ASSESSMENT OF

CLINICAL FLOW CYTOMETRY

LABORATORY PRACTICE

First Edition 2018

Australasian Cytometry Society Laboratory Assessment Document

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Contents

The Australasian Cytometry Society (ACS) was established in 1979 and incorporated in 1992 with the aim of promoting research, development and applications in, and to disseminate knowledge of flow cytometry.

A function of the ACS is to assist with development and application of clinical flow cytometry applications for hospitals and laboratories in the diagnosis and treatment of disease. This includes the preparation of guidelines, assessments and education programs. Guidelines produced by the ACS are issued as reference material to provide laboratories and accrediting agencies with minimum requirements for testing considered acceptable for good laboratory practice.

Failure to follow these guidelines and assessments may pose a risk to public health and patient safety.

SCOPE

The ACS *'Assessment of Clinical Flow Cytometry Laboratory Practice*' is an ACS document to be read in conjunction with ACS document '*Guidelines for Clinical Flow Cytometry Laboratory Practice*'. This document outlines guidelines for good medical pathology practice where the primary consideration is patient welfare, and where the needs and expectations of patients, laboratory staff and referrers (both for pathology requests and inter-Laboratory referrals) are safely and satisfactorily met in a timely manner.

This document is for use in assessing laboratories providing clinical flow cytometry services.

ABBREVIATIONS

IANZ	means International Accreditation New Zealand, accreditation body of the Testing Laboratory Registration Council of New Zealand
NPAAC	means National Pathology Accreditation Advisory Council

DEFINITIONS

CD	Cluster definition number used to identify individual markers eg CD3 for the pan T cell antigen
Cocktail	means an antibody reagent test mixture pre-prepared for use over the period of time validated.
Competent clinical flow cytometrist	means a person who has a minimum of two years clinical flow cytometry experience, and who has been documented to be competent in clinical flow cytometry according to the Laboratory's Quality System
Guidelines for Clinical Flow Cytometry Laboratory Practice	means the overarching document broadly outlining standards for good clinical flow cytometry laboratory practice where the primary consideration is patient welfare, and where the needs and expectations of patients, Laboratory staff and referrers (both for pathology requests and inter-Laboratory referrals) are safely and satisfactorily met in a timely manner.
In vitro diagnostic medical device (IVD)	means a medical device test if it is a reagent, calibrator, control material, kit, Specimen receptacle, software, instrument, apparatus, equipment or system, whether used alone or in combination with other diagnostic goods for in vitro use. It must be intended by the manufacturer to be used in vitro for the examination of Specimens derived from the human body, solely or principally for the purpose of giving information about a physiological or pathological state, a congenital abnormality or to determine safety and compatibility with a potential recipient, or to monitor therapeutic measures. The definition of an IVD does not encompass products that are intended for general Laboratory use that are not manufactured, sold or presented for use specifically as an IVD.
marker	means an antibody directed to an antigen of interest in or on a cell used for diagnostic purposes
standard	Means a minimum requirement for a procedure, method, staffing resource or laboratory facility that is required before a laboratory can attain accreditation

INTRODUCTION

This ACS document, together with '*Guidelines for Clinical Flow Cytometry Laboratory Practice'* is intended to be used in clinical flow cytometry laboratories to assist good practice in relation to flow cytometry for use during laboratory assessments.

Guidelines referred to are intended to serve as consensus recommendations for best medical laboratory practice have been developed by ACS members and associates with reference to other guidelines as published in peer reviewed journals.

The Guidelines are not Standards. The Guidelines should be read in conjunction with the current version of the ACS '*Guidelines for Clinical Flow Cytometry Laboratory Practice'.*

For clarification Standards are described as:

• A Standard is the minimum requirement for a procedure, method, staffing resource or laboratory facility that is required before a laboratory can attain accreditation. The use of the verb 'must' in standards indicates mandatory requirements for pathology practice.

In each section of this document, points deemed important for practice are identified as either 'Guidelines' or 'Commentaries', as follows:

• A Guideline is a consensus recommendation for best medical laboratory practice for a procedure, method, staffing resource or facility. Guidelines are prefaced with a 'G' (e.g. G2.2**)**. The use of the word 'should' in each Guideline within this document indicates a recommendation for good pathology practice.

• A Commentary may be provided to give clarification to the Guidelines as well as to provide examples and guidance on interpretation. Commentaries are prefaced with a 'C' (e.g. C1.2) and are placed where they add the most value.

Note: ACS documents can be accessed at: www.cytometry.org.au

ASSESSMENT OF
CLINICAL FLOW CYTOMETRY LABORATORY PRACTICE

This assessment is intended for use in assessing laboratory processes according to the ACS '*Guideline for Clinical Flow Cytometry Laboratory Practice'.*

Assessment 'Point' refers directly to the ACS guideline reference number.

