

CANCER ANTIGEN 19-9

CATALOG NUMBER: A1020

LOT NUMBER: TBD

Storage:	-20°C or Colder	Expiration Date:	<Lot Specific>
Source:	Cell Culture Supernatant	Manufacture Date:	<Lot Specific>
Buffer and pH:	PBS Buffer, pH =7.4 ± 0.2	Preservative:	0.1% Sodium Azide
Filtration:	0.2 µm filtered		

Product Performance Specifications

Testing	Specifications	Unit of Measurement	Methodology
Protein Quantitation	60,000 to 200,000	U/mL	cobas CA 19-9 Assay
Purity Ratio	≥600	U/mL/OD280	U/mL/OD280 (Purity Ratio)
CA 15-3	<20% of 19-9 Concentration	U/mL	cobas CA 15-3 Assay
CA 125	<20% of 19-9 Concentration	U/mL	cobas CA 125 Assay
CEA	<20% of 19-9 Concentration	ng/mL	cobas CEA Assay
CA 72-4	<13% of 19-9 Concentration	U/mL	cobas CA 72-4 Assay
Cyfra 21-1	As Reported	ng/mL	cobas Cyfra 21-1 Assay
NSE	<20% of 19-9 Concentration	ng/mL	cobas NSE Assay
Total Protein	≤200	O.D. Units	OD280

***Specific Lot values may vary**

OTHER:

All fetal bovine serum from which this product was manufactured was collected at USDA inspected abattoirs within the United States of America.

TESTING:

The Cell Line Supernatant was tested and found non-reactive for HIV 1/2, HBsAg, HCV, HIV-1 (NAT) and HCV (NAT) by current FDA methods. Please note that the samples tested were Cell Culture Supernatants, not serum and not appropriate for use in these assays.

CAUTION:

In-Vitro use only. Products are intended for research or manufacturing of non-injectable products only. This material was tested as stated above in the testing section. Nevertheless, products of human origin should be considered potentially infectious and handled according to universal precautions. The safe and responsible handling of the products listed above is the responsibility of the customer. We accept no liability for injury or illness resulting from the use and/or handling of the product. The customer assumes responsibility for the proper disposal of all materials in accordance with Federal and State regulation. For use in research or remanufacture of non-injectable products not subject to license under PHS Act Sec. 351 only.

WARRANTY:

Golden West BioSolutions, LLC makes no claim or warranty that this product will perform or is suitable for use in a customer's application. It is the customer's responsibility to evaluate and qualify the product's suitability for the customer's intended use or application. Furthermore, this product is a biological material and lots may vary so it is the customer's responsibility to determine if an evaluation of each lot is warranted.

