



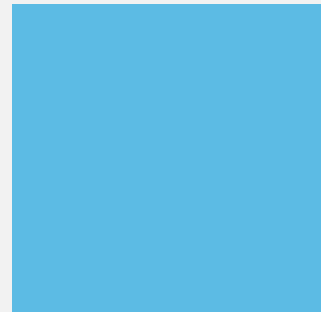
DAKEWE

Presenter:
Xiaoyan (Sophia) Shen
International Product Specialist

DAKEWE © 2022

CONTENTS

- Company Overview
- Product Portfolio
- Global Customers
- Future Development



Company Overview

DAKEWE

达科为 DAKEWE

· Achievement · Science · Impact

Mission

Develop biotechnology,
make impact on human health

Vision

The leader of the industry

20,000 m²

R&D centre in top 3 industrial park
HQ neighbour with Tencent, Huawei, Mindray



- ▲ Nanshan HQ
- ◀ Pingshan R&D centre

DAKEWE



QUALIFIED MANUFACTURER

FDA U.S. FOOD & DRUG ADMINISTRATION
 U.S. Food and Drug Administration
 Center for Devices and Radiological Health
 Document Mail Center - W556-G558
 12001 New Hampshire Avenue
 Silver Spring, MD 20903-0002

This message is to acknowledge receipt of your **Initial Product Report**, which was filed pursuant to the regulations for the administration and enforcement of the Radiation Control for Health and Safety Act of 1968 (21 CFR 20.22, Code of Federal Regulations, Subchapter D), as they pertain to the submission information description below. If your submission is a report, it has been filed according to reporting requirements in 21 CFR 20.22, Code of Federal Regulations (CFR), Part 20.22. Your submission has been assigned an internal subject file name after "RADREP". Your submission has been assigned an ACCESSION NUMBER which can be used by you and FDA to identify your submission.

WARNING:
 THE ACCESSION NUMBER ASSIGNED TO YOUR SUBMISSION DOES NOT IMPLY CONSENT OR CONSTITUTE AN APPROVAL OF ANY REPORT, APPLICATION FOR VARIANCE OR EXEMPTION, NOTIFICATION, OR ANY OTHER SUBMISSION OR ITS CONTENTS. THE ACCESSION NUMBER IS ONLY AN ACKNOWLEDGMENT THAT YOU HAVE RECEIVED YOUR SUBMISSION. IT WILL BE REVIEWED BY FDA. ITS EXCLUSION IS YOUR RESPONSIBILITY. IT IDENTIFIES YOUR SUBMISSION FOR PRODUCTS OR PRODUCT FAMILIES IDENTIFIED IN THIS MESSAGE.

Do not place the label to comply with FDA regulations may result in notification of affected persons and corrective actions at no cost to the purchaser, pursuant to 21 CFR Part 1003 - Disclosure of Defect or Failure to Comply and 21 CFR Part 1004 - Repurchase, Repair, or Replacement of Defective Products.

Please be aware that the following (CDRH Product Codes) have been assigned to the product(s) described in this report:
 885 (related to non-Industry Rate Meter)

DAKEWE 达科为
 EC DECLARATION OF CONFORMITY

Product: Slide Stainer
Model: DP260, DP260L, DP261
Manufacturer: Dakewe (Shenzhen) Medical Equipment Co., Ltd.
Address: 601, 1st Building, Shenzhen Biological Medicine Innovation Industry Base, Jiu-Hu Road 14th, Kang ZI Street, Pingshan New District, Shenzhen, China

This is to certify that the above products comply with:
 EN 15237:2004 EN 14871:2007
 EN 980:2008 EN 1041:2008
 EN 62304:2006 EN 1041:2008
 and in vitro diagnosis medical devices DIRECTIVE 98/79/EC

CE

[Signature]
 Dakewe (Shenzhen) medical equipment Co., Ltd.
 General Manager
 Aug 15, 2017

Dakewe (Shenzhen) medical equipment Co., Ltd.
 601, 1st Building, Shenzhen Biological Medicine Innovation Industry Base,
 Jiu-Hu Road 14th, Kang ZI Street, Pingshan New District, Shenzhen, China

nqa

This is to certify that the Quality Management System of
Dakewe (Shenzhen) Medical Equipment Co., Ltd.
 (Inkai Road, Cuihu, 4184000900001)
 Operator Address: 601, 1st Building, Shenzhen Biological Medicine Innovation Industry Base,
 Jiu-Hu Road 14th, Kang ZI Street, Pingshan New District, Shenzhen City, Guangdong Province,
 China
 Registered Address: 601, 1st Building, Shenzhen Biological Medicine Innovation Industry Base,
 Jiu-Hu Road 14th, Kang ZI Street, Pingshan New District, Shenzhen City, Guangdong Province,
 China

applicable to:
 Design, development, production and sales of slide stainer within the scope of registration certificate(s)

This registration is registered by NQA against the jurisdiction of
ISO 9001:2008

This registration is subject to the company maintaining quality management systems to the above standard, which will be reviewed by NQA.
 Certified items also require regular surveillance monitoring, the validity of certificates shall be maintained for the positive result of audit.
 The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn) and NQA's website (www.nqa.com.cn)

[Signature]
 Managing Director

Certificate number: 43709
 Date: 31 July 2017
 Valid Until: 31 March 2019
 EAC Code: 19

UNAS

This is an ISO 9001 certificate issued in accordance with a report of an audit carried out by the certification authority UNAS (CNCA 1904).
 The certificate is issued in accordance with the requirements of the International Standard for Registration of Certification Bodies (ISO 17021).
 The certificate is issued in accordance with the requirements of the International Standard for Registration of Certification Bodies (ISO 17021).



