WORLD HEALTH ORGANIZATION

SECRETARIAT OF THE PACIFIC COMMUNITY

5th LABNET MEETING: STRENGTHENING PACIFIC LABORATORY QUALITY MANAGEMENT SYSTEMS (LQMS) TOWARDS ACCREDITATION (Noumea, New Caledonia, 17-20 September 2013)

Referral of Biological Samples in the Pacific PPHSN LabNet Reference Laboratories

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1. ACRONYMS AND ABBREVIATONS

CDC Centre for Disease Control

CNMI Commonwealth of the Northern Marianna Islands

DBS Dry Blood Spots

DLS Diagnostic Laboratory Services
ELISA Enzyme Linked Serum Assay

ESR/NCBID Institute for Environment Science & Research / National Centre for

Biosecurity

FSM Federated States of Micronesia
GPHL Guam Public Health Laboratory
HIV Human Immunosuppressed Virus
IATA International Air Transport Association

IFA Immunofluorescent Assay
ILM Institute Loius Malarde'
IMVS Institute of Veterinary Science
IPNC Institute Pasteur New Caledonia

L1 Level 1 L2 Level 2 L3 Level 3

MATT Microscopic Agglutination Test

MH Mataika House

NRL National Reference Laboratory PCR Polymerase Chain Reaction

PICT Pacific Island Countries and Territories
PIHOA Pacific Islands Health Officers Association

QHFSS Queensland Health Forensic Science Services

QMRL Queensland Mycobacterium Reference Laboratory

QUT Queensland University of Technology

RDT Rapid Diagnostic Test

RMI Republic of the Marshall Islands

RNA Ribonuclease

SPC Secretariat of the Pacific Community
STI Sexually Transmitted Infections

VIDRL Victoria Infectious Disease Laboratory

WHO World Health organization
WHOCC WHO Collaborating Centre

2. ACKNOWLEDGEMENT

Many organizations and individuals who have proactively moved the way forward to improve shipping biological specimens across the Pacific and internationally should be acknowledged. PIHOA and CDC in the North Pacific, WHO and SPC in the South Pacific have been dynamic forces in addressing compliance to IATA regulations for improved laboratory results. Input from the various reference laboratories have enhanced shipping from the islands, making the activity less stressful and less complicated compared to what it was a decade ago.

The reference laboratories have contributed to their willingness in diagnosis and confirmations for our Pacific Islands. Discussions moved forward in November 2012 during the SPC Laboratory visits to some of the Level 3 (L3) laboratories on improving relationships and shipping process. Other improvements have been through regular communications with individual reference laboratories on their commitments.

Discussions and communications with Airlines, courier services and transport agencies and authorities have made shipping a routine laboratory task in most cases.

Last, but not the least, the individual laboratory managers representing the PICT in making sure shipping compliance is a routine commitment to improved laboratory results.

3. BACKGROUND INFORMATION

For the purpose of standardized shipping protocols and compliance with IATA (International Airline transportation Association), shipping logistics in the Pacific have been addressed effectively through LabNet and regional partner organizations, airlines and courier services collaborations that are available in the region. Guidelines now include national shipping manuals that comply with IATA Dangerous Goods Regulation annual editions.

Shipping biological specimens in the Pacific 2-3 decades ago was a dreaded activity for laboratory staff. Many a times the buck was passed around the lab until a brave lab technician volunteered to perform the task. Shipments were on hold because there was very little knowledge on the transportation requirements. The use of dry ice and its packaging was not clear. In a particular incident, a life was taken when the package with dry ice exploded in an ambulance before it reached the airport for transportation to a reference lab. Another example was concerning laboratory sputum samples to be transported to a reference lab, being stacked in a cupboard for 2 months awaiting the return of a lab technician who was away on an extended personal leave. Transportation of specimens in glass tubes often arrived to the receiving labs all cracked resulting in contamination of other specimens in the same bag.

Most laboratories have standardized shipping mechanisms, although there is room for improvement. Improved shipping process provides our clinical and Public Health laboratory support in patient care and Public Health lab-based surveillance. Communications between laboratories have improved, and initiatives are being taken by laboratory managers to ensure that their laboratories comply with IATA regulations.

