Sakura SMART Automation

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Subjects to Cover

- GGC Equipment Projects
- Pressures in histopathology
- Productivity & continuous flow
- Sakura SMART Automation
- Paraform® Cassette System
- GGC Pathology Sakura Trial & Validation Process
- Results of Phase 1

GGC Equipment Projects

- Digital Pathology Trial
- Arcos Block Management
- New “Special Stains” Platform
- Kos Microwave Processor
- BoneSTATION
- HPV Platform Procurement
- Sakura SMART Automation

Pathology staff seem to 

or at least 

their Equipment!

The Beastie Boy's?

Why trial SMART Automation?

Pressures within histopathology Labs

- Workload demand
- (GGC x1300 blocks daily)
- Focus on Performance (KPI's)
- Turnaround time
- Staff Pressures/Skill mix
- Cost pressures
- Health & Safety requirements
- Increased quality requirements (UKAS)

Inefficiencies

Bottlenecks

Waste (are we lean enough?)

Limited standardisation

Multiple protocols

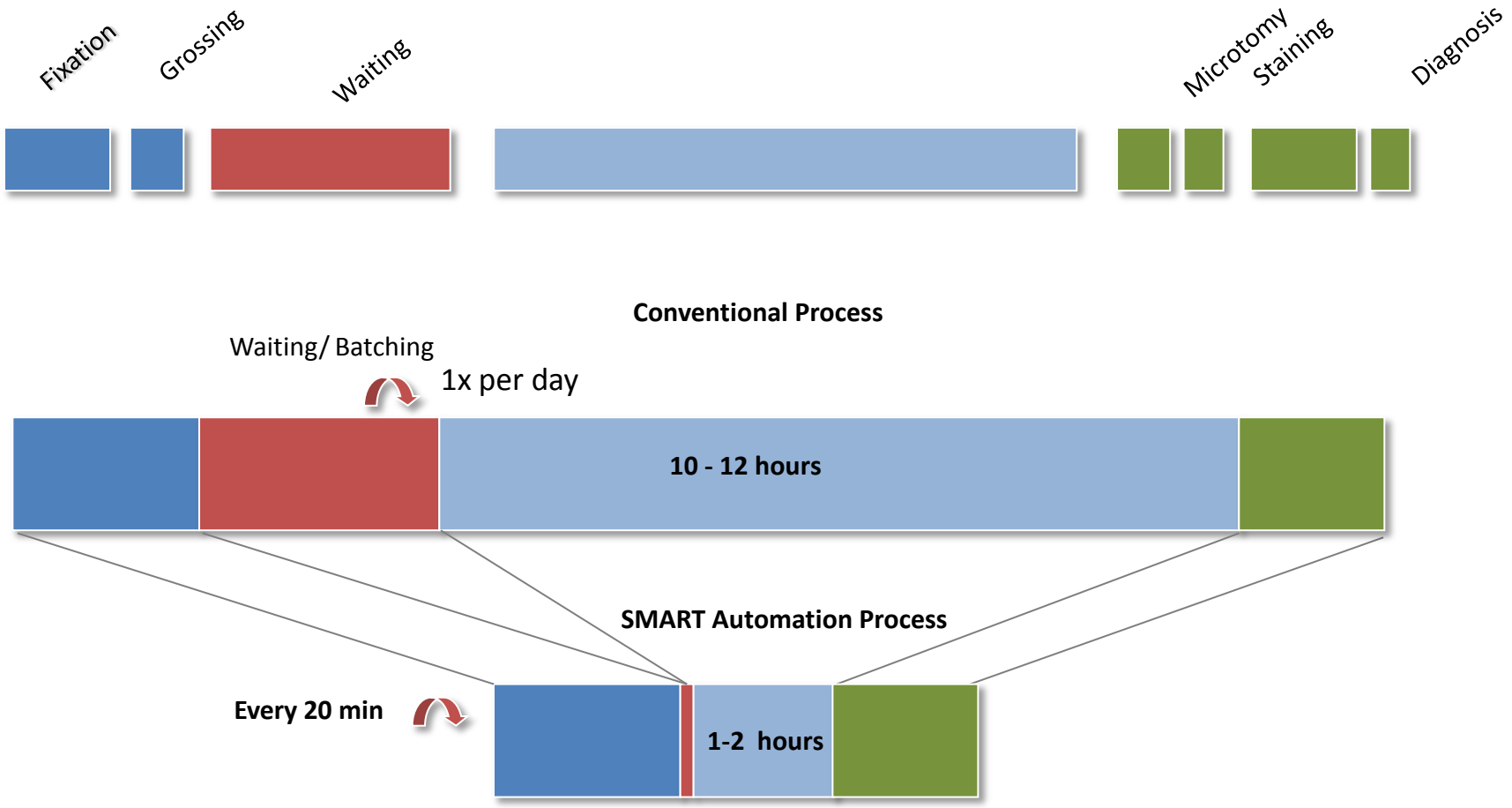
Without Compromising Quality!

SMART Automation, maximizing productivity

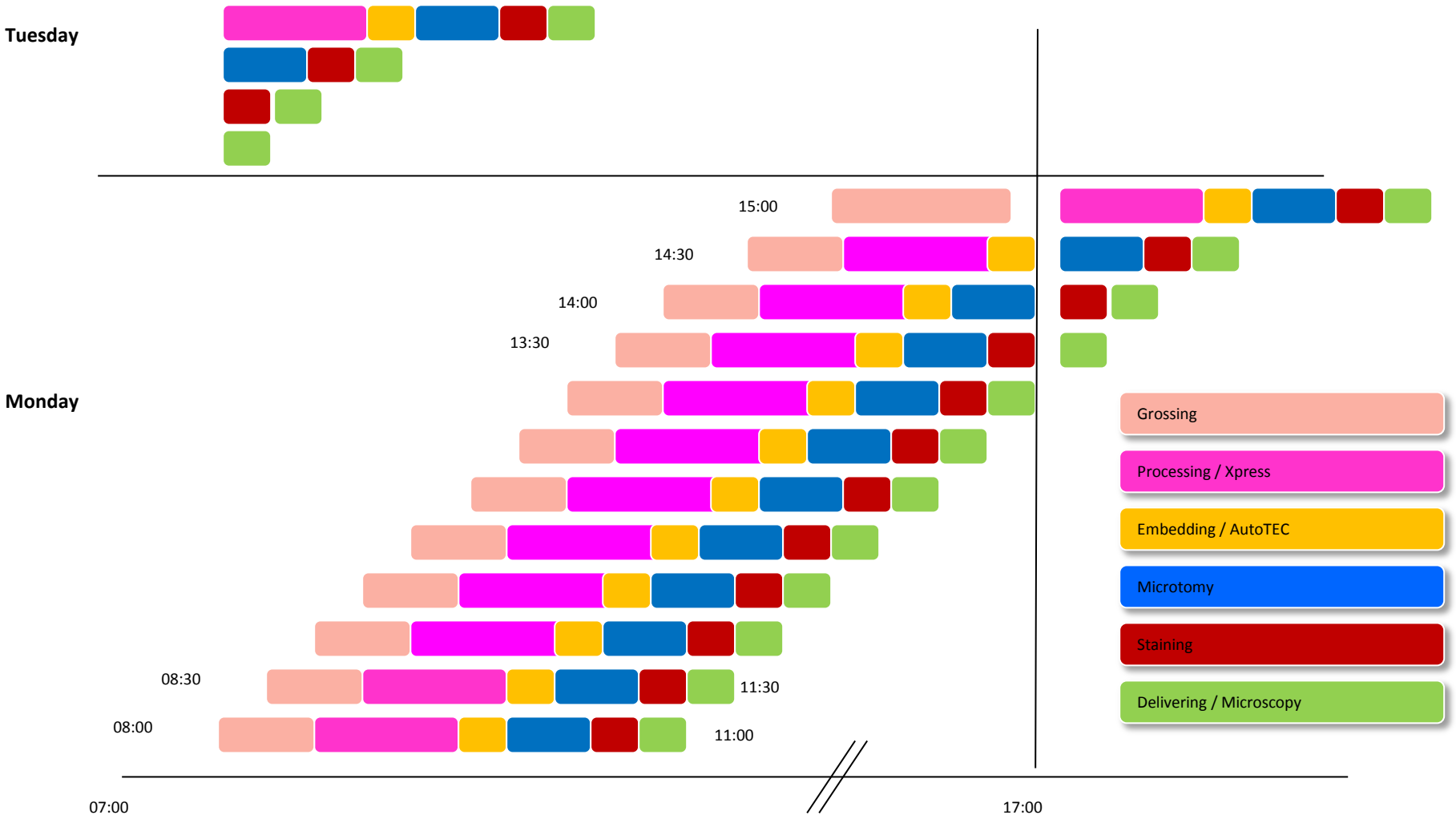
SMART Automation, maximised productivity

