

<u>Test items</u>	<u>Purpose of test and subject diseases</u>	<u>Determination method</u>	<u>Use of kits</u>	<u>Insurance score</u>
E. Others				
E-1 immune complex	Diagnosis of auto-immune disease	EIA,	yes	350
E-2 interferon (gamma)	Resistance to cell necrosis (beta) Antitumor properties of cells	RIA, EIA	yes	no
E-3 interleukin	Diagnosis of inflammatory reactions, infectious disease	EIA	yes	no

Overview of each market can be summarized as follows:

A. Tumor Markers

CEA and AFP are the two major items with long-standing substantial market share. Beta2-microglobulin and ferritin have followed them and in 1985 CA19-9 entered into the dramatically expanding market. Tumor markers are usually applied for screening and monitoring after treatment as a combination assay. For example, in the case of a test for pancreas cancer, diagnosis accuracy can be enhanced by the combination of three test items, CEA, CA19-9 and KMO-1. It is the same for the monitoring of after-treatment. It is not sufficient to test with a single marker. Thus, the diagnostics market has been expanded by the increase in the number of tests which enables the application of a combination of two or more test items. This indicates that there are few markers having very high accuracy.

The revision of health insurance scores to be implemented from April 1990 (refer to Appendix 3-1) will have an adverse effect on this market. There has been no restriction of invoicing of insurance scores in the past, but invoicing can be made only once for screening test and only monthly base invoice is allowed for monitoring test. Therefore, it is most likely that combination assays will not be conducted for monitoring. This may reduce the demand of tumor markers.

B. Diabetes

It is estimated that there are 2.5 to 3 million diabetes patients in Japan. Among them, approximately 200,000 people take insulin. The major test item has been blood sugar and promising markers such as haemoglobin A1, haemoglobin A1C, urine albumin and fructosamine have appeared on the market. Thus, the market is growing. Self-testing of blood sugar at home is also being expanded.