



Content

- Development of the medical programme
- Local situation and requirements
- Features of the medical programme
- Progress of the medical programme



The medical programme

- First launched on 16 February 2004
- **Before 2004**, no accreditation programme for medical laboratories, big laboratories sought overseas accreditation such as NATA or CAP
- **ISO 15189** *Particular requirements for quality and competence of Medical Laboratories*— accreditation criteria for medical laboratories first published in Dec 2003
- HKAS's programme - Voluntary
- Accreditation service **only** for **local** medical laboratories

Scope of Accreditation

Discipline	Test areas	Discipline	Test areas
Anatomical pathology 病理解剖學	<ul style="list-style-type: none"> * Autopsy * Histology * Cytology 	Haematology 血液學	<ul style="list-style-type: none"> * Complete blood picture * Coagulation * Special haematology * Blood banking
Chemical pathology 化學病理學	<ul style="list-style-type: none"> * General chemistry * Lipid profiles * Hormones * Enzymes * Drug of abuse testing * Therapeutic drug monitoring * Special chemistry * Tumour markers 	Microbiology 微生物學	<ul style="list-style-type: none"> * Bacteriology * Virology culture serology * Mycology * Parasitology
Immunology 免疫學	<ul style="list-style-type: none"> * Immunochemistry * Autoantibody detection * Immune cell function and enumeration 	Medical genetics 醫學遺傳學	<ul style="list-style-type: none"> * Molecular genetics * Cytogenetics

What are the regulatory requirements for operating a medical laboratory in Hong Kong?

- No regulatory requirement on the operation of a medical laboratory
- Requires **business registration** and be a legal entity
- Regulates the personnel working in a medical laboratory under the **Supplementary Medical Professions Ordinance** – (SMPO)
- Accreditation is voluntary

SMPO (CAP 359)

- Starting from early 1990s, **all medical laboratory technologists** have to be **registered** with the Medical Laboratory Technologists Board (MLT Board) under Department of Health
- Medical technologists are registered under three parts
- **Only Part I** registered medical technologists may **work independently** in a medical laboratory
- **Parts II and III** have to **work under supervision**
- There must be a Part I registered medical technologist on the Board of Directors of a medical laboratory

ISO15189:2012

Medical Laboratories - Requirements for quality and competence



HOKLAS Policies laid down
local requirements for personnel

Categories of accredited laboratories

- Categorised into “P” and “S” laboratories according to the whether the **Laboratory Director** is a **P**athologist or a **S**cientist
- Both accredited to the **same ISO standard “ISO 15189”** – meet all management and technical requirements of ISO 15189



Sample scope to show pathologists indication

LABORATORY
DIRECTOR

PATHOLOGIST IN
CHARGE OF THE
ACCREDITED
DISCIPLINE

		Registration Number: 833P Page 1 of 17 9 March 2011 Ref: 833P-01	
No. 833P		Department of Pathology, Kwong Wah Hospital, Hospital Authority 醫院管理局廣華醫院病理部	
ADDRESS 地址		Yu Chun Keung Memorial Medical Centre, Kwong Wah Hospital, 25 Waterloo Road, Kowloon, Hong Kong 香港九龍彌敦道25號, 廣華醫院余振強紀念醫療中心	
		(i) Anatomical Pathology Laboratory, 2/F and 8/F, Yu Chun Keung Memorial Medical Centre (ii) Core Chemical Pathology & Haematology Laboratory, 5/F, Yu Chun Keung Memorial Medical Centre (iii) Special Chemical Pathology & Haematology Laboratory, 6/F, Yu Chun Keung Memorial Medical Centre (iv) Microbiology Laboratory, 7/F, Yu Chun Keung Memorial Medical Centre (v) Mycobacteriology Laboratory, 9/F, Yu Chun Keung Memorial Medical Centre	
LABORATORY DIRECTOR 化驗所主管		Pathologist Director 病理學主管: Dr. Hui Pak Kwan 許伯鈞醫生 MBBS, FRCPath, FHKCPath, FHKAM (Pathology)	
AUTHORISED REPRESENTATIVE 委任代表		Mr. Chan Kin Ping 陳建平先生	
ENQUIRY 查詢		: Mr. Chan Kin Ping 陳建平先生 Tel. 35172466 Fax 23854514 E-mail chankp@ha.org.hk	
CLIENTELE 服務對象		: Public and private hospitals and clinics 公營及私營醫院和診所	
PATHOLOGIST IN CHARGE OF THE ACCREDITED DISCIPLINE 負責認可範疇的病理學專科醫生		Anatomical Pathology 解剖病理學 (Full-time 全職) Dr. Mak Kong Ling Clinical Microbiology and Infection 臨床微生物學及傳染病 (Full-time 全職) Dr. Tse Wing Sze Cindy	
SCOPE OF ACCREDITATION 認可範圍:			
Accredited Test Category 認可試驗類別	Medical Testing 醫學測試		
Accredited Discipline 認可範疇	Anatomical Pathology Chemical Pathology Clinical Microbiology and Infection Haematology Medical Genetics	解剖病理學 化學病理學 臨床微生物學及傳染病 血液學 醫學遺傳學	



