

OIE Reference Laboratory Reports Activities

Activities in 2013

This report has been submitted : 2014-02-06 22:01:08

Name of disease (or topic) for which you are a designated OIE Reference Laboratory:	White spot disease
Address of laboratory:	Maricultural Organism Diseases Control & Molecular Pathology Laboratory Yellow Sea Fisheries Research Institute, Chinese Academy of Fishery Sciences 106 Nanjing Road, Qingdao Shandong 266071 CHINA (PEOPLES REP. OF)
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Name (including Title) of Head of Laboratory (Responsible Official):	Dr. Jie Huang, Senior Researcher
Name (including Title and Position) of OIE Reference Expert:	Dr. Jie Huang, Senior Researcher
Which of the following defines your laboratory? Check all that apply:	Governmental Research Academic

ToR: To use, promote and disseminate diagnostic methods validated according to OIE Standards

1. Did your laboratory perform diagnostic tests for the specified disease/topic for purposes such as disease diagnosis, screening of animals for export, surveillance, etc.? (Not for quality control, proficiency testing or staff training)

Yes

Diagnostic Test	Indicated in OIE Manual (Yes/No)	Total number of test performed last year	
		Nationally	Internationally
Indirect diagnostic tests			
Histopathology	Yes	43	0
Bioassay	Yes	6	0
T-E staining	Yes	4	0
Direct diagnostic tests			
PCR	Yes	283	2
LAMP	Yes	15	0
qPCR	Yes	6	0

**ToR: To develop reference material in accordance with OIE requirements, and implement and promote the application of OIE Standards.
To store and distribute to national laboratories biological reference products and any other reagents used in the diagnosis and control of the designated pathogens or disease.**

2. Did your laboratory produce or supply imported standard reference reagents officially recognised by the OIE?

No

3. Did your laboratory supply standard reference reagents (non OIE-approved) and/or other diagnostic reagents to OIE Member Countries?

Yes

Type of reagent available	Related diagnostic test	Produced/ provide	Amount supplied nationally (ml, mg)	Amount supplied internationally (ml, mg)	No. of recipient OIE Member Countries	Region of recipients
WSSV-infected tissues	infection experiment	Provide	30g (positive)	0	1	<input type="checkbox"/> Africa <input type="checkbox"/> Americas <input checked="" type="checkbox"/> Asia and Pacific <input type="checkbox"/> Europe <input type="checkbox"/> Middle East
High sensitive detection kits for detection of white spot syndrome virus (WSSV)	WSSV detection	Produced	110 kits	0	1	<input type="checkbox"/> Africa <input type="checkbox"/> Americas <input checked="" type="checkbox"/> Asia and Pacific <input type="checkbox"/> Europe <input type="checkbox"/> Middle East

4. Did your laboratory produce vaccines?

No

5. Did your laboratory supply vaccines to OIE Member Countries?

No

ToR: To develop, standardise and validate, according to OIE Standards, new procedures for diagnosis and control of the designated pathogens or diseases

6. Did your laboratory develop new diagnostic methods validated according to OIE Standards for the designated pathogen or disease?

Yes

7. Did your laboratory develop new vaccines according to OIE Standards for the designated pathogen or disease?

No

Name of the new test or diagnostic method or vaccine developed	Description and References (Publication, website, etc.)
single-step multiplex PCR for simultaneous detection of WSSV and IHNV	Yang B, Song X-L, Huang J, Shi C-Y, Liu Q-H, Liu L. A single-step multiplex PCR for simultaneous detection of white spot syndrome virus (WSSV) and infectious hypodermal and haematopoietic necrosis virus (IHNV) in penaeid shrimp. J Fish Dis, 2006, 29(5): 301-305.
LAMP detection method for WSSV	Huang J, Zhang Q-L, Song X-L, Yang B, Liu L. The isothermal amplification kit for detection of white spot syndrome virus of Shrimp and its detection methods. Chinese patent: ZL200810139949.4, 2010-11-10.
Gene chip detection method for shrimp pathogens	Huang J, Jing XY, Yang B, Zhang QL, Yan L, Wang XH, Zhang BC, Song XL, Shi CY, Liu L. 2012. Gene chips and the detection methods for detection of multiple pathogens of shrimp. Chinese Patent, ZL201010243399.8, 2012-7-18.
T-E staining method for diagnosis of WSD	Huang J, Yang B, Chen A-P, Song X-L Shi C-Y, Yang C-H, Wei Q. Diagnostic protocols for White spot disease of shrimp, Part 5: T-E staining method with fresh tissue. National Standard of People's Republic of China, 2012, GB/T 28630.5-2012, Issued by the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China, Standards Press of China, Beijing.
Binding activity assay of WSSV	Feng S, Li G, Feng W, Huang J. Binding of white spot syndrome virus to Artemia sp. cell membranes. J Virol Methods, 2013, 193: 108-111.

