

# गुरू श्री गोरक्षनाथ ब्लड बैंक एवं कॉम्पोनेन्ट सेन्टर

गोरखनाथ मंदिर परिसर, गोरखनाथ, गोरखपुर-273015

पत्राक					
न नापा	****	 	 	 	

### सुचना

ब्लड बैंक सुरक्षा को अधिक महत्व देते हुए अपनी जांच की विधाओं में सुधार के लिए निरंतर प्रयासरत रहता है, परन्तु कोई अधिक आर्थिक बोझ रोगी के उपर ना पड़े इसलिए अपने हाथ खींच लेता है। इसी कड़ी में विगत एक माह पूर्व श्री विजॉन कुमार मिश्रा Governing Body Member Dipp. Ministry of commerce & industry, Government of India का आगमन गुरु श्री गोरक्षनाथ चिकित्सालय में हुआ था और उन्होंने ब्लड बैंक का भी निरिक्षण किया। श्री मिश्रा ब्लड बैंक तथा ब्लड बैंक की कार्य प्रणाली को देखकर बहुत प्रसन्न हुए, उन्होंने फिर पूछा की इतने आधुनिक ब्लड बैंक में आप NAT जॉच की सुविधा कयों नहीं करा पा रहे हैं। ब्लड बैंक प्रभारी डा० अवधेश अग्रवाल ने इसका उपरोक्त उत्तर दिया, रोगियों के उपर अतिरिक्त आर्थिक बोझ मुख्य मुद्या है, श्री मिश्रा ने ब्लड बैंक से प्रभावित होकर एक प्रस्ताव रखा की यदि वह आर्थिक बोझ किसी संस्था अथवा संगठन द्वारा उठा लिया जाए तो क्या यह ब्लड बैंक NAT की सुविधा उपलब्ध करा पाएगा, इस पर डा० अवधेश अग्रवाल ने उन्हें आश्वासन दिया कि यदि आप यह आर्थिक बोझ हमारा कम कर देंगे तो यह ब्लड बैंक तत्काल NAT की जांच को प्रारंभ कर देगा।

श्री मिश्रा ने आगे कहा की एक समुचित प्रस्ताव ब्लंड बैंक की तरफ से आप मुझे भेजें मैं प्रयत्न करुँगा की यह आर्थिक सहयोग ब्लंड बैंक को उपलब्ध करा सकूं। ब्लंड बैंक ने उनको एक प्रस्ताव दिनांक 05/09/18 को भेजा है तथा यह आशा करता है कि श्री मिश्रा इस प्रस्ताव पर विचार करते हुए उचित कार्यवाही करेंगे।

ब्लड बैंक द्वारा भेजे गए प्रस्ताव की प्रतिलिपि संलग्न है।

डा० अवधेश अग्रवाल

उप मुख्य चिकित्साधिकारी एवं ब्लंड बैंक प्रभारी गुरु श्री गोरक्षनाथ चिकित्सालय गोरखनाथ

गोरखपुर

Bejon Kumar Misra
Governing Body Member
Dipp. Ministry of commerce & industry,
Government of India

Respected Sir.

Respected Mr. Misra as per talk with you during your visit to Gorakhnath Hospital & Blood Bank regarding giving us an aid to the Blood Bank to conduct better testing for Blood Born viral markers like HCV, HBV, HCV by the latest available technique NAT testing.

I am providing introductory aspect of Gorakhnath Temple, Gorakhnath Hospital & Blood Bank. There by a proposal for our Blood Bank to start NAT testing for all patients.

Guru Shri Gorakshnath Blood Bank was stabilized in 2005 in continuation with progress of the hospital. This Blood Bank initially was licensed for issue of Whole Blood only. The Blood Bank also showed tremendous growth and the component section was stabilized in 2007. Looking at the high demand of platelets for the patient of the dengue, encephalitis, and other viral fevers spreading as endemic disease in Purvanchal. This Blood Bank kept on increasing the facilities available to the patients. During this course the Blood Bank added Bio-Metric system to combat professional donor input in 2008. To safe guard and remove to a great extent the manual error, Bar Coding system was installed for the issue of Blood & Blood Components, the same year 2008. For safe supply of Blood column Gel technique was started for cross matching in year 2014. Looking at the critically ill and marked thrombocytopenia in some dengue cases Platelet Apheresis machine was installed. This proved to be a life saver for severe cases.

