



QUALITY MANAGEMENT REVIEW SEMINAR

VIRUS SEROLOGY

by

Louis TONG


Panel Head

27 Sep 2013





Background

- Over 23 years
 - Established in 1990
 - About 12 participants during the earliest stage
 - Collaborated with HKIMLSQAP through the years
 - Accredited in 2010
- 

PTP Providers

- List of current PTP providers in Hong Kong

Name of Proficiency Testing Provider
Government Laboratory
Hong Kong Institute of Medical Laboratory Sciences - Quality Assurance Programme Limited
Hong Kong Red Cross Blood Transfusion Service
Virology Division, Public Health Laboratory Services Branch, Centre for Health Protection, Department of Health
No. of Accredited Proficiency Testing Providers: 4

- PTP002 certificate
- PTP003 certificate

Certificate of Accreditation - PTP003



Hong Kong Accreditation Service
香港認可處

Certificate of Accreditation 認可證書

This is to certify that
特此證明

**HONG KONG INSTITUTE OF MEDICAL LABORATORY SCIENCES -
Quality Assurance Programme Limited**
香港醫務化驗學會品質保證計劃有限公司

Flat 1711, Floor 17, Block C, Bell House, 525-543 Nathan Road, Kowloon, Hong Kong
香港九龍彌敦道525-543號寶寧大廈C座17樓1711室

has been accepted by the HKAS Executive, on the recommendation of the Accreditation Advisory Board, as a
為香港認可處執行機關根據認可諮詢委員會建議而接受的

HOKLAS Accredited Proficiency Testing Provider
「香港實驗所認可計劃」認可能力驗證提供者

This Proficiency Testing Provider meets the requirements of ISO/IEC 17043:2010 "Conformity assessment - General
此能力驗證提供者符合ISO/IEC 17043:2010《合格評定 - 能力驗證的通用規定》所訂的要求，
requirements for proficiency testing" and it has been accredited for providing proficiency testing
獲認可提供載於香港實驗所認可計劃《認可能力驗證提供者名冊》內的指定能力驗證項目
schemes as listed in the HOKLAS Directory of Accredited Proficiency Testing Providers

The common seal of the Hong Kong Accreditation Service is affixed hereto by the authority of the HKAS Executive
香港認可處根據認可處執行機關的權限在此書上通用印章

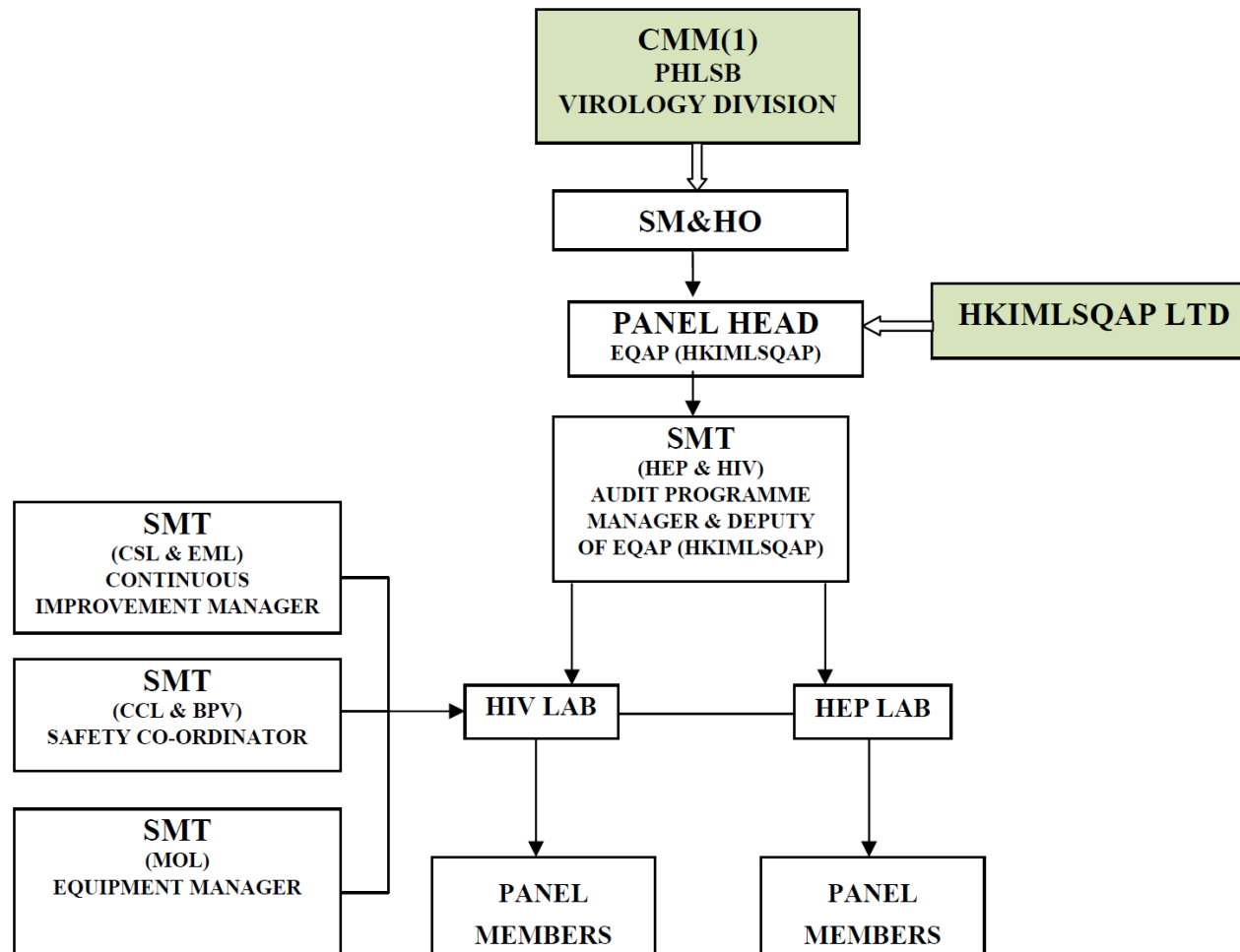
CHAN Sing Sing, Terence, Executive Administrator
執行幹事 陳成城
Issue Date: 26 October 2010
簽發日期：二零一零年十月二十六日

Registration Number: **PTP 003**
註冊號碼：



Date of First Registration: 26 October 2010
首次註冊日期：二零一零年十月二十六日

Organization chart of EQAP (Virus Serology, HKIMLSQAP)





Medical & technical staff involved

- Lab Director
 - Medical officer(s)
 - Panel Head
 - Deputy of panel Head
 - Panel members
 - Managers/Coordinators of
 - Continuous Improvement Programme
 - Audit
 - Equipment &
 - Safety
- 




Panel members

- K.L. TONG
 - M.C. WONG
 - Y.K. HO
 - S.Y. KONG
 - W.W. CHOY
 - W.L. LAU
 - W.C. LEE
- 



Services provided

- ① Objectives
 - ② Time schedule
 - ③ Tests
 - ④ Survey reports
- 

Objective Criteria for Performance Evaluation of Participants (Virus Serology)

Objective Criteria for Performance Evaluation of Virology Serology

In each quarterly survey exercise three sets of five serum/plasma samples will be sent to participating laboratories for testing of HIV antibody, anti-HCV and HBsAg/anti-HBs. Survey data must be returned for statistical analysis before the due dates; otherwise, "Late Return" will be stated in the survey report.

Initial reactive results with a confirmation/referral test will score two; whereas correct initial reactive result without further confirmation/referral test will score one. Retest the initial reactive sample using the same method without neutralisation will not be considered as a confirmatory test.

