Scottish Association for Histotechnology

The Future for Cellular Pathology

Allan Wilson
SPAN Manager

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What I will cover today

New and potential future developments in Pathology

- Workforce developments
- Workload developments
- Technology developments
- Future developments
- The lab of the future??
- No product placements!

Histopathology service delivery

- Increasing centralisation
- Driven by Carter report and Sustainability & Transformation Plans (STP) in England
- Centralisation of surgical specialties
- Network approach
- Centralisation of specialist services such as molecular pathology
- Central approval of specialist tests (Scottish molecular pathology network)
- Digital pathology

Immunohistochemistry

- Increasing automation
- Role of support workers
- Move to “ready to use” markers & kits
- Ever expanding range of new markers
- New Pathologists are heavily dependant
- Panels ordered before H&E’s are seen
- Increasing use in diagnostic cytology
- Impact of accreditation to ISO15189

Cervical cytology

- Increasing centralisation
- Move to HPV primary screening
- Many countries already committed
- Australia started on 1st May 2017
- Wales to start in September 2018
- Impact on workforce
- Biomedical scientist roles in the "HPV first" service

Diagnostic cytology

- Impact of centralisation of cervical cytology
- Use of ICC and molecular pathology
- Loss of cytopathologist focus
- Move to cytology reported by specialist
- Rapid On Site Evaluation (ROSE)
- Real potential for development
- IBMS ASD in non-gynae

Mortuary and post mortem service

- Declining requests for hospital post mortems
- Declining interest among pathologists (diploma now optional)
- Centralisation of service
- Professionalisation of workforce
- Changes to death registration (post Shipman inquiry)
- Impact of rising number of bariatric bodies

Workforce developments

- Advanced roles for biomedical scientists
  - Cervical cytology
  - Tissue dissection
  - Histopathology reporting
  - Molecular Pathology
  - Rapid On-Site Evaluation (ROSE)
- Blurring of professional boundaries
- Australia and New Zealand college of pathologist approach – Faculty of Science
- Increasing opportunities for biomedical scientists
- Changing roles for Pathologists

Laboratory accreditation

- Move from Clinical Pathology Accreditation (CPA) to ISO 15189 assessed by UK Accreditation Services (UKAS)
- Impact on the service
- Professional body response
- Government response

Digital pathology

- A potential game changer!
  - Full slide scanning
  - Digital education
  - Remote reporting
  - Digital analysis
  - Artificial intelligence
  - Computer based reporting
  - Second opinions
  - Storage and archiving
- An enabler for future developments!
  - Look at radiology!


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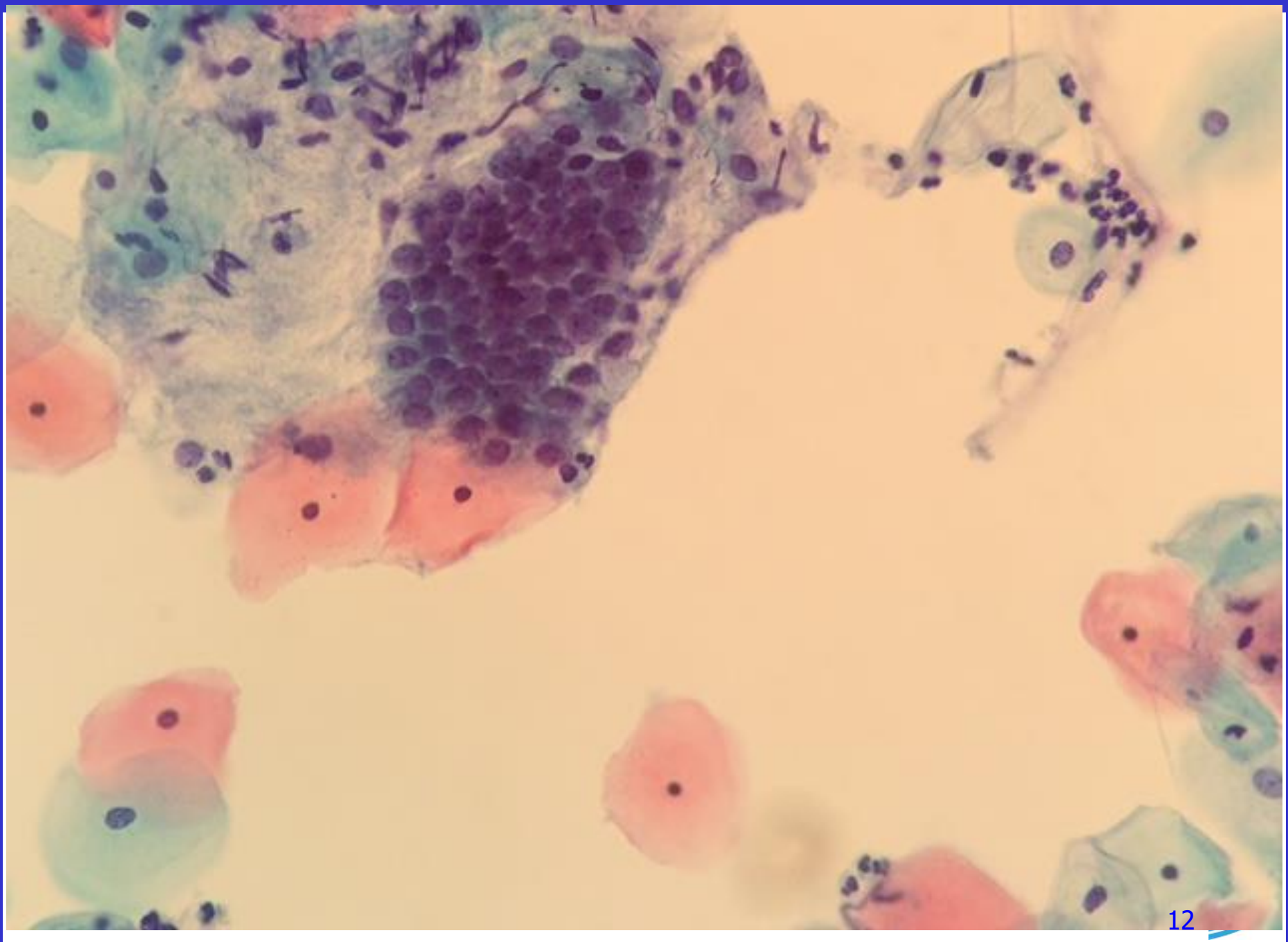

