

## **Explanatory notes on the Scope of Accreditation**

The Scope of Accreditation of a laboratory is the list of tests for which the laboratory has been assessed and accredited by HOKLAS. A laboratory may seek HOKLAS accreditation for all or part of its activities. The Scope of Accreditation of each laboratory is published in the “HOKLAS Directory of Accredited Laboratories” and is also posted on the HKAS website [www.info.gov.hk/itc/hkas](http://www.info.gov.hk/itc/hkas). A laboratory can only issue HOKLAS endorsed report with the HKAS accreditation mark on it for tests accredited by HOKLAS. A HOKLAS endorsed report shall be signed by a HOKLAS approved signatory of the issuing laboratory.

For medical testing, a laboratory may be accredited for testing-only services and/or tests that require clinical interpretation by pathologists under all circumstances regardless of the test results. Where clinical interpretation is required for a particular test, this will be stated in the scope. A laboratory, however, will only be accredited for a test requiring clinical interpretation if a qualified pathologist is available to provide such service. Tests requiring clinical interpretation are defined in the supplementary criteria of different disciplines.

For medical laboratories under the supervision of full-time pathologists, the pathologist’s name and his specialty will be specified in the laboratory’s scope. Similarly, names and specialties of consulting pathologists are also shown in the scope. Samples of Scope of Accreditation for laboratories under the supervision of full-time pathologists and those not under such supervision are provided in [Annex 1](#) and [Annex 2](#) respectively.

When accreditation is granted to a laboratory, the head of HKAS Executive will send a notification letter to the laboratory to inform it of the terms of accreditation, which will include the Scope of Accreditation and the names of approved signatories. HKAS Executive will further issue a certificate of accreditation to the laboratory. The certificate of accreditation shall include name of the scheme under which the accreditation is granted (i.e. the Hong Kong Laboratory Accreditation Scheme), the Test Category (i.e. Medical Testing), the International Standard to which the accreditation criteria is based (i.e. ISO 15189), the registration number, name and address of the laboratory and the date on which it is issued. If a laboratory is under the supervision of full time pathologist, this will also be indicated on the certificate. Samples of the accreditation certificate for laboratories with and without full time pathologist are shown in [Annex 3](#) and [Annex 4](#) respectively.

**Annex 1**  
**Scope of Accreditation for**  
**Laboratories Supervised by Full-time Pathologists**

No. XYZ

**Very Good Medical Laboratory Ltd.**  
**好好化驗所有限公司**

**ADDRESS** : 123 Very Good Road, Hong Kong.  
**地址** : 香港好好路 123 號

**AUTHORISED** : Mr. WONG Ho-ho  
**REPRESENTATIVE** : 黃好好先生  
**委任代表**

**ENQUIRY** : Mr. WONG Ho-ho  
**查詢** : 黃好好先生

Tel. 電話 : 1231 2312  
Fax. 傳真 : 1234 1234  
**E-mail** 電子郵件 : verygood@verygood.com.hk

**LABORATORY** : **Full-time pathologist 全職病理專科醫生:**  
**SUPERVISED BY** : Dr. CHAN Tai-man (Haematology)  
**負責主理化驗所** : 陳大文醫生  
MBChB, , MRCP, FHKCPath

**Consulting pathologist 諮詢病理專科醫生:**  
Dr. WONG Ho-yan (Microbiology)  
黃好人醫生  
MBChB, , MRCP, FHKCPath

**CLIENTELE** : Public  
**服務對象** : 公眾

**Scope of Accreditation 認可範圍:**

TEST CATEGORY 試驗類別	ITEMS, MATERIALS OR PRODUCTS TESTED 試驗項目、物料或產品	SPECIFIC TESTS OR PROPERTIES MEASURED 特定試驗或量度的特性	SPECIFICATION, STANDARD METHOD OR TECHNIQUE USED 規範、標準方法或應用技術
Medical Testing	Blood and body fluids	Cell enumeration and typing	In-house method 123 (Blood counter, blood staining and microscopy)
		Cytochemistry for diagnosis of haematolymphoid malignancies ( <i>Clinical interpretation required</i> )	In-house method ABC
	Faeces and rectal swabs	Intestinal parasites	Direct microscopy by wet mount (Manual of Clinical Microbiology, 8 <sup>th</sup> ed.)