False negative result is considered as incorrect and will be assigned a score of "-1". False positive result will be either assigned as "0" or "-1" and that will depend on the indication of confirmation/referral testing or not respectively.

Any equivocal (\pm) result without the indication of confirmation or referral testing will score zero. Equivocal result for intended positive specimen with the indication of confirmation or referral testing will score one; whereas equivocal result to be confirmed or referred for the intended negative specimen will score two.


Time Schedule

http://www.hkimls.org/regist.htm HKIMLS Quality Assurance...

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 **香港醫務化驗學會 有限公司** **Hong Kong Institute of Medical Laboratory Sciences Ltd.**
Formerly Hong Kong Medical Technology Association (Founded 1966)

HKIMLSQAP Registration

[Registration form](#)

[Time Schedule for The Year\(2013\)](#) **NEW**

[Time Schedule for The Year\(2012\)](#)

[AFB Smear](#)

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[Haematology & Serology](#)

[Interpretative Quality Assurance Programme in Haematology](#)

[Medical Microbiology](#)

[Neisseria gonorrhoeae Susceptibility Testing](#)

[Joint Quality Assurance Programme in Clinical Microbiology](#)

**Hong Kong Institute of Medical Laboratory Sciences
Quality Assurance Programme Ltd.**

2013 Time Schedule

Task	Survey			
	First	Second	Third	Fourth
Date of Assembly	23.02.13	04.05.13	03.08.13	02.11.13
Survey Material Dispatch	25.02.13	06.05.13	05.08.13	04.11.13
Return of Results for AFB, HS, MM and VS	11.03.13	20.05.13	19.08.13	18.11.13
Return of Results for NGST	11.03.13	-	19.08.13	-
Return of Results for VNAT	-	22.05.13	-	-
Return of Results for AP	13.03.13	22.05.13	21.08.13	20.11.13
On-line Posting of Preliminary Results	18.03.13	27.05.13	26.08.13	25.11.13
Report Dispatch	04.05.13	03.08.13	02.11.13	15.02.14

This is a tentative schedule. HKIMLSQAP reserves the right to change the schedule without prior notice to the participants.

155%

Testing

HIV Serology

Survey materials:

Five serum samples are provided.

Test requested:

Anti-HIV investigation.

Hepatitis Serology

Survey materials:

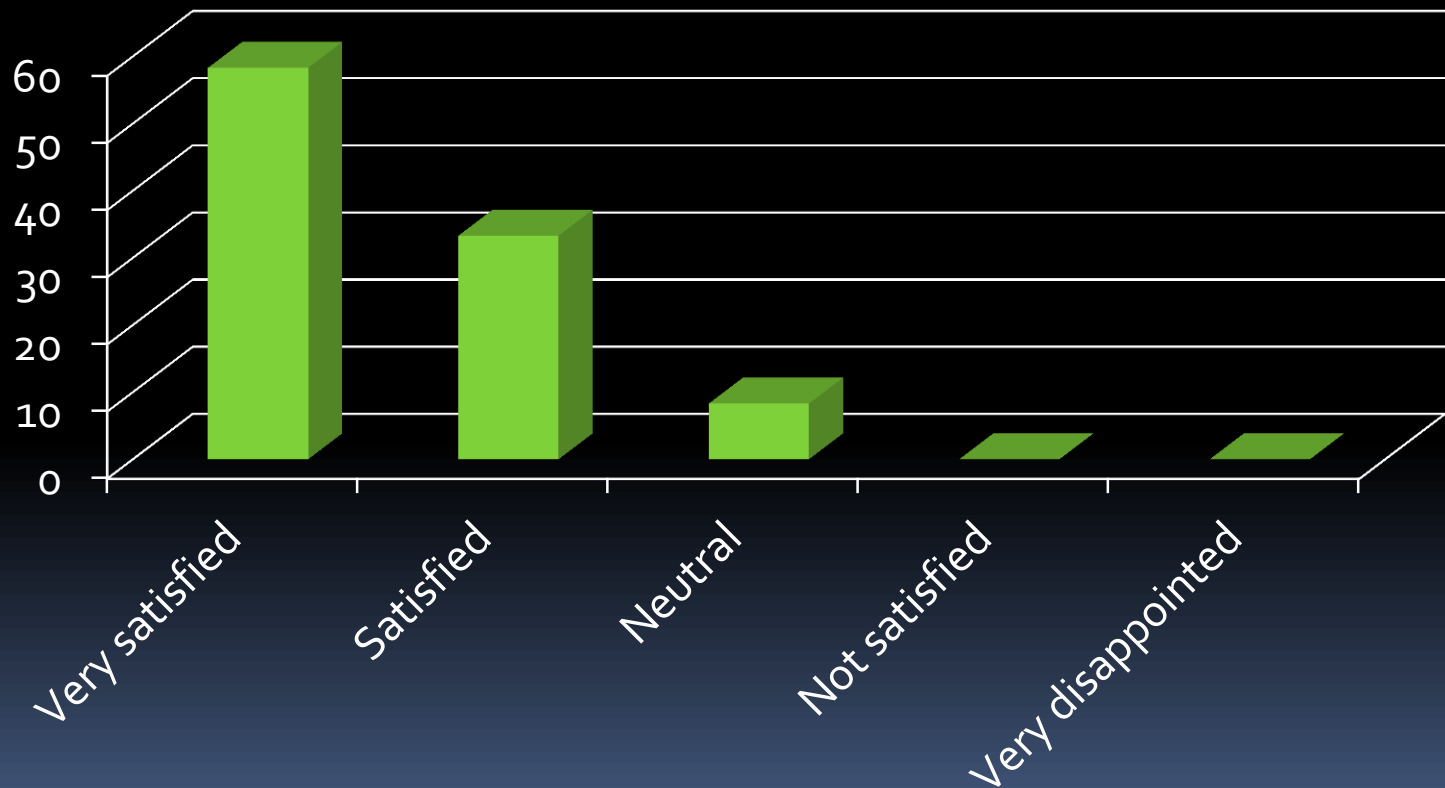
Ten serum samples are provided.

Tests requested:

anti-HCV, HBsAg and/or anti-HBs assessment.