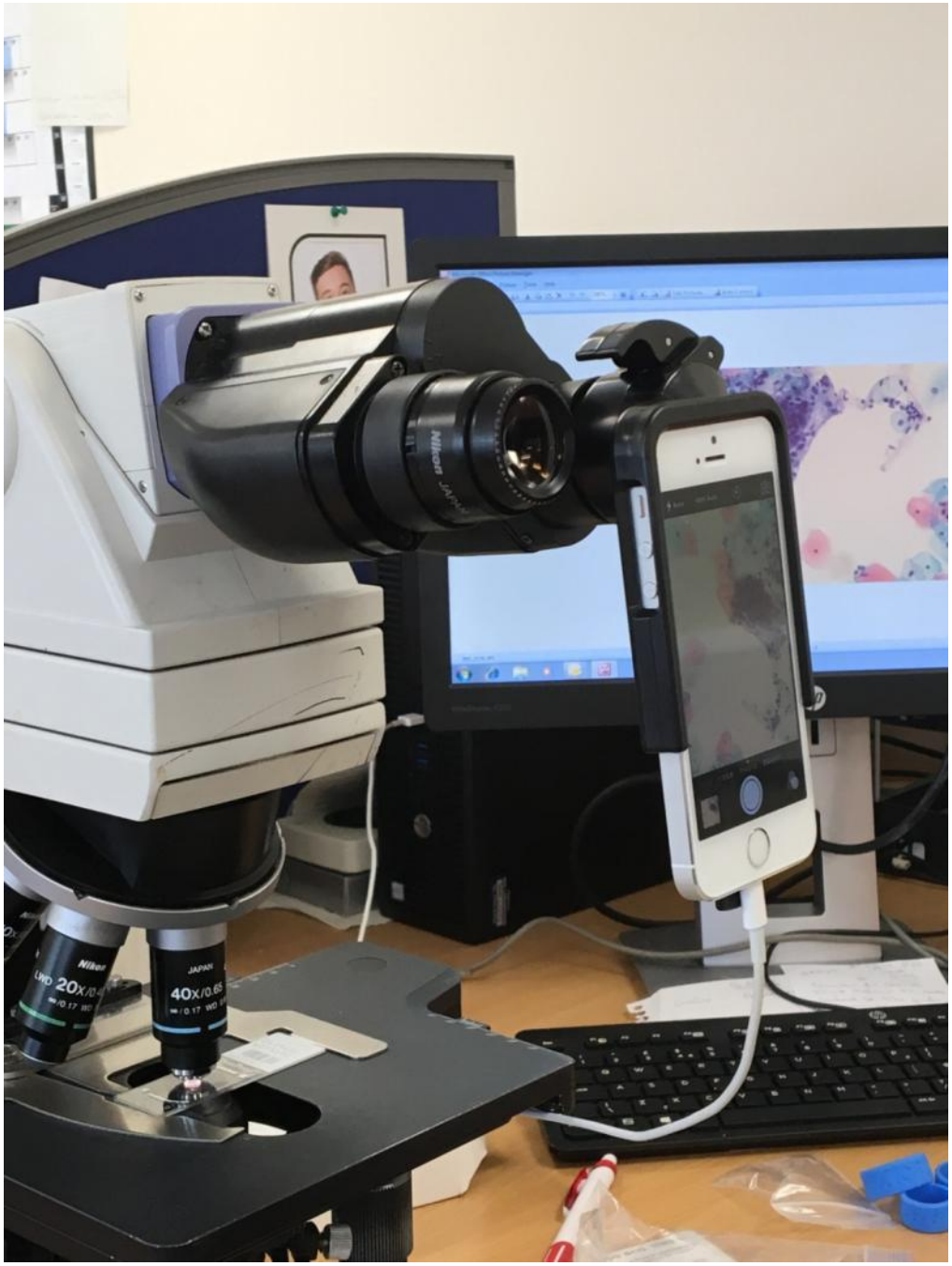
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13th EUROPEAN CONGRESS

