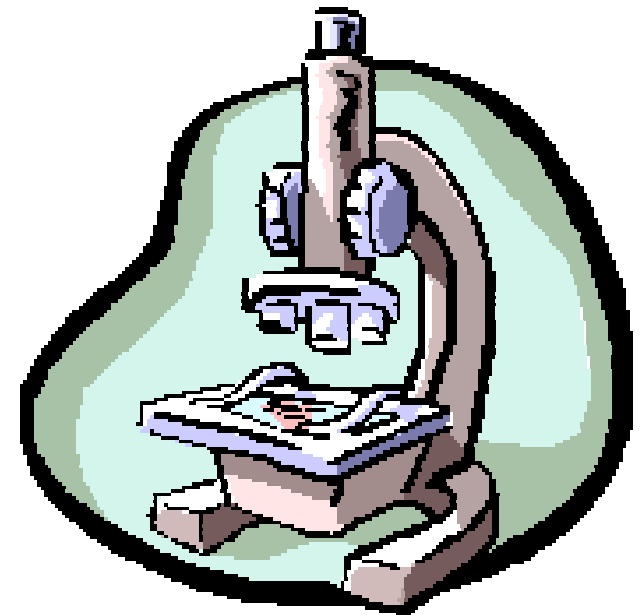


Quality Assurance and Quality Control in the Pathology Dept.

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2nd IBDC, 9th February, 2012





Pathology as a black hole??

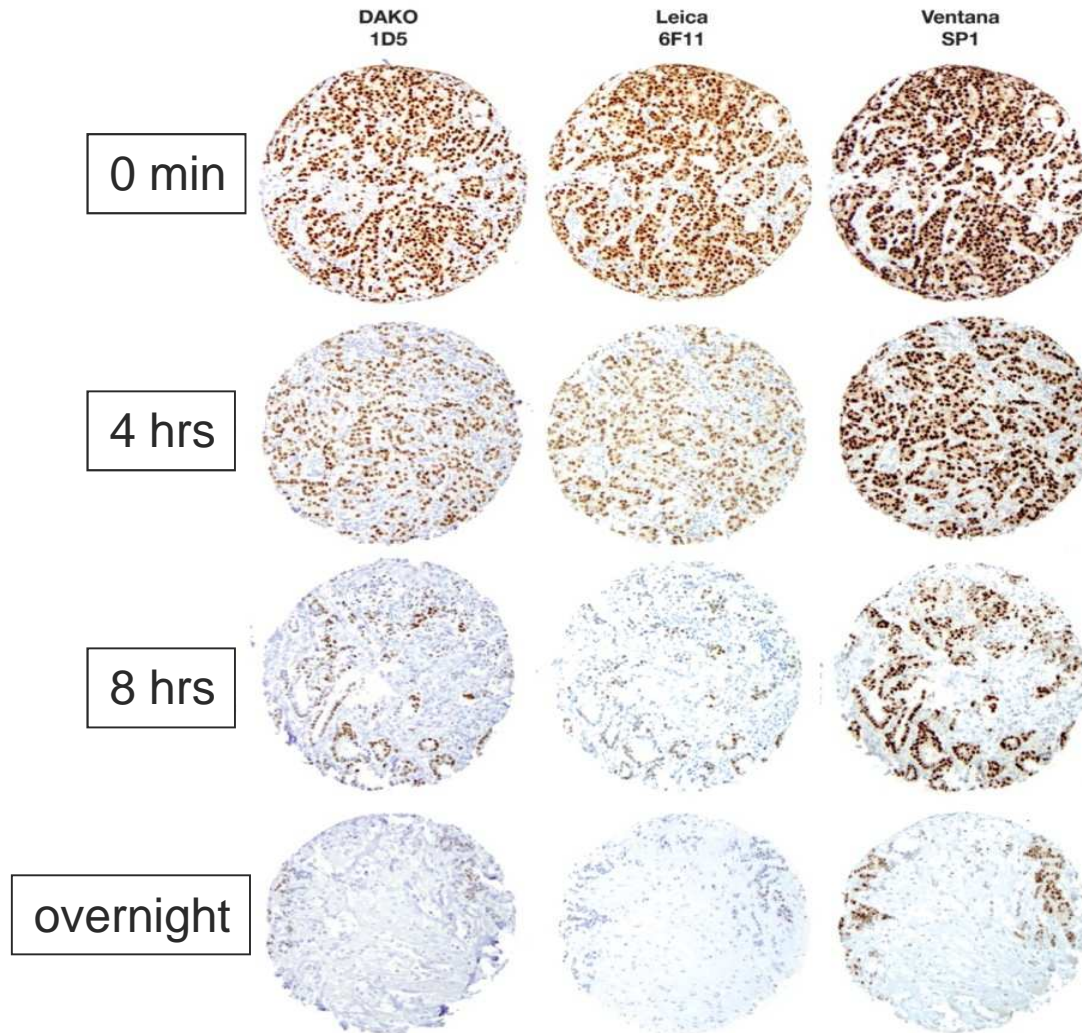




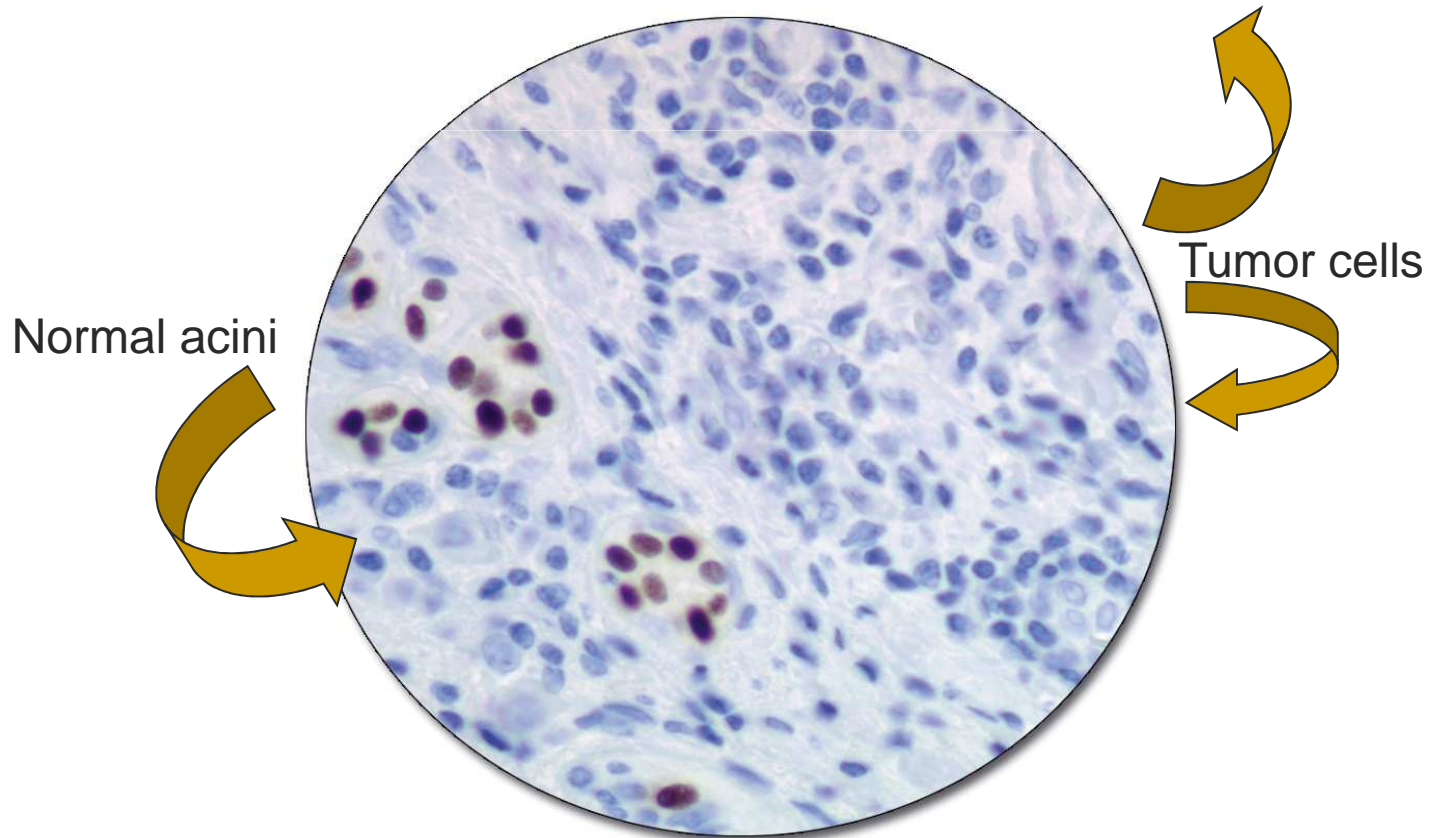
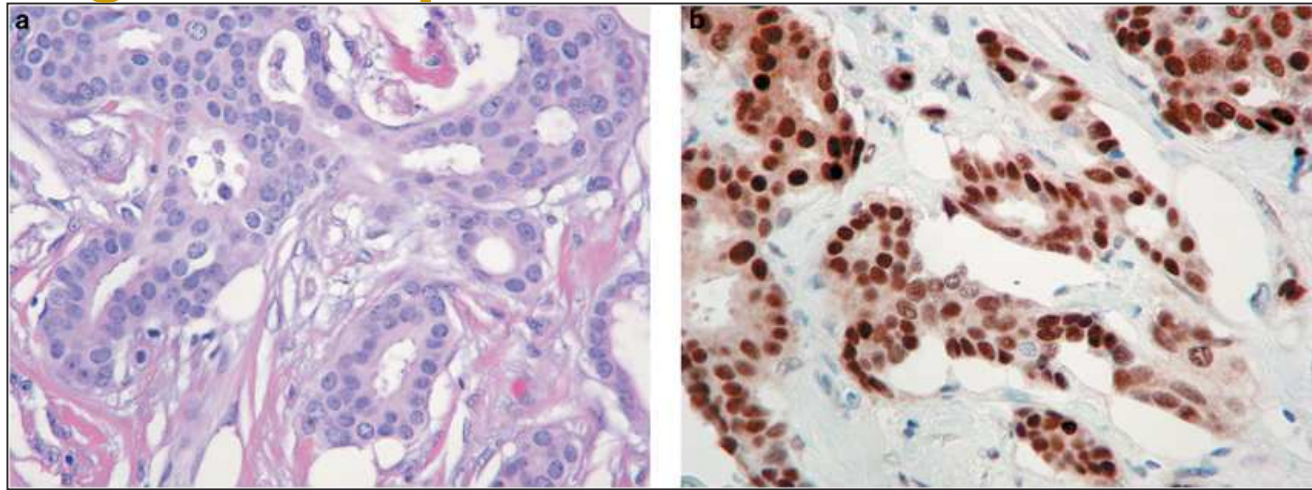
- Unique subject
- Labor intensive
- Numerous steps
 - Pre analytical
 - Analytical
 - Post analytical
- Cooperation with clinicians

