

The clinical microbiology laboratory in 2020

POC Testing in Clinical Microbiology

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28th

ECCMID

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21 – 24 April 2018

Disclosures

- **Advisory Board/Consultant**
 - Merck
- **Research Support**
 - Accelerate Diagnostics
 - bioMérieux
 - Bio-Rad
- **Honorarium**
 - Merck
- **Travel Reimbursement**
 - Merck
 - Copan

Objectives

By the end of this session, you should be able to:

1. To describe the **role of POC devices in clinical microbiology** today and in the future
2. To illustrate **challenges** regarding the use of POC devices in microbiology
3. To list **guidance documents** regarding the use of POC in microbiology

Paradigm Shift

in Microbiology

NEW

TECHNOLOGIES

- ➊ Automation and Smart Incubation
- ➋ Rapid Microbial Identification
- ➌ Rapid Antimicrobial Susceptibility Testing
- ➍ Automated Random Access Syndromic Assays
- ➎ Novel Methods (magnetic resonance, metabolomics)
- ➏ Point-of-Care Testing

Paradigm Shift

in Microbiology

BEFORE: 8-4pm LAB
TECHNOLOGIES

- ① Automation and Smart Incubation
- ② Rapid Microbial Identification
- ③ Rapid Antimicrobial Susceptibility Testing
- ④ Automated Random Access Syndromic Assays
- ⑤ Novel Methods (magnetic resonance, metabolomics)
- ⑥ Point-of-Care Testing

FUTURE: 24/7 LAB & POC

POC Testing Definition

1. Medical diagnostic testing at or near the **point of care**—that is, **at the time and place of patient care.**
2. **POC laboratories** set up in remote regions to facilitate access to testing.

POC Testing – Current State

- Primarily lateral flow immunoassay based
- New nucleic acid amplification based assays
- Many available but primarily target:
1. GAS 2. Influenza 3. HIV 4. Hepatitis C
- Performed in clinics, emergency departments, ICUs, some pharmacies
- Primarily performed by physicians, pharmacists, nurses

TABLE 1 Examples of CLIA-waived tests for infectious diseases^a

Disease or pathogen	Principle	Measurand	No. of tests ^b
Group A <i>Streptococcus</i> (GAS)	LFIA	GAS antigen	79
	Molecular	Bacterial DNA	2
Infectious mononucleosis	LFIA	Heterophile antibodies	44
<i>Helicobacter pylori</i>	LFIA	IgG antibodies to <i>H. pylori</i>	35
	Biochemical ^c	Urease enzyme activity	7
	LFIA	<i>H. pylori</i> antigen	1
Influenza types A and B	LFIA	Influenza type A and B antigens	12
	Molecular	Viral RNA	2
	Biochemical	Neuraminidase enzyme activity	1
Respiratory syncytial virus	LFIA	Respiratory syncytial virus antigen	9
HIV-1 and HIV-2	LFIA	Antibodies to HIV-1/2	4
	LFIA	HIV-1 antigen, antibodies to HIV-1/2	1
HIV-1	LFIA	Antibodies to HIV-1	4
Influenza type A	LFIA	Influenza type A antigen	4
Influenza type B	LFIA	Influenza type B antigen	4
Urinary tract infections ^d	Biochemical	Catalase enzyme activity	2
Influenza A/B and RSV	Molecular	Viral RNA	2
<i>Trichomonas vaginalis</i>	LFIA	<i>T. vaginalis</i> antigen	2
Adenovirus	LFIA	Adenoviral antigen	2
<i>Borrelia burgdorferi</i> (Lyme disease)	LFIA	IgG and IgM antibodies to <i>B. burgdorferi</i>	1
<i>Treponema pallidum</i> (syphilis)	LFIA	Antibodies to <i>T. pallidum</i>	1
Hepatitis C virus	LFIA	Antibodies to hepatitis C virus	1
<i>Gardnerella vaginalis</i> , <i>Bacteroides</i> spp., <i>Prevotella</i> spp., and <i>Mobiluncus</i> spp.	Biochemical	Sialidase enzyme activity	1



**Lateral Flow
Immunoassay
with optical
reader
(results in
5 min)**



ES&MID eLibrary
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Lateral Flow Immunoassay (results in 20 min)

OraQuick Rapid
Antibody
Test
ADVANCE® **HIV-1/2**

OraQuick Rapid
Antibody
Test
HCV





NEAR* based

(results in
<15 min)

(*Nicking Enzyme
Amplification Reaction)

Alere i, Roche





PCR based
(results in
~20 min)

cobas Liat System, Roche



POC Testing – Future State

- 1. Increased menu to include more targets using NAAT based technologies**
- 2. Novel methodologies**
- 3. Focus on syndromic testing**
 - Performed in increasing numbers of clinics, emergency departments, ICUs, pharmacies
 - Performed by physicians, pharmacists, nurses, other health care providers