This Blood Bank was loaded with work so an auto cell separator was installed for components which produced effective and quality products. In



this separator facilities for leuco reduction is also available and leaucoreduced PRBC is being issued to the patients. This was done in year 2015.

Till now part making of the Blood and Components for children was done by manual technique in laminar air flow chamber. In the year 2016 compodock machine was introduced which helps making parts accurately and effectively in total closed system. By introducing this Compo Dock we could alleviate the minimal amount of infection which could have been transmitted with the manual separation. This Blood Bank equipped with many more equipments, several BBR, Deep Freezers, Incubator, Cryo water Bath etc. (detailed list is attached). This Blood Bank has been involved in academic deliberation also where we would invite eminent scientists of high International repute from transfusion medicine from all over India. We have so far conducted five CME's on various subjects.

Following is the brief information about the work load in our Blood Bank.

Supply Year	Total Issue	Whole Blood	Packed Cell	FFP	Platelet	Cryo	Total Donor	SDP
January 2017 To December 2017	32833	540	21912	3039	7292	14	22052	36

#### Introduction

- India's glorious past of rich cultural, spiritual and mythological traditions has been enunciated by the insurmountable contributions of "Shivavatar" MAHAYOGI GURU GORAKHNATH JI. In fact, the contribution and impact of the 'YOGI' has been so phenomenal that this ancient historical town derives its very name from him.
- Mahayogi Guru Gorakshnath ji had been a pioneer in reiterating/ reviving the country's spiritual and YOGIC heritage in modern India. The sage's teachings and yogic practices are a veritable treasure trove, not only India but for the entire human race.

#### **Gorakhnath Temple**

The fame of Gorakhnath temple is synonymous with the "seat of meditation" of Mahayogi Guru Gorakshnath. A legend says that this temple was initially established as small monastery in the "TRETA YUG". The temple complex, in its present magnificent and glorious from, has come about owing to the stellar contribution of the legendry saint, Brahmleen Mahant Digvijaynath Ji Maharaj as also the previous

(3)

Since Independence, the "Gorakshpeeth" has been actively involved in serving the local populace in the field of yoga, Education, Health and Spiritual & religious well being. In order to fulfill its aim of building a strong and capable nation, then Gorakshpeethadhishwar Mahant Digvijay Nath Ji Maharaj, established the 'MAHARANA PRATAP SHIKSHA PARISAD' in the year 1932. The first institution of this trust, namely, Maharana Pratap Inter College is still providing its services to the society in the Civil Lines area of Gorakhpur city and is regarded as a highly reputed institution. The Mharana Pratap Siksha Parisad has since grown manifold, in the service of the nation, and now encompasses more than three dozen educational, vocational training and medical institutes.

Continuing with its commitment to facilities provision of quality higher education in the region, in 1958, the Gorakshpeeth offered the premises (to include the structure, area and all assets) of Maharana Pratap Degree College for the established of the present day Deen Dayal Upadhyay Gorakhpur University. Till date, the commerce & Education Faculty and also MBA Department of Deen Dayal Upadhyay Gorakhpur University are

functioning in the erstwhile Mahrana Pratap College premises.

The organization has also had an astounding contribution in the field of medicine and healthcare in the region. Under the stewardship of the then Gorakshpeethadhishwar Mahant Avedya Nath Ji Maharaj, the Digvijaynath Ayurvedic Chikitsalya had been providing quality healthcare for the past 35 years. Continuing with this effort, in 2003 the Guru shri Gorakshnath Chikitsalya was established, to cater to the requirement of provision of appropriate, reliable and economical medical treatment to the ailing patients of the region, with modern and cost effective healthcare. It is towards this end, that current Gorakshpeethadhishwar Mahant Yogi Aditya Nath Ji Maharaj, with his inherent foresight, scientific and modern thinking, has envisaged the establishment of an Institute of Medical Sciences.

Eastern UP is still trailing behind in the field of education health and development. The deficiency of health care and treatment facilities in the public / government sector is being taken care of by Gorakshpeeth through their institutions mentioned above, viz Mahant Digvijaynath Ayurved Chikitsalya and Guru Shri Gorakshnath Chikitsalya . The Guru Shri Gorakshnath Chikitsalya presently has a capacity of 350 beds, including a crisis expansion ward of 50 beds.

## 1, Benefits of NAT Technology over Elisa Technology:

**A, NAT** for blood screening should be ideal as it is based on **Real Time PCR technology** which is used worldwide for viral screening and diagnostic purposes. **PCR**, a **Nobel Prize winning technology**, is the most widely-used, tried and tested technology in any molecular diagnostic set up. Further, this technology is used in more than a million research labs worldwide.

