Reliance Life Sciences Pvt. Ltd.
R-282, TTC Area of MIDC, Thane - Belapur Road,
Rabale, Navi Mumbai - 400 701, Maharashtra, INDIA.
Phone: +91-22-3533 8000 • Fax: +91-22-3533 8099

Reliance
Life Sciences

Agreement

This agreement made and entered into at Mumbai on 01st day of January 2020 (Effective Date), between **Reliance Life Sciences Pvt. Ltd.**, a Company incorporated under the Company's Act, 1956 having its registered office at Dhirubhai Ambani Life Sciences Centre, R – 282, TTC area of MIDC, Thane - Belapur Road, Rabale, Navi Mumbai 400 701, Maharashtra, India. (Hereinafter referred to as "**RLS**") which expression shall unless repugnant to the context shall mean and include its successors and assigns of the ONE PART.

AND

N.D.M.V.P.S. Medical College & Hospital a Registered Blood Bank having its office at 131, Ground Floor, OPD Building, Adgaon, Taluka & District Nashik – 422003, Maharashtra (Hereinafter referred to as "**NDMVPS**") which expression shall unless repugnant to the context shall mean and include its Board of Directors, Officers and its medical staff of the OTHER PART.

Whereas:

A. **NDMVPS** has represented to **RLS** that **NDMVPS** is registered, as a Private blood bank and is located at Nashik, Maharashtra.

B. **NDMVPS** has represented to **RLS** that they possess necessary and valid license in form 28C to separate human plasma from human whole blood, as prescribed in Drugs & Cosmetics Act 1940 and Rules thereafter, as amended and applicable from time to time. A copy of the valid license in Form 28C is provided to **RLS** and is attached hereto to this Agreement as Annexure 4.

C. **NDMVPS** has represented to **RLS** that they possess expertise, adequate resources, manpower and infrastructure in collection, processing and storing plasma.

D. **RLS**, inter alia, is engaged in research and development in biotechnology and Plasma products.

E. **NDMVPS** separates blood components from donated blood and has offered to supply to **RLS** surplus plasma to enable **RLS** to carry out research, product development and commercial initiative using plasma.

F. Based on the representations made by **NDMVPS**, **RLS** has agreed to procure surplus fresh frozen plasma or stored plasma from **NDMVPS** on the terms and conditions as stated hereunder.

Reliance Life Sciences Pvt. Ltd. Navi Mumbai

IN CONSIDERATION OF THE COVENANTS AND CONDITIONS SET FORTH HEREIN, THE PARTIES AGREE TO THE FOLLOWING:

1. Definitions

The following terms shall unless the context otherwise requires, have the meaning ascribed to them below

1	Plasma	:-	Plasma is liquid portion separated from human Blood.
2	FFP	:-	FFP (Fresh frozen plasma) is plasma separated from whole blood and stored and frozen at or below –30°C within 6 hrs of blood collection.
3	SP	:-	SP (stored plasma) is plasma separated from whole blood after 6 hrs and within 72 hrs of blood collection which is stored at or below – 20°C.
4	"Elisa"	:-	Enzyme linked immunosorbent assay
5	Anti-"HIV" test	:-	Testing of HIV 1 and 2 (Human Immunodeficiency Virus) antibodies in plasma/serum.
6	Anti-"HCV" Test	:-	Testing of HCV (Hepatitis C Virus) antibodies in Plasma/serum
7	HbsAg	:-	Testing of Hepatitis B surface antigen in plasma/serum
8	VDRL	:-	Testing of Sexually Transmitted Diseases.
9	Unit	:-	Blood bag containing Plasma from one donor.
10	CDP	:-	Cryo Deficient Plasma – Plasma remaining after separation of cryoprecipitate and stored at –30°C

2. Responsibilities

a. **NDMVPS** shall separate plasma from blood collected from voluntary non-remunerated donors as per the Part XB of Drugs and Cosmetics Act, 1940 as amended from time to time and as per the establishment of National Blood Policy.

b. **NDMVPS** represents and warrants that **NDMVPS** has obtained and ensures the validity and effectiveness of all approvals, licenses, permits, permissions, sanctions applicable for collection, storage, processing, distribution of Human Blood, Human Blood components & Blood Products.

c. **NDMVPS** shall supply Fresh frozen plasma (FFP) to **RLS** of such quality and quantity (in units) as agreed under in this Agreement.

