



Enhancing the science in the global fight to end HIV

Bringing the world closer to realizing the 95-95-95 targets

A major goal of the United Nations' effort to address the world HIV epidemic is the UNAIDS 95-95-95 target: by the year 2030, 95% of all people living with HIV will know their HIV status; 95% of all people with a diagnosed HIV infection will receive sustained antiretroviral therapy; and 95% of all people receiving antiretroviral therapy will have viral suppression.

This 95-95-95 target is helping to drive improved access to antiretroviral drugs (ARVs) in resource-limited settings, and thus drive the need for more widespread drug-resistance surveillance testing. To help meet this global need, the Applied Biosystems™ HIV-1 Genotyping Kit with Integrase harnesses gold-standard Sanger sequencing technology to amplify and reliably sequence RNA from the diverse and rapidly evolving HIV-1 virus.

The kit enables reliable genotyping of HIV-1 from human EDTA plasma and dried blood spot (DBS) samples to detect resistance to protease, nucleoside reverse-transcriptase, non-nucleoside reverse-transcriptase, and integrase inhibitors.

Broader subtype coverage

- Unlike older legacy Sanger sequencing-based methods, this kit detects mutations in HIV-1 subtypes A, B, C, D, F, G, CRF01_AE, CRF02_AG, and CRF06_cpx
- Focused detection on consensus drug resistance mutations (DRMs) in the protease and reverse transcriptase (PR/RT) and integrase (IN) regions of the HIV-1 *pol* gene
- Generates genotyping results for EDTA plasma and DBS samples

Efficient and scalable workflow

- Lot-to-lot consistency
- Premixed reagents to minimize pipetting steps
- Total run time of about 20 hours for processing 16 samples from extracted viral RNA to results
- Total hands-on time of approximately 4.5 hours

A trusted assay developed and manufactured by a trusted partner

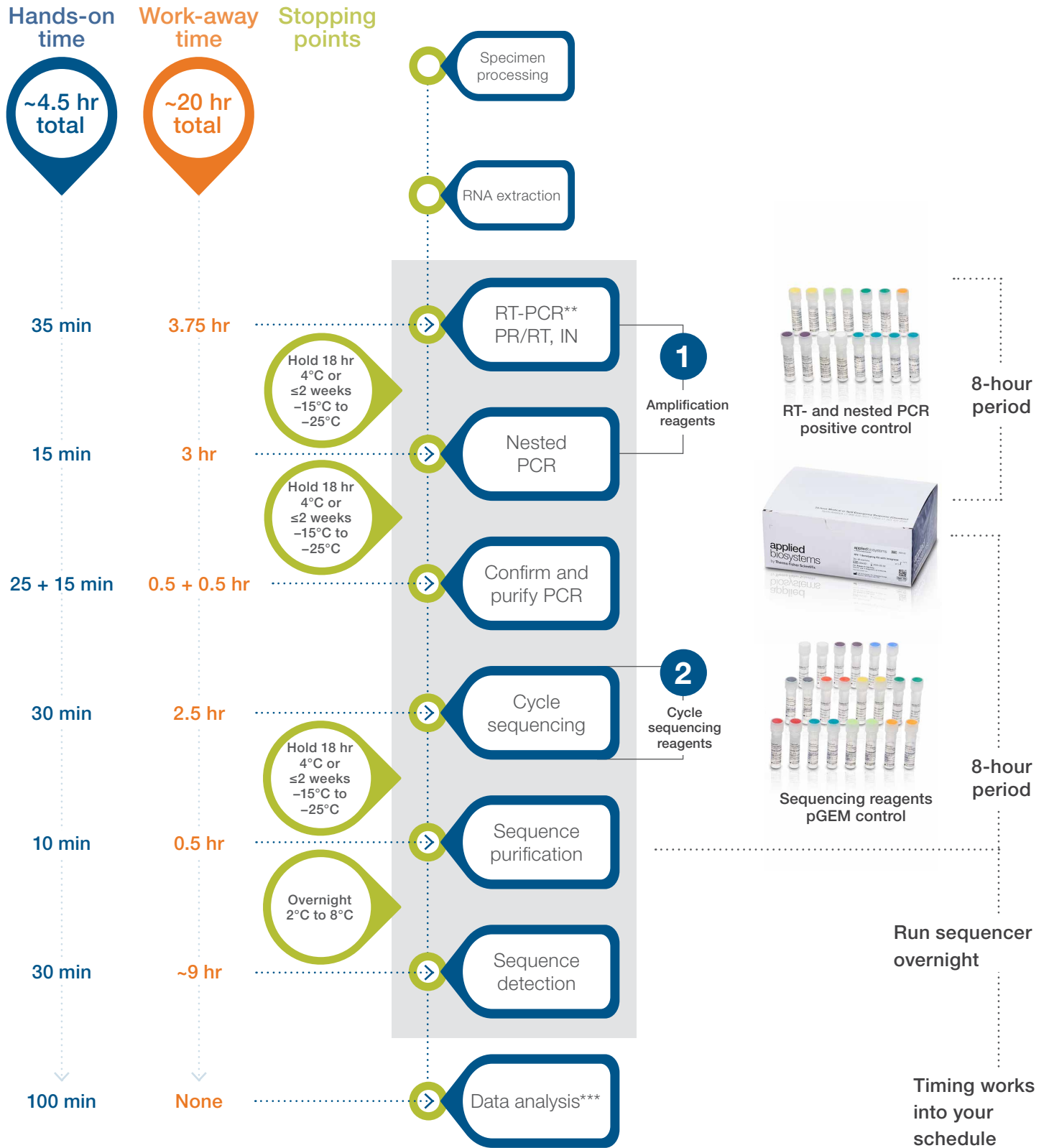
- Improved Applied Biosystems™ assay workflow, developed by Thermo Fisher Scientific in collaboration with the US Centers for Disease Control and Prevention (CDC)

