

Product Data Sheet – Humanized, Monoclonal Antibody

Product description	Anti-Rubella Virus monoclonal antibody, IgM, in human matrix, chimeric	
Order No.	MAB129.001H	
Lot No.	Lot specific	
Clone	B16B11F8	
Preparation	<p>The antibody has been generated in transgenic mice whose sequence for the IgM heavy chain constant region is replaced by the corresponding human sequence. After immunization of mice, a hybridoma cell line has been established. The antibody is produced industrially by standard hybridoma cell line techniques under sterile conditions.</p> <p>The antibody was purified by a proprietary method and is presented in an IgG depleted and delipidized human serum matrix.</p>	
Preservatives	1.5 mL/L ProClin™ 950 (Sigma-Aldrich) 1.0 mL/L ProClin™ 300 (Sigma-Aldrich)	
Antibody specificity	Validated by SERION ELISA <i>classic</i> Rubella Virus IgM (Institut Virion\Serion GmbH)	
Total IgM concentration	Specification: 100 – 150 µg/mL Result: Lot specific Determined by Human IgM Platinum ELISA (Thermo Fisher Scientific) and standardized with IgM from human serum (Sigma-Aldrich)	
Total IgG concentration	Specification: <1 mg/mL Result: Lot specific Determined by Human IgG Total Platinum ELISA (Thermo Fisher Scientific)	
Bioburden	Specification: Total aerobic microbial growth < 1000 CFU/mL Result: Lot specific	
Storage/shipment	2 – 8 °C	Shipment at 2 – 8 °C or on dry ice
Date of manufacture	Lot specific	
Expiry date	36 months from date of manufacture (under recommended storage conditions)	
Manufacturer	Institut Virion\Serion GmbH, Germany	
Safety statement	This material is tested negative for HbsAg, HIV-1, HIV-2 and HCV by FDA approved methods. Since no method can guarantee the absence of infective agents, this product should be handled with appropriate safety precautions.	

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

Date: 2024-02-14