BIO-RAD

VIROTROL® II

REF **00104A** 1 x 5 mL
00104B 1 x 5 mL

CE 0459

IVD

ENGLISH

THESE REAGENTS MUST NOT BE SUBSTITUTED FOR THE MANDATORY POSITIVE AND NEGATIVE CONTROL REAGENTS PROVIDED WITH COMMERCIAL TEST KITS.

INTENDED USE

VIROTROL II is an unassayed positive control prepared from processed human plasma or serum and is intended for use with *in vitro* assay procedures for determination of antibodies to Hepatitis B Surface Antigen (anti-HBs) and qualitative assay procedures for determination of antibodies to Hepatitis A Virus (anti-HAV). This product is intended to provide a means of estimating precision and has the potential for detecting systematic deviations from specific laboratory testing procedures.

SUMMARY

Monitoring the performance of laboratory test procedures through use of a well-designed quality assurance program provides added confidence in the reliability of test results obtained for unknown specimens (1-2). Use of independent quality assurance control reagents provides a means for monitoring performance of laboratory procedures on a routine basis and analyzing system performance on a retrospective basis. Routine monitoring of test performance will assist the laboratorian in identifying random or systematic errors and detecting trends, biases or other problems as they occur. A laboratory's analyses can be compared with those of other laboratories or with its own prior analyses by routinely analyzing test samples that have been obtained from a large common pool. Inclusion of this product in every test run will provide the laboratory with a means of estimating precision and monitoring overall system performance on a run-to-run basis. Proper use of this product can assist laboratories in analyzing and identifying problems in a test run and improving the quality and proficiency of routine testing.

PRINCIPLES OF THE PROCEDURE

This product was designed for use with *in vitro* assay procedures for purposes of monitoring assay performance and maintaining quality assurance. This product is prepared from processed human plasma or serum and other human sourced proteins. Source materials have been chemically treated and processed to eliminate unwanted components and to ensure stability of the final product. Although this product DOES NOT HAVE ASSIGNED VALUES, each lot of material is designed to be reactive within a target range established by each laboratory with each lot of this product. This product should be analyzed in the same manner as unknown specimens according to instructions supplied by the manufacturer of the test kit being used.

REAGENT

This product is prepared from processed human plasma or serum reactive for antibodies to Hepatitis B Surface Antigen (anti-HBs) and antibodies to Hepatitis A Virus (anti-HAV), proteins from human sources, antimicrobial agents as preservative, and stabilizers. Human source materials reactive for anti-HBs markers have been treated to inactivate infectious agents (3).

STORAGE AND STABILITY

This product will be stable until the expiration date (printed on the bottle label) when stored unopened at 2 to 8°C. Once opened, this product will be stable for 60 days.

To prevent leakage or wetting of caps, the bottles should be stored upright. Plugs and screw caps should remain on bottles while in storage.

This product is shipped under ambient conditions.

PROCEDURE

1. This product may be included in a test run following the stepwise procedure provided by the test kit manufacturer for unknown specimens.
2. Prior to use, allow this product to reach room temperature.
3. Mix contents by gentle swirling or inversion prior to dispensing. Do not vortex or mix by vigorous shaking.
4. Avoid microbial contamination when opening and dispensing from the bottle.
5. Dispense this product from bottle using dropper tip. Do not remove dropper tip from bottle.
6. After each use return this product to refrigerated (2 to 8°C) storage.

Safety Precautions

1. Wear protective clothing and gloves when handling samples or reagents.
2. Clean any spillage by immediately and thoroughly wiping up with a suitable disinfectant such as 1% sodium hypochlorite solution.
3. Handle and dispose of all specimens, controls and materials used in testing as though they contain infectious agents (4-5).
4. Dispose of any discarded materials in accordance with the requirements of your local waste management authorities. In the event of damage to packaging, contact the local Bio-Rad Laboratories Sales Office or Bio-Rad Laboratories Technical Services.