d. **NDMVPS** shall perform the anti- HIV, HBsAg, HCV and VDRL and certify that the plasma supplied to **RLS** are tested negative by Elisa for HIV, HBsAg, HCV and VDRL tests on the plasma before supplying it to **RLS**.

e. **NDMVPS** shall be responsible for labeling and packing of Units to be supplied to **RLS**, as per the guidelines laid down by FDA. **NDMVPS** shall certify that the minimum requirements with regard to the regulations on labeling, packing and dispatch have been observed in accordance with Drugs and Cosmetics Act 1940 and rules prevailing from time to time.

f. **NDMVPS** shall ensure the validity and effectiveness of all approvals, licenses, permits permissions applicable for collection, storage, processing, distribution of human blood, human blood components and blood products till the term of this

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Agreement and shall provide copies of the same to **RLS**. **NDMVPS** also undertakes to renew the license from time to time prior to expiry

g. **NDMVPS** warrants that the plasma shall be supplied to **RLS**, within 12 months of its date of manufacture.

h. **NDMVPS** shall be responsible to provide the list of units supplied with each consignment. Certificate of Testing and the list of plasma units supplied will be provided as per the format given in Annexure 1 and Annexure 2.

i. **NDMVPS** shall supply Plasma solely to **RLS** during the term of the Agreement.

j. **RLS** should inform **NDMVPS** forthwith regarding any cancellation or suspension of the license or consent issued by authority for collection, transportation and manufacturing / research of life-saving plasma proteins from Fresh Frozen Plasma.

k. **NDMVPS** should inform **RLS** forthwith regarding any cancellation or suspension of the license or consent issued by authority for blood collection, component separation and other related activities.

3. Vendors Audit

Without prejudice to the contents of Article 2, **RLS** shall be entitled, but not obliged, to conduct audit of the facility of **NDMVPS** for verification of the quality or quantity of the plasma agreed to be supplied by **NDMVPS** to **RLS**.

4. Financial Arrangements

a. **RLS** shall from time to time coordinate with **NDMVPS** for supply of plasma.

b. **NDMVPS** shall charge **RLS @ Rs. 2400/- per liter for FFP** supplied to **RLS** in accordance with this agreement.

c. **NDMVPS** shall raise invoice on **RLS** for the said supply hereto, and shall be mailed to **RLS** at the address mentioned in article 16 herein.

d. The volume of plasma in each bag will be calculated by the following formula

Volume of Plasma in bag = (Weight of filled plasma bag – weight of empty plasma bag) / 1.03

5. Logistics

The parties shall mutually decide as to the logistics of the Units to be delivered from **NDMVPS** to **RLS**'s site. **RLS** would supply the necessary secondary packing materials free of cost and also bear the cost of transportation of Plasma from **NDMVPS** to **RLS**.

6. Representations and Warranties by NDMVPS

a. **NDMVPS** is a valid and subsisting duly registered Blood Bank and is not extinguished either by the Settlor or by any other statutory authority.

b. **NDMVPS** is entitled and has authority to enter into this Agreement.

Reliance Life Sciences Pvt. Ltd. Navi Mumbai

c. **NDMVPS** has not done anything or omitted to do anything which would in any manner affect or prejudice the rights and obligations of **RLS** under this Agreement.

d. **NDMVPS** has obtained all the necessary Licenses, clearances, and permissions from the authorities concerned as are required for entering this Agreement and shall maintain valid throughout the Term of this Agreement, and all the requisite approvals, licenses, permissions, etc., as may be required under law for the time being in force.

e. Plasma supplied to **RLS** shall meet the specifications attached hereto as Annexure 3 (Specifications) and made a part hereof. If Specifications are revised during the term of this agreement both parties will agree to all revisions prior to implementation.

f. Plasma provided to **RLS** hereunder is not adulterated or misbranded within the meaning of Drugs and Cosmetics Act as amended from time to time.

7. Representations and Warranties by RLS

a. **RLS** is a corporation duly organized and existing under the laws of its incorporation.

b. **RLS** is entitled and has authority to enter into this Agreement.

c. **RLS** has not done anything or omitted to do anything which would in any manner affect or prejudice the rights and obligations of **NDMVPS** under this Agreement.

d. **RLS** has obtained all the necessary clearances and permissions from the authorities concerned as are required for entering this Agreement.