Time to Tissue Fixation

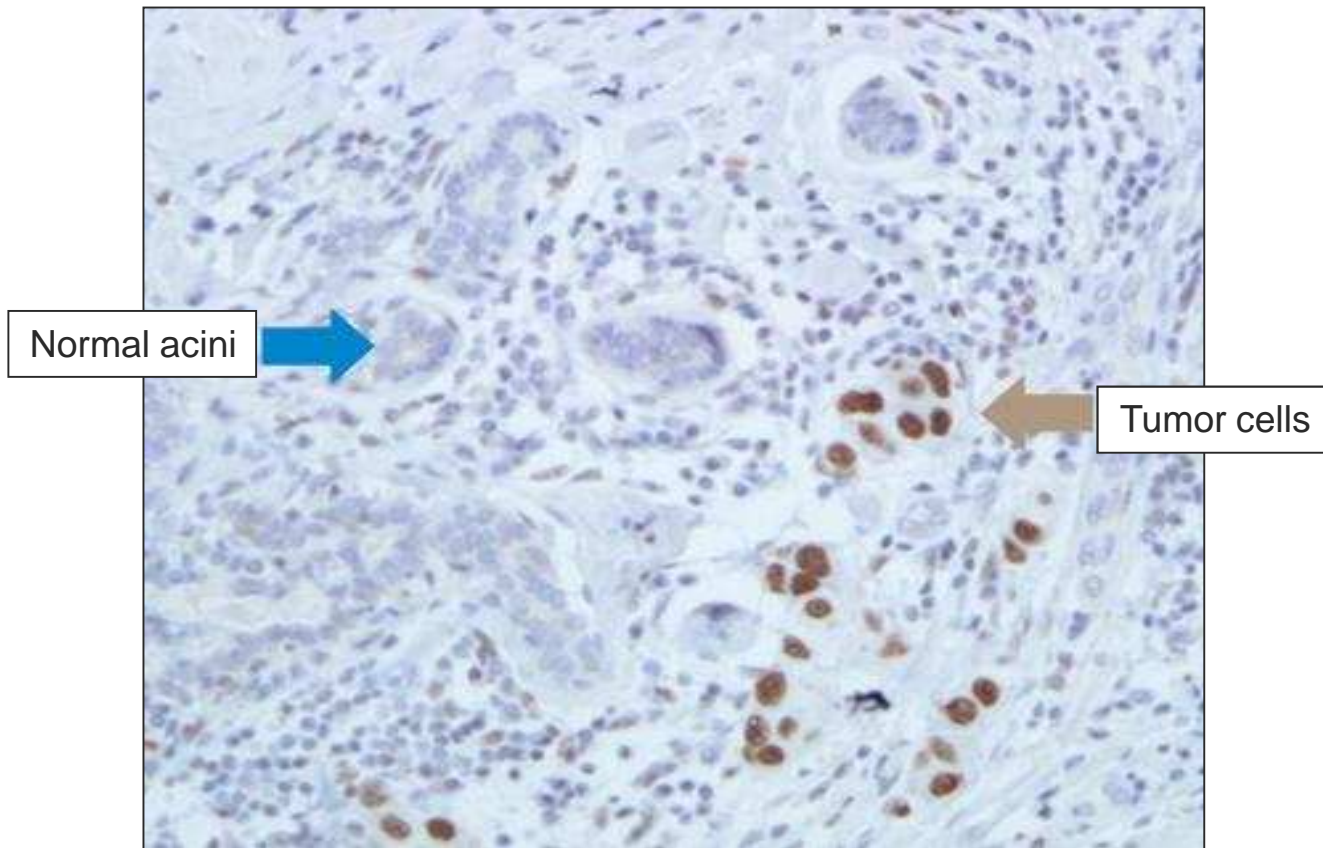
Estrogen receptor



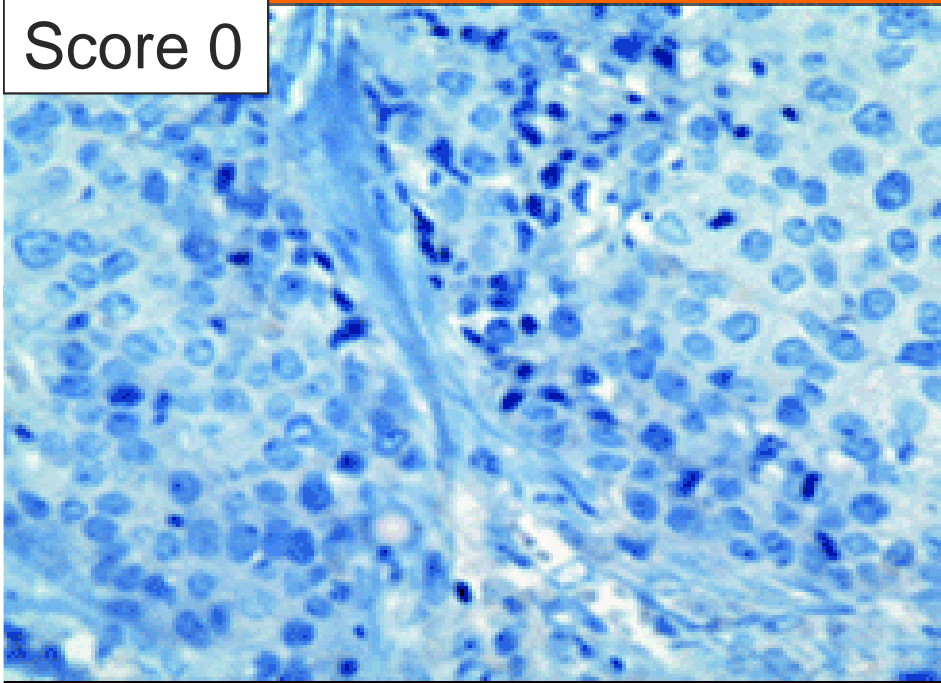
Estrogen Receptor Immunohistochemistry



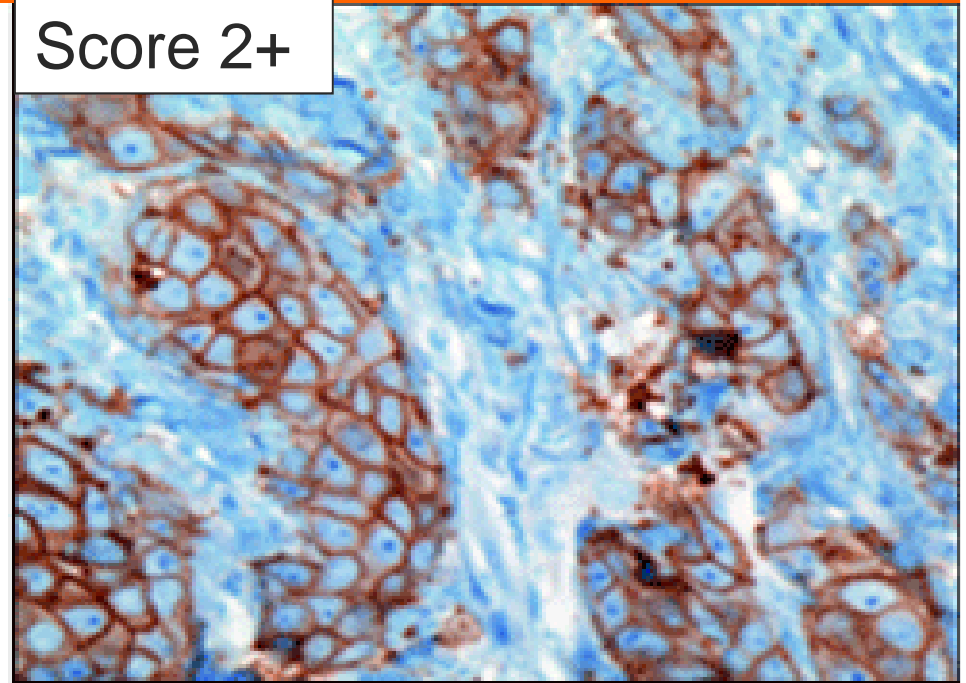
Problematic Staining