ToR: To provide diagnostic testing facilities, and, where appropriate, scientific and technical advice on disease control measures to OIE Member Countries

8. Did your laboratory carry out diagnostic testing for other OIE Member Countries?

Yes

Name of OIE Member Country seeking assistance	Date (month)	No. samples received for provision of diagnostic support	No. samples received for provision of confirmatory diagnoses
AUSTRALIA	May, 2013	0	12
KOREA (REP. OF)	Sept., 2013	0	1
INDIA	Nov., 2013	0	1

9. Did your laboratory provide expert advice in technical consultancies on the request of an OIE Member Country?

Yes

Name of the OIE Member Country receiving a technical consultancy	Purpose	How the advice was provided
VIETNAM	FAO/MARD Joint Final Technical and National Consultations on "Early Mortality Syndrome (EMS) or Acute Hepatopancreatic Necrosis Syndrome (APHNS) of Cultured Shrimp"	Presentation on the research progresses and control experiences from China
CHINA (PEOPLE'S REP. OF)	To provide diagnostic advices and prevention resolutions for shrimp farms in China	in loco
CHINA (PEOPLE'S REP. OF)	To provide technological training and advices for the administration of aquatic animals health in China	Training lectures on the diagnostic methods and prevention measures for shrimp diseases.
THAILAND	To participate the technical consultation on the "Relationship between real-world broodstock management practices, inbreeding and severity of Disease: the BHF - Nexus"	Providing of expertise during the discussion.
MEXICO	To provide our knowledge on the new disease of shrimp	Upon the queries from OIE Sub regional Representation for Central American and Mexican official, information on our recent research progress was introduced via emails

ToR: To carry out and/or coordinate scientific and technical studies in collaboration with other laboratories, centres or organisations

10. Did your laboratory participate in international scientific studies in collaboration with OIE Member Countries other than the own?

Yes

Title of the study	Duration	Purpose of the study	Partners (Institutions)
Development of diagnostic techniques of emerging aquatic pathogenic viruses and investigation of virus prevalence	Feb., 2013- Feb., 2014	The purpose of the study was to develop the rapid diagnostic assay of high specificity and sensitivity of the emerging viruses, which included fathead minnow nidovirus (FHMNV), golden shiner reovirus (GSRV) and epizootic epitheliotropic disease virus. And also, study of investigation of the emerging viruses prevalence was also conducted.	Michigan State University
Enhancement of saponin on the immersion immune effects of bacterial vaccines to marine fish	Jan., 2012- Dec., 2015	To reveal the mechanism of the enhancement of saponin on fish immersing vaccination and the pathway fish uptaking vaccine in water.	Lake Superior State University

ToR: To collect, process, analyse, publish and disseminate epizootiological data relevant to the designated pathogens or diseases

11. Did your Laboratory collect epizootiological data relevant to international disease control?

Yes

12. Did your laboratory disseminate epizootiological data that had been processed and analysed?

Yes

13. What method of dissemination of information is most often used by your laboratory? (Indicate in the appropriate box the number by category)

a) Articles published in peer-reviewed journals: 13

Song X-L, Zhang Y, Wei S, Huang J. Effect of the different enzymatic hydrolysis methods on the bioactivity of peptidoglycan in *Litopenaeus vannamei*, Chinese Journal of Oceanology and Limnology, 2013,31(2): 374-383.

Sun Y, Song X-L, Liu F, Li Y-H, Huang J. Isolation and identification of *Bacillus* sp. and evaluation its effect on WSSV disease resistance in *Litopenaeus vannamei*. Journal of Fisheries of China, 2013,37(4): 574-583.