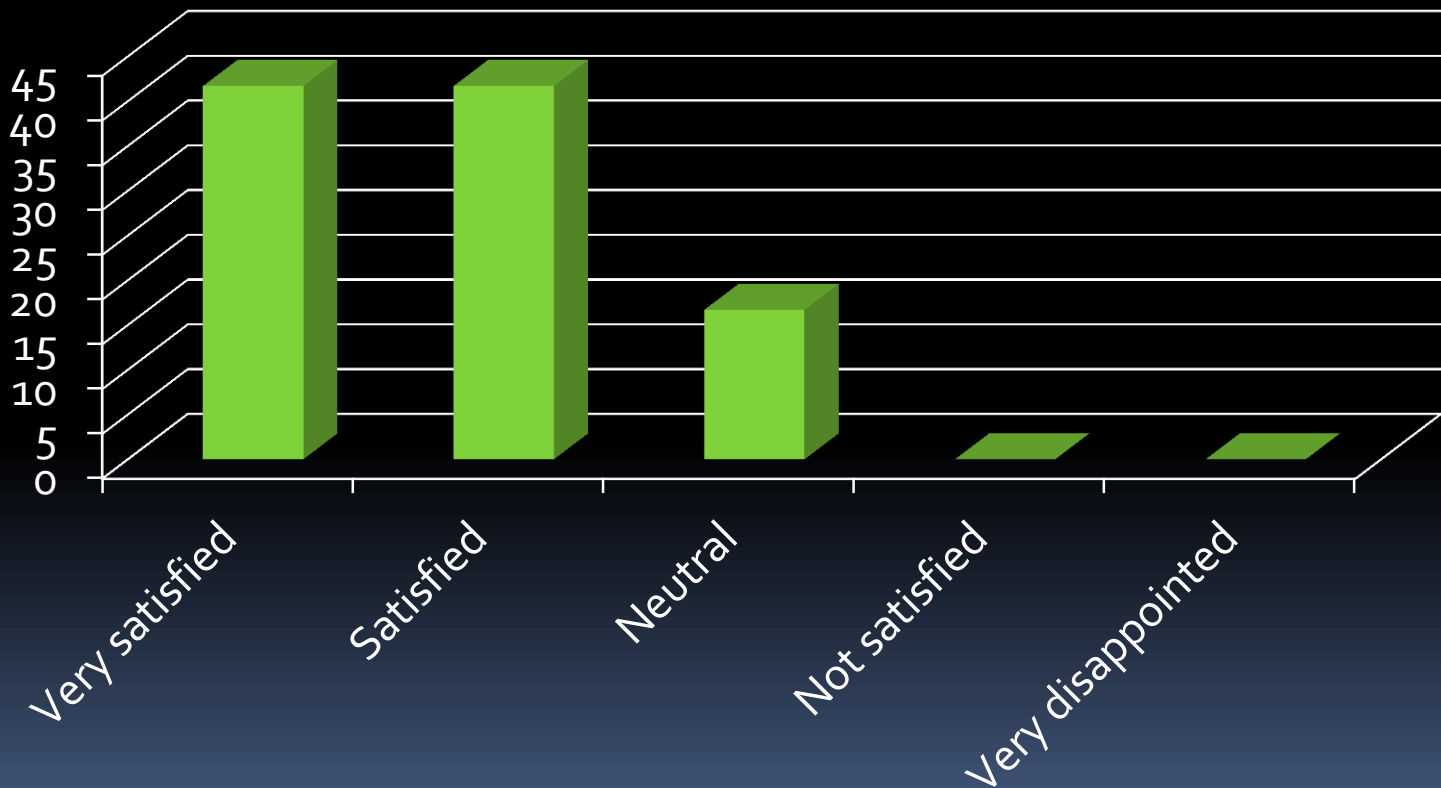
Number of Samples Per Survey

Percent



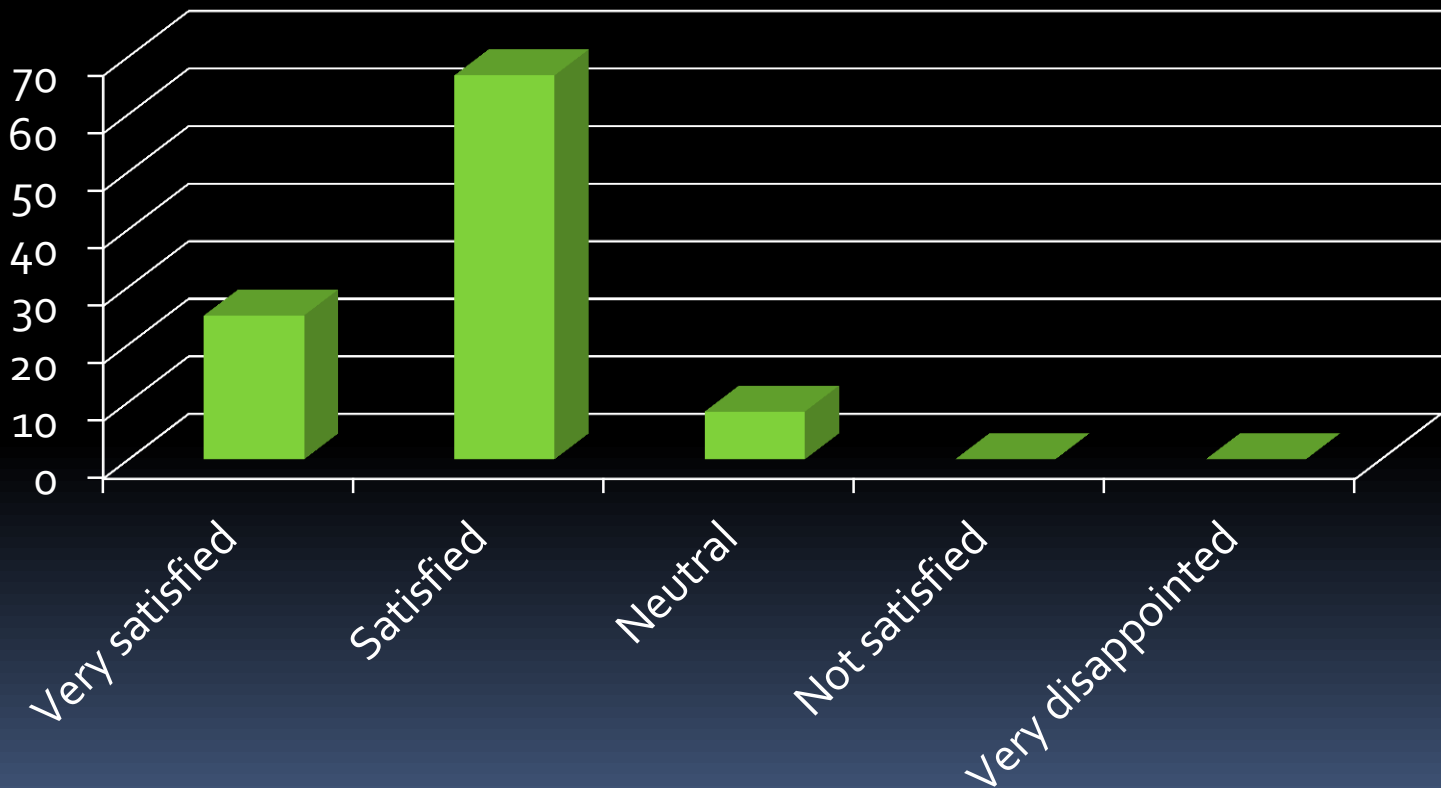
Delivery of Survey Materials

Percent



Adequate Testing Time

Percent




Frequency Per Year

Percent





Survey Reports

- Preliminary report
 - Survey report
 - Annual report
- 

Example of Preliminary Report

HKIMLSQAP for Virus Serology

Second Distribution 2013

Distribution Date: 6 May 2013

Intended Results

Specimen Number	Anti- HIV-1	HBsAg	Anti-HBs	Anti-HCV
VS 1316	Positive			
VS 1317	Positive			
VS 1318	Negative			
VS 1319	Positive			
VS 1320	Positive			
VS 1321		Positive	Negative	
VS 1322		Positive	Negative	
VS 1323		Positive	Negative	
VS 1324		Positive	Negative	
VS 1325		Negative	Positive	
VS 1326				Positive
VS 1327				Weak Positive
VS 1328				Positive
VS 1329				Positive
VS 1330				Negative

Access of Preliminary Report

Percent



Example of Survey Report



Hong Kong Institute of Medical Laboratory Sciences Quality Assurance Programme Limited

In collaboration with

Virology Division
Public Health Laboratory Services Branch
Centre for Health Protection
Department of Health

Virus Serology

Survey Report: Two (2013)

