Manejo de Riesgos y Pruebas de POCT

Juan David Garcia

Director, Laboratory Services Department of Pathology & Laboratory Services

Director of Operations, John Sealy Diagnostic Center

Assistant professor, Clinical laboratory Science

Universidad de Texas Medical Branch

Escanee este código QR para descargar esta presentación. O puedes descargarlo en este enlace: https://drive.google.com/file/d/1CK8EYSMrRg2a4K9egi-ygVD4O_E3a-rk/view?usp=drive_link

ADLM Association for Diagnostics & Laboratory Medicine™ Formerly AACC

Disclaimer…

In the past 12 months, I have had a significant financial interest or other relationship with the manufacturer(s) of the product(s) or provider(s) of the service(s) that will be discussed in my presentation

En los ultimos 12 menses, no he recibido ningina retribucion monetaria de los fabricantes de los productos que hacen parte de esta presentacion.

Agenda

- Breve Historia de POCT
- Desarrollo del POCT en los 10 ultimos anos
- Diferentes aplicaiones del POCT en el area Medica
- Investigacion y desarrollo de nuevas technologias
- Consideraciones para Desarrollar y Mantener un Programa de POCT
- Estructura del Programa de POCT

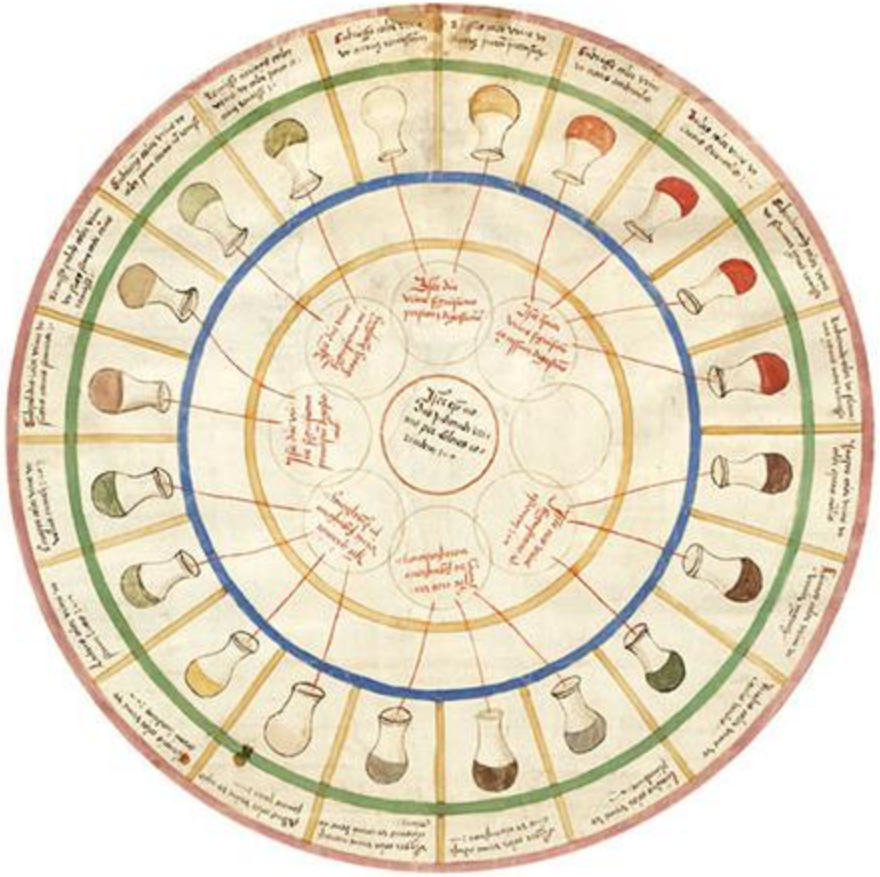
Historia del POCT: Papyrus de Berlin

This is the actual text of the Berlin Papyrus as translated into English by Dawson:[6]

Another test for a woman who will bear or a woman who will not bear. Wheat and spelt: let the woman water them daily with her urine like dates and like *sh'at* seeds in two bags. If they both grow, she will bear: if the wheat grows, it will be a boy; if the spelt grows, it will be a girl. If neither grows, she will not bear.

https://www.cnn.com/2018/08/31/health/ancient-egypt-medical-knowledge/index.html

Analisis de Orina



Uso Medicinal de Leeches

A woodcut from a 1639 treatise by Joannis Mommarti depicting a woman applying a medicinal leech to her forearm. In the early 19th century the medicinal leech soared in popularity, says Caroline Rance. (Photo by Everett Collection Historical/Alamy Stock Photo)

Figure 4 François-Joseph-Victor Broussais (1772–1838).

Historical Article: *Hirudo medicinalis*: ancient origins of, and trends in the use of medicinal leeches throughout history

I.S. Whitaker[a,*], J. Rao[b], D. Izadi[c], P.E. Butler[d]

[a] *Department of Anatomy, University of Cambridge, Cambridge, UK*
[b] *Department of Oral and Maxillofacial Surgery, South Manchester University Hospitals NHS Trust, Manchester, UK*
[c] *Addenbrooke's Hospital School of Clinical Medicine, University of Cambridge, Cambridge, UK*
[d] *Royal Free Hospital, London, UK*

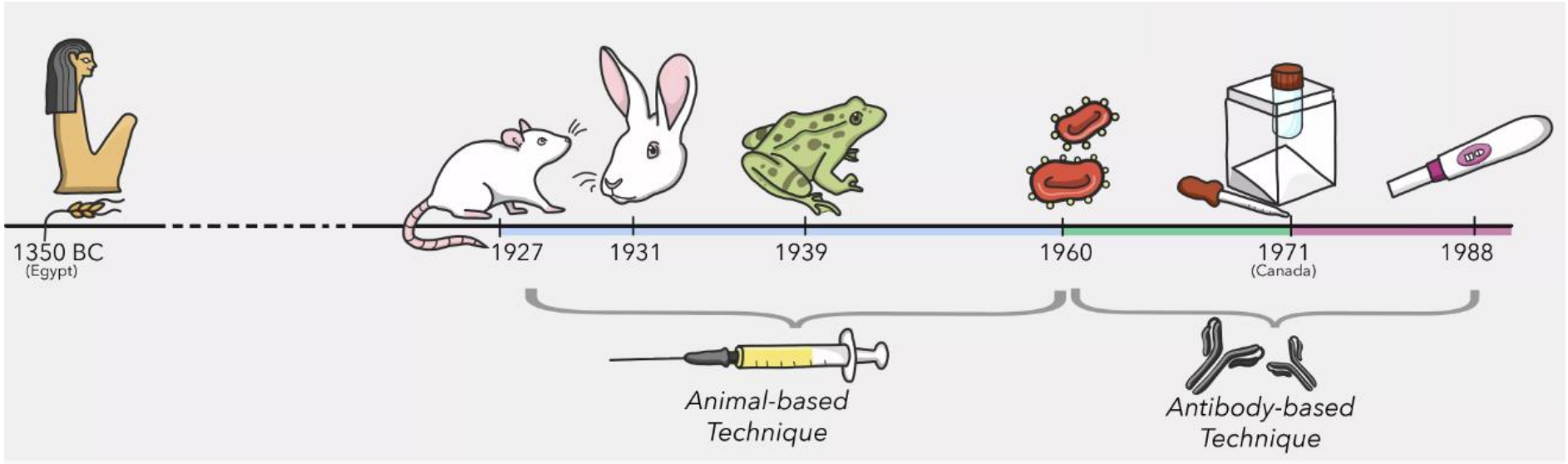
Table 1. History of laboratory medicine

Year	Event	Diagnosite fields
4000 BCE	Egyptians, Pregnancy diagnosed using urine to germinate seed	Urinalysis
460-355 BCE	Hippocrates, Urine bubbles in patients with kidney diseases	
129-200 AD	Galen, Urine is a filtrate of blood	
800	Theophilus Protospatharius, First treatise on urine test	
1661-1665	Marcello Malpigihi, Recognition of the cellular components of blood by microscoopy	Hematology
18th century	William Hewson, Discovered the presence of a coagulable substance in blood	
18th century	J.W. Tichy, Microscopic analysis of urine sediment	
1827	Richard Bright, Albumin in the urine of patients with edema	
1831	First cholera outbreak in UK William O'Shaughnessy, Blood of dehydrated patients contained less water than normal	
1843	Gabrial Andral, Published Pathological Hematology	
1854	John Snow, Advanced public hygiene and epidemiology after cholera outbreak Jules Dobpsq, Designed the colorimeter	Microbiology
1859	Charles Darwin, The Origin of Species	
1866	Gregor Mendel, Discovered the inheritance of "factors" in pea plants	
1881	Pasteur, Produced a vaccine against anthrax	
1882	Robert Koch, Discovered Tuberculosis	
1883	Robert Koch, Discovered the tubercle bacillus	
1884	Robert Koch, Formulated the Koch's law	
1886	Max Jaffe, Quantitated creatinine using the alkaline picrate method	
1890	Behring, Discovered the antitoxin of diphtheria	
1891	Robert Koch, Discovered cutaneous (delayed-type) hypersensitivity	
1893	T.W. Richards, Invented the nephelometer	
1895	Franz Ziehl and Friedrich Neelsen, Modified the acid-fast staining process for the diagnosis of tuberculosis William Röentgen, Discovered X-rays.	
1896	Ferdinand Widal, Developed agglutination test for typhoid bacillus	

