

The trifecta to aid in targeted HIV treatment

Helping make state-of-the-art HIV drug resistance testing accessible to all

A major goal of the United Nations' effort to address the world HIV epidemic is the UNAIDS 95-95-95 target [1]: 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 drive improved access to antiretroviral drugs (ARVs) in resource-limited settings, and thus drive the need for more widespread drug-resistance surveillance and individual-level testing. To help meet this global need, the *in vitro* diagnostic (IVD) Applied Biosystems™ TaqPath™ Seq HIV-1 Genotyping Kit harnesses gold-standard Sanger sequencing technology to amplify and reliably sequence RNA from the diverse and rapidly evolving HIV-1 virus in a broad range of subtypes.

The kit enables reliable genotyping of HIV-1 from human EDTA plasma and dried blood spot (DBS) samples to detect genomic mutations in the protease, reverse transcriptase, and integrase regions of the *pol* gene as an aid in the monitoring and treatment of HIV-1-infected individuals.

Broader subtype coverage

- Unlike 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
- Detection focused 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

- The IVD kit enhances interlaboratory comparability of HIV-1 genotyping results
- Premixed reagents and optimized workflows improve laboratory operations and resource allocation
- Total run time of about 20 hours for processing 16 samples from extracted viral RNA to results with convenient stopping points per 8-hour period
- Total hands-on time of approximately 4.5 hours

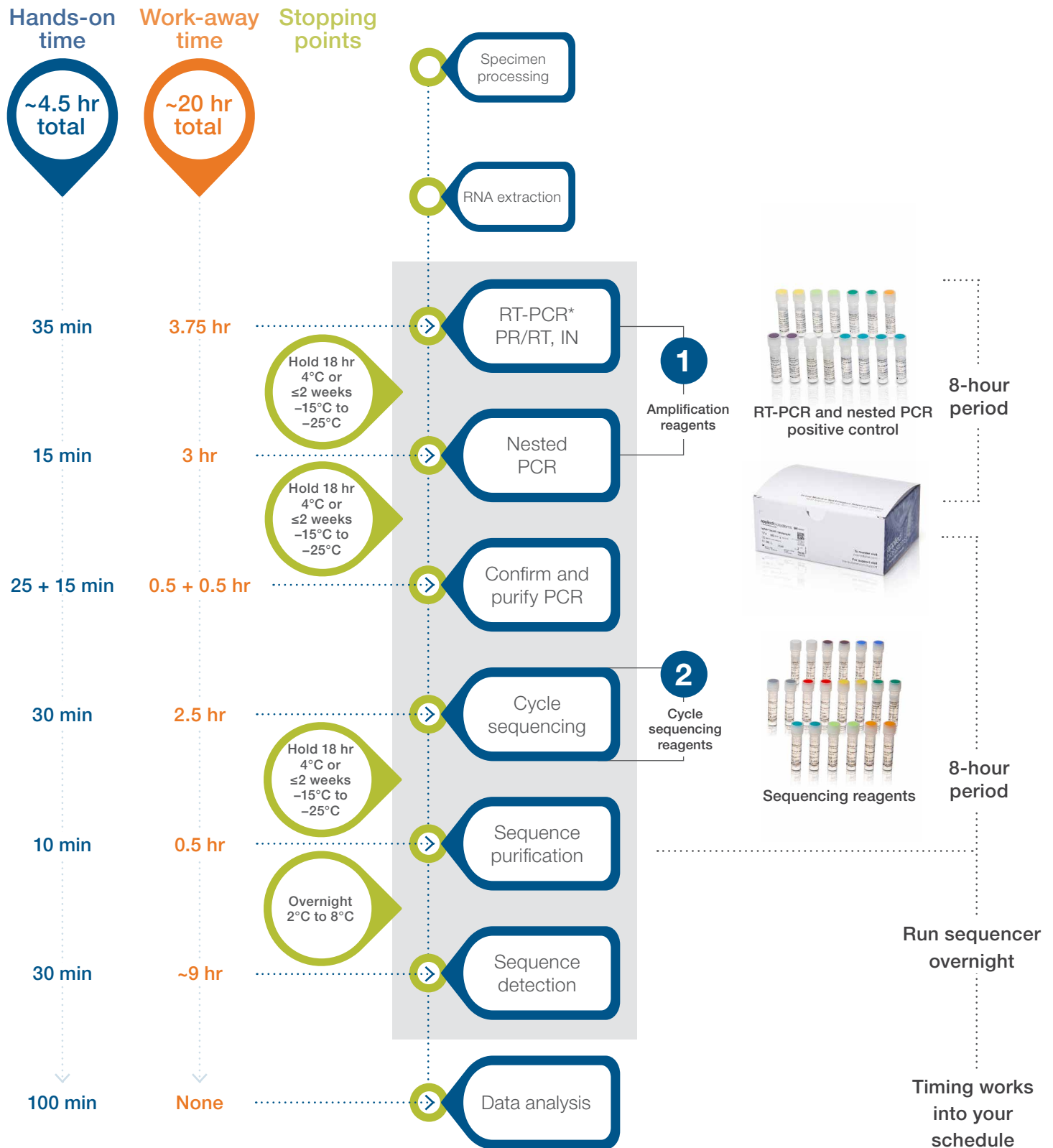
A trusted assay developed and manufactured by a trusted partner

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

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New TaqPath Seq HIV-1 Genotyping Kit

Scenario: 16 extracted HIV-1 RNA samples plus 2 positive controls from RT-PCR through capillary electrophoresis (CE) leads to the use of 2 full 96-well plates for the Applied Biosystems™ 3500xL instrument to run overnight.



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

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 [2]. 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.

* Testing for individual and patient management in low- and middle-income countries is limited to the availability of tests, adequate treatment options, and in-country expertise to interpret and utilize results.

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

The TaqPath Seq HIV-1 Genotyping Kit 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 individual-level test results



The TaqPath Seq HIV-1 Genotyping Kit offers broad coverage of sample source, subtype, and drug resistance mutations

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		
Coverage of drug resistance mutations of significance	See resources found at thermofisher.com/hivdr-ivd for more details		
Limit of detection (EDTA plasma, copies/mL)	Subtype A	Subtype B	Subtype C
	5,000	1,000	1,000

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

TaqPath Seq HIV-1 Genotyping Kit instrument solutions

For use with Applied Biosystems instruments:

For PCR thermal cycling:

- Veriti Dx 96-well Thermal Cycler, 0.2 mL
- Veriti 96-well Thermal Cycler, 0.2 mL
- GeneAmp PCR System 9700 Fast Thermal Cycler

For DNA CE sequencing:

- 3500 Dx and 3500xL Dx Genetic Analyzers
- 3500 and 3500xL Genetic Analyzers

Shipping and storage conditions

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

Ordering information

Product	Quantity	Cat. No.
TaqPath Seq HIV-1 Genotyping Kit (includes amplification and cycle sequencing modules)	48 tests	A54401
Materials required (not included in the kit)		
BigDye XTerminator Purification Kit, GPLR	100 preps	A55219
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	A55242

If you have any questions, please email
HIV_genotypingcustomerinquiry@thermofisher.com

 For more information, contact your representative or go to thermofisher.com/hivdr-ivd

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