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www.ema.org.mx

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POCT *within* the Mexican Association of Clinical Laboratory Sciences (CMCLC)

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MEXICO

POCT Global impact

- The global POC diagnostics market over the forecast period of 2013 to 2018 is poised to grow at a CAGR of 9.3% from 2013 to 2018, to reach \$27.5billion by 2018.
- Based on the type of end users, the global POC diagnostics market has been segmented into patient professional monitoring kits and patient self-monitoring kits
- CAGR compound annual grow rate

By: marketsandmarkets.com
Publishing Date: September 2014
Report Code: MD 2702

Global POC Diagnostics Market

- A number of factors such as:
 - increasing prevalence of infectious diseases in developing countries,
 - rising incidences of lifestyle diseases such as cardiac diseases and diabetes,
 - rising usage of home-based POC devices, and
 - technological advancements with regard to development of advanced,
 - faster, and easy-to-use devices are stimulating the demand for POC testing.

POC Global Diagnostics Market

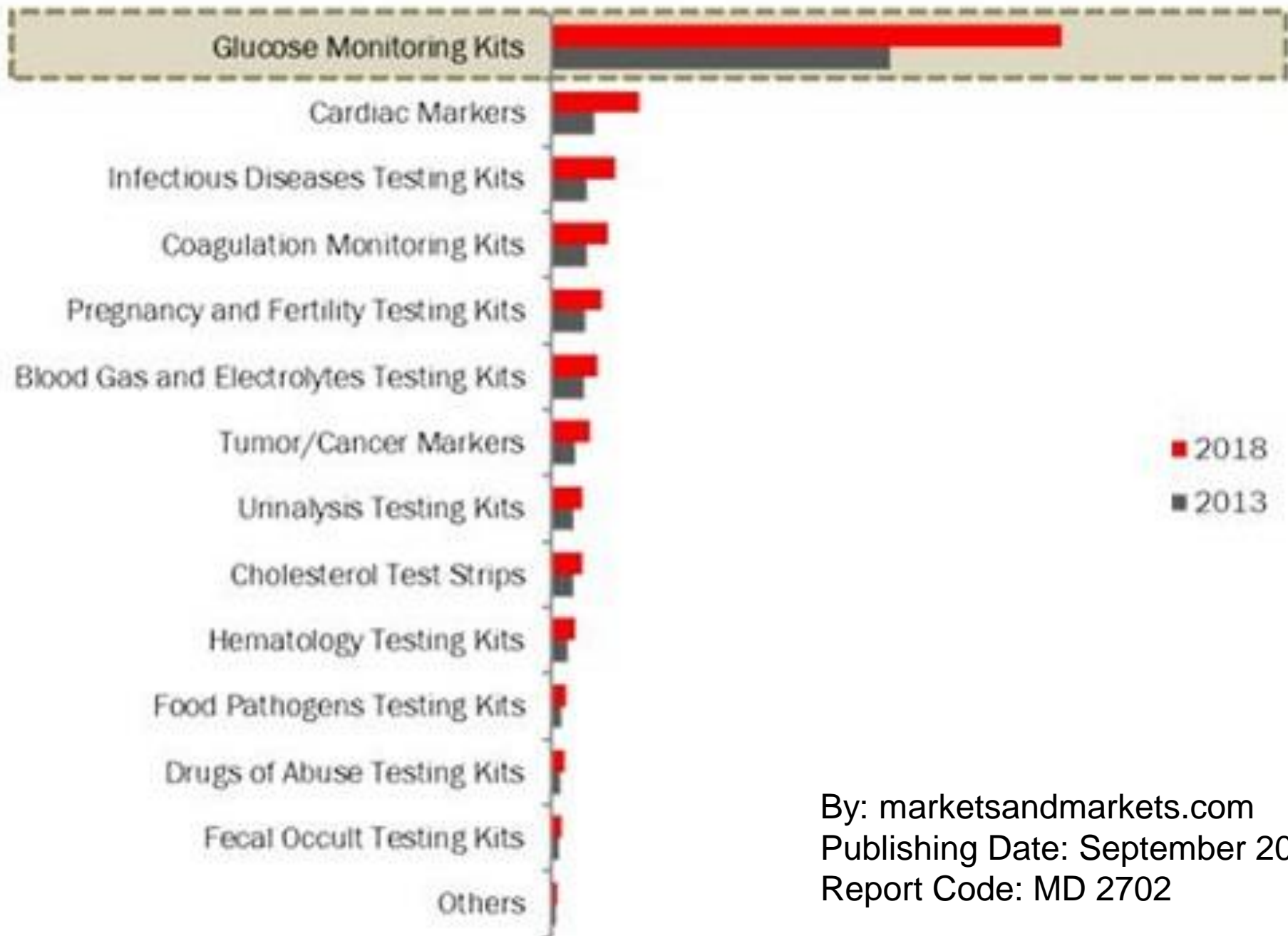
- infectious diseases testing kits,
- glucose monitoring kits,
- coagulation monitoring kits,
- urinalysis testing kits,
- hematology testing kits,
- cholesterol test strips,
- drugs of abuse testing kits,
- cardiac markers,
- blood gas/electrolytes testing kits,
- tumor/cancer markers, pregnancy and fertility testing kits,
- fecal occult testing kits, food pathogens testing kits, and others.