Chai P-C, Song X-L. Effects of *Bacillus* PC465 added in feed on the growth rate and expression of STAT gene of *Litopenaeus vannamei*. (Chinese J) Progress in Fishery Sciences, 2013, 34(3):97-103.

Li G-Y, Sun Y, Song X-L, Huang J, Xie G-S, Potential probiotics supplement may impact intestinal digestive enzyme and bacteria composition of *Litopenaeus vannamei*, (Chinese J) Progress in Fishery Sciences, 2013, 34(4):84-90.

Li Q, Liu Q-H, Huang J, F0ATP synthase b-chain of *Litopenaeus vannamei* involved in White Spot Syndrome Virus infection, Virus Genes, 2013.47: 42-48.

Li Q, Liu Q-H, Huang J, VP292 of white spot syndrome virus interacts with VP26, Indian Journal of Virology, 2013, 24(1):54-58.

Sun F, Liu Q-H, Hung J. Expression of HSP60 and HSP90 in shrimp *Litopenaeus vannamei*. during WSSV infection, (Chinese J) Progress in Fishery Sciences, 2013, 34(2): 90-95.

Ma F-F, Liu Q-H, Huang J, Expression of white spot syndrome virus VP12 and it's interaction with VP24 and VP26. (Chinese J) Progress in Veterinary Medicine, 2013, 34(1): 11-15.

Sun Z, Wang X-H, Huang J, The biochemical analysis of a microbial floc and its effect on the immunity of *Litopenaeus vannamei*. Journal of Fisheries of China, 2013, 37(3): 473-480.

Hu X-G, Zhao P, Li Y-H, Song X-L, Ma S, Huang J, Isolation and identification of heterotrophic nitrosobacteria from bio-flocs and analysis of their characteristics, (Chinese J) Progress in Fishery Sciences, 2013, 34(5): 97-103.

Feng S, Li G, Feng W, Huang J. Binding of white spot syndrome virus to *Artemia* sp. cell membranes, Journal of Virological Methods, 2013, 193: 108-111.

Du Y-B, Wang Z-J, Yang B, Zhang X-H, Huang J. The ammonium protected RNA preservation method and its effects for shrimp tissue at normal temperature. (Chinese J.) Progress in Fishery Sciences, 2013, 34(3): 88-96.

Zhang X-G, Zhao P, Wang G-C, Wang X-H, Pan L-Q, Huang J. The environment and production efficiencies of bio-floc aquaculture for *Litopenaeus vannamei* under different stocking density. (Chinese J.) Progress in Fishery Sciences, 2013, 34(3): 111-119.

b) International conferences: 5

Huang J. Microbial Approaches in Bio-floc Technology for the Health Management of Aquaculture. The International Annual Meeting of Korean Society for Microbiology and Biotechnology, July 3-5, 2013. Pyeongchang, Korea .

Huang J. Concept Note for Section 4 in the Aquatic Code. the OIE Aquatic Animal Health Standards Commission Meeting, Mar 10-15; Sep 29- Oct 4, 2013, Paris, France.

Huang J. Progress of the research on EMS/AHPNS in China: *Vibrio parahaemolyticus* and suspected Yellowhead virus isolated from EMS/AHPNS cases, the FAO/MARD Joint Final Technical and National Consultations on "Early Mortality Syndrome (EMS) or Acute Hepatopancreatic Necrosis Syndrome (APHNS) of Cultured Shrimp" (TCP/VE/3304), Jun 25-27, 2013, Hanoi, Vietnam.

Huang J. Updates in Chapter 1.3. Diseases Listed by the OIE, NACA 12th Adversary Group Meeting on Aquatic Animal Health, Nov 11, 2013, Bangkok, Thailand.

Huang J. Outcomes of recommendations from OIE General Session and the meeting of Aquatic Animal Health Standards Commission. NACA 12th Adversary Group Meeting on Aquatic Animal Health, Nov 11, 2013, Bangkok, Thailand.

c) National conferences: 9

He X, Liu Q-H, Huang J. Protection and immune response of fusion protein of VP28 & Hsp70 to *Litopenaeus vannamei* against white spot syndrome virus. The 2013 Annual Conference of Chinese Society of Aquaculture, Oct. 22-25, 2013, Hefei, China.

Huang J. Progress of the research on EMS/AHPNS in China: *Vibrio parahaemolyticus* and suspected Yellowhead virus isolated from EMS/AHPNS cases. Symposium of Fish Disease Section of the Chinese Aquaculture Society, Nov 5-10, 2013, Haikou, China.