IATA certification and re-certification is an ongoing activity that PIHOA and SPC have jointly taken on board to facilitate and assist the PICTs to meet IATA regulations. Each PICT should have at least 2 laboratory persons certified to pack and ship biological specimens. Each certification is valid for 2 years, thus re-certification is an ongoing process that requires sustainable funding.

Certified boxes and shipping material are purchased by individual PICT but agencies such as WHO and SPC contribute when requested

4. MAPPING DETAILS OF THE LABORATORY LEVELS IN THE PACIFIC

Level 1 (L1) labs are the labs of the PPHSN member countries and territories. They should have ready access to Level 2 (L2) or Level 3 (L3) lab confirmation services for selected diseases. (22 PICTs). Most L1 laboratories would not have the capacity to either screen or confirm suspected infections or diseases nationally. Under the PPHSN laboratory network, LabNet, reference laboratories have been identified. This simplifies shipping logistics and works towards appropriate Turn-Around-Times of laboratory results. Requirements are proposed for the preparedness by individual National laboratories to meet IATA regulations of transporting biological specimens internationally. Below are some of the responsibilities and guidelines for a L1 laboratory in regards to referral of biological specimens:

- Ensuring that there are **current IATA certified shippers** at all times for routine and emergency shipments of biological specimens to known reference lab destinations
- Ensuring that there are IATA certified shipping boxes and packing materials for routine and emergency shipments.
- Having an updated shipping manual to record all the reference labs utilized internationally, including recording of: contact details, contact persons, specific protocols to be met, current import permits / documentations, local courier service contacts and phone numbers, current certified shippers and payment methods of shipping costs.
- Identifying local airlines and courier services that will comply with IATA regulations.

L2 regional labs perform the first level of confirmation tests for L1 labs. The analyses and techniques used at the L2 level require more training and equipment than those used at L1 labs. L2 labs are further supported by L3 labs. L2 regional labs may also serve as L1 labs in their country or territory. There are currently four L2 Labs identified (Appendix I and II) at strategic geographic locations to support identification and confirmation of certain specific infections only. These confirmations provides urgent and diagnostic results for clinical purposes as well as Public Health concerns

L3 labs are reference laboratories with disease specific roles. They are usually internationally recognized labs (e.g. WHO collaborating centers), located in the Pacific Rim countries (mainly Australia, New Zealand and USA). In addition to the L3 disease-specific role, they perform more sophisticated, less urgently needed tests, giving important epidemiological information for the region or in the context of the worldwide surveillance of major diseases, This could included for instance further characterizations e.g genotyping, phylogenetic analysis providing virus or bacterial lineage.

5. CHALLENGES & DISCUSSIONS

- Sustaining the increasing shipping cost and expenses in the Pacific with limited resources The use of a revolving fund to improve funding issues.
- Absence of reliable courier services in some PICT Review shipping services in country
- Documentation of shipping protocols both for local and international shipments Implementation of LQMS / SOP in the area of Biological referrals nationally and internationally
- Training plans for the IATA certification as an ongoing activity

6. SHIPPING WITH DRY BLOOD SPOT METHOD

One new recently introduced method in the Pacific and that has the potential to address some of the above challenges is the use of dried blood spots (DBS). DBS specimens are clinical specimens collected by carefully applying a few drops of blood, freshly drawn by finger stick with a lancet from adults, or by heel stick with a lancet from infants, onto specially manufactured absorbent specimen collection (filter) paper. The blood is allowed to thoroughly saturate the paper and is air dried for a minimum of 3 hours. These are then enclosed and sealed in a high quality bond envelope.

The dried blood spot specimens must NOT be packaged in airtight, leak-proof plastic bags. This is due to that the lack of air exchange in the inner environment of a sealed plastic bag causes heat buildup and moisture accumulation that can damage the dried blood spot test substances. In addition, various chemicals that can adversely affect the test substances in the dried blood spots could leak from these plastics and thus cause incorrect analytical test results. The inclusion of desiccant packs will aid in prevention of moisture accumulation if using a plastic bag, but shipping conditions are uncontrolled and desiccant has a limited effectiveness.

