Virchows Archiv

European Journal of Pathology

Volume 481 · Supplement 1 · September 2022

Springer
428 • 481(S1) S1-S364 (2022)
ISSN: 0945-6317 (print)
ISSN: 1432-2307 (electronic)

European Society of Pathology

European Society of Pathology

34th European Congress of Pathology

The Art of Next Generation Pathology

3 – 7 September 2022
Congress Center Basel, Switzerland

www.esp-congress.org

Abstracts

OFP-10-006
Image-based identification of HER2 status in H&E-stained breast cancer slides

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Background & objectives: Determination of HER2 status is critical for prognosis and guiding treatment decisions in breast cancer patients. Here we present a method to detect HER2 expression directly from routinely prepared diagnostic H&E slide images, using an image-based deep learning approach.
Methods: A HER2-classifier was generated using 251 H&E-stained slide images and their relevant IHC and FISH status from the pathology department at Sourasky Medical Center. Convolutional neural network (CNN) analysis was performed on on-the-fly augmented images. Multiple instance learning (MIL) algorithms and ranking training schemes were applied to create the categorical HER2-classifier (positive/negative), powered by Imagene-AI.
Results: The HER2-classifier was evaluated on a validation set including H&E images only of 104 retrospective cases. The model performance values were 87.5% sensitivity, 85.9% specificity, 86.14% accuracy and 0.89 AUC. To further evaluate the AI-solution additional 245 cases were analysed. In this set, a high proportion (n=9/20; 45%) of false callings was observed in samples with HER2 IHC=3. The IHC slides of samples with score 3 in the set were re-evaluated by two pathologists. While three of the 9 false-negative cases (33%) status was changed to 2, by at least one pathologist, there were no changes in the true-positive group (n=9).
Conclusion: Implementation of Image-based solution to routine pathology workflow can support fast, cost-effective and standardized method for biomarker detection. We evaluated the use of an AI-model to analyse HER2 status compared to conventional IHC and FISH methods. Analysis of 349 cases resulted in 85.3% accuracy. IHC, manually analysed by pathologists, is a subjective method with both intra- and inter-observer discordance's reported. An AI-solution can support the routine workflow flagging cases where re-evaluation can support the pathologist analysis of difficult cases.