AcroMetrix™ HSV-2 Low CSF Control



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

REF 951302 AcroMetrix HSV-2 Low Control

Product Use

The AcroMetrix™ HSV-2 Low CSF Control is intended for use in assessing the performance of nucleic acid test procedures for the determination of Herpes Simplex Virus-2 (HSV-2) DNA. 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 HSV-2 Low CSF Control contains HSV-2 that was propagated in tissue culture, purified by sucrose density gradient, and diluted in a proprietary physiological matrix designed to mimic naturally occurring human samples found in cerebrospinal fluid.

The AcroMetrix HSV-2 Low CSF Control was designed to meet the need for unassayed controls to be used for molecular testing of HSV-2 viral load in human samples. The AcroMetrix HSV-2 Low CSF Control helps to ensure that nucleic acid testing procedures for HSV-2 DNA are consistent across manufacturers, testing laboratories, operators, platforms and assay formats.

Principles of the Procedure

The AcroMetrix HSV-2 Low CSF Control has been carefully formulated to mimic naturally occurring human specimens containing HSV-2. Additionally, the intact virus format of the AcroMetrix HSV-2 Low CSF Control allows for verification of an effective viral DNA extraction procedure. Therefore, the controls can be used to monitor all procedural steps in any test procedure designed for measuring HSV-2 DNA in human serum, plasma, whole blood, or CSF. Since the control contains intact, encapsidated viral particles, the test methodology should include an extraction step that releases the viral DNA and makes it available for amplification and/or detection, as appropriate to the test.

The AcroMetrix HSV-2 Low CSF Control contains active HSV-2. While the control is unassayed, and does not have an assigned value, results are reported as copies per milliliter (copies/mL).

Expected results utilizing the AcroMetrix HSV-2 Low CSF Control must be established by the end user for their particular HSV-2 DNA assay. The controls are for Research Use Only and DO NOT HAVE ASSIGNED VALUES.

Reagents

Catalog Number	HSV-2 DNA Control Name	Control Designation	Quantity
951302	AcroMetrix HSV-2 Low CSF Control	+	5 x 0.5 mL

The AcroMetrix HSV-2 Low CSF Control contains Proclin™ 300 as a preservative.

Precautions and Warning

DANGER: The AcroMetrix HSV-2 Low CSF Control contains active HSV-2 and should be considered 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 specimens 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 HSV-2 Low CSF Control be stored at -20°C to -80°C to ensure highest quality. Controls may be stored at 2°C to 8°C for up to 7 days after thawing with

Instructions for Use

Thaw the AcroMetrix HSV-2 Low CSF Control at room temperature, vortex briefly, and immediately place on ice. To minimize degradation of the AcroMetrix HSV-2 Low CSF Control, avoid freezing the remaining material and follow the recommended storage instructions indicated above. There will be a decrease in the viral load after multiple freeze-thaw cycles.

The AcroMetrix HSV-2 Low CSF Control should be handled and tested in a manner identical to that required for samples run in the HSV-2 DNA test procedure being evaluated. Follow the appropriate instructions and recommendations for the handling and testing of samples.

Limitations

The AcroMetrix HSV-2 Low CSF Control is intended for Research Use Only, and DOES NOT HAVE AN ASSIGNED VALUE. Not for use in diagnostic procedures.

References

- 1. 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.

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