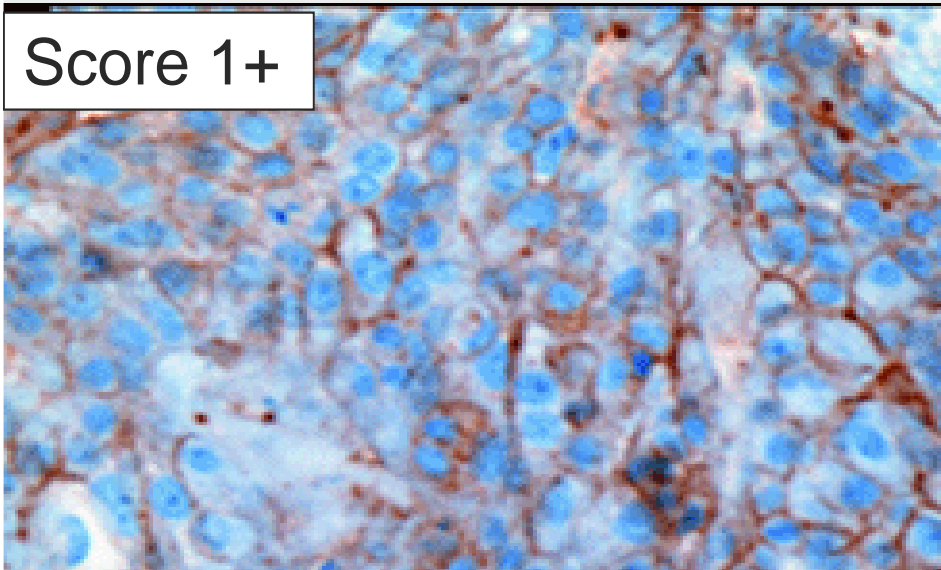
Score 0



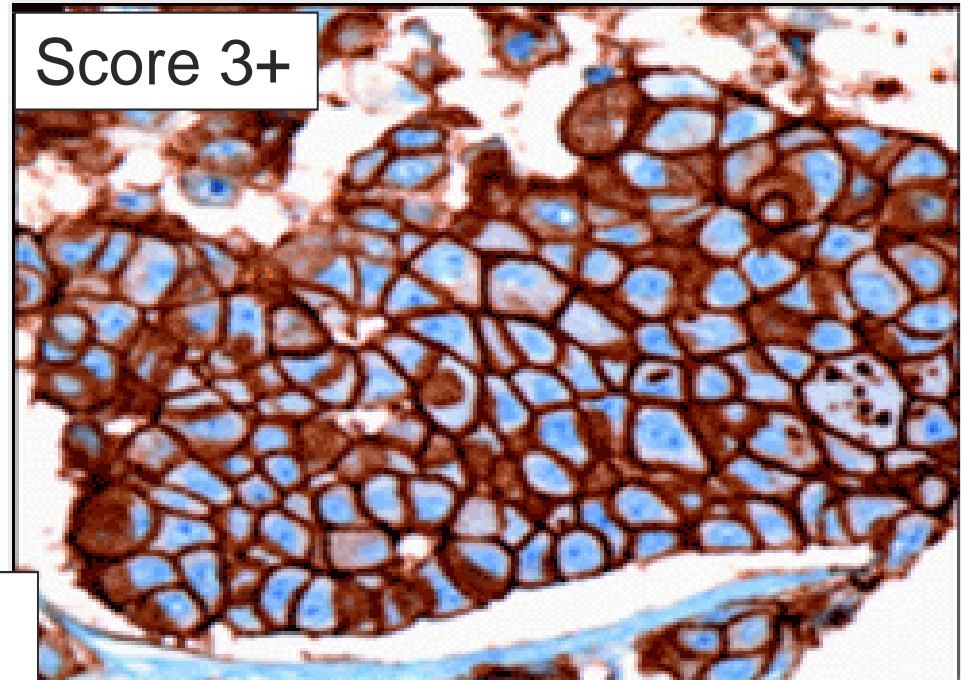
Score 2+



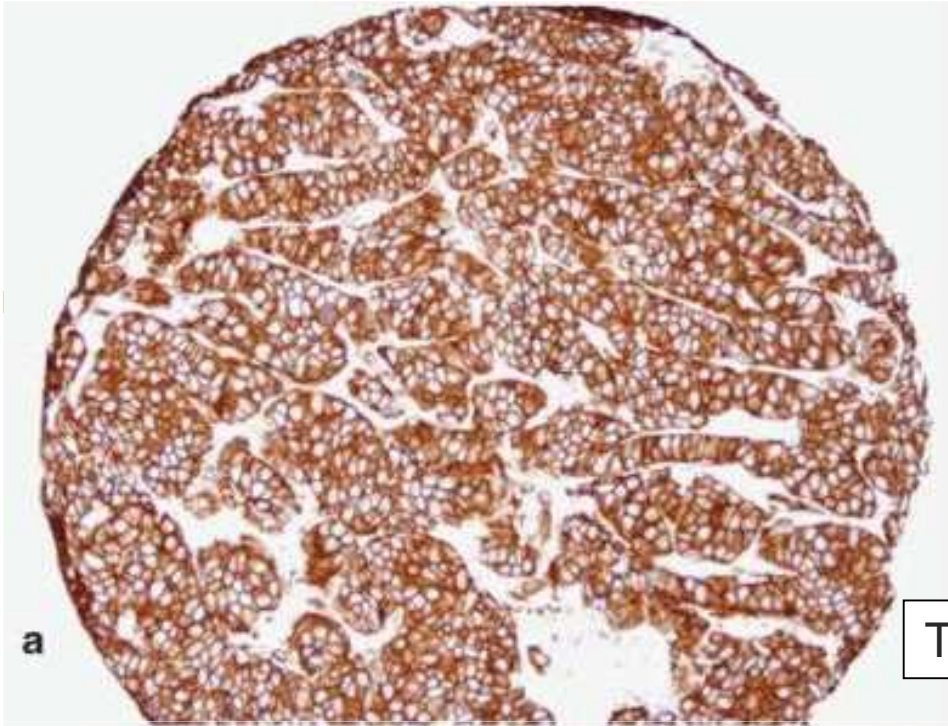
Score 1+



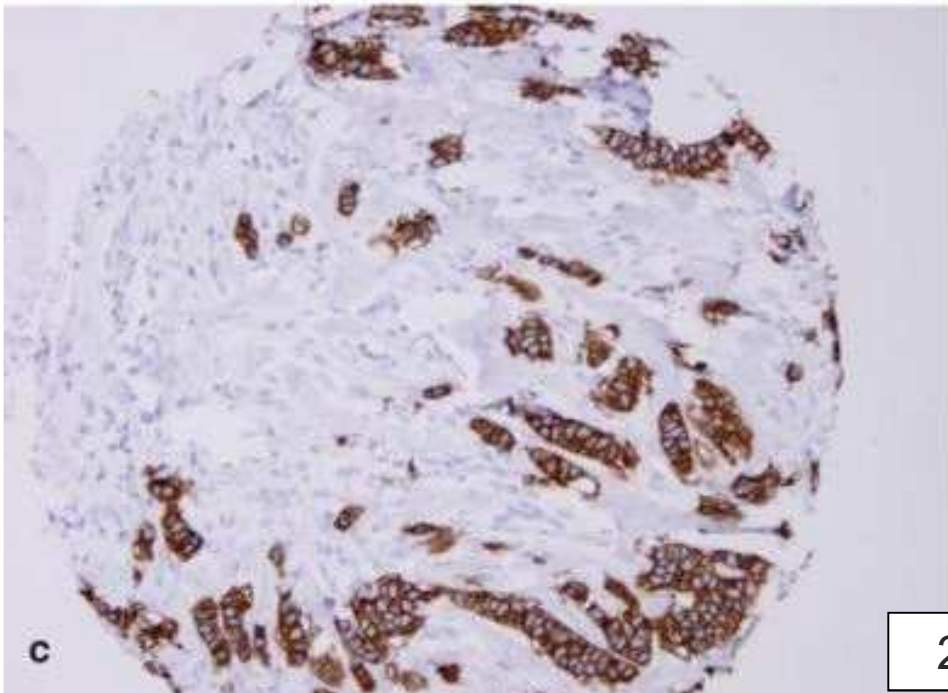
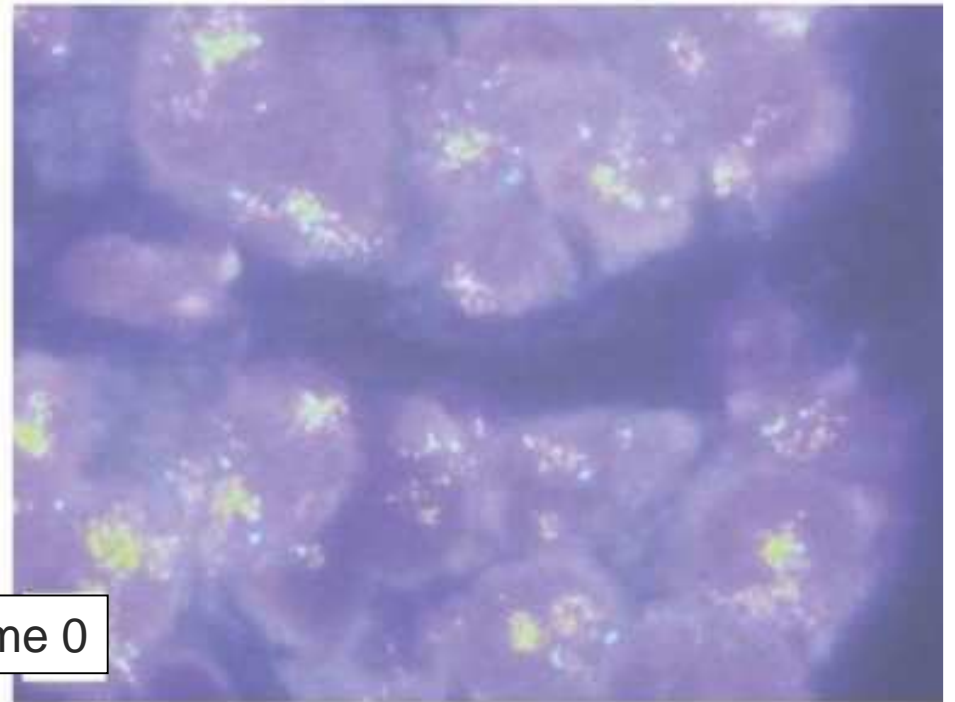
Score 3+



