

PRODUCT INFORMATION

CYFRA 21-1 EIA

The CYFRA 21-1 EIA is a one-step, solid phase, quantitative assay for the measurement of soluble cytokeratin 19 fragments in serum. The measurement of CYFRA 21-1 levels may be useful in the monitoring and prognosis of non-small cell lung cancer. CYFRA 21-1 continues to be investigated in patients with bladder, head-& neck and breast cancer.

Simple Assay Format

- Tool for the management of lung cancer
- Easy to Use one-step immunoassay
- CE Marked

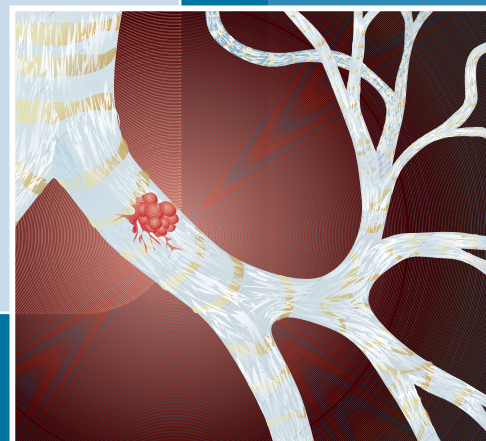
SPECIFICATIONS

PRODUCT NO 211-10

| | |
|-------------------------|-----------------------------|
| Results within: | 2 hours, one step procedure |
| Detection limit: | ≤ 0.5 ng/mL |
| Measuring range: | 0.5–50 ng/mL |
| Sample volume: | 50 µL |
| Hook effect: | No hook up to 1100 ng/mL |
| Stability: | 18 months at 2–8° C |
| Incubation temp: | 20–25° C |
| Recovery: | 100 ±20% |
| Detection: | 620 nm or 405 nm |

Other Lung Cancer Markers available from Fujirebio Diagnostics

| Product Name | Product Number |
|------------------|----------------|
| CanAg NSE EIA | 420-10 |
| CanAg ProGRP EIA | 220-10 |
| CanAg SCC EIA | 800-10 |
| CanAg CEA EIA | 401-10 |
| MESOMARK® | 801-900 |



GLOBAL LEADER

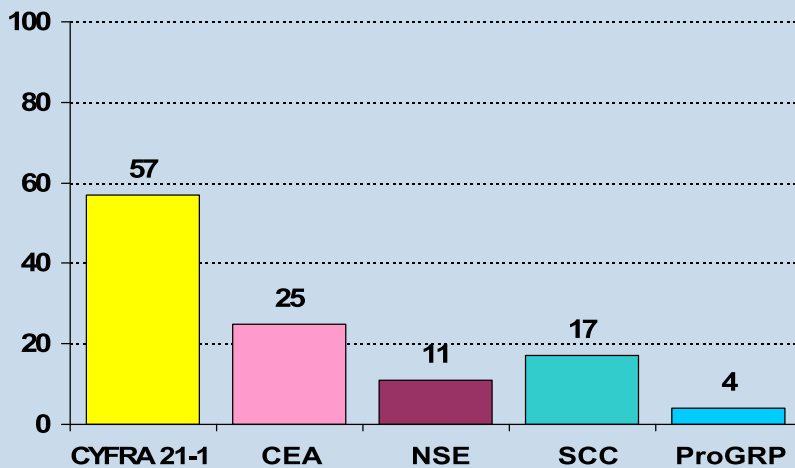
CYFRA 21-1 EIA

Differential - Diagnosis Histology

Non-Small Cell Lung Cancer (n=1089)

Sensitivity [%]

Specificity 95%



P Stieber, University of Munich, 2007

Sensitivity of biomarkers commonly measured in lung cancer patients (NSCLC vs benign lung disease) at 95% specificity.

| ITEM | QUANTITY |
|--|---------------------------|
| Microplate, streptavidin coated, 96 wells | 1 plate, 12 x 8 breakable |
| CALIBRATORS | |
| CYFRA 21-1 Calibrator A | 1 x 8 mL |
| CYFRA 21-1 Calibrator B | 1 x 1 mL |
| CYFRA 21-1 Calibrator C | 1 x 1 mL |
| CYFRA 21-1 Calibrator D | 1 x 1 mL |
| CYFRA 21-1 Calibrator E | 1 x 1 mL |
| CYFRA 21-1 Calibrator F | |
| CONTROLS | |
| CYFRA 21-1 Control 1 | 1 x 1 mL |
| CYFRA 21-1 Control 2 | 1 x 1 mL |
| Biotin Anti-CYFRA 21-1 monoclonal antibody | 1 x 15 mL |
| Tracer, HRP Anti-CYFRA 21-1 | 1 x 0.75 mL |
| TMB HRP-Substrate | 1 x 12 mL |
| Stop Solution | 1 x 15 mL |
| Wash Concentrate | 1 x 50 mL |

Fujirebio Diagnostics Inc.
201 Great Valley Parkway
Malvern, PA 19355-1307
USA

+1 610 240 3800 phone
+1 610 240 3949 fax
info@fdi.com e-mail
www.fdi.com website

Fujirebio Diagnostics AB
Elof Lindälvsgata 13
PO Box 121 32
SE-402 42 Göteborg
Sweden

+46 31 85 70 30 phone
+46 31 85 70 40 fax
info@fdab.com e-mail
www.fdab.com website