ON DIGITAL PATHOLOGY

– HOSTED BY THE GERMAN SOCIETY OF PATHOLOGY –

www.digitalpathology2016.org

MAY 25th–28th, 2016

LANGENBECK-VIRCHOW-HAUS

BERLIN, GERMAN

13th European Congress on Digital Pathology

- Telepathology
- Data Integration and Modelling
- Virtual Microscopy
- Computer Aided Diagnosis
- Topology
- Imaging in Clinics and Research
- Clinical Workflow Integration
- Digital Pathology Workflow Integration
- Molecular & Integrative Pathology

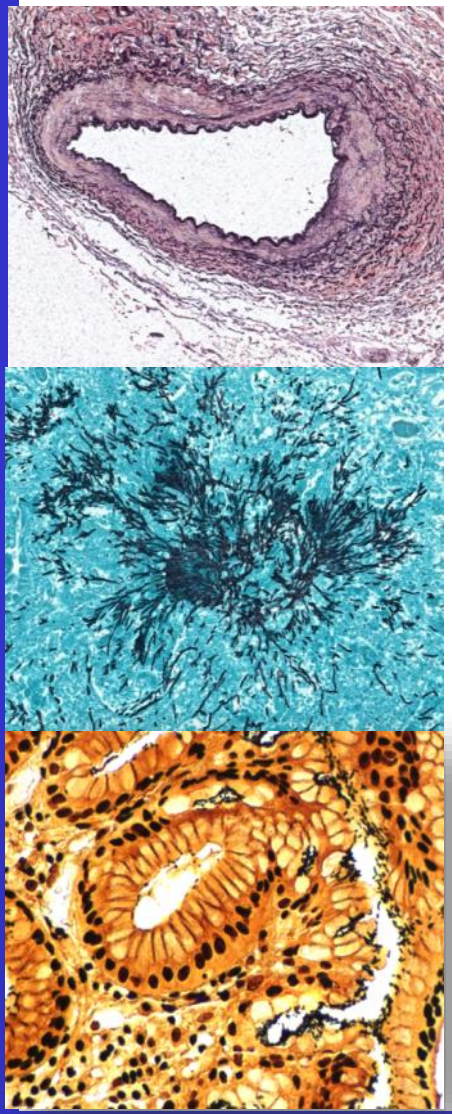
Digital pathology v PACS

- The Doubting Dollar by *Luke Perkocha*
- Pathology and radiology aren't equal, and the arguments for radiology's digital transition don't necessarily hold true for pathology's
- Digital pathology holds promise for image analysis and quality assessment, but other applications don't make financial sense – yet
- *Kaiser-Permanente in Northern California*

Automation in Histopathology

- H&E Staining/coverslipping
- Special stains
- Cytology processing
- Imaging in cytology
- Automated embedding
- Automated microtomy
- Archiving
- Digital pathology
- Diagnostic Algorithms/Artificial Intelligence

Automated Special Stains



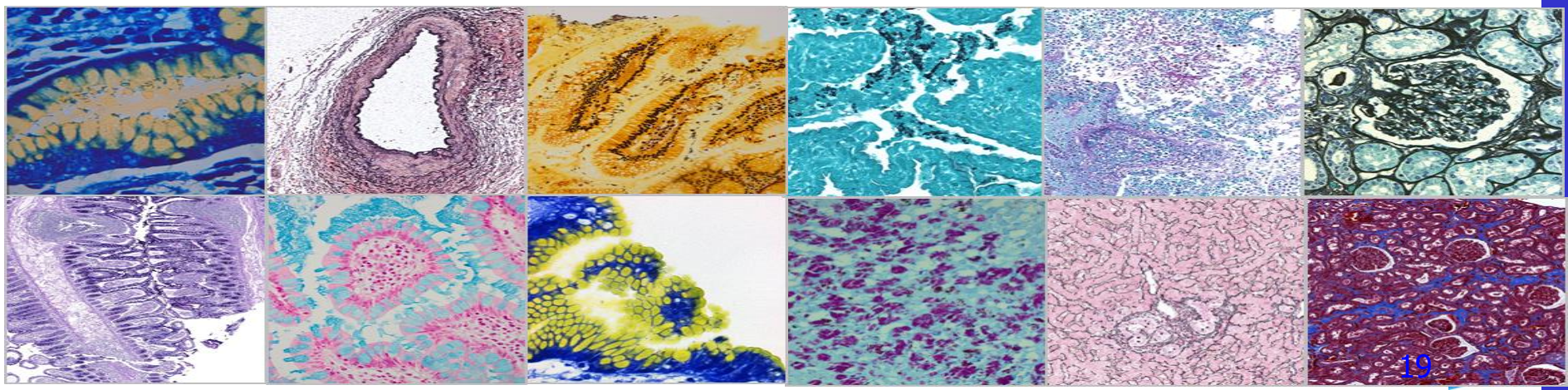
Roche Benchmark system

- **Workflow**
- 20 slides positions, 25 reagent positions
- Process integration {baking & depar}
- Elimination of temperature batching
- **Quality**
- Individual slide heating
- Selectable control for colour balance and clarity
- **Safety**
- Sealed reagents, No solvent exposure
- Reagents barcoded/inventory management

https://youtu.be/QmU32-TaxWw

Automated special stains: Benchmark stain repertoire

- AFB (Acid Fast Bacilli)
- Alcian Blue for PAS
- Alcian Blue
- Alcian Yellow
- Congo Red
- Diastase
- Elastic Stain
- Giemsa
- GMS II
- Gram Stain
- Iron Stain (Perls)
- Jones H&E or Jones Light Green
- Light Green for PAS
- Mucicarmine
- PAS
- Reticulum Stain
- Steiner Stain (Wathin Starry)
- Trichrome Stain