Dried blood spot specimens can be shipped or transported by mail or other carrier with very limited or no risk of occupational exposure to blood or other potentially infectious material and is less expensive that the normal shipments of serum and blood. "Universal precautions" are to be followed in collecting and preparing these specimens for shipment. Standard filter paper collection kits should be enclosed and sealed in high quality paper mailers -- ideally, extra-strong, tear-proof, air-permeable, and water resistant envelopes. These steps provide reasonable safety from occupational exposure and maintain optimal specimen integrity.

In the Pacific, ILM and INPC (APPENDIX I and II) are the two laboratories currently receiving DBS for dengue, leptospirosis and chikungunya testing and confirmation using DBS samples. Most Pacific Island laboratories are using DBS for infant HIV diagnosis, samples being referred to the New South Wales Reference Laboratory (APPENDIX I and III). Transportation using DBS technology is less expensive, safer and more convenient in comparison to the traditional serum and blood sample shipments.

7. APPENDICES

7.1 APPENDIX I - LIST OF PPHSN LABNET REFERENCE LABORATORIES

L 2 LABORATORIES

| 1. | Fiji | Mataika House laboratory |
|----|------------------|------------------------------|
| 2. | Guam | Guam Public Helth Laboratory |
| 3. | French Polynesia | Institute Louis Malarde' |
| 4. | New Caledonia | Institute Pasteur |

L3 LABORATORIES (WHO COLLABORATING LABORATORIES)

| 1. | Australia | WHOCC for Influenza Melbourne (VIDRL) |
|----|-----------|--|
| 2. | Australia | WHOCC for Measles Melbourne (VIDRL) |
| 3. | Australia | WHOCC for Arbovirus Queensland (QUT) |
| 4. | Australia | WHOCC for Leptospirosis Queensland (QHFSS) |

L3 LABNET LABORATORIES

| 5. | New Zealand | Institute for Environment Science & Research/National Centre | |
|----|-------------|--|--|
| | | for Biosecurtiy for Infectious Disease Wellington | |
| | | (ESR/NCBID) | |
| 6. | Australia | National Reference Laboratory (NRL) Melbourne | |
| 7. | Australia | Queensland Health & Forensic Science (QHFSS) | |
| 8. | Hawaii | Hawaii State Laboratory, Honolulu | |
| 9. | Australia | New South Wales State Reference Laboratory for HIV | |

L3 PATLAB (TB LABORATORIES)

| 1. | Australia | Queensland Mycobacterium Reference Laboratory (QMRL) |
|----|------------------|---|
| | | Brisbane Qld |
| 2. | Australia | Institute of Medical Veterinary Science (IMVS) Adelaide |
| 3. | New Zealand | Lab Plus Auckland |
| 4. | Hawaii | Diagnostic Laboratory Services (DLS) Honolulu |
| 5. | French Polynesia | Institute Louis Malarde' (ILM) |
| 6. | New Caledonia | Institute Pasteur Noumea (IPNC) |

7.2 APPENDIX II - L2 LABORATORY CAPABILITIES AND CONFIRMATION TESTING

MATAIKA HOUSE (MH) LABORATORY FIJI

Although there are 8 PICT that have direct flights to Fiji, only a few have utilized the MH laboratory. All international flights into Fiji arrives in Nadi, thus transportation to Suva must be pre planned for appropriate specimen storage if need be.