8. General Provisions

All consignments of plasma shall be accompanied by the following:

a. Batch release certificate to the effect that they were prepared in accordance with the local regulatory requirements for Blood and Blood Banks. The Protocol and its annexes may be amended or supplemented by the Parties to this Agreement.

b. List of plasma units supplied to **RLS** on letterhead of **NDMVPS** duly signed by the authorized person as per format in Annexure 2.

c. **RLS** is entitled to retest the plasma in minipools each comprising 10-12 individual plasma units for HIV – I & II antibodies, HBsAg, and HCV- PCR.

d. In the case of discrepancy between the physical units received and the list of plasma units provided by **NDMVPS**, **RLS** shall be entitled to reject the plasma units with discrepancy if appropriate clarifications are not received from **NDMVPS** within two weeks from intimation by **RLS**, without any costs or consequences.

e. Neither party will be liable to the other party for any indirect, incidental, consequential, special or punitive damages including but not limited to loss of production, loss of income or loss of profits arising out of claims brought by the other party to this agreement.

Reliance Life Sciences Pvt. Ltd. Navi Mumbai

9. Indemnification

Each party agrees and undertakes to indemnify and keep the other party harmless from and against all costs, expenses, claims, liabilities, penalties etc., which the other party might incur on account of a breach of the representation and warranties furnished by each party under this agreement or any act of gross negligence and / or willful misconduct in performance of its obligations hereunder.

10. Intellectual Property Rights and confidentiality.

a. All rights to inventions or discoveries arising from the use of plasma supplied by **NDMVPS** to **RLS** shall solely vest with **RLS**.

b. **RLS** and **NDMVPS** shall maintain utmost secrecy about all data, particular methods, recipes, formulas, details, drawings and other confidential proprietary information exchanged between them (all this information is called confidential information).

c. This confidential information shall be used by the parties for purpose of this agreement only and the same shall not be divulged, disclosed or communicated to any third party without prior written permission of **RLS** or **NDMVPS** as the proprietors of such confidential information as the case may be.

d. However, restrictions as to confidentiality shall not be applicable to such information which are:

i. In a public domain without any breach on the part of any of the parties to this agreement.
ii. The receiving party is already in possession of such information.
iii. Is independently developed by such party.
iv. Is required to be disclosed under the applicable laws or under statutory requirements.

11. Term

This Agreement shall commence on the date of signing by both the parties and shall continue for a period of Two (2) years from the Effective Date. The parties have the option to extend the Agreement at terms mutually agreed upon by both the parties unless earlier terminated.

12. Termination

a. Either party may terminate this Agreement with or without giving any reasons whatsoever by giving 30 days prior written notice of to the other party.

b. In the event of breach non defaulting party shall be entitled to terminate the agreement by providing written notice, of 30 days to the defaulting party. If defaulting party fails to remedy the breach within 30 days of receiving notice, this agreement shall terminate immediately upon expiry of the aforementioned 30 days period.

c. Either party may terminate the agreement immediately in the event any law or government-enacted regulation or decree renders the performance by a Party of its obligations hereunder onerous or otherwise inexpedient; or as mutually agreed by both the parties.

Reliance Life Sciences Pvt. Ltd. Navi Mumbai

d. Upon expiry of the Agreement for any reason, **NDMVPS** shall promptly return to **RLS** all the written instructions, if any, issued by **RLS**.

13. Amendments

Any amendments or modifications of this Agreement may only be made upon mutual consent and have to be made in writing.

14. Arbitration

The parties shall attempt in good faith to resolve promptly any dispute arising out of or relating to this Agreement by negotiation. If the matter cannot be resolved in the normal course of business any interested party shall give the other party written notice of any such dispute not resolved, after which the dispute shall be referred to more senior executives of both parties, who shall likewise attempt to resolve the dispute. In case an amicable settlement of disputes arising in connection with the present Agreement or further agreements resulting thereof is not possible within 30 days of the arising of dispute, such disputes shall be referred to a sole Arbitrator acceptable to both parties under the provisions of the Arbitration and Conciliation Act, 1996. The place of arbitration shall be Mumbai and language of the arbitration shall be English.

15. Governing Law & Jurisdiction

This Agreement shall be governed by and construed in accordance with Indian Law. It is mutually agreed by and between the parties hereto that only an appropriate court of jurisdiction in Mumbai shall be entitled to entertain and try any disputes arising out of or in connection with the Arbitration under Article 14 hereto.