Automated embedding/microtomy

- Relatively recent development
- Still struggling to get a foothold
- Inevitable way forward for large centralised laboratories
- Sakura are the main players

Tissue-Tek® AutoSection® Automated Microtome

Efficiency

- Automated trimming freeing up experienced technicians
- Less rework due to high consistent quality, saving cost
- Easy and safe recutting leading to less spare sections and decreased over production
- Highly improved ergonomics, reducing labour cost

Speed

- 10 second Auto-trimming
- Perfect fit with Tissue-Tek® AutoTEC® & Paraform

Quality

- Eliminating tissue loss , especially important with recuts due to AutoAlign™ technology
- Precise and consistent high-quality sectioning for every technician and tissue type
- Consistent section thickness, especially important with IHC

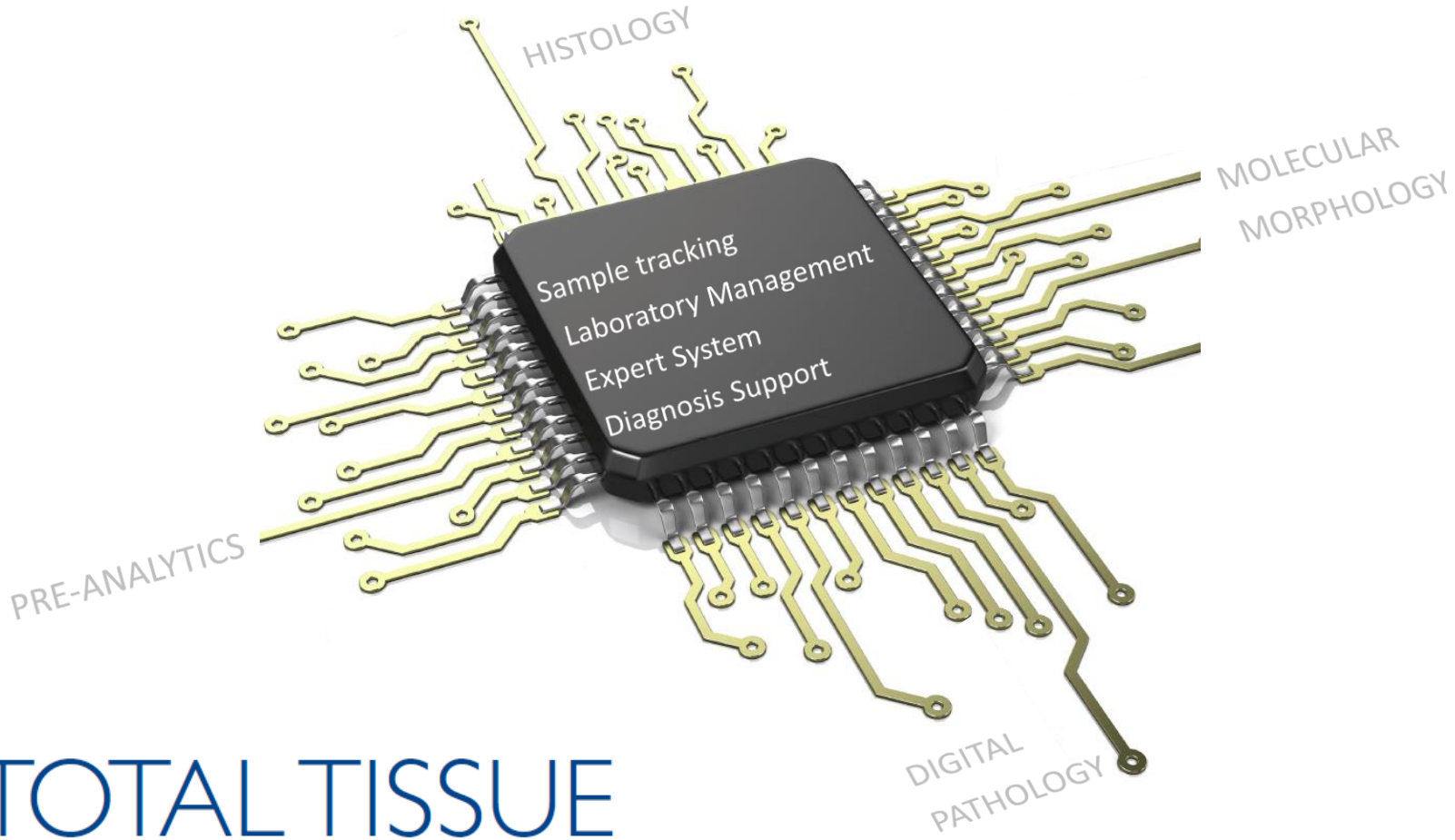
SMART Automation

- Consistent
- High quality
- Standardisation
- Eliminates errors
- Eliminates variation
- Increased productivity
- Reduced time to diagnosis
- 80% of cases in 24hrs

