Canadian Immunology Quality Assessment Program

CIQAP

Quality Assessment Program for CD4 T-Cell enumeration

Sexually Transmitted and Blood Borne Infections Division
National Microbiology Laboratory
JC Wilt Infectious Disease Research Centre
Public Health Agency of Canada
745 Logan Avenue, Winnipeg, MB
R3E 3L5
https://ciqap.canada.ca/
ciqap@phac-aspc.gc.ca

CANADIAN QUALITY ASSESSMENT PROGRAM FOR CD4 - T CELL ENUMERATION

The Canadian Quality Assessment Program (CIQAP) for CD4-T Cell Enumeration is operated and managed by the National Sexually Transmitted and Blood Borne Infections (STBBI) Division of the Public Health Agency of Canada. The National STBBI Division developed CIQAP in collaboration with the Canadian HIV Trials Network (CTN) and other national agencies in 1989. The goal of CIQAP is to improve the health of Canadians living with HIV/AIDS through the provision of a National Proficiency Testing Program for monitoring disease progression, technology development and evaluation, and national and international collaborations. CIQAP headquarters are housed within the National Sexually Transmitted and Blood Borne Infections Division at the JC Wilt Infectious Diseases Research Centre in Winnipeg, Canada.

Version_2022

Dr. Tamsir O. Diallo
Phone (204) 789-6509
Fax (204) 318-2221
ciqap@phac-aspc.gc.ca

This booklet provides general information to Canadian laboratories about the Quality Assessment Program for CD4 testing

Public Health Agency of Canada | Agence de santé publique du Canada

TABLE OF CONTENTS

INTRODUCTION

Human Immunodeficiency virus infection (HIV) leads to severe immunodeficiency. CD4 T-cell enumeration is frequently used as a clinical surrogate marker for the measurement of disease progression and immune reconstitution in HIV/AIDS patients. A reproducible and accurate measurement of T-cell subsets, such as CD3+4+, CD3+8+ and CD3+, is critical in monitoring the immune system and the effect of drug interventions.

The National STBBI Division developed the Canadian Immunology Quality Assessment Program (CIQAP) in collaboration with the Canadian HIV Trials Network (CTN) and other national agencies in 1989.

OBJECTIVE

The primary objective of CIQAP is to ensure reproducible and accurate T-cell subset measurements by flow cytometry. The STBBI manages the entire CIQAP, and provides remedial action and assistance to the laboratories when required in both official languages.

CIQAP MANAGEMENT PROGRAM

The CIQAP focuses on improving the quality of laboratory practices by sending participants whole blood specimens for immunophenotyping by flow cytometry. Data collection takes place through a web database platform and statistical results are provided in a performance report to each participant. The program is intended to be an interactive flow cytometry quality improvement program with open lines of communication between the quality improvement team and the participants.

QUALITY ASSESSMENT MATERIAL

Three whole blood specimens are sent to each participant. Two samples are HIV positive and one in HIV negative. The participants receive a 1.5mL vacutainer tube of each sample. All preparations are processed as routine blood specimens upon arrival and must be handled according to laboratory biosafety guidelines.

SAMPLE DISTRIBUTION

The quality assessment material is distributed three times a year according to a pre-established shipping schedule. A notification is sent by email to each participant three weeks prior to the survey. The laboratory confirms their participation by logging into the CIQAP website and clicking on the accept button. Samples are sent by courier using land or air transportation depending on the location of the laboratory in Canada.

The sample specimens are packaged according to regulations of the Transportation of Dangerous Goods Act. Certified personnel package the individual vacutainer tubes according to the packing instructions for STP-210 Biological Substance, Category B Ambient Shipping System from SAFTPAK (www.saftpak.com).

SAMPLE ANALYSIS

Three specimens are to be processed upon arrival for leukocyte phenotyping. Each laboratory is required to report lymphocyte T-cell subset percentages of CD3+, CD3+CD4+ and CD3+CD8+. Percentage values are to be reported with two decimal places. Absolute count values are to be measured by the Single Platform Method based on absolute count beads such as Flow-Count or TruCount[1]. Absolute count values are to be reported in whole numbers only as cells/µL.