POC Diagnostics Market players

- The POC diagnostics market is a diversified and competitive market with a large number of players.
- Excluding blood glucose monitoring kits, the POC diagnostics market is dominated by and depending on their core competencies by Roche Diagnostics Ltd. (Switzerland), Alere Inc. (U.S.), Siemens AG (Germany), and Beckman Coulter, Inc. (U.S.).

POC Diagnostics Market players

- The key players in the global blood glucose monitoring kits market are:
 - Roche Diagnostics Limited (Switzerland),
 - Johnson & Johnson (U.S.),
 - Bayer AG (Germany), and
 - Abbott Laboratories (U.S.).



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POCT applications

- Point-of-care testing (POC) is now possible in many areas of clinical medicine.
- its application is in four areas: self-monitoring; community testing primarily in the pharmacy
- **In MEXICO:** Self-monitoring and emergency units are on demand

POC in the Americas / North America

- As of 2013, North America (comprising the U.S., Canada, and Mexico) held the largest share of the global POC diagnostics market.
- This large share is primarily attributed to the huge and increasing addressable patient population base.
- Moreover, the development of accurate and rapid testing kits is further driving the growth of the POC diagnostics market in North America.

POC in the Americas / South America

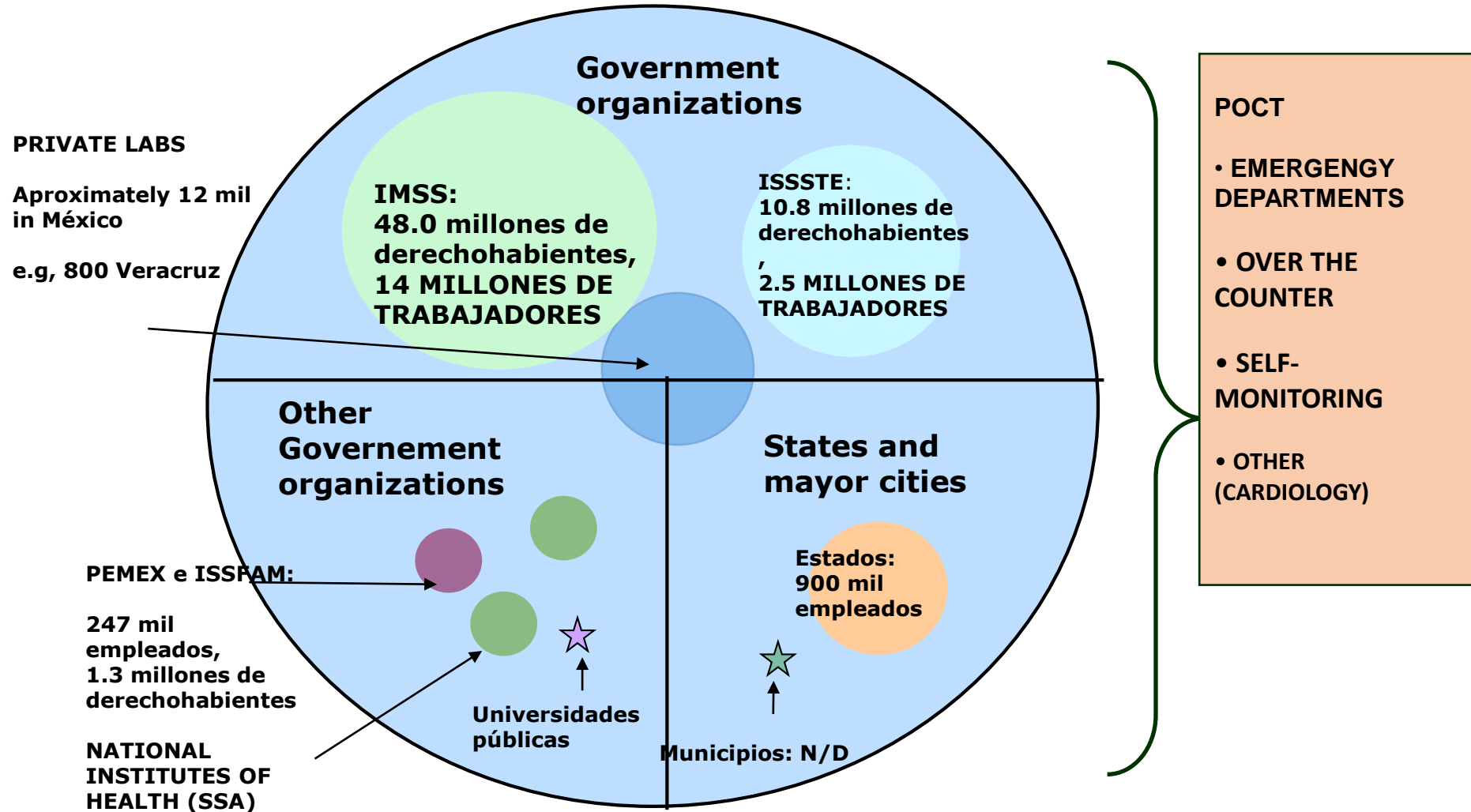
- Geographic Analysis

Further breakdown of the Latin American POC diagnostics market into Brazil, Argentina, and Rest of Latin America.

PoC in Mexico ?

Main barriers: high cost of devices, lack of policies and implementation, mostly used by physicians in the intensive care unit

Laboratory Medicine in MEXICO



Disciplines accredited based on ISO 15189

- Microbiology