SAME DAY DIAGNOSIS

"We have significantly increased output with the same number of people"

Cellular Pathology is changing…



TOTAL TISSUE DIAGNOSTICS™

From surgical specimen to diagnosis

A.MENARINI diagnostics

A Fully-Integrated, Cellular Pathology

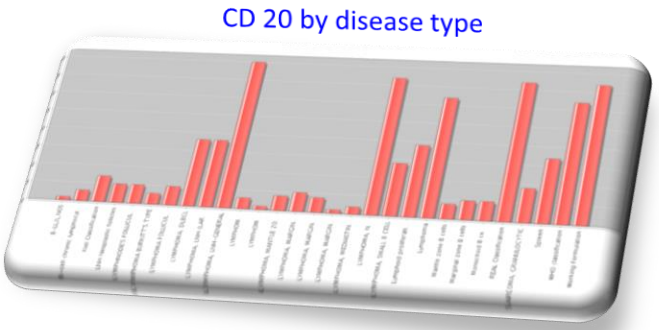
Laboratory Management Solution

Pre-analytical → Histology → Molecular Morphology → Digital Pathology

from surgical specimen to diagnosis

Tracking and Management System

- Open-Platform Tracking Solution
- Cellular Pathology Report
- Statistical Reporting Package
- Archive Management
- Inventory Management System



Take control of patient tissue blocks

The Thermo Scientific™ Syntri™ Arcos™ Block Management System is designed to minimize errors, increase productivity and keep your laboratory's resources focused on what matters most – positive patient outcomes.

Lost blocks – a thing of the

- The Arcos system mainta of all blocks in storage th accessed and searched a
- Check-out and check-in every block is, who check back and why it was nee
- Readily identify blocks ch than anticipated.

Increased accuracy

- The Arcos system elimin to the hand-sorting proce
- After check-out, blocks c any tray. When scanned, automatically updated.

Database integrity

- Redundant protection: yo automatically updated on the Arcos scanner. The u to automatically archive choice of secure storage network- or cloud-based
- Control individual user da and modification permiss

Archived in an instant

- Simply place your blocks in the Arcos tray right at the microtome. At the end of the day, push the tray into the scanner. In about two minutes, the Arcos system will scan, photograph and record the position of every block in the tray. Simply enter the location where you will store the tray and your database is immediately updated.
- No more time consuming manual sorting; scan hundreds of blocks at once.

Reliable retrieval

- Find tissue blocks quickly and easily. Select the block you're after and the Arcos system will tell you where the tray is located in your archive, and the exact position of the block within the tray.
- Time to return the block to storage? Simply place it in the next tray to be scanned, the Arcos system will automatically update your database to reflect its new position.

Proven savings

- The Arcos system has been shown to save thousands of man-hours per year in busy laboratories – up to one-and-a-half full time employees.
- The system's speed and efficiency allow you to keep your laboratory's resources focused on what matters most – positive patient outcomes.

A natural fit for your workflow:

- The compact form factor of the scanner is designed to fit neatly within space-challenged laboratories.
- Save up to three meters (ten feet) of workspace previously reserved for sorting and stacking blocks.

ure. simple. savings.

A breakthrough in tissue block management

- Protect precious patient tissue blocks from misplacement and loss
- Fast, flexible and efficient storage and retrieval
- A natural fit for modern laboratories

Thermo SCIENTIFIC

Automation in cervical screening

- Liquid based cytology (the enabler)
- Automated sample processing
- Automated screening
- Imaging assisted screening
- HPV testing
- Sample handling

ThinPrep 5000 with AutoLoader

- Automatically process up to 160 specimens.
- Continuous loading of new samples /supplies- minimal tech involvement
- Up to 8 hours walk-away time
- Automatic vial capping/uncapping
- Slide ID/Barcodes printed on slides, plus other info from LIS- eliminates chain of custody issues
- Footprint: 54in x 28in x 57in