186 + Patents

Current Location : Patent Search > Quick Search > Quick Search

Search Item : Applicant/Assignee 达科为 Search

Settings : DisplayFields FilterDocuments Sorting DateRange

LanguagePreference Statistic

Operations : Select All Deselect Add To Favorites View Document(s) View All Documents

Add To Analysis DB Add All To Analysis DB

JumpTo 1 Page Total 19 Page 186 Counts

Application No. CN202210046567.7 [Invention] Application Date 2022.01.17 [Publication] Hide

Application No. :CN202210046567.7 Hide

Application Date :2022.01.17

Publication No. :CN114073865A

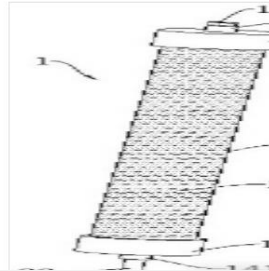
Publication Date :2022.02.22

Invention Title :去除血清中外泌体的方法及过滤装置

IPC Classification No. :B01D17/02;B01D17/038;G01N1/28;

Applicant/Assignee :深圳市达科为生物工程有限公司;

Inventor :姜维;胡春苗;吴庆军;



INNOVATIVE COMPANY

CO-FOUNDERS



CEO
Andy Wu
吴庆军



General Manager
Craig He
何俊峰

MILESTON E

'99

Dakewe Biotech Company
established

'04

Started biological reagent
development

'06

"Shenzhen Hi-Tech Enterprise"

'16

Stock listed
"National Hi-Tech
Enterprise"

'17

BioSci Inc. US branch

'20

IPO in progress
Europe branch planning

GATHER GLOBAL TALENTS

- Including medical, biological, molecular, mechanical and electronic multidisciplinary talents
- Overseas employees in the US, France, India and Brazil

800

Employees

+

46%

Bachelor

15%

**PhD, Master
and above**

SOLID GLOBAL STRATEGIC PARTNERSH IP



Korea ▪ Indonesia ▪ Malaysia ▪
India ▪ Russia ▪ Saudi Arabia ▪
Uzbekistan ▪ Ethiopia ▪ Australia ▪
▪ South Africa ▪ **United States** ▪
Canada Germany ▪ France ▪ Italy
Thailand
▪ Belgium ▪ Poland ▪
Portugal ▪ Argentina ▪ Austria ▪
Greece
Brazil ▪ Spain ▪ Latvia ▪
Switzer Czech Republic ▪
Kenya ▪ Cyprus ▪
Pakistan ▪
United Arab Emirates ▪ Qatar **DA**