16. Notices

All notices in context of this Agreement will be served to the following persons as per the address detailed.

Name :
Title :
N.D.M.V.P.S. Medical College & Hospital
131, Ground Floor,
OPD Building,
Adgaon,
Taluka & District Nashik – 422003,
Maharashtra.

Mr. Sasi Kumar
Reliance Life Sciences Pvt. Ltd.
R – 282, TTC area of MIDC,
Thane Belapur Road,
Rabale,
Navi Mumbai 400 701.

Reliance Life Sciences Pvt. Ltd. Navi Mumbai

IN THE WITNESS WHEREOF THE PARTIES hereto, have subscribed their hands to this Agreement on the day and year first here in above written,

Reliance Life Sciences Pvt. Ltd.

Reliance Life Sciences Pvt. Ltd. Navi Mumbai

By: _____

Name: Mr. Sasi Kumar

Title: Head – Plasma Proteins

N.D.M.V.P.S. Medical College & Hospital

MVPS MEDICAL COLLEGE HOSPITAL & RESEARCH CENTRE ADGAON NASHIK

By: _____

Name: Dr. Patil Mrunal

Title: DEAN

MVPS Dr Vasantrao Pawar Medical College Hospital & Research Centre, Nashik

VC:- 3192484

ANNEXURE 1

(On letter head of blood bank)

Certificate of Testing and Quality

Date:

Plasma type (pls tick): Fresh Frozen Plasma / Frozen Plasma / Cryo poor plasma
Reference #:
Number of plasma units:
Number of boxes:
We certify that the surplus plasma units mentioned in the attached list are being supplied to Reliance Life Sciences for manufacturing life-saving plasma proteins. The plasma has been separated from human whole blood collected from voluntary non-remunerated blood donors in accordance with Indian Federal Drugs and Cosmetic Act 1940 and Rules 1945.
The following tests have been performed individually on all the plasma units being sent in this consignment.

Test	Test Method	Test Kit Name	Manufacturer of test kit	Acceptance criteria
HBsAg (Hepatitis B Surface Antigen)				
HCV Ag-Ab				
Anti HIV – I&II (Human Immunodeficiency Virus I&II antibodies)				
Malaria Parasite				
Syphilis				

We hereby certify that all plasma units were screened and tested non-reactive for HIV I&II antibodies, Hepatitis B surface antigen, Hepatitis C antibody and negative for Malaria parasite and syphilis.
The storage temperature is routinely at -30 deg C or colder, after taking into consideration the expected variances to account for normal defrost cycles, loading and unloading.

Authorized Signatory
Name:
Designation:

Reliance Life Sciences Pvt. Ltd. Navi Mumbai

ANNEXURE 2

LIST OF FFP UNITS SUPPLIED TO RELIANCE LIFE SCIENCES

Date:

Name of the blood bank: **N.D.M.V.P.S. Medical College & Hospital**

Type of plasma:

Storage temperature:

This is to certify that the following units of Fresh Frozen Plasma, which are transferred to the stock of Reliance Life Science, Mumbai, were screened by internationally accepted testing methods and found NEGATIVE for HBsAg, HIV I & II Antibodies, HCV and VDRL.

Sr. No.	Donor Unit No.	Date of collection dd/mm/yyyy	Expiry date dd/mm/yyyy	Collection time	Separation date and time	Volume (mL)	Blood Group

For **N.D.M.V.P.S. Medical College & Hospital**

Authorized Signatory
(_____)

Reliance Life Science (I) Pvt. Ltd. Navi Mumbai

ANNEXURE 3

PLASMA SPECIFICATIONS **SPECIFICATION**					Reliance Life Sciences
Title	**Specification for sourcing plasma from blood banks**				
Group	**Plasma Proteins**				
Ref No.		**Revision**	06	**Date**	14/02/2019
Next Review on		02/2021			

1. Objective:

To state the specifications to source surplus human plasma from licensed blood banks in India for manufacture of Plasma proteins.

