

# Visitect® CD4 T-cell test – from concept to the WHO essential diagnostics list

**David Anderson**, Mary Garcia, Robyn Lloyd, Suzanne Crowe, Alan Landay<sup>b</sup>, Tom Denny<sup>c</sup>, Andrew Shepherd\*, Minh Pham, Stanley Luchters, Burnet Institute, Melbourne; <sup>b</sup>Rush University IA, USA; <sup>c</sup>Duke University NC, USA; \*Omega Diagnostics Scotland (deceased).

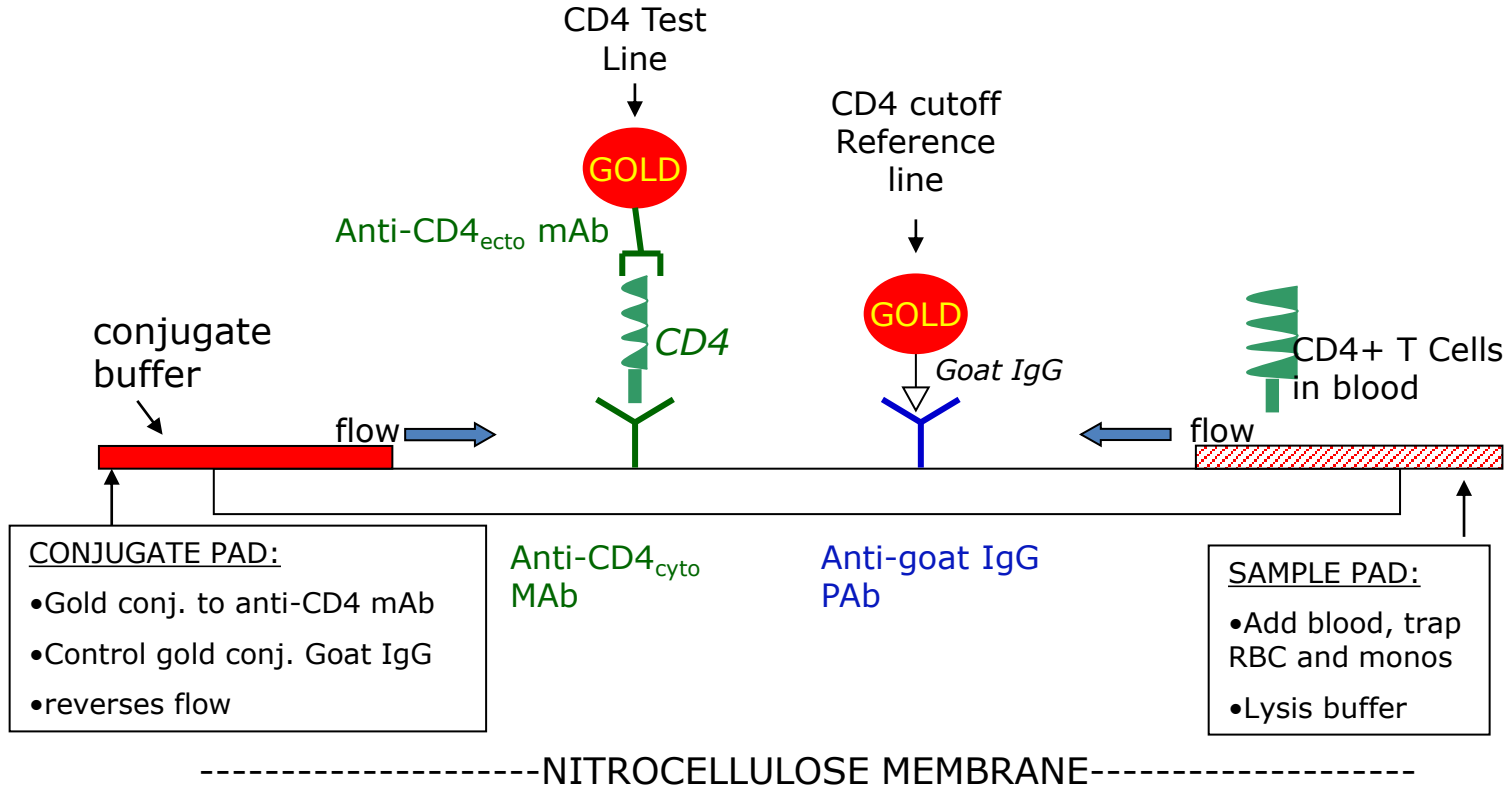
[david.anderson@honorary.burnet.edu.au](mailto:david.anderson@honorary.burnet.edu.au)

