



USE OF NON FDA APPROVED UNIGOLD

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Introduction

- The Core lab have used the Unigold kits since 2004
- UniGold was approved by FDA in 2003
- The Lab was unknowingly using the non FDA approved Unigold



Introduction

- The two kits from Trinity Biotech have different lot#
 - Unigold Recombigen (US Market/FDA Approved) 1206506
 - Unigold (African Market) 1206502



Problem Background

- Missed key detailed in the protocol and NL communications
 - SMILE
 - IMPAACT
 - MTN
 - ACTG
- Misinformation by suppliers



Implications

- Protocol deviation
 - Study stopped/delayed
 - Completion of PD/note to file for each participant

- Lengthy processes of validation and approval of the new kit version



Corrective Action

- Reviewed communication from Networks, HPTN and SMILE in regards to Rapid HIV Reporting and FDA kit approval.
- The lab worked closely with NL to identify reliable source for the FDA approval Unigold Recombigen kits



Corrective Action

SOP written and approved

- Validation completed for Unigold Recombigen
- All MTN-020 samples were re-analyzed



NL Support

- Lab still receives support from NL in relation to kit supplies that are not available locally
- Established a relationship with BARC for study supplies of kits

Steps Instituted to Prevent Future Occurrence

- Detailed review of protocol kit requirements
- Submission of equipment/reagent reference/product# to the NL for FDA approval verification
- Identification of reputable/reliable supplier for different kits as per NL requirements



Lessons Learned

- Small details
 - Big implications
- Make thorough review of all study and Network documents