		Clinical Chemistry	Molecular Diagnostics
1900	K. Lansteiner, Discovered the ABO groups		
1905	H.J. Bechtold, Discovered immunodiffusion		
1908	Todd and Sanford, First edition of *Clinical Diagnosis by Laboratory Methods*		
1910	Thomas Hunt Morgan, Discovered the sex-linked inheritance of the first mutation in the fruit fly, *Drosophila*		
1920-1939	Tests for serum phosphorus (1920), serum magnesium (1921), protein electrophoresis (1926), erythrocyte sedimentation rate (1929), alkaline phosphatase (1930), lipase (1932), amylase and acid phosphatase (1938), and ammonia (1939)		
1941	Beckman, Commercialized DU spectrophotometers		
1946	Becton Dikinson Co., Commercialized Vacutainer®, evacuated serum collection tubes		
1950	Development of radioimmunoassay		
1952	Development of immunoelectrophoresis		
1953	Francis Crick and James Watson, Discovered the three-dimensional structure of DNA		
1959	Technicon Corp, Commercialized the single channel "Auto-Analyzer", the first clinical laboratory chemical analyzer Solomon Berson and Rosalyn Yalow, Developed the first immunoassay for insulin		
1961	Becton Dickinson Co., Commercialized disposable hypodermic syringes and needles		
1969	Development of high-performance liquid chromatography		
1985	Invention of PCR		
1992	Conception of real time PCR		
1996	First application of DNA microarrays		
2001	First draft versions of the human genome sequence		

Lab Med Online. 2017 Apr;7(2):53-58.
https://doi.org/10.3343/lmo.2017.7.2.53

Evolucion de la Prueba de Embarazo en Orina



3.369 anos has pasado y???????

POCT y sus Nuevas Aplicaciones en las Diferentes Áreas Medicas

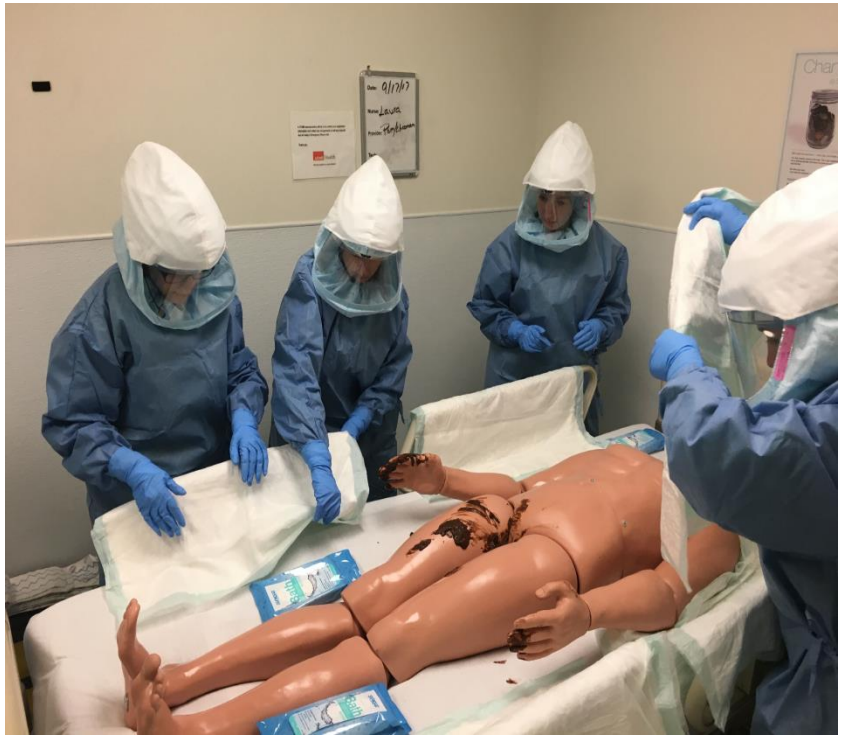
Causas del desarrollo del POCT

- Ambiente actual del sistema de salud
- Nuevas metodologías de pago por parte de las aseguradoras
- Nuevas regulaciones
- Modelos de medicina preventiva: Admisiones y Readmisiones
- Tele medicine
- Alta demanda de instrumentos de uso fácil y rápido
- Demanda del mercado

Aplicaciones en las Diferentes Áreas Medicas

1. Unidad de Biocontaiment para Ebola
2. Laboratorio Móvil en el Servicio de Urgencias y Sala de operaciones
3. Uso de PCR, ADN fetal en sangre materna para tamizaje prenatal,
4. ADN en sangre para el tamizaje del cáncer,
5. reloj inteligente para la monitorización de pruebas en sangre,
6. pruebas médicas en teléfonos inteligentes (smartphones)
7. Investigación y desarrollo en POCT

Unidad de Biocontaiment para Ebola



Laboratorio Mobil

VANDERBILT UNIVERSITY MEDICAL CENTER

REPORTER

www.mc.vanderbilt.edu/reporter | Friday, March 9, 2012 | VUMC Weekly Publication

'Coag on a Cart' offers real-time lab test results

by Jessica Pasley

When lab tests are required for procedures and surgeries performed in operating rooms, samples are traditionally sent to a lab within the hospital.

Clinicians then wait for results. But in an OR setting, scenarios can change minute to minute.

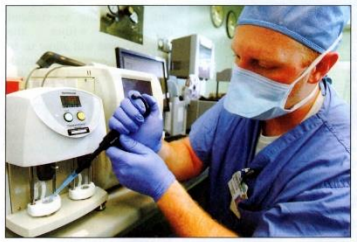
Thanks to Coag on a Cart, a new program at Vanderbilt University Medical Center, real-time data is now available to the medical team for use in liver transplant cases.

Three diagnostic instruments that perform select testing to help determine the patient's ability to form a clot have been grouped together to create a mobile lab.

Seven highly trained medical technologists operate the machines.

"The tests that they are performing are rarely done outside of a lab setting," said Arnulfo Delgado, director of Diagnostic Laboratories at Vanderbilt. "Essentially, we are bringing the lab to the OR.

"We now have the ability to reduce the amount of wait time, which has had a positive impact on patient care," said Delgado. "Seventy-five percent or more of the decisions that physicians make are based on lab tests. Nothing beats being right there in the OR and giving them real-time results."



Anne Rayner

Phillip Denton, medical technologist in Diagnostic Laboratories, places a patient sample on the TEG (thromboelastography) instrument for a platelet study.

In the four months that the program has been running, 44 cases have benefited from the new technology.

Projections call for 116 cases to use Coag on a Cart in the new fiscal year that begins in July.

"This has been a way to bring the lab to us and it has really been a phenomenal change," said Michael Pilla, M.D., associate professor of Clinical Anesthesiology and associate director of the Anesthesiology Residency Program.

"Overall, it has improved patient care and allowed us to more judiciously choose what our next steps will be.

"In many liver transplant cases, we don't have a lot of time. This is a surgery where you can go from no blood loss to massive blood loss in a blink of an eye," said Pilla. "Coag on a Cart provides a level of comfort. We have precise information that will guide our clinical decision making in real time."

The three instruments that are combined to create a mobile laboratory include: Sysmex pocH100i Hematology Analyzer (which provides hematocrit and platelet counts); Stago STA Satellite Hemostasis System (for Fibrinogen, Prothrombin Time or PT and Partial Thromboplastin Time of PTT); and a Haemoscope TEG Instrument (for platelet studies).

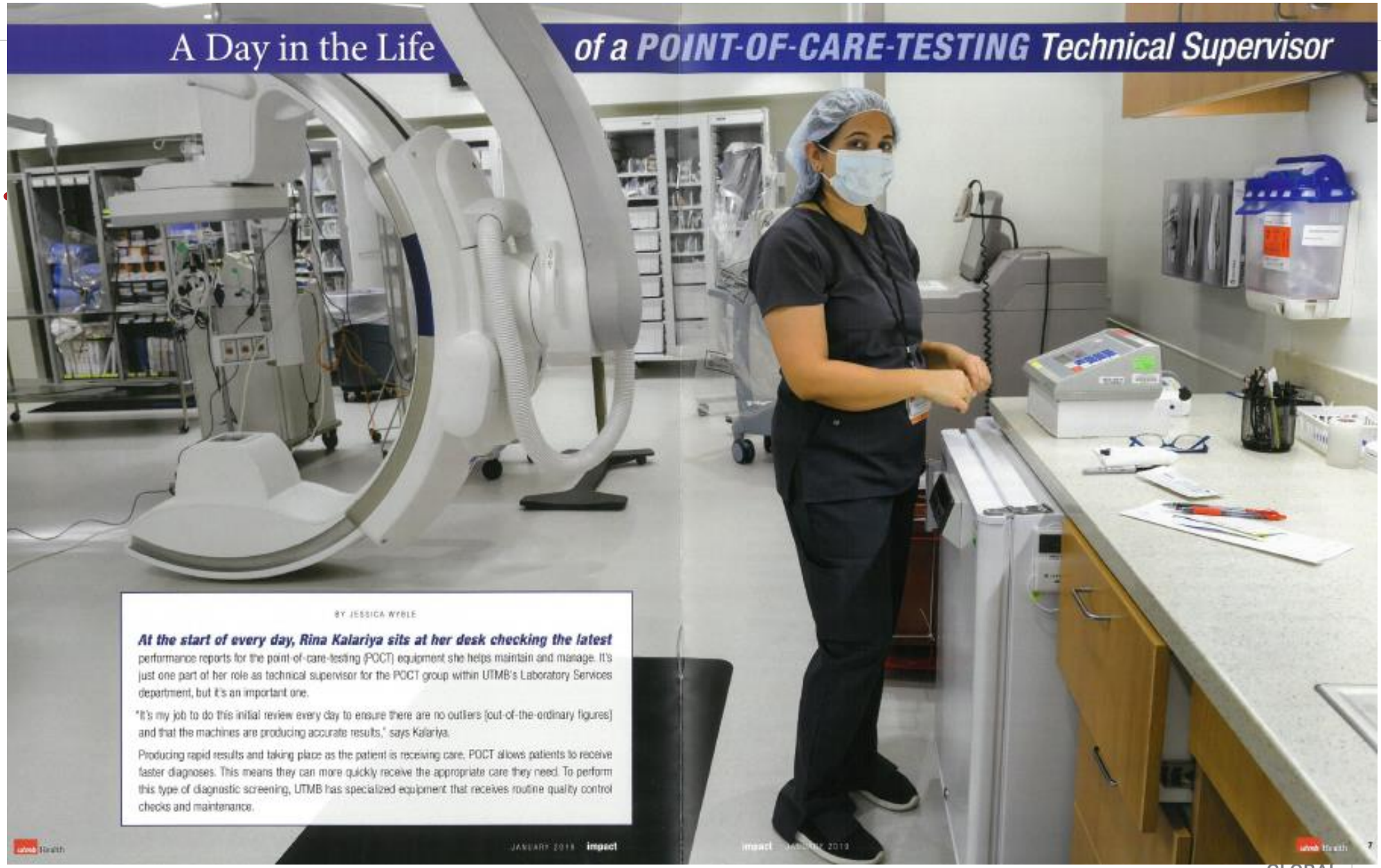
The concept for this program came in 2008 with the arrival of Michael Laposata, M.D., Ph.D., Edward and Nancy Fody Professor and executive vice chair of Pathology, Microbiology and Immunology.