2. Abbreviations:

RLS	Reliance Life Sciences
BB	Blood Bank
PCR	Polymerase Chain Reaction
HBsAg	Hepatitis B surface antigen
TTD	Transfusion transmissible diseases
HIV	Human Immunodeficiency virus
HBV	Hepatitis B virus
HCV	Hepatitis C virus
Kg	Kilogram
ml	Milli litre
g	grams
SOP	Standard operating procedure
VDRL	Veneral disease research laboratory

3. Plasma specifications:

3.1 Each individual Whole blood donation from which the plasma has been separated should have been tested for the following:

	Prepared by	Reviewed by	Approved by
Initials	**SK**	**MVK**	**VAR**

Reliance Life Sciences Pvt. Ltd. Navi Mumbai

Sr No.	Test	Acceptance Criteria
1	HBsAg (surface antigen)	Non reactive
2	HIV antibody	Non reactive
3	HCV antibody	Non reactive
4	VDRL	Negative
5	Malarial Parasite	Negative

3.2 As a manufacturer of plasma proteins, RLS is entitled to test the plasma by serology and / or PCR either individually or in pools.

3.3 Each individual plasma unit to be labeled as per Drugs & Cosmetics Act, 1940 and Rules 1945.

3.4 Each plasma unit to be supplied to RLS within 12 months of the collection / manufacture date.

3.5 Each plasma unit should have at least 2 sealed segments (each tail of 5 cm in length) filled with plasma to enable RLS to test the plasma.

3.6 Plasma units should be free from Red cell contamination.

3.7 Plasma units which appear lipemic will not be acceptable.

4. General specifications.

4.1 BB shall collect plasma/whole blood from healthy, voluntary and non-remunerated donors as per the guidelines provided by Food and Drug Administration (India) and Drugs & Cosmetics Act, 1940 and Rules 1945 and other applicable regulations and guidelines prevailing from time to time.

4.2 Every consignment of plasma should be accompanied by a list (on letter head of blood banks) mentioning the units in the consignment along with Certificate of Testing.

5. Storage requirements

5.1 Plasma should always be stored at or below – 30°C till it is shipped to RLS.

Reliance Life Science Navi Mumbai

Gmail laxmichandra jamdar <lacky.jamdar@gmail.com>

[Fwd: MVP - Draft Agreement]

1 message

mvp medical college nashik <admin@mvpmcn.com> Thu, Feb 18, 2016 at 4:26 PM
Reply-To: mvpmedical_nashik@rediffmail.com
To: lacky.jamdar@gmail.com

---------- Original Message ----------
Subject: MVP - Draft Agreement
From: Bindu.Nair@Relbio.com
Date: Thu, February 11, 2016 6:34 pm
To: admin@mvpmcn.com

Dear Madam,

Please find attached a 'Draft Agreement' for your review.

Kindly go thru the same and revert with changes, if any.

On receipt of inputs from you, I shall arrange to send the original signed copy of the agreement.

Looking forward to have a fruitful and long association with you.

Thanks & Regards,

Bindu Nair
Reliance Life Sciences Pvt Ltd,
Dhirubhai Ambani Life Sciences Centre
Thane Belapur Road,
Rabale, Navi Mumbai.
Ph: 022 - 67678061
Mo: +919967607037

2 attachments

untitled-[1.2].html
4K

Agrmnt MVP Nashik.doc
68K

VENDOR NAME	LOCATION	Plasma Recd Date	Accepted FFP Volume	
M. V. P. HOSPITAL BLOOD BANK	NASHIK	24.04.2015	58.536	
		26.07.2015	38.496	
		21.09.2015	41.022	
		30.11.2015	35.699	
		13.02.2016	43.8	
		29.03.2016	62.452	419
		30.06.2016	70.8	466
		26.09.2016	96.345	697
		15.11.2016	53.284	400
		28.07.2017	78.3	551
		11.10.2017	97.727	652
				350

Jan-17 .

is agreement made and entered into at Mumbai on 1st day of April 2016 between **Reliance Life Sciences Pvt. Ltd.**, a Company incorporated under the Company's Act, 1956 having its registered office at Dhirubhai Ambani Life Sciences Centre, Thane -Belapur Road, Rabale, Navi Mumbai 400 701, Maharashtra, India. (hereinafter referred to as **"RLS")** which expression shall unless repugnant to the context shall mean and include its successors and assigns of the ONE PART

AND

MVP Hospital having its registered blood bank at O - 131, Ground Floor, OPD Building, M V P Hospital, Vasantdada Nagar, Adgaon, Nashik – 422003 hereinafter referred to as **("MVP")** which expression shall unless repugnant to the context shall mean and include its Board of Directors, Officers and its medical staff of the OTHER PART.