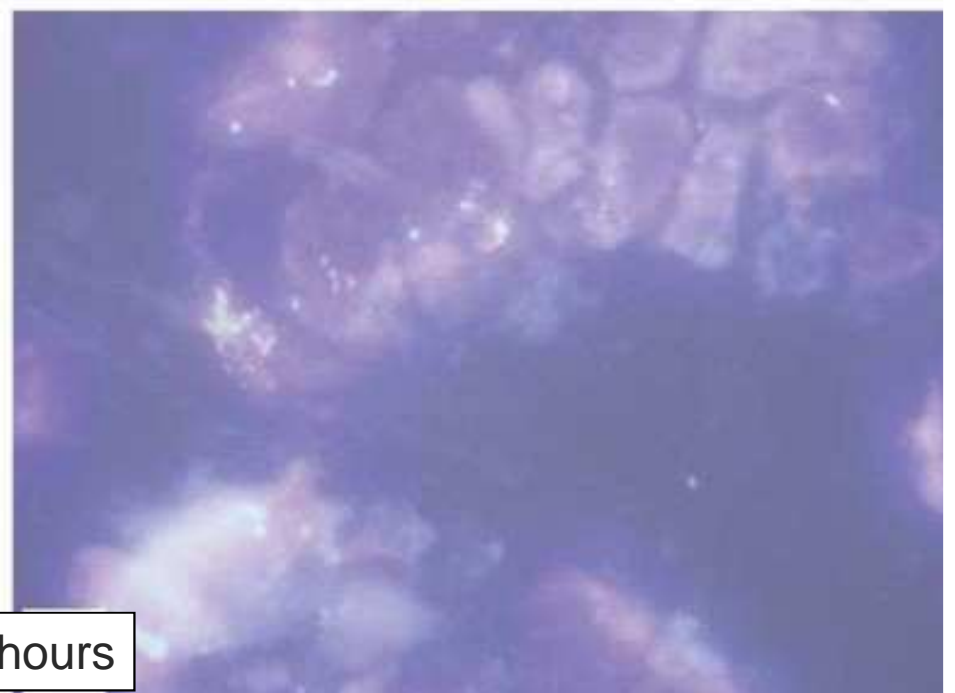
Her2 Immunohistochemistry

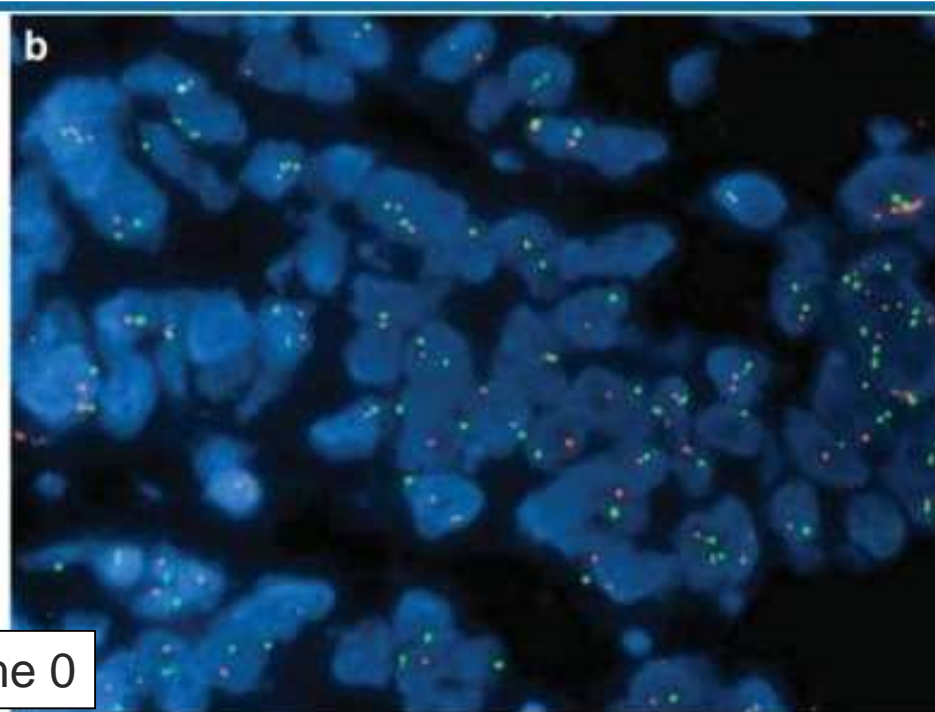
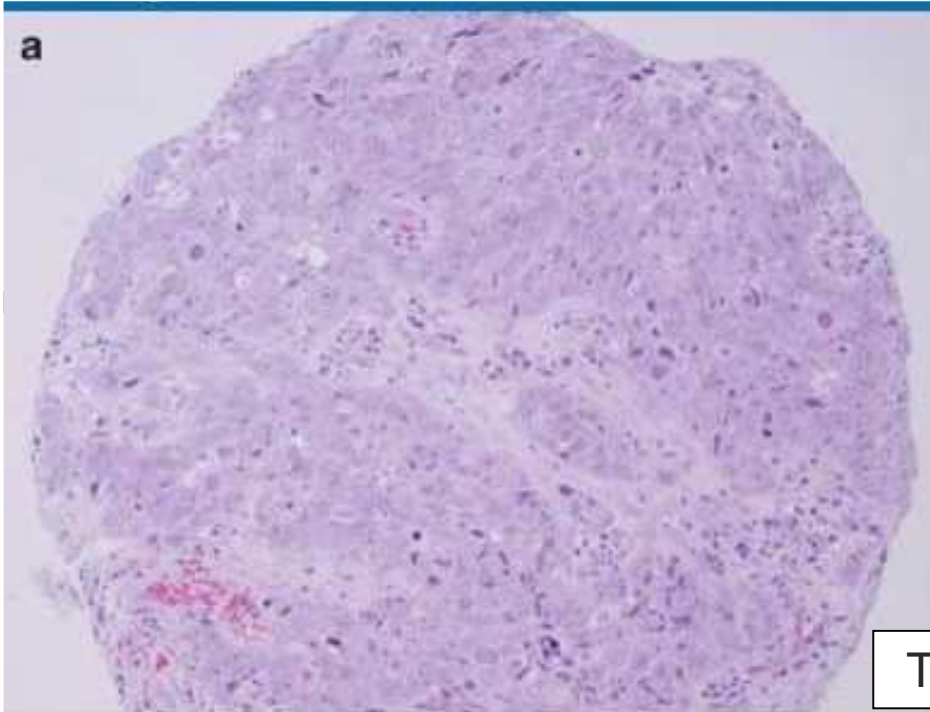


Time 0

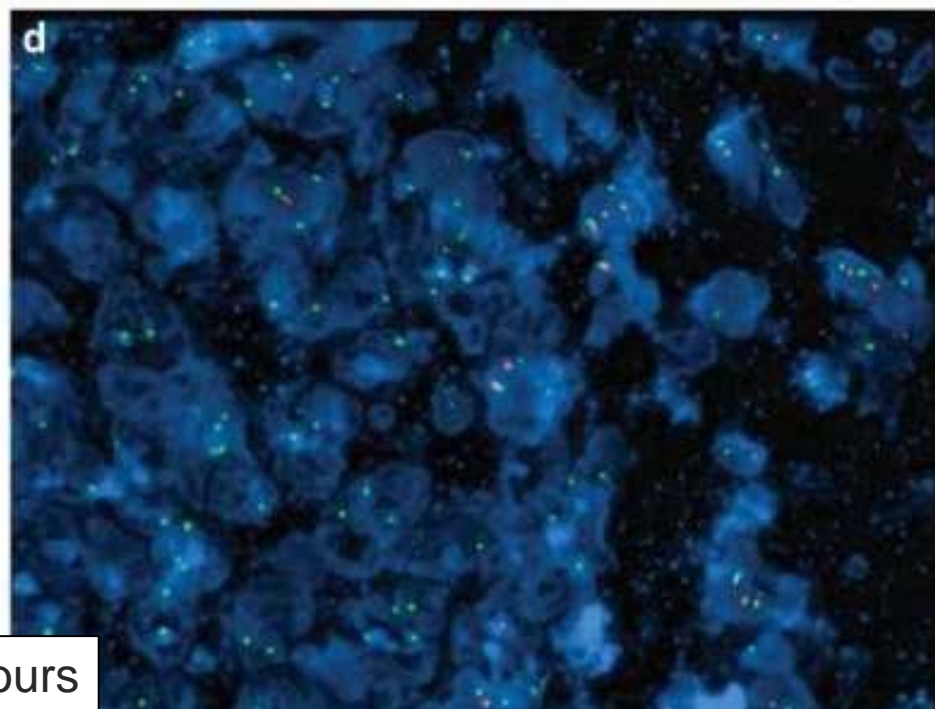
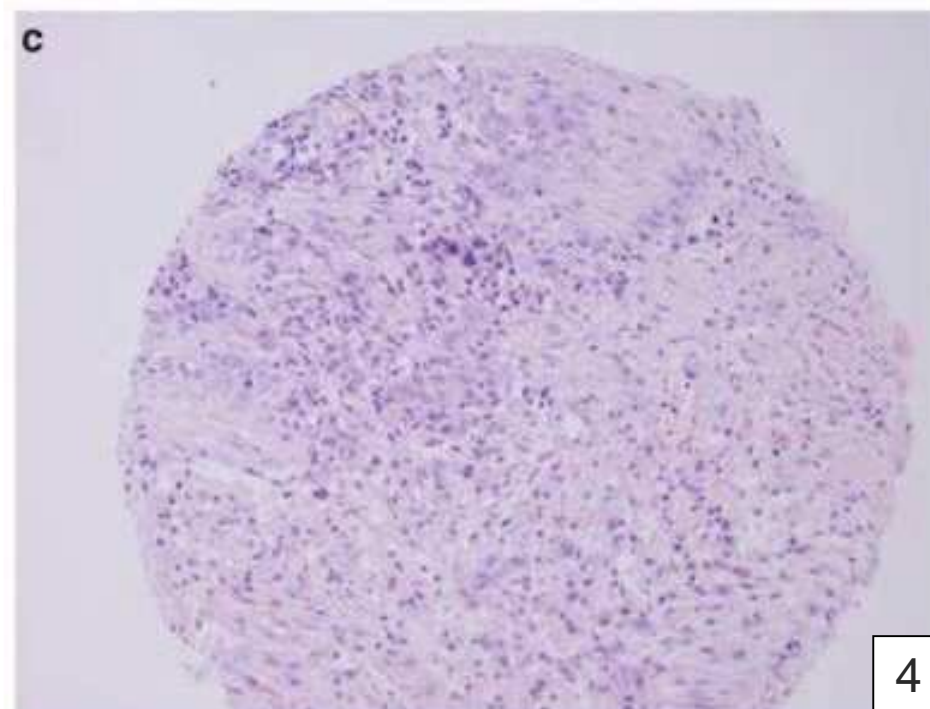


