

eeDAP Registration Study

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FDA

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Study purpose

- The main idea of eeDAP system is helping user view same ROI on glass slide and WSI image. Thus, high accuracy of registration is a pre-requirement.
- The purpose of this study is evaluating the eeDAP system registrations quality.

Study methods

1. Choose 10 ROIs per slide. The center of each ROI should be a small target: a corner of cell or tiny structure.
2. In digital image, use cross reticle to locate the target
3. After registration, reader looks through the eyepiece and uses the ruler reticle to measure the distance between the target and the center

Task-specific Registration

There are 3 registrations:

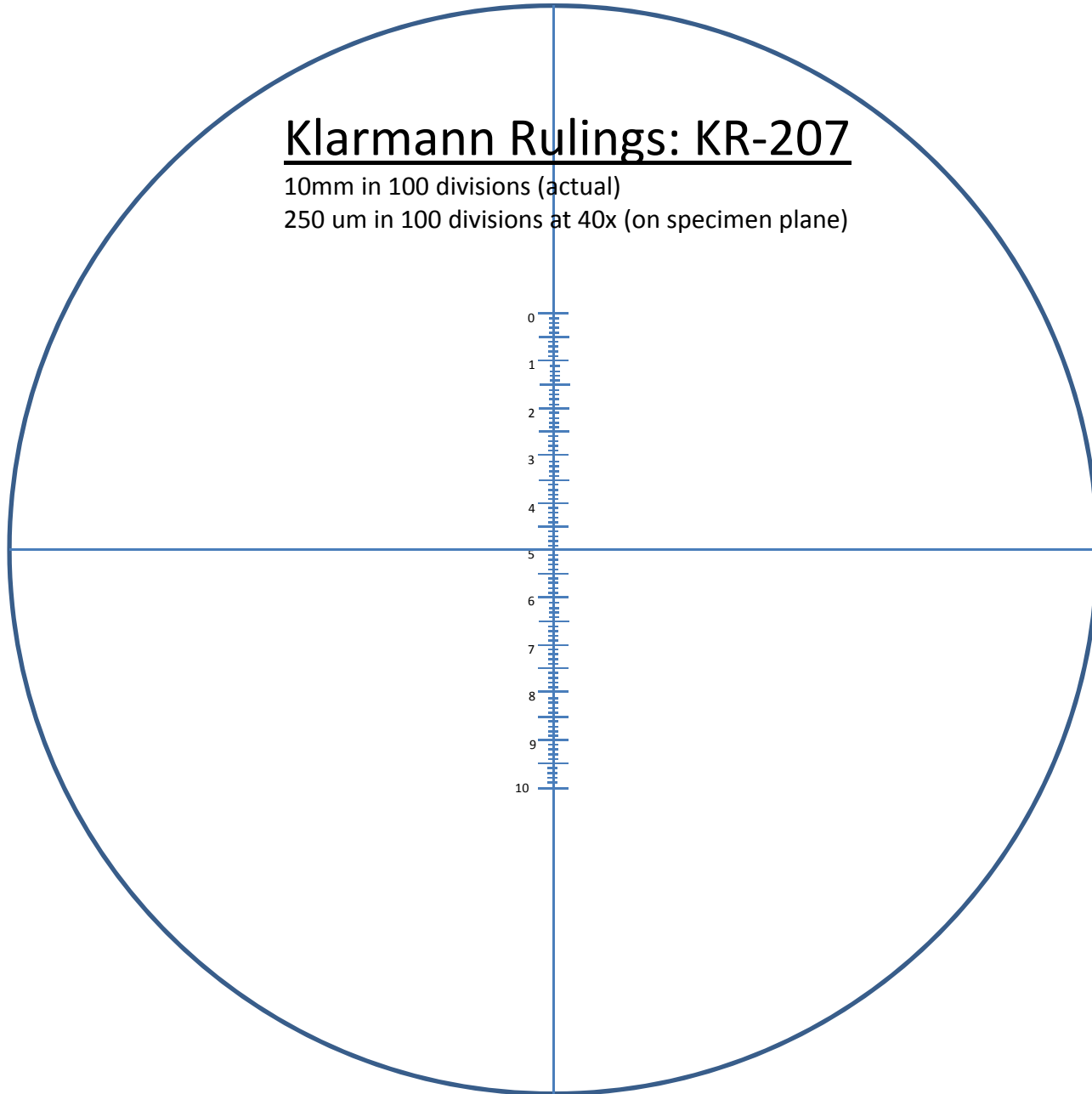
- **Fast Registration:** Use 300x300 pixels camera image, and the whole extracted WSI ROI.
- **Best Registration:** If the WSI ROI is larger than 600x600, use 300x300 pixels camera and whole WSI ROI. If the WSI ROI is small, use whole camera image.
- **Automatic registration:** software automatically does **Fast registration** when stage arrives at the task area (without focusing the microscope).

