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**NAT takes Blood Safety in Bangalore to global standards by reducing transmission of HIV and hepatitis**

*Rotary TTK, Bangalore opens centralized Nucleic Acid Testing Technology (NAT).*

**/24-7PressRelease/** - BANGALORE, INDIA, December 30, 2007 - Rotary TTK, Bangalore opens centralized Nucleic Acid Testing Technology (NAT). During the launch Dr Latha Jagannathan Medical Director and Managing Trustee Rotary TTK Blood Bank said "We believe it is our duty to ensure blood safety as the patient has a right to expect it, and the medical fraternity has an obligation to create awareness on this crucial subject."

Hemogenomics, a Bangalore based company has been instrumental in bringing state-of-the-art technologies for disease prevention, diagnosis and monitoring. The company has started its operations by bringing Nucleic Acid Testing (NAT) into India for making blood safer. The promoters of this company are Mr. N Vaghul (Chairman ICICI), Dr. Ashok Ganguly (former MD & Chairman Hindustan lever, current Chairman ABP and ICICIONesource), Mr. Subhash Bagaria (Chairman & MD - Millipore India & Kemwell Group) Dr. William J Rutter (Founder - Chiron, his lab invented the Hepatitis B vaccine and discovered Hepatitis C) and Sumit Bagaria (President, Hemogenomics Pvt. Ltd.)

Speaking at the National Blood Safety Seminar Series organized across India by Chiron and Hemogenomics, Mr. Sumit Bagaria, President, Hemogenomics said "We are dedicated to creating awareness and influencing the mindsets of the healthcare providers and the Government to offer its citizens the choice for the safest possible blood. Nucleic Acid Testing (NAT) is used for the screening of human immunodeficiency virus - 1 (HIV-1), Hepatitis B (HBV) and Hepatitis C (HCV) virus in donated blood. This test is the first simultaneous, single tube NAT solution for HIV-1, HCV and HBV. It is a direct test where it actually detects the viral nucleic acid (RNA/DNA). Being a direct test it reduces the window of detection for all these three viruses from the current available serological (ELISA) tests. NAT combines the advantages of direct detection of the organism with sensitivity several orders of magnitude higher than that of traditional methods. The screening of blood for infectious markers (anti HIV 1 & 2, anti HCV and HBsAg) is done using Government approved test kits (Elisa or Rapid Kits). Despite these efforts, residual risk of transfusion-transmitted infections remains because of donors in the pre-seroconversion (window period), viral variants, non-seroconverting (immunosilent) or delayed seroconverting carriers (atypical seroconversion). Nucleic Acid Testing (NAT) along with serological testing can reduce this residual risk to a great extent because it involves highly specific detection of an infectious agent (the virus itself) with much higher sensitivity. "

NAT is a recently developed technology that allows detection of very small amounts of genetic material (DNA or RNA) by a process of massive copying (amplification) of a gene fragment. Currently, donors of blood and plasma are tested for Hepatitis B surface antigen, antibodies to HCV, antibodies to HIV and sometimes HIV-1 antigens, which are the virus' own proteins. However, there is still a "window period" during which a donor can be infected, but have negative screening tests. With the use of Individual Donor Testing (IDT) NAT for HCV, the "window period" for detection of HCV is reduced by 67 days (from an average of 72 days to 5 days). For HIV-1, the average window period with antibody tests is 22 days. Antigen testing cuts the window period to approximately 16 days and NAT further reduces this period to 5.6 days. Given the high rate of sero-positivity of HIV, HCV and HBV in India and keeping in mind the high percentage of first time and replacement donors, it is likely that adding NAT to the current screening tests will have a very significant reduction in Transfusion Transmitted Infections making our blood safer.

Mr. Sumit Bagaria further said "A look at the NAT experience of various countries in the SE Asia region shows that every country has been benefited from this technology. In Singapore, among the 466,779 samples tested by NAT since October 2007 they were able to pick 9 HCV and 10 HBV NAT yield samples (1 in 24,567). Similarly in Thailand, Hong Kong and in Korea the NAT yield rate is 1 in 11, 676, 1 in 202,500 and 1 in 1, 46,628 respectively. Despite these countries having a very stringent donor counseling and screening process, a high rate of regular repeat voluntary donation, and use of the most sensitive serological tests, they were able to identify a significant number of samples which were NAT reactive but sero-negative. In India, Indraprastha Apollo Hospitals, Delhi has taken the initiative for NAT implementation for the first time in the country. In the first nine months of implementing NAT, they were able to pick five (3 HBV and 2 HCV) NAT yield samples among 13,331 samples tested (1 in 2,666)."

