



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

YY/T 1865-2022

**General technical requirements for BRCA mutation detection kit
and database(High-throughput sequencing)
(English Translation)**

Issued on: October 17, 2022

Implemented on: October 1, 2023

Issued by: State Drug Administration

Table of Contents

What this standard covers	1
Document data	2

What this standard covers

This standard specifies the kit requirements for BRCA gene mutation detection kits and databases, the data composition of the database, the data specifications of the database, and the data management and interpretation standards of the database. This standard is applicable to the quality control of BRCA gene germline mutation detection kit, BRCA gene mutation detection database and BRCA gene mutation interpretation. This standard does not apply to the detection of BRCA gene somatic mutations and the detection of BRCA gene mutations by the dideoxy method (Sanger).

Document data

Estimated length of the Chinese original: 22,270 words.