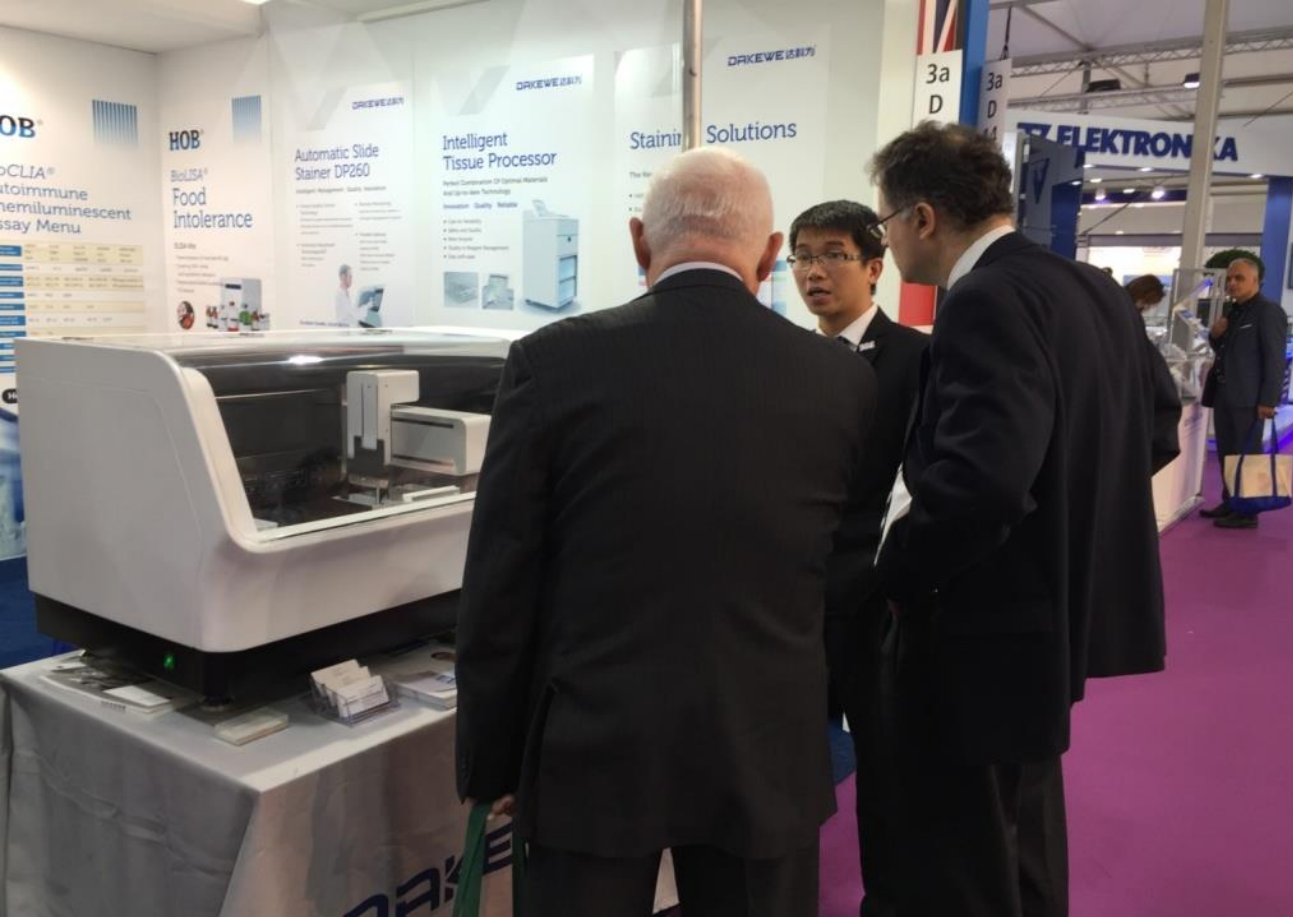
14
BRANCHES

Business partners in

53
**COUNTRIES &
REGIONS**

BiosciTM

US subsidiary
Sacramento, CA



2019 MEDICA, Dusseldorf, Germany



2018 Carrefour Pathologie, France

DEMONSTRATE DAKEWELAB TO THE WORLD

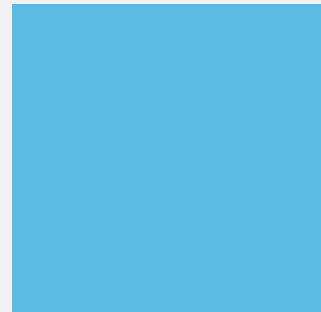
The image shows a Zoom meeting interface. On the left, a presentation slide features two DAKWE printers: the S200 Slide Printer and the C10/C100 Cassette Printer. The slide text reads: "Say goodbye to manual writing" and "S200 Slide Printer C10/C100 Cassette Printer". The DAKWE logo is in the bottom right of the slide. The Zoom meeting controls at the bottom show 434 participants and a "离开" (Leave) button.

On the right, the Zoom participant list includes:

- Angela-DAKEWE (我)
- Studio (主持人)
- Sophia S... (联席主持人)
- Didik Setyo H... (联席主持人)
- Didik SH (联席主持人)
- Djulpi Indola... (联席主持人)
- Panitia CP PP ... (联席主持人)
- Panitia CP PP ... (联席主持人)
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- Panitia CP PP... (联席主持人)

2022 Institut Akuntan Publik Indonesia (IAPI)

DEMONSTRATE DAKWE TO THE WORLD



Product Portfolio

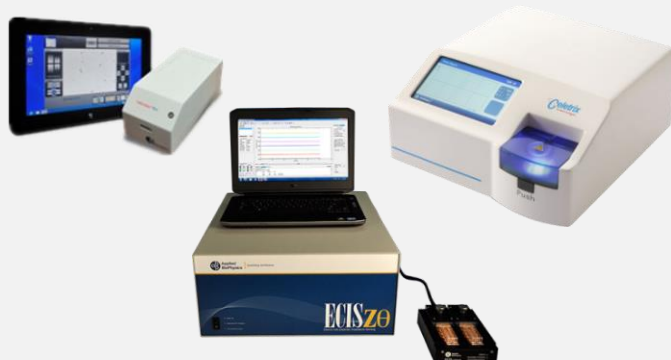
DAKEWE

Bioscience

Biological
Reagents



Scientific
Instruments



Biomedicine

Blood
collection
related



Pathology
equipment

DAKEWE

Pathology Equipment Portfolio



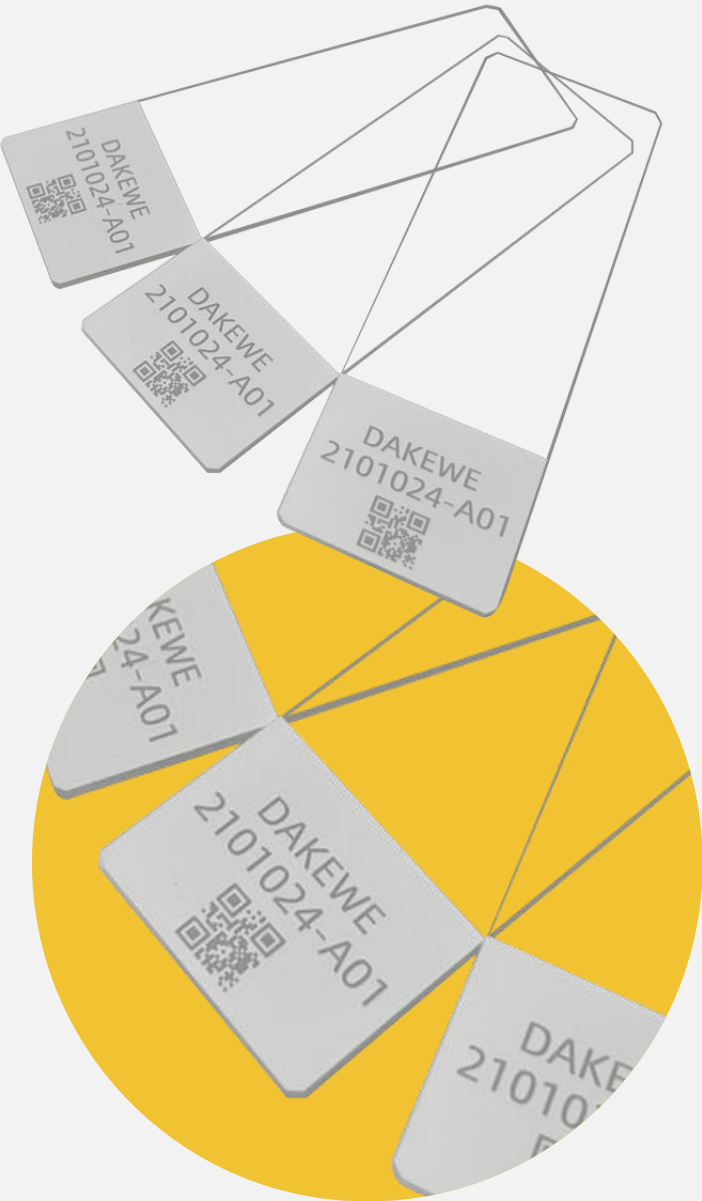


Say goodbye to manual writing

S200 Slide Printer
C10/C100 Cassette Printer

Boost efficiency Prolong storage

- Ultra-violet laser etching technology - melt surface
- Alphanumeric, symbols, 1D & 2D codes
- Resistant to processing chemicals, liquids and scratch, non-fading
- Fast
- Quiet
- Consumables free, easy to maintain