| appropriate specimen store | | | |
|----------------------------|--|---|-----------------|
| Contact details | Fiji Centre for Communicable Disease Control | | |
| | Mataika House Building | | |
| | Tamavua, Suva Fiji | | |
| | Ph: +679 3324226 | | |
| | Fax: | +679 3320444 | |
| Contact Person | Dr E | ric Rafai eric.rafai@govnet.gov | <u>.fi</u> |
| | Mr U | J <mark>raia Rabuatoka</mark> <u>uraia.rabuatok</u> | a@govnet.gov.fj |
| | | | |
| PICT accessible to MH | Fiji, | Kiribati, Tuvalu, Solomon Is, | |
| | | | |
| Shipping Logistics | Air F | Pacific, Solomon Air, DHL, | |
| | | | |
| INFECTIONS/DISEASE | | TESTS / SPECIMEN | CONFIRMTION |
| | | | |
| Influenza | | IFA & PCR (NSP swabs / | Yes |
| | | wash) | |
| Dengue | | ELISA & PCR (Serum) | Yes |
| Leptospirosis | | EISA & PCR (Serum) | Yes |
| Measles | | ELISA (Serum) | Yes |

GUAM PUBLIC HEALTH LABORATORY (GPHL)

The Cepheid GeneXpert Flu (Influenza) assay is an automated, assay for the qualitative detection of Influenza A and Influenza B viral RNA. It differentiates 2009 Influenza H1N1 from seasonal Influenza A and B. Preferred respiratory specimens for influenza testing includes nasopharyngeal swabs/aspirates or Nasal swabs/wash./aspirates.

| Contact details | Guar | Guam Public Health Laboratory | | |
|-----------------------|--------------|---|-------------|--|
| | Depa | Department of Public Health & Social Services | | |
| | 123 (| 123 Chalna Kareta | | |
| | Man | Mangilao Guam 96913-6304 | | |
| | Ph: (| 671)735-7142/735 7355 | | |
| | Fax: | (671)734-2104/735 7158 | | |
| Contact Person | Mrs | Mrs Josephine O'mallan Josephine.omallan@dphss.guam.gov | | |
| | Ms Mary Jean | | | |
| | mjjja | mjjjac@yahoo.com | | |
| | | | | |
| PICT accessible to MH | Guar | n, RMI, FSM, Palau, CNMI | | |
| Shipping Logistics | Unite | ed Airlines cargo, TNT | | |
| INFECTIONS/DISEASE | | TESTS | CONFIRMTION | |
| | | | | |
| Influenza | | RDT, IFA & Cepheid | Yes | |
| | | GeneXpert | | |
| Measles & Rubella | | ELISA | Yes | |

INSTITUTE LOIUS MALARDE' LABORATORY (ILM)

For access from the Pacific Island laboratories direct flights into French Polynesia is via New Zealand, Cook Islands and New Caledonia.

| Contact details | | ut Louis Malarde' | |
|-----------------------|--------|--|-------------|
| | | BP 30-98713 Papeete – Tahiti | |
| | _ | Polynesie francaise | |
| | Tel: | Tel: (689) 416 468 | |
| | Fax: | (689) 431 590 | |
| | http:/ | /www.ilm.pf | |
| Contact Person | Dr C | Cao-Lormeau Van-Mai <u>mlormeau@</u> | ilm.pf |
| | Dr | | |
| | | | |
| PICT accessible to MH | Frenc | ch Polynesia, Cook Islands, & Inter | rested PICT |
| Shipping Logistics | Frenc | French Polynesian Air, Air Carlin, DBS shipping protocol applies | |
| INFECTIONS/DISEASE | | TESTS | CONFIRMTION |
| | | | |
| Dengue | | Serum / DBS | yes |
| Chikungunya | | Serum / DBS | yes |
| Leptospirosis | | Serum / DBS | yes |

INSTITUTE PASTEUR (IPNC)

The only PICT that has direct flight to New Caledonia is Vanuatu and French Polynesia

| Contact details | Instit | ute Pasteur de Nouvelle-Caledonie | |
|-----------------------|---|-----------------------------------|-------------|
| | 9-11 | Avenue Paul Doumer | |
| | BP 6 | 1 – 98845 Noumea Cedex | |
| | Nouv | velle Caledonie | |
| | Ph: (| 587) 27 02 85 | |
| | Fax: | (687) 27 33 90 | |
| Contact Person | Dr Ann-Claire Gourant agaourinat@pasteur.nc | | |
| PICT accessible to MH | New Caledonia, Vanuatu, interested PICT | | CT |
| Shipping Logistics | Air C | Carlin | |
| INFECTIONS/DISEASE | | TESTS | CONFIRMTION |
| | | | |
| Dengue | | Serum / DBS | yes |
| Chikungunya | | Serum / DBS | yes |
| Influenza | | IFA / Serology / RT-PCR | yes |
| Leptospirosis | | Serum / MATT / RT-PCR | yes |