Reticle Choice

Klarmann Rulings: KR-207

10mm in 100 divisions (actual)

250 μm in 100 divisions at 40x (on specimen plane)



Draft study

Fast Registration Evaluation:

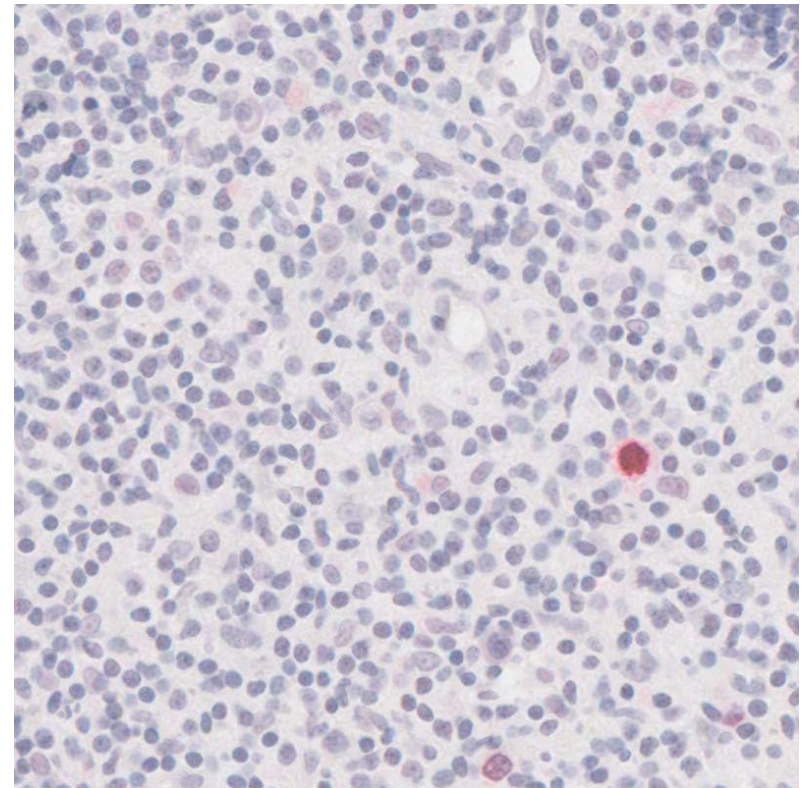
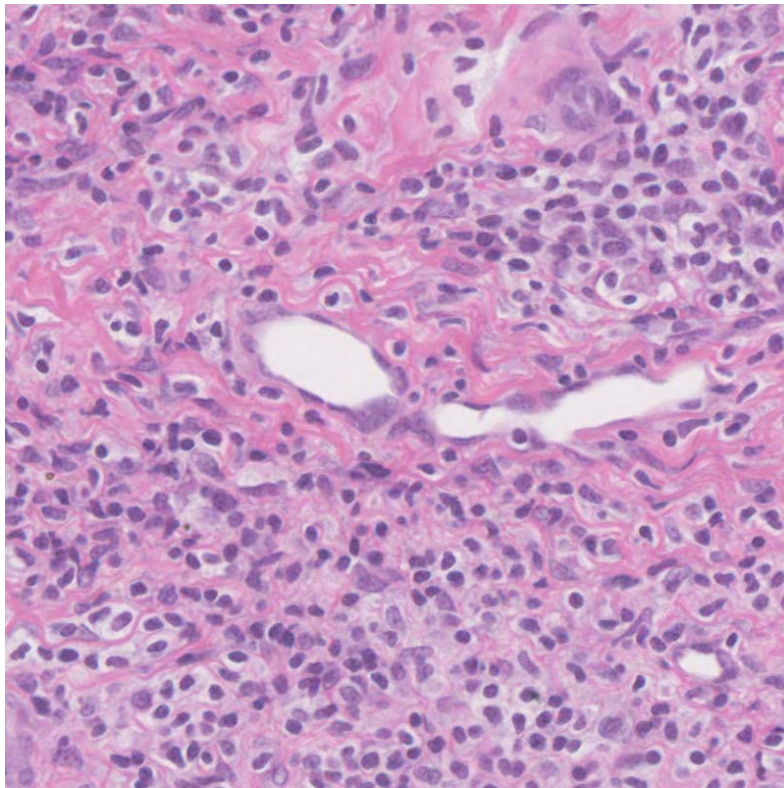
2 readers, 2 slides, 20 ROIs.

