

# Global Access Program FAQ Document

### Roche expands HIV Global Access Program to include EID testing

*Program expands access to care through special pricing* 

Roche recently launched the Global Access Program for HIV viral load testing which expands access to diagnostic testing. Roche supports the UNAIDS 90:90:90 goal and the Diagnostics Access Initiative by expanding access to testing through affordable pricing to those countries hardest hit by the disease. The Program, in partnership with UNAIDS, CHAI, PEPFAR, and the Global Fund on a new Global Access Program for HIV viral load testing was launched at the 69<sup>th</sup> UN General Assembly. Through this program, Roche is providing special access pricing on the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test version 2.0 for qualifying organizations in eligible countries.

In July 2015, during the 8<sup>th</sup> IAS Conference on HIV Pathogenesis, Treatment and Prevention in Vancouver, British Columbia, Canada, the announcement was made to expand the program to include early infant diagnosis

#### **Frequently Asked Questions**

#### What is the special pricing?

The access price is \$9.40/test including proprietary reagents and consumables. In countries where Roche operates via a distributor, an additional mark-up may apply.

## In countries where Roche operates via distributors what are the measures for price coherence and preventing adverse intermediation?

As with all companies, Roche is not allowed to impose end-customer pricing to distributors as this violates antitrust law. We may only recommend prices and are not allowed to take measures to make distributors adhere to these prices.

#### Is this a price per test or price per patient?

The price is inclusive of the Roche supplied controls but does not include any repeat testing that may be required if a run or sample should fail.



#### What exactly is included in the \$9.40?

For viral load testing

	KIT CAP-G/CTM HIV-1 V2.0 EXPT-IVD	
5212294190	(HIV VL)	48 Tests
3137082001	Tube-K Box of 12x96/Cob.TaqMan	96x 12racks
3587797190	KIT CAP-G/CTM WASH RGT 5.1L IVD	5.1L
3755525001	SPU	24x12racks
3137040001	Tube-S Box of 12x24/Cob.AmpliP	24x12racks
3287343001	Tip-K 1,2 mm ID Box of 12 x36	36x12racks

#### For early infant diagnosis testing

	KIT CAP-G/CTM HIV-1 Qual V2.0 EXPT-	
6693083190	IVD	48 Tests
6989861190	CAP/CTM specimen pre-extraction	
	diluent	5 x 78mL
3137082001	Tube-K Box of 12x96/Cob.TaqMan	96x 12racks
3587797190	KIT CAP-G/CTM WASH RGT 5.1L IVD	5.1L
3755525001	SPU	24x12racks
3137040001	Tube-S Box of 12x24/Cob.AmpliP	24x12racks
3287343001	Tip-K 1,2 mm ID Box of 12 x36	36x12racks

#### What is not included in the \$9.40 price?

The \$9.40 global access price is ex-works and does not include non-proprietary consumables and reagents (i.e., gloves, pipettes, lab coats, PBS) used in the testing lab; sample collection materials, including Dried Blood Spots (DBS) kits and EDTA tubes; machine leasing costs, service and maintenance for the platforms; or service and maintenance of third-party laboratory equipment. In countries where Roche operates via a distributor, an additional mark-up may apply.

#### What additional costs should a country expect to incur?

As mentioned above, the \$9.40 does not include any distributor costs. In addition the customer needs to purchase (or pay through reagent rental) for a COBAS<sup>®</sup> AmpliPrep Instrument and COBAS<sup>®</sup> TaqMan<sup>®</sup> Analyzer and the required service and maintenance contract.



#### Which customers are affected?

The access pricing will only be available to qualifying Government and NGO organizations in eligible countries. The list of countries and organizations is available on this website.

#### Does this affect current contracts?

The initiative is to enable scale up in countries where price has been a barrier. This pricing is not intended for current contracts, the pricing is intended to enable scale up.

#### Does this pricing include instruments and servicing?

No, the agreed pricing is for the test and consumables, instruments and servicing are excluded.

#### Has there been an agreement on special prices for instrument sales as well?

Pricing for the instruments, training, service and support that will be required for implementation has not been discussed. Due to variable local conditions this will have to be addressed at a country level.

#### How does this affect reagent rental agreements?

The price is for reagents and consumables only and so the instrument portion would need to be in addition to this. How that is applied will be subject to the local sales organizations.

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