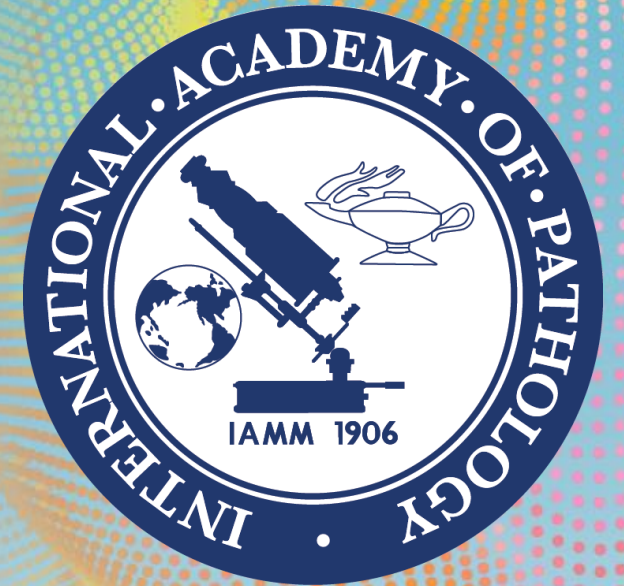


Implementation of Digital Pathology in a Private Australian Laboratory

Dr Melissa Holmes

Histopath Diagnostic Specialists



 The 48th Annual Scientific Meeting *of the*

Australasian Division of the
International Academy of Pathology

Disclosure of Relevant Financial Relationships

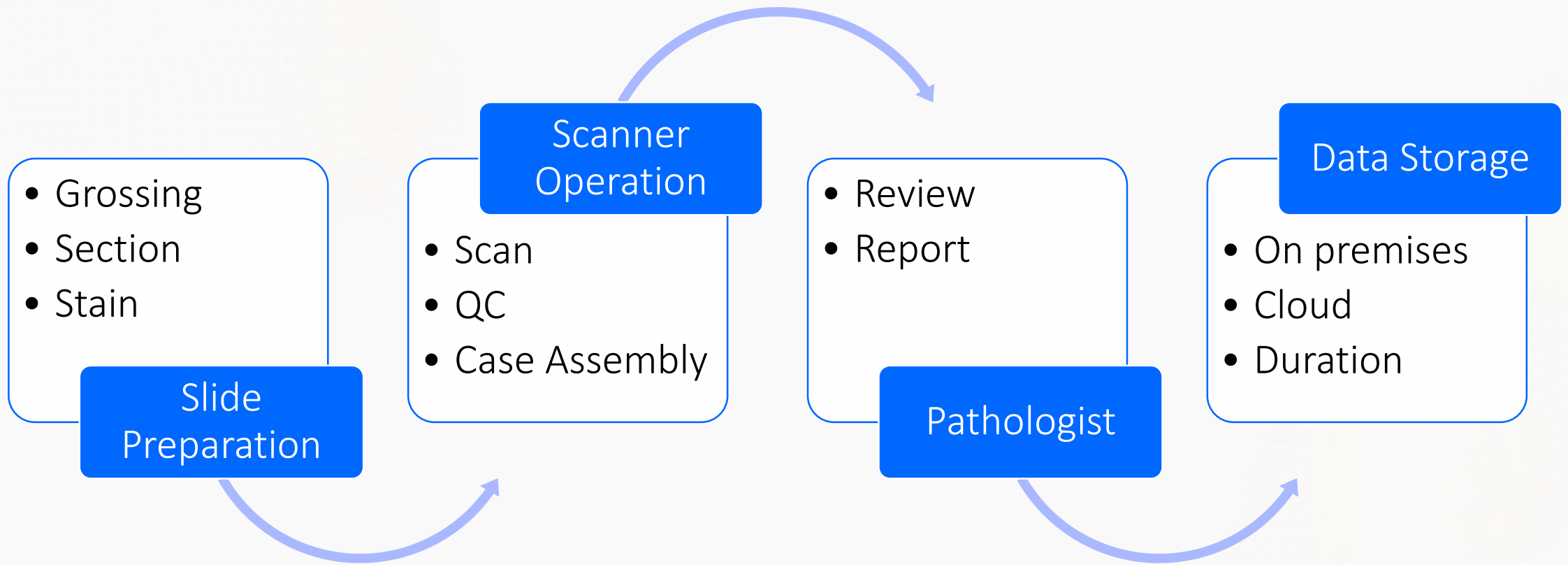
No disclosures

What is Digital Pathology

Not just the scanners and whole slide image (WSI) viewer

= conversion of a glass microscope slide containing processed diagnostic tissue or cells into a digital image

- Tools, system, infrastructure, processes
- Needs whole lab system and processes
- Needs people, technology, IT, data storage



Why go Digital?

- Primary diagnosis
- Telepathology
- Education
- Research
- Image analysis and AI

Benefits

- Potentially more accurate patient diagnosis and management
- Potential to enhance the reproducibility and accuracy of quantitative assessments
 - More accurate measurements
 - Image analysis to count mitoses, score Ki67, IHC (HER2, ER, PR)
 - AI
- Enable better communication
 - External consultation and second opinions
 - Case reviews at MDTs
- Enhance access for teaching and research
- **Ability to work remotely**
- Long term electronic storage of digital images
 - No deterioration/fading like glass slides
 - Less space required compared to glass slides

Risks

- Data security
 - Risk of unauthorised access
 - Risk of data being altered or deleted
 - Risk of data ransom
- Extra steps of scanning
- Learning curve - loss in time efficiency, comfort, diagnostic discrepancy
- Very small objects may be difficult to see - bacteria, eosinophils, mast cells, H.pylori
- Can't polarise - cannot identify amyloid using Congo Red or crystals
- Long term storage of files - need ongoing access to files and therefore open file formats (DICOM)

Histopath

Celebrating 25 years

Our Experience

Histopath

Largest independent private histology laboratory in Australia
(Sydney)

11 pathologists

Process 120,000 cases per year, 1,300 blocks per day

LEAN workflow

Small biopsies and resections

Derm, GIT, urology, endocrine, gynae, H&N, gen surg

2019 Roche DP200

- Prostate core bx
- IBEX

November 2022

- **3DHitech P1000 scanners x4**
- Education of Lab staff
- Software testing/slide viewer

