memorial Hospital, Mumbai	118. Daignostic Molecular Laboratory, Dept of
	300.	*National Centre for Cell Sciences, Pune	Microbiology, Dr. Vasantrao Pawar Medical
	301.	*National Environmental Engineering	College Hospital & Research Centre,
		Research Institute, Nagpur	Vasantdada Nagar, Adgaon, Nashik
	302.	Sant Gadge Baba Amravati University,	
		Amravati	Nanavati Hospital, Swami Vivekananda
	303.	#RCSM Govt. Medical College, Kolhapur	Road, Mumbai
	304.	Model Rural Health Research Unit	120. Krsnaa Diagnostics Pvt Ltd, Lt. Jayabai
		(MRHRU), Sub District Hospital, Agar,	Nanasaheb Sutar Maternity Home, Pune
		Dahanu, Palghar	121. Dhruv Pathology and Molecular Diagnostic
	305.	*Indian Institute of Science Education and	Lab, Third Floor, Aditya Enclave, Central
13471		Research (IISER); Pune	Bazaar Road, Ramdaspeth, Nagpur
	306.	Govt. Medical College, Jalgaon	122. Dept of Molecular Biology & Genetics,
	307.	District General Hospital, Ahmednagar	Krishna Institute of Medical Sciences,
	308.	Government Medical College, Baramati	Karad, Satara
	309.	#Govt. Medical College, Chandrapur	123. Lab Services, Ayugen Biosciences Pvt Ltd,
	310.	#Govt. Medical College, Yavatmal	562/1, Shivajinagar, Pune
	311.	Swami Ramanand Teerth Rural	124. MGM Medical College and Hospital, Navi
		Government Medical College, Ambajogai	Mumbai
	312.	Government Medical College, Gondia	125. #Ruby Hall Clinic, Dept of Laboratory,
	313.	Agharkar Research Institute, Pune	Grant Medical Foundation, 40, Sassoon
	314.	District General Hospital, Ratnagiri	Road, Pune
			126. D. Y. Patil Medical College, Kolhapur

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for its facilities at

PLOT NO 1 & 2, NH4 JUNCTION, SION - PANVEL EXPRESS WAY, MUMBAI, MAHARASHTRA, INDIA

in the field of

Medical Testing

Certificate Number:

MC-2166

Issue Date:

26/04/2022

Valid Until:

25/04/2024

This certificate remains valid for the Scope of Accreditation as specified in the annexure subject to continued satisfactory compliance to the above standard & the relevant requirements of NABL. (To see the scope of accreditation of this laboratory, you may also visit NABL website www.nabl-india.org)

NOILEN . INDIA . SEINO

Name of Legal Identity : Mahatma Gandhi Mission

Signed for and on behalf of NABL



N. Venkateswaran Chief Executive Officer





Laboratory Name :	aboratory Name : MGM MEDICAL COLLEGE & HOSPITALS, CENTRAL LABORATORY, PLOT NO 1 NH4 JUNCTION, SION - PANVEL EXPRESS WAY, MUMBAI, MAHARASHTRA, INE				
Accreditation Standard	ISO 15189:2012				
Certificate Number	MC-2166	Page No	1 of 5		
Validity	26/04/2022 to 25/04/2024	Last Amended on	14/06/2022		

