



Global Access Program

**take aim**  
**at HIV**

## **Increasing access to HIV diagnosis**

*COBAS® AmpliPrep/COBAS® TaqMan®  
HIV-1 Qualitative Test, v2.0*





# The importance of early infant diagnosis

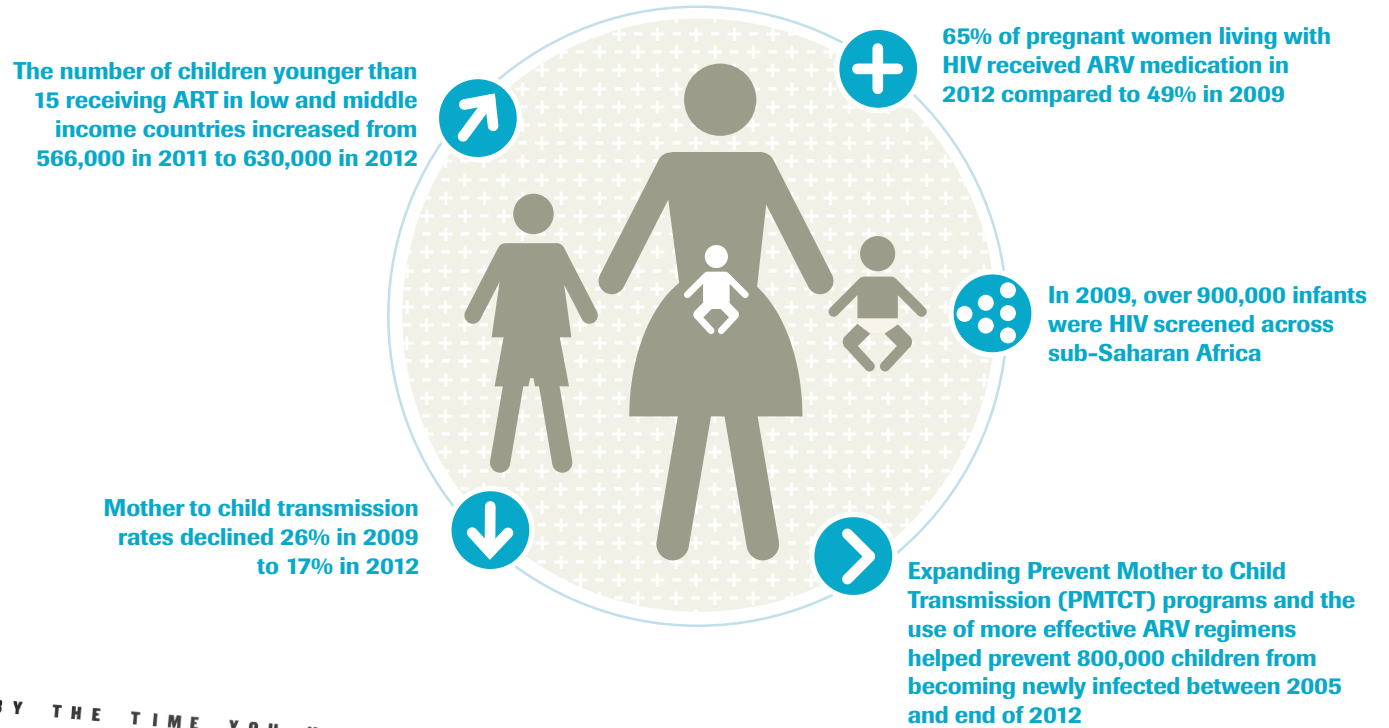


Early testing of HIV-exposed infants must be given priority within the global and national scale-up of preventative mother-to-child-transmission (pMTCT) programmes. Much can be learned from the successful interventions implemented by a number of countries in sub-Saharan Africa with substantially higher coverage of early infant diagnosis: as much as 80%.

Early diagnosis in infants and young children is a major challenge. Infants born to mothers infected with HIV-1 may have maternal antibodies to HIV-1, and the presence of HIV-1 nucleic acid in the infant indicates active HIV-1 infection. Infected infants might not exhibit any symptoms of HIV infection of AIDS. Antibody tests are ineffective in children because the mother's antibodies remain in the child's system following birth. In fact, antibody tests in infants may yield false positive results for up to 15 months, and the uncertainty surrounding the HIV status of the child has a negative effect on the potential clinical management of the child.