**Annex 2**  
**Scope of Accreditation for Laboratories**  
**NOT Supervised by Full-time Pathologists**

**No. XYZ**

**Very Good Medical Laboratory Ltd.**  
**好好化驗所有限公司**

**ADDRESS** : 123 Very Good Road, Hong Kong.  
**地址** : 香港好好路 123 號

**AUTHORISED REPRESENTATIVE** : Mr. WONG Ho-ho  
**委任代表** : 黃好好先生

**ENQUIRY** : Mr. WONG Ho-ho  
**查詢** : 黃好好先生

Tel. 電話 : 1231 2312  
 Fax. 傳真 : 1234 1234  
 E-mail 電子郵箱 : verygood@verygood.com.hk

**LABORATORY SUPERVISED BY** : Full-time pathologist 全職病理專科醫生:  
**負責主理化驗所** : Nil 無

**Consulting pathologist** 諮詢病理專科醫生:  
 Dr. CHAN Tai-man (Haematology)  
 陳大文醫生  
 MBChB, MRCP, FHKCPath

**CLIENTELE** : Public  
**服務對象** : 公眾

**Scope of Accreditation 認可範圍:**

TEST CATEGORY 試驗類別	ITEMS, MATERIALS OR PRODUCTS TESTED 試驗項目、物料或產品	SPECIFIC TESTS OR PROPERTIES MEASURED 特定試驗或量度的特性	SPECIFICATION, STANDARD METHOD OR TECHNIQUE USED 規範、標準方法或應用技術
Medical Testing	Blood and body fluids  Faeces and rectal swabs	Cell enumeration and typing  Intestinal parasites  Bacterial pathogens	In-house method 123 (Blood counter, blood staining and microscopy)  Direct microscopy by wet mount (Manual of Clinical Microbiology, 8 <sup>th</sup> ed.)  Culture, identification and antimicrobial susceptibility tests (Manual of Clinical Microbiology, 8 <sup>th</sup> ed.)

**Annex 3**  
**Accreditation Certificate for Laboratories**  
**under the Supervision of Full-Time Pathologists**



Hong Kong Accreditation Service

香港認可處

*This is to certify that*

**ABC MEDICAL TESTING LABORATORY**

.....  
Rm 209, 2/F, ABC Plaza, Central, Hong Kong

at the address of.....  
.....

*has been accepted by the HKAS Executive,  
on the recommendation of the Accreditation Advisory Board, as a*

***HOKLAS Accredited Laboratory***

*This laboratory meets the requirements of ISO 15189:2003 – Medical laboratories – Particular requirements for quality and competence and it has been accredited for performing specific tests or calibrations as listed in the HOKLAS Directory of Accredited Laboratories within the Test Category of*

**MEDICAL TESTING (under the supervision of full-time pathologist)**

.....  
*The common seal of the Hong Kong Accreditation Service is affixed hereto by the authority of the HKAS Executive.*

Executive Administrator

Issue Date :

Registration Number

**HOKLAS**

Date of First Registration :

*This Certificate is issued subject to the terms and conditions laid down by HKAS.*

**Annex 4**  
**Accreditation Certificate for Laboratories**  
**NOT under the Supervision of Full-Time Pathologists**

Hong Kong  
Accreditation  
Service



香港認可處

*This is to certify that*

**ABC MEDICAL TESTING LABORATORY**

.....  
Rm 209, 2/F, ABC Plaza, Central, Hong Kong

at the address of.....  
.....

*has been accepted by the HKAS Executive,  
on the recommendation of the Accreditation Advisory Board, as a*

***HOKLAS Accredited Laboratory***

*This laboratory meets the requirements of ISO 15189:2003 – Medical laboratories – Particular requirements for quality and competence and it has been accredited for performing specific tests or calibrations as listed in the HOKLAS Directory of Accredited Laboratories within the Test Category of*

**MEDICAL TESTING**

.....  
*The common seal of the Hong Kong Accreditation Service is affixed hereto by the authority of the HKAS Executive.*

Executive Administrator

Issue Date :

Registration Number



Date of First Registration :

*This Certificate is issued subject to the terms and conditions laid down by HKAS.*