S.No	Discipline / Group	Materials or Products tested	Component, parameter or characteristic tested / Specific Test Performed / Tests or type of tests performed	Test Method Specification against which tests are performed and / or the techniques / equipment used
		Permanent	Facility	
1	CLINICAL BIOCHEMISTRY	Serum	Albumin	BCG
2	CLINICAL BIOCHEMISTRY	Serum	AlkalinePhosphatase	IFCC(Kinetic Colour test with AMP buffer)
3	CLINICAL BIOCHEMISTRY	Serum	ALT/SGPT	IFCC without Pyridoxal phosphate (Kinetic UV test)
4	CLINICAL BIOCHEMISTRY	Serum	Amylase	pNPG7(kinetic Colour test)
5	CLINICAL BIOCHEMISTRY	Serum	AST/SGOT	IFCC without Pyridoxal phosphate (Kinetic UV test)
6	CLINICAL BIOCHEMISTRY	Serum	Bilirubin Direct	DPDColour test
7	CLINICAL BIOCHEMISTRY	Serum	Bilirubin -Indirect	Calculation
8	CLINICAL BIOCHEMISTRY	Serum	Bilirubin -Total	DPD Colour test
9	CLINICAL BIOCHEMISTRY	Serum	Calcium	Arsenazo III
10	CLINICAL BIOCHEMISTRY	Serum	Cholesterol HDL	CHOD - POD (Enzyme colour test, Immuno-Inhibition)
11	CLINICAL BIOCHEMISTRY	Serum	Cholesterol LDL	Calculation
12	CLINICAL BIOCHEMISTRY	Serum	Cholesterol Total	CHOD - POD (Enzyme colour test)
13	CLINICAL BIOCHEMISTRY	Serum	CK NAC	IFCC (Kinetic Colour test)
14	CLINICAL BIOCHEMISTRY	Serum	Creatinine	Modified Jaffe Kinetic Method (Kinetic colour test)
15	CLINICAL BIOCHEMISTRY	Serum	Ferritin	Electrochemiluminescence
16	CLINICAL BIOCHEMISTRY	Serum	FSH	Electrochemiluminiscence
17	CLINICAL BIOCHEMISTRY	Serum	FT3	Electrochemiluminiscence
18	CLINICAL BIOCHEMISTRY	Serum	FT4	Electrochemiluminiscence
19	CLINICAL BIOCHEMISTRY	Serum	Globulin	Calculation
20	CLINICAL BIOCHEMISTRY	Serum	Iron	Colorimetric without PPT
21	CLINICAL BIOCHEMISTRY	Serum	LDH	Lactate to Pyruvate, IFCC
22	CLINICAL BIOCHEMISTRY	Serum	LH	Electrochemiluminiscence
23	CLINICAL BIOCHEMISTRY	Serum	Phosphorus	Molybdate UV
24	CLINICAL BIOCHEMISTRY	Serum	Potassium	ISE by Indirect Method
25	CLINICAL BIOCHEMISTRY	Serum	Prolactin	Electrochemiluminiscence
26	CLINICAL BIOCHEMISTRY	Serum	PSA	Electrochemiluminescence