Best Registration Evaluation:

1 reader, 2 slides , the same 20 ROIs.

Slide choice

Two NIH Mitotic Count Pilot Study slide: one HE, one pHH3.



Results

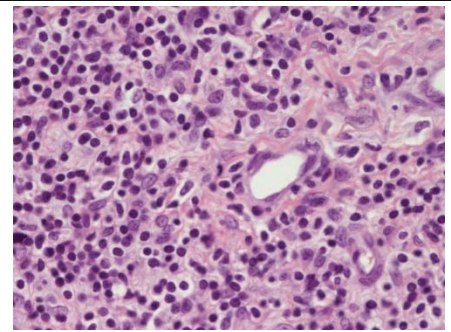
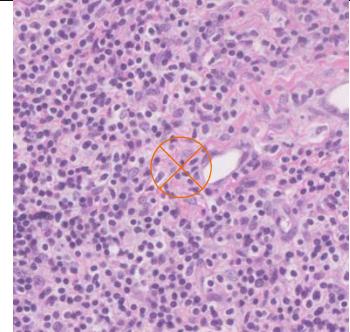
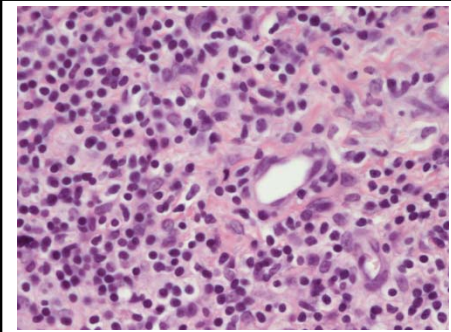
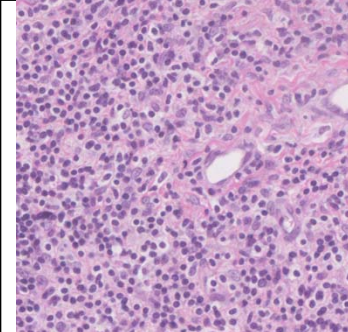
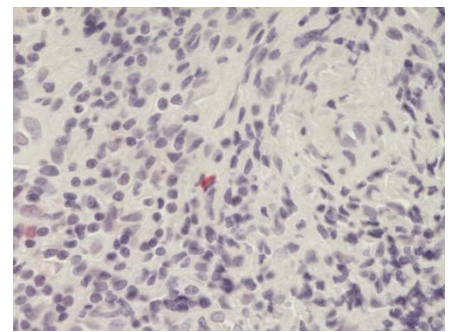
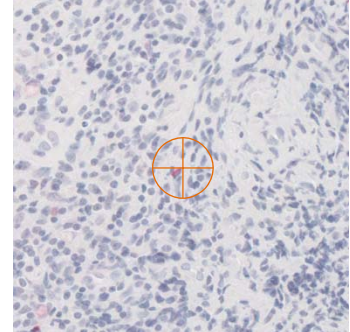
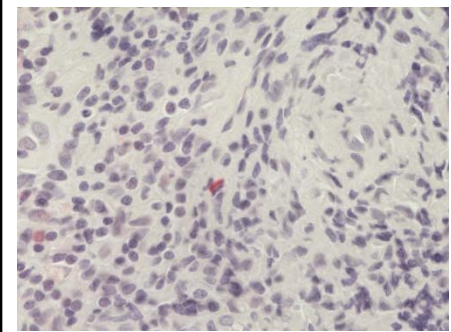
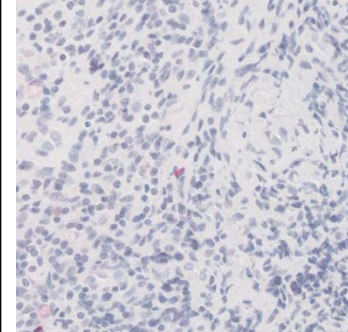
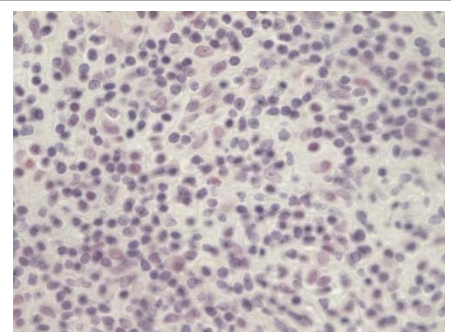
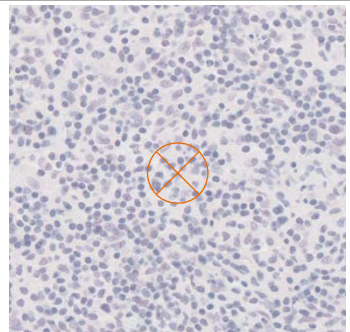
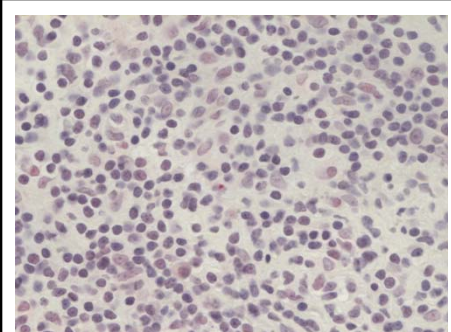
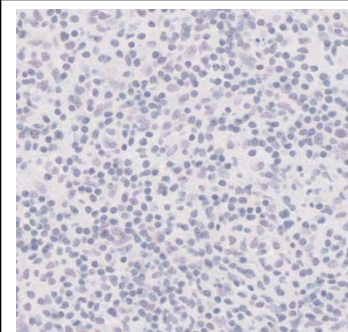
In **Fast Registration**, Two readers gave very similar results

