

For research use only. Not for use in diagnostic procedures.

REF 950499 AcroMetrix EV Negative Control
950500 AcroMetrix EV Low Control

Product Use

The AcroMetrix™ EV Controls are intended for use in assessing the performance of nucleic acid test procedures for the determination of the presence of enterovirus RNA. Routine use of external run controls enables laboratories to monitor day-to-day test variation, lot-to-lot performance of test kits, and operator variation, and can assist in identifying increases in random or systematic error. For Research Use Only. Not for use in diagnostic procedures.

Summary and Explanation

The AcroMetrix EV Low Control contains inactivated human coxsackievirus particles from strain CVA9. The AcroMetrix EV Low Control was produced by diluting quantitated enterovirus stock into OptiMatrix Clear, a proprietary synthetic matrix designed to mimic naturally occurring human cerebrospinal fluid (CSF) samples. The AcroMetrix EV Negative Control contains only OptiMatrix Clear.

Human Enterovirus is an RNA virus and a member of the Enterovirus genus of the family Picornaviridae. This group includes the polioviruses, coxsackieviruses, echoviruses, and other enteroviruses. The AcroMetrix EV Controls are designed as unassayed controls for use in qualitative molecular test procedures for enterovirus. The AcroMetrix EV Controls help to ensure that nucleic acid testing results for enterovirus RNA are consistent across manufacturers, testing laboratories, operators, platforms and assay formats.

Principles of the Procedure

The AcroMetrix EV Controls have been formulated to mimic naturally occurring human samples containing enterovirus. Additionally, the intact virus format of the AcroMetrix EV Low Control allows for the verification of effective viral RNA extraction and purification. The controls are designed to monitor all procedural steps in test procedures for determining the presence of enterovirus RNA in human specimens. Since the low positive control contains intact, encapsidated viral particles, the test methodology must include an extraction step that releases the viral RNA for transcription, amplification and detection, as appropriate to the test.

The AcroMetrix EV Low Positive Control contains inactivated enterovirus. The control has no assigned value since currently no generally accepted international enterovirus standard is available. Consistency is achieved by calibrating each lot against a highly stable enterovirus standard assigned at 100 EVU/mL (Enterovirus Units per mL).

Expected results utilizing the AcroMetrix EV Controls must be established by the end user for their particular enterovirus RNA assay. The controls are for Research Use Only and DO NOT HAVE ASSIGNED VALUES.

Reagents

Catalog Number	Enterovirus Control name	Control Designation	Quantity
950499	AcroMetrix EV Negative Control	-	5 x 0.3 mL
950500	AcroMetrix EV Low Control	+	5 x 0.3 mL

These products contain 0.5% ProClin™ 300 as a preservative.

⚠ Precautions and Warning

DANGER: Although the AcroMetrix EV Low Control contains inactivated enterovirus, all AcroMetrix EV controls should be considered potentially biohazardous. Contains ≤3% Human Serum Albumin (HSA), and ≤0.05% ProClin™ 300. Observe the universal precautions for prevention of transmission of infectious agents when handling these materials.^{1,2,3}

H317 - May cause allergic skin reaction.

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H412 - Harmful to aquatic life with long lasting effects.

Avoid breathing mist or vapor. Contaminated work clothing should not be allowed out of the workplace. Avoid release to the environment. Wear protective gloves/eye protection/face protection. In case of inadequate ventilation wear respiratory protection. If on skin: Wash with plenty of soap and water. IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If skin irritation or rash occurs: Get medical advice/attention: If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. Wash contaminated clothing before reuse. Dispose of contents/container to location in accordance with local/regional/national/international regulations.

Do not pipette by mouth. Use personal protective equipment, including lab coats, gloves and safety glasses. Do not eat, drink or smoke in areas where panels and samples are handled.

Disinfect liquids, materials or spills with a 0.5% sodium hypochlorite solution. Dispose of all materials and liquids used in the procedure as if they contained pathogenic agents.

Storage Instructions

It is recommended that the AcroMetrix EV Controls be stored at -70°C or lower to ensure consistent results until the expiration date.

The AcroMetrix EV Controls are designed for single use and excess material in each vial is to be appropriately discarded.

Do not use these products beyond the expiration date printed on the tube label.

Instructions for Use

Thaw the AcroMetrix EV Controls at room temperature, vortex briefly, and immediately place on ice.

The AcroMetrix EV Controls should be handled and tested in a manner identical to that required for samples run in the enterovirus RNA test procedure being evaluated. Follow the manufacturer's instructions and recommendations for the handling and testing of samples.

Limitations

The AcroMetrix EV Controls are intended for Research Use Only, and DO NOT HAVE ASSIGNED VALUES. Not for use in diagnostic procedures

References

- Centers for Disease Control (CDC). Recommendations for prevention of HIV transmission in health care settings. MMWR 1987; 36 (supplement no. 2S).
- Centers for Disease Control (CDC). Update: Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other bloodborne pathogens in health-care settings. MMWR 1988; 37:377-388.
- Centers for Disease Control (CDC). Guidelines for prevention of transmission of human immunodeficiency virus and hepatitis B virus to health-care and public-safety workers. MMWR 1989; 38(S-6): 1-36.

Glossary:

<http://www.thermofisher.com/symbols-glossary>



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