**B,** NAT technology is minimizing the window period as comprision to Elisa and Chemiluminiscence technology.

C,Extra layer of blood safety by using NAT technology for safest blood supply.

# D, Traceability Performance of cobas® TaqScreen MPX Test, v2.0 on Seroconversion Panels

- Complete traceability of barcoded samples, reagent cassettes and consumables from the time samples are loaded into the system till the final results are delivered.

**E,**The NAT system supports multiplexed in-vitro nucleic acid amplification testing for routine screening for the presence of hepatitis B virus deoxyribonucleic acids (HBV DNA), human immunodeficiency virus ribonucleic acids (HIV RNA) and hepatitis C virus ribonucleic acids (HCV RNA) in human plasma or serum.

**F**, Assay Performance of NAT technology, able to detect accurately the following viral markers and genotypes.

HIV-1 Group M, subtypes A, AE, B, C, D, F, G, H, J

HIV-1 Group O

HIV-2, subtypes A, B, A/B

HBV, genotypes A, B, C, D, E, F, G, H

HCV, genotypes 1a, 1b, 2a/2c, , 2b, 3a, 3a/b, 4, 4a, 4b/c, 4h, 5, 5a, 6, 6a

**G**, Five virus types detected by NAT and there's sensitivity:

- HIV -1 Group M------50.3 IU/ml
- HIV -1 Group O------18.3 copies / ml
- HIV-2----7.9 IU/ml
- HCV-----6.8 IU/mL

# (3)

#### • HBV----- 2.3 IU/mL

**H**,It reduces "window period" during which the infectious agent is undetectable by traditional screening technologies that rely on the formation of antibodies.

I,The ability to perform comprehensive and combined blood screening for several pathogens, including

Hepatitis C, Hepatitis B and HIV-1/2. Combination PCR-based test incorporated into blood donor

screening programs dramatically reduces the risk of "Transfusion Transmitted Infections.

J,Occult hepatitis B virus (HBV) infection is diagnosed when a HBV DNA test is positive but

hepatitis B surface antigen (HBsAg) is undetectable. NAT detects such Occult HBV cases.

**K,**HBV, HCV and HIV-1 have doubling rate of 2.6 days, 14.9 hours and 20.5 hours respectively. NAT is highly sensitive as it detects viral load even at low counts especially HBV has more prevalence in India and due to the high sensitivity of NAT PCR, the window period is significantly reduced.

**L**,In India, serological tests are mandated to screen donated blood samples for the presence of infectious markers (HIV1, HIV2, HBV, HCV, Malarial parasite &VDRL: As per Gazette of Indian, July 19,2000) but there still remains a small risk of viral transmission. In addition to the routine and advanced serological testing done in the Blood banks, implementation of NAT will provide additional layer of safety. This helps to narrow the "**windowperiod**" resulting in improved blood safety.

**L,** Window Period of NAT technology as compare to Chemiluminiscence and Elisa technology.



# Performance of cobas® TaqScreen MPX Test, v2.0 on Seroconversion Panels

Virus/Test	Earlier Detection			
HIV-1/2 Antibody Assay	Abbott PRISM HIV O Plus:	Abbott PRISM anti- HIV 1/2:		
HIV	13.4	13.4		
HCV Antibody Assay	Abbott PRISM HCV	ORTHO HCV Version 3.0 ELISA Test System		
HCV	29.5	29.5		
HBsAg Assay	Abbott PRISM HBsAg	ORTHO HBsAg ELISA Test System 3		
HBV	6.8	16.1		

# 1, Window Period of NAT technology as compare to Elisa technology.

Virus/Test	Days (average) Earlier Detec		
HIV-1/2 Antigen/Antibody Assay	NAT	Elisa 4 th Generation	
HIV Virus	5-6 Days	18-20 Days	
HCV Antibody Assay	NAT	Elisa Technology	
HCV Virus	15-20 Days	55- 60 Days	
HBsAg Assay	NAT	Elisa Technology	
HBV Virus	8-10 Days	24-28 Days	



#### BY Using NAT in Blood Bank extra cost required:

Taking at present work load of 22000 / donations annually ,and approx. Rs 1000 / cost of NAT per sample including of GST so extra cost on blood bank comes .