Laboratory Name :	MGM MEDICAL COLLEGE & HOSPITALS, CENTRAL LABORATORY, PLOT NO 1 & 2, NH4 JUNCTION, SION - PANVEL EXPRESS WAY, MUMBAI, MAHARASHTRA, INDIA			
Accreditation Standard	ISO 15189:2012			
Certificate Number	MC-2166	Page No	2 of 5	
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S.No	Discipline / Group	Materials or Products tested	Component, parameter or characteristic tested / Specific Test Performed / Tests or type of tests performed	Test Method Specification against which tests are performed and / or the techniques / equipment used
27	CLINICAL BIOCHEMISTRY	Serum	Sodium	ISE by Indirect Method
28	CLINICAL BIOCHEMISTRY	Serum	ТЗ	Electrochemiluminiscenc
29	CLINICAL BIOCHEMISTRY	Serum	T4	Electrochemiluminiscence
30	CLINICAL BIOCHEMISTRY	Serum	Total Protein	Biuret End PT
31	CLINICAL BIOCHEMISTRY	Serum	Triglycerides	GPO PAP (Enzymecolour test)
32	CLINICAL BIOCHEMISTRY	Serum	тѕн	Electrochemiluminiscence
33	CLINICAL BIOCHEMISTRY	Serum	UIBC	Fe-UIBC(saturationwith Iron
34	CLINICAL BIOCHEMISTRY	Serum	Urea	Urease, GLDHkinetic
35	CLINICAL BIOCHEMISTRY	Serum	Uric acid	Uricase,POD(Enzymecolour tests)
36	CLINICAL BIOCHEMISTRY	Serum	Vitamin B12	Electrochemiluminiscence
37	CLINICAL BIOCHEMISTRY	Serum	Vitamin D	Electrochemiluminiscence
38	CLINICAL BIOCHEMISTRY	Serum	VLDL	Calculation
39	CLINICAL BIOCHEMISTRY	Serum/Plasma	Glucose	Hexokinase
40	CLINICAL BIOCHEMISTRY	Urine	Calcium	Arsenoazo III
41	CLINICAL BIOCHEMISTRY	Urine	Creatinine	Modified Jaffe's (Kinetic method)
42	CLINICAL BIOCHEMISTRY	Urine	Microalbumin	Immunoturbidometric
43	CLINICAL BIOCHEMISTRY	Urine	Phosphorus	Immunoturbidometric
44	CLINICAL BIOCHEMISTRY	Urine	Urea	Urease GLDHKinetic
45	CLINICAL BIOCHEMISTRY	Urine	Uric acid	Uricase POD (Enzyme colour test)
46	HAEMATOLOGY	Plasma	APTT	Coagulation
47	HAEMATOLOGY	Plasma	Prothrombin Time	Coagulation
48	HAEMATOLOGY	Whole blood	Differential count Basophils	Electricalimpedancelaser lightscattering and dye bonding
49	HAEMATOLOGY	Whole blood	Differential count Eisinophils	Electrical impedance laser light scattering and dye bonding
50	HAEMATOLOGY	Whole blood	Differential count Lymphocytes	Electrical impedance laser light scattering and dye bonding
51	HAEMATOLOGY	Whole blood	Differential count Monocytes	Electrical impedance laser light scattering and dye bonding
52	HAEMATOLOGY	Whole blood	Differential count Neutrophils	Electrical impedance laser light scattering and dye bonding
53	HAEMATOLOGY	Whole blood	Erythrocytes Sedimentation Rate	Westergren's Method





Laboratory Name : MGM MEDICAL COLLEGE & HOSPITALS, CENTRAL LABORATORY, PLOT NO 1 NH4 JUNCTION, SION - PANVEL EXPRESS WAY, MUMBAI, MAHARASHTRA, IN					
Accreditation Standard	ISO 15189:2012				
Certificate Number	MC-2166	Page No	3 of 5		
Validity	26/04/2022 to 25/04/2024	Last Amended on	14/06/2022		

S.No	Discipline / Group	Materials or Products tested	Component, parameter or characteristic tested / Specific Test Performed / Tests or type of tests performed	Test Method Specification against which tests are performed and / or the techniques / equipment used
54	HAEMATOLOGY	Whole blood	Hematocrit	Calculated from the RBC count & MCV
55	HAEMATOLOGY	Whole blood	Hemoglobin	Cyanide free method
56	HAEMATOLOGY	Whole Blood	Malaria Antigen	Ag-Ab Immunoassay [HRP 2 for p. Falciparum and PAN specific for pLDH for Plasmodium species (P. Falciparum, P. Vivax, P. malariae, P. Ovale)]
57	HAEMATOLOGY	Whole Blood	Malarial Parasites	Staining of Thick & Thin Smear : Field Stain A & B & Leishman Stain
58	HAEMATOLOGY	Whole Blood	Mean CorpuscalVolume(MCV)	Low angle light scatter
59	HAEMATOLOGY	Whole Blood	MeanCorpuscularHaem. Concent.(MCHC)	Calculated
60	HAEMATOLOGY	Whole Blood	MeanCorpuscularHaemoglonin(MCH)	Calculated
61	HAEMATOLOGY	Whole Blood	Peripheral Smear	Microscopy by Leishman/ Field's stain
62	HAEMATOLOGY	Whole Blood	Platelets	Electrical impedance laser light scattering and dye bonding
63	HAEMATOLOGY	Whole Blood	RBC	Electrical impedance laser light scattering and dye bonding
64	HAEMATOLOGY	Whole Blood	Total LeucocyteCount (TLC)	Electrical impedance laser lights cattering and dye bonding
65	HISTOPATHOLOGY	Tissue blopsy& Largespecimen	H&E	Tissue processing by semiauto histokinetteand cuttting by leica microtome
66	MICROBIOLOGY & INFECTIOUS DISEASE SEROLOGY	Blood	Aerobic culture &Sensitivity	Conventional & Kirby Bauer's Disc Diffusion method
67	MICROBIOLOGY & INFECTIOUS DISEASE SEROLOGY	Blood	BloodCulture	Automated Blood culture system
68	MICROBIOLOGY & INFECTIOUS DISEASE SEROLOGY	Serum	ASO	Slide Agglutination
69	MICROBIOLOGY & INFECTIOUS DISEASE SEROLOGY	Serum	CRP	Slide Agglutination
70	MICROBIOLOGY & INFECTIOUS DISEASE SEROLOGY	Serum	Dengue IgG, Dengue NS1	Immunochromatography
71	MICROBIOLOGY & INFECTIOUS DISEASE SEROLOGY	Serum	Dengue IgG, IgM	Immunochromatography
72	MICROBIOLOGY & INFECTIOUS DISEASE SEROLOGY	Serum	HBsAg	Immunochromatography