"All the pieces fell into place when I arrived at Vanderbilt because it is so collaborative and embraces innovation," said Laposata. "Vanderbilt was smart enough to know the impact this type of change would have on patient outcomes.

"What was most clear upon first use was that surgical procedures were running more smoothly, which was translating to quicker patient recovery," he said. "The way we manage these testing devices, we have cut out steps, reduced run and wait times for tests while providing instantaneous communication.

"From my perspective, this is just phase one," said Laposata. "We will learn how to adapt this for use in other circumstances."

Although Coag on a Cart is currently offered only for liver transplantations, there is a growing interest to use it for additional disciplines throughout the Medical Center.


A Day in the Life of a POINT-OF-CARE-TESTING Technical Supervisor
BY JESSICA WYBLE
At the start of every day, Rina Kalariya sits at her desk checking the latest performance reports for the point-of-care-testing (POCT) equipment she helps maintain and manage. It's just one part of her role as technical supervisor for the POCT group within UTMB's Laboratory Services department, but it's an important one.
"It's my job to do this initial review every day to ensure there are no outliers (out-of-the-ordinary figures) and that the machines are producing accurate results," says Kalariya.
Producing rapid results and taking place as the patient is receiving care, POCT allows patients to receive faster diagnoses. This means they can more quickly receive the appropriate care they need. To perform this type of diagnostic screening, UTMB has specialized equipment that receives routine quality control checks and maintenance.
JANUARY 2019 impact

Tecnologias en POCT: PCR

Healthcare Associated Infections	Xpert® MRSA NxG	Active MRSA surveillance testing in 45 minutes*
	Xpert® SA Nasal Complete	Pre-surgical testing for *S. aureus* and MRSA in about an hour
	Xpert® MRSA/SA BC	Detection of MRSA and *S. aureus* in positive blood cultures in about an hour
	Xpert® MRSA/SA SSTI	Detection of MRSA & *S. aureus* skin and soft tissue infections in about an hour
	Xpert® *C. difficile*	Detection of *Clostridium difficile* in just over 30 minutes*
	Xpert® *C. difficile/Epi*	Detection and differentiation of *Clostridium difficile* & the epidemic 027 strain in 45 minutes
	Xpert® *vanA*	On-demand testing to assist with VRE surveillance in just over 30 minutes*
	Xpert® Carba-R	Detection of the carbapenem-resistance genes encoding KPC, NDM, VIM, OXA-48 and IMP in 48 minutes from isolates, rectal swabs, or perirectal swabs
	Xpert® Norovirus	Rapid identification and differentiation of Norovirus GI and GII in less than one hour*
Critical Infectious Diseases	Xpert® **Xpress** Strep A	Rapid detection of Group A Streptococcus DNA in as soon as 18 minutes*‡
	Xpert® **Xpress** Flu	Rapid detection of Flu A and Flu B in as soon as 20 minutes*‡
	Xpert® **Xpress** Flu/RSV	Rapid detection and differentiation of Flu A, Flu B, and RSV in as soon as 20 minutes^‡
	Xpert® MTB/RIF	Detection of MTB and rifampin resistance mutations in less than two hours
	Xpert® EV	Fast molecular diagnostic testing for enterovirus in 2.5 hours
	Xpert® Ebola†	Detection of Ebola Zaire virus in 98 minutes
Women's & Sexual Health	Xpert® CT/NG	Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* infections in 90 minutes
	Xpert® TV	Detection of *Trichomonas vaginalis* in male and female specimens in as soon as 40 minutes*
	Xpert® GBS	Intrapartum screening for Group B *streptococcus* during labor/ delivery in 35 minutes*
	Xpert® GBS LB	Antepartum screening from LIM broth for Group B *streptococcus* in 35 minutes*
Oncology & Genetics	Xpert® FII & FV	Identification of genetic risk factors for thrombosis in 30 minutes

Moving Molecular Testing Beyond the Lab

Tecnologias en POCT: Genetic testing

Atlas Genetics - Atlas Genetics io system

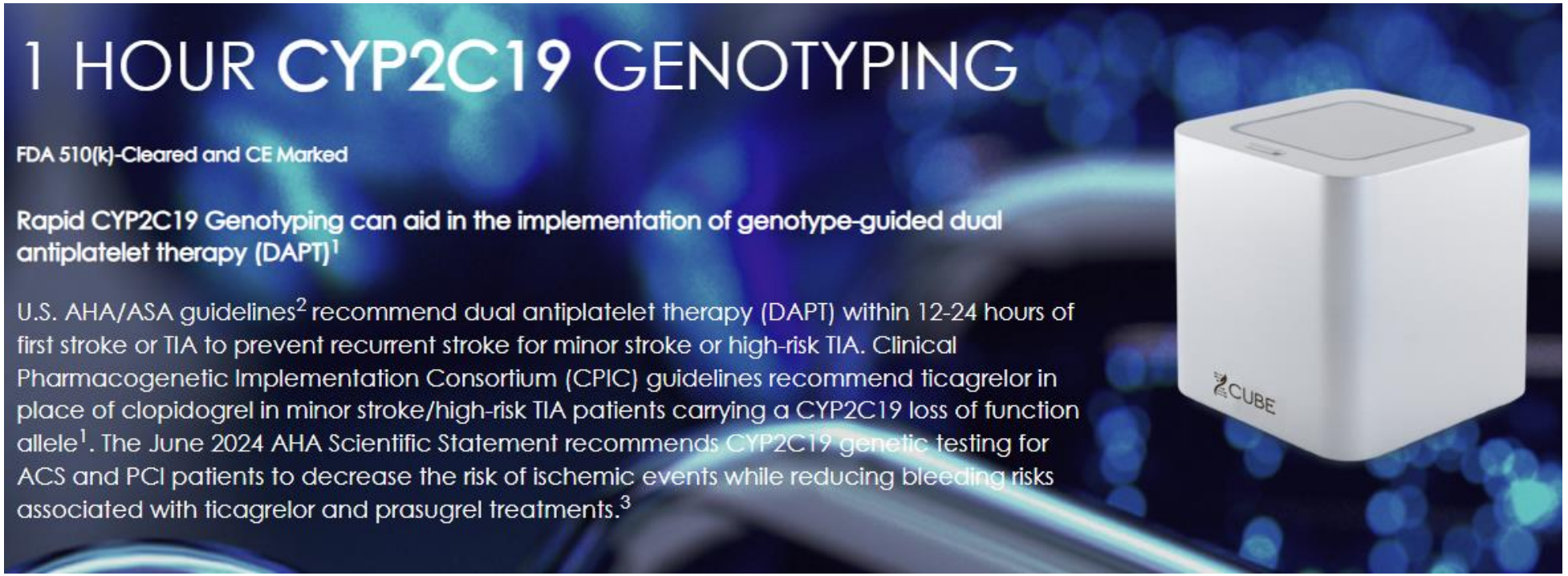
Dimensions: 268 x 260 384 mm (h x w x d)