Whereas:

A. MVP Blood bank has represented to RLS that they possess expertise, adequate resources, manpower and infrastructure in collection, processing and storing plasma.

B. RLS, inter alia, is engaged in research and development in biotechnology.

C. MVP Blood bank separate blood components from donated blood and has offered to supply the surplus plasma to RLS to enable RLS to carry out research, product development and commercial initiative using plasma.

D. Based on the representations made by MVP Blood bank, RLS has agreed to procure fresh frozen plasma or stored plasma, from them on the terms and conditions as stated here under.

IN CONSIDERATION OF THE COVENANTS AND CONDITIONS SET FORTH HEREIN, THE PARTIES AGREE TO THE FOLLOWING:

1. Definitions

The following terms shall unless the context otherwise requires, have the meaning ascribed to them below

1	Plasma	:	Plasma is liquid portion separated from human Blood.
2	FFP	:	FFP (Fresh frozen plasma) is plasma separated from whole blood and stored and frozen at or below –30°C within 6 hrs of blood collection.
3	SP	:	SP (stored plasma) is plasma separated from whole blood after 6 hrs and within 72 hrs of blood collection which is stored at or below – 20°C.
4	"Elisa"	:	Enzyme linked immunosorbent assay
5	Anti-"HIV" test	:	Testing of HIV 1 and 2 (Human Immunodeficiency Virus) antibodies in plasma/serum.
6	Anti-"HCV" Test	:	Testing of HCV (Hepatitis C Virus) antibodies in Plasma/serum
7	HbsAg	:	Testing of Hepatitis B surface antigen in plasma/serum
8.	VDRL	:	Testing of Sexually Transmitted Diseases.

	Unit	:	Blood bag containing Plasma from one donor.
10	CDP	:-	Cryo Deficient Plasma – Plasma remaining after separation of cryoprecipitate and stored at –30°C

2. Responsibilities

a. MVP Blood bank shall collect plasma from the donors as per the guidelines provided by Food and Drug Administration of the respective state in which established and Drugs and Cosmetics Act, 1940 and as per the establishment guidelines of the respective blood bank.

b. MVP Blood bank shall supply surplus Fresh frozen plasma (FFP) or Stored plasma (SP) to RLS as and when available.

c. MVP Blood bank shall perform the anti- HIV, HBsAg, HCV and VDRL and certify that the plasma supplied to RLS are tested non reactive by Elisa for HIV, HBsAg, HCV and VDRL tests on the plasma before sending it to RLS.

d. MVP Blood bank shall be responsible for labeling the units to be supplied to RLS, as per the guidelines laid down by FDA. MVP shall certify that the minimum requirements with regard to the regulations on labeling, packing and dispatch have been observed.

e. MVP Blood bank shall supply to RLS for documentation purpose, a copy of its valid FDA license for manufacture of blood and blood components.

f. MVP Blood bank warrants that the plasma shall be supplied to RLS, within 24 months of its date of manufacture.

g. MVP Blood bank shall be responsible to provide the list of units supplied with each consignment. A soft copy of the list will be provided as per the format given in Annexure 1.

h. MVP Blood bank shall supply plasma exclusively to RLS during the term of the Agreement.

3. Vendor Audit

Without prejudice to the contents of Article 2, RLS shall be entitled, but not obliged, to conduct audit of the facility of MVP for verification of the quality or quantity of the plasma agreed to be supplied by MVP Blood bank.

4. Financial Arrangements

1. RLS shall from time to time coordinate with MVP for supply of plasma.

2. MVP Blood bank shall raise invoice on RLS for the supply hereto, and shall be mailed to RLS at the address mentioned in article 14 herein.

   RLS shall pay to MVP Blood bank @ Rs. **1600/- per liter for the FFP and Rs. 550/- per litre for CDP** in accordance with this Agreement.

3. RLS shall make the payment either by cheque, demand draft, pay order or such other modes of payment as agreed between the parties.