2 hours

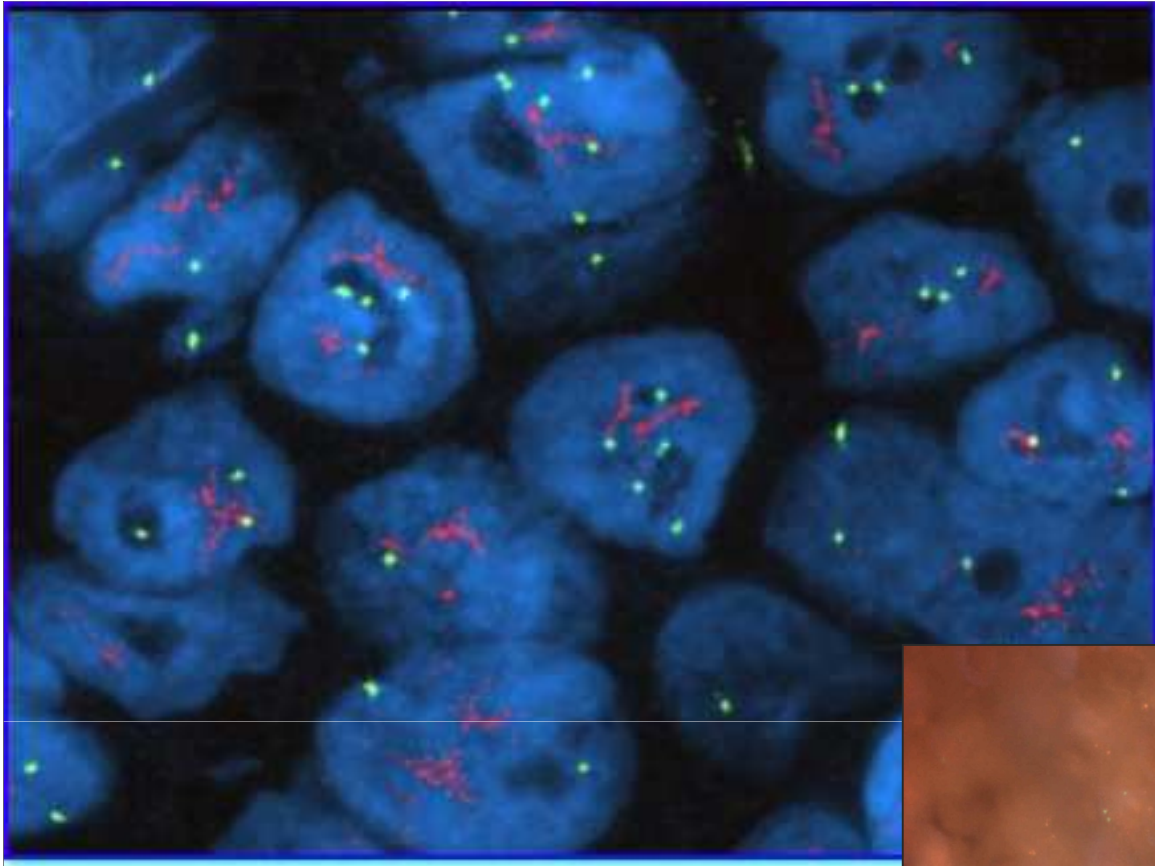




Time 0



4 hours

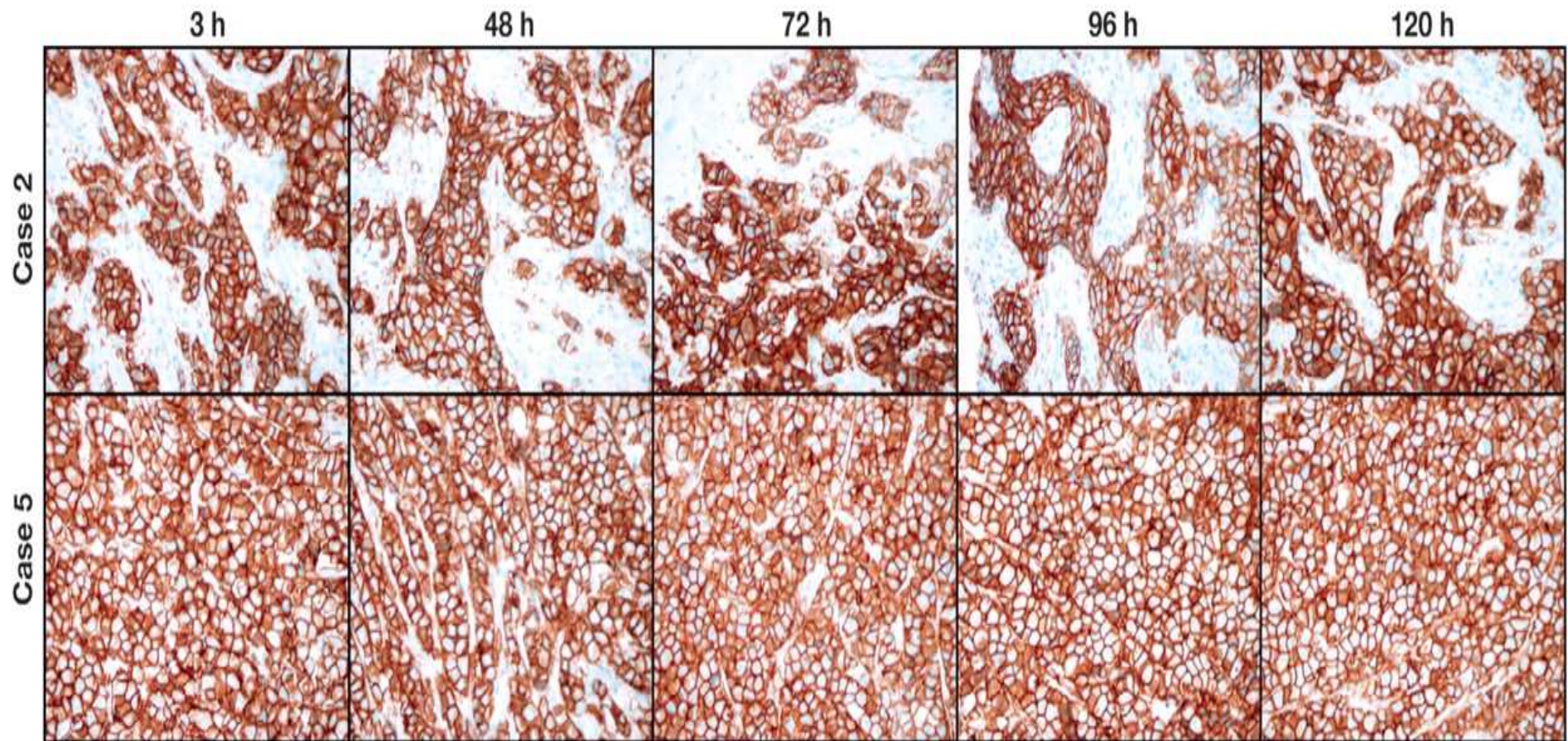


Her2 FISH/Optimal result

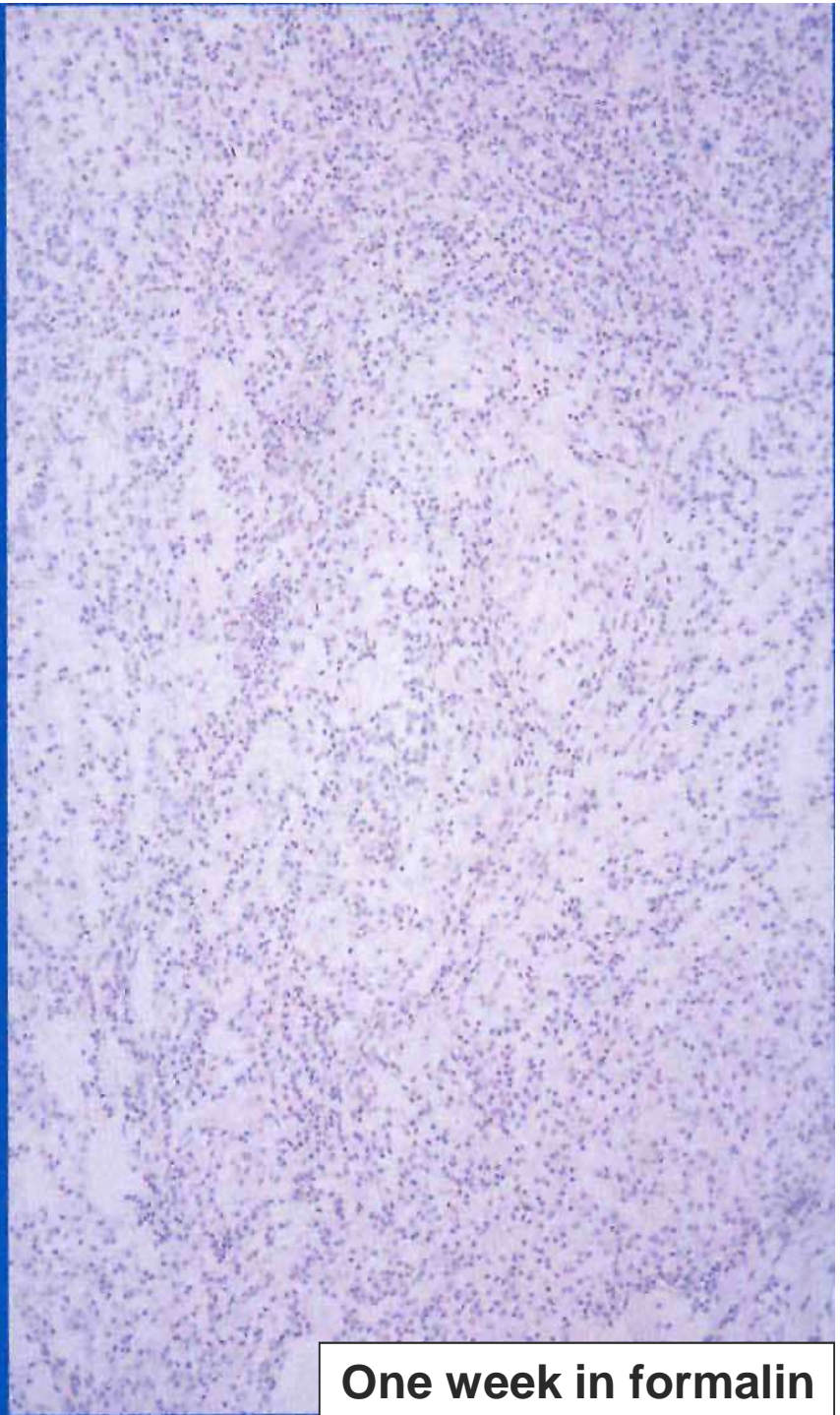
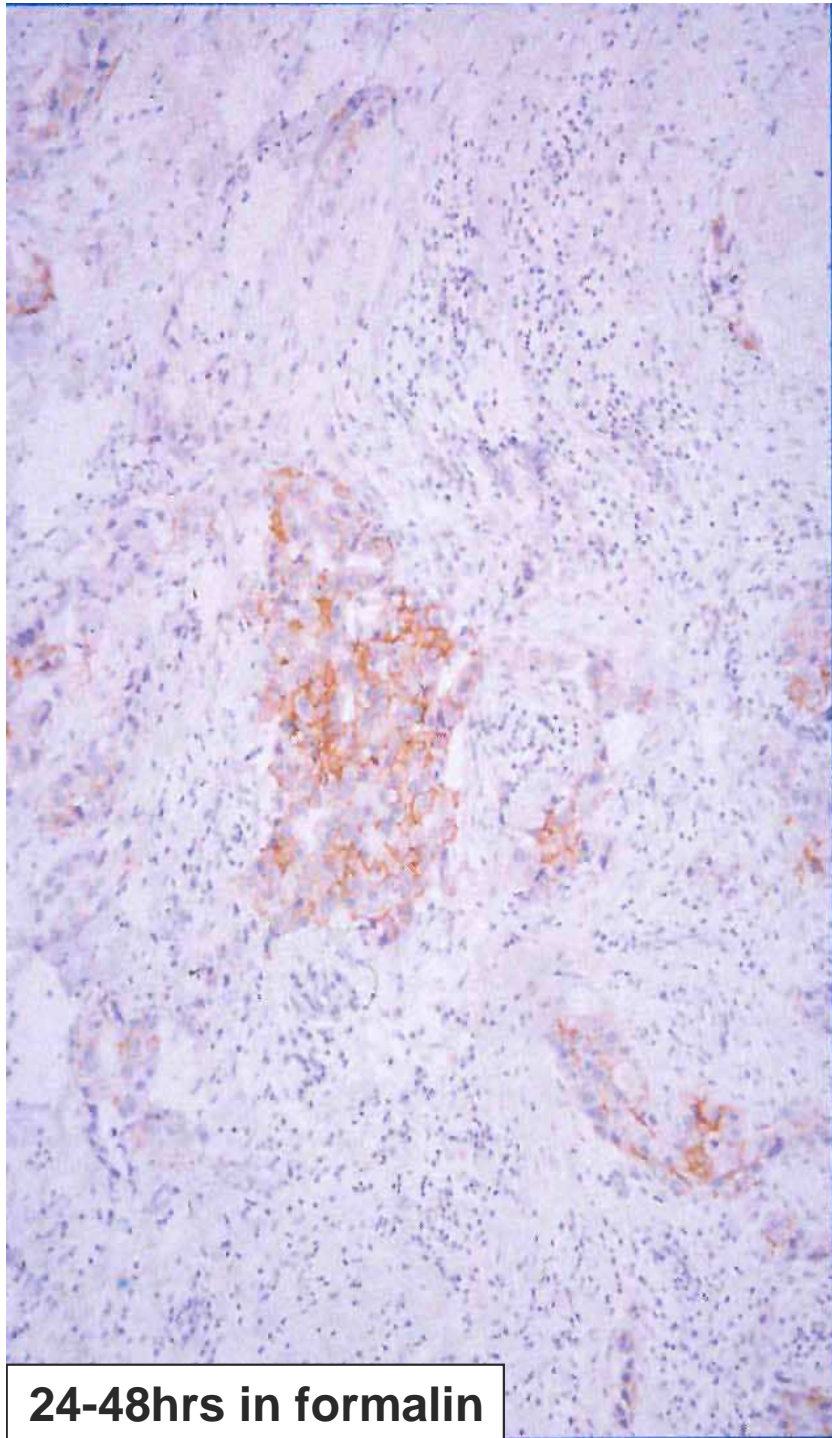
Her2 FISH/Under fixation effect



