



Seal Safe
Vacuümverpakken en fixeren

Nicolette Kürten

30 May 2022



A.MENARINI
diagnostics

CELL PATHOLOGY Agenda

- Introduction Menarini Benelux
- Milestone Medical vacuum technology
- Seal Safe in OR or Pathology laboratory
- Seal Safe - Live demonstration
- Questions

CELL PATHOLOGY Introduction

- ≡ Innovation in diagnostics since 1987
- ≡ European network
- ≡ Distributor
- ≡ Own portfolio



MILESTONE
H E L P I N G
P A T I E N T S



CELL PATHOLOGY Introduction



TOGETHER TO PROVIDE YOU TOTALLY

Milestone was founded in 1988 as a company specialized in **advanced microwave instrumentation** for analytical and organic chemistry labs.

We are an industry leader in this field, with a **worldwide installed base of over 20,000 systems** in large and small research institutions, universities and industrial laboratories.

CELL PATHOLOGY Introduction

Control of preanalytical step

Plebani M. Carraro P. Mistakes in a stat laboratory: Types and frequency.

Clin Chem 1997; 42: 1348-1351

*Focus on the pre-analytical steps, where **68%** of errors take place.*

Preanalytical quality improvement: from dream to reality.

Lippi G. et al: Clin Chem Lab Med **2011 July**, 49 (7)

*Pre-analytical errors still account for nearly **60-70%** of all problems occurring in laboratory diagnostics. Most of them are attributable to mishandling procedures during collection, handling, preparing or storing the specimen.*

CELL PATHOLOGY Introduction

- ≡ **ASCO/CAP Guideline Recommendations for Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer., Arch Pathol Lab Med-Vol 131, January 2007/2013**
Results – Approximately 20% of current HER2 testing maybe inaccurate.

CELL PATHOLOGY Introduction

Belgian Biosafety Server



Home Kennisgevingsprocedures ▾ Regelgevingskader ▾ Thematisch gebied ▾ Historische achtergrond ▾ FAQ Evenementen ▾ Over de SBB ▾ * NEW (10-03-2022) *

Kennisgevingsprocedures / Ingeperkt gebruik GGO's/pathogenen / Hulpmiddelen / Ingeperkt gebruik - Herziening van de indeling van formaldehyde

Ingeperkt gebruik - Herziening van de indeling van formaldehyde

Sinds 1 januari 2016 moeten de nieuwe indeling (inclusief de veranderingen inzake de acute giftigheid) en de regels voor etikettering worden toegepast op formaldehyde en op mengsels die een bepaalde hoeveelheid formaldehyde bevatten. Het kankerverwekkende effect (categorie 1B) is van toepassing vanaf een drempelwaarde van 0,1% en het mutagene effect (categorie 2) vanaf een drempelwaarde van 1% (Verordening Nr. 2015/491).
gene niet als formaldehyde en op mensels die een bepaalde hoeveelheid formaldehyde bevatten. Het kankerverwekkende effect (categorie 1B) is van toepassing vanaf een drempelwaarde van 0,1% en het mutagene effect (categorie 2) vanaf een drempelwaarde van 1% (Verordening Nr. 2015/491).
ten die voor dergelijke onderworpen aan de ing behoren biociden die worden gebruikt als agentia om oppervlakken mens of dier worden gebruikt) of tot categorie PS3 (dierhygiëne, producten voor het desinfecteren van materialen en oppervlakken in verband met de huisvesting of het vervoer van dieren).

CELL PATHOLOGY Introduction



CELL PATHOLOGY vacuum technology

Tissue Safe (2010)/
Tissue Safe Plus (2016)

Seal Safe (2013)

Ultra Safe (2020)



CELL PATHOLOGY vacuum technology

The results of histological and immunohistochemical (IHC) staining has been comparable to those specimens previously and simultaneously received in formalin pots, and there has been no detrimental effects on the quality of the histological or IHC slides produced or on subsequent reporting after using the TissueSAFE and SealSAFE systems.



Reducing formalin exposure risks in the management of surgical specimens

HISTOPATHOLOGY

To combat concerns about the dangers posed by the use and transport of formalin solutions, histopathology staff in Sheffield explored an innovative biospecimen transfer system, as Karen Lester explains.

Concerns about the health effects of formalin exposure, together with the reclassification of formaldehyde as a Class 1 carcinogen (IARC) has prompted

formalin on receipt. Fixation is performed within the histopathology department where staff are trained to handle formalin safely over downdraft benches and have

At NGH the campus is large and the histopathology department is situated across the site from the theatres. On this site, large specimen pots containing formalin are supplied to the theatre units where they are stored until required. When a specimen has been taken, the pot is transported to the satellite laboratory.

