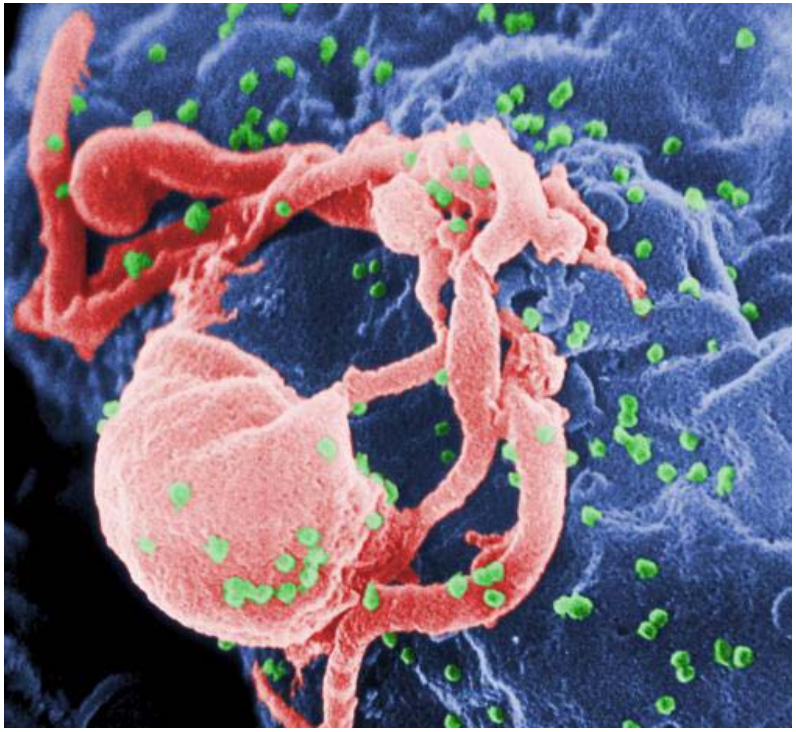
CD4 Positive T Cell Counts

MTN-009 Training

Durban, South Africa

May 7, 2010

CD4+ T Cells



From CDC.gov

Green = virus

Blue = CD4 T Cell

Orange = another type of cell

- **What are they?**
  - Part of the immune system
  - Help protect the body against infection
  - Type of cell that HIV infects
- **Why do we count them?**
  - Monitor disease progression

CD4+ T Cell Count

- In 1 ml of blood (1/5 teaspoon or ~1 drop), if a person has:

- **700 – 1000 CD4+ T cells**
  - Healthy immune system in a person not infected with HIV

- **<200 CD4+ T cells**
  - HIV positive person progresses to AIDS
  - The body's immune system is no longer strong enough to prevent illness and infection
    - There is an increased risk of opportunistic infections

Why do CD4+ T Cell Count in MTN-009?

- CD4+ T Cell count is the only laboratory criteria used to determine eligibility for ART
- Participants who are HIV infected need to know their CD4 T as soon as possible, even if viral load results are not yet available

Therapy Initiation Based on CD4

World Health Organization (WHO) Recommendations

CD4 criteria for the initiation of ART in adults and adolescents

CD4 (cells/mm³) [a]	Treatment recommendation [b]
<200	Treat irrespective of clinical stage [c] **[A-III]**
200–350	Consider treatment and initiate before CD4 count drops below 200 cells/mm³ [c d e] **[A-III]**
>350	Do not initiate treatment **[A-III]**

a CD4 cell count should be measured after stabilization of any intercurrent condition.

b CD4 cell count supplements clinical assessment and should therefore be used in combination with clinical staging in decision-making.

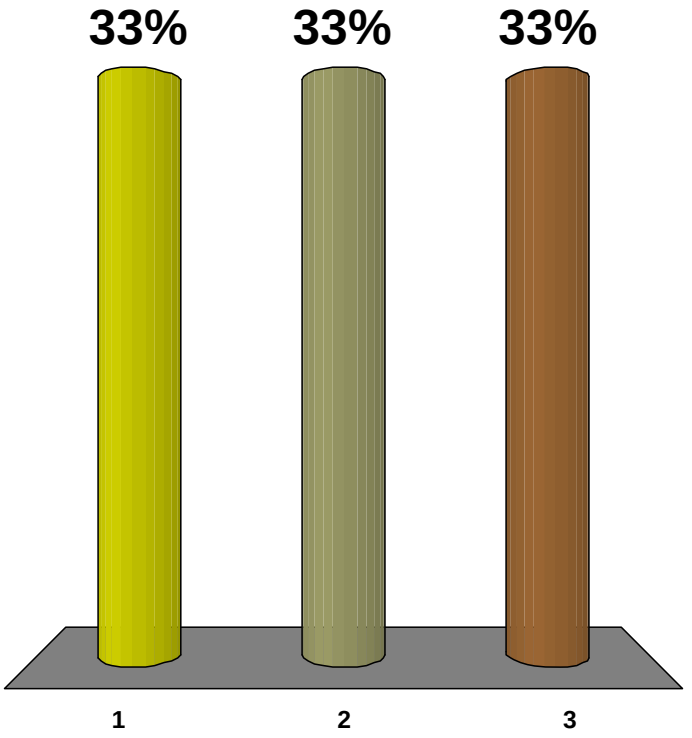
c A drop in the CD4 cell count below 200 cells/mm³ is associated with a significant increase in opportunistic infections and death.