>30%	67%	80%
Increased productivity	Reduced time to diagnose	Cases are ready within 24 hours

Remove bottlenecks and waiting time: Improving turnaround time



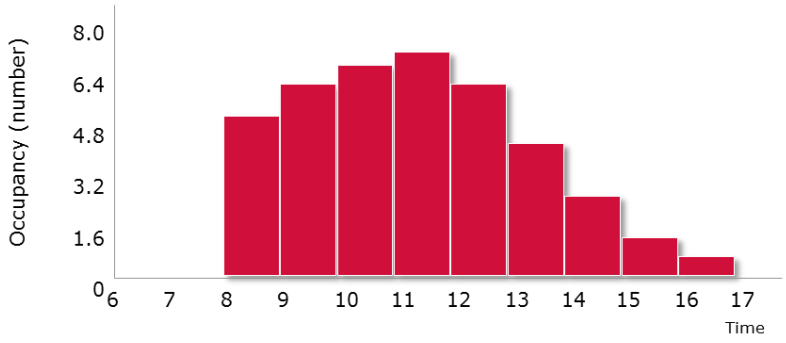
Continuous workflow



Batch process vs. continuous process

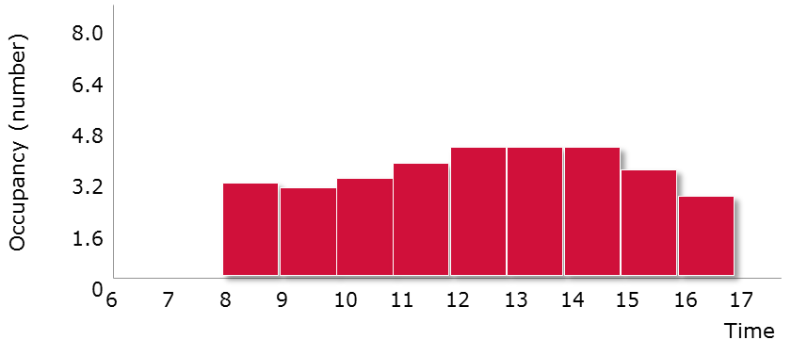
Batch process

Occupancy of shift Conventional Technicians (per 60 min)



Continuous process

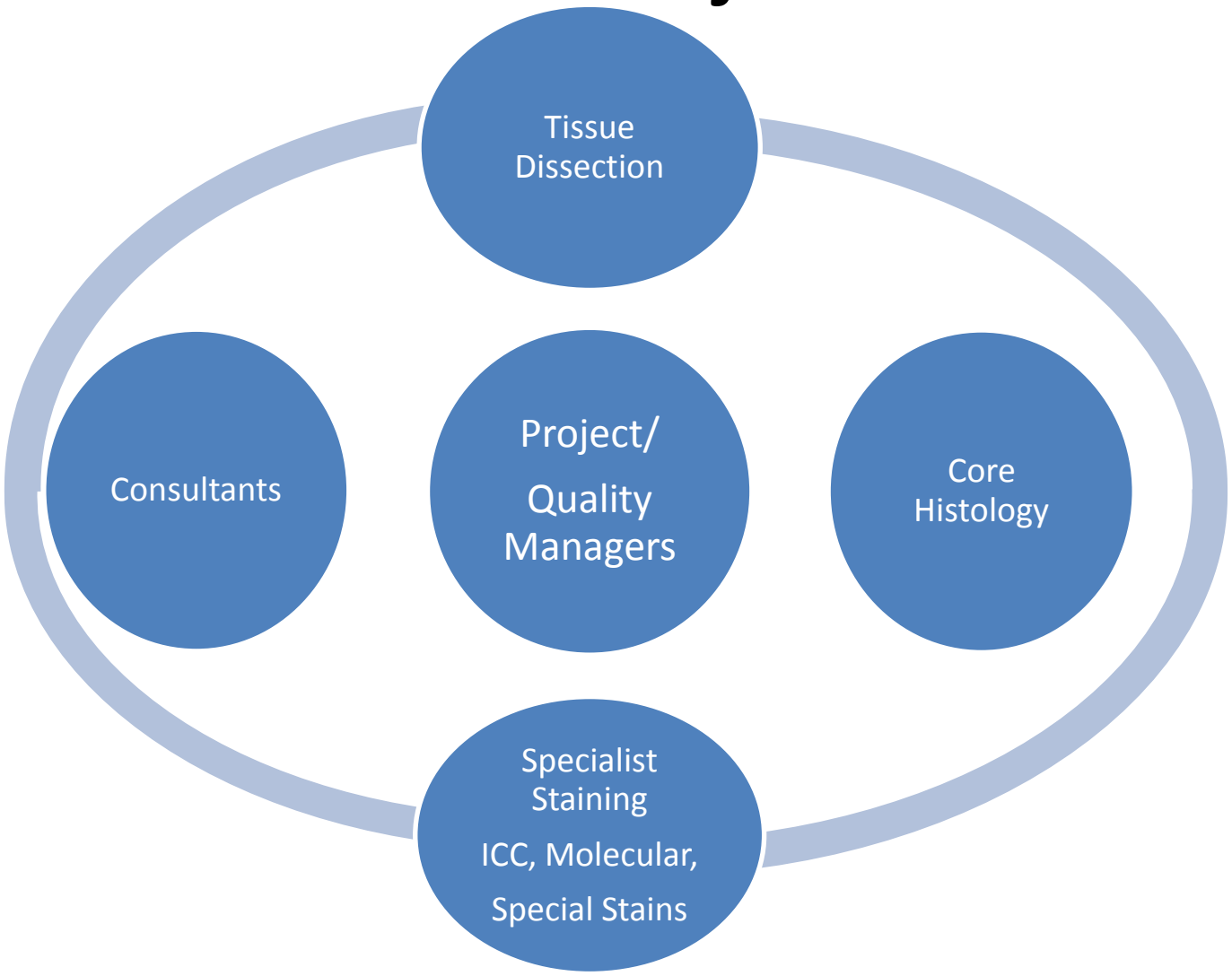
Occupancy of shift Automation Technicians (per 60 min)



GGC Sakura Trial

- 6 months trial
  - Tissue-Tek ® Xpress® x120
  - Tissue-Tek® AutoTEC® a120
  - Paraform® Cassette system
- Equipment Installed 3 & 4 Sep
- Training 6-14 Sep
  - Paraform® Workshops & Champion training
  - AutoTEC® a120 training
  - Paraform® microtomy training
  - Xpress® x120 training
- Set up Project Team
  - Technical Staff, Medical Staff, Project/Quality Manager, Sakura

GGC Sakura Project Team



Tissue-Tek® Xpress® *x120*

Efficiency

- Continuous efficient workflow/ Loading every 20 minutes:
  - Workload leveling & Increased productivity
  - 2 Processing cycles (1 hour for 2mm, 2 hour 3 mm)
  - Fewer human errors and rework → Reduced cost
- Reagent volume reduction of more than 80%