Laboratory Name :	MGM MEDICAL COLLEGE & HOSPITALS, CENTRAL LABORATORY, PLOT NO 1 & 2, NH4 JUNCTION, SION - PANVEL EXPRESS WAY, MUMBAI, MAHARASHTRA, INDIA			
Accreditation Standard	ISO 15189:2012			
Certificate Number	MC-2166	Page No	4 of 5	
Validity	26/04/2022 to 25/04/2024	Last Amended on	14/06/2022	

S.No	Discipline / Group	Materials or Products tested	Component, parameter or characteristic tested / Specific Test Performed / Tests or type of tests performed	Test Method Specification against which tests are performed and / or the techniques / equipment used
73	MICROBIOLOGY & INFECTIOUS DISEASE SEROLOGY	Serum	нси	Dot Immunoassay
74	MICROBIOLOGY & INFECTIOUS DISEASE SEROLOGY	Serum	HIV 1 and 2	Lateral flow Immunochromatography
75	MICROBIOLOGY & INFECTIOUS DISEASE SEROLOGY	Serum	HIV	Dot Immunoassay
76	MICROBIOLOGY & INFECTIOUS DISEASE SEROLOGY	Serum	RA	slide agglutination
77	MICROBIOLOGY & INFECTIOUS	Serum	RPR	Slide Flocculation
78	MICROBIOLOGY & INFECTIOUS DISEASE SEROLOGY	Serum	Signal HIV	lmmunodot assay
79	MICROBIOLOGY & INFECTIOUS DISEASE SEROLOGY	Serum	WIDAL	Slide &Tube agglutination
80	MICROBIOLOGY & INFECTIOUS DISEASE SEROLOGY	Sputum, Urine, CSF, Ascetic fluid, Pleural fluid, Peritoneal fluid, Synovial fluid, Gastric Lavage, Bronchial Alveolar Lavage, Pus, Stool, ET Secretions, Suction Tip, Central Venous Catheter Tip, Foley's Tip, Jelco Tip, Tissue/ Biopsy, Swabs, Clot, Eye, Ear, Urethral, Cervical, Semen, OT Swabs, Exposed Plates, Gastric Aspirates, Conjunctival, Corneal, Umbilical, BAL	Aerobic Culture & Sensitivity	Conventional & Kirby Bauer's Disc diffusion Method
81	MICROBIOLOGY & INFECTIOUS DISEASE SEROLOGY	Sputum, Urine, Ascetic fluid. Pleural fluid, Peritoneal fluid, Synovial fluid, Gastric Lavage, Bronchial Alveolar Lavage, Pus, CSF	Gram stain	Microscopy
82	MICROBIOLOGY & INFECTIOUS DISEASE SEROLOGY	Sputum, Urine, Ascetic fluid. Pleural fluid, Peritoneal fluid, Synovial fluid, Gastric Lavage, Bronchial alveolar Lavage, Pus, CSF.	Ziehl Neelsen stain	Microscopy
83	MICROBIOLOGY & INFECTIOUS DISEASE SEROLOGY	Stool	cyst, ova, trophozoites and larvae	Microscopy
84	MOLECULAR TESTING	EDTA Whole Blood	HIV-1 RNA Quantitative	Real Time RT PCR (closed system)
85	MOLECULAR TESTING	EDTA Whole Blood	HIV-1 RNA Quantitative	Real Time RT PCR (open system)
86	MOLECULAR TESTING	Nasopharyngeal / Oropharyngeal swab	H1N1 RNA Qualitative	Real Time RT PCR (Closed System)
87	MOLECULAR TESTING	Nasopharyngeal / Oropharyngeal swab	H1N1 RNA Qualitative	Real Time RT PCR (open system)





