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**INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

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**Common used serum tumor marker tests - Clinical practice and
quality management
(English Translation)**

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Foreword

This standard was drafted in accordance with the rules given in GB/T 1.1-2009.

This standard was drafted. Tongji Medical College of Huazhong University of Science and Technology, Second Hospital of Shandong University, Xijing Hospital of the Fourth Military Medical University, Zhejiang Affiliated Obstetrics and Gynecology Hospital of Jiang University Medical College, Longhua Hospital affiliated to Shanghai University of Traditional Chinese Medicine, Beijing Hospital.

Introduction

Since the 1960s, alpha-fetoprotein (AFP) and carcinoembryonic antigen (CEA) have been discovered and used in clinical tests, tumor markers the concept has been widely accepted by the medical community and has been widely valued and studied by scientists in the medical field all over the world. Currently known tumor markers There are hundreds of kinds of clinical medical workers who need to have guidance on medical practice to adapt to the needs of current clinical testing.

Clinical application and quality management using serum tumor marker detection." Clinical

application and quality management of commonly used serum tumor markers

1 Scope

This standard specifies the clinical application and quality management requirements for the detection of commonly used serum tumor markers.

This standard applies to clinical laboratories as well as units that develop and produce tumor marker reagents.

2 Normative references

The following documents are indispensable for the application of this document. For dated references, only the dated version applies to this document.

For undated references, the latest edition (including all amendments) applies to this document.

GB/T 20470 clinical laboratory inter-room quality evaluation requirements WS/T 414 Inter-room quality evaluation results application guide Validation of analytical performance of commercial quantitative kits in WS/T 420 clinical laboratories WS/T 460 prostate specific antigen detection for prostate cancer clinical application WS/T 492 clinical test quantitative measurement project precision and accuracy performance verification

3 Terms and definitions

The following terms and definitions apply to this document.

Tumor marker tumor marker; TM in the process of malignant tumor development and proliferation, abnormally produced by the tumor cells themselves or by the body's reaction to tumor cells and/or elevated substances that reflect the presence and growth of tumors, including proteins, hormones, enzymes (isozymes), polyamines, and oncogenes.

Products, etc., are present in the blood, body fluids, cells or tissues of patients, and can be measured by biochemistry, immunology and molecular biology.

It is of value in the auxiliary diagnosis, differential diagnosis, therapeutic observation, recurrence monitoring and prognosis evaluation of tumors.

Carbohydrate antigen carbohydrate antigen; CA the tumor-specific macromolecular glycoprotein antigens recognized by monoclonal antibodies developed by hybridoma technology can be divided into two categories, namely High-molecular mucin-like tumor markers (such as CA125, CA15-3, CA27-29, CA549, etc.) and blood group antigenic tumor markers (such as CA19-9, CA50, CA72-4, etc.).

4 Clinical application of commonly used serum tumor markers

This document mainly includes alpha-fetoprotein, carcinoembryonic antigen, neuron-specific enolase, squamous cell carcinoma antigen, cytokeratin 19. Nine tumor markers including fragment, gastrin releasing peptide precursor, carbohydrate antigen 125, carbohydrate antigen 15-3 and carbohydrate antigen 19-9.

4.1 Alpha-fetoprotein (AFP)

A 591 amino acid glycoprotein synthesized by the liver and yolk sac in the early stage of fetal development. It is located in albumin and alpha₁ during electrophoresis.

Between globulins. AFP is high in the neonatal period and drops to 10 µg/L to 20 µg/L by the age of 1 year, and the AFP content in adult serum is very low.

When hepatocytes undergo malignant transformation, AFP content is significantly increased, which is an important indicator for clinical diagnosis of primary liver cancer.

4.1.1 Reference interval

The reference interval for serum AFP detection may vary depending on the method, instrument, and reagent. Therefore, each laboratory should follow the reagent instructions.

Establish your own reference intervals with clinical practice.

4.1.2 Screening

Serum AFP combined with liver ultrasound can be used as a screening for high-risk populations of primary liver cancer. High-risk population with hepatitis B virus (HBV) and/or hepatitis C virus (HCV) infection, long-term alcoholics, and family history of primary liver cancer, screening age male ≥ 40 years old, women ≥ 50 years old, should be checked every 6 months.

4.1.3 Auxiliary diagnosis

4.1.3.1

Serum AFP is the most commonly used tumor marker for clinical diagnosis of primary liver cancer (referred to as liver cancer). For serum AFP $\geq 400\mu\text{g/L}$ for more than 1 month, or $\geq 200\mu\text{g/L}$ for 2 months, excluding pregnancy, active liver disease and germline embryogenic tumors. After that, liver cancer should be highly suspected, and B-ultrasound examination should be performed. If necessary, CT/MRI and biopsy should be performed to confirm the diagnosis. Serum AFP for liver cancer the positive rate of diagnosis is generally about 70%, and about 30% of liver cancer patients have negative AFP detection. Therefore, AFP cannot be used to diagnose liver cancer.

4.1.3.2

Elevated serum AFP can also be found in germline embryogenic tumors, such as testicular non-seminoma, yolk sac tumor, malignant teratoma. Also seen in other malignant tumors, such as gastric cancer, colorectal cancer.

4.1.3.3

AFP in serum of patients with acute or chronic hepatitis and cirrhosis may increase in different degrees, mostly between 20 and 200 µg/L.

It gradually declined in 2 months as the condition improved.

4.1.3.4

After 3 months of pregnancy, serum AFP is elevated, mainly from the fetus. Abnormally elevated AFP in maternal serum can be seen in Fetal neural tube defects, spina bifida, no brain and so on. AFP can enter amniotic fluid from an open neural tube resulting in an abnormal increase in amniotic fluid content.

Abnormally decreased AFP in maternal serum, suggesting that the fetus has a risk of Down's syndrome. Therefore, monitoring of AFP concentration in maternal serum and amniotic fluid it can be used for prenatal diagnosis of fetal neural tube defects and Down's syndrome.

4.1.4 Prognosis assessment

Serum AFP is an important marker for judging the prognosis of primary liver cancer. High concentration of serum AFP suggests a poor prognosis.

4.1.5 Efficacy and recurrence monitoring

4.1.5.1

Serum AFP measurement helps to monitor the response of liver cancer patients to treatment. After liver cancer surgery, serum AFP concentration drops to the reference area in the meantime, the operation is effective; if the serum AFP is only partially reduced, it means that the operation is not complete or there is a metastatic lesion.

4.1.5.2

Serum AFP can be used for follow-up and recurrence monitoring after liver cancer surgery or liver transplantation in liver cancer patients. Within 2 years after surgery, it should be tested every 3 months and every 6 months within 3 to 5 years.

4.2 Carcinoembryonic antigen (CEA)

A complex acid glycoprotein, which is mainly found in adult cancer tissues and fetal gastrointestinal tissues, is a broad spectrum of swelling Tumor marker.