Approved Signatories

Specified tests requiring clinical input from qualified pathologists are listed in respective supplementary criteria of the discipline – **only qualified pathologists in the relevant pathology discipline can be signatories** of these tests



Assessment Frequency Monitoring Plans

Three types of monitoring plans

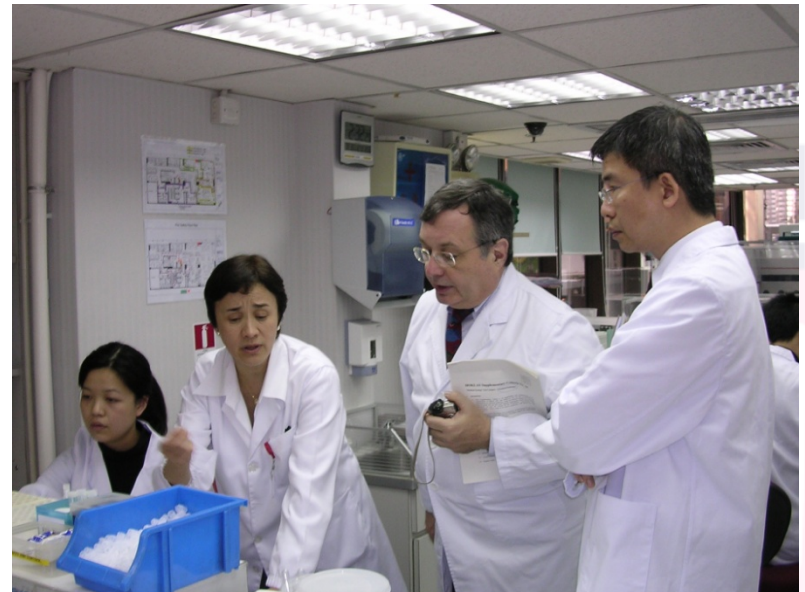
- **Plan A** – reassessment every 2 years; surveillance every 12 m
- **Plan B** – reassessment every 3 years; surveillance every 12 m
- **Plan C** – reassessment every 4 years; surveillance every 16 m

Prerequisite for application

- No. of significant system NC;
- Percentage of activities having no significant NCs;
- Staff turnover rate;
- Proficiency testing performance