Huang J. Progress of the research on EMS/AHPNS in China: *Vibrio parahaemolyticus* and suspected Yellowhead virus isolated from EMS/AHPNS cases. Symposium of Mariculture Section of the Chinese Aquaculture Society, Nov 4-8, 2013, Shaoxing, China.

Zhang Q-L, Huang J. A new Nodavirus caused the covert mortality of shrimp. The 6th Crustacean Conference of China, Dec 9-11, 2013, Qingdao, China.

Huang J. The diagnosis and prevention of shrimp diseases. The Training Workshop of Diagnostic Laboratory for Aquatic Animal Health, Aug 15, 2013, Urumchi, China.

Huang J. The diagnosis and prevention of shrimp diseases. The Training Workshop of Diagnostic Laboratory for Aquatic Animal Health of Ningbo fishery Science, Oct 25, 2013, Ningbo, China.

Huang J. The diagnosis and prevention of shrimp diseases. The Veterinary Conference of China, Oct 29, 2013, Guilin, China.

Huang J. The diagnosis and prevention of shrimp diseases. The Training Workshop of Diagnostic Laboratory for Aquatic Animal Health of Guangxi, Oct 30, 2013, Guilin, China.

Huang J. The diagnosis and prevention of shrimp diseases. The Training Workshop of Diagnostic Laboratory for Aquatic Animal Health of tianjin, Nov 27, 2013, tianjin, China.

d) Other:

(Provide website address or link to appropriate information) 6

Song X-L, Huang J, Yang B, Liu L. A probiotic preparation which can enhance the ability of anti-virus disease for culture shrimp. Chinese patent: ZL201080003969.4, Authorized announcement, 19 Jun., 2013.

Liu Q-H, Huang J, Chen W-B, Liang Y. White Spot Syndrome Virus VP292 polypeptide and application. Chinese patent: ZL200910140993.1, Authorized announcement, Jun., 2013.

Zhang Q-L, Huang J, Shi C-Y, Wang Q-T, Liang Y, Liu L. Reaction reagents of nucleic acid isothermal amplification that can be preserved and transported at room temperature. Chinese patent: ZL201210179864.5, Authorized announcement, 18 Sept., 2013.

Zhang Q-L, Huang J, Shi C-Y, Liang Y, Wang Q-T, Li M-X. Preservation method of reagents of nucleic acid isothermal amplification based on the using of gel. Chinese patent: ZL201210178918.6, Authorized announcement, 6 Nov., 2013.

Zhang Q-L, Huang J, Yang B, Song X-L, Liu Q-H, Liu L. Preservation method and relative reagents of PCR reagents based on the using of gel. Chinese patent: ZL201210178919.0, Authorized announcement, 18 Sept., 2013.

Zhang Q-L, Huang J, Li M-X, Yang B, Wang C-M, Xu H. Preservation method and relative reagents of PCR reagents based on the using of porosint. Chinese patent: ZL201210192845.6, Authorized announcement, 23 Oct., 2013.

ToR: To provide scientific and technical training for personnel from OIE Member Countries

To recommend the prescribed and alternative tests or vaccines as OIE Standards

14. Did your laboratory provide scientific and technical training to laboratory personnel from other OIE Member Countries?

No

ToR: To maintain a system of quality assurance, biosafety and biosecurity relevant for the pathogen and the disease concerned

15. Does your laboratory have a Quality Management System certified according to an International Standard?

No

Explain Quality Management System in adoption process or currently in place

According to the requirements of QMS, we have finished the renovation of the diagnostic laboratory for OIE RL in 2013. The Quality Management System upon the CNAS standards following the ISO17025 was established by drafting, examining, and approving of the documented procedures of the QMS, including a Quality Manual, a Procedure Document, Standard Operation Procedures (SOPs) and Records of Technology and Quality. The laboratory staff was regularly trained and evaluated for the qualification and appointed with certification according to the QMS. The laboratory has obtained satisfactory results in participation of three rounds of international and national proficiency testing for detection of aquatic animal pathogens in 2013. The laboratory carried out diagnostic tests for 295 samples from 3 countries under the QMS controls and the positive results from the diagnostic testing and other testing in the laboratory were quarterly reported to the Veterinary Authority of China, for subsequently reporting to the OIE, according to the Quarterly Aquatic Animal Disease Report (QAAD) requirements. We are preparing for the application of the certification of CNAS in 2014. Detail information on this issue please see the additional comments for this report on the Progress for Establishment and Maintenance of the Quality Management System and Laboratory Accreditation.

