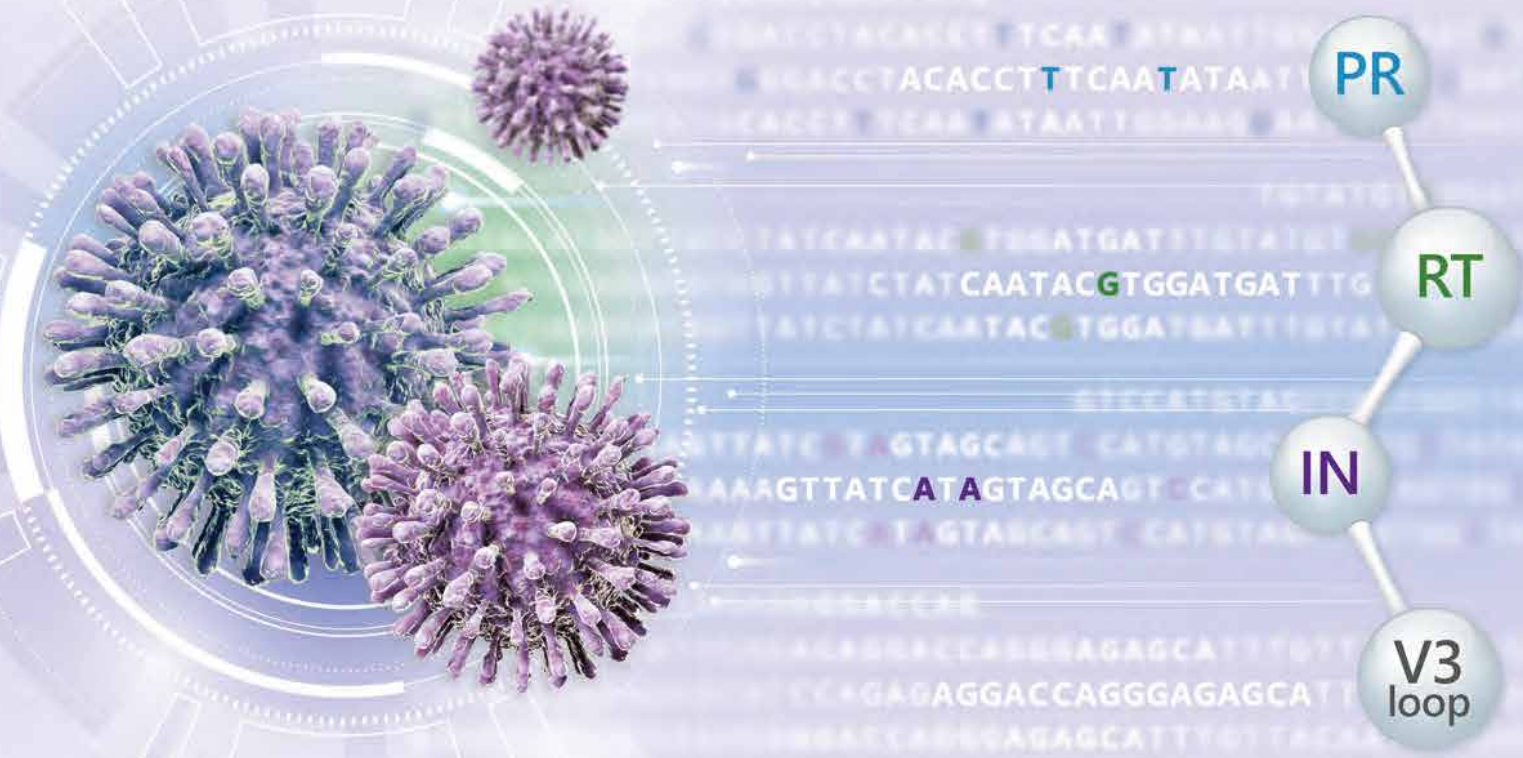
ARROW DIAGNOSTICS



CE IVD

HIV-1

Solution **v2**

Rev. 01/2022

ADX SEQ®

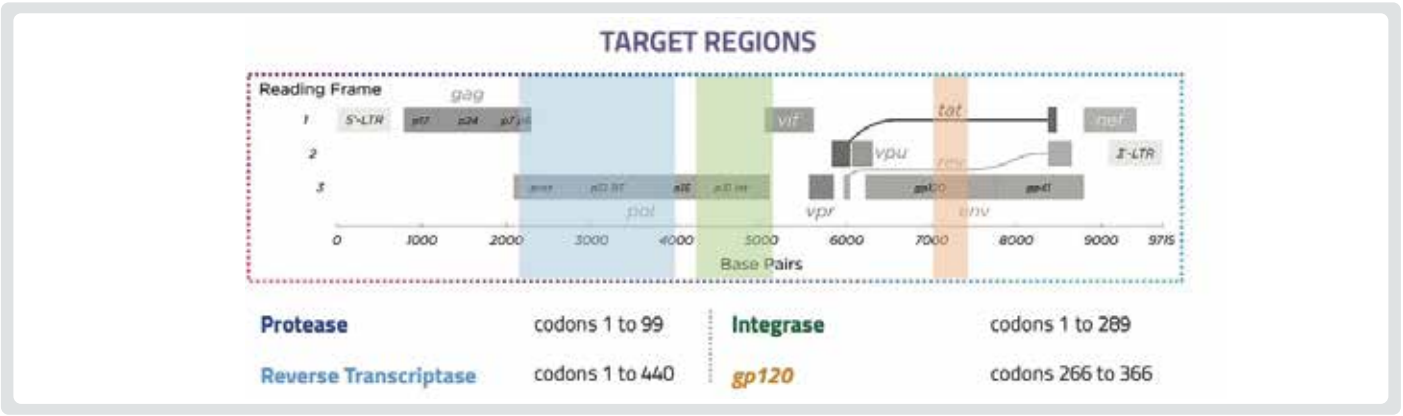
HIV-1 SOLUTION v2

Clinical Relevance

Antiretroviral therapy is subject to continuous changes and improvements, such that people currently treated for HIV-1 live longer and have a better quality of life. The HIV-1 virus can replicate very quickly in the individual and, during the replication process, can introduce several mutations that increase the ability to replicate, even during treatments with antiretroviral drugs, against which the virus may acquire resistance. In the clinical context, the availability of a standardised test for resistance to HIV-1 drugs genotyping and evaluation is crucial for the success of pharmacological treatments.
Having a standardised test for genotyping and evaluation of drug resistance in the clinical setting is of fundamental importance for the success of the patient's treatment by promoting the objectives of anti-HIV-1 therapy whose aim is to increase the quality of life of the individual by lowering the viral load for as long as possible, protect or promote the recovery of the immune system and reducing the occurrence of diseases related to immunosuppression.

Intended Use

The HIV-1 Solution v2 kit is a qualitative *in vitro* device based on the amplification by RT-PCR of viral RNA regions (Protease, Reverse Transcriptase, Integrase and gp120) followed by sequencing in Next Generation Sequencing (NGS) for virus genotyping and HIV-1 Drug Resistance (HIVDR) detection in samples of human plasma/serum. This product can be used as an aid to diagnosis in the ART therapy and in patient follow-up after the treatment.



Sample Type

- Plasma
- Serum

... of HIV-1 positive patients

NGS Instruments

- Illumina® MiSeq™
- Illumina® iSeq™ 100

Performance Features

- Library preparation within 8 hours
- Viral copy input: > 500 cp/ml
- HIV-1 Drug Resistance detection
- HIV-1 Genotyping (including CRFs)
- HIV-1 Tropism (gp120)
- Data analysis can be performed with dedicated software (developed by SmartSeq S.r.l.)

RNA Extraction – Validated Methods

- QIAamp® UltraSens Virus Kit (Qiagen)
- NUCLISENS® easyMAG (Biomérieux)
- EZ1® Virus Mini Kit 2.0 (Qiagen)
- Any other extraction method available in the laboratory can be used after validation.