Comments for noncompliance can be made in the table in Appendix.

1. PREANALYTICAL PHASE

POINT	DESCRIPTION	COMPLY
G1.1	**Specimen Collection and Storage**	
G1.1	Appropriate anticoagulant and storage are used according to sample type and disease investigation.	
G1.2	Specimen Transport	
G1.2.1	Transport, storage and rejection criteria conditions are followed according to individual test guidelines	
G1.2.2	Viability testing is performed for some tests on samples more than 24 hours after collection or if there is obvious deterioration of the sample.	
G1.3	Specimen Check	
G1.3.1	Primary collection samples have the patients name and two identifiers (eg date of birth, medical record number, test/accession number), including collection date, sample type and/or collection site.	
G1.3.2	A protocol for return unlabeled/mismatch specimens according and criteria for rejection is followed as described in the laboratory department manual.	
1.4	Antibody Reagents	
G1.4.1	New antibodies introduced into the laboratory are correctly validated by clinical correlation.	
G1.4.2	Reagents are not used beyond expiry dates.	
G1.4.3	Cocktail antibody preparations for flow tests is correctly validated and each lot tested prior to use.	
G1.4.4	Reagent titration if performed follows manufacturer's instructions and IVD guidelines.	

2. ANALYTICAL PHASE

POINT	DESCRIPTION	COMPLY
G2.1	Sample Analysis	
G2.1.1	Sample preparation for assays seek to minimize manipulation of the cells and maximize preservation of their viability and antigenic integrity	
G2.1.2	Appropriate software and gating are used for individual flow tests	
G2.2	Performance Measures	
G2.2.1	Analysers are set up, monitored, maintained and documented using appropriate material, reviewed by a competent clinical flow cytometrist	
G2.2.2	A control is prepared and run on a regular basis in parallel with patient samples where appropriate. A positive (and/or negative) reagent control is run either daily or with each assay performed.	
G2.2.3	Where absolute numbers (eg cells/uL) are reported, a control reagent has specified ranges for the analytes measured, and reasons for and deviations determined.	
G2.2.4	A minimum number of target cellular events is collected according to the flow test, reporting style suited (quantitative or qualitative) and criteria for rejection determined for individual flow tests.	
G2.2.5	Sensitivities for each assay are calculated, documented and reviewed when new assays are setup or when alterations to assay methods, technologies or reagents change	
G2.2.6	Each laboratory has established reference limits for antigens being tested where appropriate.	

3. POST ANALYTICAL PHASE

POINT	DESCRIPTION	COMPLY
3.1	Reports	
G3.1.1	Interpretation and report comments are made and verified by competent clinical flow cytometrist or suitably trained medical officer.	
G3.1.2	Where quantitative (numerical) results are given, reference ranges are provided where appropriate.	
G3.1.3	Reports are completed in a timely manner and in a time commensurate with clinical need. Depending on the test this should be less than a few hours eg CD34 pre-harvest counts to no longer than 5 working days for haematology oncology reports.	

3.2	Data Storage	
G3.2	Electronic data (FCS) have backup copies and storage for the period required by NPAAC, IANZ.	
3.3	Laboratory Staff	
G3.3.1	There is documented evidence flow staff are given sufficient time and resources to achieve and maintain their skills.	
G3.3.1	The flow cytometry laboratory is supervised by a scientist with demonstrated experience in all aspects of flow cytometry testing, interpretation and quality management.	

REFERENCES

For backgorund on the methods, interpretation and publications refer to the references cited in ACS documents '*Guidelines for Clinical Flow Cytometry Laboratory Practice*' available on the ACS website.

NPAAC Reference Documents

Requirements for Medical Pathology Services, First Edition, 2013
Print ISBN: 978-1-74241-913-8, Online ISBN: 978-1-74241-914-5, Publications approval number: 10207

Regulatory Requirements for In-house IVDs, Version 2.0, March 2016, Australian Government, Department of Health, Therapeutic Goods Administration

Requirements for the Development and Use of In-house In Vitro Diagnostic Devices (IVDs,) Third Edition 2014
ISBN: 1 74186 158 6; Online ISBN: 1 74186 159 4; Publications Approval Number: 3957

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Further ACS clinical flow cytometry guidelines documents are available on the website: www.cytometry.org.au

Email: clinicalguidelines@cytometry.org.au

APPENDIX

The table below may be used for laboratory assessment records and reviews.

FLOW CYTOMETRY LABORATORY ASSESSMENT

Laboratory Assessed: Date:

Procedure Assessed: Assessment by:

POINT	COMMENT	RECOMMENDATION	ACTION

POINT	COMMENT	RECOMMENDATION	ACTION