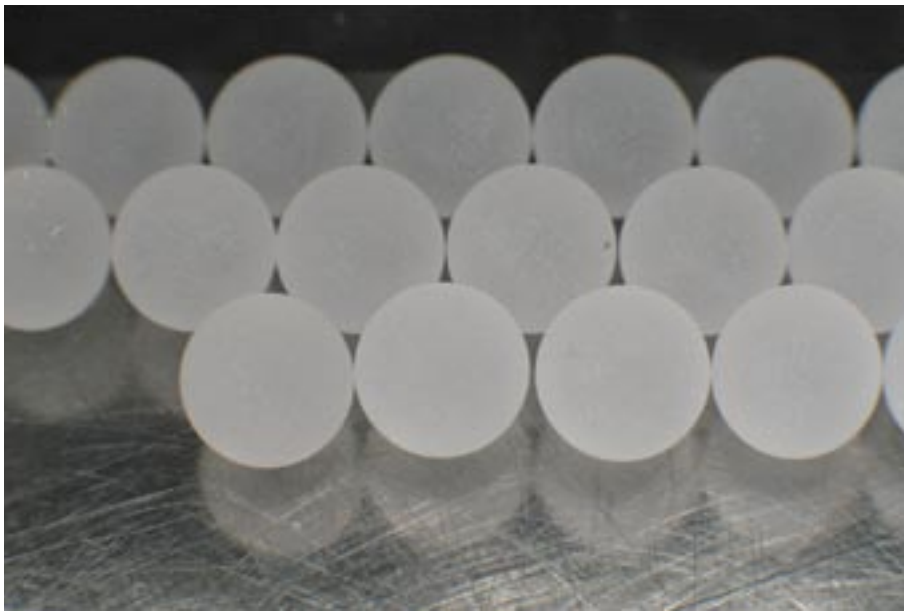


A tool for cancer care management

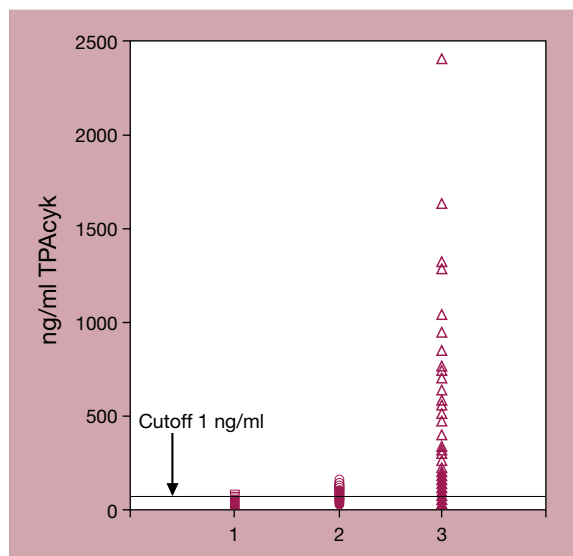


TPAcyk is a monoclonal TPA marker for the monitoring of tumor cell activity, with well defined performance characteristics for patients with epithelial cell carcinomas. This TPA marker provides an ability to predict disease status prior to conventional methods and offers a reliable tool for efficient disease treatment and early decision making.

TPAcyk – a TPA marker for management of cancer patients

The monoclonal TPAcyk measures the key epitopes of TPA (Tissue Polypeptide Antigen), well known as a sensitive indicator of tumor cell activity. It has been reported to be particularly useful in the management of patients with different epithelial cell carcinomas, in establishing prognosis, in treatment monitoring and in follow-up of patients after concluded therapy. Thus, TPAcyk can provide the physician with an efficient

and reliable indicator of the total course of the disease, measured in terms of tumor cell activity and not tumor burden. The possibility to add the valuable information that quantitative serum TPAcyk determinations gives to the overall clinical picture, supports both an earlier evaluation of treatment efficiency and a more accurate prediction of clinical outcome.



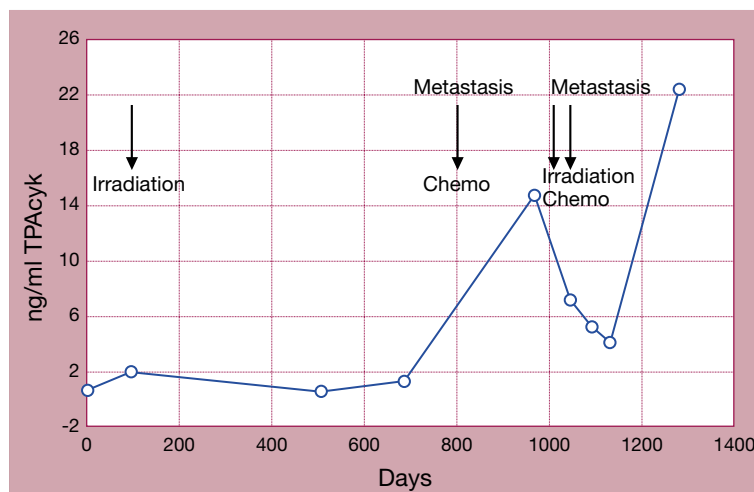
Scattergram of serum samples from apparently healthy individuals (1), benign diseases (2), and patients with epithelial cell carcinomas (3).

