

Deep Learning-based Digital Pathology Algorithm Overcomes Tumor Content Limitations for FGFR Alteration Detection in Non-Muscle Invasive Bladder Cancer

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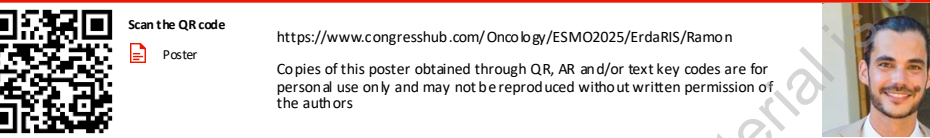
Key Takeaway: Impact to Business/Patients

Deep Learning-based H&E screening may enable FGFR testing from minimal tissue, supporting molecular profiling in NMIBC patients with limited tumor availability.

Learnings & Conclusions

MIA:BLC-FGFR accurately identifies FGFR alterations from a single H&E-stained WSI in NMIBC samples, including those with limited tumor tissue. This approach may help extend molecular testing to patients with small biopsies, potentially supporting broader access to emerging targeted therapies.

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Introduction/Background

Problem Statement

- Tumor volume in non-muscle invasive bladder cancer (NMIBC) can vary, and in some cases, limited tissue may affect the feasibility of certain diagnostic workflows.

Solution

- Here, we demonstrate that an AI-based digital pathology algorithm, **MIA:BLC-FGFR**, can accurately detect the presence of susceptible **FGFR** alterations from a single **H&E**-stained whole slide image (WSI) in **NMIBC** tissue samples, including those with limited tissue availability—highlighting its potential to support molecular profiling.

Methodology

MIA:BLC-FGFR:

- MIA:BLC-FGFR** consists of an image quality control (QC) preprocessing stage, a Foundation Model (FM) pre-trained on ~55k unlabeled digital WSIs from various sources (multiple scanners models, hospital systems, labs, diseases, tissue sites), and a classification module to enable inference of **FGFR** status from H&E-stained images. Figure 1 showcases the schematic of **MIA:BLC-FGFR**.

Experiments:

- We evaluated **MIA:BLC-FGFR** on 169 whole slide images (WSIs) derived from **NMIBC** tissue blocks. Each block was tested for **FGFR** alterations using a RT-PCR assay performed on unstained slides from the corresponding block.
- Among these blocks, 67% (113/169) required multiple unstained tissue slides from the same block to achieve the required tumor area for RT-PCR assay, resulting in the use of 410 additional unstained slides to obtain tissue assay results.
- MIA:BLC-FGFR** was tested on whole slide images (WSIs) from slides with various tumor areas. Performance was assessed against varying minimum tumor area thresholds on the WSIs: $\geq 100 \text{ mm}^2$, $\geq 50 \text{ mm}^2$, $\geq 25 \text{ mm}^2$, $\geq 10 \text{ mm}^2$, $\geq 5 \text{ mm}^2$, and $\geq 1 \text{ mm}^2$, with tumor surface area obtained computationally.

Results

- Overall, 410 (243%) additional slides were needed to obtain **FGFR** results with the RT-PCR assay on 169 patients compared to **MIA:BLC-FGFR**, which required one slide per patient to provide an **FGFR** result.

Tumor Area on Single Slide	$\geq 100 \text{ mm}^2$	$\geq 50 \text{ mm}^2$	$\geq 25 \text{ mm}^2$	$\geq 10 \text{ mm}^2$	$\geq 5 \text{ mm}^2$	$\geq 1 \text{ mm}^2$
Trial	TAR-210 Ph1 ¹					
Reference	RT-PCR Assay					
Dataset size	56	82	114	141	152	165
NPA	70%	73%	80%	80%	80%	81%
PPA	93%	89%	85%	84%	84%	78%
auROC	90%	89%	90%	88%	88%	87%

¹<https://www.clinicaltrials.gov/study/NCT05316155>

- Results in the table above showcase that **MIA:BLC-FGFR** exhibited consistent performance across various tumor areas, with auROC ranging from 87% for tissues with $\geq 1 \text{ mm}^2$ to 90% for $\geq 100 \text{ mm}^2$.