**POC23, Sydney, March 2023**

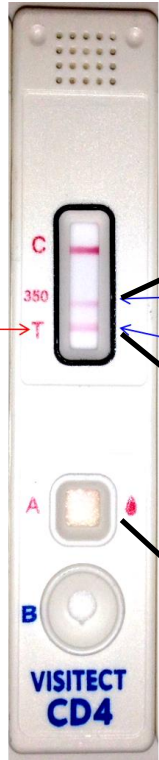
## **Declaration of interests:**

- DA MG RL SC AL are inventors of the Visitect CD4 patents (Burnet Institute) licensed to Omega Diagnostics, Scotland (AS) (CD4 business sold to AccuBio in 2022)
- DA is President and Chief Scientist of Nanjing DeShi Diagnostics, China (startup company)  
[brunswickbiotech@gmail.com](mailto:brunswickbiotech@gmail.com)

# CD4 T-cell counts needed for HIV treatment initiation (until 2016) and still important: Initial lateral flow product concept, 2007 (CD4 Initiative grant application)



## Visitect® CD4 (2014) and Visitect® CD4 Advanced Disease (2017)



Procedural control

Reference

Test line(s)

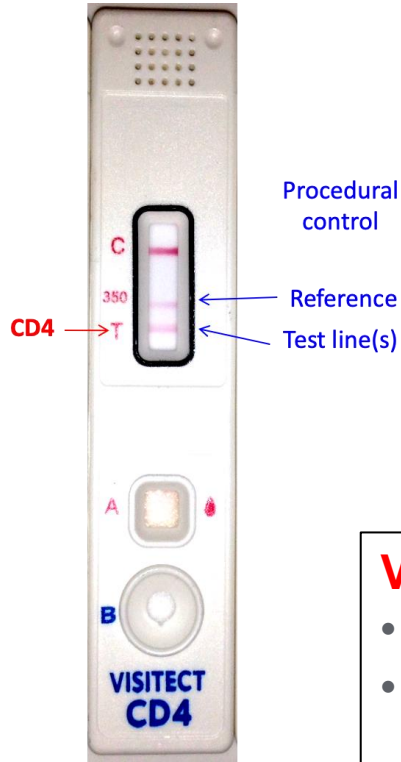
### 3. CD4 cutoffs!

- $\leq 200 / \text{mm}^3$  (initial design brief)
- $\leq 350 / \text{mm}^3$  from 12/2009
- "Treat all" in 2016 (but many countries stuck with 350)
- Increasing recognition of HIV Advanced Disease ( $\leq 200 / \text{mm}^3$ ), recommended 2020 for newly Dx / re-engaged

2. Selective detection of full-length CD4 (not soluble CD4) (ecto/cyto MAbs) and high correlation with CD4 counts

1. Retention of monocytes and RBCs - RosetteSep

## Visitect® CD4 (2014, 350 cutoff) and Visitect® CD4 Advanced Disease (2017, 200 c/o)



- Visitect® Advanced Disease achieved **WHO Prequalification** in 2020
- Omega Diagnostics partnered with CHAI and UNITAID for programme rollout in 7 African countries in 2022.
- In use in >70 countries
- Visitect® CD4 will be used for nearly all CD4 testing in Nigeria as of 2022

### Validated two important principles for future lateral flow tests

- Capacity for selective cell depletion (RosetteSep)
- Use of Visual reference line for semi-quantitative tests (WHO prequalification and programmatic validation)

## Development team



AMERICAN  
SOCIETY FOR  
MICROBIOLOGY

Journal of  
Clinical Microbiology®

## Field Performance and Diagnostic Accuracy of an Instrument-Free Point-of-Care CD4 Test Performed by Different Health Workers in a Rural Area of Nigeria

Stanley Luchters,<sup>a,b,c</sup> Karl Technau,<sup>d</sup> Yasmin Mohamed,<sup>a,b</sup> Matthew F. Chersich,<sup>e</sup> Mary L. Garcia,<sup>a</sup> James Forbes,<sup>f</sup> Andrew Shepherd,<sup>f</sup> Ashraf Coovadia,<sup>d</sup> Suzana

## Business team



Prof Oche Agbaji, Nigeria MOH  
(Satisfied customer)

**THANKYOU** - HIV patients at the Alfred Hospital, Melbourne, and the funders – without whom it would not have been possible