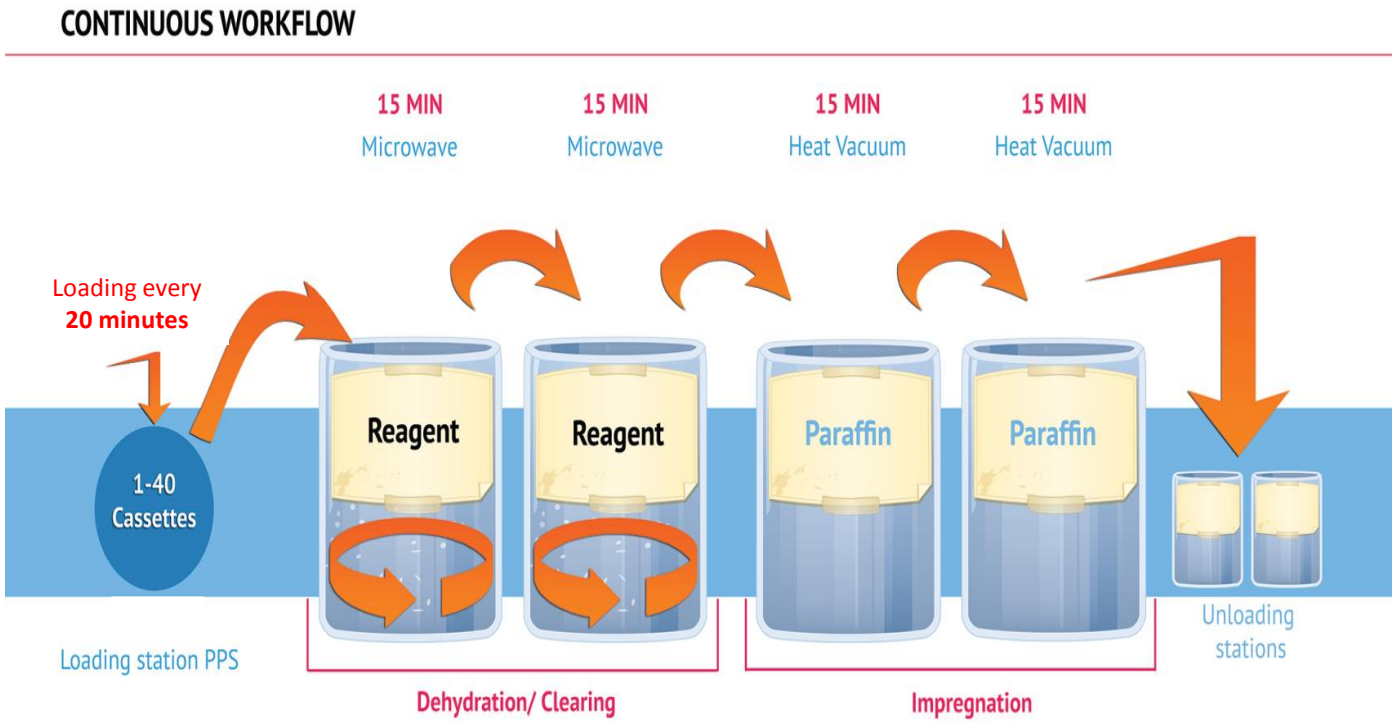
Speed

- Standardized 1-hour processing/ Loading every 20 minutes
- Throughput of 120 cassettes/ hour leading to 960 cassettes in an 8-hour shift
- Unmatched one day diagnoses for most tissue types
- Reduced patient waiting time

Quality

- Excellent morphology and sharp nuclear details due to gentle microwave technology
- Standardized reproducible results: QC ready to use reagent kits
- Formalin- and xylene free processing

Tissue Processing with 2 reagents



- Low power microwave and reliable vacuum technology
- Circular microwave patterns eliminate hot and cold spots

Tissue-Tek® AutoTEC® *a120* & Paraform®

Efficiency

- Fully automated embedding
- A continuous efficient workflow
- Free up capacity for more value adding work
- No block scraping (dispenses exact amount wax)

Speed

- Continuous loading and unloading
- 120 cassettes per hour/ Loading every 20 minutes
- Perfect fit with Tissue-Tek® Xpress® *x120*
    - Same throughput: 120 cassettes per hour

Quality

- Eliminating orientation mistakes, mix up and tissue loss
- Tissue oriented at grossing & “locked” in Paraform®
- Standardised block quality

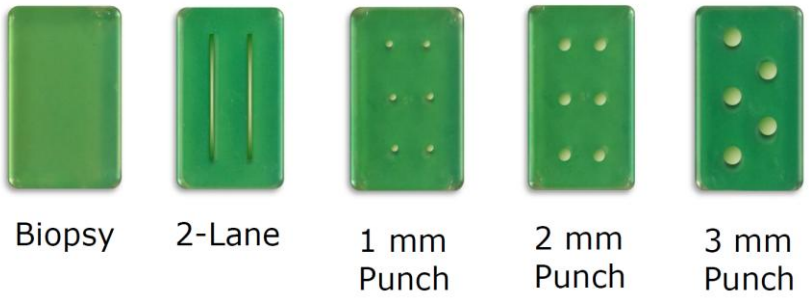
Paraform® Cassette System

Six Paraform® inner cassettes types

- Paraform® Standard Cassette
- Paraform® Biopsy Cassette
- Paraform® 13*13 Biopsy Cassette
- Paraform Core Biopsy Insert
- Paraform Shave Biopsy Insert
- Paraform Orientation Biopsy Insert

Five Paraform® Tissue Orientation Gels

- Paraform® Biopsy Orientation Gel
- Paraform® 2-Lane Orientation Gel
- Paraform® 1 -2 - 3 Punch Orientation Gels

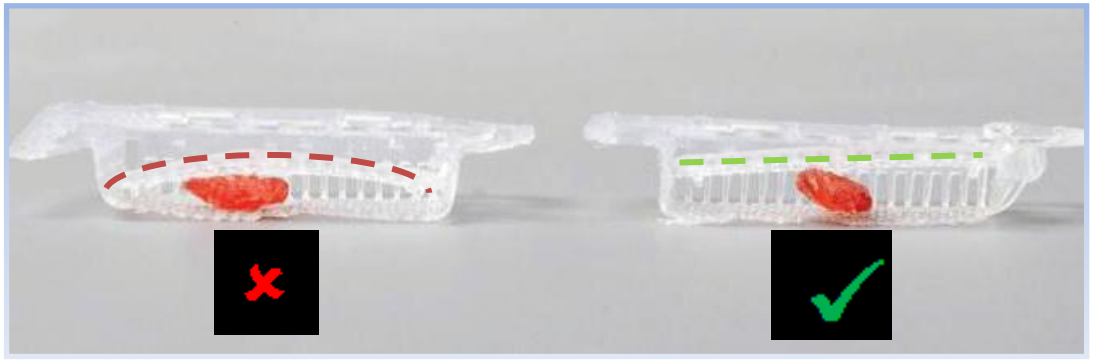


Paraform® Cassette System

- Fluor-polymer resin
- Sectionable
- Non-toxic
- Chemically stable
- Non-reactive
- Compatible with traditional processing methods