Weight: 10 kg

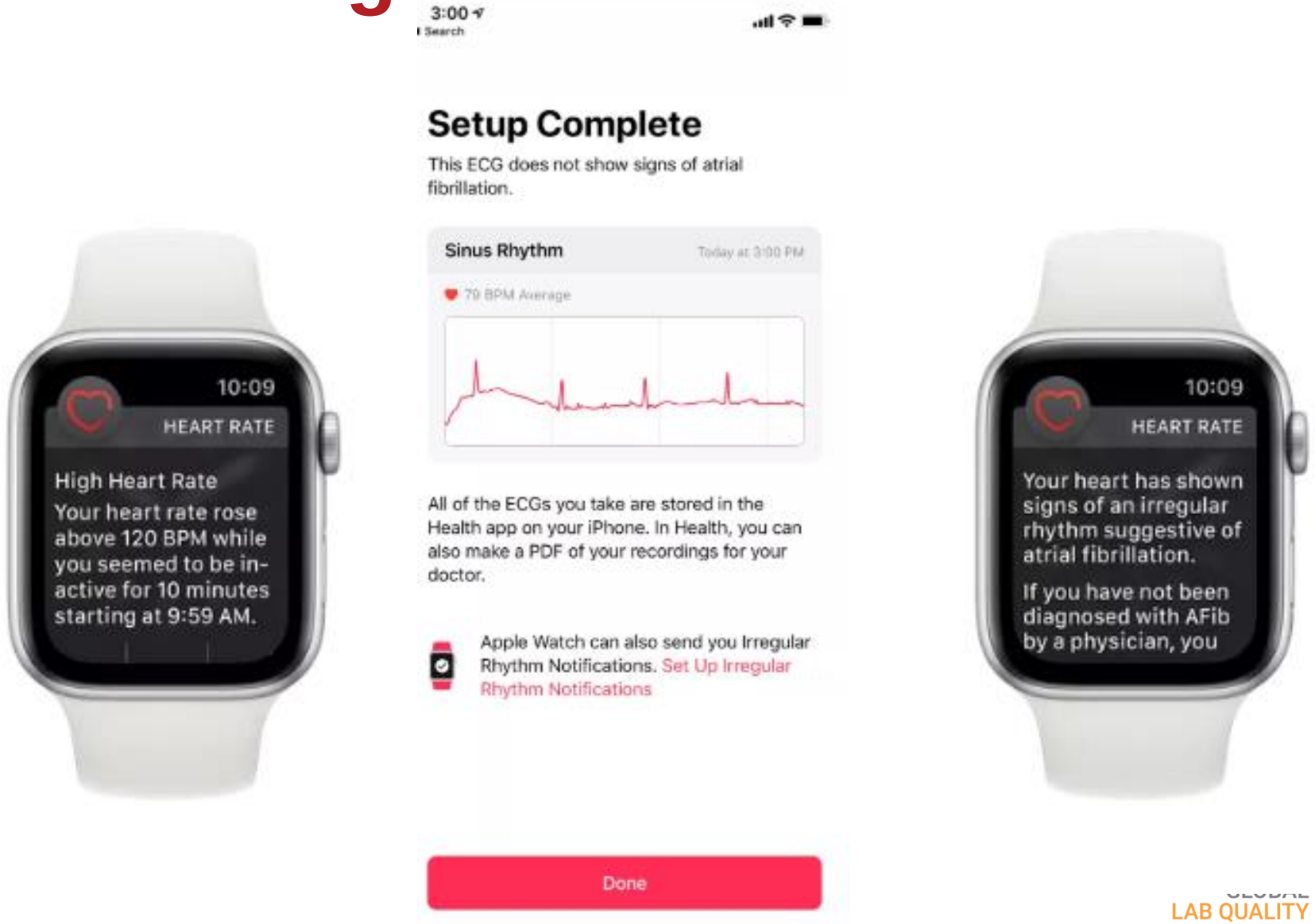
Assays: Sexually Transmitted & Hospital Aquired Infections

The Atlas Genetics io system is a rapid diagnostic platform designed for use in decentralised laboratories, point-of-care

Nuevas Tecnologias en POCT: PGX



Nuevas Tecnologías en POCT: Wearables

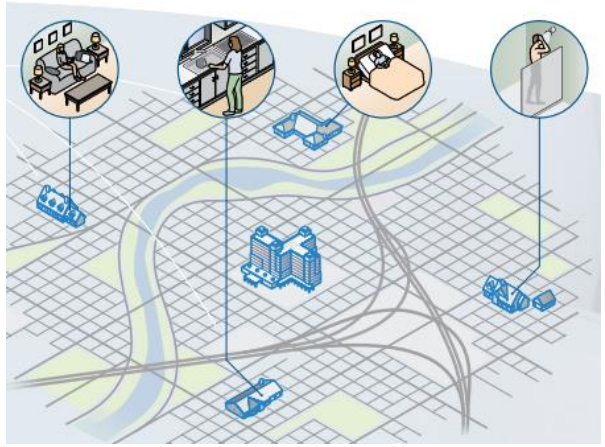


Nuevas Tecnologías en POCT: Wearables

Continuous glucose monitoring provides a more complete picture of a patient's glucose levels, compared to what they'd be able to glean from a single fingerstick reading from a blood glucose meter (BGM). Greater access to more frequent glucose insights can support more effective diabetes management for you and, ultimately improving patient outcomes.

Nuevas Tecnologías en POCT: Wearables

Complete, Real-time Data from one **VitalPatch®** Biosensor.



Nuevas Tecnologías en POCT: Wearables

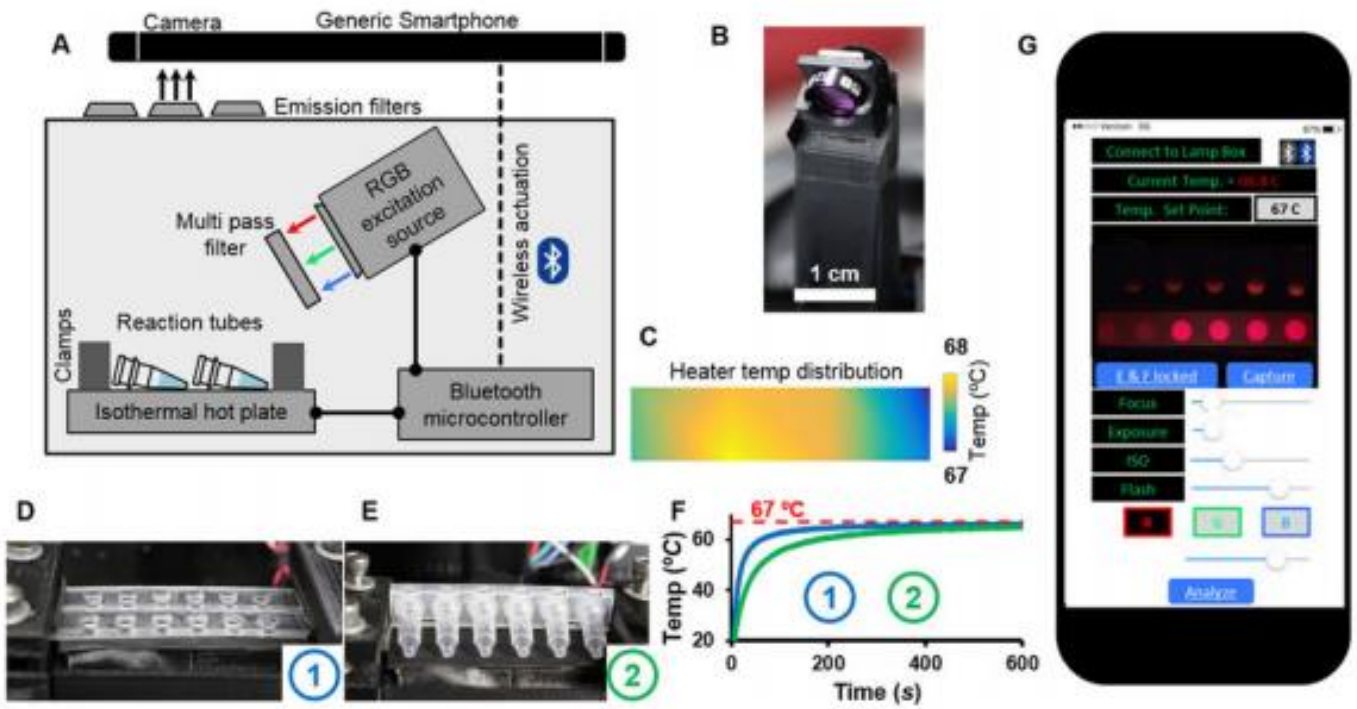


Figure 4. Zika virus sensor. (**A**) Test tubes placed on Isothermal hot plate are imaged using the smartphone camera with the LED acting as a light source. (**B**) Smartphone application interface. (**C**) Measured heat map of surface temperature indicating uniform heating with less than 1° C temperature variation. (**D**) Off the shelf PCR polypropylene tubes. (**E**) Custom made laser-cut reaction wells. (**F**) Measurements show improved thermal management with custom reaction wells. (**G**) Smartphone wirelessly controls the heating lamp and excitation source and is also responsible for capturing and analyzing illuminated reagents. Reprint adapted with permission from [63].

Nuevas Tecnologías en POCT: ABO

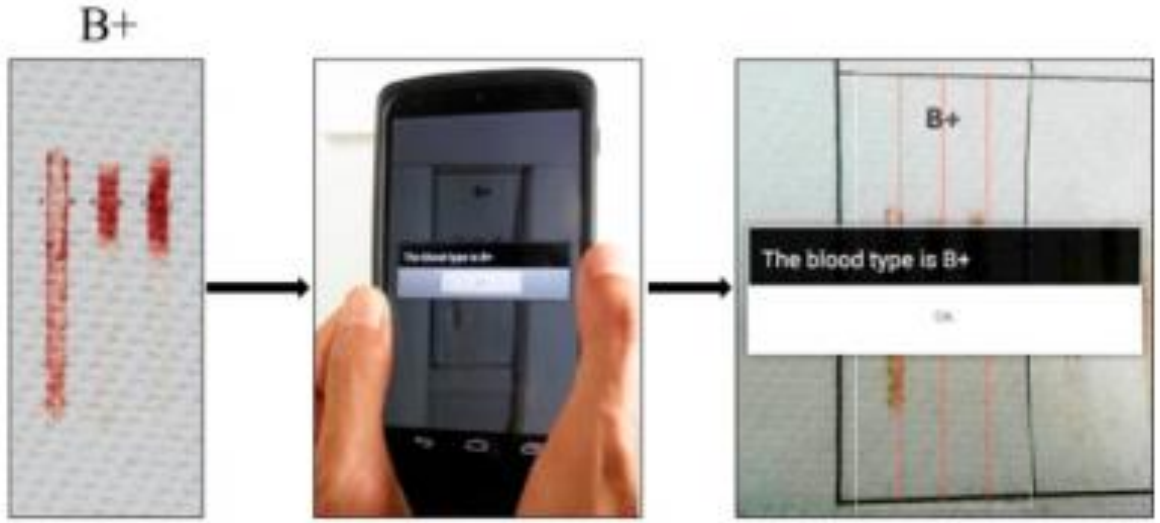


Figure 5. Blood type detection using smartphone. (**a**) Paper sensor with blood-tracks visible in channels. (**b**) Smartphone app developed for interpreting the sensor's result. (**c**) Detected blood type is displayed as text. Reprint adapted with permission from [67]. Copyright 2018 American Chemical Society.

