

APTIMA® HIV-1 and HCV Auto Detect Reagents

For *in vitro* diagnostic use.

500 test kit.

Intended Use

The APTIMA® HIV-1 and HCV Auto Detect Reagents are to be used with the APTIMA® HIV-1 RNA Qualitative and APTIMA® HCV RNA Qualitative Assays.

Summary and Explanation of the Test

The APTIMA HIV-1 and HCV Auto Detect Reagents are used in the APTIMA HIV-1 RNA Qualitative and APTIMA HCV RNA Qualitative Assays. A detailed description of their use is given in the appropriate APTIMA Assay package insert.

Warnings and Precautions

- A. For *in vitro* diagnostic use.
- B. Use routine laboratory precautions. Do not pipette by mouth; do not eat, drink, or smoke in the laboratory work area. Wash hands thoroughly after handling APTIMA HIV-1 and HCV Auto Detect Reagents.
- C. Avoid microbial and ribonuclease contamination of APTIMA HIV-1 and HCV Auto Detect Reagents.
- D. Do not combine any reagents or fluids without specific instructions.
- E. Avoid contact of APTIMA HIV-1 and HCV Auto Detect Reagents with skin, eyes, and mucous membranes. Wash with water if contact with these reagents occurs. If spills of these reagents occur, dilute with water before wiping dry and follow appropriate site procedures.
- F. Some reagents of this kit are labeled with risk and safety symbols according to the European Directive 1999/45/EC and should be handled accordingly.

Material Safety Data Sheets are available upon request.

The following reagent contains 6% sodium hydroxide:

Auto Detect 2



C. Corrosive

R35 S1/2 S26
S37/39 S45

- | | |
|--------|---|
| R35 | Causes serious corrosions |
| S1/2 | Keep in a locked place and out of reach of children |
| S26 | In case of contact with eyes, rinse immediately with plenty of water and seek medical advice |
| S37/39 | Wear suitable gloves and eye/face protection |
| S45 | In case of accident or sickness, seek medical advice immediately and show this container or label |

Storage and Handling Requirements

The APTIMA HIV-1 and HCV Auto Detect Reagents are stable when stored unopened at room temperature (15°C to 30°C) until the expiration date. Do not use after expiration date.

Materials Provided

APTIMA HIV-1 and HCV Auto Detect Reagents - Cat. No. 2162

Symbol	Component	Quantity	Description	Storage
R1	Auto Detect 1	1 x 240 mL	Aqueous solution containing hydrogen peroxide and nitric acid	15°C to 30°C
R2	Auto Detect 2	1 x 240 mL	1.6 N sodium hydroxide	15°C to 30°C

Materials Required, Sold Separately

APTIMA HIV-1 RNA Qualitative Assay

APTIMA HCV RNA Qualitative Assay

For testing protocols, refer to the appropriate APTIMA Assay package insert.

Reagent Preparation

Once opened, the APTIMA HIV-1 and HCV Auto Detect Reagents are stable for 30 days when stored at room temperature. Record the date the reagent was first opened (OPEN DATE) in the space provided on the label.

Procedure

The APTIMA HIV-1 and HCV Auto Detect Reagents may be used with the APTIMA HIV-1 RNA Qualitative Assay or the APTIMA HCV RNA Qualitative Assay. A detailed description of their use is given in the appropriate APTIMA Assay package insert.

Interpretation of Results

Failure to achieve expected results, as described in the appropriate APTIMA Assay package insert, is an indication of an invalid run. Possible sources of error include test kit deterioration, operator error, faulty performance of equipment, specimen deterioration, or contamination of reagents.

Limitations of the Procedure

Assays must be performed, and results interpreted according to the instructions provided in the appropriate APTIMA Assay package insert.

Deviations from these procedures may produce unreliable results. Use of outdated APTIMA HIV-1 and HCV Auto Detect Reagents may produce erroneous results.

Expected Results

Please reference the *Quality Control Procedures* and *Interpretation of Results* sections of the appropriate APTIMA Assay package insert for expected results.



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