References

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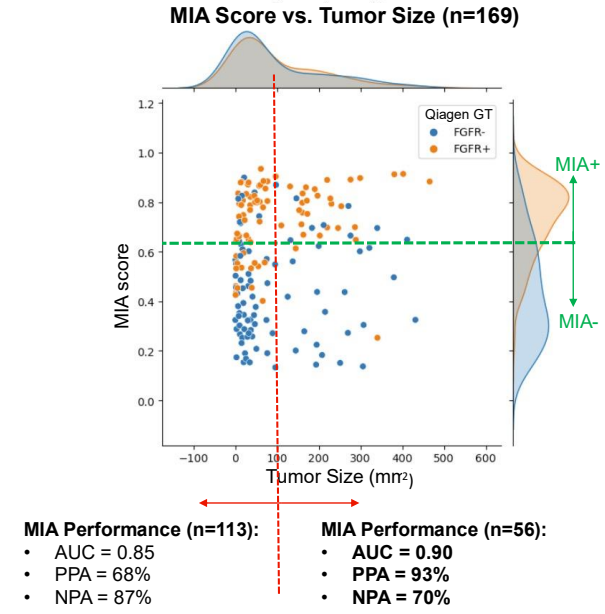
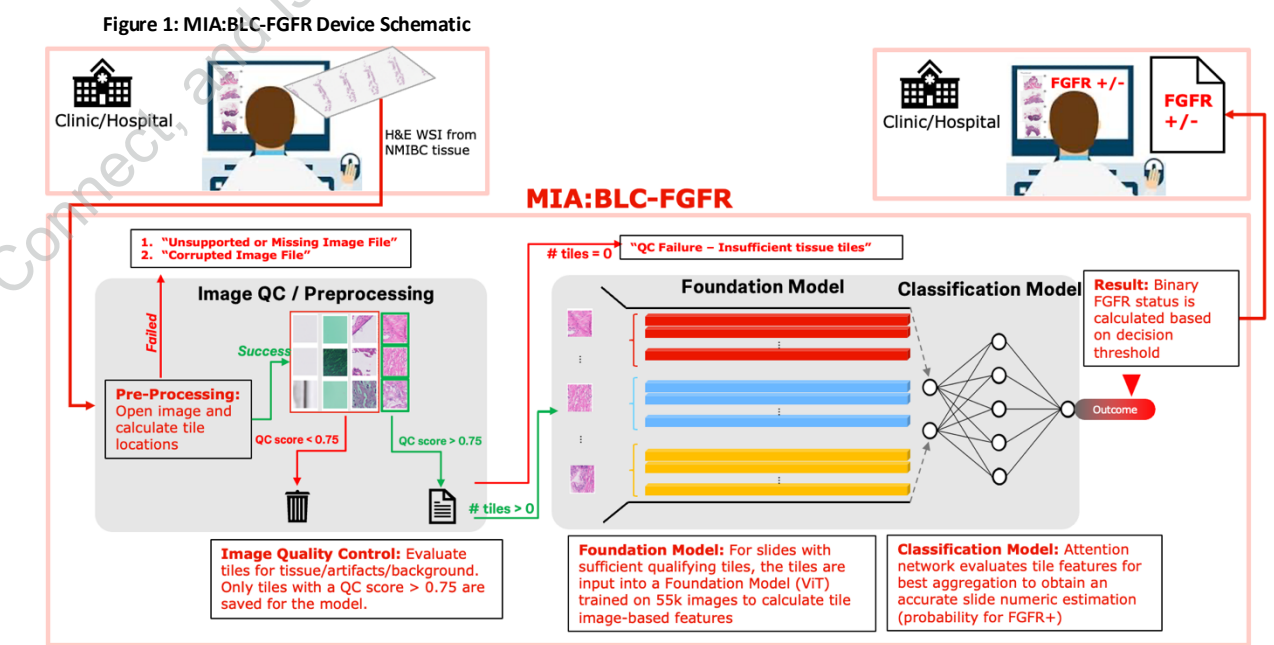
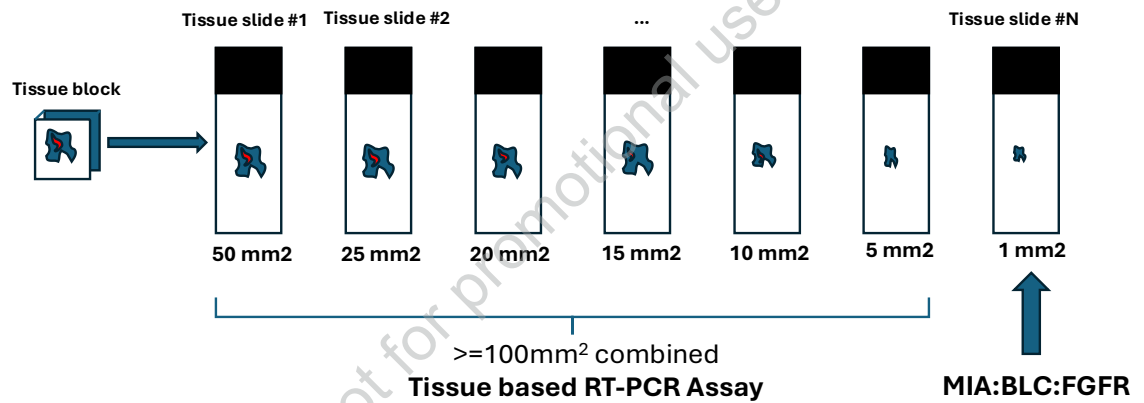


Figure 2: This plot highlights MIA scores vs the tumor size colored as per RT-PCR reference result.

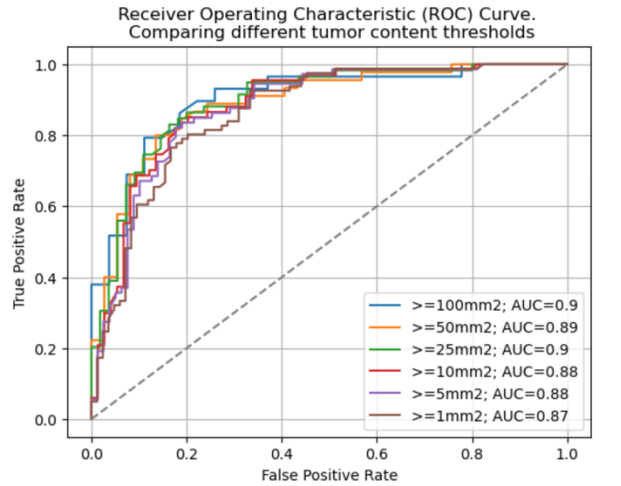


Figure 3: auROC curves at different tumor content sizes. MIA maintains its high performance when lower tumor content threshold at 1mm²