Nuevas Tecnologias en POCT: LOC

LOC (Lab on a Chip). Micrichips

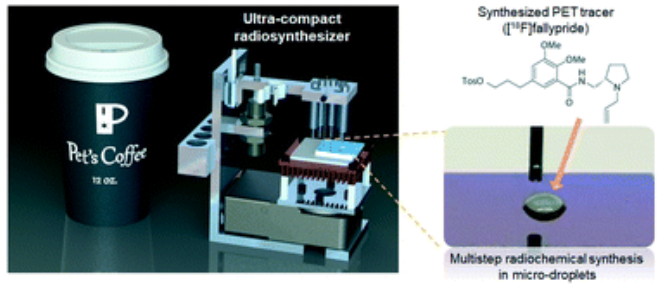
- Minutarizacion de los componetes,
- microelectronics y microfluidos
- Chips hechos de silicona
- LOC tiene poco uso
- (iSTAT)

Paper

Ultra-compact, automated microdroplet radiosynthesizer

Jia Wang, Philip H. Chao and R. Michael van Dam

An ultra-compact microdroplet platform was developed for multi-step synthesis of radiolabeled tracers for positron emission tomography (PET).



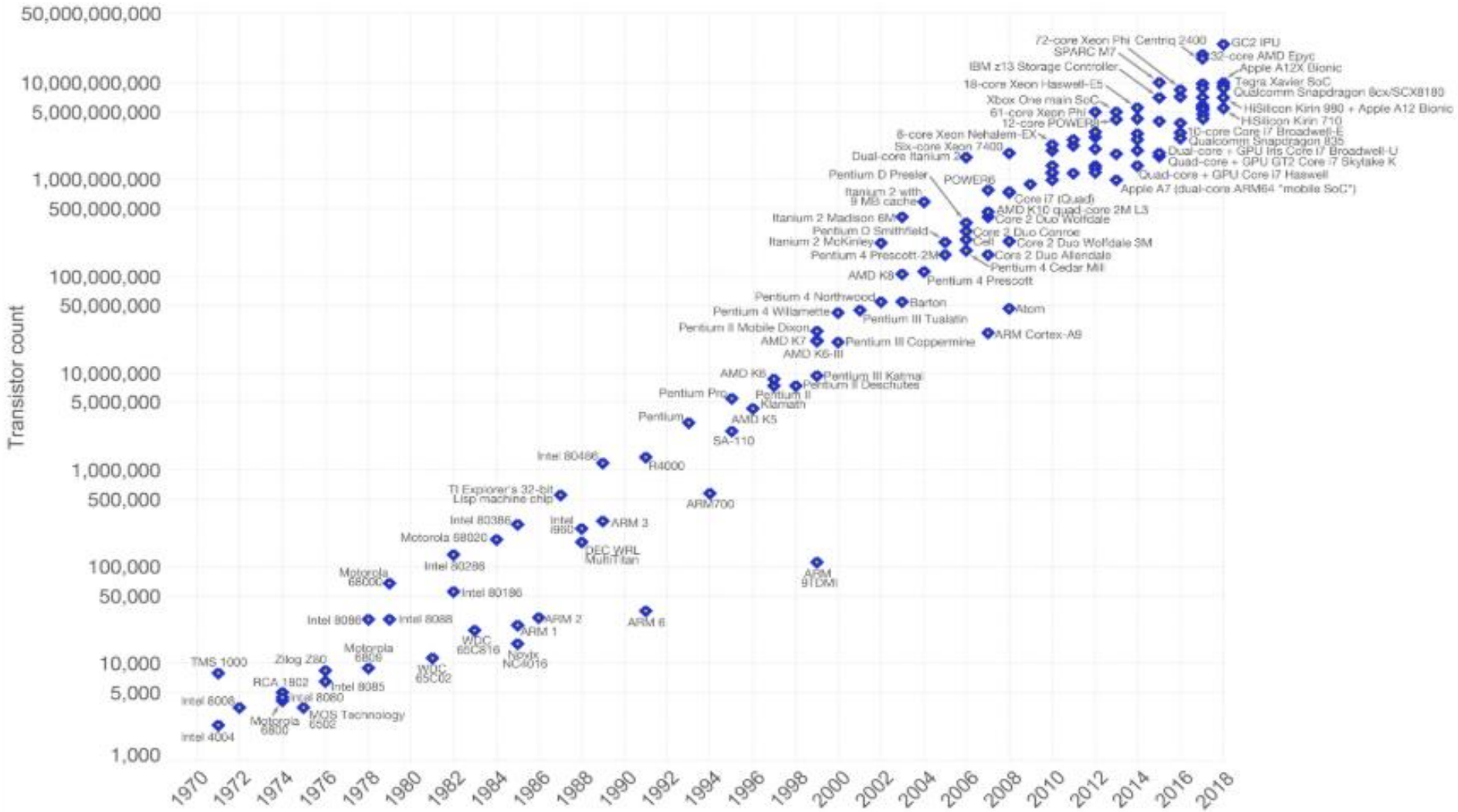
The article was first published on 30 May 2019

- **Moore's Law** Velocidad de los computadores incrementa al doble cada dos anos

Moore's Law – The number of transistors on integrated circuit chips (1971-2018)

Moore's law describes the empirical regularity that the number of transistors on integrated circuits doubles approximately every two years. This advancement is important as other aspects of technological progress – such as processing speed or the price of electronic products – are linked to Moore's law.

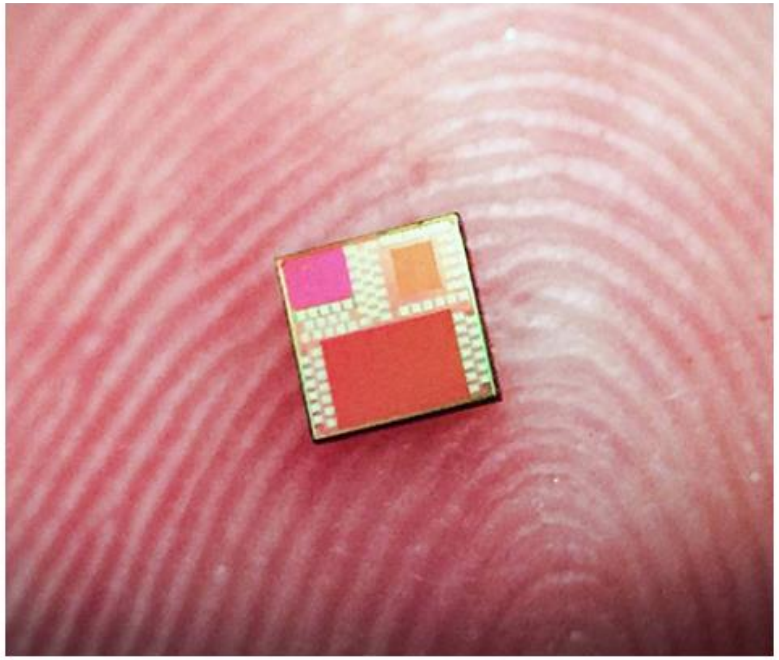
Our World in Data



Data source: Wikipedia (https://en.wikipedia.org/wiki/Transistor_count)
The data visualization is available at OurWorldinData.org. There you find more visualizations and research on this topic.

Researchers at Princeton University Develop Tiny Biosensor Chip That Can Be Manufactured Cheaply and Possibly Perform Diagnostics Inside the Human Body

Jun 26, 2019 | Digital Pathology, Instruments & Equipment, Laboratory Instruments & Laboratory Equipment, Laboratory Management and Operations, Laboratory News, Laboratory Operations, Laboratory Pathology, Laboratory Testing, Management & Operations



The miniature device (above) uses standard microchip technology consisting of tiny metal layers. It's those layers that serve as the biosensor. The chip measures a mere four millimeters (approximately 5/32 of an inch) per side, and according to the University of Princeton scientists, it can be mass produced in a cost-effective manner using standard manufacturing techniques and does not require detailed assembly. (Photo copyright: Lingyu Hong/University of Princeton.)