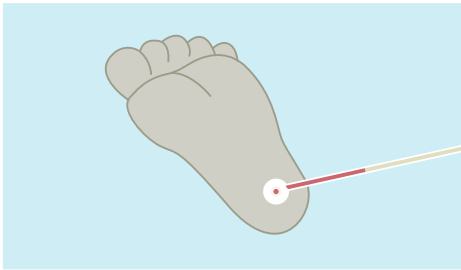
Detection of HIV-1 RNA is indicative of active HIV infection. Early diagnosis of HIV in infants is made possible using molecular based tests and allows for rapid implementation of anti-retroviral therapy (ART) in infected children. Roche's HIV Qualitative assay reduces this time of uncertainty significantly by providing reliable and accurate information on whether the baby is truly infected with HIV or not.

The use of dried blood spots (DBS) can facilitate PCR testing, and more importantly make sample collection easy, even from the smallest infant. A quick heel prick is all that's required to produce an adequate sample. By collecting small quantities of blood and collecting it on specially designed collection cards, using a simple heel or finger prick method we simplify both blood collection and sample transportation while minimizing stress for the mother and child. This creates sustainable solutions for the challenges posed within resource-limited settings.



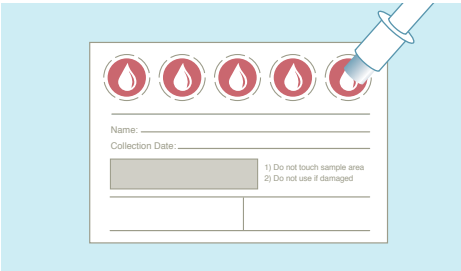
# Sustainable and optimized workflow

The COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Qualitative Test, v2.0 is based on four major processes: (1) obtaining specimen; (2) specimen preparation to isolate HIV-1 nucleic acids; (3) automated sample preparation of nucleic acids and (4) reverse transcription of target RNA to generate complementary DNA (cDNA), PCR amplification of target DNA and cDNA, and simultaneous detection. The workflow is automated using the COBAS® AmpliPrep Instrument with the COBAS® TaqMan® Analyzer or the COBAS® TaqMan® 48 Analyzer. For DBS specimens, a manual pre-extraction step is required.



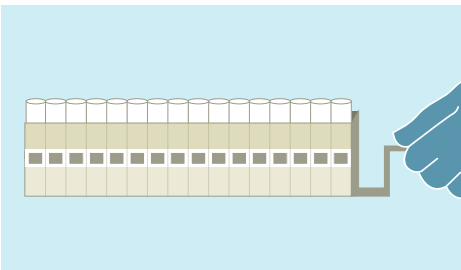
**Obtain sample & preparation of dried blood spots**

Collect dried blood spot samples (DBS) using appropriate clinical procedures. DBS are prepared by collecting 70 µL of human whole blood onto a delineated circle on a filter card or specimen collection card, and allowing it to dry at ambient temperature for at least 3 hours.



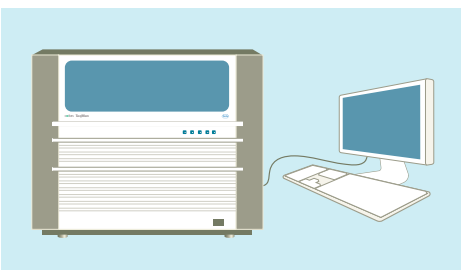
**Extraction from paper filter & resuspension**

For early infant diagnosis testing, remove one full single dried blood spot from the filter card and place into a COBAS® AmpliPrep S-tube. To resuspend the DBS simply add COBAS® AmpliPrep/COBAS® TaqMan® Specimen Pre-Extraction Reagent (SPEX) into the S-tube, and incubating at an elevated temperature with mixing.



**Automated specimen preparation**

The samples are then ready for automated specimen preparation on the COBAS® AmpliPrep Instrument.



**Automated amplification and detection**

Amplification occurs on the COBAS® TaqMan® Analyzer. The innovative Dual Target HIV-1 assay measures two unique regions of the HIV-1 genome, which are not subject to selective drug pressure.

This innovative Dual Target HIV-1 test measures two unique regions of the HIV-1 genome, which are not subject to selective drug pressure. Therefore drug induced mutations should not impact the assay's ability to detect the virus accurately. In turn, more accurate results drive better decisions for a positive impact on patients' lives.

The COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Qualitative Test, v2.0 is a qualitative in vitro diagnostic, total nucleic acid amplification test for the qualitative detection of HIV-1 DNA and RNA in human EDTA plasma or dried blood spots (DBS).

BY THE TIME YOU HAVE READ THIS, HIV-1 WILL HAVE MUTATED.  
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#### References

1. HIV InSite Kohnlwedge Base Chapter, July 2001, Andre T. Pavia, MD, University of Utah. <http://hivinsite.ucsf.edu>

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