DAKEWE

Large in/output capacity

Maximum flexibility

Six metal hoppers

450 - 600 multi-color cassettes

Output tray

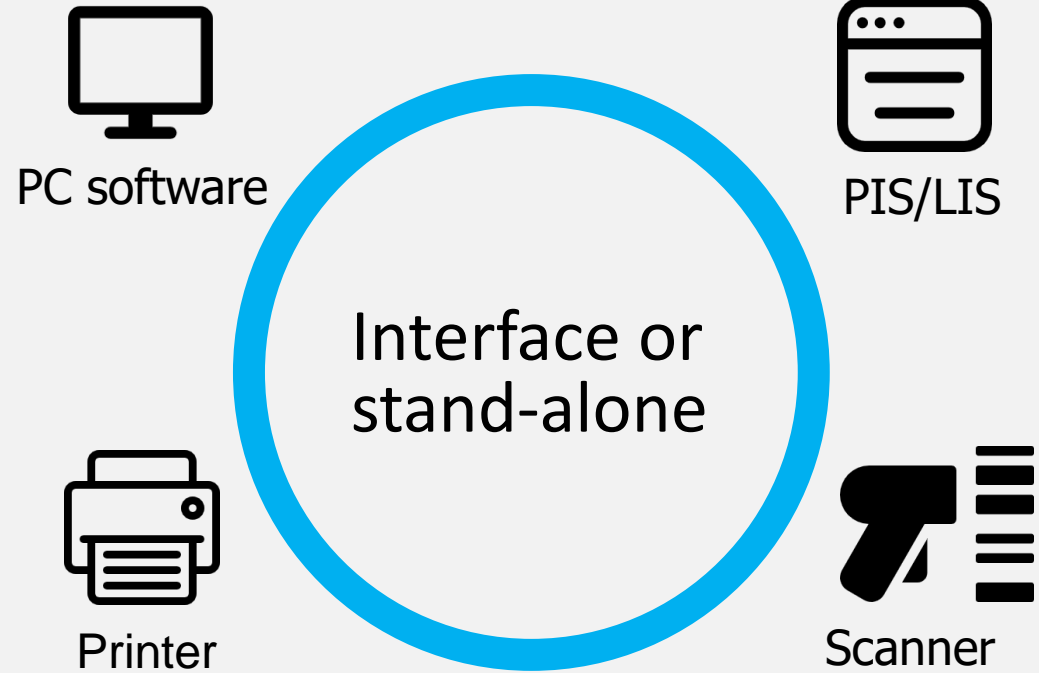
100 printed cassettes in order, can take out the whole tray when printing finish

True color recognition

No need to load cassettes in corresponding channel - C100 recognizes the color and print on the correct cassettes



Seamless integration into your current workflow





Tissue processing all in your control

**HP300/HP300 Plus
Automated Tissue Processor**

1
Retort

300
Cassettes

Secure your specimen

- Reagent concentration detection - reduce potential errors in replenishment
- Double air pump liquid delivery system

Save on reagents

- Paraffin purification - prolong wax lifespan
- Lid heating

Save your time

- External drain & fill
- Smart swap - enable automatic definition of the reagent sequence