16. Is your laboratory accredited by an international accreditation body?

No

17. Does your laboratory maintain a "biorisk management system" for the pathogen and the disease concerned?

Yes

(See *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals 2012, Chapter 1.1.3* or *Manual of Diagnostic Tests for Aquatic Animals 2012, Chapter 1.1.1*)

ToR: To organise and participate in scientific meetings on behalf of the OIE

18. Did your laboratory organise scientific meetings on behalf of the OIE?

No

19. Did your laboratory participate in scientific meetings on behalf of the OIE?

Yes

Title of event	Date (mm/yy)	Location	Role (speaker, presenting poster, short communications)	Title of the work presented
NACA 12th Adversary Group Meeting on Aquatic Animal Health	11/13	Bangkok, Thailand	speaker	Outcomes of Recommendations from OIE General Session and the meeting of Aquatic Animal Health Standards Commission
NACA 12th Adversary Group Meeting on Aquatic Animal Health	11/13	Bangkok, Thailand	speaker	Updates in Chapter 1.3. Diseases Listed by the OIE
the FAO/MARD Joint Final Technical and National Consultations on "Early Mortality Syndrome (EMS) or Acute Hepatopancreatic Necrosis Syndrome (APHNS) of Cultured Shrimp" (TCP/VE/3304)	6/13	Hanoi, Vietnam	speaker	Progress of the research on EMS/APHNS in China: <i>Vibrio parahaemolyticus</i> and suspected Yellowhead virus isolated from EMS/APHNS cases
Regional Seminar for OIE Delegates on Activities of Specialist Commissions and the Regional Conference	11/13	Cebu, Philippines	participant	Report from the Aquatic Animal Health Standards Commission

ToR: To establish and maintain a network with other OIE Reference Laboratories designated for the same pathogen or disease and organise regular inter-laboratory proficiency testing to ensure comparability of results

20. Did your laboratory exchange information with other OIE Reference Laboratories designated for the same pathogen or disease?

Yes

21. Was your laboratory involved in maintaining a network with OIE Reference Laboratories designated for the same pathogen or disease by organising or participating in proficiency tests?

No

22. Did your laboratory collaborate with other OIE Reference Laboratories for the same disease on scientific research projects for the diagnosis or control of the pathogen of interest?

No

ToR: To organise inter-laboratory proficiency testing with laboratories other than OIE Reference Laboratories for the same pathogens and diseases to ensure equivalence of results

23. Did your laboratory organise or participate in inter-laboratory proficiency tests with laboratories other than OIE Reference Laboratories for the same disease?

Yes

Note: See Interlaboratory test comparisons in: Laboratory Proficiency Testing at: <http://www.oie.int/en/our-scientific-expertise/reference-laboratories/proficiency-testing> see point 1.3

Purpose for inter-laboratory test comparisons ¹	No. participating laboratories	Region(s) of participating OIE Member Countries
Regional Proficiency Testing Programme for Aquatic Animal Disease Laboratories in Asia-Pacific	above 30	<input type="checkbox"/> Africa <input type="checkbox"/> Americas <input checked="" type="checkbox"/> Asia and Pacific <input type="checkbox"/> Europe <input type="checkbox"/> Middle East

ToR: To place expert consultants at the disposal of the OIE

24. Did your laboratory place expert consultants at the disposal of the OIE?

Yes

Kind of consultancy	Location	Subject (facultative)
OIE expert for WSD	remote by Emails	Final discussion on the OIE Procedure of Scientific assessment for the certification of Insulated isothermal PCR with fluorescent probe test
Meeting of Aquatic Animal Health Standards Commission	Paris, France	March meeting of AAHSC for the revision of Aquatic Code and Aquatic Manual
Meeting of Aquatic Animal Health Standards Commission	Paris, France	October meeting of AAHSC for the revision of Aquatic Code and Aquatic Manual
NACA 12th Adversary Group Meeting on Aquatic Animal Health	Bangkok, Thailand	Informing the outcomes of OIE AAHSC for the NACA 12th Adversary Group Meeting on Aquatic Animal Health
Regional Seminar for OIE Delegates on Activities of Specialist Commissions	Cebu, Philippines	Discussion on the regional strategies for the communication and implementation on the OIE standards
Meeting of the Country Comments for the OIE Standards of Aquatic Animal Health	Qingdao, China	Discussing and drafting the country comments for the OIE standards of aquatic animal health