HOLOGIC

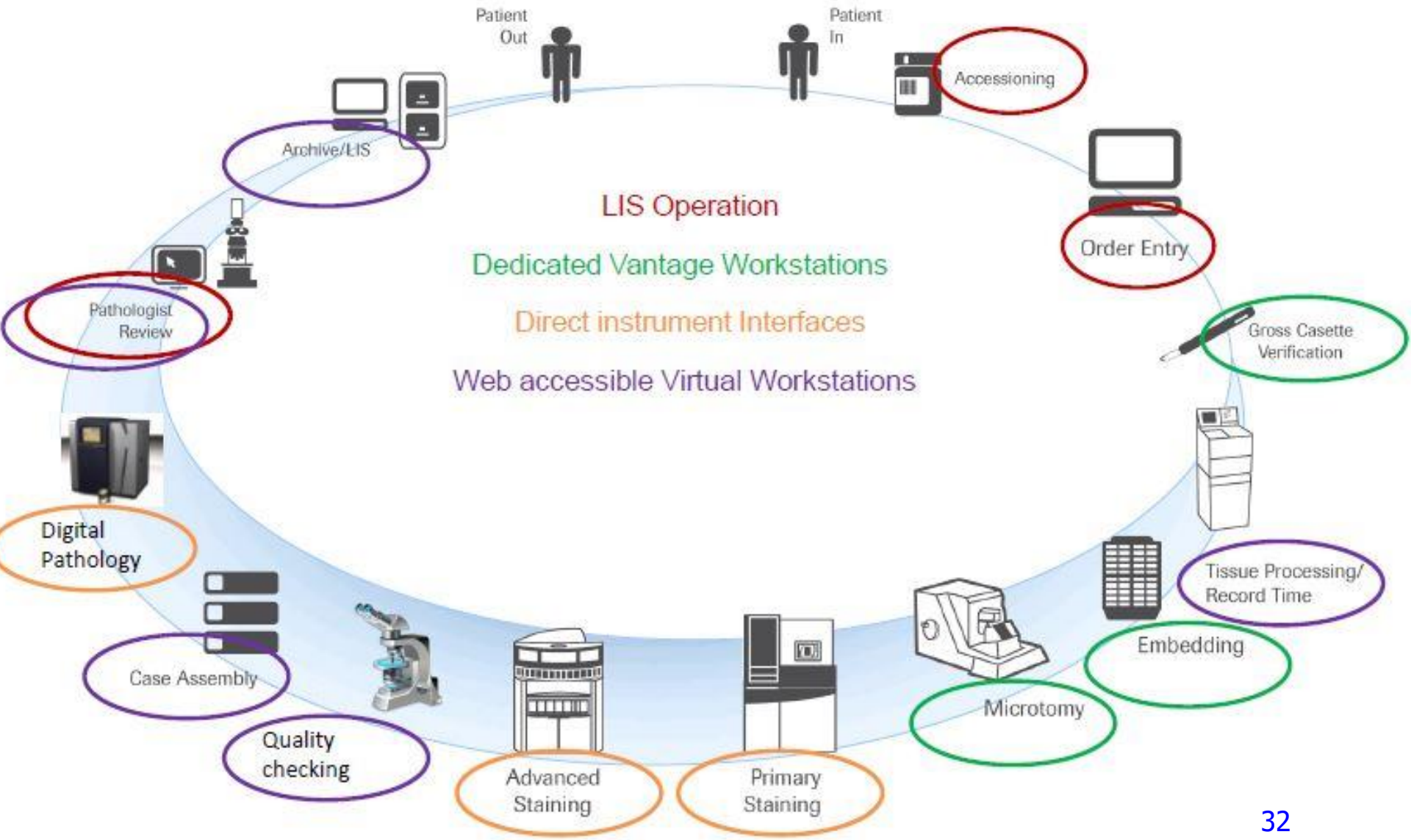
Complete Automation for Cervical Health Screening

One vial. Multiple options. One complete solution.

Tracking systems

- End to end tracking: source to archiving
- Track and trace labelling (like Amazon!)
- Interface with LIMS
- Error reduction
- Bar code driven
- One slide/block at a time approach
- Stock control and JIT ordering (like Tesco!)
- Staff productivity data
- Roche Vantage, Leica Cerebro

VANTAGE integration



VANTAGE

Workflow & Tracking

Blend of computer
HARDWARE & SOFTWARE

- An automated & sophisticated histology **specimen tracking system.**
- **Management system:** Process, quality and productivity in the lab
- A tool to assist in the laboratory **leaning** process

1
- Automated embedding
- Automated microtomy

2
- Automated staining
- Automated coverslipping

3
- Automated scanning
- Automated slide archiving

4
- Automated pre-screening by AI

Changing face of the workforce

- Increasing roles of support workers
- Decreasing number of biomedical scientists in cell path
- Part time posts
- Feminisation of the cell path workforce
- Advanced practice roles
- Glass ceilings beginning to develop holes.....

Histopathology reporting by biomedical scientists

- First biomedical scientists now reporting biopsies and resections
- Intensive training
- Close co-operation with RCPath
- Dramatic progress, unprecedented in other countries
- Recognition of biomedical scientists

Advanced practitioner role in cervical cytology

- Now dominate cervical cytology in the UK
- Declining number of cytopathologists (diploma now optional)
- Advanced practitioners have filled the gaps
- Service now led by biomedical scientists
- Wider screening programme role
- Role in HPV primary screening laboratories
- Consultant equivalent