HP300 Plus





Consistent cooling and sectioning

**6250 Cryostat
CT520 Cryostat**



Dual powerful compressor

From ambient to working
in 1 hour

Separate temperature settings

Chamber, freezing shelf,
specimen holder, blade holder

Auto chamber illumination

LED sensor light with adjustable
brightness

CT520 Cryostat

Large screen

12.1 inch touch screen,
easy to operate

Protect your safety

UV disinfection and nano-silver
coating

Quality sectioning with ultimate experience

MT1 Microtome

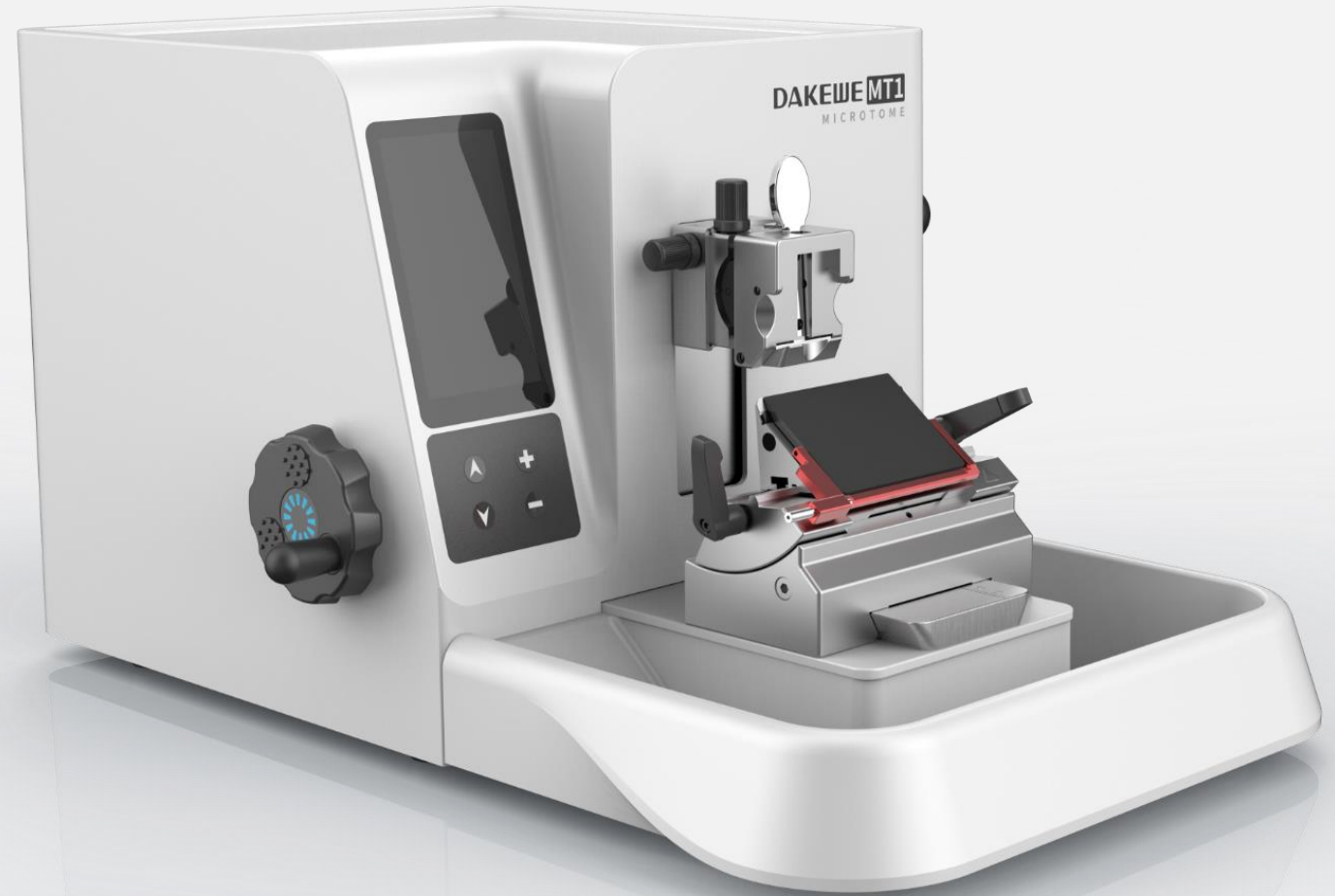


Quality sections, smooth sectioning

- Patented zero specimen position with visible graduation
- Stable dovetail groove blade holder
- Ultra-precise, sleek rail with cross roller bearings

You way of operation

- Drive coarse feed wheel as a knob, a wheel, or with the rubber finger pad
- “Rock” handwheel to advance specimen without a complete rotation





DP360 + CS500 Fully Automated Combo System

DP360

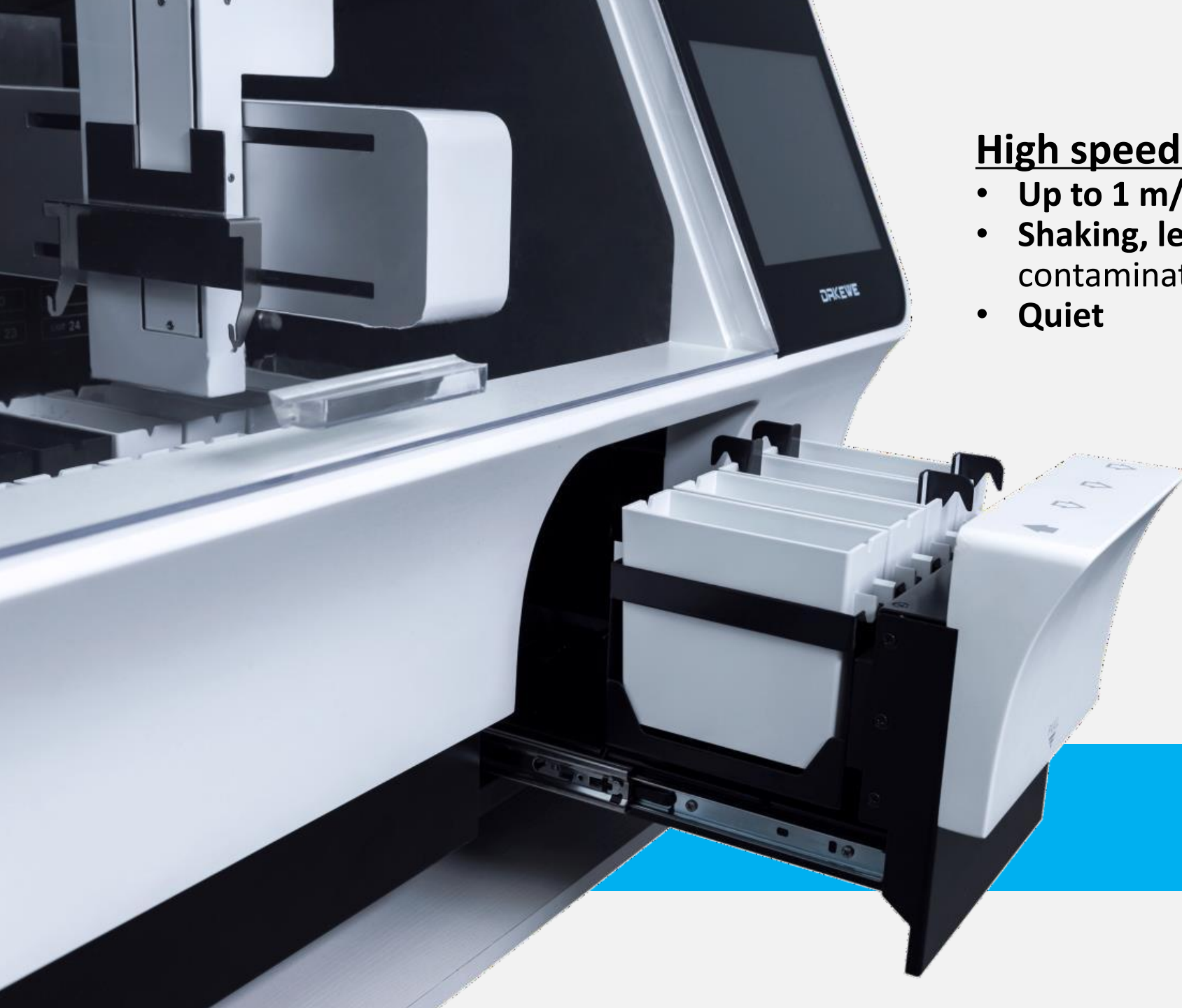
26 stations
1 oven
4 individual wash

High throughput

Up to 11 racks of
30 slides at a time
Run different protocols
simultaneously

**10.1 inch colour touch
screen**





High speed, accurate robotic arm

- **Up to 1 m/s**, reduce overall process time
- **Shaking, leaching and vibrating** to prevent contamination
- **Quiet**

