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)

**Enhancing the science in the global fight to end HIV**

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

Hands-on time
~4.5 hr total

Work-away time
~20 hr total

Stopping points
Specimen processing
RNA extraction

35 min
3.75 hr
RT-PCR**
PR/RT, IN

15 min
3 hr
Nested PCR

25 + 15 min
0.5 + 0.5 hr
Confirm and purify PCR

30 min
2.5 hr
Cycle sequencing

10 min
0.5 hr
Sequence purification

30 min
~9 hr
Sequence detection

100 min
None
Data analysis***

* 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.
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

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

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

The 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

<table>
<thead>
<tr>
<th>Shipping condition</th>
<th>Dry ice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Storage condition</td>
<td>–25°C to –15°C</td>
</tr>
</tbody>
</table>
Ordering information

<table>
<thead>
<tr>
<th>Product</th>
<th>Quantity</th>
<th>Cat. No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV-1 Genotyping Kit with Integrase: includes amplification and cycle sequencing modules</td>
<td>48 tests</td>
<td>A55120</td>
</tr>
<tr>
<td>Materials required but not provided in the kit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BigDye XTerminator Purification Kit</td>
<td>100 preps</td>
<td>4376486</td>
</tr>
<tr>
<td>3500xL Genetic Analyzer 24-Capillary Array, 50 cm</td>
<td>1 array</td>
<td>4404689</td>
</tr>
<tr>
<td>3500 Genetic Analyzer 8-Capillary Array, 50 cm</td>
<td>1 array</td>
<td>4404685</td>
</tr>
<tr>
<td>POP-7 Polymer for 3500/SeqStudio Flex Series Genetic Analyzers</td>
<td>384 samples 960 samples</td>
<td>4393708 4393714</td>
</tr>
<tr>
<td>Anode Buffer Container (ABC), for 3500/SeqStudio Flex Series Genetic Analyzers</td>
<td>4 pack</td>
<td>4393927</td>
</tr>
<tr>
<td>Cathode Buffer Container (CBC), for 3500/SeqStudio Flex Series Genetic Analyzers</td>
<td>4 pack</td>
<td>4408256</td>
</tr>
<tr>
<td>Conditioning Reagent, for 3500/SeqStudio Flex Series Genetic Analyzers</td>
<td>1 each</td>
<td>4393718</td>
</tr>
<tr>
<td>Septa Cathode Buffer Container, for 3500/SeqStudio Flex Series Genetic Analyzers</td>
<td>10 each</td>
<td>4410715</td>
</tr>
<tr>
<td>Septa for 96-Well Plates, for 3500/SeqStudio Flex Genetic Analyzers</td>
<td>20 each</td>
<td>4412614</td>
</tr>
<tr>
<td>E-Gel EX Agarose Gels, 2%</td>
<td>10 gels</td>
<td>4401002</td>
</tr>
<tr>
<td>FastRuler Middle Range DNA Ladder, ready-to-use</td>
<td>20 gels</td>
<td>4402002</td>
</tr>
<tr>
<td>ExoSAP-IT PCR Product Cleanup Reagent</td>
<td>1,000 µL</td>
<td>SM1113</td>
</tr>
<tr>
<td></td>
<td>200 µL</td>
<td>78200.200.UL</td>
</tr>
</tbody>
</table>

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

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

For Research Use Only. Not for use in diagnostic procedures. © 2022 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified. pGEM is a trademark of Promega Corp. Exatype is a trademark of Hyrax Biosciences. COL021762 1122