Assessment team

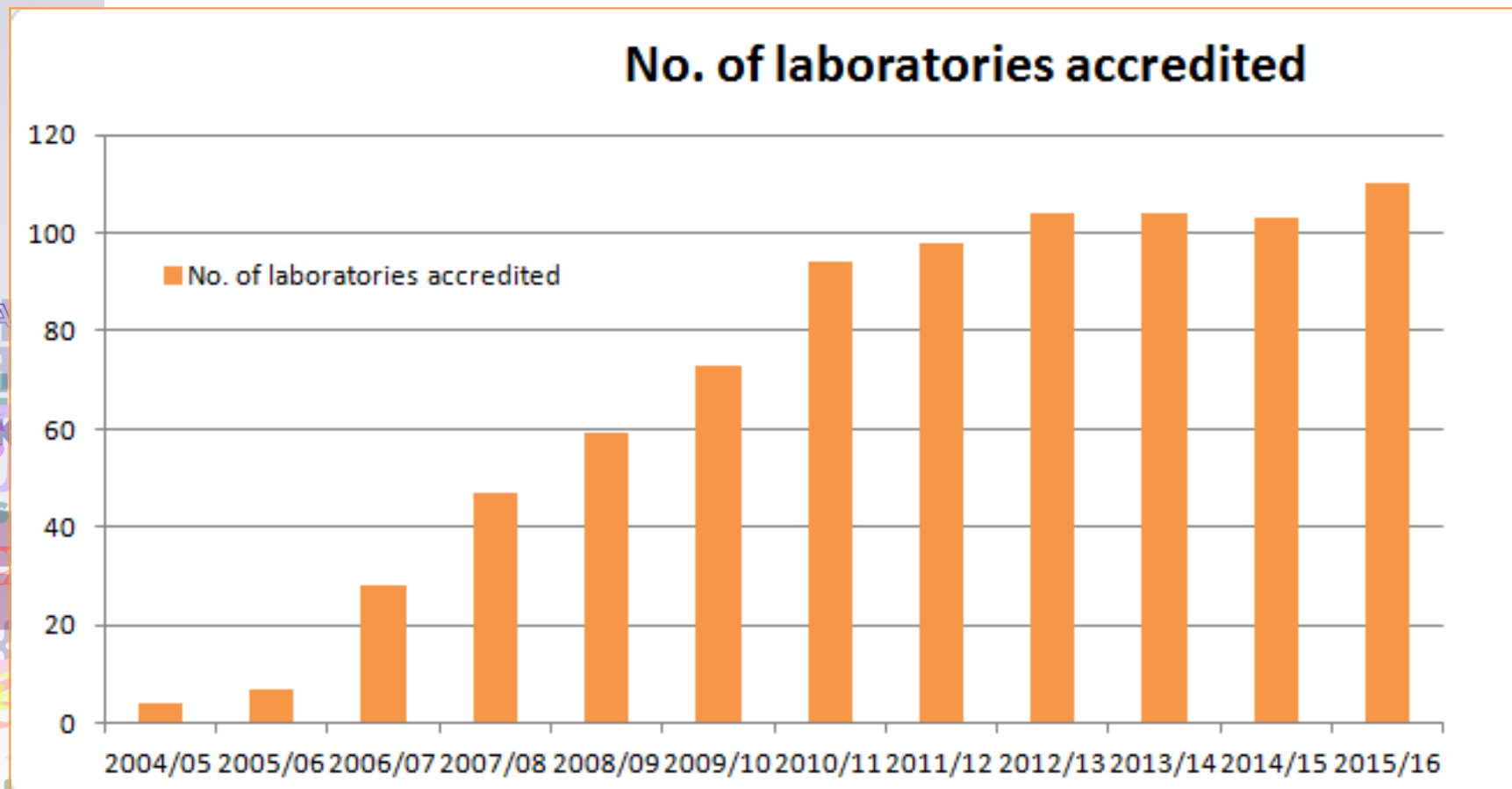
- HKAS officer – management system
- Technical assessors – one pathologist and one scientist for each discipline
- 2 days/discipline



Recruitment of assessors

- Fellows of Hong Kong College of Pathologists
- Experienced scientific officers and medical technologists
- Up till Sep 2016, **72 pathologists and 80 scientists/technologists are appointed** as technical assessors for medical testing

Total number of medical laboratories accredited since 2004



Progress of the medical programme

Nature of Institute	Approx. No. of organisations	Already accredited
Pathology departments under Hospital Authority (including Red Cross)	19 Hospitals	<div>HOKLAS 17</div> <div>NATA 2</div> <div>CAP 1 *</div>
Laboratories under Dept of Health	5 Divisions/Services	HOKLAS 5
Private hospitals	12 Hospitals**	<div>NATA 1</div> <div>HOKLAS 4</div>
Commercial laboratories from yellow pages	> 150 medical laboratories (including collection centres and X-ray laboratories)	<div>HOKLAS 16</div> <div>(include 22 laboratories and 29 collection centres)</div>
Commercial laboratories that annual provide returns to DH	40	HOKLAS 16

* One hospital got both CAP and HOKLAS

** including one private hospital soon to provide service; one stopped service from 2012

No. 808P

Department of Pathology, Alice Ho Miu Ling Nethersole Hospital (AHNH), Hospital Authority