	Unit	:	Blood bag containing Plasma from one donor.
10	CDP	:-	Cryo Deficient Plasma – Plasma remaining after separation of cryoprecipitate and stored at –30°C

2. Responsibilities

a. MVP Blood bank shall collect plasma from the donors as per the guidelines provided by Food and Drug Administration of the respective state in which established and Drugs and Cosmetics Act, 1940 and as per the establishment guidelines of the respective blood bank.

b. MVP Blood bank shall supply surplus Fresh frozen plasma (FFP) or Stored plasma (SP) to RLS as and when available.

c. MVP Blood bank shall perform the anti- HIV, HBsAg, HCV and VDRL and certify that the plasma supplied to RLS are tested non reactive by Elisa for HIV, HBsAg, HCV and VDRL tests on the plasma before sending it to RLS.

d. MVP Blood bank shall be responsible for labeling the units to be supplied to RLS, as per the guidelines laid down by FDA. MVP shall certify that the minimum requirements with regard to the regulations on labeling, packing and dispatch have been observed.

e. MVP Blood bank shall supply to RLS for documentation purpose, a copy of its valid FDA license for manufacture of blood and blood components.

f. MVP Blood bank warrants that the plasma shall be supplied to RLS, within 24 months of its date of manufacture.

g. MVP Blood bank shall be responsible to provide the list of units supplied with each consignment. A soft copy of the list will be provided as per the format given in Annexure 1.

h. MVP Blood bank shall supply plasma exclusively to RLS during the term of the Agreement.

3. Vendor Audit

Without prejudice to the contents of Article 2, RLS shall be entitled, but not obliged, to conduct audit of the facility of MVP for verification of the quality or quantity of the plasma agreed to be supplied by MVP Blood bank.

4. Financial Arrangements

1. RLS shall from time to time coordinate with MVP for supply of plasma.

2. MVP Blood bank shall raise invoice on RLS for the supply hereto, and shall be mailed to RLS at the address mentioned in article 14 herein.

   RLS shall pay to MVP Blood bank @ Rs. **1600/- per liter for the FFP and Rs. 550/- per litre for CDP** in accordance with this Agreement.

3. RLS shall make the payment either by cheque, demand draft, pay order or such other modes of payment as agreed between the parties.

Plasma volume calculation

The volume of plasma in each bag will be calculated by the following formula

Volume of Plasma in bag = [Weight of filled plasma bag – weight of empty plasma bag (30 gm)] / 1.03

5. Logistics

RLS would supply the necessary primary and secondary packing materials free of cost and also bear the cost of transportation of Plasma from MVP to RLS. The packing and transportation will be entirely RLS's responsibility.

6. Representations and Warranties by MVP Blood bank

1. MVP Blood bank is a valid and subsisting duly registered Charitable / Private Hospital / Private Commercial/ Government Blood Bank and is not extinguished either by the Settler or by any other statutory authority.
2. Plasma supplied to RLS shall meet the specifications attached hereto as Annexure 2 (Specifications) and made a part hereof. If specifications are revised during the term of this agreement both parties will agree to all revisions prior to implementation.
3. Plasma provided to RLS hereunder is not adulterated or misbranded within the meaning of Drugs and Cosmetics Act.

7. General Provisions

All consignments of plasma shall be accompanied by the following

a) Batch release certificate to the effect that they were prepared in accordance with the FDA guidelines. The Protocol and its annexes may be amended or supplemented by the Parties to this Agreement.

b) List on the letter head duly signed by the authorized person as per format in Annexure 1.

c) RLS is entitled to retest the plasma in minipools each comprising 10-12 individual plasma units for HIV – I & II antibodies, HBsAg, and HCVPCR. If any minipool is found reactive then the entire minipool would be discarded.

In case of discrepancy between the physical units received and the list of plasma units provided by MVP Blood bank RLS shall be entitled to reject the plasma units with discrepancy if appropriate clarifications are not received from MVP without any costs and consequences.

8. Intellectual Property Rights.

All rights to inventions or discoveries arising from the use of plasma supplied by MVP Blood bank to RLS shall solely vest with RLS.

9. Term

This Agreement shall commence on the date of signing by both the parties & shall continue for a period of one year from the Effective Date, until terminated by either parties giving not less than two (2) months notice in writing without assigning any reason thereof. The parties have the option to extend the Agreement at terms mutually agreed upon by both the parties.

10. Termination

a. Either party may terminate this Agreement by giving a prior notice of two months to the other party without giving any reasons whatsoever.

b. Upon expiry of the Agreement for any reason, MVP Blood bank shall promptly return to RLS all the written instructions, if any, issued by RLS.