INTEGRATION

- Powerpath
- Scanners
- Labflow

October 2023

- **Primary diagnostic reporting**

May 2024

- SECTRA

Hardware Testing

- Consultation
- IT
- MDTs
- Education

January 2023 Validation

- Phase 1

September 2023

- **NATA** accredited for DP

Jan 2024

- Ongoing validation (Phase 2)
- Re-education
- Automation

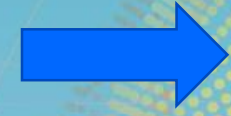


Automation Workflow

Sakura Xpress x120



Sakura AutoTEC a120



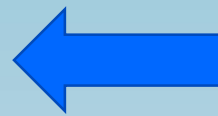
Sakura AutoSection



DNS AS410M



DAKO CoverStainer



3DH P1000



Pathologist Workstation

At least 2 screens including 32-inch 4K monitor

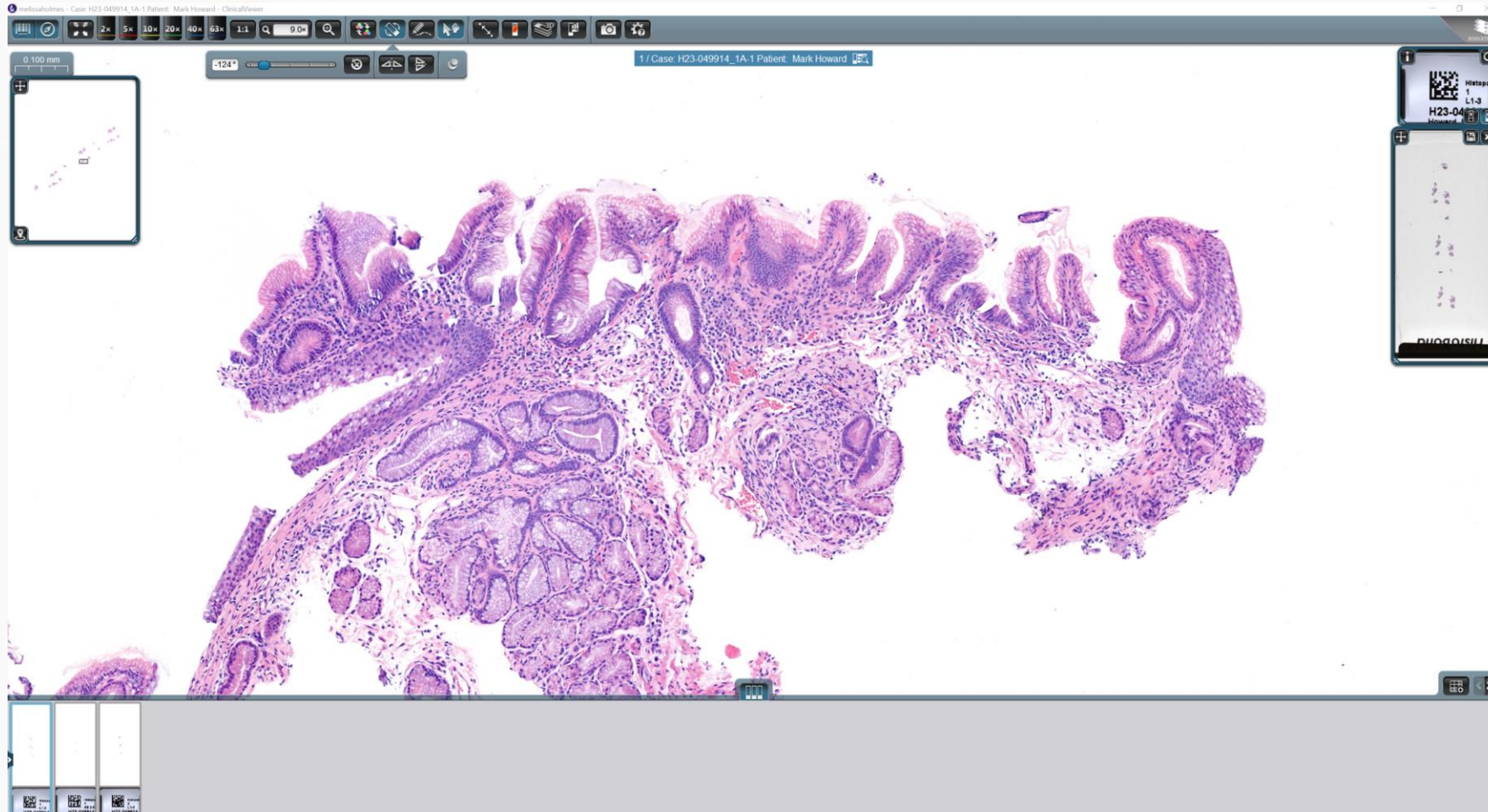
Ergonomic mouse

Option sit-stand table



Slide Viewer

3D Hitech



Challenges

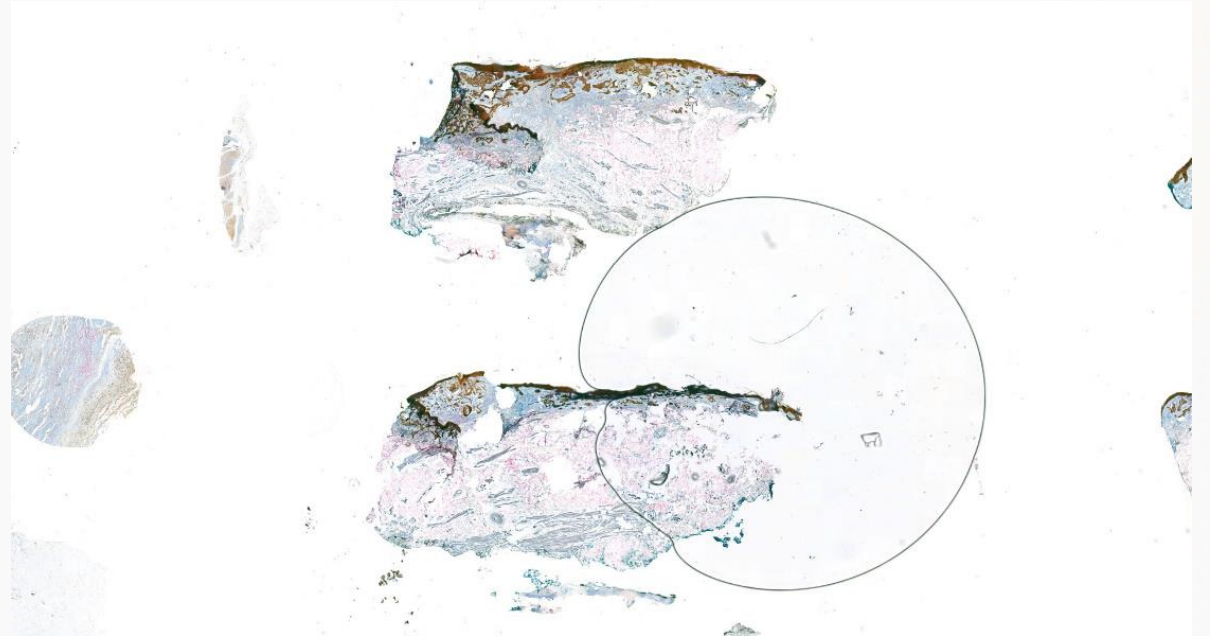
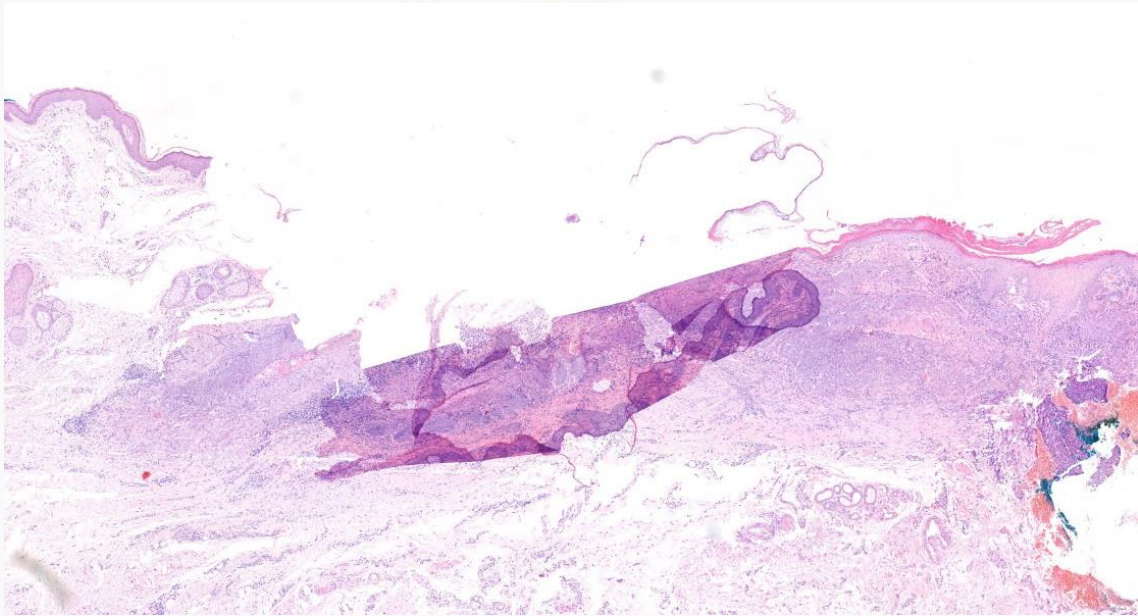
- Slide quality - WSI only as good as the slide produced
 - AB stain - counterstain
 - Oven at allocation
- LIMS - No good one available!
- IT
- Integration into lab system and LIMS+++ - Labflow
- Quality systems
- Validation - NPAAC
- Accreditation - NATA
- Acceptance - scientists, pathologists
- Data storage
- Support - SECTRA



