# Continuous AI-supported surveillance of IHC assay performance for sustainable staining quality

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## INTRODUCTION

In diagnostic histopathology, tissue sections with a few µm thickness are examined microscopically, whereby the thickness and quality of the tissue can vary. In the context of a specific investigation, e.g. for biomarkers by immunohistochemistry (IHC), various antibodies and detection systems are used[1].

In recent years, efforts have been made to unify the technologies and standardize the processes in the laboratory in order to ensure consistent quality and avoid misinterpretation, even by experienced pathologists[2]. Here we present a workflow supported by artificial intelligence (AI) that continuously captures quality parameters and even makes early deviation trends obvious.

## METHODS

In addition to the paraffin sections, antigen-specific cell lines are applied to the slide as standardized reference samples and stained in the staining machine (in this case Roche Benchmark Ultra).

The stained slides are then scanned with high resolution (Philips UFS). With the help of in-house developed software, image and relevant metadata are extracted and aggregated from the LIS.

These data are uploaded to the Qualitopix® web suite (Visiopharm A/S) where they are analyzed in near real time.

## RESULTS

Since the start of the project in May 2022, a total of 545 quality tests have been carried out almost continuously. Since June 2023, a systematic evaluation of the test results for HER2/Neu (*Figure 1*), Ki-67 and PD-L1 has also been carried out with the help of a standardized reference sample (total n = 178).

Due to the cloud-based software Qualitopix®, deviations could be detected at an early stage and usually eliminated at a very reasonable time (e.g. through early batch replacements or changing the position in the staining device).

There were also noticeable quality fluctuations due to a combination of two otherwise non-critical reagents or batches, the analysis of which would otherwise have been much more time-consuming and cumbersome.

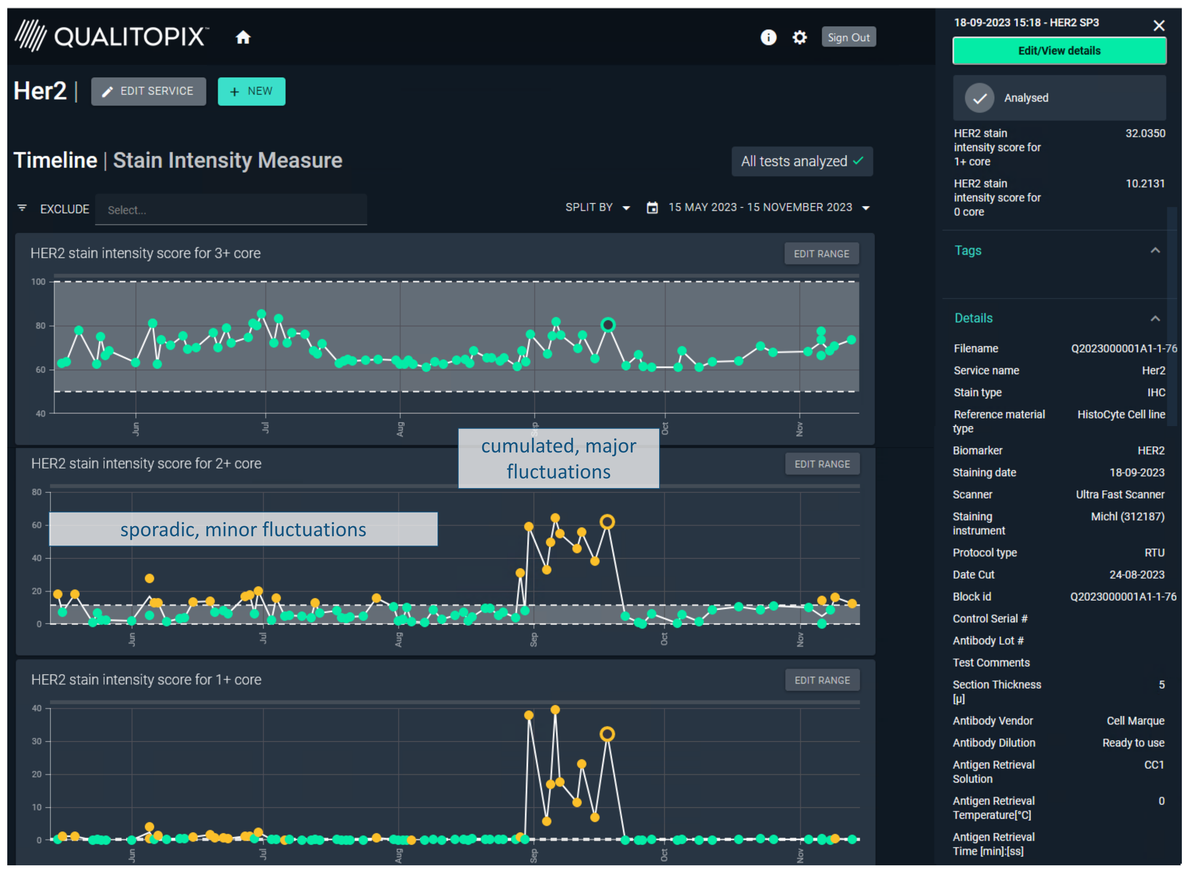
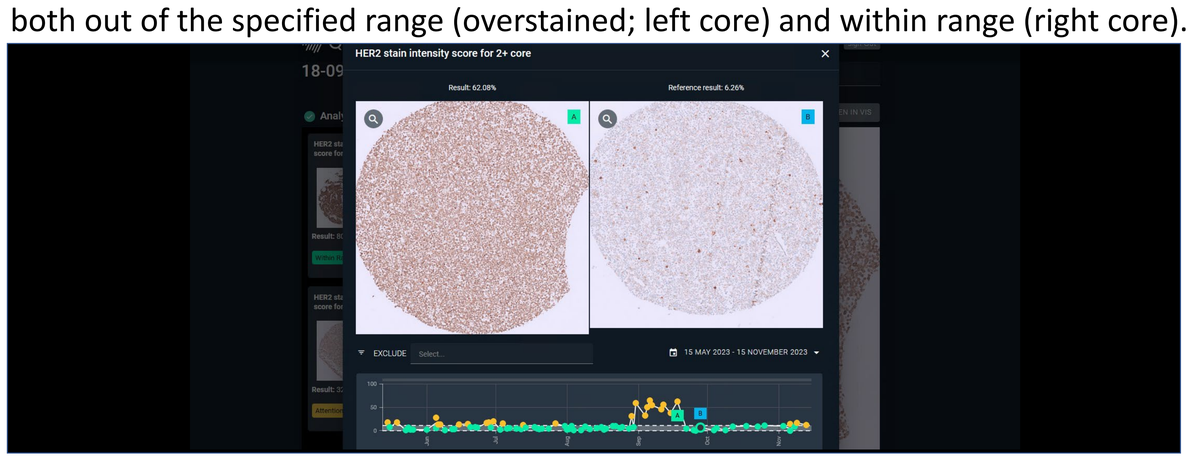



Fig. 1. Top: Qualitopix dashboard showing longitudinal Her2/neu quality assessments and metadata for individual tests. Bottom: Comparison of test samples both out of the specified range (overstained; left core) and within range (right core).




## CONCLUSION

Thanks to an AI-supported quality control workflow using Qualitopix® from Visiopharm, relevant quality fluctuations can even be recognized as a trend in histopathological routine operation at an early stage.

The standardized evaluation of a large number of relevant parameters thus enables early root cause research and problem solving.

**Literature**

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