

Clinical Significance & Intended Use

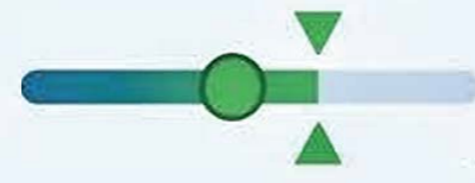


• **Specialized Cancer Marker Monitoring**

Designed to monitor subjects diagnosed with pancreatic, colorectal, gastric, and hepatic carcinomas.



Expected Normal Values: ≤ 40 U/ml



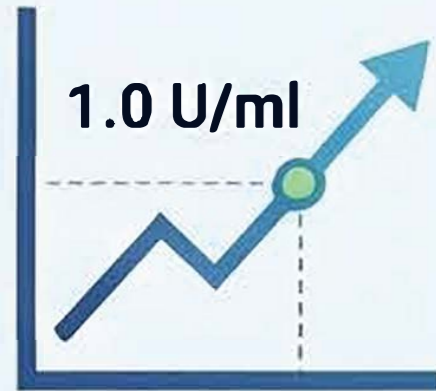
Typical concentration range for healthy, non-pregnant subjects using this specific assay method.



• **Human Serum Analysis**

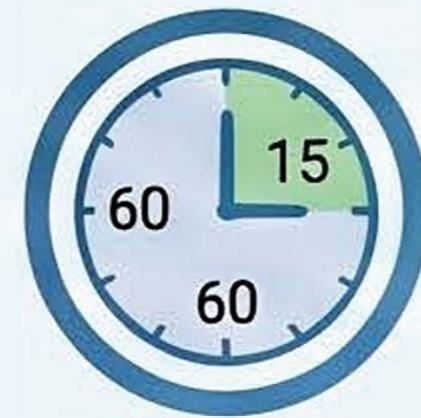
Requires only a 25 µl serum sample for accurate quantitative determination.

Technical Specifications & Performance



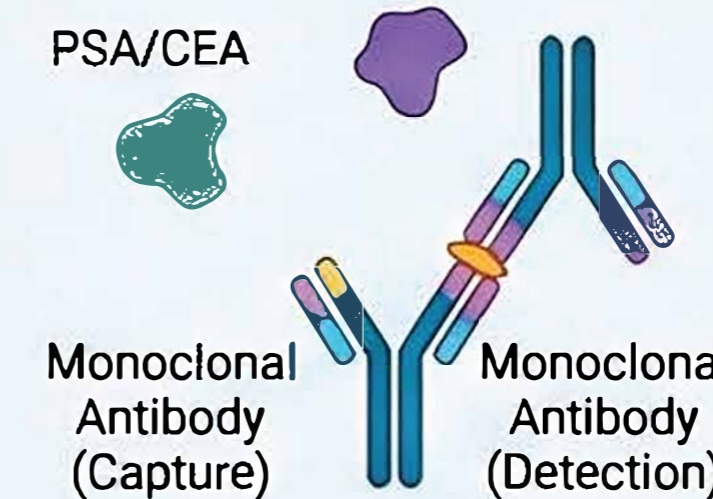
• **1.0 U/ml Analytical Sensitivity**

High-precision detection capable of measuring CA-19-9 concentrations from 0 to 500 U/ml.



• **135-Minute Total Incubation**

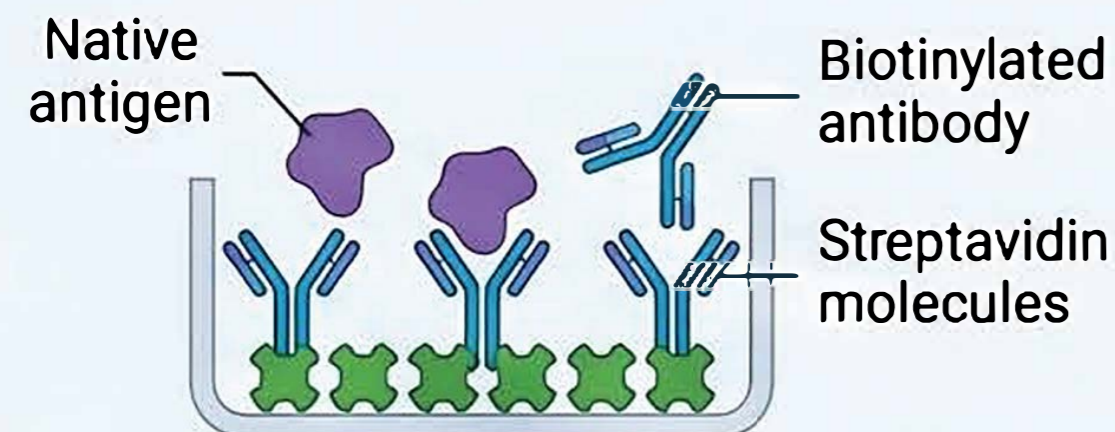
Optimized three-step incubation process (60/60/15 mins) for rapid, consistent results.