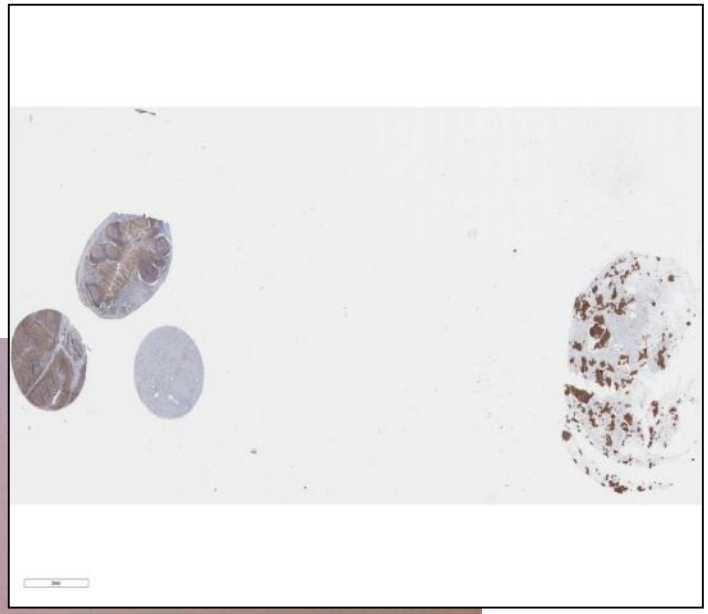
Training and specialism

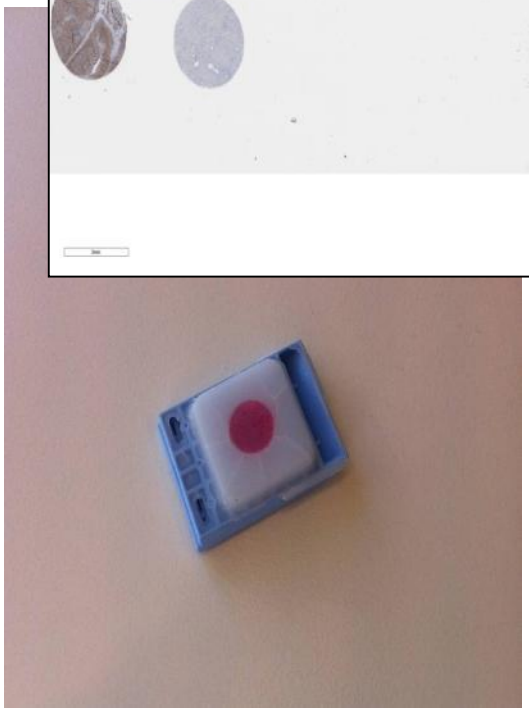
- Review of IBMS portfolios and qualifications
- Potential modularisation of specialist portfolios
- Introduction of molecular pathology course and Certificate in Expert Practice
- Access to ASD qualifications
- Development of histopathology reporting qualifications

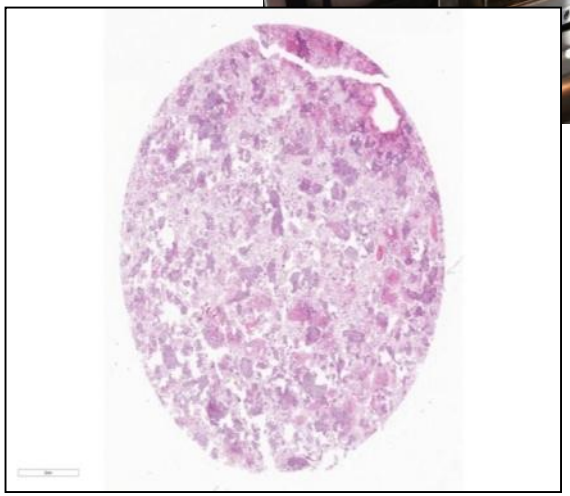
Advances in diagnostic cytology

- Molecular pathology
- Immunocytochemistry
- Flow cytometry
- Cell blocks
- ROSE/EBUS
- FISH
- Next Generation Sequencing (NGS)
- Doing more with less...

Cellient for immunohistochemistry on cell blocks







The future: workforce

- Further development of advanced roles for biomedical scientists
- Increasing role of support workers
- Develop relationships with medical staff and medical colleges
- Blurring of professional boundaries
- Inevitable move to BMS reporting
- Changing role of Pathologists

The future: workload

- Increasing diagnostic biopsies (Scottish cancer statistics)
- ? Declining cancer resections
- ? Increasing IHC requests
- Declining role for EM, special stains
- Increasing role of molecular pathology in diagnosis, tumour typing and prognostic markers (may reduce IHC)
- Tissue banking
- Personalised medicine

What is driving the change

- Rethinking patient pathways
- Personalised medicine
- Increasing specialisation
- Shrinking financial resource
- Advances in clinical procedures which do not require pathology
- Added value from cellular pathway
- Expansion of traditional roles
- Advances in technology

External reports

- Cancer Research UK (CRUK)
- Nuffield Trust report
- NHS Improvement
  - Cervical cytology
  - Histopathology
- Carter report

Cancer Research UK's pathology report

16 recommendations, key findings which these recommendations are based on:

- Demand is increasing – both due to more referrals, but also more complexity per referral.
- Consultant capacity (numbers) has been increasing, but not as much as demand.
- As a result – drop in research/changes in ways of working; difficulty recruiting; outsourcing and backlogs; waiting times increasing

Other new developments

- Liquid biopsies: Tumour type–specific, multi-biomarker next-generation sequencing (NGS) assays with >98% specificity in genes found in plasma samples.
- Low-Cost Microendoscope: low-cost solution opens new doors for low-resource regions and, in many cases, allows operators to rule out malignancy without the need for a pathologist to review biopsies