Laboratory Name :	MGM MEDICAL COLLEGE & HOSPITALS, CENTRAL LABORATORY, PLOT NO 1 & 2, NH4 JUNCTION, SION - PANVEL EXPRESS WAY, MUMBAI, MAHARASHTRA, INDIA		
Accreditation Standard	ISO 15189:2012		
Certificate Number	MC-2166	Page No	5 of 5
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S.No	Discipline / Group	Materials or Products tested	Component, parameter or characteristic tested / Specific Test Performed / Tests or type of tests performed	Test Method Specification against which tests are performed and / or the techniques / equipment used
88	MOLECULAR TESTING	Nasopharyngeal / Oropharyngeal swab	SARS coV-2 RNA Qualitative	Real Time RT PCR closed system



National Accreditation Board for Hospitals & Healthcare Providers

(Constituent Board of Quality Council of India)

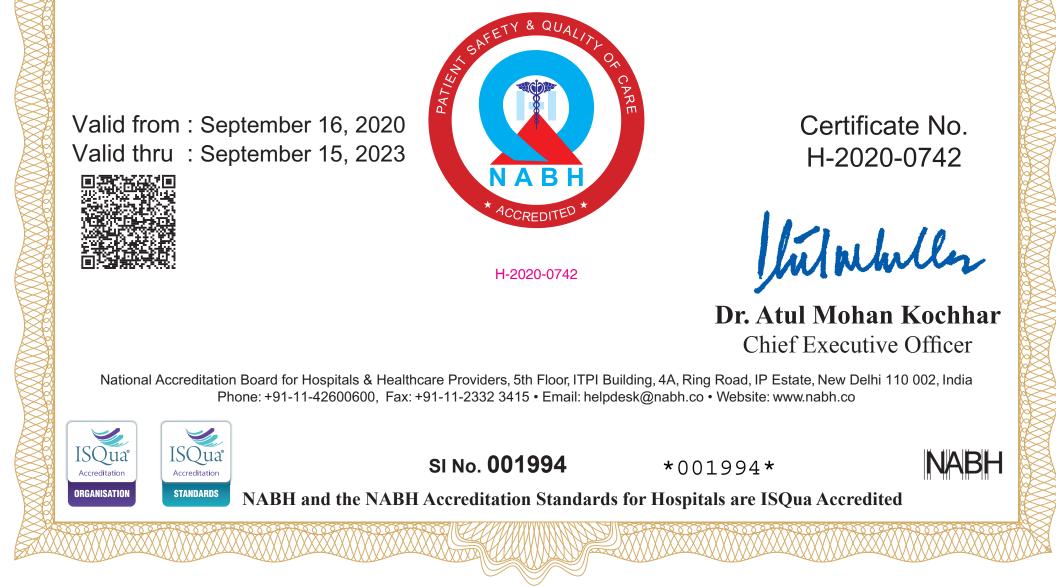
CERTIFICATE OF ACCREDITATION

MGM Medical College & Hospital

Sector1, Plot 1 & 2, Kamothe, Navi Mumbai Raigarh - 410209, Maharashtra

has been assessed and found to comply with NABH Accreditation Standards for Hospitals. This certificate is valid for the Scope as specified in the annexure subject to continued compliance with the accreditation requirements.