7.3 APPENDIX III - L3 LABORATORIES (WHO COLLABORATING CENTRE LABORATORIES)

7 4

| 7.4 COUNTRY | INFECTION | CENTRE | CONTACT INFORMATION |
|-------------|---------------------|--------------------------|---|
| Australia | Influenza | WHOCC for | Dr Ian Barr ian.barr@influenzacentre.org |
| Tustrana | IIIIuciiza | Influenza Melbourne | Dr Patrick Reading |
| | | (VIDRL) | Patrick.reading@influenzacentre.org |
| | | (TDILL) | WHOCC for Reference & Research on |
| | | | Influenza |
| | | | 10 Wreckyn St |
| | | | North Melbourne |
| | | | Victoria, Australia |
| | | | Ph: +613 9389 1761 |
| | | | Fax: +613 9389 1881 |
| Australia | Measles & | WHOCC for Measles | Dr Mike Catton mike.catton@mh.org.au |
| | Rubella | Melbourne (VIDRL) | Victorian Infectious Disease Reference Lab |
| | | | (VIDRL) |
| | | | Victoria Australia |
| | | | Ph: 613 9342 2636 |
| Australia | Polio | WHOCC for Polio | Fax: 613 9342 2666 |
| Austrana | Polio | WHOCC for Polio | Dr Bruce Thorley <u>bruce.Thorley@mh.org.au</u> Polio Reference Laboratory |
| | | | Victorian Infectious Disease Reference Lab |
| | | | (VIDRL) |
| | | | Victoria Australia |
| | | | Ph: +613 9342 2607 |
| | | | Fax: 613 9342 2665 |
| Australia | Dengue | WHOCC for | Dr John Aaskov j.aaskov@qut.edu.au |
| | Chikungunya | Arbovirus Queensland | WHOCC for Arbovirus Reference & |
| | West Nile | (QUT) | Research |
| | Ross River | , | Institute of Health & Biomedical Innovation |
| | | | QUT 60 Musk Avenue |
| | | | Brisbane Australia 4059 |
| | | | Ph: 617 3138 6193 |
| Australia | Leptospirosis | WHOCC for | Dr Lee Smythe |
| | | Leptospirosis | lee.smythe@health.qld.gov.au |
| | | Queensland (QHFSS) | WHOCC for Leptospirosis |
| | | | Queensland Health Forensic and Science |
| | | | Seivices (QHFS) |
| | | | 39 Kessels Road |
| | | | Coopers Plains QLD 4109 |
| | | | Australia |
| | | | Ph: +617 3274 9151 |
| Australia | LIIV (Infant | New South Wales | Fax: +617 3000 916 |
| Australia | HIV (Infant DBS) | Reference lab for HIV | Philip Cunningham p.cunningham@amr.org.au |
| | טטט) | Keteletice 180 101 fil V | New South Wales (NSW) State Reference |
| | | | Laboratory for HIV |
| | | | Level 4 Lowy Packer Building |
| | | | 405 Liverpool Street, Darlinghurst NSW |
| | | | 2010 Australia |
| | | | Ph: +61 2 8382 4900 |
| | | | Fax: +61 2 8382 4901 |