- Coagulation
- Hematology
- Parasitology
- Urinalysis
- Molecular Biology
- Clinical Chemistry
- Immunology
- Toxicology
- Virology
- Genetics
- **PRUEBAS
DESECENTRALIZADAS
(POCT)**

Reference: www.ema.org

Laboratory regulations / accreditation in Mexico

National society input

- There are general regulations but no policy to follow regarding who is supervising the analysis or quality control competence
- A WG on POC is being established at the Mexican accreditation entity (ema, a.c.) www.ema.org.mx

Laboratory regulations / accreditation in Mexico

National society input

- Physicians at Emergency units, and nurses are running the POC devices, but no colaboration is being put in place to improve quality management.
- At this moment, there is no laboratory accredited by ISO 15189 on POC

What are the main challenges for expanding the role of POC?

Edward R. Ashwood, MD, professor of pathology at the University of Utah School of Medicine and vice president for government relations at ARUP Laboratories: **Test mix is a formidable challenge for POC testing...Companies that manufacture POC devices will be well served to concentrate on the high-volume tests.**

What are the main challenges for expanding the role of POC?

Ashwood....continues

- Successful implementation will allow them to amortize the high development and **regulatory costs** over a large number of units.
- POC testing will grow to about a hundred of the most common tests.

Summary....

- POC testing in Mexico is not used as desirable
- CMCLC has a very important task to do with key players at the Mexican Health Care System
- Considering POC accreditation, labs require to implement the standard.
- A multidisciplinary WG on POC is needed to move forward

Thank you!

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