d The initiation of ART is recommended for all patients with any WHO clinical stage 4 disease and some WHO clinical stage 3 conditions, notably pulmonary TB (see Section 12.1) and severe bacterial infections.

e The initiation of ART is recommended in all HIV-infected pregnant women with WHO clinical stage 3 disease and CD4 <350 cells/mm³ (see Section 11.2).

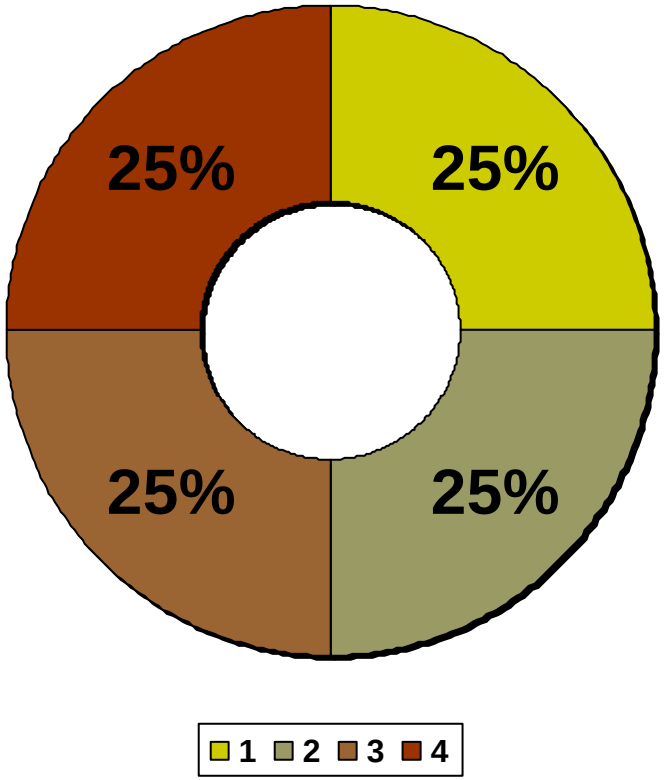
You do a CD4 count on an HIV-positive MTN-009 participant. Their CD4 count is 150 cells/ml. What does this mean?

1. **This count is very low. Participant is at risk for AIDS and should immediately be referred to a clinic for potential treatment with ARV.**
2. **This count is very high. Assay should be repeated.**
3. **There is not enough information to know.**



You are doing QA/QC on a CRF for an HIV positive MTN-009 participant and find that someone has written 150,000 for the CD4 T cell count. Is there a problem?

1. **No, this person is very healthy.**
2. **No, but this person is very sick and should be referred for ART.**
3. **Yes, there is a mistake. No one has a CD4 count this high.**
4. **Yes, because you should do CD4 only for HIV negative MTN-009 participants.**

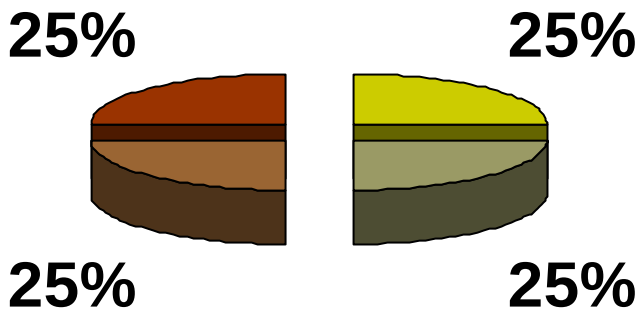


Who should get a CD4+ T Cell Count in MTN-009?