. Upon expiry or prior termination of the Agreement all the amounts due to MVP Blood bank shall be paid by RLS immediately.

11. Amendments

Any amendments or modifications of this Agreement may only be made upon mutual consent and have to be made in writing

12. Arbitration

In case, any dispute or difference arises at any time between the parties hereto as to the construction, meaning or effect of this Agreement or any clause or matter herein contained, the same shall be referred to the arbitration in accordance with the Indian Arbitration & Conciliation Act, 1996 or any statutory modification or enactment thereof for the time being in force.

The Arbitration will be held in Mumbai, India.

13. Governing Law & Jurisdiction

This Agreement shall be governed by and construed in accordance with Indian Law. It is mutually agreed by and between the parties hereto that only an appropriate court of jurisdiction in Mumbai shall be entitled to entertain and try any disputes arising out of or in connection with the Arbitration under Article 14 hereto.

14. Notices

All notices in context of this Agreement will be served to the following persons as per the address detailed.

Mr Sasi Kumar
Reliance Life Sciences Pvt. Ltd.
R – 282, TTC area of MIDC,

Thane Belapur Road, Rabale
Navi Mumbai - 400 701
Dr Ashwini Patil
O - 131, Ground Floor,
OPD Building,
M V P Hospital,
Vasantdada Nagar, Adgaon, Nashik - 422003.

IN THE WITNESS WHEREOF THE PARTIES hereto, have subscribed their hands to this Agreement on the day and year first here in above written,

Reliance Life Sciences Pvt Ltd.

Name: Sasi Kumar
Title: Head – Plasma Sourcing

MVP Hospital

Name: Dr. Archana. Patil
Title: HOD Blood Bank.

ANNEXURE 1

LIST OF FFP UNITS SUPPLIED TO RELIANCE LIFE SCIENCES

Date:

Name of the blood bank:

Type of plasma:

Storage temperature:

This is to certify that the following units of Fresh Frozen Plasma, which are transferred to the stock of Reliance Life Science, Mumbai, were screened by internationally accepted testing methods and found non reactive for HBsAg, HIV I & II antibodies, HCV antibodies and VDRL.

S. No.	Donor / Unit No.	Date of collection dd/mm/yyyy	Expiry date dd/mm/yyyy	Collection time	Separation Date & time	Volume (ml)	Blood group

For MVP Hospital

ANNEXURE 4

[(See Rule 122.F)]

License Copy

Certificate of Renewal of licence to operate a blood bank for processing of Whole Human Blood and/or preparation for sale or distribution of its components.

Certified that licence number **NKD/35** granted on 01.01.2009 to **M/s N.D.M.V.P.S. Medical College & Hospital** for the operation of Blood Bank for processing of Whole Human Blood and/or* for preparation of its components at the premises situated **131, Ground Floor, OPD Building, Adgaon, Taluka & District Nashik** renewed with effect from **05.01.2019 to 04.01.2024.**

1. **Name(s) of items: -**
   1. Human Blood (I.P.)
   2. Platelate Concentrate (U.S.P.)
   3. Fresh Frozen Plasma (B.P.)
   4. Packed Red Cells Concentrate (I.P.)

2. **Name(s) of competent technical staff :-**

a) Medical Officer
1) Dr. Mrs Archana Ukey
2) Dr. Pradip Jadhav
3) Dr. Ujwal Patil

b) Blood Bank Supervisor
1. Mrs. Seema Malode
2. Mr. Vinod Susar

c) Blood Bank Technician
1. Mr. Manish Saraf
2. Mrs. Kaveri Jamdhade

d) Registered Nurse
1) Mrs. Suryawanshi Ranjana
2) Mrs. Ahire Sarla

JOINT COMMISSIONER FOOD & DRUGS ADMINISTRATION • NASHIK DN. NASHIK •

(D.M. Bhamray)
Licensing Authority&
Joint Commissioner (Nashik Division)
Food & Drug Administration .M.S. Nashik

Dated :30 /05/2019

Central Licensing Approving Authority

Dy. G. [illegible]
Dte. General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road, ITO
New Delhi-110 002

MVPS Dr. Vasantrao Pawar
Medical College, Hospital & RC
Adgaon, Nashik
File No.
Inward 1876/19-20
Date 26/07/19

DEAN
MVPS's Medical College
Hospital & Research Centre, Nashik