Once in the laboratory at NGH the specimens are fixed overnight, formalin is drained off and the specimens bagged up and transported to RHH for dissection and histological analysis, to bring it into

CELL PATHOLOGY vacuum technology



ADAPTATION OF HOSPITAL
SERVICES INVOLVED, BECOMING
PACKAGING OF SUBSTANCES

Authors: Pérez L, Sanz Y, Martínez A,
Ortiz N, Pastor M, Moreno M,
Pathology Department, Hospital

CONCLUSIONS

We reduced the use of formaldehyde in areas without ventilation systems, thus improving risk control.

Also packaging/preservation has been improved, up to three days after its extraction, guaranteeing suitability for further immunohistochemical or molecular studies. Design and implementation new protocols for sample processing, adequate fixation and facilitate re-tapping avoiding overfixation.

Reform of physical plant, with extraction systems and negative pressure environment, new tables and bells of carving with exposure control and adapted for ergonomics and occupational safety.

salud
servicio aragonés
de salud

SERVICE AND OTHER
BELONGING AND

Martínez A, Rodríguez M,

CELL PATHOLOGY vacuum technology

- Fresh vacuum-packed specimens entering the laboratory have been shown not to be compromised in quality with respect to downstream routine diagnostic testing, ensuring pathologists are able to perform accurate diagnosis.

GENOMICS

Fresh tissue handling pathway for the 100,000 Genomes Project

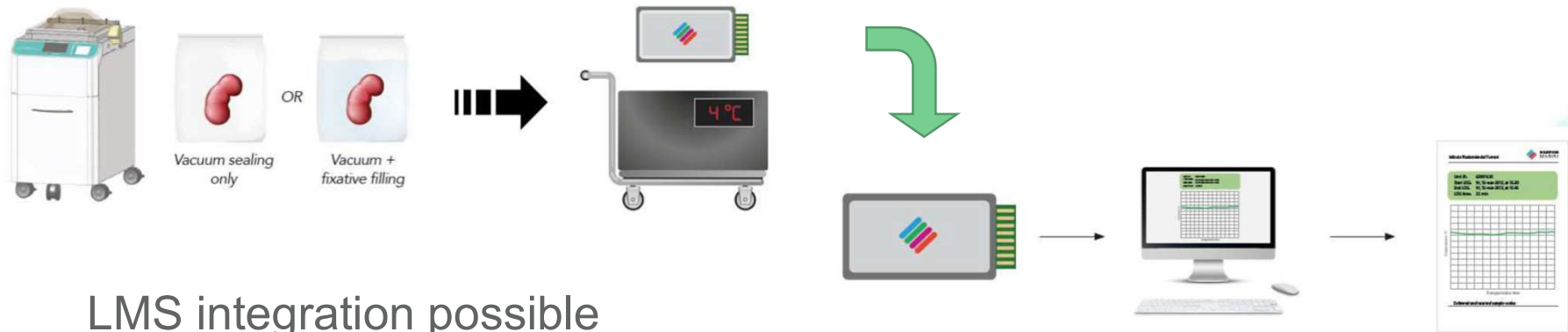
In order to optimise and standardise the handling of fresh tissue for The 100,000 Genomes Project, four partner trusts of the West Midlands Genomic Medicine Centre have adopted an innovative vacuum-packing solution.

The West Midlands Genomic Medicine Centre (WMGMC) is one of 13 created by NHS England to transform diagnosis and treatment for patients with cancer and rare diseases, and aims to deliver for

Warwickshire NHS Trust, and George Eliot NHS Trust – have adopted vacuum packing for the collection and transportation of surgical specimens from participants who have been recruited into

