Aptima HIV-1 Proficiency Panel

For training purposes only.

These reagents must not be substituted for the mandatory positive and negative calibrator reagents provided with licensed test kits.

Intended Use

The Aptima HIV-1 Proficiency Panel is to be used for assessing proficiency in laboratory testing procedures (1). The panel is formulated for use with the Aptima HIV-1 RNA Qualitative Assay and no other HIV-1 assay.

Summary and Explanation of the Test

Establishing and monitoring operator performance in test procedures is a key component of laboratory training and quality assurance programs. Proper use of test panels can assist laboratories in improving the quality and proficiency of routine testing. This single use panel is labeled for use in a masked fashion, as deemed appropriate by laboratory management.

Warnings and Precautions

A. For training purposes only.

B. **CAUTION: The members of this panel contain human blood products. The HIV-1 Positive Panel Members in this kit contain human plasma that is HIV-1 RNA positive and have been heat-treated to inactivate the virus. The Negative Panel Members have been assayed by FDA licensed tests and found non-reactive for the presence of hepatitis B surface antigen (HBsAg), HIV-1 p24Ag and antibodies to HIV-1, HIV-2 and HCV. No known test method can offer complete assurance that products derived from human blood will not transmit infectious agents. All human blood sourced materials should be considered potentially infectious and should be handled with Universal Precautions (2, 3).** If spillage occurs, immediately disinfect, then wipe up with a 0.5% (final concentration) sodium hypochlorite solution (diluted bleach) or follow appropriate site procedures.

C. Use Universal Precautions when handling panel members and materials that come in contact with the panel members. Proper handling and disposal methods should be established according to local, state and federal regulations. Only personnel trained in the use of the Aptima HIV-1 RNA Qualitative Assay and in handling infectious materials should perform this type of diagnostic procedure.

D. Each panel member is designed for a single use. Excess material in each vial is to be appropriately discarded.

E. This product contains sodium azide as a preservative. Do not use metal tubing for reagent transfers. If solutions containing azide compounds are disposed of in a plumbing system, they should be diluted and flushed with generous amounts of running water. These precautions are recommended to avoid accumulation of deposits in metal piping in which explosive conditions could develop.

F. Use routine laboratory precautions. Do not pipette by mouth; do not eat, drink or smoke in the laboratory work area. Wear disposable gloves and laboratory coats when handling panel members. Wash hands thoroughly after handling panel members.

G. Avoid microbial and ribonuclease contamination of panel members. Use of filtered, disposable pipette tips is strongly recommended.

H. Reagents in this kit are labeled with risk and safety symbols according to the European Directive 1999/45/EC and should be handled accordingly.

Materials Provided

Note: For information on any hazard and precautionary statements that may be associated with reagents, refer to the Safety Data Sheet Library at www.hologic.com/sds.

Aptima HIV-1 Proficiency Panel - Cat. No. 2160

Component	Quantity	Description	Storage
HIV-1 Positive Panel Members	63 x 1 mL	Inactivated HIV-1 RNA positive plasma in defibrinated normal human plasma, nonreactive for hepatitis B surface antigen (HBsAg), and antibodies to human hepatitis C virus (anti-HCV) when tested by FDA-licensed assays, containing gentamicin and 0.2% sodium azide as preservatives	-15°C to -35°C
Negative Panel Members	27 x 1 mL	Defibrinated normal human plasma, nonreactive for hepatitis B surface antigen (HBsAg), HIV-1 p24Ag, antibodies to human immunodeficiency virus type 1 (anti-HIV-1) and type 2 (anti-HIV-2), and antibodies to human hepatitis C virus (anti-HCV) when tested by FDA-licensed assays, containing gentamicin and 0.2% sodium azide as preservatives	-15°C to -35°C

Materials Required, Sold Separately

Aptima HIV-1 RNA Qualitative Assay

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

Storage and Handling Requirements

The panel members are stable when stored unopened at -15°C to -35°C until the expiration date. Do not use after expiration date.

