Validation of Histology Tissue Processing.
Designed Innovation to manage the risk in Histopathology workflow

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Background

Proper tissue processing guarantees quality to the specimen and preserves morphological and molecular information, which are mandatory for the correct diagnosis. This is critical for the selection of the appropriate target therapy treatment, potentially even leading to therapeutic failures.

For this reason every innovation aimed at obtaining improvements of histological samples quality and safety is of great benefit.

SAMAR Medical Center, in collaboration with Diapath S.p.A., was interested in the validation of the new generation Tissue Processor Donatello Series 2.

Validation & Quality Assessment Input Form

Histology Evaluation Scale (tissue processing, embedding, cutting):
- High Quality = 1
- Standard Quality = 2
- Low Quality = 3

Pathologist' Microscopic Evaluation for Diagnosis:
- Ideal for Diagnosis = 1
- Standard Quality = 2
- Unacceptable for Diagnosis = 3

Design

Evaluation of a new generation Tissue Processor (Donatello Series 2, Diapath S.p.a., Italy) was performed at SAMAR Medical Center, Rome, Italy, with aims to:
- integrate this new processor into their workflow;
- evaluate specimen quality.

Technical quality of blocks processing and slide cutting was accessed by histotechicians. Quality of H+E staining, special stains and immunohistochemical stains were evaluated by pathologists with a standard input form. About 20.000 specimens (5 months) were dissected and split by two pathologists. Three parts scheme with free text comments were used for histology assessment and pathologist' microscopic evaluation.

Samples

SAMAR Medical Center routine:
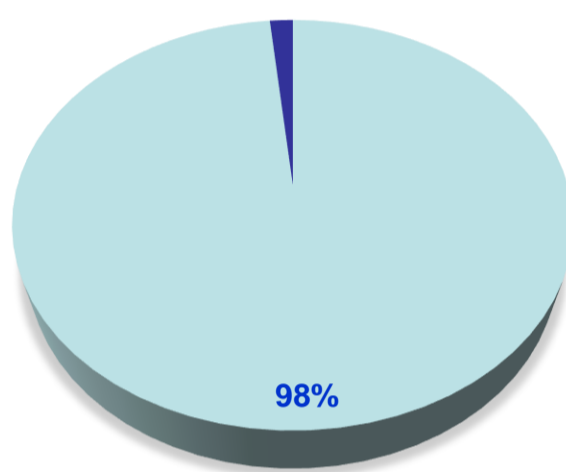- 60% surgery
- 30% biopsies
- 10% skin

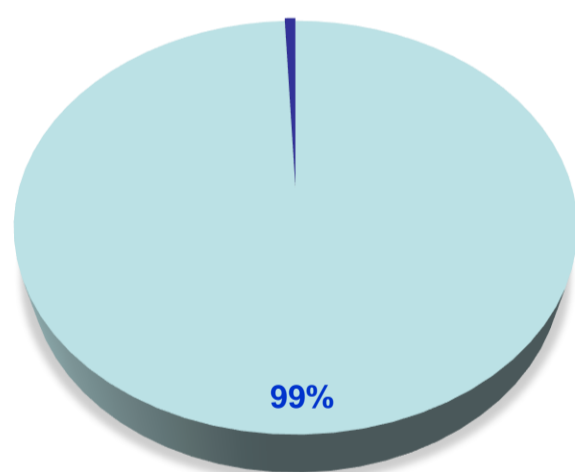| SURGERY		BIOPSIES	
40%	Small Surgery	50%	Gastrointestinal
20%	Gynecological	15%	Gynecological
10%	Breast	15%	Prostate
10%	Colon	10%	Breast
8%	Thyroid	5%	Bladder
5%	Prostate	2%	Lung
5%	Gastric	2%	Bone Marrow
2%	Others	1%	Hepatic

Results

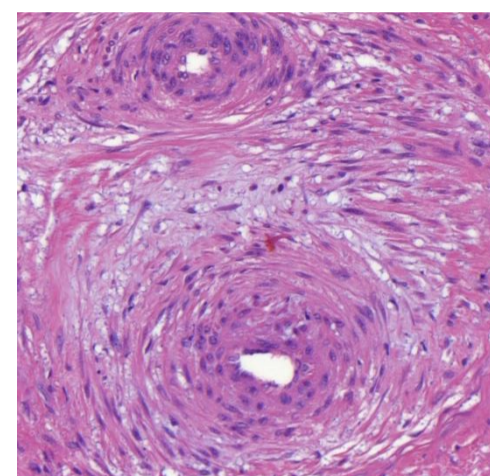### Quality of block processing, embedding, cutting

