

COMPANION DIAGNOSTICS

The use of anticancer therapeutics that target defined molecular abnormalities present in the cancer requires reliable detection of these cancer-specific characteristics. The FDA typically approves specialized tests, called companion diagnostics, alongside the approvals of molecularly targeted therapeutics or immunotherapeutics.

Companion diagnostics:

Accurately match patients with a specific therapy



Are stringently tested for accuracy, sensitivity, and fidelity



Are regulated by the U.S. Food and Drug Administration



Allow patients to receive a treatment to which they are most likely to respond



Allow patients identified as very unlikely to respond to forgo treatment with the therapeutic and thus be spared adverse side effects