Paraform® Cassette System


STOP



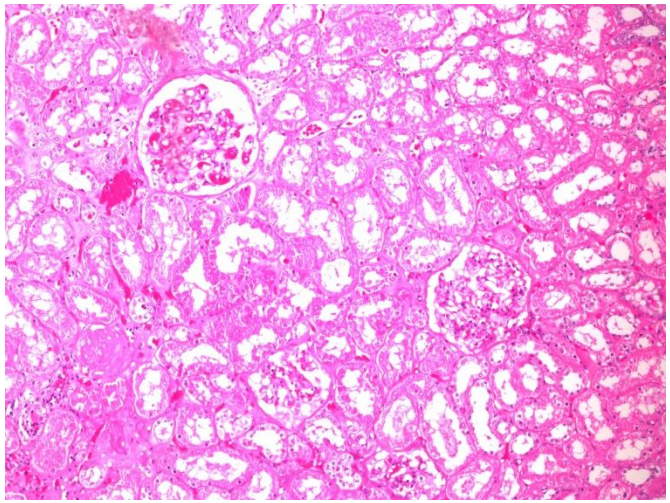
GGC Pathology Validation Plan

- Phase 1
  - Parallel processing of various tissue (x 20 Composite blocks each processing cycle)
  - Comparative review of H&E's (SMART Automation & Conventional)
  - Validation of ICC, Molecular, Special Stains
- Phase 2a
  - Extra blocks of Gynae, Skin, Gall Bladder & Appendix (x 50 of each)
  - Processed in parallel and evaluated
- Phase 2b
  - Specimen types evaluated in Phase 2a processed using the Sakura system
  - cases reported as part of the general allocation
- Phase 3a
  - other tissue types processed using the Sakura system only (x 20 of each)
  - Stage 1-4 (different tissue specialties)
  - E.g. Stage 1 (Urology, Placenta, Renal, Liver)
- Phase 3b
  - Specimen types evaluated in Phase 3a processed using the Sakura system
  - cases reported as part of the general allocation

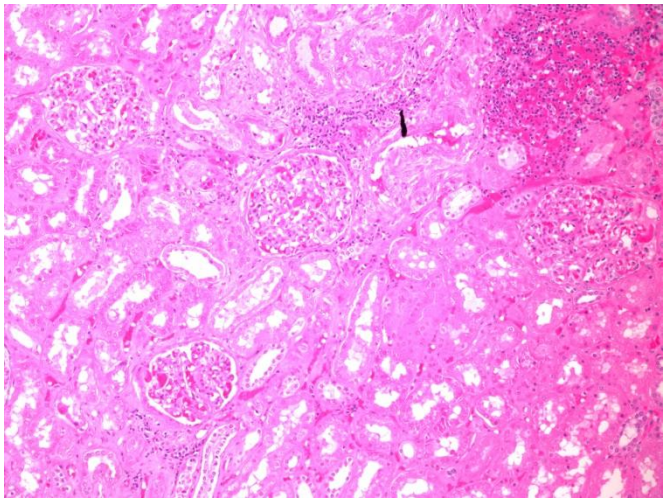
Other Validation Considerations

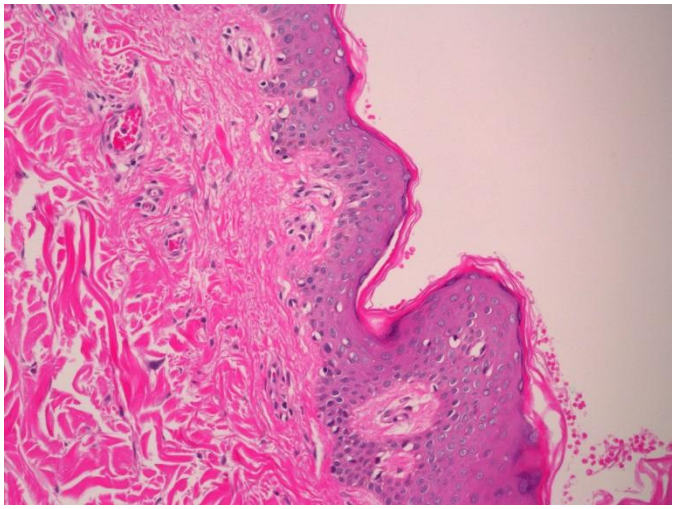
- *Compare diagnostic quality*
  - *Compared to traditional processing methods*
- Workflow
  - continuous workflow v's batched workflow
- Assess pre & post implementation times
  - Assess any increased dissection/microtomy time
- TAT
  - Comparison of time taken for 1st H&E available
- Microtome blade usage
  - Audit increased usage of blades using Paraform®
- Assess Carry-over
- Tissue thickness limits v's processing cycles

