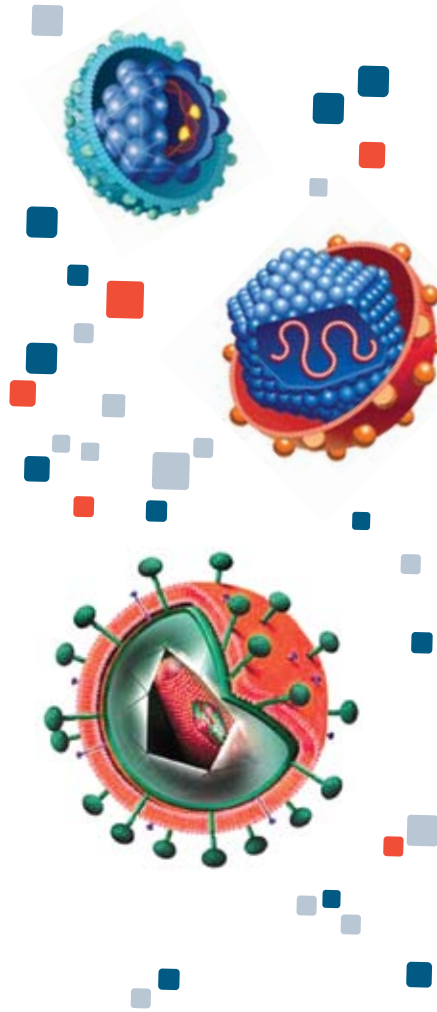


Amplisens

biotechnologies



 **InterLabService**

InterLabService (ILS) presents AmpliSens® PCR and Real-Time PCR kits developed and produced by Russian Central Research Institute for Epidemiology

Key features:

- wide range of pathogen detection
- high specificity and sensitivity
- ready-to-use reagents
- cost-effectiveness

MULTIPLEX

AmpliSens® MultiPrime Real-Time PCR kit

HCV/HBV/HIV Testing of donated blood

- Simultaneous detection of HCV, HBV, HIV-1, and HIV-2
- Enhanced sensitivity compared to serological analysis
- Testing of both individual samples and mini-pools
- Possibility of usage in PCR workflow automation
- Compatibility with various nucleic acid extraction solutions



«AmpliSens® HCV/HBV/HIV-FL» Real-Time PCR kit



is intended for simultaneous detection of **hepatitis C virus RNA (HCV)**, **hepatitis B virus DNA (HBV)**, **human immunodeficiency virus type 1 RNA (HIV-1)** and **type 2 RNA (HIV-2)** in blood samples by Real-Time PCR.

«AmpliSens® HCV/HBV/HIV-FL» was developed by the Russian Central Research Institute for Epidemiology to provide safety control tests during blood transfusions, transplantations, and preparation of blood products. Investigation of plasma samples combined into mini-pools is also admissible.

Options for automation

- **Real-Time PCR** provides direct detection of viral RNA/ DNA;
- **Plasma samples or their pools** are recommended for analysis. Serum, blood components, biopsy samples, etc. can also be used;
- **Extraction** is performed **from large volume of clinical samples (up to 1 ml)** to ensure maximal sensitivity of the test;
- **Analysis** is conducted **in one tube**, targets are independently detected in five or four channels (with or without HIV-2, correspondingly)

HCV RNA ● Green HIV-1 RNA ● Yellow
HBV DNA ● Orange HIV-1 RNA ● Crimson
Exogenous internal control ● Red

Testing of blood - two approaches:

- **consequent:**
PCR analysis is performed only for samples determined as negative in ELISA.
cost-effective
time-consuming
- **parallel:**
PCR and ELISA are performed for all plasma samples.
comprehensive
expensive

Soft-hardware complex for testing of donated blood



Plasma Pooling

«AmpliSens HCV/HBV/HIV®-FL» reagent kit can be used for analysis of individual samples as well as for several plasma samples combined into a mini-pool. Plasma pooling allows reducing price of analysis and increasing laboratory throughput.

Number of plasma samples recommended for mini-pools is 4-10 with total volume of 1000 µl.

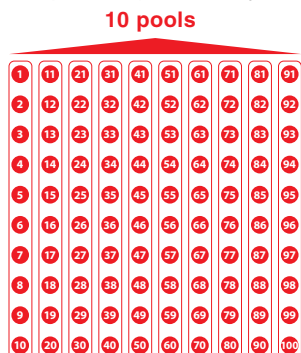
Plasma pooling techniques:

Single pooling – every single sample is a part of only one pool.

100 samples = 10 pools

This way of pooling is recommended if:

- frequency of positive samples in PCR analysis is less than 1% (applicable if samples are negative in ELISA);
- there is no need to decode mini-pools promptly



Double pooling (matrix pooling) – every single sample is a part of 2 pools.

100 samples = 20 pools

This way of pooling is recommended if:

- frequency of positive results after PCR analysis is $\geq 1\%$ (PCR analysis is done in parallel to ELISA);
- there is a necessity in fast decoding of positive mini-pools



Nucleic Acid Extraction

Methods recommended for nucleic acid extraction from blood plasma

Manual methods:

- RIBO-prep – precipitation method (from 100 µl);
- RIBO-sorb – sorbent method (from 100 µl);
- MAGNO-sorb – magnetic bead-based method (from 200 or 1000 µl).