What does pronged fixation do?



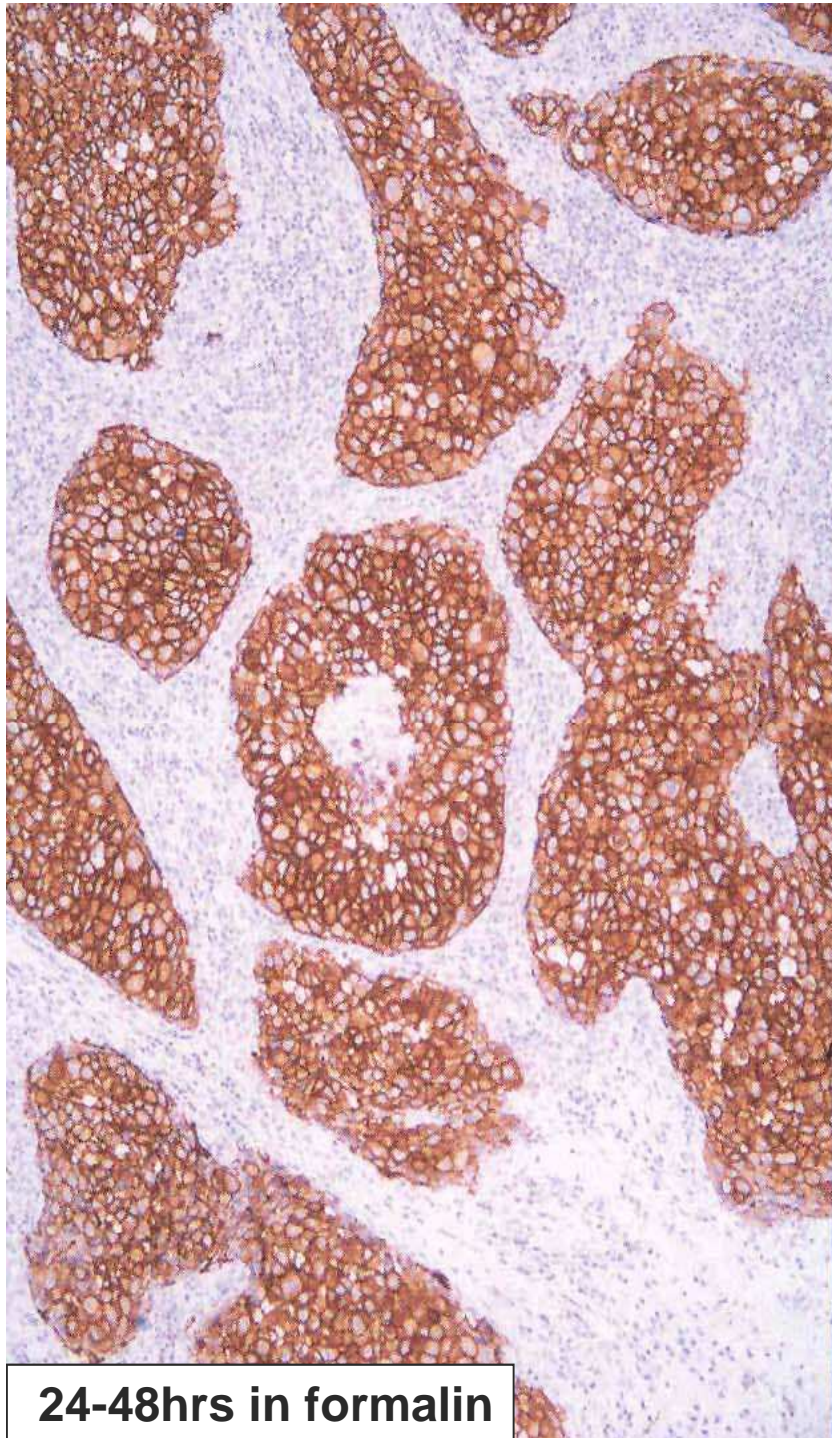
**Her2
IHC
2+**



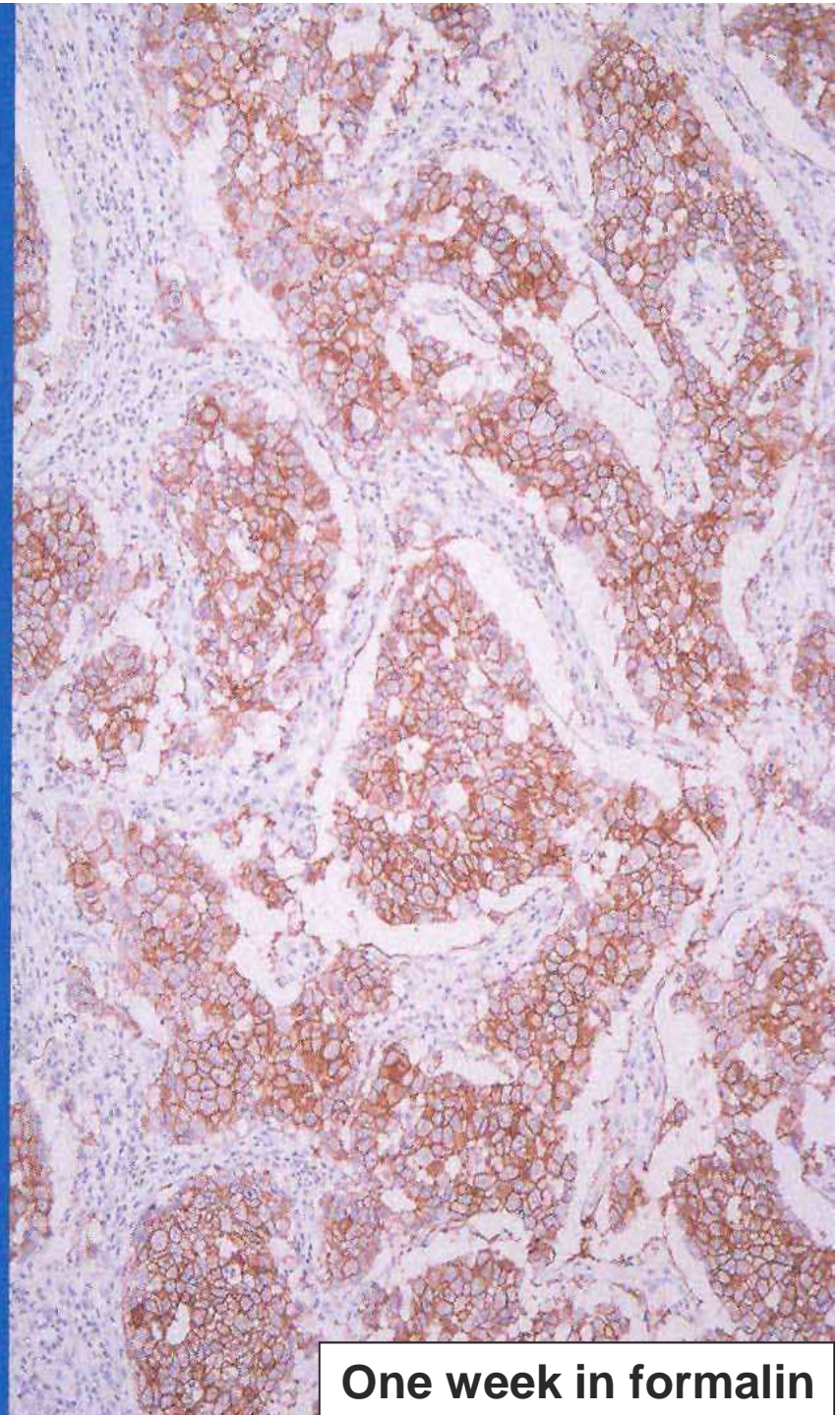
24-48hrs in formalin

One week in formalin

**HER2
IHC
3+**



24-48hrs in formalin



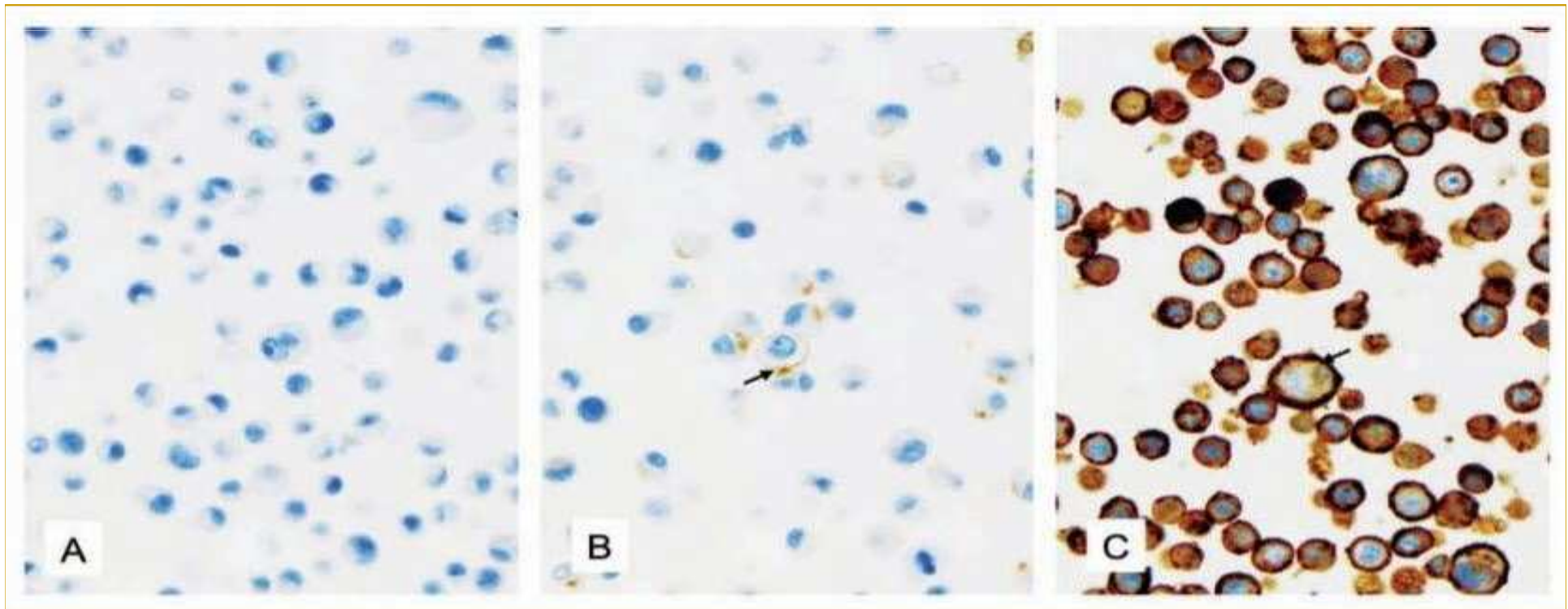
One week in formalin

Her2 standardized controls

Score 0

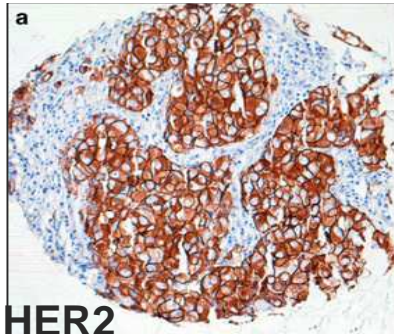
Score 1

Score 3

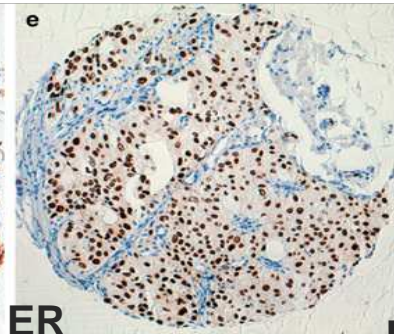


**IHC on old
and fresh TMA
slides**

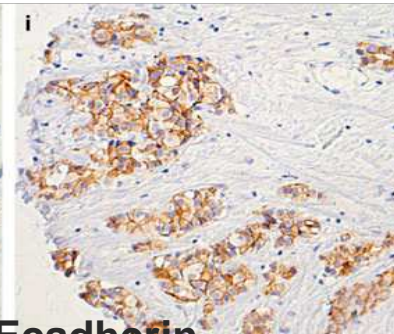
fresh



HER2

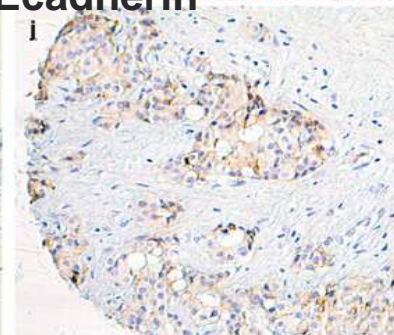
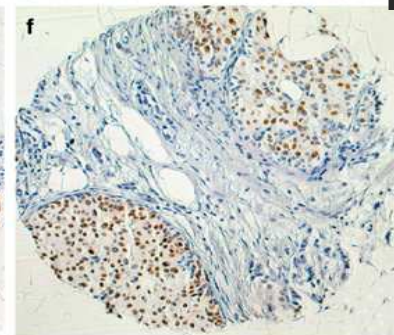
