# DiviTum® TKa TEST RESULTS

FINAL REPORT

Laboratory director : Page: 1 of 1

Patient name: **Profile 2**

Order by:

| Date of birth : | Sex: | Patient ID: |
|---|---|---|
| MM /DD/YYYY | F | |

Notes:

| Report recipient : | Contact info : |
|---|---|
| | |

## Patient sample information

| | |
|---|---|
| Ordered: | 12/01/2022 |
| Collected: | 05/31/2023 12:00 PM |
| Type: | Serum |
| Reported: | |
| Sample ID: | |
| Institution sample ID: | |

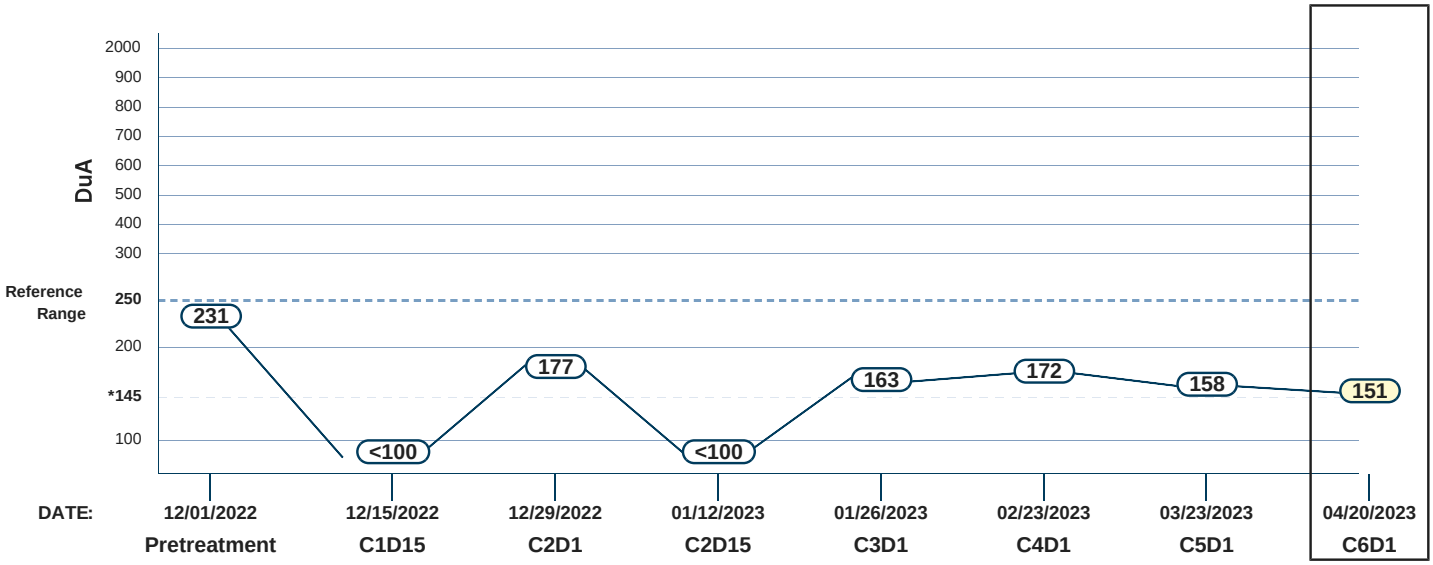
## History of test results

DiviTum® Units of Activity (DuA)

Reference range : < 250 DuA

| | | | |
|---|---|---|---|
| 04/20/2023 | 151 | 12/15/2022 | <100 |
| 03/23/2023 | 158 | 12/01/2022 | 231 |
| 02/23/2023 | 172 | | |
| 01/26/2023 | 163 | | |
| 01/12/2023 | <100 | | |
| 12/29/2022 | 177 | | |

## Thymidine Kinase activity (TKa)




* < 145 DuA for patients treated with CDK4/6 inhibitor .[23]

### General test information:

- TKa values are associated with disease progression within 30 days or 60 days from sampling
- TKa values < 250 DuA are associated with decreased likelihood of disease progression within the next 30 days or 60 days post testing (81% and 82% specificity, respectively )
- TKa values < 250 DuA have negative predictive values for disease progression of 97% and 94% for 30 days or 60 days, respectively, post-testing progression -free survival (PFS )
- Testing for TKa should be used in conjunction with other clinical methods used for monitoring metastatic breast cancer patients
- DiviTum TKa should not be used for cancer screening or diagnosis
- DiviTum TKa is not for "serial testing" because the test result at a given time point does not compare to the test result at previous time point, but to a fixed cutoff value
- DiviTum TKa is not indicated as a stand -alone test to determine the outcome of disease nor to suggest or infer an individual patient's likely benefit from therapy

### Limitations:

- 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
- Patients who have high levels of triglycerides may show falsely elevated TKa values when tested, and who have high levels of bilirubin (conjugated ) may show falsely depressed TKa values when tested with DiviTum TKa
- Patients who are taking cisplatin may show falsely depressed TKa values when tested with DiviTum TKa
- The effects of chemotherapy on DiviTum TKa have not yet been fully evaluated


**References 1.** Paoletti C, Barlow WE, Cobain E, et al.Evaluating serum thymidine kinase 1 in patients with hormone receptor-positive metastatic breast cancer receiving first -line endocrine therapy in the SWOG S0226 trial. Clin Cancer Res. 2021;27 (22):6115-6123.**2.** Malorni L, De Laurentiis M, Bianchini G, et al. Serum thymidine kinase 1 activity in patients with hormone receptor positive (HR +)/HER2 negative (HER2 –) advanced breast cancer (aBC ) treated in first line with ribociclib and letrozole in the BioltaLEE trial. Poster presented at: European Society for Medical Oncology (ESMO ) Congress (held virtually ); September 16-21, 2021. **3.** Malorni L, Tyekucheva S, Hilbers FS, et al; International Breast Cancer Study Group; Breast International Group and PYTHIA Collaborators. Serum thymidine kinase activity in patients with hormone receptor-positive and HER2 -negative metastatic breast cancer treated with palbociclib and fulvestrant. Eur J Cancer. 2022;164:39-51. **4.** US Food and Drug Administration. July 2022 510(K) Clearances. US Food and Drug Administration website. https://www.accessdata .fda .gov/cdrh_docs /pdf20 /K202852 .pdf. Published July 29, 2022. Accessed March 1, 2023.**5.** Bergqvist M, Nordmark A, Williams A, et al. Thymidine kinase activity levels in serum can identify HR+ metastatic breast cancer patients with a low risk of early progression (SWOG S0226). Biomarkers. 2023 doi: 10.1080/1354750X.2023.2168063.





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