Workflow Overview

15 MIN — "setup" (hands on time)

- ✓ HIV-1 genomic RNA extraction

80 MIN — Target PCR

- ✓ **Amplification by One-Step PCR of genomic target regions**
  (Protease, Reverse Transcriptase, Integrase, gp120)

35 MIN — "setup" (hands on time)

- ✓ **Quality Control of Target PCR products**
  (e.g. agarose gel electrophoresis or digital alternative)
- ✓ **Purification of Target PCR products using AMPure® XP beads**

30 MIN — Index PCR

- ✓ **Barcoding of samples via individual indices**
  (up to 96 different barcodes available)

60 MIN — Purification & Pool Normalization

- ✓ **Purification of Index PCR products using AMPure® XP beads**
- ✓ **Quality Control of purified Index PCR products**
  (e.g. agarose gel electrophoresis or digital alternative)
- ✓ **Quantification of purified Index PCR products**
  (e.g. via Qubit™ fluorometer or similar method)
- ✓ **Normalization and pooling of the library**

Up to 24 hours — NGS Sequencing

- ✓ **Illumina® MiSeq™**
- ✓ **Illumina® iSeq™100**

Data Analysis

- ✓ **SmartVir software (developed by SmartSeq s.r.l.)**
  (recommended software for data analysis)

We recommend evaluating any data obtained by always referring to a patient's clinical history and other diagnostic information available to best interpret the results of the HIV-1 drug resistance mutations identified. The patient's medical history and other diagnostic information may be very useful when reporting mutations that are considered questionable for the clinician.

Performance Features

- Sequencing of 4 genomic target regions in a single reaction (Protease, Reverse Transcriptase, Integrase, gp120)
- Library preparation within 8 hours
- Viral copy input: > 500 cp/ml
- HIV-1 Drug Resistance detection
- HIV-1 Subtyping (including CRFs)
- HIV-1 Tropism (gp120)
- Data analysis can be performed with dedicated software (develoed by SmartSeq S.r.l.)

Sequencing Information

Illumina® Kit	Number of samples	Sequencing time (Illumina® Official Data)
MiSeq™ Reagent Nano Kit v2 (500 cycles) - cod: MS-103-1003	8	~ 28 h
MiSeq™ Reagent Kit v2 (500 cycles) - cod: MS-102-2003	96	~ 39 h
iSeq™ 100 i1 Reagent (300 cycles) - cod: 20031371	16	~ 17 h

Ordering Information

			Cat. No.
AD4SEQ	HIV-1 Solution v2	32 rxns	AD-003.032

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