Results So Far – H&E

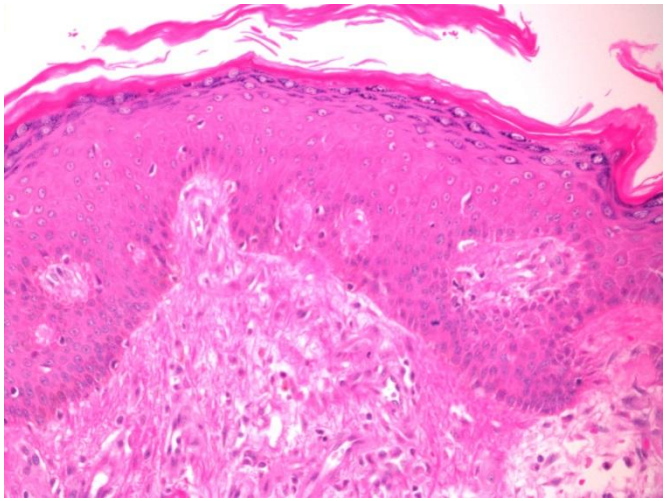


Kidney

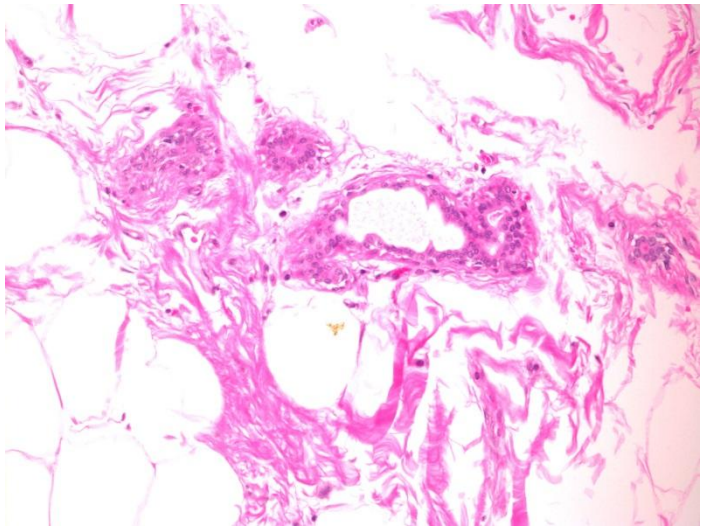




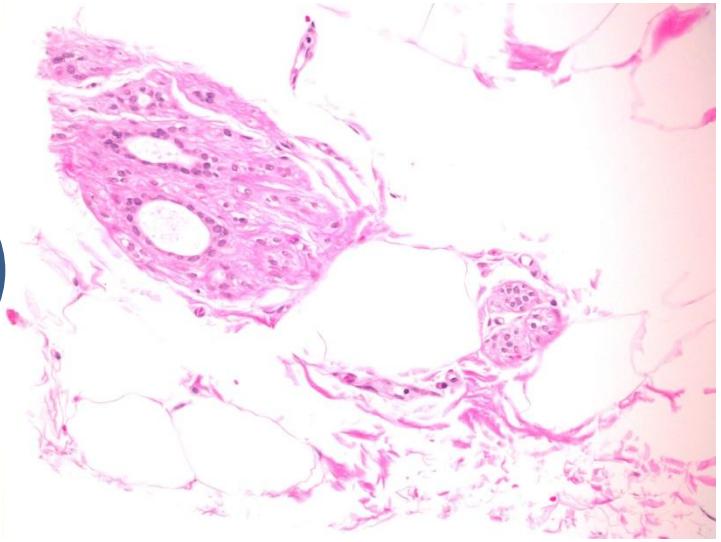
Skin

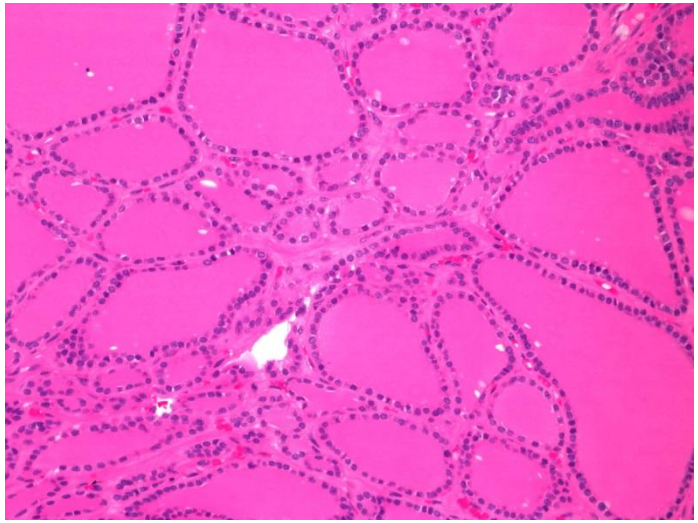


H&E – cont.