Nuevas Tecnologias en POCT: µPADs Microfluidos (Base de Papael)

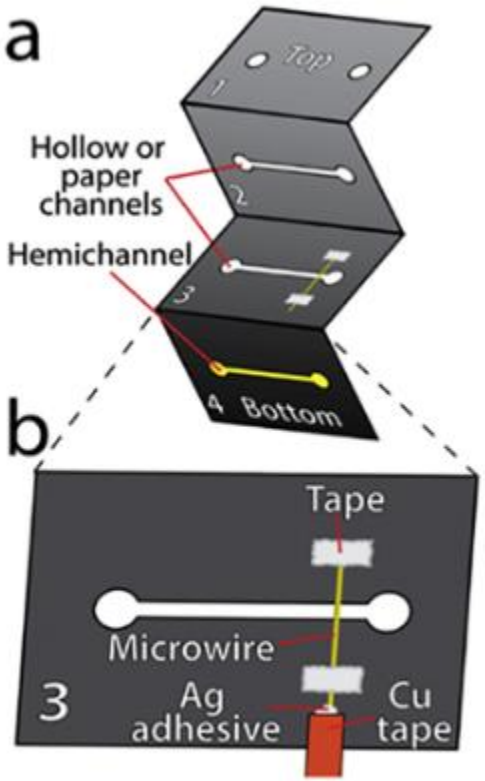


Fig. 2. Schematic representing the fabrication of the hollow channel origami PAD (HC-oPAD). A) Layers 1 through 4 of the HC-oPAD. B) Incorporation of the microwire electrode into the hollow channel device.

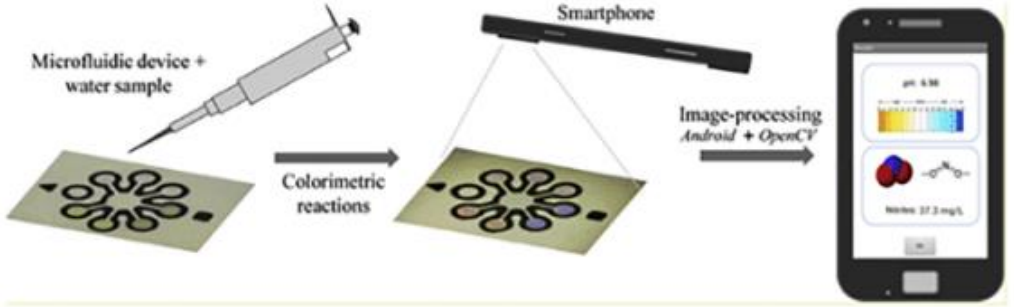


Fig. 4. Scheme showing use of the paper-based device to determine pH and nitrite concentration with analysis by smartphone [51].

Consideraciones para Desarrollar y Mantener un Programa de POCT

GLOBAL LAB QUALITY INITIATIVE | ADLM

Consideraciones

- Expectativas del programa
- Justificación clínica
- Quién tendrá supervisión
- Quién realizará las pruebas
- Capacitación y evaluación de competencias
- Pruebas de aptitud

Consideraciones

- Estructura Organizacional
- Revisión del control de calidad
- Aseguramiento de la calidad
- Infraestructura de IT
- Facturación & Reporte de resultados
- Documentación

GLOBAL LAB QUALITY INITIATIVE ADLM

Organizacion del Programa de POCT

GLOBAL LAB QUALITY INITIATIVE | ADLM

Estructura Organizacional

- Diseño para:
  - Entidad única (por ejemplo, hospital)
  - Múltiples entidades dentro de una organización (por ejemplo, sistema de entrega integrada)

Comité de Dirección de POCT: Miembros

Interdepartamental

- Ejemplos de miembros:
  - Coordinador de POCT, VP del hospital, médicos, gerentes de enfermería, representante de compras, representante del LIS, laboratorio

Steps of the Testing Process

Patient

Need for Test

Order

Patient Preparation

Specimen Collection

~~Processing~~

Transport to Lab

~~Lab Receipt~~

Analysis

Result Verification

Acknowledge Result

Order Treatment

Treatment

Preanalytical

Analytical

Postanalytical

POCT expedites TAT by eliminating several steps

Funciones del Comité de Dirección de POCT

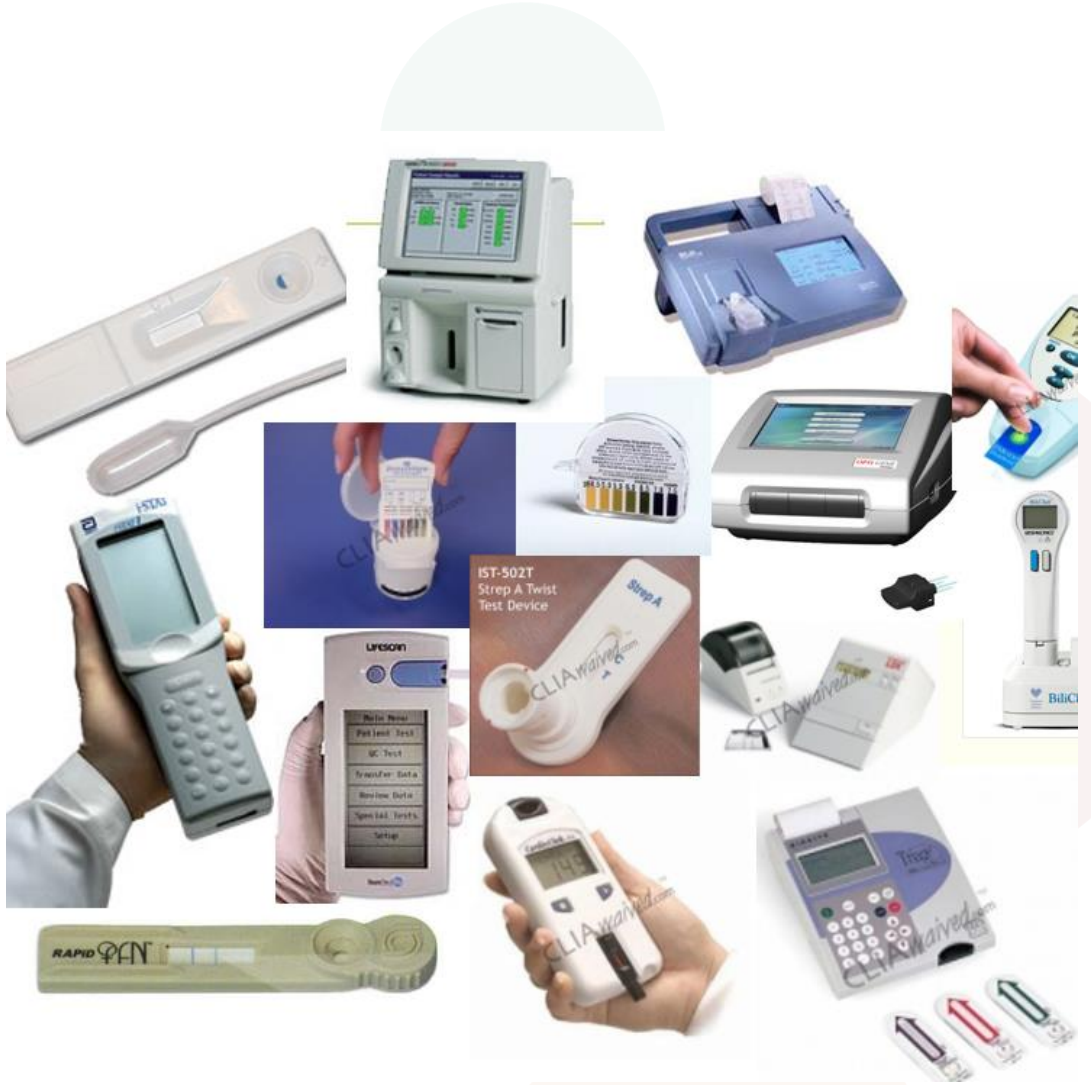
- Aprobar nuevos test POCT
- Proporcionar un espacio para presentaciones de nuevos métodos/dispositivos
- Monitorear el cumplimiento
- Realizar revisión de la utilización
- Revisar las tasas de errores
- Evaluar el impacto del programa

POCT Steering Committee

- **Clave – COMUNICACIÓN**
- **Crear un ambiente y estructura para una comunicación óptima, entrada de ideas, y resolución de problemas**

Criterios de selección

- Menú de pruebas
- Requisitos de volumen de muestra
- Personal que realizará las pruebas
- Requisitos de capacitación
- Cumplimiento normativo
- Costo
- Requisitos de rendimiento



GLOBAL LAB QUALITY INITIATIVE | ADLM

Criterios de selección

- Control de Calidad
  - “On-Board” or Analyzer controls – built-in device controls or system checks
  - Internal QC – laboratory-analyzed liquid surrogate sample controls
  - External QC – External quality assurance (EQA) blind proficiency surveys
  - Other types of QC – control processes either engineered by a manufacturer or enacted by a laboratory to ensure result reliability

Criterios de selección

- Gestión de datos/Conectividad
- Reporte de resultados (incluyendo críticos)
- Facturación, si corresponde

Validación de Instrumento/Método (cuando corresponda)

- Exactitud
- Correlación de muestras divididas vs. método de referencia
- Precisión sensibilidad y especificidad, incluyendo sustancias interferentes
- Rango reportable / linealidad
- Rango de referencia

Después de la Implementación

- Correlacionar resultados: realizar comparaciones periódicas programadas
- Establecer criterios de aceptación/rechazo
- Realizar entre el dispositivo de POCT y el laboratorio, y entre dispositivos de POCT

Entrenamiento

- Las pruebas suelen ser realizadas por personal no de laboratorio
- La calidad de los resultados está vinculada a la capacidad de realizar la prueba correctamente
- Los resultados del POCT se utilizan para tomar decisiones rápidas de tratamiento; la capacitación es más crítica
- Un programa bien diseñado puede mejorar el rendimiento del POCT

Responsabilidad del Laboratorio en POCT

- Proporcionar procedimientos
- Proporcionar una lista de verificación de capacitación
- Asistir en la capacitación o designar a entrenadores específicos
- "Entrenar al entrenador“
- Proporcionar material de prueba
- Evaluar resultados
- Mantenimiento de registros