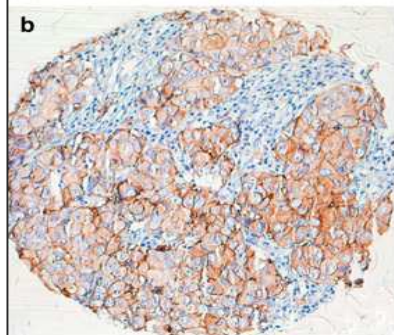


ER

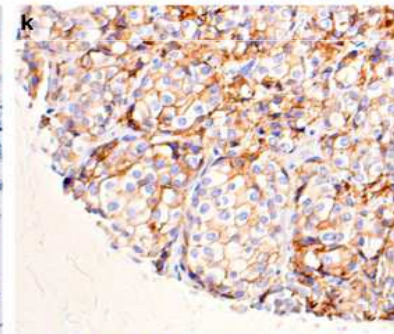
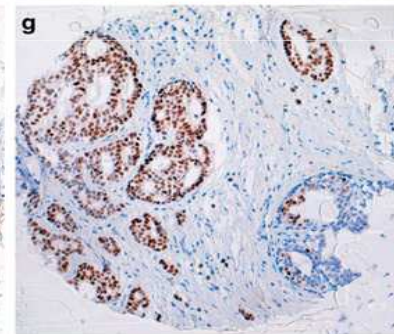
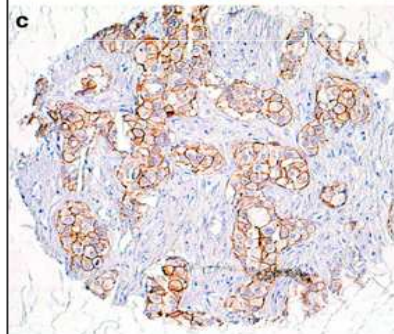


Ecadherin

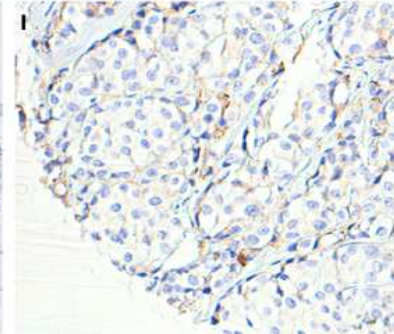
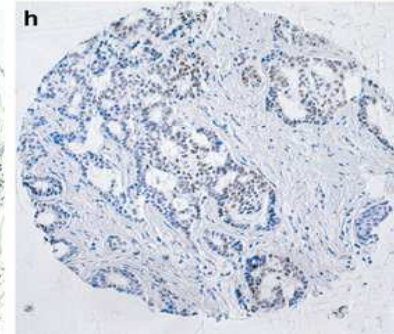
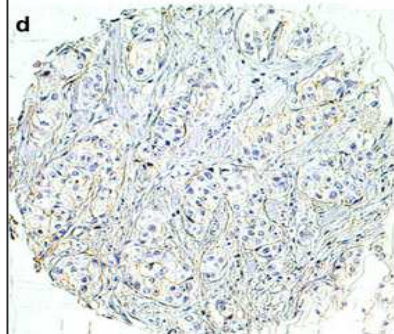
old



fresh



old





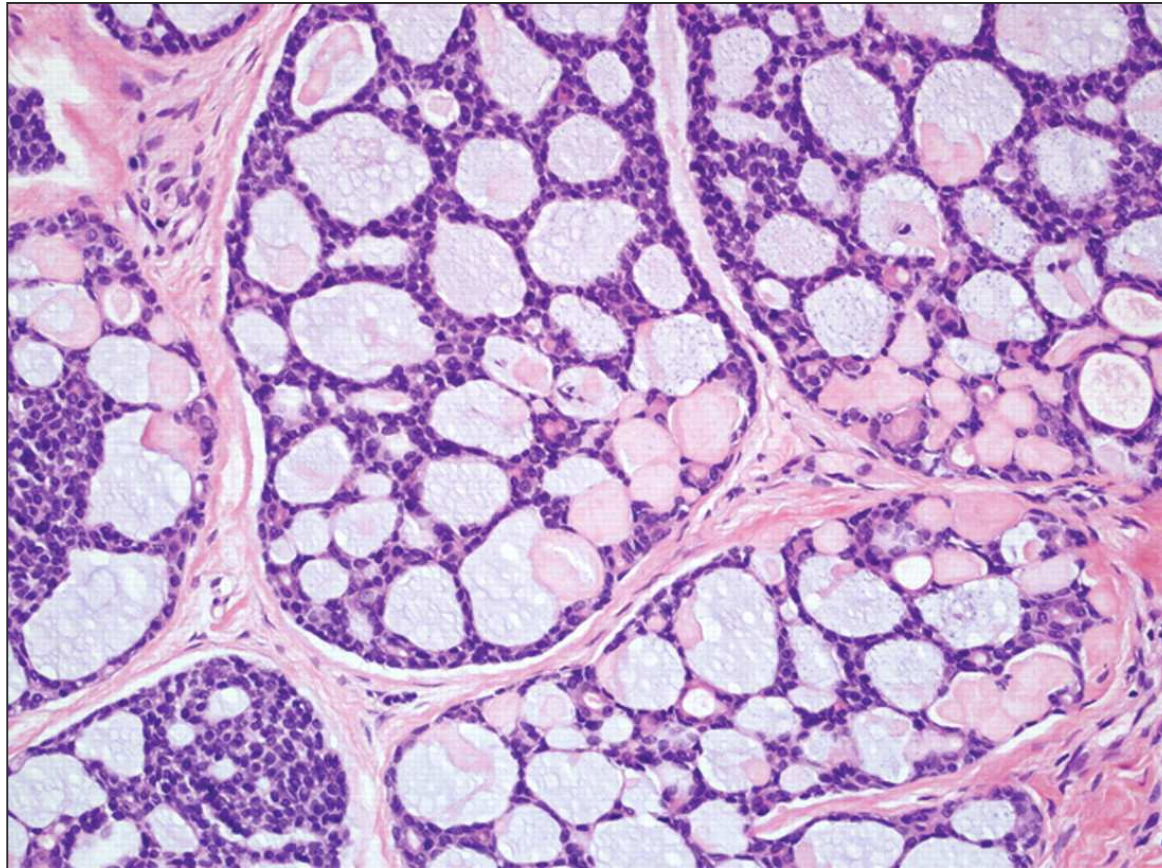
**So as you see
Everything has got to be
under control.**

QA/QC should be implemented on all Diagnostic elements:

- Morphology
- Immunohistochemistry
- Molecular studies
- Genomics

Can we use one without the other?