Mahatma Gandhi Mission's MEDICAL COLLEGE

Sector-1, Kamothe, Navi Mumbai - 410 209. Ph: (022) 27437992, 27433404, 27437900 (PBX (1-200) E-mail: mgmmcnb@gmail.com, Web: www.mgmuhs.com

MGM/MED_C/2021 /15 75,

Date : 21/09/2021

To, The Dist Programme Director NACO/ART Alibaug Dist. Raigad. Maharashtra

Ref: National AIDS Control Organization's letter no: T11020/87/2006/NACO(ART) dated 30th June 2021.

Sir,

With reference to letter received form NACO, New Delhi, we are forwarding herewith the Undertaking for Operationalization of Antiretroviral Therapy (ART) Centre in the given performa.

Thanking you,

Yours faithfully,

Dean



Dean MGM Madical College & Hospital Ramothe, Navi Mumbai-410209 Encl : Undertaking duly signed by ART MO, Med. Supdt & Dean

Dean



Mahatma Gandhi Mission's **MEDICAL COLLEGE** Sector-1, Kamothe, Navi Mumbai - 410 209.

Ph: (022) 27437992, 27433404, 27437900 (PBX (1-200) E-mail: <u>mgmmcnb@gmail.com</u>, Web: <u>www.mgm</u>uhs.com

MGM/MED_C/2021 /1568(2)

Date : 21/09/2021

Undertaking by Private Medical Colleges for Operationalization of Antiretroviral Therapy (ART) Centres

Certificate / Undertaking given by Mahatma Gandhi Mission's Medical College, Sector-1, Kamothe, Navi Mumbai-410 209, in reference to National AIDS Control Organization's letter no: T11020/87/2006/NACO(ART) dated 30th June 2021.

- 1. We undertake that our Institute namely MGM Medical College & Hospital, Kamothe, Navi Mumbai-410 209 agrees to abide by the Roles of Private Medical College as laid down in the above mentioned letter.
- 2. We certify that our Institute shall provide Infrastructure and Human Resource for ART Center as per the Operational Guidelines for ART Services issued by NACO.
- 3. We certify that our Institute shall provide all health services related to provision of ART and treatment of opportunistic infection, free of cost to patients who require treatment.
- 4. We certify that all the Rules and regulations would be followed and the prescribed documents will be maintained as per the Operational Guidelines for ART Services.
- 5. We certify that our Institute is not engaged in any corrupt practice.
- 6. We undertake that the Antiretroviral Drugs (ARVs) made available by State AIDS Control Society under the National AIDS Control Programme for ART Centres shall not be used for any purpose other than for People Living with HIV (PLHIV) registered in our ART Center.
- 7. In-case of dispensing ARVs to PLHIV from other ARTC/State/Country, the institute would seek approval on case to case basis from SACS/NACO.
- 8. Any violation of this shall be ground for unilateral discontinuation of ART Centre by State AIDS Control Society with one-month notice.
- 9. We shall follow the provisions under HIV/AIDS Prevention and Control Act 2017 and on any ground, no PLHIV shall face stigma and discrimination at our institute.
- 10. We undertake that our Institute shall follow National AIDS Control Programme's "Guidelines on confidentiality of data of protected persons under HIV/AIDS Prevention and Control Act 2017.
- 11. We shall respect the autonomy and privacy of the patients, obtain written informed consent from the patients before initiating ART, and maintain confidentiality of the patients.
- 12. We shall regularly report to SACS/NACO in prescribed formats.

Signed & sealed for and on behalf of MGM Medical College & Hospital, Kamothe, Navi Mumbai-410 209.