Reagent Preparation

Thaw panel members at room temperature (15°C to 30°C) and mix thoroughly by gentle inversion. Once thawed, use panel members within 4 hours, treating them as samples following the procedures from the Aptima HIV-1 RNA Qualitative Assay package insert.

Procedure

Any lot of Aptima HIV-1 Positive Panel Members or Negative Panel Members may be used with any master lot of Aptima HIV-1 RNA Qualitative Assay reagents.

The Aptima HIV-1 Proficiency Panel is for use with the Aptima HIV-1 RNA Qualitative Assay. For testing protocols, refer to the Aptima HIV-1 RNA Qualitative Assay package insert.

Instructions for Use

The Aptima HIV-1 Proficiency Panel members are provided as single use vials. These panel members may be included as samples in a Aptima HIV-1 RNA Qualitative Assay run according to the Aptima HIV-1 RNA Qualitative Assay package insert.

Quality Control

Since the Aptima HIV-1 Proficiency Panel members do not have assigned values, it is recommended that each laboratory run the Aptima HIV-1 Proficiency Panel in their Aptima HIV-1 Assay system and obtain the expected results prior to routine use.

Interpretation of Results

The Aptima HIV-1 Proficiency Panel members do not have assigned values.

Laboratories must use statistically valid methods to determine whether proficiency results are within acceptable limits. Failure to achieve the expected results listed below may be an indication of unsatisfactory test performance. Possible sources of error include operator error, faulty performance of equipment, or contamination of reagents.

Limitations of the Procedure

The Aptima HIV-1 Proficiency Panel must not be substituted for the mandatory positive and negative calibrator reagents provided with licensed test kits.

Assays must be performed, and results interpreted, according to the instructions provided in the Aptima HIV-1 RNA Qualitative Assay package insert. Deviations from these procedures may produce unreliable results.

The Aptima HIV-1 Proficiency Panel is provided for quality assurance purposes and must not be used for calibration or as a primary reference preparation in any test procedure. Adverse shipping and/or storage conditions or use of outdated panel members and/or reagents may produce erroneous results.

Specific Performance Characteristics

The Aptima HIV-1 Proficiency Panel has been extensively tested and found to reproducibly yield the expected results when tested in the Aptima HIV-1 RNA Qualitative Assay. Performance characteristics of the Aptima HIV-1 Proficiency Panel in assays other than the Aptima HIV-1 RNA Qualitative Assay have not been established.

The Aptima HIV-1 Proficiency Panel has been designed to produce the expected results (reactive/nonreactive) when used in the proper manner with the Aptima HIV-1 RNA Qualitative Assay following procedures supplied in the Aptima HIV-1 RNA Qualitative Assay package insert for testing unknown samples. It is recommended that each laboratory ensure that the expected results for the Proficiency Panel are obtained prior to routine testing. Procedures for implementing a quality assurance program and monitoring test performance on a routine basis must be established by each individual laboratory.

Expected Results

The expected results when tested in the Aptima HIV-1 RNA Qualitative Assay are listed below:

Panel Member	Expected Result	Quantity per Panel
A	Reactive (+)	1
B	Nonreactive (-)	3
C	Reactive (+)	2
D	Reactive (+)	2
E	Reactive (+)	2

Bibliography

1. **Green IV, G. A., R. N. Carey, J. O. Westgard, T. Carten, L. A. Shabesky, D. Achord, E. Page, and A. V. Le. 1997.** Quality control for qualitative assays: quantitative QC procedure designed to assure analytical quality required for an ELISA for hepatitis B surface antigen. Clin Chem **43**:9, 1618-1621.
2. CDC recommendations for prevention of HIV transmission in health care settings. 1987. MMWR 36 (supp. 2).
3. **29 CFR Part 1910.1030.** Occupational Exposure to Bloodborne Pathogens; Final Rule, Federal Register/ Vol. 56, No. 235/ December 6, 1991.

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