#### NO OF DONATIONS X COST OF NAT PER SAMPLE.

1st Year: No of donations---22000 x 1000 -- Rs 2,20,00000 (Rs 2 crore twenty lacs)

2 <sup>nd</sup> Year: No of donations----23000 x 1000--Rs 2,30,00000. (Rs 2 crore thirty lacs)

3rd Year: No of donations----24000 x 1000----Rs 2,40,00000. (Rs 2 crore forty lacs)

4 th Year:No of donations----25000 x 1000----Rs 2,50,00000 (Rs 2 crore fifty lacs)

5 th Year: No of donations----26000 x 1000----Rs 2,60,00000 (Rs 2 crore sixty lacs)

All elisa / Chemiluminiscence positive samples will no be run on NAT

- = 350 approx in number every year
- $= 350 \times 1000$
- = 350,000.00 (Three Lakh fifty thousands)

Taking here the cost on higher side and inclusive of all taxes GST and workload of blood bank also increasing every year and presumed 1000 donations extra per year calculated the cost. This is the extra cost on blood bank apart from elisa.

All elisa / Chemiluminiscence negative samples will run on NAT as missed by elisa.

#### ARE YOU SURE THE BLOOD YOU RECEIVED IS SAFE?

Routine screening test of blood collected currently includes detection of antibody antigen against HIV 1 & 2 , HBV, & HCV.

Chances of missing "window period infection" are high using these techniques

Though most of the Blood Banks use ELISA as a gold standards to detect HIV/HBV/HCV. But PCR technology detection reduces the window period to a great extent.

Automated NAT (Nuclcic Acid Testing) for HIV 1 & 2, HBV, HCV detects infection much earlier.

NAT screening for blood is one of the best available technology based on real time PCR. It amplifies and detects RNA/DNA of viruses.

## Frequently Asked Questions on NAT

# What is NAT (Nucleic Acid testing)?

NAT is a highly sensitive method of blood screening that is used to detect human immunodeficiency Virus (HIV-1 & 2 ), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV) in blood.

#### What is window period?

The period of time between initial infection and detection of antibodies is called the "window period". NAT reduces the window period by direct detection of low levels of viral genetic materials

# What is the different between present ELISA screening methods and NAT?

Present traditional ELISA screening tests require the presence of antibodies to trigger a positive test reaction. NAT detects low levels of direct viral genetic material before antibodies are formed in the body hence ensures a safer blood compared to the present screening methods (serology)

#### Why ask for NAT Blood?

By asking for NAT tested Blood I will be sure that I get the safest possible blood. Free of lethal viruses like HIV-1&2, HBV & HCV.

### Advantages of NAT Blood?

- Shortens the window period to a great extent.
   NAT detects HIV in 3-4 days, HBV in 8-10 days from the day of infection where as ELISA fourth generation detects HIV in 18-20 days, HBV in 24-28 days and HCV in 15-20 days by NAT & ELISA 55-60 days from the day of infection.
- 2. Detect occult HBV cases.
- 3. Detects immunosilent donors and
- 4. Medicolegle aspect-



Litigation cases reported from different blood banks has to pay huge compensation due to transfusion of window period contaminated blood with Elisa screening.

We are liable to litigation

Thereby, NAT tested blood is taken as worlds safest blood till date.

# Why Guru Shri Gorakshnath Blood Bank wants to implement NAT?

a. To ensure maximum safety of blood issued.

b. NAT is the highest tested standards for quality of blood globally as on date.

c. **Guru Shri Gorakshnath Blood Bank** NAT and move will introduce in tandem with rest of the world like US & Europe to ensure safe blood.

d. Guru Shri Gorakshnath Blood Bank the only Blood Bank to implement and issue NAT blood in the state of U. P. in charitable sector and this will be the 5th installation in U. P.

How much should I pay for NAT Blood?

The additional few hundred rupees will ensure highest safe Blood Just costs slightly more than the Elisa tested blood but is many times safer (some of the cost incurred is born by the blood bank)

As proposed by you if this short tall in the cost of NAT testing is made by resources made available to us, we shall be able to start NAT testing in our Blood Bank without any extra burden on the pocket of patients. This will enable us to supply safest of Blood & Components to the society there by saving quite few no of lives in addition to the present Elisa tested supplies.

Thanking You,

Sincerely your's

Dr. Awadhesh Agrawal

Gorakhpur

Dv. CMO & I/c Blood Bank

Guru shri Gorakshnath Chikitsalya Gorakhnath

Gorakhpur