Pre-analytic



Pre-analytic



Tips

Educate all staff - admin, scientists, pathologists

Involve IT early

Develop quality systems and compliance early

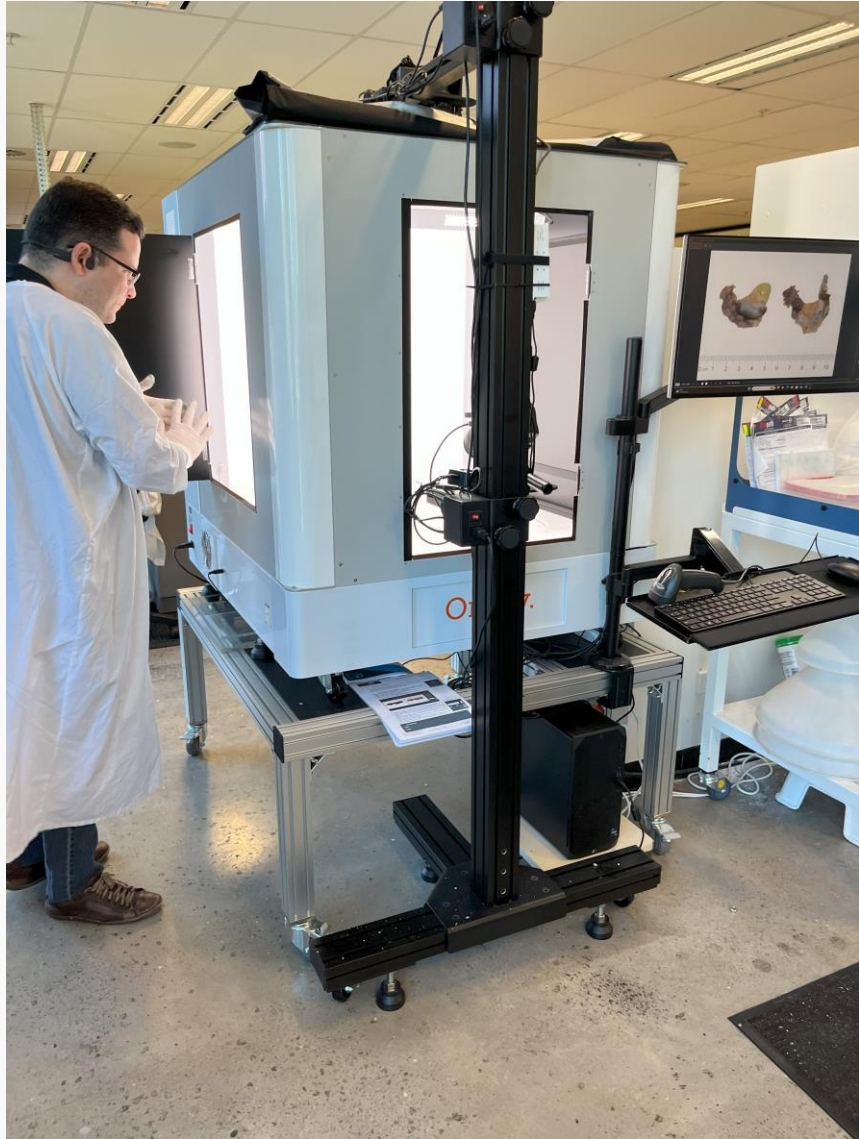
Make it enjoyable for pathologists

- Good WSI viewer

- Ergonomics

 - Space mouse, roller ball

 - Sit-stand tables



Validation Study

- Hardware: 3DHistech P1000 Panoramic scanner
- Software: 3DHistech whole slide image viewer
- Case Types: All histology cases including H&E, special stains and immunohistochemistry
- Aim: To ensure equivalence (non-inferiority) of WSI compared to glass slides viewed under the microscope