Semi-automatic methods:

- «NucliSENS® easyMAG» workstation («bioMérieux», France) with use of reagent kit EM-plus (from 100-1000 µl).

Automatic methods:

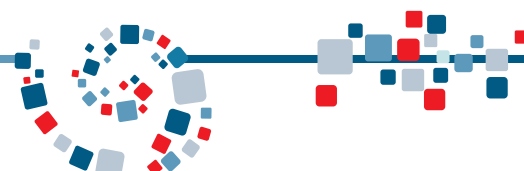
- Neon 100-1-4 workstation (Xiril, Switzerland) for pooling and QIASymphony SP/AS (QIAGEN, Germany) for nucleic acid extraction and sample preparation for PCR.

Sensitivity

Extraction volume, µl	Extraction method	Analytical sensitivity (detection in a pool*)			
		HCV, IU/ml	HBV, IU/ml	HIV-1, copies/ml	HIV-2**, copies/ml
100	RIBO-prep RIBO-sorb «NucliSENS® easyMAG» + EM-plus	100	50	200	600
200	MAGNO-sorb	50	25	100	300
1000	MAGNO-sorb «NucliSENS® easyMAG» + EM-plus QIASymphony Virus/Bacteria Midi Kit	10	5	20	60

*Sensitivity for individual samples is multiply dependent on dilution during pooling

**Reagent kits: Cat.No TR-V62-Ms and R-V62(RG,Dt)



Advantages of «AmpliSens® HCV/HBV/HIV-FL» Real-Time PCR kit

- Multiplex reaction in one tube saves time and costs
- Analytical sensitivity and specificity correspond to the highest worldwide standards
- Mini-pools (up to 10 samples in each pool) can be tested along with individual samples
- Combination of reverse transcription and amplification reactions simplifies the protocol and reduces number of possible mistakes
- Automatic or manual extraction from 1000 µl of blood plasma ensures maximal sensitivity
- Test reveals infected persons even if ELISA-results are negative and serve as confirming investigation for ELISA-positive samples
- Protected RNA extraction controls and DNA amplification controls allow monitoring of every step of analysis
- Automated soft-hardware complex was developed to analyze samples and interpret results
- Real-Time PCR kit was approved in state trials and evaluated at large blood transfusion stations and transplantation centers

Ordering Information

Cat. №	Name	Description
TR-V62-Ms (RG,Dt)-CE	«AmpliSens® HCV/HBV/HIV-FL»	Detection of Hepatitis C (HCV) RNA, B (HBV) DNA, HIV-I RNA, and HIV-II RNA (5 optical channels are required). Complete set of kits (nucleic acid extraction kit «MAGNO-sorb», reverse transcription and Real-Time PCR kits) for use with RG and Dt. 100 tests
R-V62(RG,Dt)-CE	«AmpliSens® HCV/HBV/HIV-FL»	Detection of Hepatitis C (HCV) RNA, B (HBV) DNA, HIV-I RNA, and HIV-II RNA (5 optical channels are required). Reverse transcription and Real-Time PCR kits for use with RG and Dt. Kits are recommended for RNA/DNA extraction: MAGNO-sorb variant 1000, reagents for «NucliSENS® easyMAG» (+ reagent set EM-plus), RIBO-prep, RIBO-sorb. 100 tests
R-V50-4x (RG,iQ,Mx,Dt)-CE	«AmpliSens® HCV/HBV/HIV-FL»	Detection of Hepatitis C (HCV) RNA, B (HBV) DNA, and HIV-I RNA (4 optical channels are required). Reverse transcription and Real-Time PCR kits for use with RG, iQ, Mx, and Dt. Kits are recommended for RNA/DNA extraction: MAGNO-sorb variant 1000, reagents for «NucliSENS® easyMAG» (+ reagent set EM-plus), RIBO-prep, RIBO-sorb. 100 tests
K2-16-1000-CE	MAGNO-sorb	Kit for DNA/RNA extraction from 1000 µl of human plasma and blood serum. Magnetic bead-based method. For manual or automated extraction using Neon 100-1-8 (Xiril's Robotic Workstation). 100 tests
K2-16-200-CE	MAGNO-sorb	Kit for DNA/RNA extraction from 200 µl of human plasma and blood serum. Magnetic bead-based method. For manual or automated extraction using Neon 100-1-8 (Xiril's Robotic Workstation). 100 tests
K2-9-Et-100-CE	RIBO-prep	Kit for RNA/DNA extraction from blood plasma, liquor, saliva, amniotic fluid, and swabs. Precipitation method. 100 tests
K2-1-Et-100-CE	RIBO-sorb	Kit for RNA/DNA extraction, universal. Silica sorbtion method. 100 tests
K2-15-96-CE	EM-plus	Additional reagent kit for RNA/DNA extraction on automatic station «NucliSENS® easyMAG» with use of «AmpliSens® HCV/HBV/HIV-FL». 100 tests