Dispatch Date: 6 May 2013

Date of report: 5 August 2013

Laboratory Code: 029

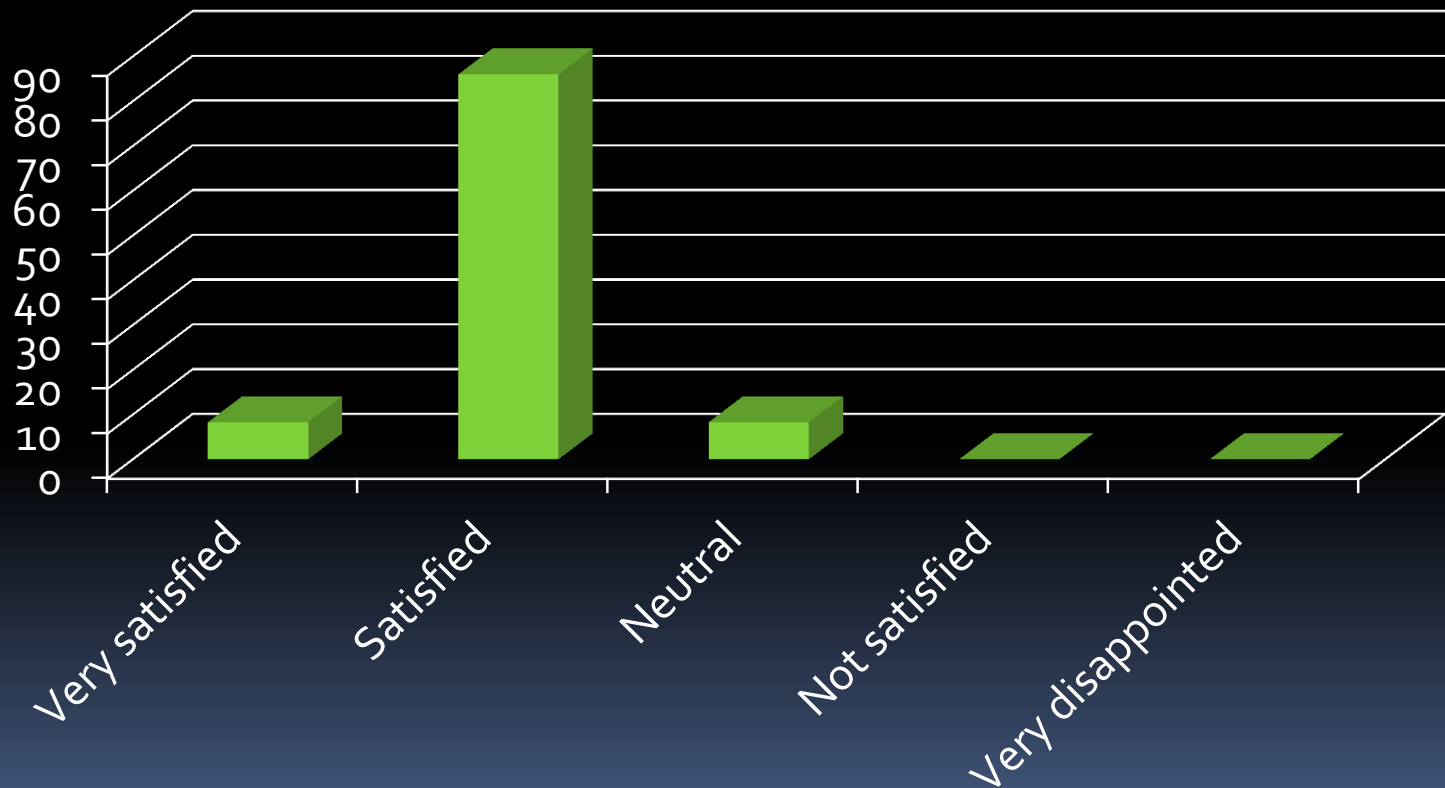
Prepared by: Mr. TONG Kwok-leung, Virus Serology Panel Head

Authorized by: Mr. Albert LI, Chairman of HKIMLSQAP

Hong Kong Accreditation Service has accredited this proficiency testing provider under Hong Kong Laboratory Accreditation Scheme for specific proficiency testing schemes as listed in the HKAS directory of accredited proficiency testing providers. The results shown in this report were determined by this proficiency testing provider in accordance with its terms of accreditation.
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Quality of Survey Report

Percent



Annual Report

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What's New

- > On-line submission of Haematology and Serology survey data
- > In addition to Virus Serology, *Neisseria gonorrhoeae* Susceptibility Testing is now HKAS-accredited.
- > HKIMLSQAP Announcement
- > HKAS Certification

[2008](#)[2009](#)[2010](#)[2011](#)[2012](#)

to HKIMLSQAP

Programmes at a nominal cost

A consortium of enthusiastic and energetic medical laboratory professionals assembled in 1988 to study the feasibility of establishing a quality assurance programme to promote the high standard of medical laboratory techniques, ensure comparability of analytical methodologies and solve technical problems among medical laboratories.

Kong. Upon completion of the research for nearly two years, HKIMLSQAP (HKMTAQAP) was launched as the first ever run indigenous programme in Hong Kong in February 1990.

<http://hkimlsqap.org/index.aspx>

Annual Report 2012



Hong Kong Institute of Medical Laboratory
Quality Assurance Programme Ltd.

香港醫務化驗學會品質保證計劃

HKIMLSQAP 2012 Annual Report

Specialty Report

Virus Serology

V. Unexpected issues observed in 2012

Non-conformities encountered commonly in the returned results are categorized in Table 17.

Table 17. Unexpected issues observed in the surveys in 2012

Category	Observation	Involved test/assay
Incorrect result (n = 5)	In Survey One, a participant (048) indicated a false positive anti-HBs result for VS1208.	Roche Anti-HBs
	In Survey Four, two participants (236 & 898) obtained false reactive HBsAg results for VS1251 (Lab 236 reported an overall negative result after confirmation).	Abbott Architect HBsAg- Qualitative II

http://hkimlsqap.org/information/AR/q2012/q2012cont.htm HKIMLSQAP Ltd. - 2012 A...

檔案(F) 編輯(E) 檢視(V) 我的最愛(A) 工具(T) 說明(H)

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HKIMLS QAP Hong Kong Institute of Medical Laboratory Sciences Quality Assurance Programme Ltd. 香港醫務化驗學會品質保證計劃有限公司

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Specialty Report

Virus Serology

VI. Recommendations

The improvement areas noted in the four survey exercises of 2012 can be categorized into five different entities namely, incorrect result, outlier of sample result, sensitivity of assay, use of expired assay for testing and transcription error.