New HIV-1 Genotyping Kit with Integrase workflow

Assumption: 16 extracted HIV-1 RNA samples* +

2 positive controls + 2 vector control samples from RT-PCR through CE

→ 2 full 96-well plates for the Applied Biosystems™ 3500xL instrument to run overnight



* RNA extraction can be performed using the Applied Biosystems™ MagMAX™ Viral/Pathogen Nucleic Acid Isolation Kit for HIV-1 Dried Blood Spots.

** Sample is split for PR/RT and IN testing at RT-PCR stage.

*** Easy-to-read sequencing results with free access to Exatype™ software for assembly and interpretation.

Enabling solutions to follow WHO testing recommendations

The World Health Organization (WHO) recommends that HIV drug resistance prevention, monitoring, and response be integrated into every national HIV program and into routine cascade data review activities.* With the adoption of integrase inhibitor treatment, monitoring of drug resistance is critical to establish a baseline and to proactively prevent unnecessary emergence and transmission of HIV.

* From "Consolidated HIV strategic information guidelines: driving impact through program monitoring and management", WHO, April 2020

The HIV-1 Genotyping Kit with Integrase helps to address the needs of resource-limited settings

- Cost-effective assay
- Scalable workflow offering
- Easy-to-read sequencing results
- Free software for assembly and interpretation
- Ready-to-use reagents providing:
 - improved reproducibility performance lot-to-lot
 - improved agreement with peer laboratories on external quality assurance (EQA) and laboratory proficiency programs
 - enhanced laboratory efficiencies, offering time to focus on resistance surveillance or study test results



The HIV-1 Genotyping Kit with Integrase offers broad sample source and subtype coverage

Sample type	RNA extracted from EDTA plasma and dried blood spots**
Subtype coverage (HIV-1 Group M)	A, B, C, D, F, G, CRF01_AE, CRF02_AG, and CRF06_cpx
Analysis	Free access to Exatype analysis software

** DBS samples must be processed within 2 weeks of collection under ambient storage conditions.

HIV-1 Genotyping Kit with Integrase broad instrument solutions

For use with Applied Biosystems™ instruments:

For PCR thermal cycling:

Veriti™ 96-Well Thermal Cycler with 0.2 mL sample wells
 GeneAmp™ PCR System 9700 96-well
 ProFlex™ 96-Well PCR System with 0.2 mL sample wells

For DNA capillary electrophoresis sequencing:

3130 Series Genetic Analyzers
 3500 and 3500xL Series Genetic Analyzers
 3730 and 3730xl Series DNA Analyzers
 SeqStudio™ Flex Series Genetic Analyzers

Shipping and storage conditions

Shipping condition	Dry ice
Storage condition	-25°C to -15°C

Ordering information

Product	Quantity	Cat. No.
HIV-1 Genotyping Kit with Integrase: includes amplification and cycle sequencing modules	48 tests	A55120
Materials required but not provided in the kit		
BigDye XTerminator Purification Kit	100 preps	4376486
3500xL Genetic Analyzer 24-Capillary Array, 50 cm	1 array	4404689
3500 Genetic Analyzer 8-Capillary Array, 50 cm	1 array	4404685
POP-7 Polymer for 3500/SeqStudio Flex Series Genetic Analyzers	384 samples	4393708
	960 samples	4393714
Anode Buffer Container (ABC), for 3500/SeqStudio Flex Series Genetic Analyzers	4 pack	4393927
Cathode Buffer Container (CBC), for 3500/SeqStudio Flex Series Genetic Analyzers	4 pack	4408256
Conditioning Reagent, for 3500/SeqStudio Flex Series Genetic Analyzers	1 each	4393718
Septa Cathode Buffer Container, for 3500/SeqStudio Flex Series Genetic Analyzers	10 each	4410715
Septa for 96-Well Plates, for 3500/SeqStudio Flex Genetic Analyzers	20 each	4412614
E-Gel EX Agarose Gels, 2%	10 gels	G401002
	20 gels	G402002
FastRuler Middle Range DNA Ladder, ready-to-use	1,000 µL	SM1113
ExoSAP-IT PCR Product Cleanup Reagent	200 µL	78200.200.UL

If you have any questions, please email

HIV_genotypingcustomerinquiry@thermofisher.com

 For more information, contact your representative or go to [thermofisher.com/hivdr](https://www.thermofisher.com/hivdr)

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