INTERPRETATION OF RESULTS

It is recommended that each laboratory establish its own target ranges with each lot of this product. Target ranges may be established by performing replicate assays with this product using a statistically valid number of points. In order to minimize the risk of underestimating variability when establishing a target range, each laboratory should include replicate determinations from multiple test runs, multiple test kit lots and multiple operators whenever possible. Results from replicate determinations can be used by the laboratory to calculate basic statistical parameters such as mean and standard deviation from which an acceptable target range can then be established. Although individual values may not be identical to an established mean value, results obtained in the laboratory should fall within its target ranges. Results outside the range may be indicative of unsatisfactory test performance and should be investigated. Such discrepancies may be related to the following sources:

- Cross-contamination of this product with high titer specimen
- Cross-contamination of this product with non-reactive specimen or specimen diluent
- Improper equipment operation
- Deterioration or contamination of test kit reagents
- Variations in technique between different operators

Investigation and possible resolution of discrepant results may include, but should not necessarily be limited to, the following procedures:

- Verification of standardized handling techniques and proper use of this product
- Verification of proper use and handling of test kit reagents
- Retesting with a new bottle of this product
- Retesting with new test kit reagents
- Contacting the local Bio-Rad Laboratories Sales Office or Bio-Rad Laboratories Technical Services
- Contacting the manufacturer of the reagent test kit for technical support

LIMITATIONS

1. **THESE REAGENTS MUST NOT BE SUBSTITUTED FOR THE MANDATORY POSITIVE AND NEGATIVE CONTROL REAGENTS PROVIDED WITH COMMERCIAL TEST KITS.**
2. This product is provided for quality assurance purposes and must not be used for calibration or as primary reference preparations in any test procedure.
3. TEST RESULTS and INTERPRETATION OF RESULTS provided by manufacturers of commercial test kits must be followed closely when testing this product. Deviations from procedures recommended by reagent test kit manufacturers may produce unreliable results.
4. Since this product is prepared from processed human plasma or serum as well as other non-human derived constituents, incompatibilities between this product and test kits may exist on a manufacturer to manufacturer or a test kit lot to test kit lot basis. Accordingly, users should determine compatibility and performance with each new lot of test kit prior to testing specimens.
5. It is the responsibility of each laboratory to implement its own quality assurance program to determine the suitability of this product for its particular use and to establish guidelines for interpretation of results obtained with this product.
6. Since this product does not have assigned values, it is recommended that each laboratory validate the use of each lot of this product with each specific assay system prior to its routine use in the laboratory.
7. Adverse storage conditions or use of outdated reagents may produce erroneous results.
8. This product should not be used past the expiration date.
9. Alterations in physical appearance may indicate instability or deterioration of this product. If there is evidence of microbial contamination or excessive turbidity in this product, discard the bottle.

EXPECTED RESULTS

THIS PRODUCT DOES NOT HAVE ASSIGNED VALUES.

Test results using this product should be determined in the same manner as used for unknown specimens when tested using commercial test kits for detecting the presence of antibody to HBsAg and antibody to HAV.

Representative levels of reactivity in various commercially marketed test kits are presented in Table 1. Results in each data set were obtained by testing this product within a single location with a single lot of each test kit in multiple test runs (n) performed by multiple operators. THESE DATA ARE INTENDED TO BE REPRESENTATIVE OF TYPICAL TEST PROCEDURES. THEY ARE NOT INTENDED TO REPRESENT PERFORMANCE SPECIFICATIONS OF THIS PRODUCT IN ANY TEST PROCEDURE. Results may vary among methodologies, among manufacturers, among different lots of the same kit and among different laboratories. These values should be used only for information purposes and each laboratory must establish its own performance characteristics for this product.

SPECIFIC PERFORMANCE CHARACTERISTICS

This product has been designed to be reactive for antibodies to Hepatitis B Surface Antigen and antibodies to Hepatitis A Virus when used in the proper manner with many commercial test kits following procedures supplied by the reagent manufacturers for testing unknown specimens. However, levels of reactivity and specific performance characteristics will vary with different manufacturers' kits and assay procedures.

Performance characteristics of this product have not been established for quantitative or semi-quantitative procedures for the determination of antibodies to HAV.