醫院管理局，雅麗氏何妙齡那打素醫院，病理部

ADDRESS 地址

Main facility:

1/F Block C, 11, Chuen On Road, Tai Po, New Territories, Hong Kong

香港新界大埔全安路11號C座一樓

- (i) Anatomical Pathology Laboratory
- (ii) Chemical Pathology Laboratory
- (iii) Clinical Microbiology and Infection Laboratory
- (iv) Haematology Laboratory and Blood Bank
- (v) Emergency Laboratory

Branch facility:

2/F, North District Hospital, 9 Po Kin Road, Sheung Shui

香港新界上水保健路九號北區醫院二樓

- (i) Anatomical Pathology Laboratory

LABORATORY

DIRECTOR

化驗所主管

: Pathologist Director 病理學主管:

Dr. SUEN Wang Ming, Michael

孫宏明醫生

MBChB BAO(NUT), MSc, FRCPath, MIAC, FHKAM (Path), FHKCPath

AUTHORISED

REPRESENTATIVE

委任代表

: Ms. CHEUNG Mo Fong, Candy

張慕芳女士

ENQUIRY

查詢

: Ms. CHEUNG Mo Fong, Candy

張慕芳女士

Tel. 電話 : 2689 2654

Fax. 傳真 : 2664 1515

E-mail 電郵 : cheungmfc@ha.org.hk

CLIENTELE

服務對象

: Public hospitals

公營醫院

PATHOLOGIST IN

CHARGE OF THE

ACCREDITED

DISCIPLINE

負責認可範疇的病理學

專科醫生

: Anatomical Pathology 解剖病理學

Dr. SUEN Wang Ming, Michael 孫宏明醫生 (Full-time 全職)

Clinical Microbiology and Infection 臨床微生物學及傳染病

Dr. CHOW Chi Ying 周芷瑩醫生 (Consulting 諮詢)

Chemical Pathology 化學病理學

Dr. CHAN Ho Ming, Michael 陳浩明醫生 (Consulting 諮詢)

Haematology 血液學

Dr. LEUNG Fung Shan, Kate 梁鳳珊醫生 (Consulting 諮詢)

SCOPE OF ACCREDITATION 認可範圍:

Accredited Discipline

認可範疇

Anatomical Pathology

解剖病理學

Chemical Pathology

化學病理學

Clinical Microbiology and Infection

臨床微生物學及傳染病

Haematology

血液學

Medical Genetics

醫學遺傳學

Number and addresses of laboratories accredited under this registration number

Collection centres covered under this accreditation will also be listed

The laboratory where
the test is performed

Registration Number 808P
Page 10 of 31
5 February 2010
Ref: 808P-11

Department of Pathology, Alice Ho Miu Ling Nethersole Hospital (AHNH), Hospital Authority

醫院管理局，雅麗氏何妙齡那打素醫院，病理部

Chemical Pathology Laboratory: 1/F Block C, 11 Chuen On Road, Tai Po, New Territories, HK.
香港新界大埔全安路十一號, C 座一樓

DISCIPLINE 專科範疇	TEST AREA OR SAMPLE TYPE 測試範圍或樣本種類	SPECIFIC EXAMINATIONS OR PROPERTIES MEASURED 特定測試或量度的特性	METHOD OR TECHNIQUE USED 方法或應用技術
This laboratory is accredited for performing examinations and for providing clinical interpretation of examinations listed below.			
Chemical Pathology	General chemistry Plasma, Body fluid	Alanine transaminase (ALT) by Spectrophotometry Albumin by Spectrophotometry	Cobas 6000 ALT Assay Cobas 6000 Albumin Assay

Changes in the medical testing field after introduction of medical accreditation programme

- **More educational opportunities:** No. of medical technologists eligible to be Laboratory Directors increased
- **More reference resources:** As more laboratories become accredited, more technical criteria documents are available for reference
- **More platforms for information exchanges:** Seminars for exchanges are being organised by HKAS

How are the accredited medical testing laboratories doing?