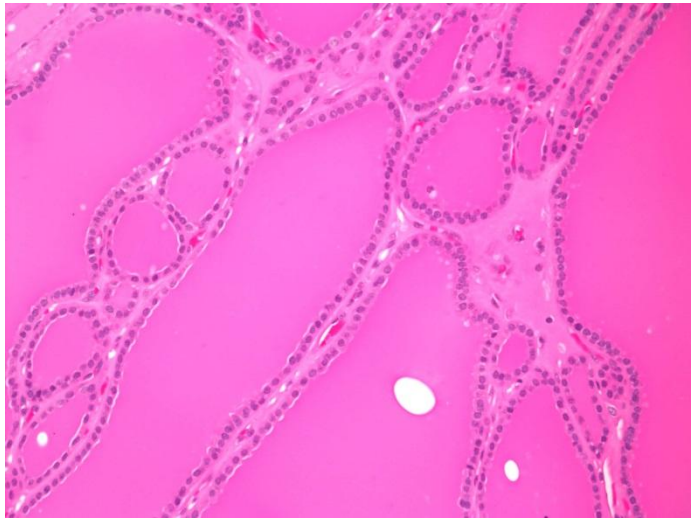


Breast

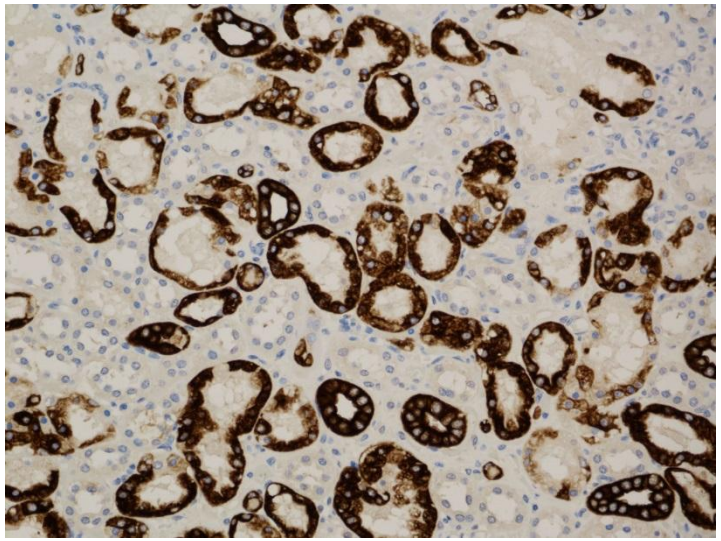




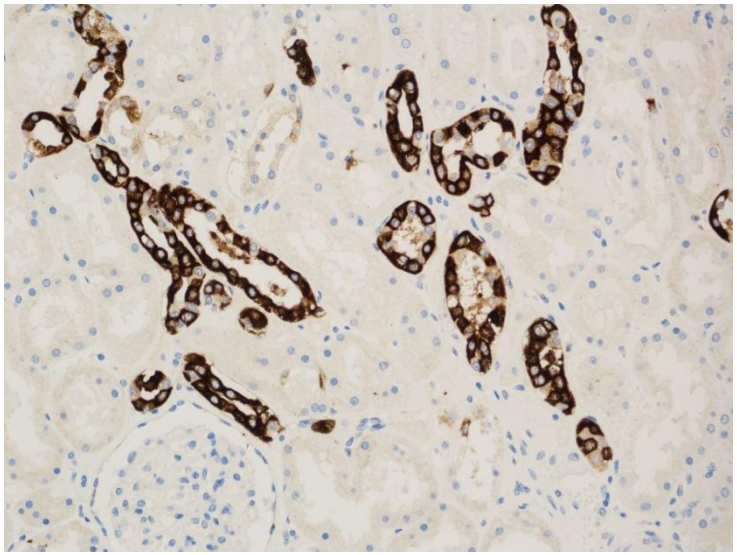
Thyroid

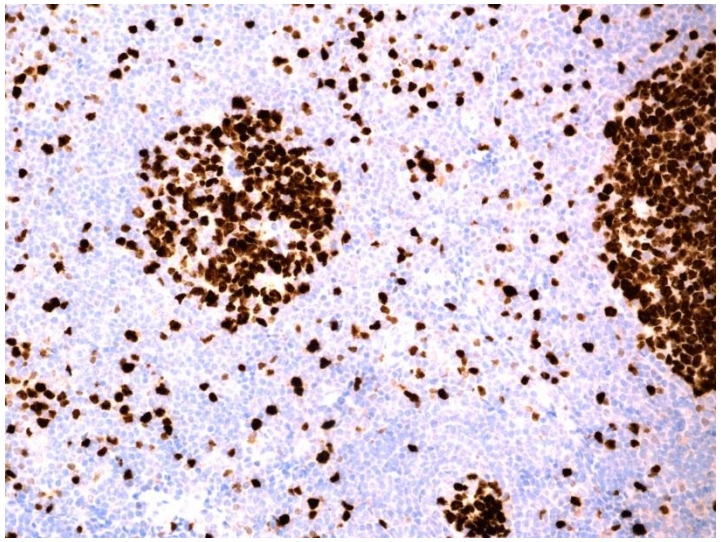


Results So Far - ICC

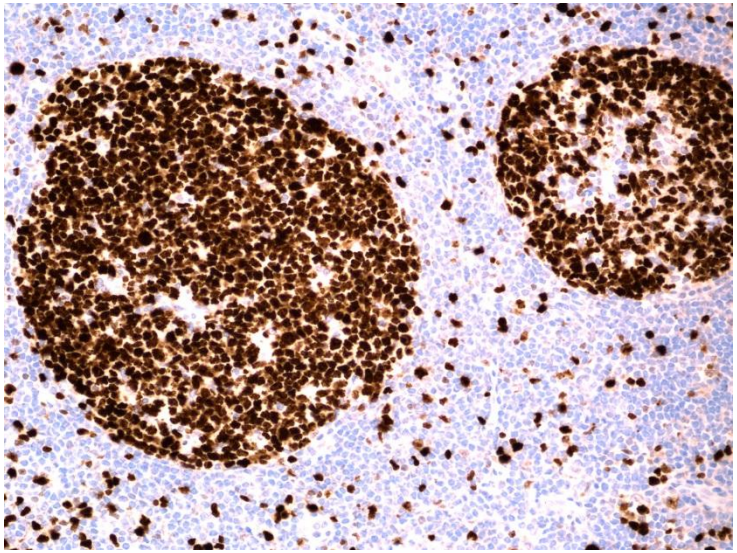


AE1/AE3

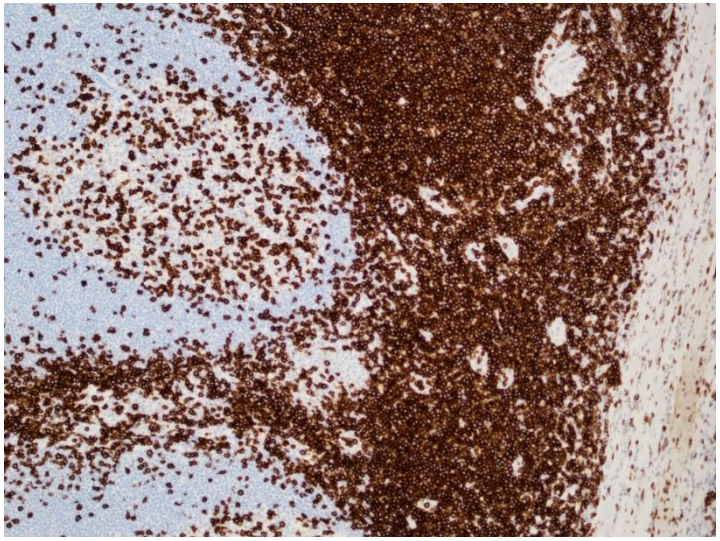




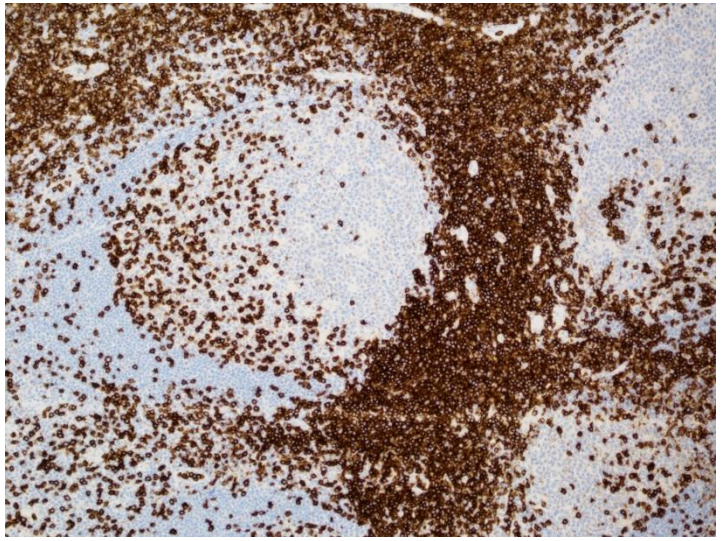
Ki-67

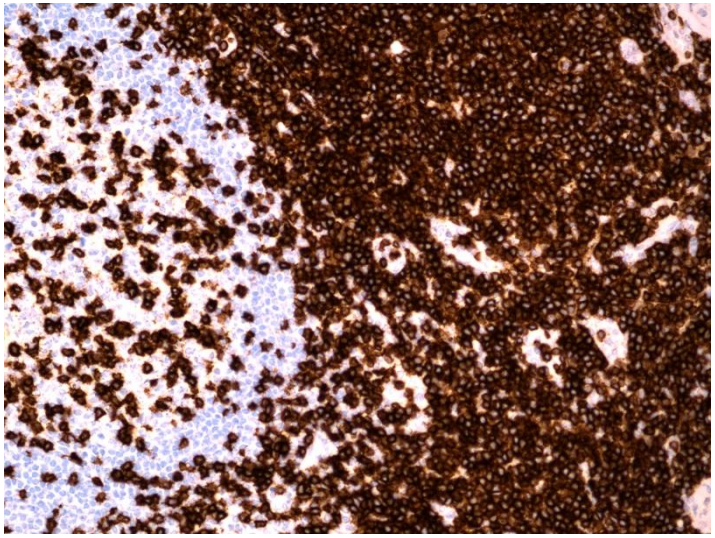


ICC – cont.