Quality assurance of clinical testing is important to ensure the accuracy and precision of test results. Errors in clinical tests may lead to spurious diagnosis, delayed treatment or increased costs associated with re-testing. In order to minimize errors, every step from pre-analytical to post-analytical procedures should be handled prudently. Laboratory automation, training of laboratory personnel and adoption of quality control programmes are main factors that govern the quality assurance of a clinical laboratory. For quality measures, analyzers should be calibrated according to the instruction given by the suppliers. Expired assays should not

179% Collaborate Sign Find

140%

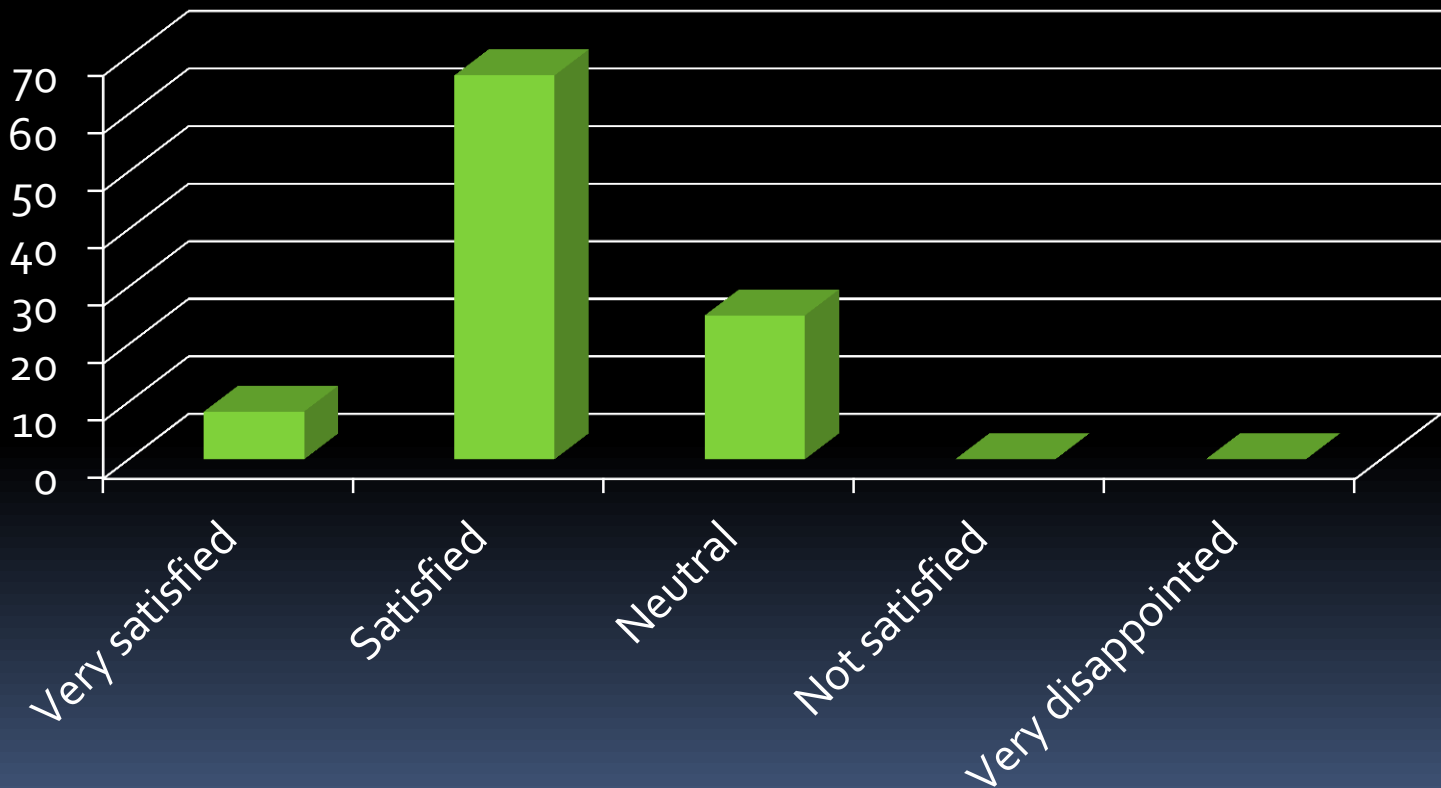


Common findings in 2012

- Incorrect results (n=5)
 - Outlier of samples (n=4)
 - Sensitivity of assay (n=4)
 - Use of expired assay (n=2)
 - Transcription error (n=3)
- 

Inter-laboratory comparison & Education Value

Percent




Participating Laboratories

(2012)

Participants (n = 42)	Local	Overseas	Percent
Government Laboratory	1	1	5.4
Public Hospital Laboratories	6	-	16.2
Private Laboratories	19	-	51.4
Private Hospital Laboratories	8	1	24.3
Other	1	-	2.7