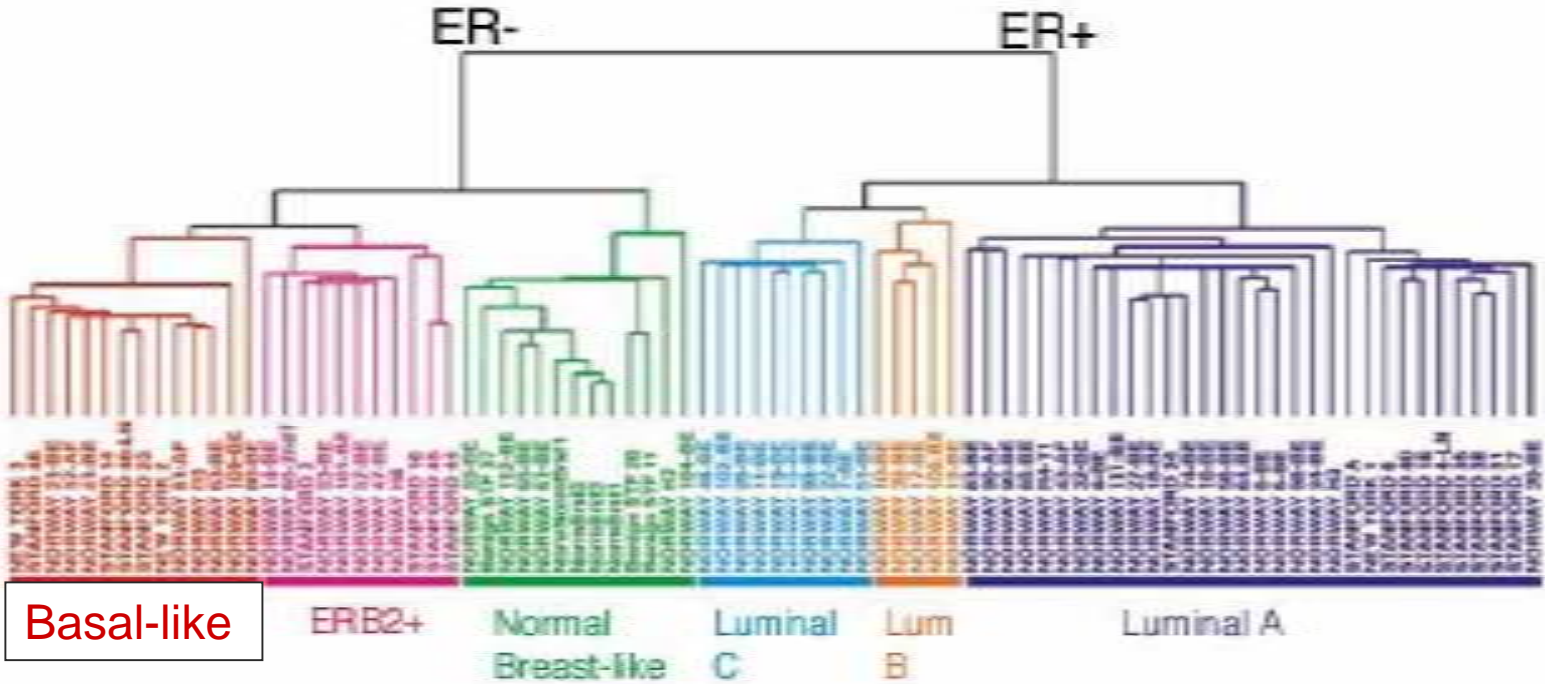
For instance go straight to genomics and skip the rest.



Adenoid cystic carcinoma

Gene expression profiling of Breast cancer

Adenoid cystic breast carcinoma is Basal-like



However, the cancers within the basal-like zone are heterogeneous:

- IDC NOS, high grade
- ILC high grade, pleomorphic
- Metaplastic, high grade
- Myoepithelial carcinoma
- High grade (oat-cell) neuroendocrine
- Apocrine
- Medullary
- **Adenoid-cystic**
- **Metaplastic , low-grade**
 - Low grade adenosquamous
 - Fibromatosis-like

Poor prognosis

Good prognosis

A decorative horizontal line with a gradient from light green to white. A black left square bracket is positioned on the left side, and a gold right square bracket is on the right side.

We have to work with hierarchal priorities.

[

Morphologic accuracy:

]

- Diagnosis
- Tumor size
- Grade
- LVI
- Lymph node status

[Immunohistochemistry]

- Hormone receptors
- Her2 receptor
- Ki67
- And others

[Molecular Testing and Profiling]

- FISH – Her2 Amplification
- Gene Expression assays:
 - Luminal A, B
 - Her2 positive
 - Triple-Negative
 - Basal-Like

Pre-analytical	Analytical	Post-analytical
Time to fixation	Assay validation	Interpretation
Method of fixation	Equipment calibration	Image analysis
Time of fixation	Standard Laboratory Procedure	Reporting
Method of tissue processing	Staff training assess.	QA procedures:
Specimen delivery	Antigen retrieval	-lab accreditation
Specimen identification	Test reagents	-Proficiency tests
Accession errors	Standard controls	-pathologists...
Clinical history adequacy	Automation	

Predictive Biomarkers

- Immunohistochemistry:
 - Fixation issues
 - Internal validation/controls
 - External validation of relevant antibodies:
ER, PR, Her2, Ki67.
- Molecular studies (**Her2-FISH/CISH/SISH**):
 - Concordance with IHC, statistics
 - External validation



Timeliness/Turn Around Time (TAT)

- Frozen sections.
- Cytology specimens.
- Core needle biopsies.
- Mammotomy specimens.
- Lumpectomy / mastectomy specimens.
- Special studies (IHC, FISH).

[Completeness of report]

A full report should contain all the following:

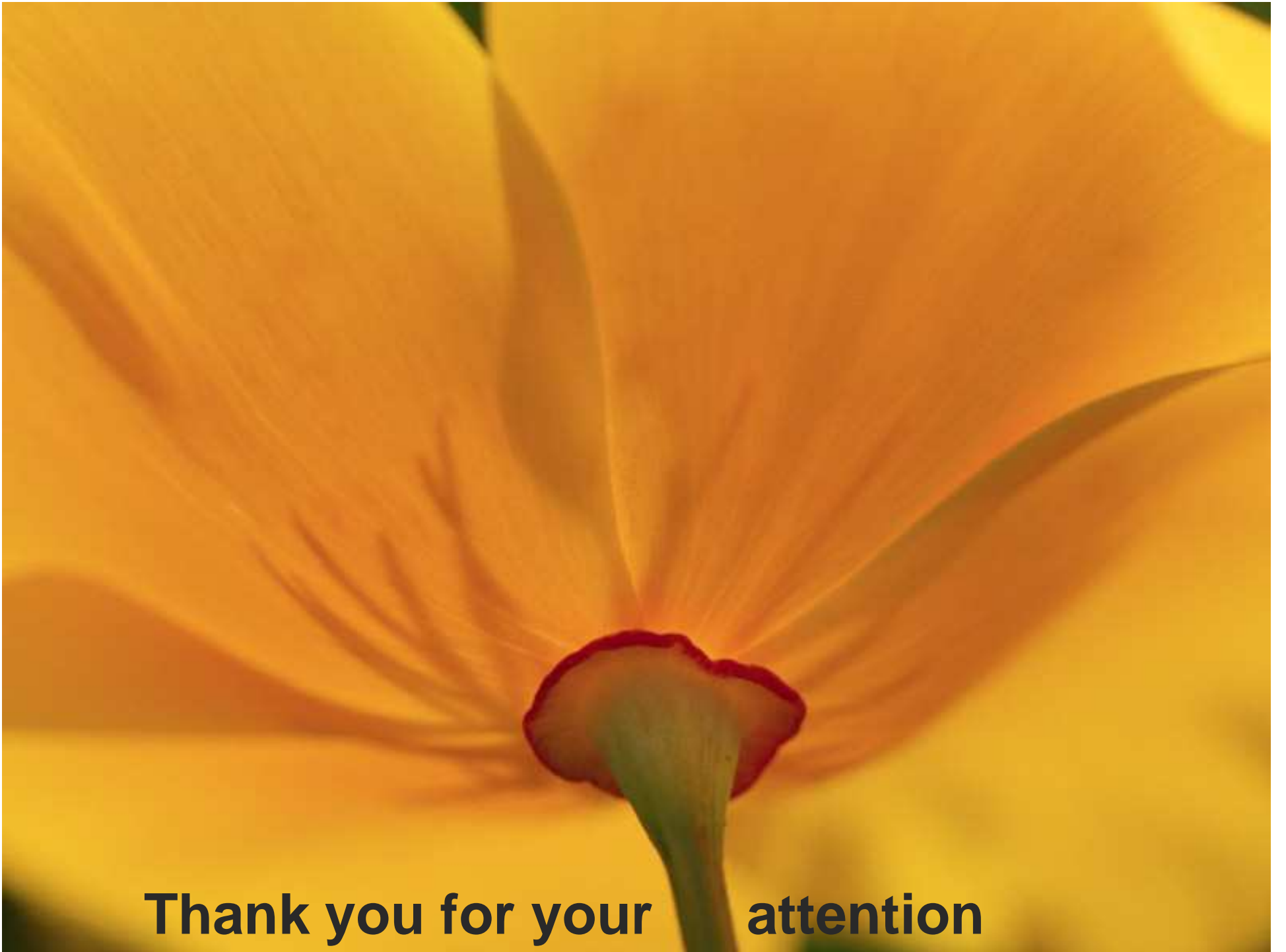
- Demographic details.
- A comprehensive macroscopic description.
- Assignment of all paraffin blocks to specific locations.
- Diagnosis/Tumor grade/Tumor size.
- Margin status.
- Receptor status (IHC, FISH).
- SLN / cALND (protocol)

[Full report (cont.) :]

- Correlation with previous cytology, CNB, FS results.
- Concordance of diagnosis with ancillary results.
- Additional pathology in the breast tissue.
- **Templates / Summary checklists–**
Make the writing of these very elaborate reports required today, easier to read by the clinicians.

And last but not least: The Availability of the Pathologist

- The multidisciplinary nature of the breast disease centers has taken the pathologist out of the laboratory into the clinical sphere where he belongs.
- The timely cross-talk with the radiologists, surgeons and oncologists enables –
 - To find out discrepancies as soon as possible.
 - To learn and understand the different radiological, clinical and pathological setups



Thank you for your attention