QUALITY CONTROL DIVISION

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Quality Control Division has been involved in quality control testing of plasma derived hepatitis B vaccine, research on hepatitis B virus, arboviruses, development of rabies vaccine, and non communicable diseases. Quality control testing was done starting from raw materials to final product to get safe and effective vaccine. The research projects were mostly involved in disease surveillance of viral infections for timely prevention of disease outbreaks. Some of the studies aimed to monitor the emergence of new viral strains or subtypes to provide base-line data for the formulation of effective candidate vaccines and for elucidating the contribution of viral genetics to the changing patterns of disease.

RESEARCH PROJECTS

1. COMMUNICABLE DISEASES

1.1 Quality control testing of plasma derived hepatitis B vaccine (2016)

During 2016, a total of 508 units of blood samples from blood banks were determined for HBs antigen by counter current immunoelectrophoresis (CIEP). Among them, 37 units with high HBs antigen titre were selected and screened for anti-HCV and anti-HIV 1 & 2 (by using ELISA) and for syphilis (by using Lumiquick Diagnostic Strip antibody test). CIEP test was done not only for HBs antigen determination in blood units, but also for in-process control of intermediate products in vaccine production 58 tests were found high titre of HBs antigen. Rabbit pyrogen test (1 test) was done on rabbit. Lowry's protein content test (75 tests) were done for in-process control of intermediate products. Mouse potency test (immunogenicity test) (1 test) was done with 175 rats for one lot of vaccine. Sterility tests (9 tests) were done using Thioglycollate Broth and Tryptone Soya Broth with positive and negative controls. General safety (abnormal toxicity test) (9 tests) were done in mice for every batch, and one test for extraneous viruses were also performed in suckling and adult mice. Monitoring of clean room by settle plate method was done in vaccine production area. Polymerase chain reaction for HBV DNA (8 tests) were done on purified products of vaccine production.

1.2 Detection of drug resistant Mutations of HBV isolates from Myanmar Hepatitis B Patients (In collaboration with Bioinformatics Division)

Myanmar is an HBV endemic country and emerging of drug resistant mutations in HBV is challenging for treatment. Total of 19 serum samples were collected during 2016. These 19 patients were referred from hepatologists. All patients had been taken antiviral drugs therapy and their viral loads were monitored by hepatologists. When their viral loads were re-increased, their antiviral drugs were changed and referred to DMR for drug resistance testing. DNA extraction and first round PCR were done and all samples revealed negative

results. This negative result may be due to the prolonged time gap between the switching of antiviral drugs and sample collection. According to this finding we should take sample of patients whose viral loads are re-increased (i.e. just before switching the antiviral drugs).

1.3 Molecular detection of chikungunya virus among inpatients with clinically suspected acute viral infection in medical units at Yangon General Hospital (2016)

Chikungunya fever or chikungunya disease is one of the common arthropod-borne viral infections in Myanmar transmitted by the bite of infected female *Aedes* mosquitoes. The aim of the research is to study the prevalence of chikungunya virus infection in adult patients presented with fever, joint pain and/or rash who attended to Yangon General Hospital by immunochromatographic test (ICT) and reverse-transcriptase polymerase chain reaction (RT-PCR) methods. A total of 100 patients presented with clinically suspected acute viral infection, viral encephalitis, meningitis and meningoencephalitis admitted to medical units were studied between January and August 2016. Out of 100 febrile patients, chikungunya IgM antibody was positive in 12(12%) by ICT and 50(50%) were positive by RT-PCR. Chikungunya IgM antibody positive cases comprised of 4(33%) patients presenting with acute viral infection, 3(25%) with viral encephalitis, 4(33%) with meningitis and 1(8%) with meningoencephalitis. Among RT-PCR positive 50 cases, 26(52%) of patients presenting with acute viral infection, 15(30%) with viral encephalitis, 6(30%) with meningoencephalitis and 3(6%) with meningitis were confirmed. Both IgM and RT-PCR positive cases were found in 3(50%) of acute viral infection patients and 3(50%) of meningitis patients.

1.1 Preliminary studies of rabies vaccine development using genetically transformed Pasteurella multocida as a vaccine stain

Although rabies is a vaccine preventable disease, the annual number of human rabies deaths globally is estimated in 2010 to be from 26,400 to 61,000. The annual cost of rabies is US$6 billion worldwide mainly cost of life saving prophylaxis is a major burden both to national economics and to poor families. Therefore, development of a safe and cost effective rabies vaccine is demanding. The transformed *P. multocida* strain was treated with Triton 100X and incubated for one hour to release glycolprotein. (One point five percent agarose gel was prepared.) Agar gel immune diffusion tests were done to test the presence of glycoprotein. There was a precipitation line between test vaccine and human rabies immunoglybulin (HRIG). This is due to the presence of glyprotein which is expressed by transformed *P. multocida* bacteria strain.

1.2 Detection of emerging arboviruses in dengue negative serum samples from Yangon Children Hospital, Yangon

A total of one hundred left-over dengue negative serum samples were used to detect emerging Arboviruses. Panel of detection of Arboviruses include Flavirus; dengue, Japanese Encephalitis, Zika, Yellow fever and West Nile virus, and Alphaviruses; Chikungunya virus, Ross River virus and Barmah Forest virus. All 100 samples were tested with Flaviruses group primers and all were negative for Flaviruses. All samples will be tested further with Alpha group primers.

SERVICES PROVIDED

LABORATORY

Sr.	Laboratory Tests	No. of tests
1.	Anti-HBs Quantitative ^{R}Immunocomb II	1048