- For H&E, 20 of 20 registrations were within 2.5 microns from center feature.
- For pHH3, 19 of 20 registrations were within 2.5 microns from center feature.
 - The outlier ROI, same for both readers, was about 100 microns from center feature.

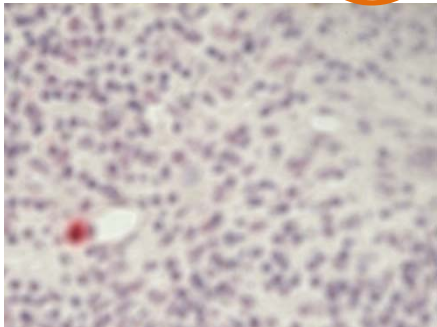
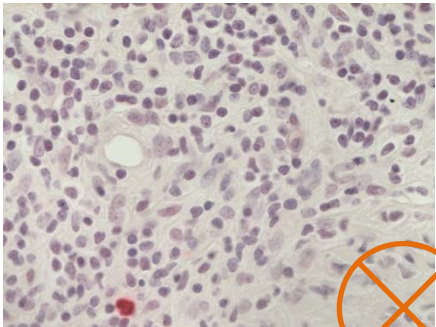
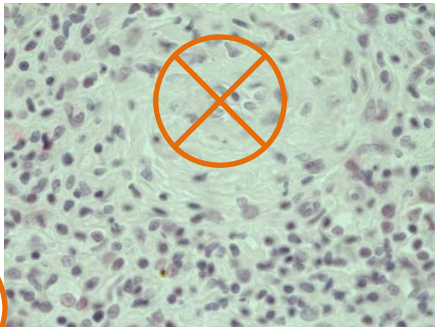
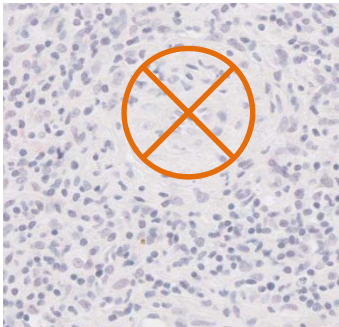
In **Best Registration**

- For all 40 ROIs in two slides, registrations were within 2.5 microns from center feature.

Fast Registration ROIs

Reader A		Reader B	
Camera Image	WSI Image	Camera Image	WSI Image
			
			
			

Outlier ROI

reader A, Fast registration camera image	reader B, Fast registration camera image	reader B, <i>Best registration</i> camera image	WSI image
 <p>A microscopy image showing a dense field of purple-stained cells. A small red spot is visible in the lower-left quadrant. An orange circle with a diagonal cross and a question mark is positioned in the upper-right area of the image.</p>	 <p>A microscopy image showing a dense field of purple-stained cells. A small red spot is visible in the lower-left quadrant. An orange circle with a diagonal cross is positioned in the lower-right area of the image.</p>	 <p>A microscopy image showing a dense field of purple-stained cells with a green tint. An orange circle with a diagonal cross is positioned in the upper-right area of the image.</p>	 <p>A Whole Slide Image (WSI) showing a dense field of purple-stained cells. An orange circle with a diagonal cross is positioned in the upper-right area of the image.</p>