



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

YY/T 1240-2023

D-dimer testing kit (immunoturbidimetric method)

D-二聚体测定试剂盒（免疫比浊法）

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Foreword

This document was issued on 13 January 2023 by the National Medical Products Administration and takes effect on 15 July 2023.

It is a YY/T standard: it is recommended rather than compulsory, but it is the method a Chinese reviewer applies when assessing a registration submission.

1 Scope

YY/T 1240 is the Chinese standard for D-dimer test kits using the immunoturbidimetric method. D-dimer is the test that rules out venous thromboembolism: a negative result in a patient at low clinical probability is enough to avoid imaging, which makes the sensitivity of the assay near the cut-off a matter of missed pulmonary embolism rather than of laboratory precision. The document sets out how such a kit is classified, the technical requirements it has to meet, the test methods that demonstrate them, and the labelling, packaging and storage rules. D-dimer is also one of the least standardised analytes between manufacturers, with units and cut-offs that do not transfer, which is part of why a national standard exists. For a diagnostics manufacturer, this is the text a Chinese registration is assessed against.

About this edition

YY/T 1240-2023 is the current edition. It was issued on 13 January 2023 and has been in force since 15 July 2023.

The interval between issue and effect is the transition period. It exists so that producers, laboratories and buyers can requalify products, revise procedures and use up

documentation before the new text becomes the one that applies. The date on this page is the official one from the record of the Standardization Administration.

Classification and status

The YY/T prefix marks an industry standard, issued by the authority for its sector rather than by the national body. It applies within that industry, and it becomes binding in the same ways a recommended national standard does: when a contract, a regulation or a declaration of conformity names it.

How a Chinese national standard is set out

Chinese national standards are drafted to the rules of GB/T 1.1, which fixes the order in which a standard is set out. The document opens with a foreword recording the issuing bodies, the relationship to any previous edition and the technical committee responsible for it. Clause 1 is the scope. Clause 2 lists the normative references - the other standards that have to be applied together with this one, and without which its requirements cannot be met. Clause 3 gives the terms and definitions. The technical clauses follow: the requirements themselves, the test or measurement methods by which conformity is established, the inspection rules that say how a lot is sampled and judged, and, for a product standard, the provisions on marking, packaging, transport and storage. Annexes, normative or informative, come last.

YY/T 1240-2023 runs to 15 pages in the English translation. What is delivered is the complete document in that order: every clause, every table, every figure and every annex of the Chinese original, with the same numbering, so that a reference to a clause number in a contract or a test report points to the same place in both languages.

About this English translation

The English edition of YY/T 1240-2023 is a full translation of the official Chinese text, not a summary, an abstract or a machine rendering left unchecked. Clause and subclause numbers, table and figure numbers and annex letters are those of the original, because they are what a specification, a purchase order or a test report cites.

Technical terms are translated against the vocabulary standards of the same field, so that a term used in YY/T 1240-2023 reads the same way as in the other Chinese standards it is used beside. Where a term has an established English form in an ISO or IEC document on the same subject, that form is used; where China's term has no foreign counterpart, it is translated literally and the Chinese is kept alongside it rather than replaced by an approximation.

Quantities, units and symbols are carried over unchanged. Chinese standards use SI, so a value in the translation is the value in the original document, not a conversion, and a limit

read from the English text is the limit that will be applied by a Chinese inspection body reading the Chinese one.

This page is compiled from the official publication record: the standard number and both titles, the issuing bodies, the dates of issue and effect. The requirements, limits, tables and test conditions are in the document itself.

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