25. Additional comments regarding your report:

Report on the Progress for Establishment and Maintenance of the Quality Management System and Laboratory Accreditation

The OIE Reference Laboratory for White spot disease (WSD), The OIE Reference Laboratory for Infectious hypodermal and hematopoietic necrosis (IHHN)
Yellow Sea Fisheries Research Institute, Chinese Academy of Fishery Sciences

Abstract

According to the requirements of QMS, we have finished the renovation of the diagnostic laboratory for OIE RL in 2013. The Quality Management System upon the CNAS standards following the ISO17025 was established by drafting, examining, and approving of the documented procedures of the QMS, including a Quality Manual, a Procedure Document, Standard Operation Procedures (SOPs) and Records of Technology and Quality. The laboratory staff was regularly trained and evaluated for the qualification and appointed with certification according to the QMS. The laboratory has obtained satisfactory results in participation of three rounds of international and national proficiency testing for detection of aquatic animal pathogens in 2013. The laboratory carried out diagnostic tests for 295 samples from 3 countries under the QMS controls and the positive results from the diagnostic testing and other testing in the laboratory were quarterly reported to the Veterinary Authority of China, for subsequently reporting to the OIE, according to the Quarterly Aquatic Animal Disease Report (QAAD) requirements. We are preparing for the application of the certification of CNAS in 2014.

1. Introduction

As the OIE Reference Laboratories for WSD & IHHN, according to the requirements on the quality management system in veterinary testing laboratory in the OIE standards, to establish and improve a system of quality assurance, biosafety and biosecurity relevant for the aquatic animal pathogens and the diseases concerned, our laboratory has arranged to apply for the accreditation of CNAS since the latter half year 2012.

China National Accreditation Service for Conformity Assessment (CNAS) is the national accreditation body of China unitarily responsible for the accreditation of certification bodies, laboratories and inspection bodies, which was the accreditation body member of IIAF, ILAC, as well as APLAC and PAC. Under the construction of Quality

Management System (QMS), ISO/IEC 17025:2005 General Requirements for the Competence of Testing and Calibration Laboratories (ISO/IEC, 2005) is to be used for laboratory accreditation of testing activities.

QMS has mainly addressed the sets of requirements of ISO/IEC 17025 and Guidance on the Application of Accreditation Criteria for the Medical Laboratory Quality and Competence in the Field of Gene Amplification Testing (CNAS-CL36: 2012) in spatial frameworks and technically valid documents.

2. Construction of environmental facility

After gradual establishment and implement of the procedures for a QMS and a preliminary commissioning lasted for 2 months, we carried out an internal quality audit by consulting an experienced evaluation expert in November, 2012. We thus concluded that the unified and open space of Room 701 was not applicable to the requirements of ISO/IEC17025 and an isolated system must be rebuilt to serve directly as a control for possible cross-contamination. Effective spatial separation was fundamental for OIE RL to participate in international standardization activities.

Based on the functional design for diagnostic activities, we started the renovation of Room 701 for building of a series of compartments since the end of April 2013. The original room was divided into Room 701-4 for reagent storage and preparation of PCR master mixes, Room 701-3 for specimen processing, Room 701-2 for gene amplification, Room 701-1 for analyte detection, and Room 703 for sample receiving, connected with aisles, common space, buffer rooms, or air shower room. Each section has separated air cleaning system, ultraviolet sterilization system, materials transferring pathways, water supply and drainage system, electrical system, and computer network. The renovation engineering of Room 701 in the laboratory finished in the middle of May 2013 and the QMS was updated based on the renovated compartments.

3. Establishment and maintenance of the QMS

The goal of the QMS in the laboratory, ensured by documented procedures which cover all parts of diagnostic activities, is to guarantee the provision of accurate, improving, impartial and good services. The documented procedures of the QMS, including a Quality Manual, a Procedure Document, Standard Operation Procedures (SOPs) and Records of Technology and Quality were drafted, examined, and renewed among the technical and administrative staffs and approved by the Head of the laboratory Dr Huang Jie, the OIE designated expert for WSD and IHNN. The approved procedures of the QMS are put into effect.