98%

■ High quality ■ Standard quality ■ Low quality
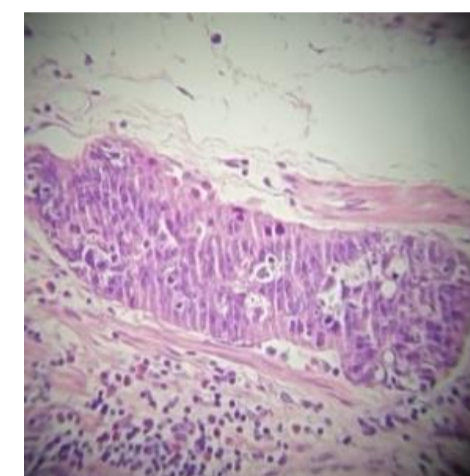
Quality of H+E staining, Special Stains and IHC

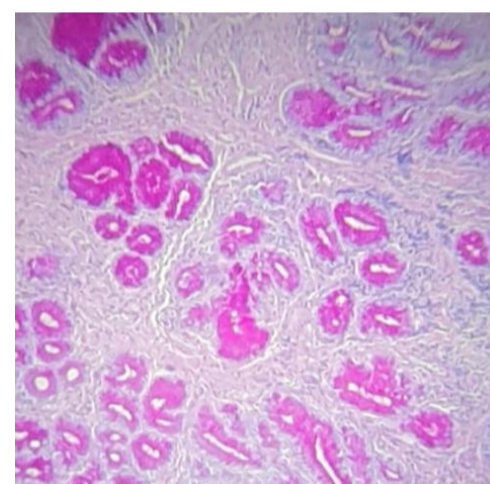
99%

■ Ideal ■ Standard ■ Unacceptable
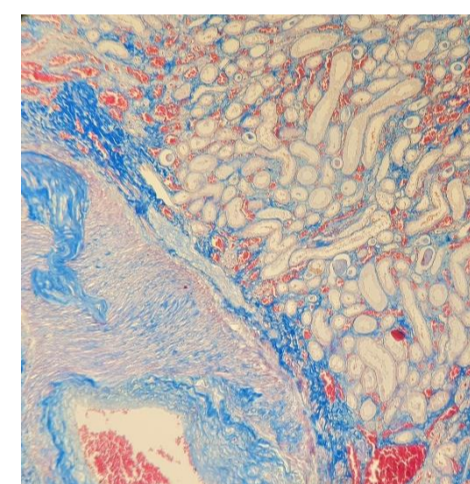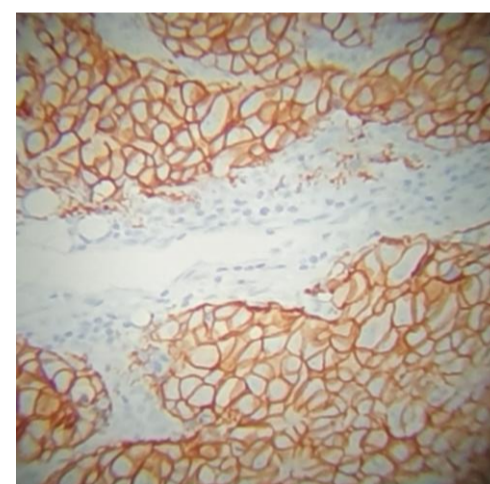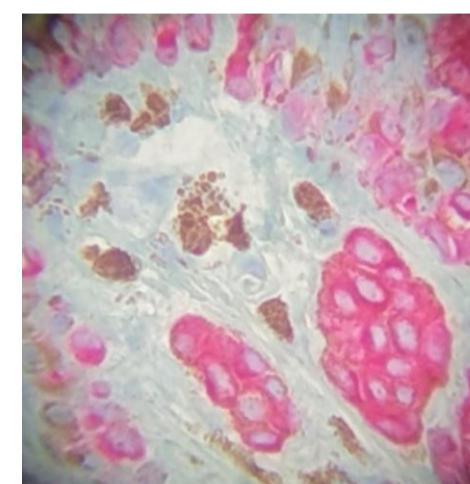
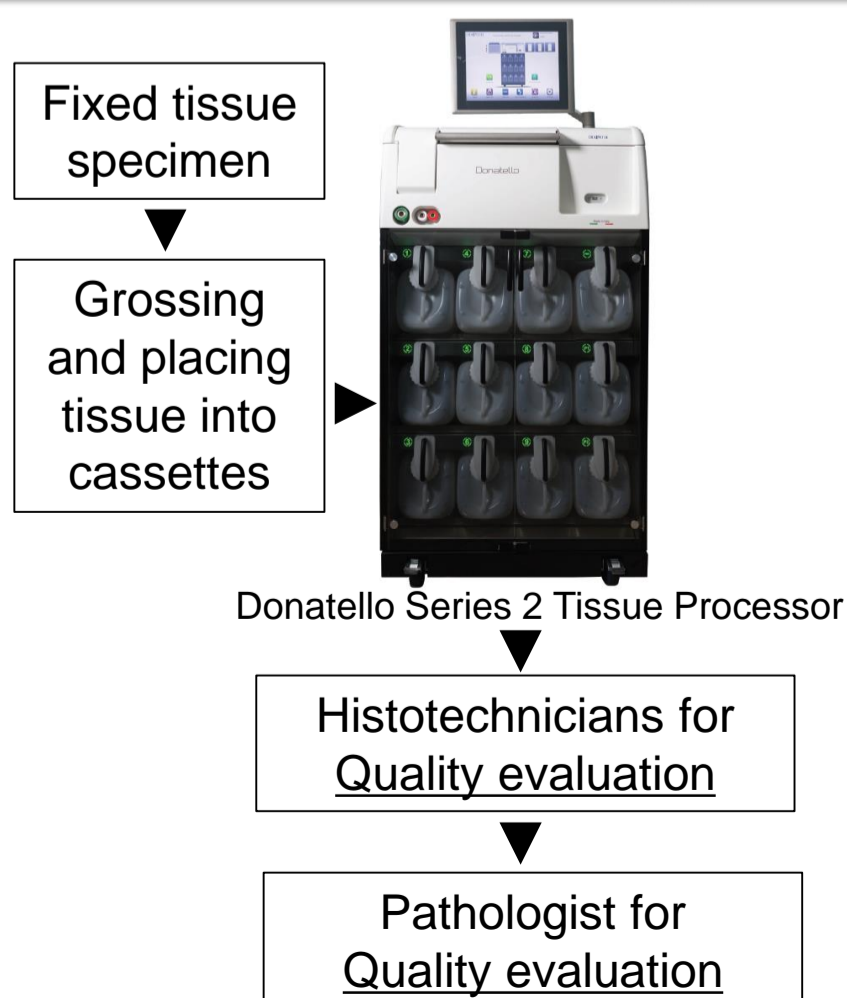## H+E, Special Stains and IHC

H+E

H+E

P.A.S. sec. Hotchkiss - McManus

Azan Thricrome

IHC (DAB), Her2

IHC (Fast Red), CK

Technical evaluation

Fixed tissue specimen

▼

Grossing and placing tissue into cassettes

▶

Donatello Series 2 Tissue Processor

▼

Histotechnicians for Quality evaluation

▼

Pathologist for Quality evaluation

Conclusions

This study validates the technical, H&E, Special Stain and IHC stain quality obtained with the new generation Tissue Processor Donatello Series 2.

The quality results experienced, in comparison with a standard tissue processor, are also enhanced by various technical improvements: Selfcheck technology, the automatic hardware check of instrument status before start, which prevents the adverse events and overnight tissue processor errors. RFID reagent replacement system, that allows reagents to be easily and securely replaced preventing possible mismatching and spillages.

Moreover, the innovative built in E.V.A. (Emergency eVoluted Algorithm), the advanced virtual algorithm makes Donatello Series 2 a real new generation Tissue Processor. E.V.A. in case of emergency, is able to independently decide which alternative pathway is the best for the safety of the samples and for the instrument itself, leveraging on the innovative hardware architecture in order to complete the processing: this unique technology is useful to prevent and solve overnight potential failures. E.V.A. is also able to interact verbally with the Histotechnicians and to guide them in the journey in different languages.