• **High Specificity Antibody Pair**

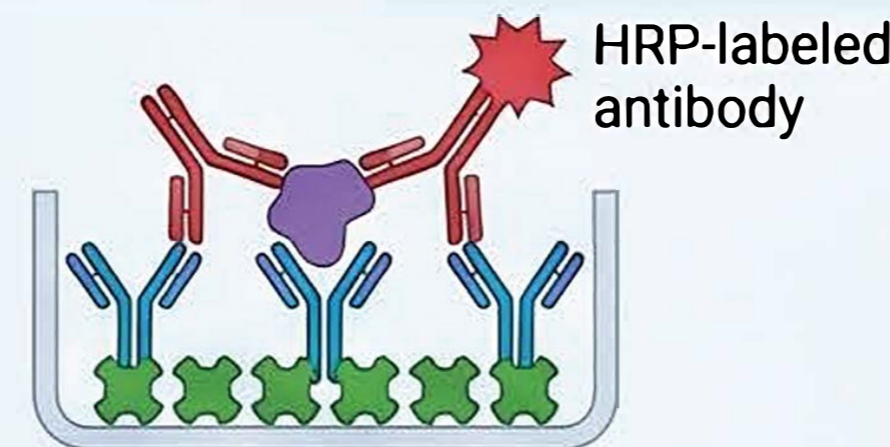
Utilizes monoclonal antibodies to eliminate cross-reactivity with other tumor markers like PSA or CEA.

Assay Principle (Sandwich Method)



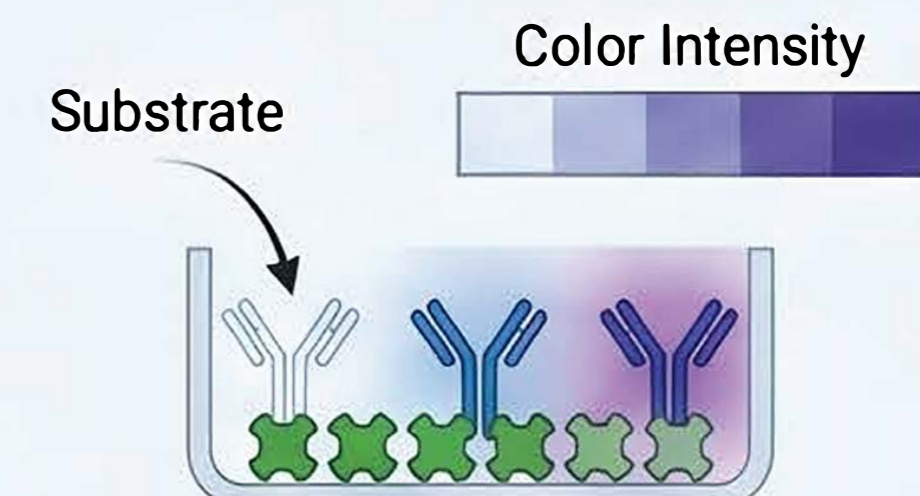
• **Streptavidin-Biotin Immobilization**

Biotinylated antibodies and native antigens form a complex that binds to streptavidin-coated wells.



• **Enzyme Conjugate Binding**

HRP-labeled antibodies bind to the immobilized antigen, creating a highly specific "sandwich."



• **Colorimetric Quantitation**

Substrate addition generates color intensity directly proportional to the CA-19-9 concentration.