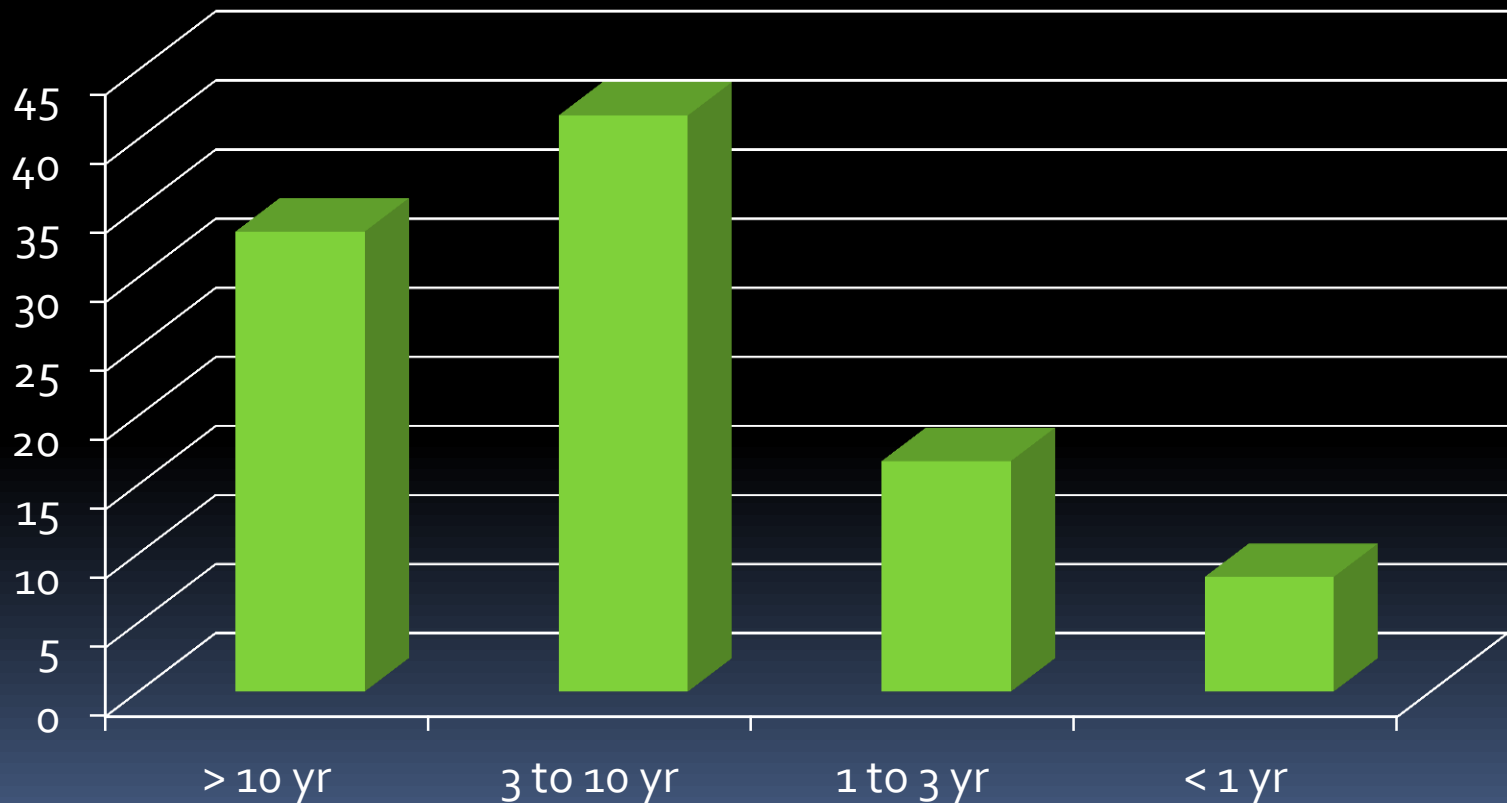


Confidentiality

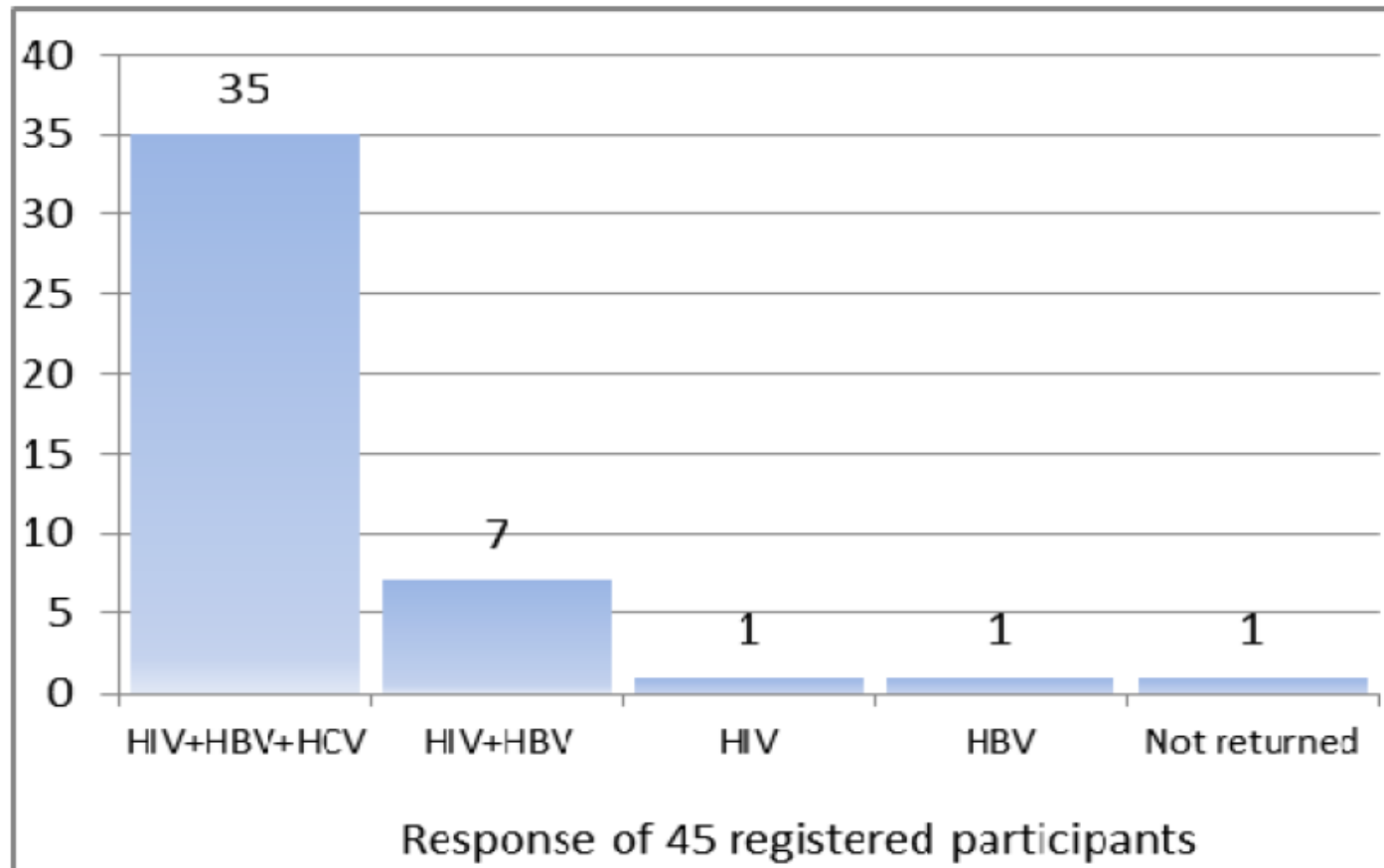
- Each participant is assigned with a laboratory code.
 - an identity for communication between the participant and HKIMLSQAP.
 - The key to decipher the identities of participants is limited to few authorized members of HKIMLSQAP Council.
 - HKIMLSQAP Council Members are forbidden to release any data to any outsiders.
 - All information on participant performance shall not be disclosed to any third party unless prior agreement with the concerned participants has been obtained or applicable laws or regulations stipulate such disclosure.
- 

Length of Joining period

Percent



Response in Survey 2 (2013)



Performance of Participants

in Survey 2 (2013)

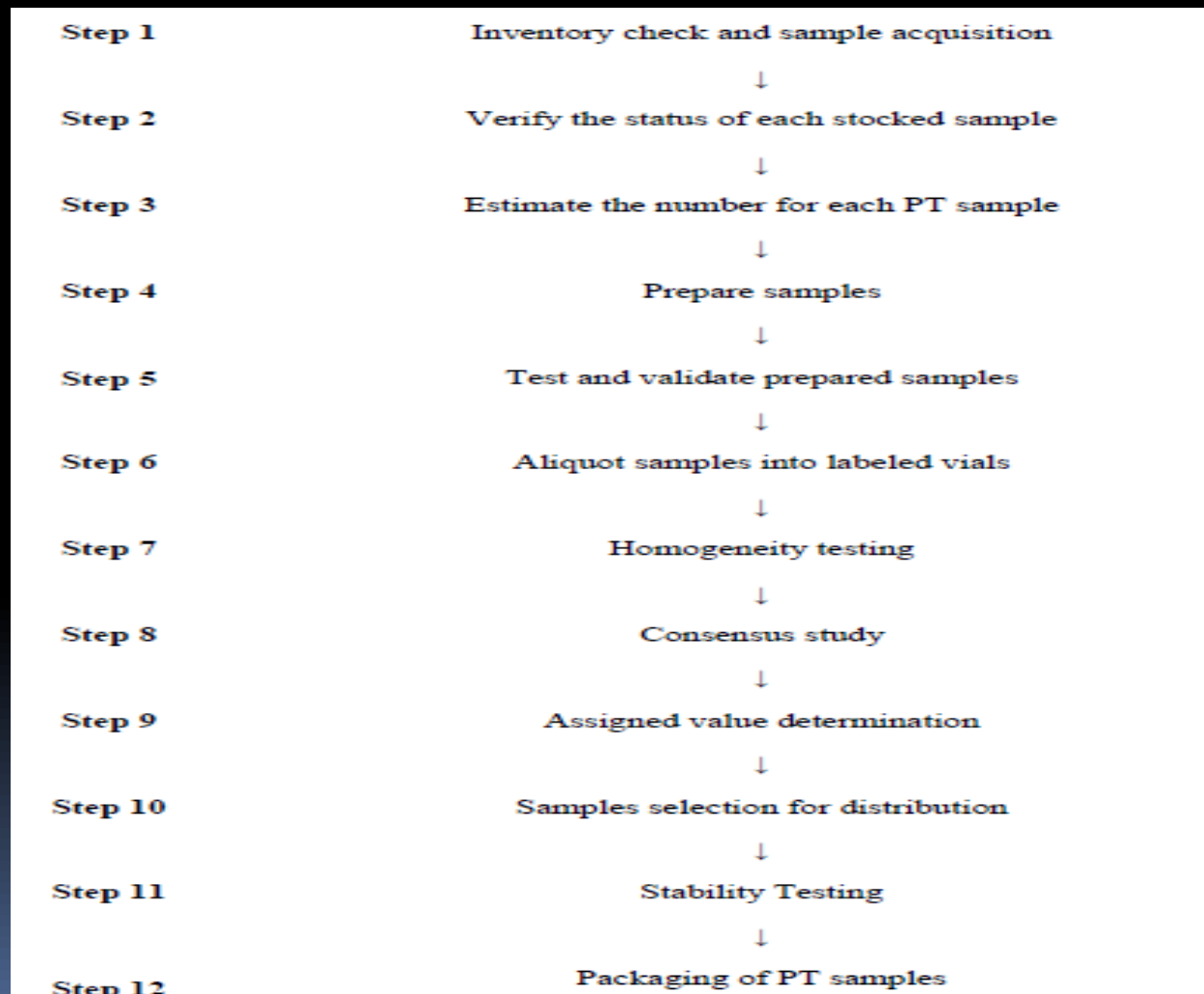
The response rates of this survey for anti-HIV, HBsAg and anti-HCV were 97.7% (43/44), 97.7% (43/44) and 97.2% (35/36) respectively. The percentage of correctly reported results for anti-HIV, HBsAg and anti-HCV testing were 100% (215/215), 100% (215/215) and 99.3% (139/140) respectively.