DATA SUBMISSION

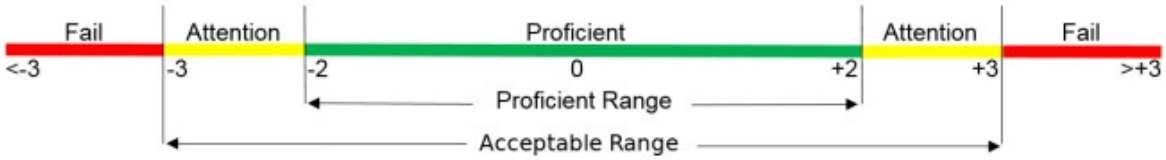
Each laboratory is given 7 to 8 working days to submit their results. The electronic submission form is located on the CIQAP website https://ciqap.canada.ca/users/sign_in?lang=en. Each laboratory is given a unique username and password to access their submission form online and submit their results confidentially. Data must be submitted prior to the database closing date outlined in the instructions provided. Flow cytometry printouts of the analysis are emailed or faxed to the CIQAP office upon submission. Electronic data files (.lmd or .fcs) must be retained for remedial action investigation.

STATISTICAL ANALYSIS

Statistical analysis defines the limits of acceptability of results obtained from participants according to a group mean value. All submitted data are tabulated to obtain the group mean value, standard deviation (SD) value and Z-score for each lymphocyte subset; both percentage and absolute count.

DATA INTERPRETATION

The performance of the laboratory is assessed using the SD index (shown in the figure below). If the reported percent or absolute count value is within ±2 SD of the mean, this is marked as “Proficient”. If the reported value is within ±3 SD of the mean, this is marked as “Acceptable”. If the reported value is greater than 3 SD or less than -3 SD of the mean, this value would be marked as “Fail” and this would require corrective measures



PERFORMANCE REPORT

A Performance Report is provided for each participant within five business days of the session closing date. This report is available on the CIQAP website and is accessible confidentially to the participant after logging in using their unique user name and password. Past performance reports are also available on the site.

Performance Reports include the following:

1. An immunophenotyping results verification sheet that summarizes the information submitted by the participant including the Laboratory name, Laboratory code, lysing protocol, flow cytometer, monoclonal antibody panel, absolute count beads used and the phenotyping results submitted.
2. A summary table of statistics including reported value, group mean value, residual, Z score for each specimen‘s T-cell subset.
4. History performance graphics illustrating the overall performance for the last six CIQAP sessions.
5. For each phenotype, a histogram showing the laboratory’s Z score value within the group distribution.

REMEDIAL ACTION

Remedial action is a critical component of the CIQAP. The turnaround time for Performance Reports is fast and provides feedback to the participant as well as the CIQAP team. This provides timely interventions that can be applied to ensure accurate clinical results, thus limiting the impact on patient therapy. Participants are contacted by email with requests for printouts of the analysis and/or electronic files for analysis when further investigation is required and guided in corrective actions needed for improvement. Due to the interactive nature of the program, participants are encouraged to communicate any concerns to the CIQAP Quality Improvement Team.

SUMMARY

The CIQAP is an interactive program that provides support and technical assistance to Canadian clinical laboratories involved with CD4 testing to ensure reproducible and accurate T-cell subset measurements by flow cytometry. To achieve sustained reduced standard deviation, the CIQAP provides a communication channel for effective feedback and integrated corrective actions.

REFERENCES

1. Mandy FF, Nicholson JK, McDougal JS. Guidelines for Performing Single-Platform Absolute CD4+ T-Cell Determinations with CD45 Gating for Persons Infected with Human Immunodeficiency Virus. CDC. MMWR Recomm Rep. 2003 Jan 31;52(RR-2):1-13.