SUPPORTING INFECTIOUS DISEASE RESEARCH

Fluzone[®] Influenza Virus Vaccine, 2004-2005 Formula

Catalog No. NR-10477

This reagent is the property of the U.S. Government.

For research use only. Not for human use.

Contributor:

National Institutes of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH)

Manufacturer:

Aventis Pasteur Inc.

Product Description:

NR-10477 is a split-virus vaccine prepared from influenza viruses A/New Caledonia/20/1999 (H1N1), A/Wyoming/3/ 2003 (H3N2) [an A/Fujian/411/2002 (H3N2)-like strain] and B/Jiangsu/10/2003 (a B/Shanghai/361/2002-like strain) that were predicted to circulate in the United States during the 2004 to 2005 influenza season.^{1,2}

NR-10477 was prepared from the extra-embryonic fluid of embryonated chicken eggs. The fluid containing the virus was harvested and inactivated with formaldehyde. The inactivated virus was concentrated and purified in a linear sucrose density gradient solution using a continuous flow centrifuge. The virus was then chemically disrupted using a nonionic surfactant (Triton[®] X-100) producing a split-virus. The split-virus was further purified by chemical means and suspended in sodium phosphate-buffered isotonic sodium chloride solution. Gelatin (0.05%) was added as a stabilizer. NR-10477 was formulated without preservatives but contains a trace amount of thimerosal (mercury derivative) from the manufacturing process.²

The hemagglutinin content was standardized according to U.S. Public Health Service requirements. Each 0.25 mL syringe contains the recommended ratio of 7.5 μ g each of the hemagglutinin antigens from influenza viruses A/New Caledonia/20/1999 (H1N1), A/Wyoming/3/2003 (H3N2) and B/Jiangsu/10/2003.

Please note that this vaccine preparation is being released for research use only and not for human use. Vaccines produced for the 2004-2005 season are now past their expiration dates.

Material Provided:

Each syringe contains 0.25 mL of split-virus vaccine in phosphate-buffered saline containing 0.05% gelatin and a trace amount of thimerosal ($\leq 0.5 \mu g$ mercury).

Packaging/Storage:

NR-10477 is packaged in a 0.25 mL pre-filled syringe. The product is provided on refrigerated bricks and should be stored at 2°C to 8°C immediately upon arrival. Do not freeze.

Citation:

Acknowledgment for publications should read "The following

reagent was obtained through BEI Resources, NIAID, NIH: Fluzone[®] Influenza Virus Vaccine, 2004-2005 Formula, NR-10477."

Biosafety Level: 1

Appropriate safety procedures should always be used with this material. Laboratory safety is discussed in the following publication: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, and National Institutes of Health. <u>Biosafety</u> in <u>Microbiological and Biomedical Laboratories</u>. 5th ed. Washington, DC: U.S. Government Printing Office, 2009; see <u>www.cdc.gov/biosafety/publications/bmbl5/index.htm</u>.

Disclaimers:

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References:

- Harper, S. A., et al. "Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP)." <u>MMWR</u> <u>Recomm. Rep.</u> 53 (2004): 1-40. PubMed: 15163927.
- 2. <u>http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm127192.htm</u>

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