Quality of Technical Services




Flowchart for preparing PT items





Quality of PT Samples

- Sample preparation
 - Sample Testing
 - Validation
 - Homogeneity
 - Stability
 - Pre-distribution testing
 - Post-distribution testing
 - Consensus study
 - Assign values for PTP samples
 - Storage & transportation
- 



Homogeneity

Homogeneity Testing

The assessment of homogeneity shall normally be performed after the proficiency test items have been packaged in the final form and before distribution to participants.

Number of required samples

Methods to be used for random selection of samples

Calculations and result analysis

Stability Testing

Stability Testing

Requirement

- (1) The proficiency test (PT) items remain stable through the proficiency testing. They shall be demonstrated to be sufficiently stable to ensure that they will not undergo any significant change through the conduct of the proficiency testing, including storage and transport conditions.
- (2) Testing is needed to confirm stability of the proficiency test items before each dispatch (i.e. pre-distribution testing).
- (3) Stability testing is performed on a set of sample which is used to monitor the stability of samples after transportation and delivered to our laboratory by the courier (i.e. post-distribution).

Consensus Study

Consensus value from expert participants

- (1) Expert participants are selected according to the following criteria:
 - History of satisfactory performance for the previous surveys of the QAP
 - Availability of specific assay(s)
- (2) The number of expert participants selected is $\geq 10\%$ of the total participants of the external quality assurance programme, e.g. at least 4 participants will be selected for a total of 40 participants.
- (3) The assigned value for each sample is $\geq 90\%$ concordance, i.e. concordant results should be obtained from 90% or more of expert participants for a consensus study.

Communications

- Confidentiality
- Direct communicate with Director of HKIMLSQAP LTD.
- Updated information on the website
- Customer satisfaction survey


Complaint Resolution

Percent






Customers Feedback

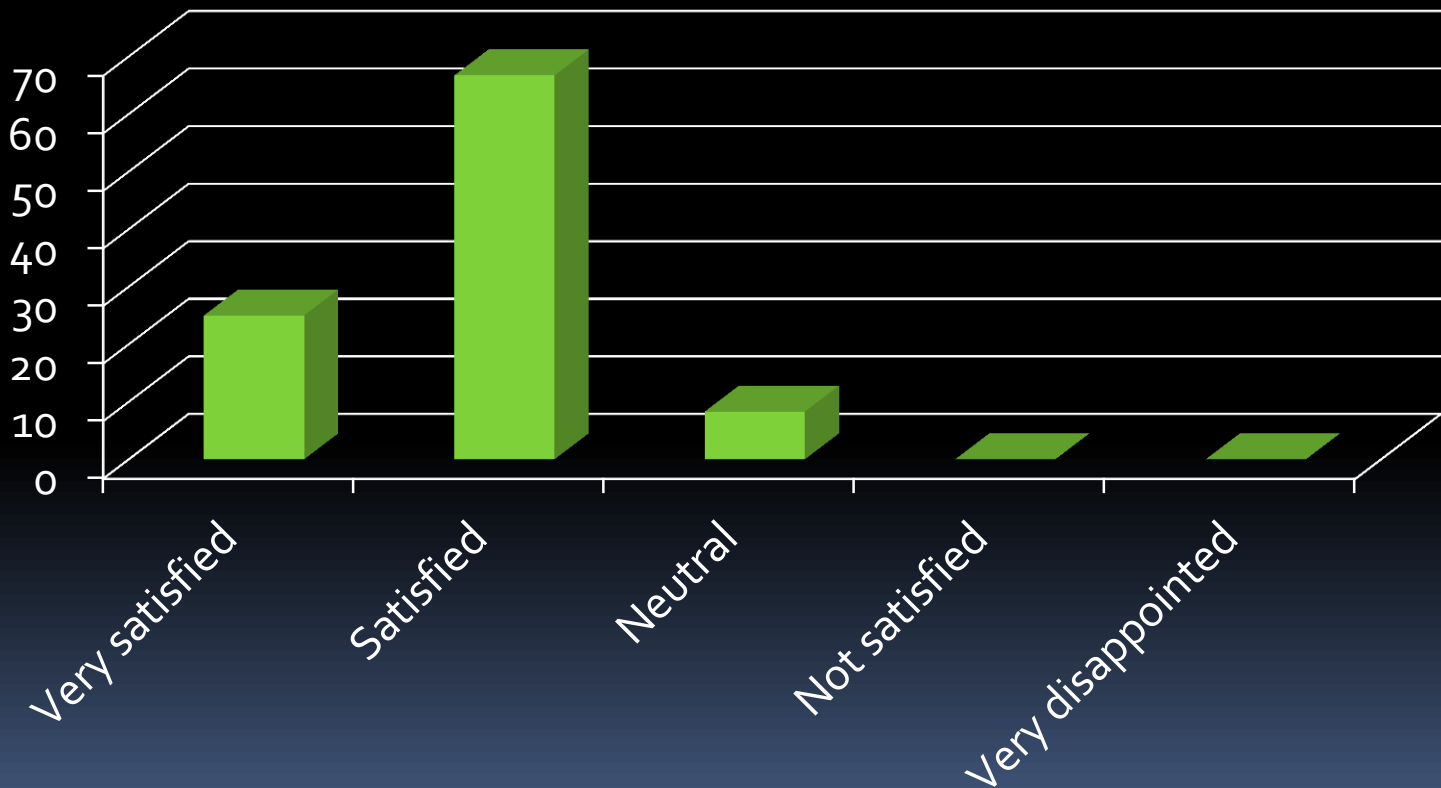


Characteristics of the VS programme (Survey Questions)

- 11 items were included:
 - Quality of service provided
 - Service is competitively priced
 - Number of survey materials per exercise
 - Frequency per year
 - Delivery and arrangement of survey materials
 - Adequate testing time
 - Mode of result submission
 - Access on-line preliminary results
 - Quality of survey report
 - Inter-laboratory comparison and education value
 - Complaint resolution
- 