Based on the QMS, the laboratory has established and maintained a quality document control system to control all documents that generated internally and introduced from external sources. As the first step of the QMS development, the targets for diagnostic activities under the QMS control were considered to cover 6 pathogens, which include white spot syndrome virus (WSSV), infectious hypodermal and hematopoietic necrosis virus (IHNNV), yellow head virus (YHV), Taura syndrome virus (TSV), infectious myonecrosis virus (IMNV), and hepatopancreatic parvovirus (HPV). The protocols in the OIE Manual of Diagnostic Tests for Aquatic Animals and China National Standards are applied in the SOPs. With total 25 elements of 5 classes, i.e. people, equipment, materials, protocols, and environments, which were set up in the QMS, all diagnostic activities are traceable.

The national regulations for biosafety control of pathogenic microorganism are strictly followed in the laboratory for the handling and management of the culture collections, samples, deleterious substance, waste disposal, and environmental facilities. We have achieved satisfactory results during the supervision and inspection of biosafety for microorganism laboratories carried out by local official veterinary authority in Qingdao in October 18th, 2013.

The laboratory staff was regularly trained according to the QMS. The annual training program is set by the Technical Supervisor Dr. Shi and Quality Supervisor Ms. Yang, based on the goals of training and objectives of skill development defined by the Head of the laboratory Dr Huang. The training program in 2013 and 2014 has been considered to focus on the implementation of the QMS documents, understanding of laboratory facility and environment, acquainting of safety requirement and operation standards. The program emphasizes the importance of the QMS rules and how it functions for the accuracy and impartiality. After training, each personal position is evaluated for the qualification and appointed with certification.

4. Proficiency testing and continual improvement

The laboratory has participated three rounds of international and national proficiency testing in 2013. One of these was held by Accreditation Administration of the People's Republic of China (CNCA) for PCR detection of Epizootic Hematopoietic Necrosis Virus (EHNV) (CNCA-13-B05) during 5 to 21, July, 2013 and we got satisfactory result. The other two rounds were Asian Regional Laboratory Testing Program for Aquatic Animal Diseases (PTP)

held by Network of Aquaculture Centers in Asia-Pacific (NACA) since 28 May, 2013, in which we have chosen 6 pathogens for testing, i.e. WSSV, IHNV, YHV, Macrobrachium rosenbergii nodavirus (MrNV), Spring viraemia of carp virus (SVCV), and red sea bream iridovirus (RSIV). We got 35 out of 36 satisfactory results in the first round and full satisfactory results in the second round of NACA PTP. And we are proceeding with the following NACA PTP for continual improvement in 2014. Besides the participation, as an OIE RL for IHNV, we provided 50g valid IHNV-infected tissue as the reference materials to support the NACA PTP before the program starting upon request from the organizer.

For the 35 out of 36 satisfactory results during the first round of NACA PTP, the reasons of variation from the expected result were investigated through a series of in-house meetings. All the sections, including reagents and consumable materials, technical operations, and environment control, were examined to determine the root cause. The top administrator and the Technical Supervisor of the laboratory conducted a final meeting in Oct., 2013, which concluded that the current operation protocols for the 2nd-step of nested PCR and the PCR strips remain risks of cross contamination. Corrective and preventive actions were decided to separate the operations for the first and the second steps during the nested PCR and to replace temporarily the PCR strips with sing tubes. The accomplishment of the 2nd round of NACA PTP with full satisfactory indicated that the actions achieved a success.

5. Diagnostic activities

The laboratory carried out diagnostic tests for 295 samples from 3 countries under the QMS controls for the detection of 6 pathogens of shrimp, including WSSV, IHNV, YHV, TSV, HPV, and IMNV and provided 25 final reports in 2013. Up to now, there is no complaint received from customers or other parties.

Positive results from the diagnostic testing and other testing in the laboratory were quarterly reported to the Veterinary Authority via the Competent Authority in Ministry of Agriculture, People's Republic of China, for subsequently reporting to the OIE, according to the Quarterly Aquatic Animal Disease Report (QAAD) requirements.