



National Institutes of Health
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External Proficiency Testing for CD4 Measurements in International Laboratories

Dear Investigator:

We are pleased that your flow cytometry laboratory will be performing CD4 measurements on samples from subjects enrolled in studies sponsored by the Division of AIDS (DAIDS) of the National Institutes of Allergy and Infectious Disease of the National Institutes of Health.

In order to ensure meaningful study results, it is important that the CD4 measurements are done correctly and reliably, and therefore, DAIDS has determined that all international CD4 laboratories that support its studies must participate in the proficiency testing program that is provided by the UK NEQAS in Sheffield, England. Every two months, The UK NEQAS sends out 2 fixed, coded samples that the participating laboratories tests and the results are sent back to the UK NEQAS to determine if they are correct. If a laboratory is having difficulties, help is provided by one of the contracts that DAIDS has – the Immunology Quality Assessment Program (IQA) at Duke University in Durham, North Carolina in the USA with Tom Denny as the Principal Investigator. The IQA is also the provider of external proficiency testing panels to CD4 laboratories in the USA.

Before the laboratory can start testing samples from study subjects, we are asking that you please:

- Fill out the attached survey and return it to the IQA as indicated on the survey
- Successfully test a 20-sample panel sent to you by the UK NEQAS

When the IQA receives your filled survey, it will notify the UK NEQAS about enrolling your laboratory in the proficiency testing program and then you will be contacted directly by the UK NEQAS with complete specific information about participation in the program (including who to contact when samples do not arrive, to request repeat samples, and to receive technical assistance for running the samples). The UK NEQAS for Leucocyte Immunophenotyping has Professor John T. Reilly as its Director with Dr David Barnett overseeing the day-to-day operation. For questions regarding UK NEQAS please contact Dr David Barnett at d.barnett@btconnect.com or telephone +44 114 267 3600. More information about the UKNEQAS proficiency testing program for CD4 can be found on the web at: www.ukneqasli.org

The IQA will be receiving reports from UK NEQAS about your performance in the proficiency testing program and will be contacting you if there are difficulties. The IQA will work with you until such difficulties are resolved. There are many forms of help. It could be as little as an email exchange and a request to review your histograms, or as extensive as a visit from the IQA. The results of participation in the UK NEQAS external proficiency testing and efforts by the IQA to help should not be regarded as punitive. You may initiate contact with the IQA if you have any questions related to flow cytometry, even if it has nothing to do with CD4 proficiency testing. The international CD4 specialist at the IQA is John Wong and he can be contacted by phone at 001 919 681 4066 or by email at john.wong@duke.edu. You may also contact Raul

Louzao, the IQA Manager, at 001 919 684 5861 or at raul.louzao@duke.edu. John and Raul are available to receive calls from 8:00am to 5:00pm US Eastern Standard Time. If there are questions regarding the UK NEQAS program such as requesting repeat specimens or clarification of the reports then please contact Liam Whitby by email at l.whitby@btconnect.com.

We are happy that you can participate in our studies and we thank you for doing so. We hope that your participation in the UK NEQAS proficiency testing and any benefits that you gain from the assistance of the IQA will put your laboratory in a favorable position to participate in various research and health care efforts. If you have any question about our requirement to participate in the UK NEQAS CD4 proficiency testing program and be responsive to IQA's efforts to help, please contact me at dlivnat@niaid.nih.gov.