Quantitative determination of CD4+ T-cells at point of care

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More than 95% of HIV-infected patients live in developing countries. Antiretroviral therapies are becoming increasing available to people in both developed and developing countries, but a major roadblock to expanded treatment is the need for monitoring of CD4 T-cell levels to determine when patients should commence therapy (a level of <350 CD4+ T-cells/µl). This typically requires sophisticated equipment (such as Flow cytometry), expensive reagents and highly trained personnel, with limited availability in developing countries. There is a clear need for CD4 tests that can be used at the point of care with minimal infrastructure.

Through a 6-year program of innovation and development funded by NHMRC, Doris Duke Foundation, MRCF and the CD4 Initiative, the team led by A/Prof David Anderson and Prof Suzanne Crowe at the Burnet Institute have produced a world-first rapid point of care (lateral flow) test for CD4 T-cells, which uses a finger-prick sample of blood, gives visual results in 40 minutes, and requires minimal training and no additional equipment. Commercialisation of this test is under active negotiation.

With support from ACH^2 and in collaboration with Axxin Ltd, Melbourne, an optional test reader instrument has been developed to assist with manufacturing, test result documentation and for training purposes, as well as for running tests where the instrument can be made available in small clinics. Commercialisation of this instrument is also proceeding, with additional support for CE mark registration from the Burnet's spinoff company, See-D4 Ltd, and a major grant from the Small Technology Industry Uptake program of the Victorian State Government.