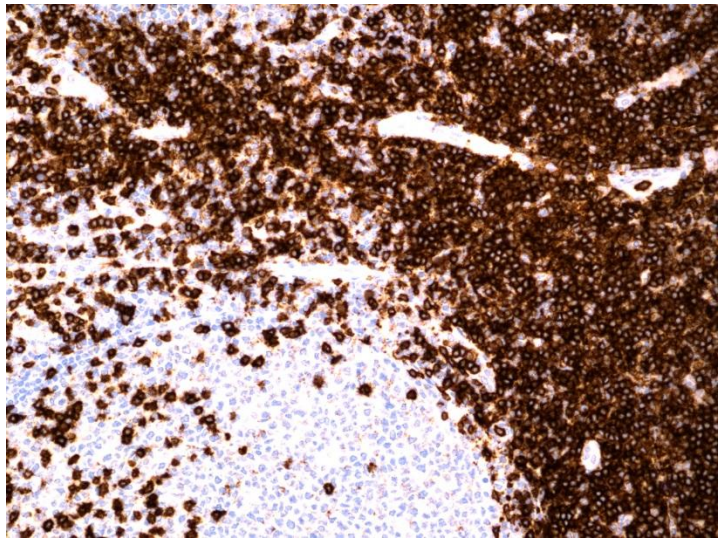


CD3
x10

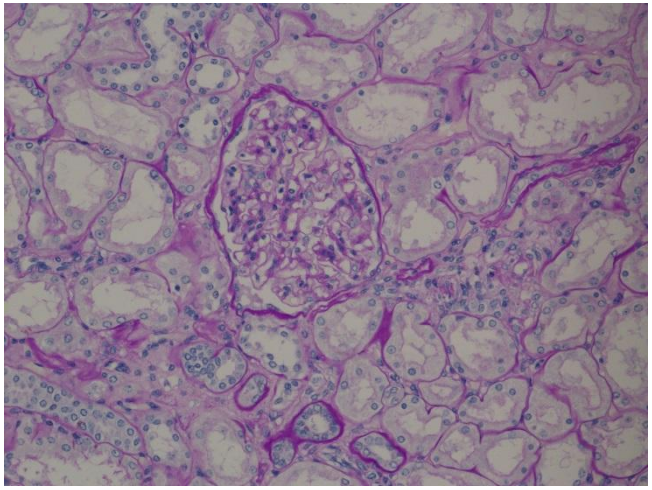




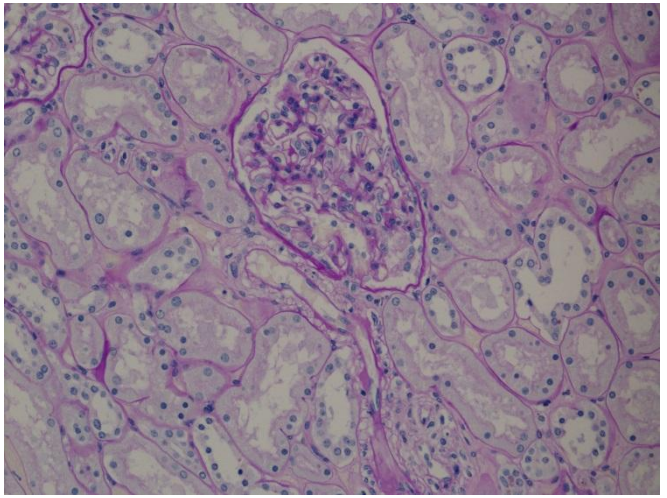
CD3
x20

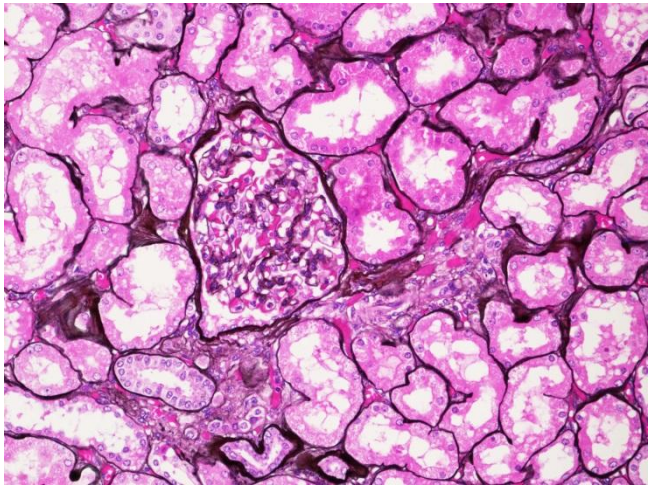


Results So Far – Special Stains

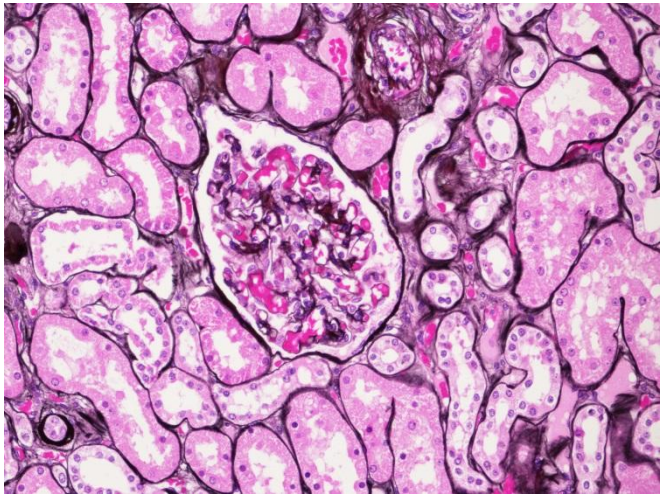


PAS

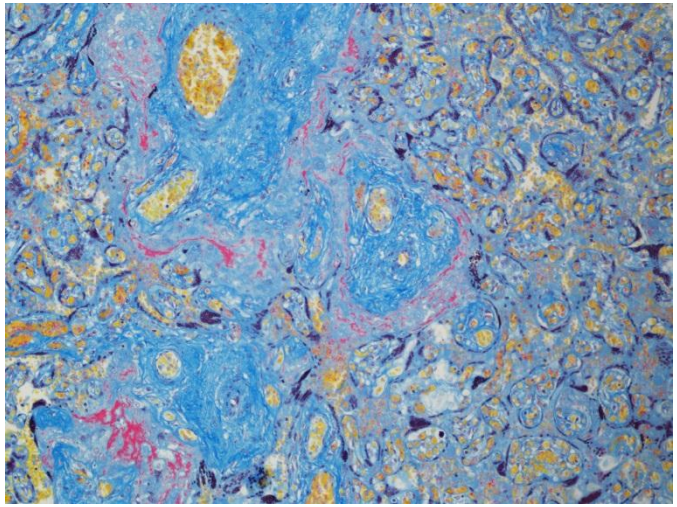




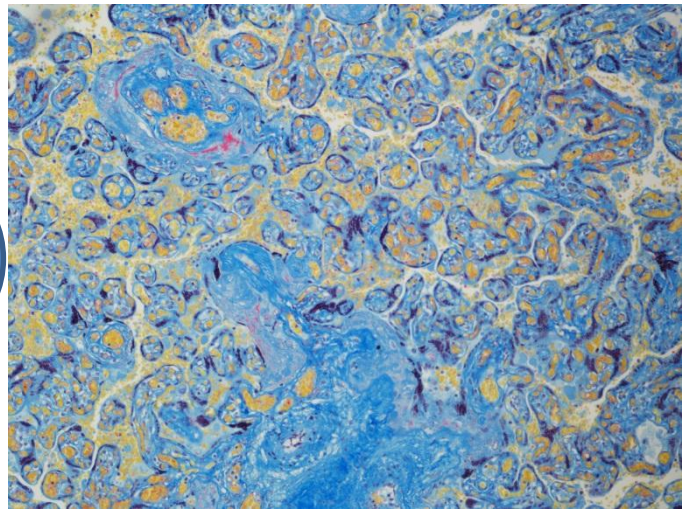
Meth Ag

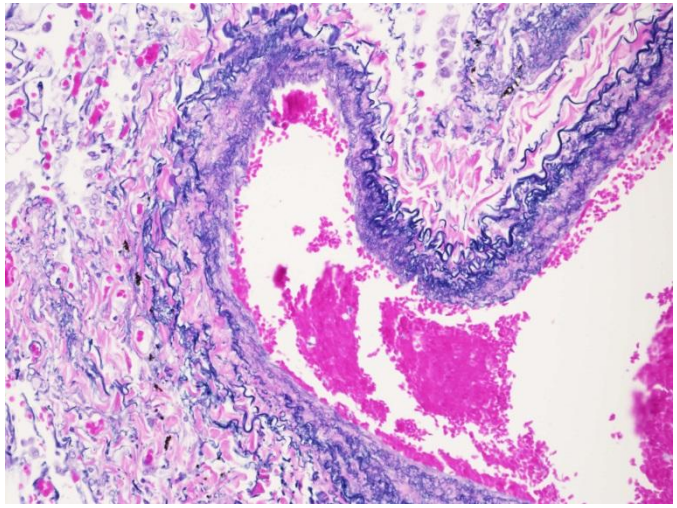


Special Stains - cont.