Load/exit drawer with flexible station setting

- Set as loading, exit, or reagent station according to laboratory requirements

DP360

Attentive quality control, satisfying results, saving on reagents



Reagent management

- Record reagent usage
- Color indicator for reagent replenishment

Patented Automatic Adjustment Technology (AAT)

- Automatically extend staining time in each step to accommodate reagent dilution
- Consistent result over time

Remote monitoring

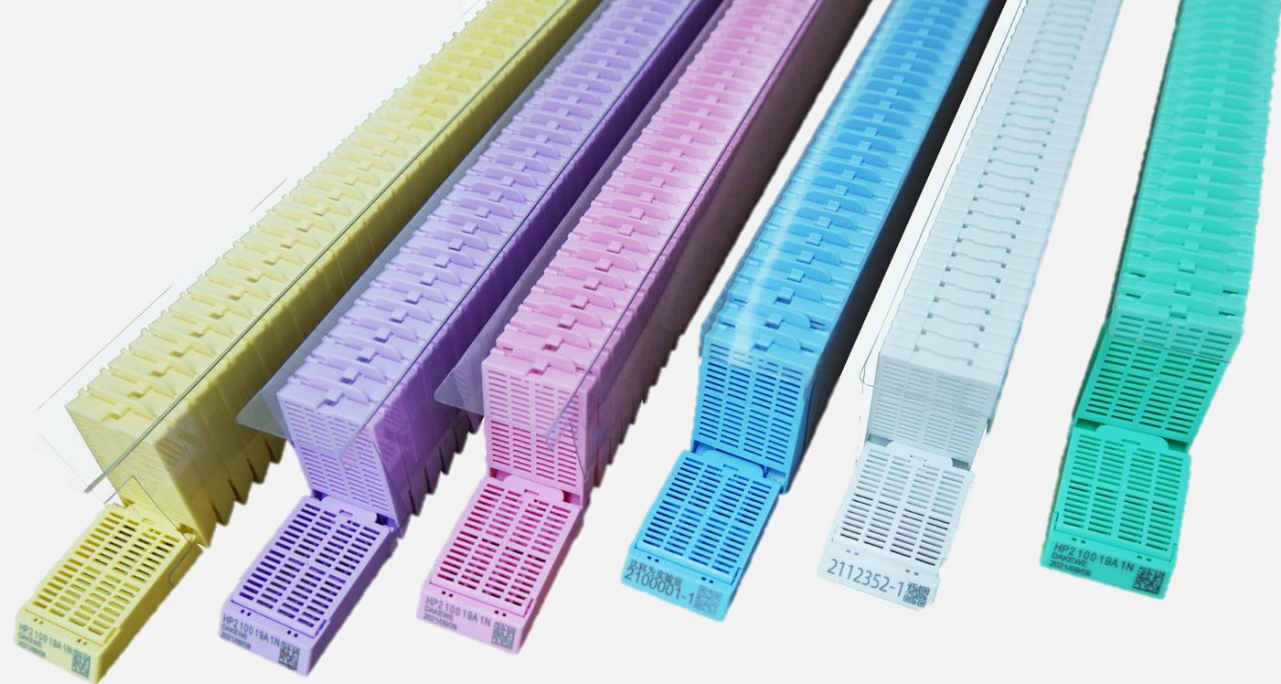
- Know the progress and error while away



Seamless integration

- Stained slides deliver automatically from DP360 or use as a stand-alone coverslipper
- Reversed dock for integration, **no extra connector needed**
- Traceability - information deliver from DP360 automatically, record protocol used, operator, batch of reagents used...

CS500



**Satisfying
result with our
consumables**



国际达学堂 病理半月谈

结直肠锯齿状息肉的病理诊断与分子通路



丁显仲 教授

- 芝加哥LOYOLA大学医学中心病理系副教授、胃肠病理专科主任
- LOYOLA大学组织学核心实验室主任

直播时间: 2022年3月13日晚20:00

邵春奎 教授

- 中山大学附属第三医院病理科主任
- 中华医学会病理学分会 委员
- 广东省医学会病理学分会 主任委员



主持嘉宾

课程大纲

- 结直肠锯齿状病变分类和病理学特征
- 结直肠锯齿状病变的分子病理
- 锯齿状病变诊断困难分子病理基础

扫描二维码立即预约直播

>>>



Dakewe



国际达学堂 病理半月谈

MALT 淋巴瘤病理机制新进展

直播时间 2022年2月27日晚20:00

授课嘉宾

杜明清 教授

- 剑桥大学病理系, 肿瘤病理教授
- 剑桥大学附属医院, 分子病理主任医师



主持嘉宾

李小秋 教授

- 复旦大学附属肿瘤医院病理科副主任、淋巴造血病理专科负责人
- 中国国家卫生健康委能力建设和继续教育中心淋巴瘤专科建设项目专家组顾问暨病理学组组长



直播内容

重点介绍近年来有关MALT的遗传学研究进展, 揭示淋巴上皮病变在淋巴瘤发生中的致病作用, 并解释其形态学特征。

扫描二维码立即预约直播

>>>

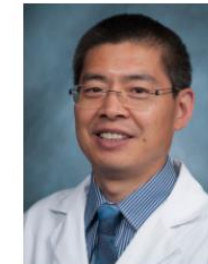


Dakewe college of continuing education

Biweekly webinar with reputable overseas speakers

Professor of Oncological Pathology
Division of Cellular and Molecular Pathology

Department of Pathology
University of Cambridge



Xianzhong Ding

M.D., PH.D.