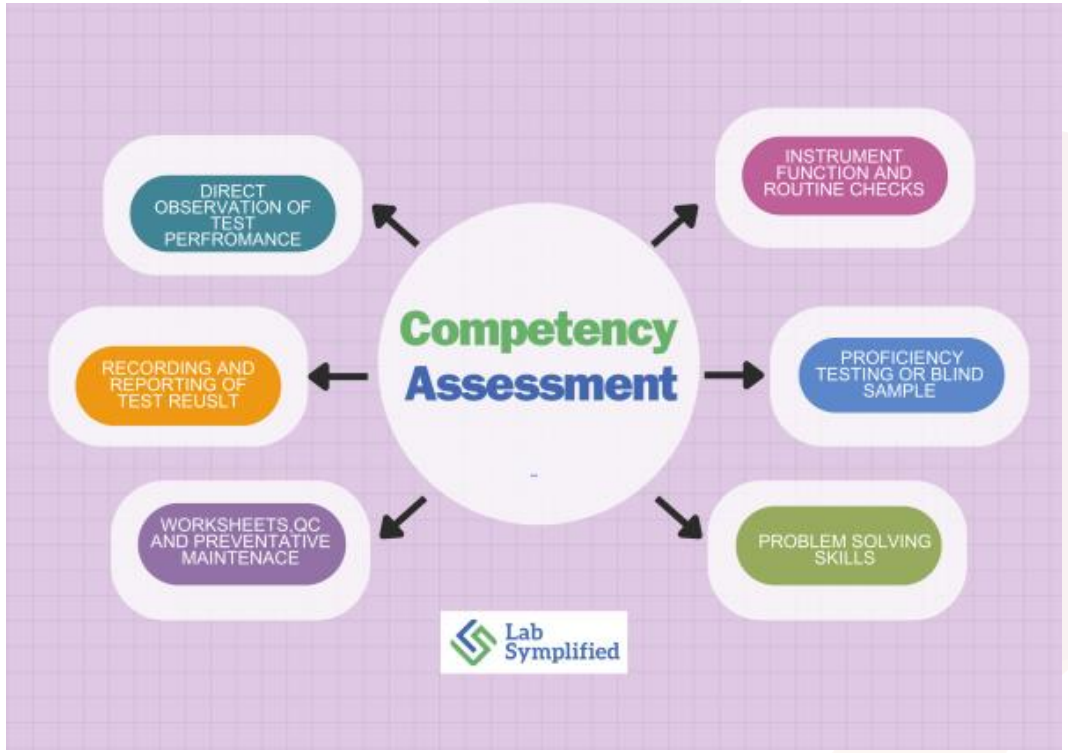
GLOBAL LAB QUALITY INITIATIVE | ADLM

Programa de Capacitación Integral

- Proporcionar información suficiente al personal que realiza las pruebas
- Entender las limitaciones del resultado
- Saber cuándo solicitar asistencia

Elementos de la Lista de Verificación de Capacitación (Checklist)

- Leer el procedimiento
- Mantenimiento
- Reactivos
- Control de calidad
- Requisitos de la muestra
- Observación directa (realizar una prueba simulada de un paciente)



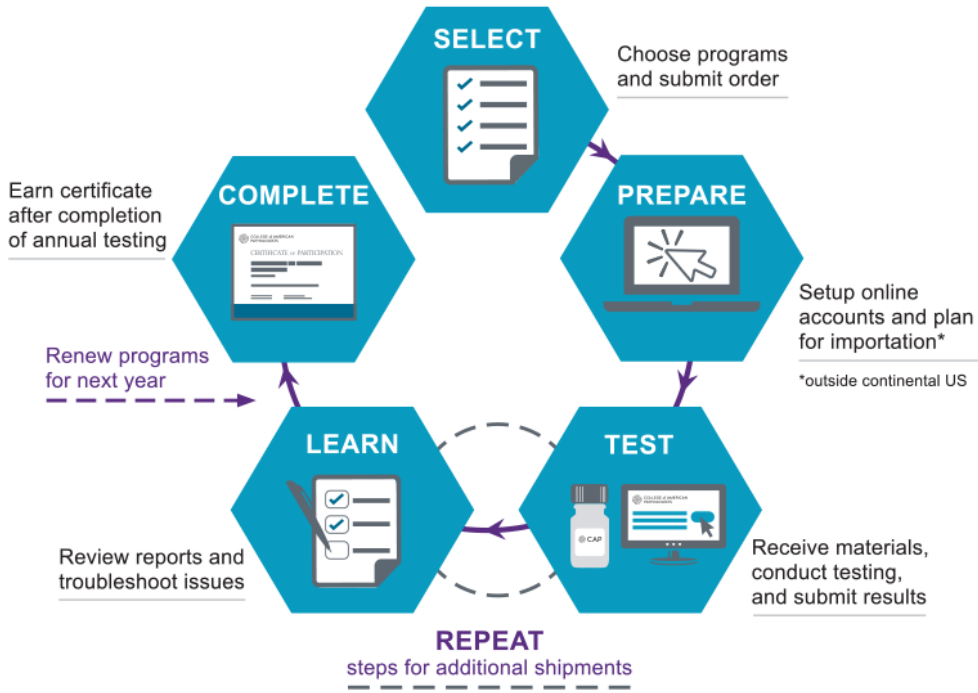
GLOBAL LAB QUALITY INITIATIVE ADLM

Elementos de la Lista de Verificación de Capacitación (Checklist)

- Reporte de resultados: software y/o documentación en papel, rangos de referencia y críticos
- Seguridad
- Información del operador (nombre, ID del operador, piso)
- Firma del entrenador
- Puede complementarse con un cuestionario

Pruebas de Aptitud - Si corresponde o para cumplimiento normativo

- Asegúrese de tener una estructura
- Ordenar las pruebas apropiadas
- Documentar la recepción de los envíos de PT
- Programar la distribución
- Distribuir al departamento de POCT
- Reportar resultados al proveedor de PT
- Mantener la documentación



GLOBAL LAB QUALITY INITIATIVE | ADLM

Control de Calidad

- Evalúa el instrumento
- Evalúa los reactivos
- Evalúa al operador (persona que realiza la prueba)
- Evalúa el proceso de prueba
- Debe ser realizado por el mismo personal que está probando muestras de pacientes

Conectividad de POCT

Ventajas

- Ayuda a reducir errores médicos
- Reduce la transcripción manual
- Mejora el cumplimiento del personal con los requisitos regulatorios
- Aumenta los ingresos por pruebas (si se factura)Rastrear suministros desperdiciados

Aseguramiento de la Calidad (QA): Goals

- Monitorear y documentar el rendimiento
- Minimizar el potencial de errores
- Identificar áreas para mejorar

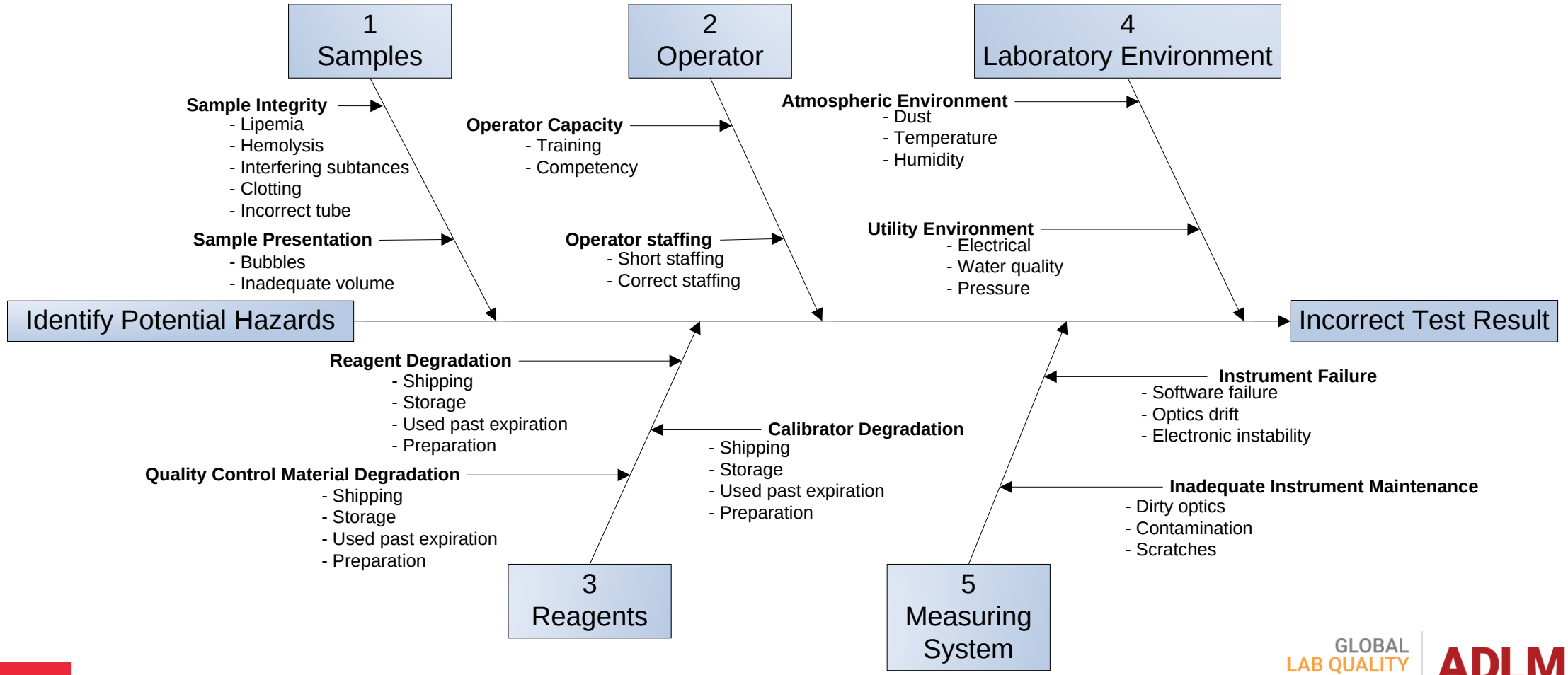
Fuentes de Error en POCT

- **Test System:**
  - Reagent contamination, deterioration, lot variation
  - Reaction fluctuations
  - Inadequate sampling
  - Improper or loss of calibration
  - Electronic or mechanical failure
  - Power supply
- **Environment:**
  - Temperature and airflow
  - Humidity
  - Light intensity
  - Altitude
- **Operator:**
  - Improper specimen prep, handling
  - Incorrect test interpretation
  - Failure to follow test system instructions

CLIA Interpretive Guidelines for Laboratories. Appendix C, Subpart K. § 493.1256 Standard: Control Procedures. Interpretive Guidelines § 493.1256(a) – (c). http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Interpretive_Guidelines_for_Laboratories.html

Human error is a substantial risk for POCT!