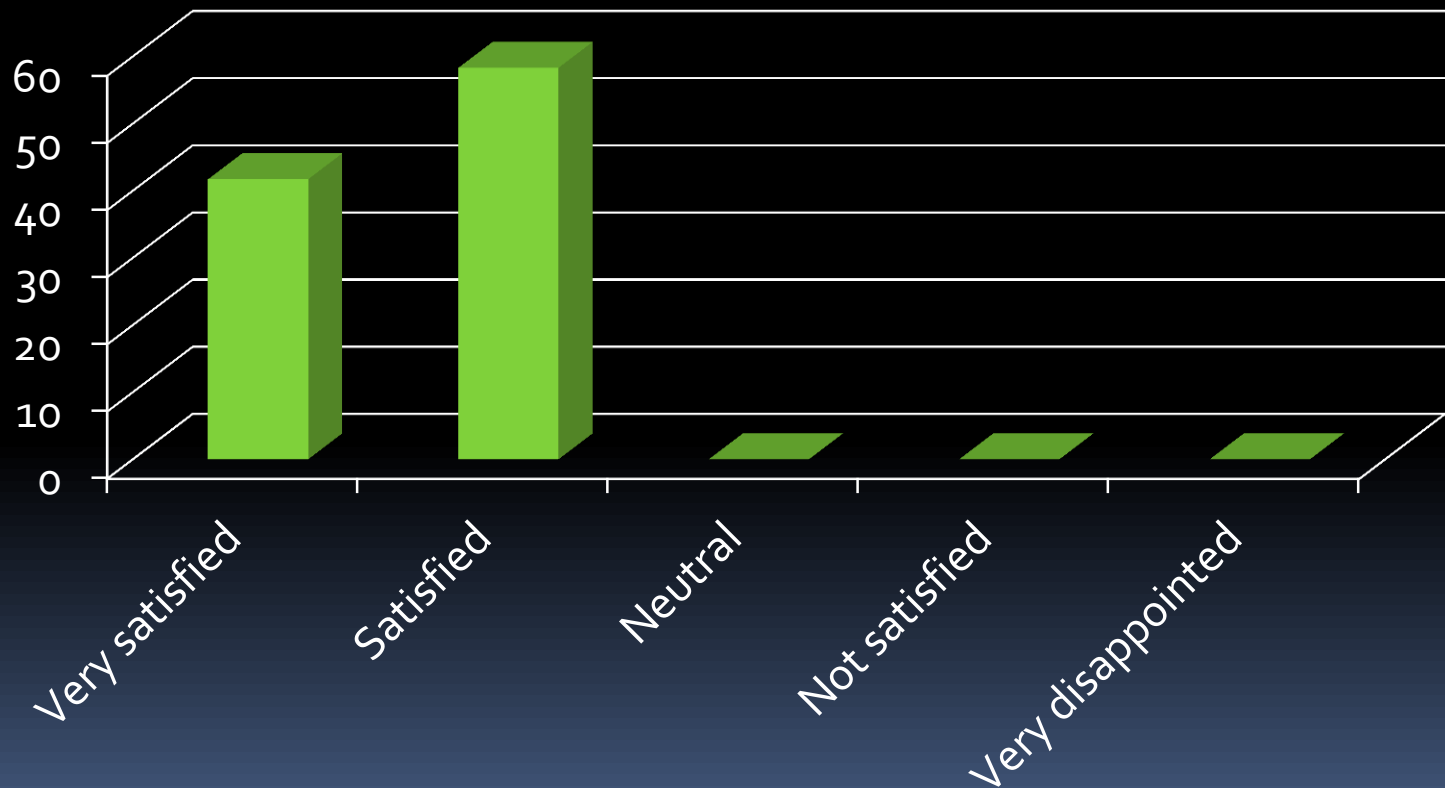
Overall Satisfaction Rate

Percent



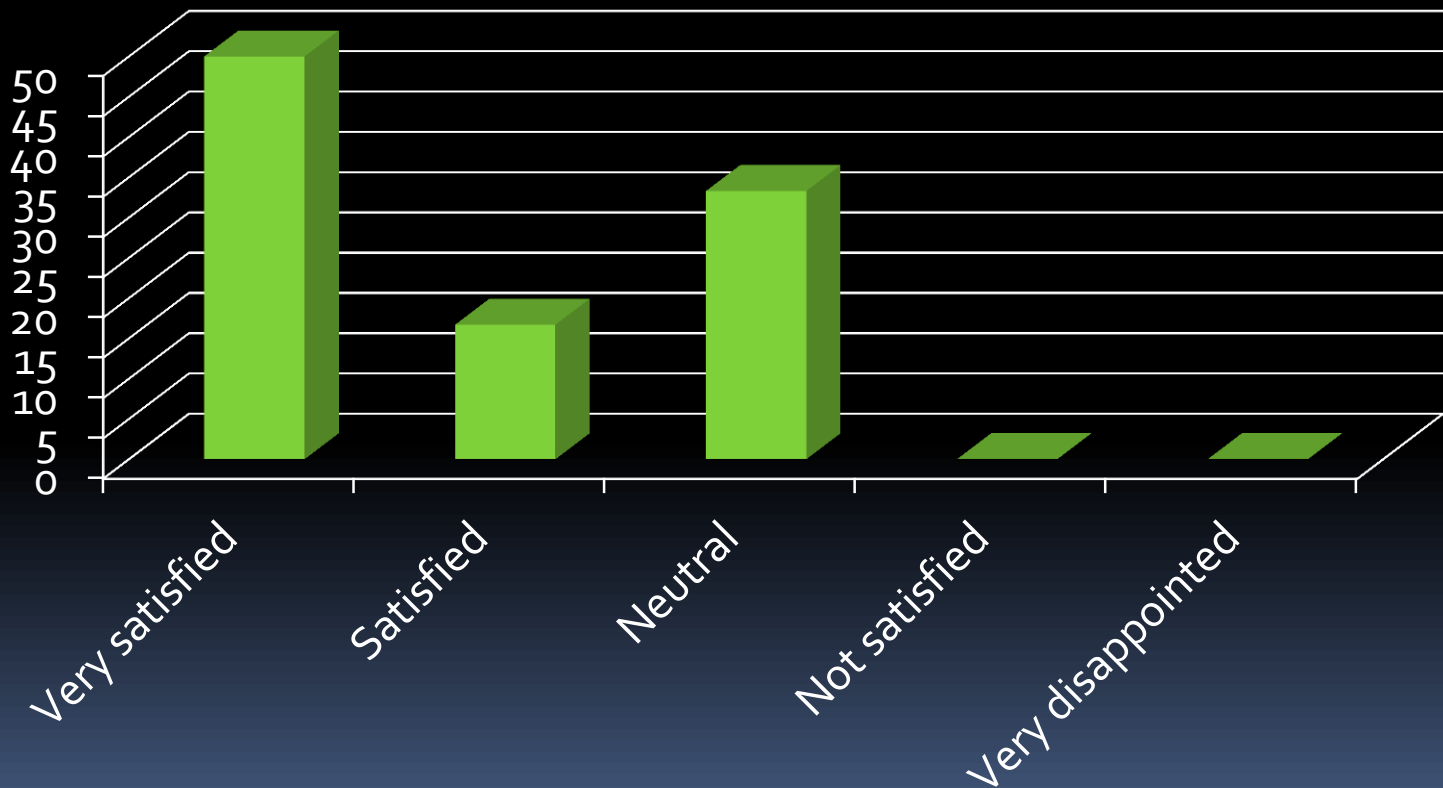
Quality of Service Provided

Percent



Money Worth Services

Percent




Mode of Result Submission

Percent






Rooms for Improvement

- On-line programme registration
 - Color printed report
 - Release survey report within a month
 - Acknowledgement of results received
 - Report by email to reduce reporting time
 - Reduce frequency of survey per year
 - Web based submission of results
- 



Conclusive Notes

- Seek for excellence
 - Continuous improve quality of services
 - Rely on your continuous feedback, participation & supports, etc.
- 



Thank You