NIAID DAIDS FLOW CYTOMETRY LABORATORY CERTIFICATION

The Immunology Quality Assessment (IQA) program is a resource designed to help immunologists evaluate and enhance the integrity and comparability of immunological laboratory determinations performed on patients enrolled in multi-site HIV/AIDS therapeutic, vaccine, and prevention investigations. Laboratories performing flow cytometric enumeration of lymphocyte subsets for network studies must participate in the IQA CD4/CD8 Immunophenotyping Flow Cytometry Quality Assessment Program.

The IQA provides proficiency testing (PT) materials to participating laboratories. Four times a year, laboratories receive a shipment comprised of 2 coded stabilized whole blood specimens for one trial. For these coded specimens, laboratories are required to measure and report the percent of T cell lymphocytes and the count [per microliter] for the following phenotypes [if available on the instrument platform]:

- CD3+CD4+ using CD45 as an anchor gate
- CD3+CD8+ using CD45 as an anchor gate

The coded specimens are measured using the same tubes and markers normally used for protocol study samples. Laboratories are evaluated every three trials for their ability to perform lymphocyte subset phenotyping on a total of 6 coded specimens.

After the closing date of each trial, the IQA receives data regarding each laboratory's performance in the trial. The laboratory MUST report results for the above listed phenotypes that fall within 2.50 standard deviations (SD) from the robust mean for each phenotype as determined by the IQA. If the lab falls outside of 2.50 SD from the robust mean for CD4 and or CD8 phenotype, they are Unsatisfactory for that sample and trial. The IQA gives comments and conducts investigations in the event of an Unsatisfactory trial.

If a laboratory receives an Unsatisfactory grade for two out of three trials, the laboratory as a whole will be considered Unsatisfactory for CD4/CD8 Immunophenotyping and may be asked to revert to back up or drop from the program at the discretion of the relevant NIAID network leadership.

LATE RESULTS

If a site is not able to participate in a trial, they must inform the IQA by email immediately.

If the IQA finds that a site has not submitted results near closing date, the IQA will email the site a reminder:

No results are registered under your account for trial [Trial ID] under the IQA CD4/CD8 Immunophenotyping via Flow Cytometry Quality Assessment Program. Please submit results by closing date or provide a reason for delay by email to avoid receiving Unsatisfactory scores for the trial samples.

The lab will earn an Unsatisfactory Score for the trial if they fail to provide an explanation prior to the trial closing date.

PERFORMANCE RATING

Laboratories are rated Satisfactory or Unsatisfactory overall for CD4/CD8 Immunophenotyping.

I. Satisfactory Status (Overall): These laboratories may accept and analyze patient specimens from their own site and other NIAID DAIDS study sites at the discretion of protocol network leadership.

Demotion from Satisfactory Status: A site receives an "Unsatisfactory" status for earning Unsatisfactory performance for two out of three trials.

II. Unsatisfactory Status (Overall): Laboratories are in an Unsatisfactory Status following demotion from Satisfactory Status.

The relevant protocol network leadership will be informed of status change by email with applicable information concerning trial performance and ongoing investigations. At the discretion of relevant protocol network leadership, a laboratory may be asked to revert to back up or drop from the program.

Promotion to Satisfactory Status: The IQA recommends positive performance in 2 consecutive trials before promoting a site from overall Unsatisfactory to Satisfactory status. The criteria for regaining Satisfactory status will be determined by a joint recommendation of the NIAID DAIDS Flow Cytometry Advisory Committee and the appropriate Executive Committee.