Fuentes de Error en POCT



Control de Infecciones

- Seguir las pautas de control de infecciones del hospital en todo momento
- Realizar higiene de manos y ponerse guantes antes de realizar pruebas de Point of Care
- Los objetos punzantes deben ser desechados en contenedores a prueba de perforaciones
- Todos los demás residuos de riesgo biologico deben ser desechados en contenedores designados

Operarios

- Solo el personal con capacitación documentada y/o evaluación de competencia actual puede realizar pruebas de Point of Care
- Joint Commission requiere al menos dos métodos de evaluación de competencia anualmente:
  - Módulo de aprendizaje en línea y examenControl de calidad o observación directa por un observador calificado

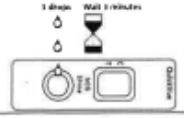
Point of Care Competence Assessment – Urine Pregnancy

NAME _____ UNIT _____ DATE _____

SIGNATURE* _____

**Your signature is equivalent to an attestation a) that you have read all policies and procedures pertaining to POCT for your unit and b) that you feel confident you can successfully perform the POCT tests on your unit.*

Urine Pregnancy (hCG)

Checklist Item	Initials	Date
1. Gather Supplies: - Quidel QuickVue HCG test kit (check for expiration date) - Sample applicator dropper		
2. Aspirate sample & apply three drops of urine specimen to the sample well. 		
3. Set timer and interpret the test after exactly three minutes. 		
4. Test Interpretation: Test results are to be read as follows: NEGATIVE, POSITIVE or INDETERMINATE. Examples:		
5. Record results in patient record.		
6. For this exercise, perform the test on QC L2, interpret, and record results here:		
7. Read urine HCG procedure.		
8. Take the quiz on the pages that follow.		

NEGATIVE	POSITIVE	INDETERMINATE
Only CONTROL line (C) is visible	Both TEST line and CONTROL line are visible	CONTROL line is NOT VISIBLE.
 *C = CONTROL,* *T = TEST*	 *C = CONTROL,* *T = TEST*	 OR *C = CONTROL,* *T = TEST* For INDETERMINATE test results, test must be REPEATED

Perform the test on QC L2 and interpret	Expected Result	Circle Your Result
Place three drop of level 2 conrol in the sample well.	**POS WTH QC OK**	**POS WITH QC OK** **NEG WITH QC OK** **INDETERMINATE**

To be completed by evaluator. MUST CHECK BOTH AREAS TO INDICATE COMPETENCE:

1st method of competence assessment (checkmark if passed):
_____Passing quiz (passing=80%; 4 out of 5 responses correct).

2nd method of competence assessment:
_____Successful Performance Monitor

Evaluator Signature:_____ **Date:**_____

ADLM

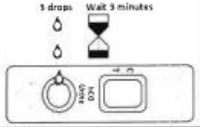
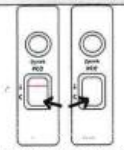
GLOBAL LAB QUALITY INITIATIVE

ADLM

Clinical Labs / Point of Care Testing   Location:____________

QC LOGS hCG Urine Pregnancy – McKesson Consult – Quality Control

- Perform Quality Control weekly and/or when opening new boxes of hCG kits (see chart below), whichever is more frequent.
- Start a new log at least each month. Laboratory Director/Designee must review all sheets for each month (may sign logs more than once).

Test	QC Instructions	Positive Expected Results	Negative Expected Results	*NOTE: INVALID TESTS*
Urine Pregnancy (hCG)	1. Obtain and label two test cards, one for negative QC and one for positive QC. 2. Place 3 drops of QC in each sample well. 3. Wait exactly 3 minutes before interpreting results.  	 **POSITIVE w/ QC OK** -This test is POSITIVE w/ acceptable internal control. -There is a line at "C" (control). This means the test is valid. -There is also a line at "T" (test). This means the test is positive.	 **NEGATIVE w/ QC OK** -This test is NEGATIVE w/ acceptable internal control. -There is a line at "C" (control) indicating that the test is valid, but there is no line at "T" (test).	 **Note that both of the above tests are missing the line at "C".** -These two examples are therefore both invalid, no matter what appears at "T". -The "C" line MUST be visible, otherwise something was wrong with the test kit. -If a test is missing "C", it cannot be reported for QC or for patients!

DOCUMENT QC BELOW

Date	Initials	Cassette Lot (on box)	Cassette Exp Date (on box)	QC Lot (on box)	QC Exp Date (on box)	QC Level	Expected Results	QC Results (circle)	Comments (ex: new box)
						Negative QC	Negative w/ QC OK	Neg w/ QC OK POS w/ QC OK Invalid – QC NOT OK	
						Positive QC	Positive w/ QC OK	Neg w/ QC OK POS w/ QC OK Invalid – QC NOT OK	
Date	Initials	Cassette Lot (on box)	Cassette Exp Date (on box)	QC Lot (on box)	QC Exp Date (on box)	QC Level	Expected Results	QC Results (circle)	Comments (ex: new box)
						Negative QC	Negative w/ QC OK	Neg w/ QC OK POS w/ QC OK Invalid – QC NOT OK	
						Positive QC	Positive w/ QC OK	Neg w/ QC OK POS w/ QC OK Invalid – QC NOT OK	
Date	Initials	Cassette Lot (on box)	Cassette Exp Date (on box)	QC Lot (on box)	QC Exp Date (on box)	QC Level	Expected Results	QC Results (circle)	Comments (ex: new box)
						Negative QC	Negative w/ QC OK	Neg w/ QC OK POS w/ QC OK Invalid – QC NOT OK	
						Positive QC	Positive w/ QC OK	Neg w/ QC OK POS w/ QC OK Invalid – QC NOT OK	
Date	Initials	Cassette Lot (on box)	Cassette Exp Date (on box)	QC Lot (on box)	QC Exp Date (on box)	QC Level	Expected Results	QC Results (circle)	Comments (ex: new box)
						Negative QC	Negative w/ QC OK	Neg w/ QC OK POS w/ QC OK Invalid – QC NOT OK	
						Positive QC	Positive w/ QC OK	Neg w/ QC OK POS w/ QC OK Invalid – QC NOT OK	
Date	Initials	Cassette Lot (on box)	Cassette Exp Date (on box)	QC Lot (on box)	QC Exp Date (on box)	QC Level	Expected Results	QC Results (circle)	Comments (ex: new box)
						Negative QC	Negative w/ QC OK	Neg w/ QC OK POS w/ QC OK Invalid – QC NOT OK	
						Positive QC	Positive w/ QC OK	Neg w/ QC OK POS w/ QC OK Invalid – QC NOT OK	

Monthly Laboratory Director/Designee Review:____________________   Date: ____________

Keep this and all Point of Care/Laboratory Documentation for 2 full years.

ADLM

Clinical Labs / Point of Care Testing

QC LOGS hCG Urine Pregnancy – Quidel One Step – Quality Control cont'd

Urine Pregnancy Quiz

QUESTION 1 – TRUE FALSE

The only acceptable sample type is urine.

CHOICES

TRUE
FALSE

FEEDBACK

The only acceptable sample is urine. Plasma, serum, and whole blood are **not** acceptable samples for POC hCG testing.

QUESTION 2 – TRUE FALSE

Reading test results past the 3 minute mark can lead to inaccurate results.

CHOICES

TRUE
FALSE

FEEDBACK

Reading test results past the 3 minute mark can lead to inaccurate results.

QUESTION 3 – SINGLE ANSWER:

Once 3 drops of sample have been applied to the test well, wait _____ minutes and read _____.

CHOICES

Wait 5 minutes and read at any time
Wait 3 minutes and read immediately
Wait 5 minutes and read immediately
Wait 3 minutes and read at any time

FEEDBACK

Remember "H-C-G, 1-2-3": 3 drops, 3 minutes.

ADLM

Thank you/Acknowledgments/Contact Info

Agradecieminto especial para:

- **Drs. Luzzi and Colon**
- **ADLM LAWG Ally and Kerry**
- **Drs. Velez and Juatiniano Grosz and Ivonne Vargas**
- **UTMB Pathology & Lab Services Staff**

Juan David Garcia
Director, Pathology & Lab Services
Director of Operations, John Sealy Diagnostic Center
Assistant professor, SHP CLS
University of Texas Medical Branch JuanDGar@utmb.edu

utmb Health