25%	1.	**All participants**
25%	2.	**Only HIV negative participants**
25%		**Only HIV positive participants**
25%	4.	**No one**

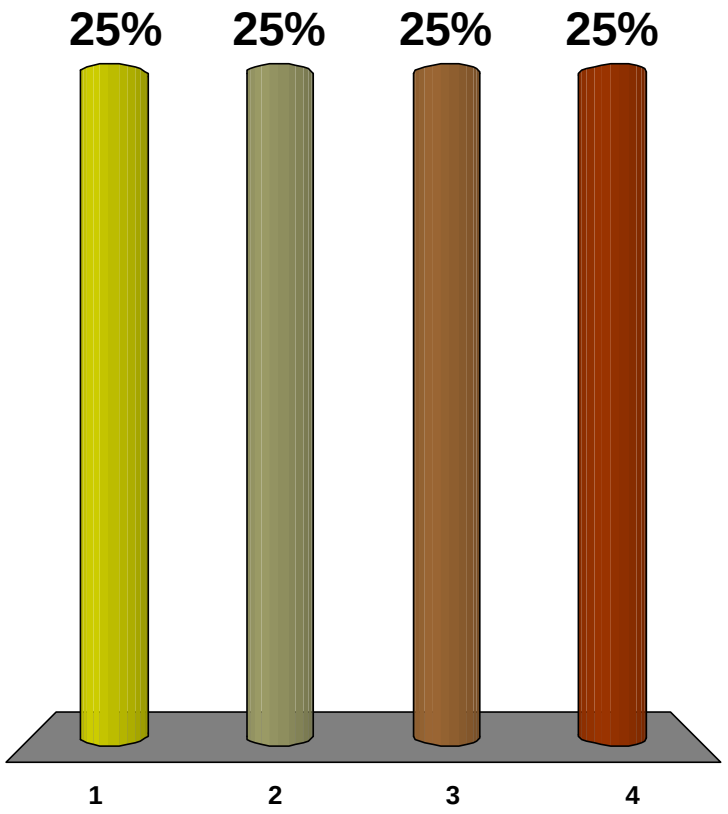
What sample type do you use to do CD4 T cell count?

1. **Serum**
2. **Whole blood**
3. **Plasma**
4. **Urine**



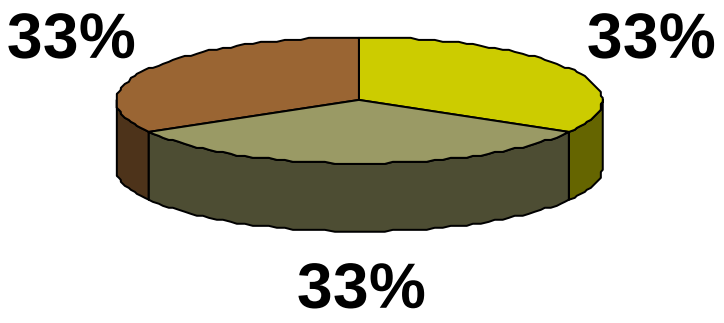
When should the results of CD4+ T Cell Count be given?

1. **These results are not given to participants**
2. **As soon as they are available**
3. **Wait until viral load and resistance results are available**
4. **Wait for viral load but do not wait for resistance**



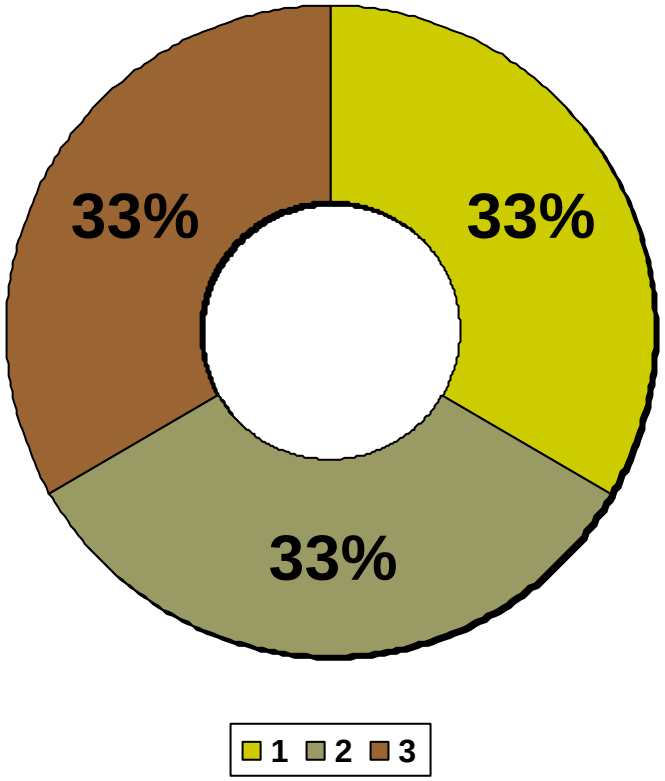
Why CD4 count is important?

1. Because it's required per protocol
2. To know when a participant needs to start HIV treatment
3. Is not important for participants but for research purposes only



What is the purpose of CD4 cells in our immune system?

1. Help fight infections
2. Provides a home for the HIV virus
3. Provides information on resistance



Questions