- Application: Implementation of digital pathology and WSI for primary diagnostic use for all histology cases

Phase 1 - Initial Validation of 60 prospective random routine cases, 20 retrospective cases.

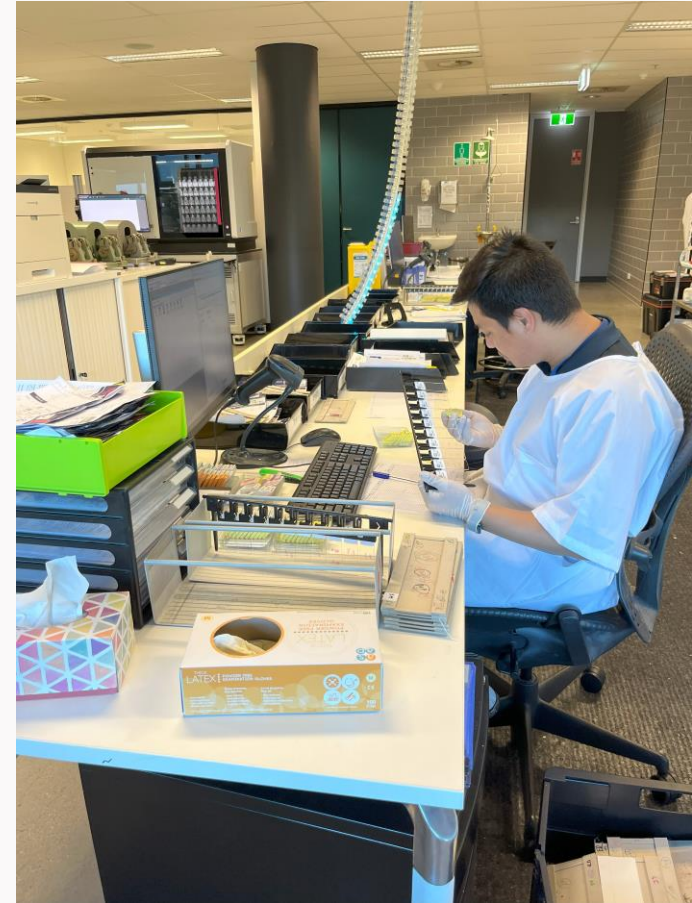
Phase 2 - Transition period

- Minimum of 20 cases per month reviewed for 6 months

Target concordance rate of 98%*

Performance Monitoring and Quality Assurance

- Pre-scanning quality check (pre-analytical)
Macro-evaluation of the slide
- Scanning auto-check (analytical)
The P1000 scanner internal quality check
- Post-scanning quality check (post-analytical)
Pathologist feedback