ABPP

- Associate Professor
- Pathology

DAKEWE



“丹娜-法伯布莱根癌症中心 & 中山大学附属第一医院肿瘤 周”系列学术研讨会

直播时间：2022年2月21-25日
20:00-22:00

Day 3-2/23 Speakers



Bradley McGregor
Clinical Director
Lark Center for Genitourinary
Oncology,DFCI
Instructor in Medicine
Harvard Medical School



LUO Junhang
Deputy Dean
Precision Medicine Institute
Deputy Director
Urology,FAH-SYSU



Mark Preston
Associate Surgeon,BWH
Assistant Professor of Surgery
Harvard Medical School



CHEN JunXing
Deputy Director
Urology,FAH-SYSU

主办单位：中山大学附属第一医院
美国哈佛大学医学院附属丹娜法伯癌症研究院
布莱根和妇女医院



达学堂同步直播
(扫码观看)



“丹娜-法伯布莱根癌症中心 & 中山大学附属第一医院肿瘤 周”系列学术研讨会

直播时间：2022年2月21-25日
20:00-22:00

Day 2-2/22 Speakers



Harshabad
Medical Oncologist,DFCI
Instructor in Medical
Harvard Medical School



CAI Shirong
Director
Unit I,GI Surgery Center,FAH-SYSU



Jiping Wang
Associate Director
Hepatobiliary Cancer
Division of Surgical Oncology,BWH
Associate Professor of Surgery
Harvard Medical School



ZHANG Xinhua
Deputy Director
Unit II,GI Surgery Center,FAH-SYSU

主办单位：中山大学附属第一医院
美国哈佛大学医学院附属丹娜法伯癌症研究院
布莱根和妇女医院

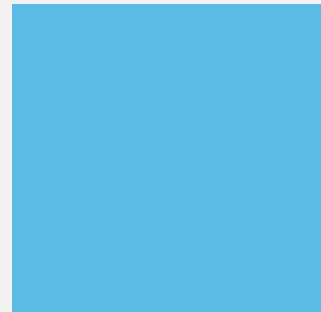


达学堂同步直播
(扫码观看)



Dakewe college of continuing education

Relay pathology webinars



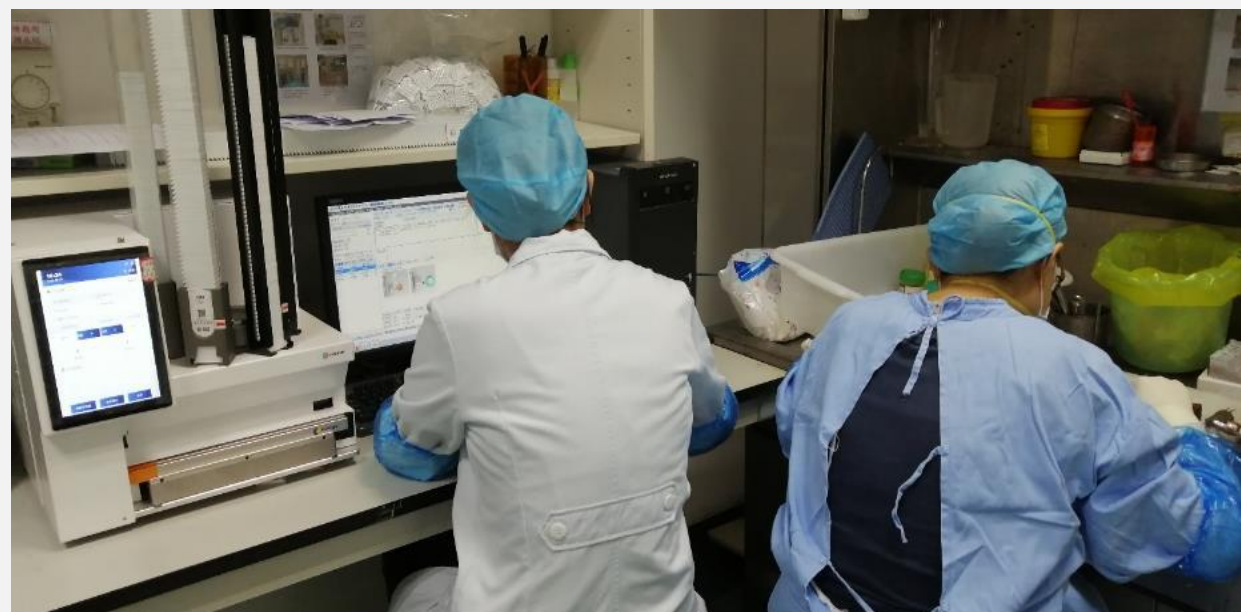
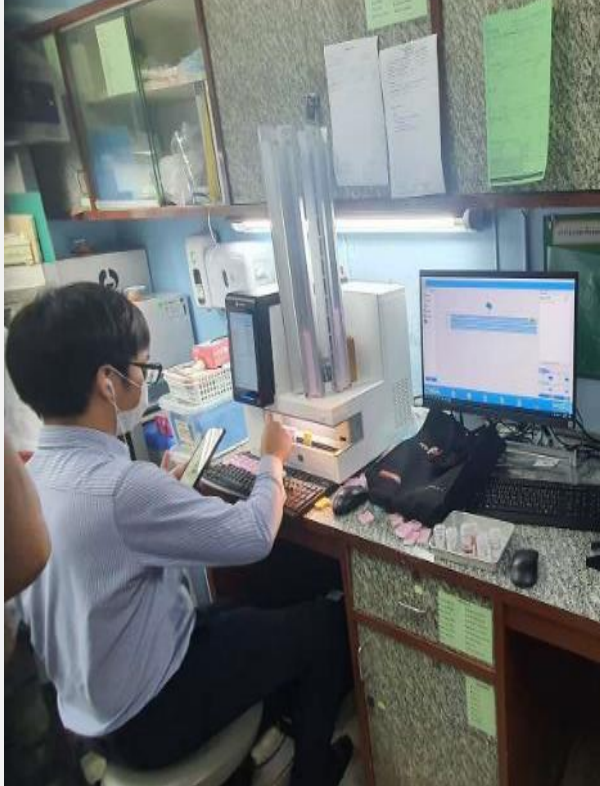
Global Customers