REF	CE	IVD			EC REP			LOT	EXP	
Catalog Number	European Conformity	*In Vitro* Diagnostic Medical Device	Caution, Consult Accompanying Documents	Manufacturer	Authorized Representative	Consult Instructions for Use	Temperature Limitation	Lot Number	Use by (YYYY-MM-DD)	

2019-03 • 16000094 (Rev. 3)

WARNINGS AND PRECAUTIONS

WARNING

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Biological source material. Treat as potentially infectious.

Each human donor unit used in the preparation of this product was tested as required by FDA accepted methods. Tests results were non-reactive or negative for evidence of infection due to Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV). However, no known test method can assure that products derived from human sources will not transmit infection. It is recommended that this product and all human specimens be handled in accordance with Biosafety Level 2 practices as described in the United States Department of Health and Human Services Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH), Biosafety in Microbiological and Biomedical Laboratories (4), or other equivalent guidelines (5,6).

Hazard (H) and Precautionary (P) statements

Contains 5-chloro-2-methyl-2H-isothiazol-3-one

H317 May cause an allergic skin reaction. **P261** Avoid breathing dust / fume / gas / mist / vapours / spray. **P280** Wear protective gloves / protective clothing / eye protection / face protection. **P363** Wash contaminated clothing before reuse. **P272** Contaminated work clothing should not be allowed out of the workplace. **P302+P352** IF ON SKIN: Wash with plenty of soap and water. **P333+P313** If skin irritation or rash occurs: Get medical advice /attention.

Safety Data Sheet (SDS) available for professional users on *www.bio-rad.com*.

GLOSSARY

ANALYTES

Antibody to HAV (Anti-HAV)

Antibody to HBsAg (Anti-HBs)

TERMS

Absorbance (Abs)
Coefficient of Variation (CV)
Cutoff/Sample Mean (CO/S)

Manufacturer/Test Kit Method

Mean
Representative Reactivities

Sample Mean/Cutoff (S/CO)
Standard Deviation (SD)
Test Runs

REPRESENTATIVE REACTIVITIES

ENGLISH

THESE DATA ARE INTENDED TO BE REPRESENTATIVE OF TYPICAL TEST PROCEDURES. THEY ARE NOT INTENDED TO REPRESENT PERFORMANCE SPECIFICATIONS OF THIS PRODUCT IN ANY TEST PROCEDURE. Reactivity of this product in any other test procedures has not been established.

TABLE 1. REPRESENTATIVE REACTIVITIES

Antibody to HBsAg (Anti-HBs)					
Manufacturer / Test Kit Method	**Test Runs (n)**	**Mean**	**SD**	**% CV**	**Sample Mean / Cutoff (S/CO)**
Abbott ARCHITECT AUSAB	20	19.52 mIU/mL	1.06	5.5	
Ortho VITROS ECi Anti-HBs	24	15.7 mIU/mL	1.6	9.9	
DiaSorin ETI-AB-AUK PLUS	10	0.363 Abs	0.054	14.9	1.80
Antibody to HAV (Anti-HAV)					
Manufacturer / Test Kit Method	**Test Runs (n)**	**Mean**	**SD**	**% CV**	**Cutoff / Sample Mean (CO/S)**
Bio-Rad MONOLISA Anti-HAV EIA	4	0.124 Abs	0.017	13.7	4.49
					Sample Mean / Cutoff (S/CO)
DiaSorin ETI-AB-HAVK PLUS	10	0.281 Abs	0.054	19.2	0.338

REFERENCES

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5. Clinical and Laboratory Standards Institute (CLSI). Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline – Third Edition. CLSI document M29-A3 (ISBN 1-56238-567-4), Clinical and Laboratory Standards Institute Wayne, Pennsylvania 19087-1898, USA 2005.
6. Clinical and Laboratory Standards Institute (CLSI) Clinical Laboratory Waste Management; Approved Guideline Third Edition. CLSI document GP05-A3 (ISBN 1-56238-744-8), CLSI Wayne, Pennsylvania 19087, USA 2011.

ORDERING INFORMATION

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Reactivities may vary among manufacturers' instruments and assays, reagent lots, and different laboratory protocols. To determine which VIROTROL product best meets your individual needs, please contact your local Bio-Rad Laboratories sales office or representative.

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