Circulating tumour cells

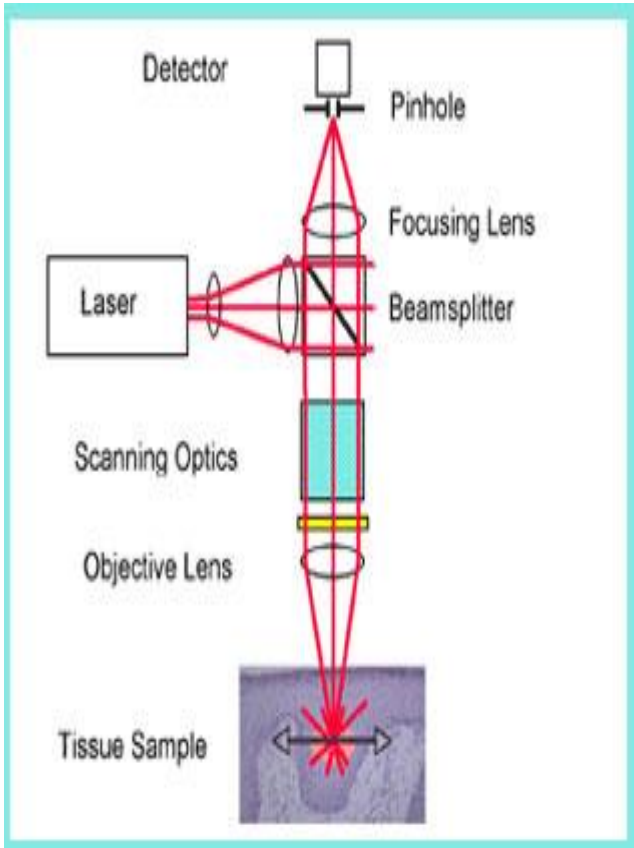
- The CELLSEARCH® Circulating Tumor Cell Kit is intended for the enumeration of circulating tumor cells (CTC) of epithelial origin (CD45-, EpCAM+, and cytokeratins 8, 18+, and/or 19+) in whole blood.
- The presence of CTCs in the peripheral blood, as detected by the CELLSEARCH® CTC Test, is associated with decreased progression-free survival and decreased overall survival in patients treated for metastatic breast, colorectal, or prostate* cancer. The test is to be used as an aid in the monitoring of patients with metastatic breast, colorectal, or prostate cancer.

Confocal laser scanning microscopy

- In vivo and ex vivo examinations using confocal laser scanning microscopy
- Allow for an optical biopsy using a non-invasive procedure.
- Cellular microstructures of skin can thereby be depicted cell by cell in clearly defined horizontal “optical cross-sections”.

Confocal laser scanning microscopy

- To generate confocal images, a laser beam in the near infrared range is directed through an interconnected lens system and a beamsplitter onto the area of skin to be examined.
- The light is reflected by the different components of the tissue and captured by the microscope to make an image.
- The image focus plane – the illuminated spot in the tissue –and the aperture of the detector are on optically conjugated focal planes


Detector
Pinhole
Focusing Lens
Laser
Beamsplitter
Scanning Optics
Objective Lens
Tissue Sample


VIVASCOPE
1500

Magnetic resonance

- Taking tissue samples to diagnose fatty liver can be replaced in most cases by a painless magnetic resonance investigation. This is the conclusion of a new study from Sweden.
- MRS makes it possible to follow small changes in the amount of fat in the liver and how it changes with time, without needing to take tissue samples from the liver.

Multiplexed Ion Beam Imaging (MIBI)

A novel approach to immunohistochemistry that uses secondary ion mass spectrometry and antibodies labelled with elemental mass tags to visualize dozens of proteins simultaneously in a single tissue section.

MIBI is compatible with formalin-fixed, paraffin-embedded tissue specimens and can achieve single molecule sensitivity across a five log dynamic range.

A novel imaging mass spectrometer has been developed capable of super resolution imaging and 100-fold faster sample throughput than previously reported.

These tools are being used to comprehensively enumerate immune cell populations in normal and neoplastic solid tissues, to construct classifiers for predicting disease progression in pre-invasive cancer lesions, and to develop quantitative IHC assays to be used in a clinical setting.

Is big beautiful?

- Already we have huge Labs in Australia. The Douglas Hanley-Moir (Sonic) operates 24/7 for Scientists and Pathologists. 4000 Blocks per day.
- This is the norm in USA
- Creeping into Europe
- The way forward?
- Not necessarily beautiful but inevitable.....

The lab of the future??

- It will be big!
- Tracking systems will be mandatory
- Different patterns of working (24/7)
- Increased complexity (prostatic cores)
- Digital pathology revolution
- Molecular pathology/genomics/genetics
- Diagnostic algorithms
- Focus on quality
- A new approach to management required

The lab of the future??

- Doing more with less (samples and staff!)
- Less specimen handling
- Controlling "downstream" (ROSE)
- More "end to end" automation
- More support staff
- Less scientists and pathologists
- More extended roles for scientists
- Increasing workload and size of department

Models for future service delivery

- Large processing labs with wide use of BMS dissection
- BMS triage based reporting
- BMS specialist reporting
- Off site pathologist specialist reporting
- Where do pathologists fit in?
- Off site frozen section reporting

What should we do?

- Plan and engage!
- Ensure you are best placed for the developing roles
- Develop training courses
- Focus on molecular pathology, dissection and reporting

Summary and conclusion

- Radical changes on how we deliver the cellular pathology service is on the horizon
- Patient and patient pathway focussed
- Centralisation is inevitable
- A new way of managing and delivering the service is required

References

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