ADVANCED SCIENCE.

Next-level mBC monitoring. DiviTum® TKa.

DiviTum TKa is the first and only FDA-cleared Tumor TKactivity Profile Test

- Thymidine kinase (TK) plays a key role in DNA synthesis and cell proliferation. Studies have shown that TK activity (TKa) is elevated in actively proliferating cancers[1,2]
- DiviTum TKa is a scientific advancement for metastatic breast cancer (mBC) that measures TKa in blood
  - **Conventional biomarkers—such as cancer antigen 15-3 (CA 15-3)—are not expressed** in all women with mBC[3]
  - **Low sensitivity of current imaging techniques:** Up to 40% of mBC patients have nonmeasurable disease[2]

A monitoring innovation for early prognosis and prediction of mBC treatment outcomes[4-8]

Unlike any other cancer biomarker

DiviTum TKa monitors disease progression by measuring TKa in postmenopausal HR+/HER2– mBC patients

Fills the current imaging gap

Assesses nonmeasurable disease that may not be detected with conventional imaging

- With measurable disease, assessing TKa may complement and improve diagnostic accuracy when imaging results are equivocal

Validated to be prognostic

for disease progression and overall survival[4,5,*]

- Lower DiviTum TKa levels are associated with lower likelihood of disease progression*

The only Tumor TKactivity Profile Test

that risk-stratifies CDK4/6 inhibitor patients into 3 validated profiles[6-8,†]

- Provides unique predictive profiles based on *Treatment Response Patterns*

Helps you determine

which patients are—or are not—responding optimally to CDK4/6 inhibitor therapy and may benefit from continuing therapy[6-8]

Only the DiviTum TKa test provides a Tumor TKactivity Profile—a measurable assessment of active TK in circulation from proliferating cells.

DiviTum® TKa

*DiviTum TKa demonstrated a negative predictive value (NPV) of 97% and 94% within 30 and 60 days post testing, respectively, in a clinical validation study that assessed 1546 banked blood samples data from 454 women with HR+ mBC who were treated with first-line endocrine therapy (anastrozole alone or anastrozole plus fulvestrant) in the randomized, phase III, SWOG S0226 clinical trial.

†In a clinical study of 287 HR+/HER2– mBC patients receiving first-line treatment with ribociclib + letrozole. TKa was analyzed at baseline, C1D15, and C2D1. On-treatment TKa values were used to identify patterns.

The only Tumor TKactivity Profile Test that provides *Treatment Response Patterns**

The DiviTum® TKa test helps you make more confident treatment decisions

- Allows you to easily track a patient's response early on—and at any time point as clinically indicated—throughout treatment
- Complements traditional imaging—particularly if CT scans are difficult to interpret

Adds value at every time point for appropriate postmenopausal, HR+ mBC patients

DiviTum TKa at baseline	Provides a snapshot of pretreatment level of tumor proliferation and disease burden, which is shown to significantly correlate with patient prognosis.[4,5,7,9]
DiviTum TKa at days 14 to 21†	TKa measured from an on-treatment blood sample provides information about how effectively a patient's tumor is responding to CDK4/6 inhibition and significantly correlates with progression-free time on therapy.[6-9,†]
DiviTum TKa at day 28‡	TKa measured at the end of a 1-week drug holiday helps determine if cancer cells are proliferating.[6,7,‡]
DiviTum TKa values over time	Monitoring values over time helps determine if a patient's disease is responding to therapy—or is likely to progress—based on level of TKa.[4] A rise in TKa levels can precede detection of progression by CT scan.[9]

*In a clinical study of 287 HR+/HER2– mBC patients receiving first-line treatment with ribociclib + letrozole. TKa was analyzed at baseline, C1D15, and C2D1. On-treatment TKa values were used to identify patterns.
†If patient is receiving a CDK4/6 inhibitor.
‡If patient is receiving palbociclib or ribociclib.

Vigilant monitoring. DiviTum TKa.

DiviTum TKa is an in vitro diagnostic device intended for the semiquantitative measurement of thymidine kinase activity (TKa) in human serum. The assay is to be used as an aid in monitoring disease progression in previously diagnosed hormone receptor positive (HR+), metastatic, postmenopausal female breast cancer patients. A TKa value of < 250 DiviTum Units of Activity (DuA) is associated with the decreased likelihood of disease progression within 30 days or 60 days post testing for patients on endocrine therapy. DiviTum TKa results should be used in conjunction with other clinical methods for monitoring breast cancer.

The DiviTum TKa test has been validated for use only with serum samples from postmenopausal women previously diagnosed with HR+ metastatic breast cancer. Accurate results are dependent on following the proper sample collection, storage, and handling procedures (see Instructions for Use, MA0016_F). Assay variability may be up to 12%.[10] The effects of chemotherapy on DiviTum TKa have not yet been fully evaluated.

DiviTum® TKa

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