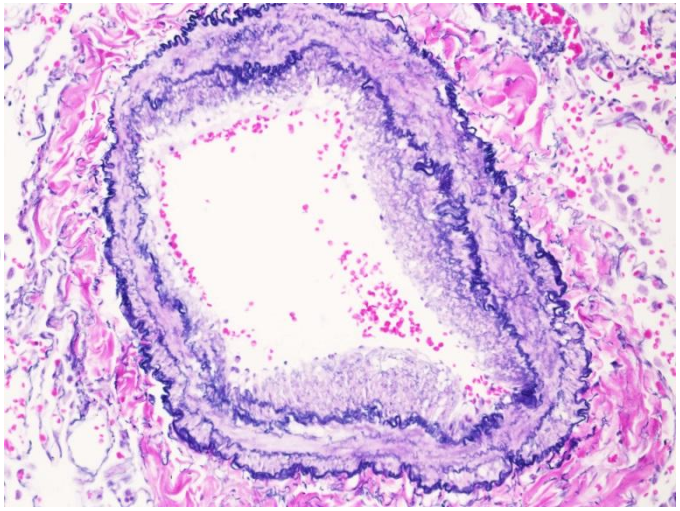


MSB



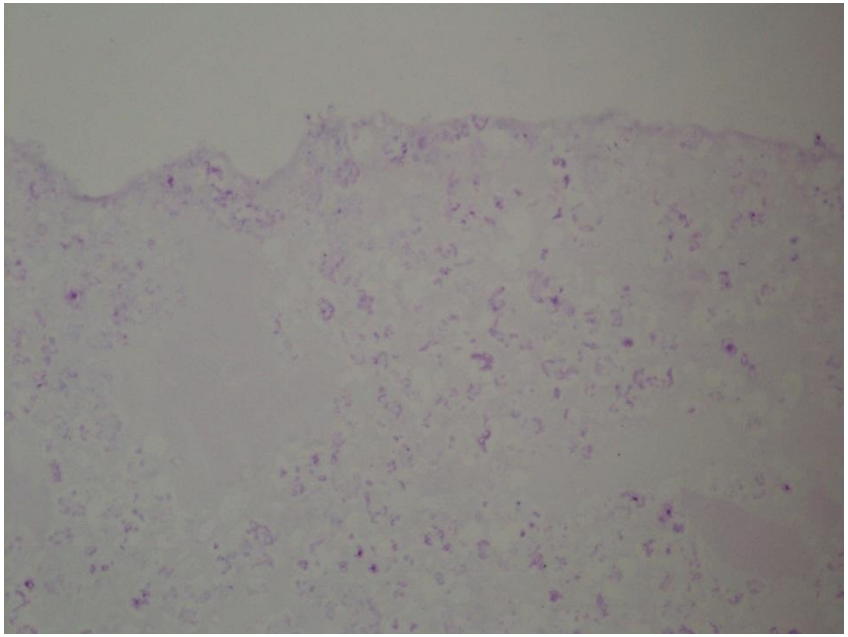


Elastic
H&E

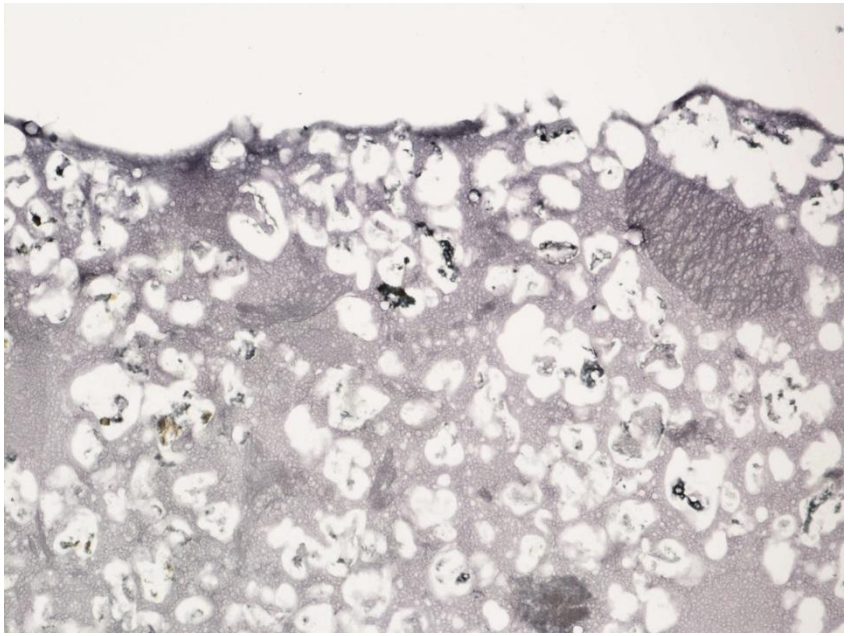


Gel Artefact

- Polysaccharide based



PAS



Meth Ag

Feedback from Phase 1

- H&E
  - Quality is acceptable
  - Perhaps some minor tweaks to optimise staining protocol
- ICC/Special stains
  - Little difference between conventional vs. Sakura
  - ICC markers used covered different antigen retrieval methods & covered a range of staining patterns
- Molecular testing
  - DNA & RNA extracted successfully
  - Concentration of DNA/RNA comparable
  - No issues with Gel inserts
  - Size ladder testing comparable
  - FISH to be performed
- Agreed to progress to Phase 2 validation

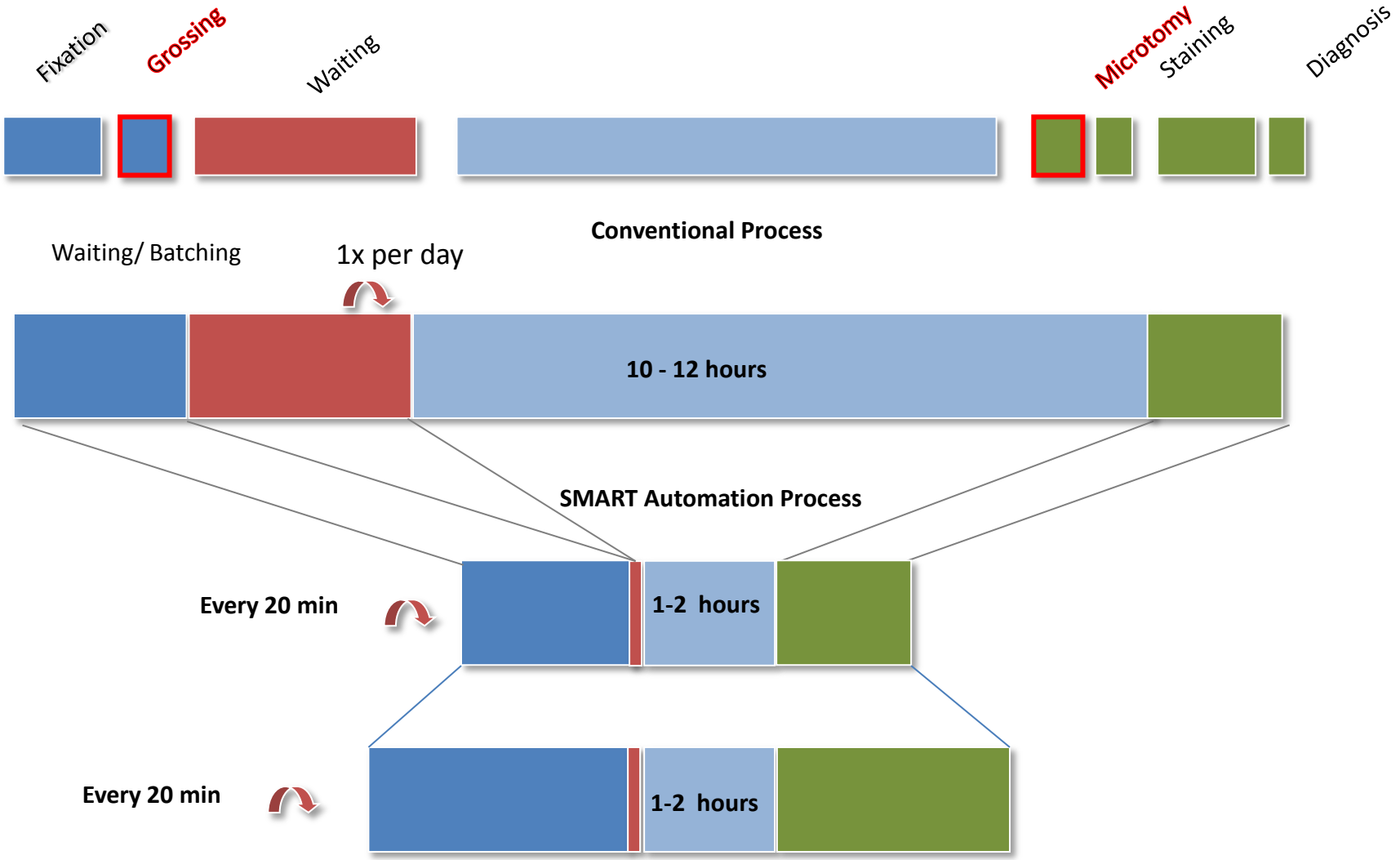
Suitable Tissue Types

- Not all Tissue types are suitable for SMART processing
  - Neuro
  - Bone
  - Fatty tissue*
- *New reagent under development which will process both fatty and non-fatty tissue
- Sakura provide guide for optimal tissue processing
  - Xpress 1 hour
  - Xpress 2 hour
  - Conventional Processing
- Approx. 70-80% could be processed by SMART Automation

Buying into Paraform®!

- Use of Paraform® cassette system
  - Fundamental change to process
  - Paraform®/Gel Artefact (Some staining techniques)
- Extra time taken at grossing stage
  - Tissue cut to 2mm or 3 mm
  - Placing Paraform® into cassette frame
  - Orientation of Tissue into Paraform® insert
  - Space within Paraform® insert – extra blocks required?
- Microtomy of Paraform® extra time taken
  - Extra blades used
  - Changes to process (face into all blocks first)?

Sakura SMART concept needs to be looked at as a whole process and not each stage of the process!



- https://sakurasl.sakura.eu/Smart-Automation
- Ian Downie
- Gillian Thatcher
- NHS GGC Pathology - Sakura Project Team


POWER
SYSTEM
START

Questions?