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WS

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

WS 213-2001

Replacing WS 213-2008

**Diagnosis for hepatitis C
(English Translation)**

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Foreword

Chapters 6 and 8 of this standard are mandatory and the rest are recommended.

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

This standard replaces WS 213-2008 "Diagnostic C standard for hepatitis C".

The main changes in this standard compared with WS 213-2008 are as follows.

- The standard name was changed to "Diagnosis of Hepatitis C";
- Added normative references (see Chapter 2);
- Revised the epidemiological history (see 4.1, 2008 version 3.1);
- Revised clinical performance (see 3.2, 2008 version 3.2);

- modified pathology (see 4.4 and Appendix B, 2008 version 3.4);
- Revised the diagnostic principles (see Chapter 5, Chapter 4 of the 2008 edition);
- Removed suspected cases of hepatitis C (see 5.1 of the 2008 version);
- Revised the differential diagnosis of hepatitis C in infants and young children (see 7.3, 6.4 of 2008 edition);
- Increased liver elasticity measurement content (see Appendix C);
- Added case report section (see Chapter 8 and Appendix D).

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The previous versions of the standards replaced by this standard are.

--WS 213-2001;

--WS 213-2008.

Hepatitis C diagnosis

1 Scope

This standard specifies the diagnostic basis, diagnostic principles, diagnosis, differential diagnosis and case report of hepatitis C.

This standard is applicable to the diagnosis of hepatitis C at various levels of medical and health institutions and their medical staff.

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 19489 General requirements for laboratory biosafety

3 Abbreviations

The following abbreviations apply to this document.

ALT. alanine aminotransferase APRI. aspartate aminotransferase/platelet ratio index AST. aspartate aminotransferase CT. computed tomography HCV. hepatitis C virus (hepatitis C virus) HCV RNA. hepatitis C virus ribonucleic acid MRI. magnetic resonance imaging PCR. polymerase chain reaction

4.1 Epidemiological history

Have received blood, blood products or other body tissues, cellular components, or organ transplants; history of hemodialysis, unsafe History of shooting or other invasive procedures such as surgery, endoscopy,, puncture, catheterization, intubation, oral consultation, acupuncture, beauty, tattoo, repair Feet; there is a history of paid blood supply; a history of injecting drugs with shared needles; occupational exposure history; sharing of toothbrushes, razors, etc. with others History of live contact; history of unprotected sexual contact with HCV-infected persons; mothers born with HCV infection at birth.

4.2 Clinical manifestations

Most patients had no obvious signs and symptoms, and some patients had fatigue, loss of appetite, nausea, bloating, and right rib discomfort or pain.

Some patients with acute hepatitis C may have mild hepatosplenomegaly, a few may have hypothermia or jaundice, and some may have extrahepatic manifestations such as joint pain.

Some patients with chronic hepatitis C have liver disease face, jaundice, liver palm, spider mites and mild liver and splenomegaly. Partial compensation period hepatitis C cirrhosis the patient has liver disease face, liver palm, spider mites, jaundice and abdominal wall or esophagus, gastric varices, and splenomegaly and hypersplenism.

Decompensated patients with hepatitis C cirrhosis have a history of ascites, hepatic encephalopathy or gastrointestinal bleeding.

4.3 Laboratory examination

4.3.1

Abnormal biochemical examination. Patients with acute hepatitis C have elevated serum ALT and AST, and some patients have elevated bilirubin. Partially slow Patients with hepatitis C and hepatitis C cirrhosis have elevated ALT, AST, and bilirubin.

4.3.2

Blood anti-HCV positive (see A.1.1 and Table A.1 in Appendix A).

4.3.3

Blood HCV RNA positive (see A.1.2 and Table A.1).

4.4 Liver histopathology

Acute, chronic hepatitis C and hepatitis C cirrhosis can present different histopathological changes (see Appendix B).

4.5.1 Acute hepatitis C

Abdominal ultrasound, CT or MRI can show mild swelling of the liver and spleen.

4.5.2 Chronic hepatitis C

Abdominal ultrasound, CT or MRI can show uneven liver parenchyma, showing a slight increase in liver or spleen. APRI scores are often < 1.5 .

4.5.3 Hepatitis C cirrhosis

Abdominal ultrasound, CT or MRI can show that the liver edge is not smooth or even jagged, the liver parenchyma is uneven or even nodular, and the portal vein is increased.

Wide, spleen increased. Liver elasticity measurements (see Appendix C) indicate cirrhosis. The APRI score is often > 2.0 .

5 Diagnostic principles

Clinical diagnosis was made based on epidemiological history, clinical manifestations, biochemical tests, and anti-HCV positive results. Based on HCV RNA positive junction Make a diagnosis. For confirmed cases, based on the defined exposure time, the time sequence of HCV RNA, anti-HCV positive results, and Liver histology and imaging and other auxiliary examination results can be distinguished as acute, chronic hepatitis C and hepatitis C cirrhosis.

6.1 Clinical diagnosis cases

Anti-HCV positive and meets any of the following.

- a) have any of the epidemiological history;
- b) have clinical manifestations;
- c) There are biochemical abnormality test results.