7.5 APPENDIX IV – Other L3 LABNET LABORATORIES

| COUNTRY | INFECTIONS | LABORATORY | CONTACT DETAILS |
|----------------|--|--|--|
| New Zealand | Influenza & other Outbreak Prone disease | Institute for Environment Science & Research/National Centre for Biosecurtiy for Infectious Disease Wellington (ESR/NCBID) | Dr Virginia Hope Virginia.hope@esr.cri.nz Dr Sue Huang sue.huang@esr.cri.nz National Centre for Biosecurity & Infectious Disease 66Ward Street Wallaceville 5028 PO Box 40158 Upper Hutt 5140 New Zealand Ph:64 4 27 65 35 681 Fax: 64 4 529 0601 |
| Australia | STI / HIV | National Reference Laboratory (NRL) Melbourne | Dr Sue Best sue@nrl.gov.au National Reference Laboratory (NRL) 4 TH Floor Healy Building 41 Victoria Parade Fitzroy Victoria Australia Ph: 61 3 9418 1123 Fax: 61 3 9418 1155 |
| Australia | Chikungunya Dengue | Queensland Health & Forensic Science Services (QHFSS) | Dr Alyssa Pyke Alyssa_pyke@health.qld.gov.au Dr Fredrick Moore Queensland Health & Forensic Science Services (QHFSS) 39 Kessels Road Coopers Plains QLD 4109 Australia Ph: +617 3000 9178 Fax: +617 3000 9186 |
| Hawaii | Influenza & Other Outbreak Prone disease | Hawaii State Laboratory, Honolulu | Dr A C Whelen chris.whelen@doh.hawaii.gov Dr Rebecca Sciulli Rebecca.sciulli@doh.hawaii.gov Hawaii State Laboratories Division Department of Health 2725 Waimano Home Road Peal City Hawaii 96782 Hawaii Ph: (808) 453 5993 Fax: (808) 251-4014 |

7.6 APPENDIX V - L3 PATLAB (PACIFIC TB REFERENCE LABORATORIES)

| COUNTRY | SPECIMENS | LABORATORY | CONTACT DETAIL |
|----------------|-----------|---|--|
| Australia | Sputum | Queensland Mycobacterium Reference Laboratory (QMRL) Brisbane Qld | Dr Chris Coulter Chris_Coulter@health.qld.gov.au Dr Sushil Pandey Sushil_Pandey@health.qld.gov.au Queensland Mycobacterium Reference Laboratory Sir Raphael Cilento Building (Block 7) Herston Hospitals Complex Herston Queensland 4029 Australia Phone: +61 7 3636 0032 Fax: +61 7 3636 1336 |
| Australia | | SA Pathology(formerly Institute of Medical Veterinary Science - IMVS) | Dr Ivan Bastian Ivan.Bastian@health.sa.gov.au Mr Richard Lumb richard.lumb2@health.sa.gov.au SA Pathology PO Box 14, Rundle Mall South Australia 5000 Australia Phone: +61 8 8222 357 Fax: +61 8 8222 3543 |
| New Zealand | | Lab Plus Auckland | Dr Sally Roberts sallyr@adhb.govt.nz Ms Maree Gillies mareeg@adhb.govt.nz LabPLUS PO Box 110031 Auckland City Hospital Auckland 1148 New Zealand Phone: +64 9 307 4949 Fax: +64 9 307 8922 |
| Hawaii | | Diagnostic Laboratory Services (DLS) Honolulu | Dr. Matthew J. Bankowski, Ph.D., D(ABMM) Diagnostic Laboratory Services, Inc. 99-859 Iwaiwa Street, Aiea, Hawaii 96701 Tel: (808) 589-5242, Fax: (808) 589-5215, Cell: (612) 801-2597 mbankowski@dlslab.com |

7.1 APPENDIX V - L3 PATLAB (PACIFIC TB REFERENCE LABORATORIES) Cont'd

| COUNTRY | SPECIMENS | LABORATORY | CONTACT DETAIL |
|---------------------|-----------|---------------------------------|---|
| French Polynesia | | Institute Louis Malarde' (ILM) | Dr Didier Musso dmusso@ilm.pf Institute Loius Malarde PO Box 98713 Papeete Tahiti French Polynesia Ph: (689) 416 470 |
| New Caledonia | | Institute Pasteur Noumea (IPNC) | Fax: Dr Ann-Claire Gourinat agaourinat@pasteur.nc Institute Pasteur de Nouvelle- Caledonie 9-11 Avenue Paul Doumer BP 61 – 98845 Noumea Cedex Nouvelle Caledonie Ph: (687) 27 02 85 Fax: (687) 27 33 90 |