Performance comparison of 27 laboratories in their initial assessment and in second reassessment

Initial Assessment			Second Reassessment		
Grading	Number	NC per lab	Grading	Number	NC per lab
S	76	3.2	S	18	0.7
M	295	10.4	M	151	5.9
R	371	13.5	R	169	6.6

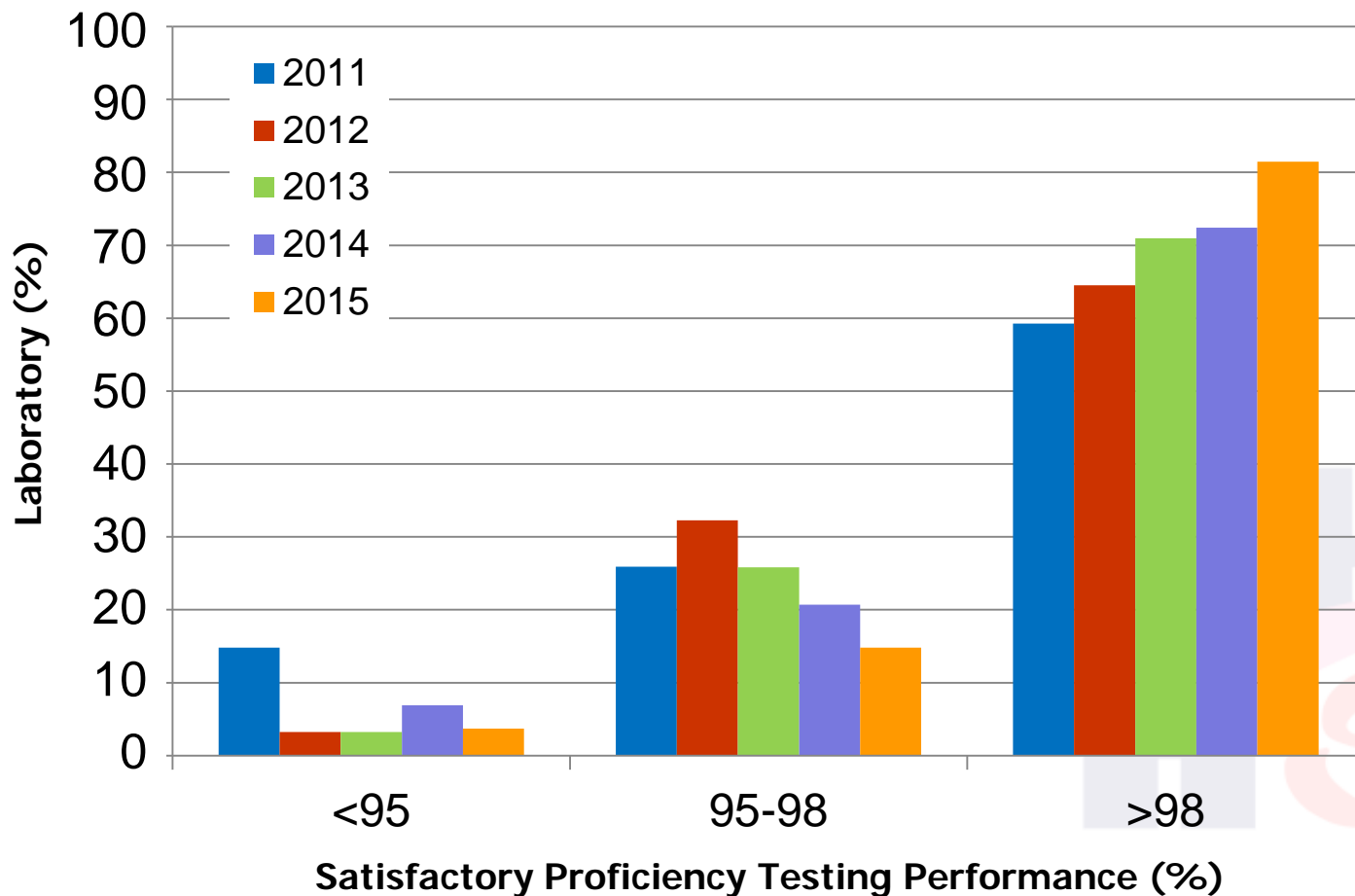
S: significant

M: minor

R: recommendation

Bella Ho, Eric Ho. The most common nonconformities encountered during the assessments of medical laboratories in Hong Kong using ISO 15189 as accreditation criteria. *Biochemia Medica* 2012;22(2):247-57.

How are the accredited medical testing laboratories doing?





Thank you!