Results

Phase 1

Pathologists	Cases	Specimens	Slides
8	669	1280	2673

Concordance - 99.25%

Discordance - 0.74%

Rescan Rate - 0.73%

Specificity - 100%

Sensitivity - 99%

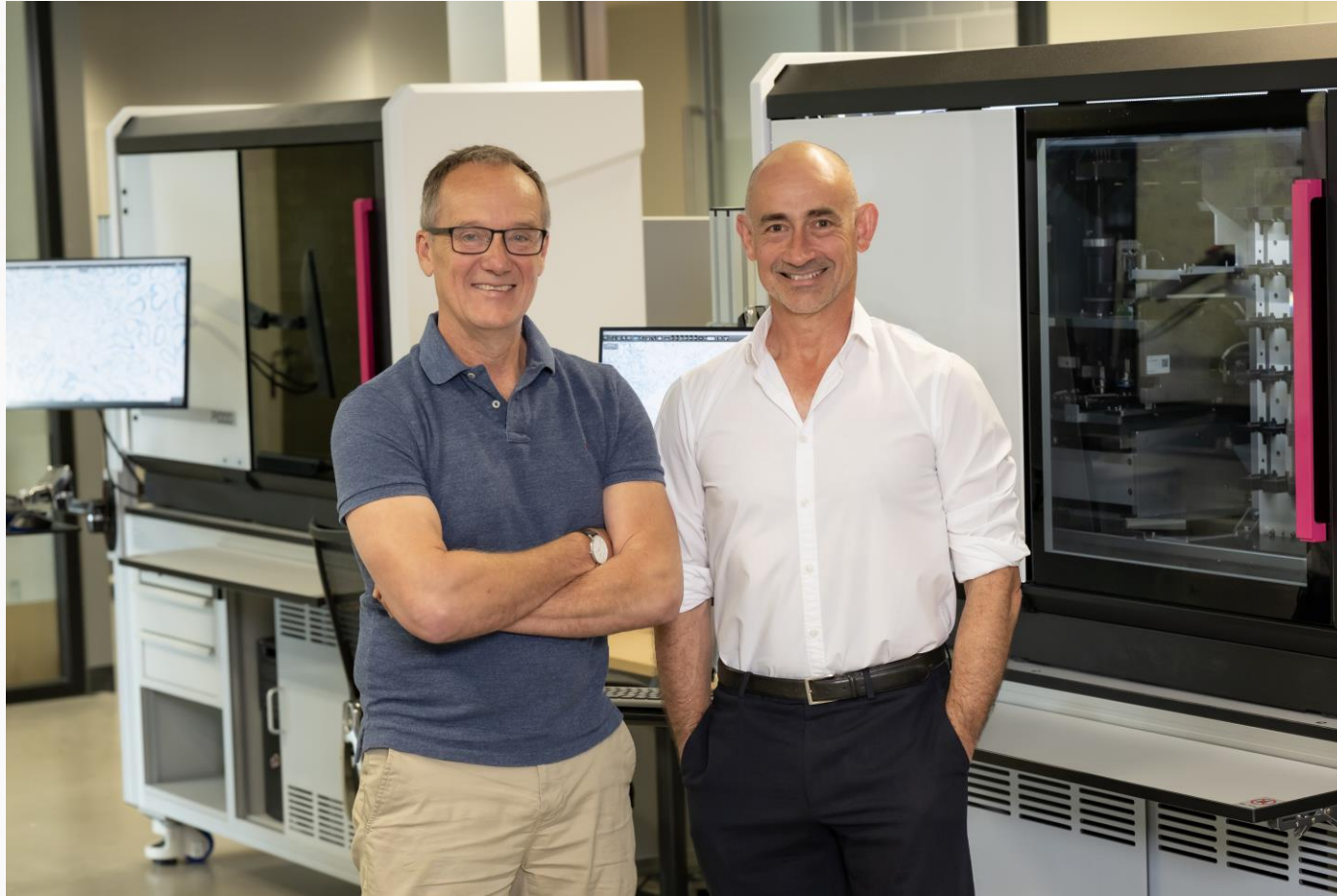
Discordant results

5 Discordant cases

- 2 Major discordant cases
 - Lentigo maligna re-excision
 - SSA with dysplasia
- 2 Minor discordant cases
 - Lichen sclerosus
 - Intradermal naevus/compound naevus
- 1 True positive
 - Prostate acinar adenocarcinoma in biopsy

Conclusion

- Demonstrated satisfactory equivalence of WSI compared to glass slide
- Discordant results were due to unfamiliarity with using the WSI viewer
- Learning curve for lab staff and pathologists
- Importance of risk management strategies throughout workflow
- Digital image is only as good as the glass slide quality



Thank You