- (1) European blood donors (95th percentile show 1.0 ng/ml).
- (2) Prostatitis, pancreatitis, cystitis, colitis and ulcus (95th percentile show 1.4 ng/ml).
- (3) Epithelial cell carcinomas. Including patients with active disease (elevated concentrations) and patients during monitoring/follow-up (low concentrations). Sensitivity 70%.

An adjunctive tool in cancer therapy

The TPA tumor marker is a well-known, widely used general marker in the monitoring of carcinomas of epithelial origin. It has proven particularly useful as an aid for the treating physician being a non-invasive, cost-effective adjunct in tumor

therapy. In several clinical studies on epithelial carcinomas, TPA has been shown to provide additional facts to improve the management of the individual patient.



Monitoring of a patient with epithelial cell carcinoma during therapy and follow-up, by repeated measurements of the TPAcyk concentration.

TPAcyk in disease monitoring

TPAcyk is a quantitative tumor marker, specifically designed for analysis of serum samples. By repeated and serial measurements of patients with epithelial cell carcinomas, TPAcyk stands as a useful and adjunctive tool in the total-care management of these patients. A low and steady

level of TPAcyk indicates a stable disease, while increased values during follow-up after treatment of the patients gives an early indication of a possible recurrence. If recurrent disease is found early, this also allows for earlier intervention and thus a more efficient disease treatment.

TPA - A tumor-associated antigen

TPA is described as a tumor-associated antigen, present in malignant tumors of epithelial cell origin. It is a circulating complex of polypeptide fragments of cytokeratins (intermediate filament proteins). The cytokeratins are epithelial cell specific. During the transformation of normal cells into malignant cells, the cytokeratin expression patterns are usually maintained.

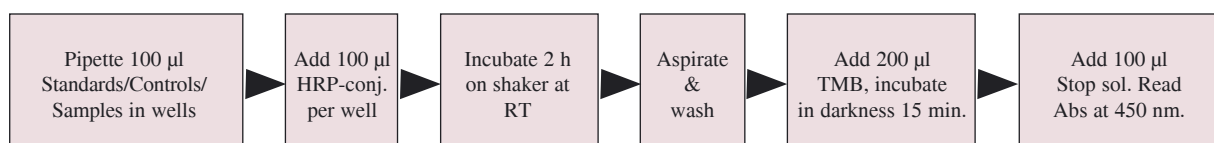
Cytokeratins are present in the circulation as partially degraded single protein fragments, forming soluble protein complexes of different sizes. The TPAcyk test is a monoclonal assay that measures the reactivity against defined epitope structures on cytokeratins 8 and 18, the key epitopes of TPA.

TPAcyk Technical Data

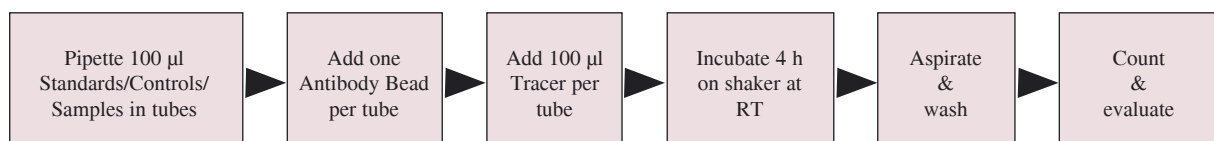
The TPAcyk assay is available as quantitative IRMA and ELISA tests. The specificity of the TPAcyk assay reagents were analyzed by immunohistochemistry, gel electrophoresis and immuno-

blotting. The monoclonal antibodies in this test are specific for TPAcyk, without detectable cross reactivity to other tumor-associated antigens that may be present in the cancer patients.

TPAcyk Methodology



ELISA Assay procedure - The sample is reacted with a microplate well coated with monoclonal antibodies against TPAcyk simultaneously with HRP-conjugated antibodies.



IRMA Assay procedure - The sample is reacted with a bead coated with monoclonal antibodies against TPAcyk simultaneously with radiolabeled antibodies.

TPAcyk

A tumor marker in Total Care Management

TPAcyk is a TPA - Tissue Polypeptide Antigen - tumor marker.

TPAcyk is a reliable indicator of tumor cell activity, especially useful in treatment monitoring and patient follow-up.

TPAcyk is particularly useful in overall management of patients with epithelial cell carcinomas.

TPAcyk value variations during monitoring of treatment indicates the efficiency of the treatment.

TPAcyk gives the physician an early warning of recurrence, thereby allowing for earlier intervention.

TPAcyk supports therapeutical decisions to optimize patient management and improve the cost/benefit ratio.

TPAcyk is a monoclonal immunoassay with reactivity against defined epitope structures on cytokeratins 8 and 18.