The application of NAT screening to the blood supply appears inevitable and various countries have implemented it. NAT screening for HIV and HCV is already prevalent. Many countries have also added HBV NAT and others are planning to add it. USA also added West Nile Virus (WNV) NAT to its blood safety program. While most developed countries and many

developing countries have added NAT as a layer of additional safety, other developing countries are now planning to do so.

Mr. David Nichols, Senior Director AP (Scientific & Regulatory Affairs) said "The future of NAT in India lies in the hand of all the doctors, health care providers and the government. To start with, NAT can be implemented in a phased manner in selected cities. Centralized NAT screening centers are hugely successful all over the world and may as well be the answer for implementing NAT in India. A centralized testing site where all the blood banks of that city will send samples and after testing results can be send electronically to respective blood banks. This model has worked very well in Thailand which has a fragmented blood banking system like India. "

Some of the countries already utilizing the benefits of NAT are- Asia Pacific Region- Australia, India, Indonesia, Hong Kong, Korea, Malaysia, New Zealand, Singapore, Thailand, Japan, Europe, Middle East & Africa- Belgium, Denmark, France, Germany, Greece, Ireland, Israel, Italy, Lithuania, Poland, Portugal, Slovenia, Slovakia, South Africa, Egypt, Spain, Switzerland, UK, Scotland. Americas- United States, Brazil, Caribbean, Canada.

Potential Impact of Single Unit of Blood Collected from Infected Donor- A single unit of whole blood collected from a donor in the window period of infection may be transfused into up to four recipients or may be added to pools of more than 1,000 units to manufacture blood-derived products.

NAT could have prevented infections, including HIV and Hepatitis in many cases in India and abroad. Recent cases of infections have been reported through blood transfusion in Peru, Kazakhstan, Denmark and in an organ transplant case in USA. In India we have seen media reports and legal cases in Apollo (Delhi), Escorts Heart (Delhi), AIIMS (Delhi), Safdurjung (Delhi), Breach Candy (Mumbai), KEM (Mumbai), PGI (Chandigarh) and many others in West Bengal, Kerala and around the country.

Pre-requisites for blood safety

The three integral aspects for blood safety are-

- Safe blood donors - through repeat voluntary donations and thorough donor screening
- Safe blood transfusion practices - better screening
- Appropriate / Rational use of blood - using components and optimizing blood usage

Challenges of Blood Screening in India:

India is the second most populous nation in the world, with a population of more than 1.2 billion that includes 2.5 million HIV, 43 million HBV and 15 million HCV infected persons. Blood Transfusion Services (BTS) in India are mainly hospital based and is governed by The Drugs & Cosmetic Act. There are about 2212 licensed blood banks (CDSCO) under different administrative controls i.e. Government 41%, Voluntary 12%, Private Hospital 22% & Private Commercial 25 %.

There is a wide gap in the demand & supply of blood as the annual collection is about 6 million against the demand of approximately 9 million. Blood collection from the voluntary blood donors constitutes only 50%. Majority of voluntary donors are first time donors, as there is little concept of regular repeat voluntary blood donation. Each and every unit of blood is screened for HBsAg, anti HIV, anti HCV, malaria & syphilis as per Drugs & Cosmetic rules before issue to patients.

Though paid blood donation is illegal in India, there is no strong monitoring or expert donor counseling in many blood banks. The prevalence of HIV, HCV and HBV among the blood donor population is 0.5%, 0.4%, and 1.4% respectively. Most of the blood banks use serological screening methods for the infectious marker screening. Most of these serological tests are not sensitive enough and very few blood banks use the more sensitive 3rd or 4th generation serological tests to screen the viral markers. Majority of the blood collected is used as whole blood as blood component preparation is just 15-20 %. Increased voluntary donation, availability of safe blood, component preparation and optimum utilization of blood products are the key needs.

Protection of our country's blood supply is of critical importance. A patient must be given the choice for 'safe blood' as per the decision of the Supreme Court which led to a National Blood Policy.

Safe Blood - safest possible blood' is now available in Bangalore. This is only the second city after Delhi to offer Individually Tested (IDT) NAT using a FDA/CE approved and globally accepted and used test. While some Hospitals may offer it to all their patient's, others are waiting on the patient's request. So it is up to us Bangaloreans to exercise our choice, and decide whether we want blood safety, for our near and dear ones.

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