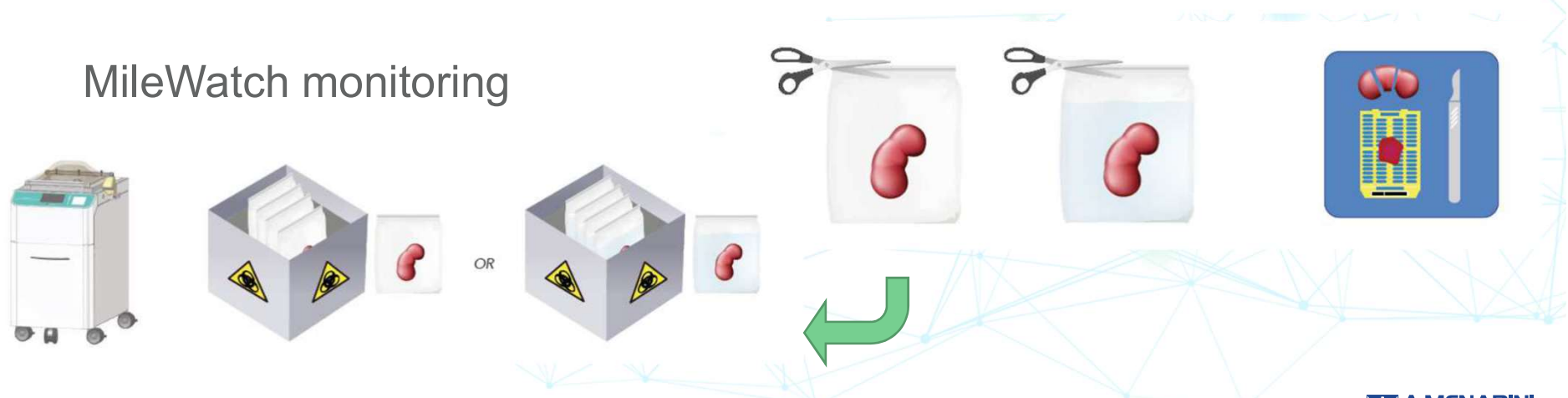
During the early phases of the project, extensive experimental work showed that fresh frozen tissue is required for optimal WGS. Formalin-fixed, paraffin wax-embedded (FFPE) samples typically generated by pathology laboratories are available in abundance. However, DNA extracted from FFPE blocks is highly variable due to DNA damage introduced by the fixation process. Formalin fixation causes i) hydrolysis of phosphodiester bonds, leading to varying degrees of DNA fragmentation, and ii) crosslinking resulting in artificial nucleotide mutations.

CELL PATHOLOGY Seal Safe in OR or Pathology laboratory



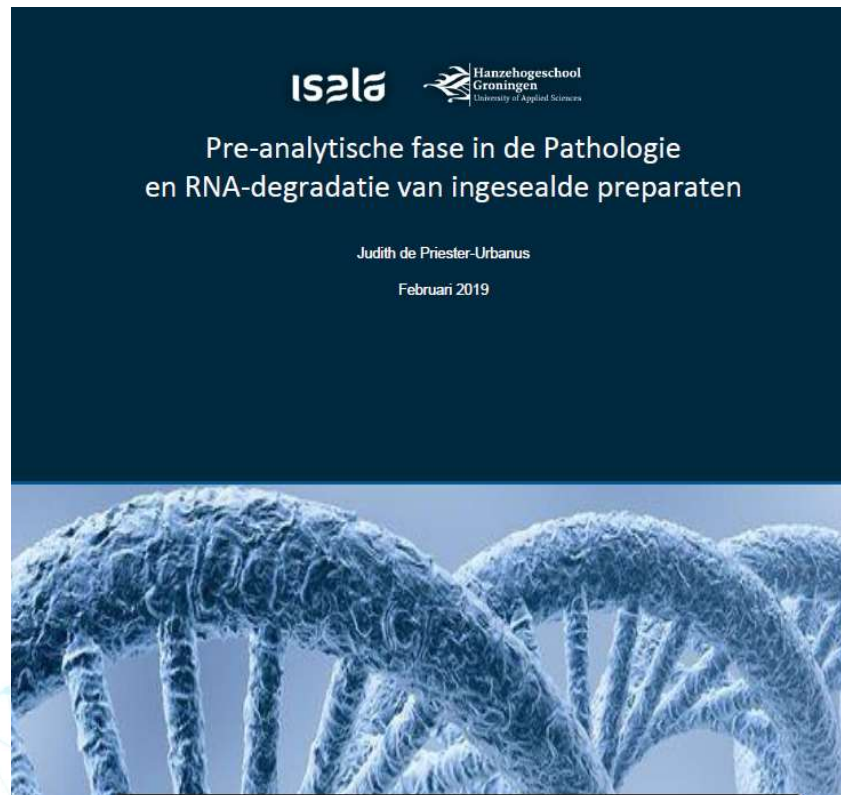
LMS integration possible

MileWatch monitoring



CELL PATHOLOGY in OR or Pathology lab

Already
placed more
than 60 units
BENELUX
market



CELL PATHOLOGY in OR or Pathology lab



Seal Safe
Thanks for your attention

Nicolette Kürten

nkurten@menarinidiagnostics.nl

Ivaneysendeyk@menarinidiagnostics.be

30 May 2022



A.MENARINI
diagnostics