DAKEWE

Cassette Printer C100 in Spain

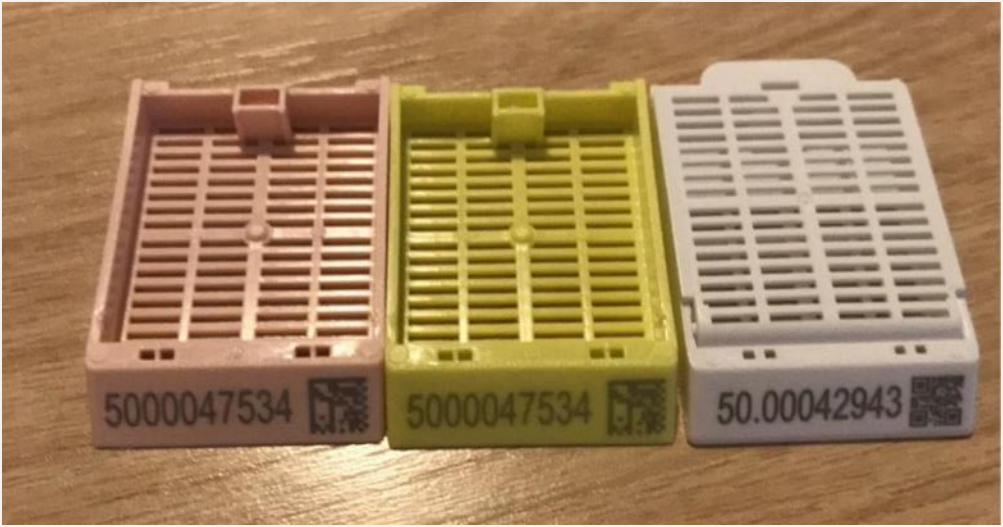


Cassette Printer C100 in Thailand



DAKEWE

Our cassette printer in Thailand



Tissue Processor HP300 in Portugal



DAKES

Tissue Processor HP300 in Germany



Cryosta t 6250 in Spain

DAKEWE



Cryostat 6250 in Thailand



DAKEWE

Combo system DP360 CS500 in Croatia



DAKESHI

Combo system DP360 CS500 in France

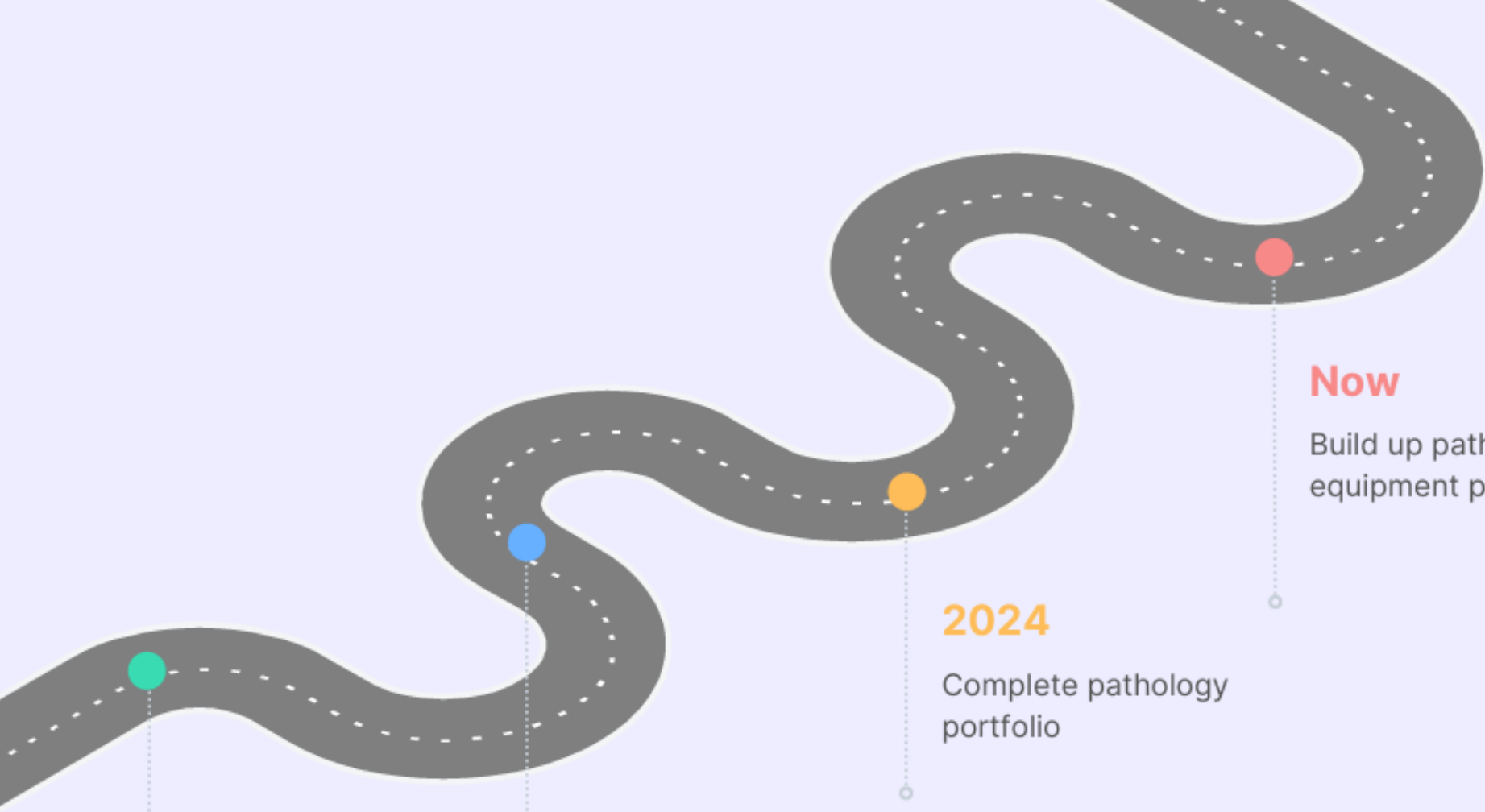


DAKEWE



Future Development

DAKEWE



2028

Mature pathology solution provider

2026

Digital diagnostics & molecular diagnostics

2024

Complete pathology portfolio

Now

Build up pathology equipment portfolio

Future Development Roadmap

For more information

Google

[Dakewe / Dakewe medical expo](#)