POC Testing – Future State

- Increasing use of POC

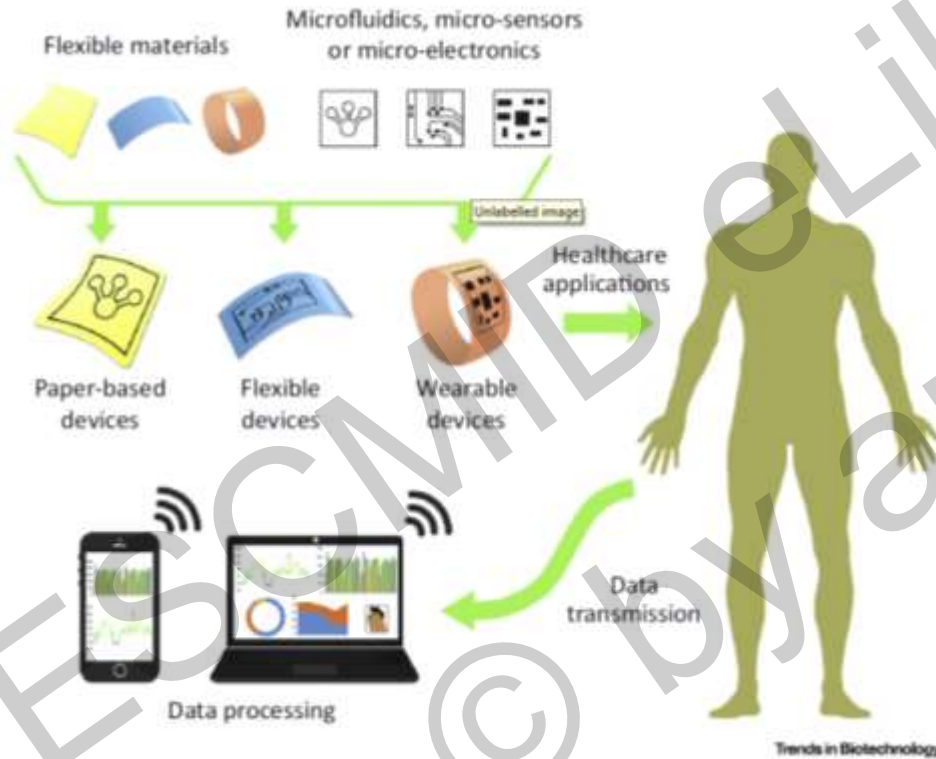


POC Testing – Future State



- Increasing use of POC
- Reducing role of laboratory “proper”

POC Testing – Future State



- Increasing use of wearable POC with real-time data analysis and artificial intelligence

Motivators

- Reduced turn-around-times
- Accessibility
- Presumed improved outcomes
- ?Profit (pharmacists, physicians)

Challenges

- Accuracy
- Oversight
- Quality
 - Verification
 - Validation (QC, QI, proficiency testing)
- Documentation
- Public Health Reporting
- Training
- Competency
- Accreditation
- Enforcement
- ?Licensing
- Ethics

On-the-spot strep throat tests offered at some Shoppers Drug Mart pharmacies

Some experts worry about accuracy of swabs, available in Alberta, B.C. and Nova Scotia





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SOCIETY FOR
MICROBIOLOGY

Journal of
Clinical Microbiology®

Comparison of the Alere i Strep A Test and the BD Veritor System in the Detection of Group A *Streptococcus* and the Hypothetical Impact of Results on Antibiotic Utilization

Gregory J. Berry,^{a*} Catherine R. Miller,^a Mariana Moreno Prats,^a Christopher Marquez,^a Olajumoke O. Oladipo,^{a*} Michael J. Loeffelholz,^a John R. Petersen^a

^aDepartment of Pathology, University of Texas Medical Branch, Galveston, Texas, USA

- **BD Veritor System (lateral flow immunoassay):**

Sn = 76.2%; Sp = 93.6%

- **Alere i Strep A Test (NAAT):**

Sn = 100 %; Sp = 91.3%

Convenience, at a cost? Pharmacies offering tests and treatment for strep, flu

CTVNews.ca Staff

Published Friday, December 2, 2016 10:00PM EST

Last Updated Monday, December 5, 2016 10:07AM EST



Convenience, at a cost? Pharmacies offering tests and treatment for strep, flu



Convenience, at a cost? Pharmacies offering tests and treatment for strep, flu



Chapter 3

Section **3.07**

Ministry of Health and Long-Term Care

Laboratory Services in the Health Sector

Multiple Concerns Noted:

1. Limited Investigation of Large In-Office Lab Test Volumes and Billings by MDs

- \$2 billion CDN spent on 260 million tests
- \$83 million CDN (4%) spent on in-office lab tests
- 120 FM (<1%) physicians responsible for 50% of tests
- 15 highest billers billed \$600,000 to \$1.4 million CDN on 600,000 to 1.4 million tests (average FM physician billed \$4,700 CDN for 600 tests)

Multiple Concerns Noted:

2. No Licensing and Quality Management of Physicians' In-Office Lab Testing

- Noted in previous audits in 1995 and 2005 but the government has not taken action

POC Accreditation Requirements



Institute for Quality
Management in Healthcare
Centre for Accreditation

Institute for Quality Management in Healthcare (IQMH) ISO 15189 *Plus*™ Point-of-Care Testing Accreditation Requirements

Version 7.1, April 2017

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POC Guidance

MINISTRY OF HEALTH AND LONG-TERM CARE

Point-of-Care Testing Policy

The policy applies to:

1. hospitals with a licensed laboratory,
2. hospitals without a licensed laboratory,
3. long-term care homes.

The policy is supplemented by a **POCT Guidance Document** specific to each type of facility.

Oversight must be completed by laboratory personnel.

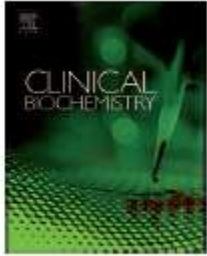
POC Guidance



Contents lists available at [ScienceDirect](#)

Clinical Biochemistry

journal homepage: www.elsevier.com/locate/clinbiochem



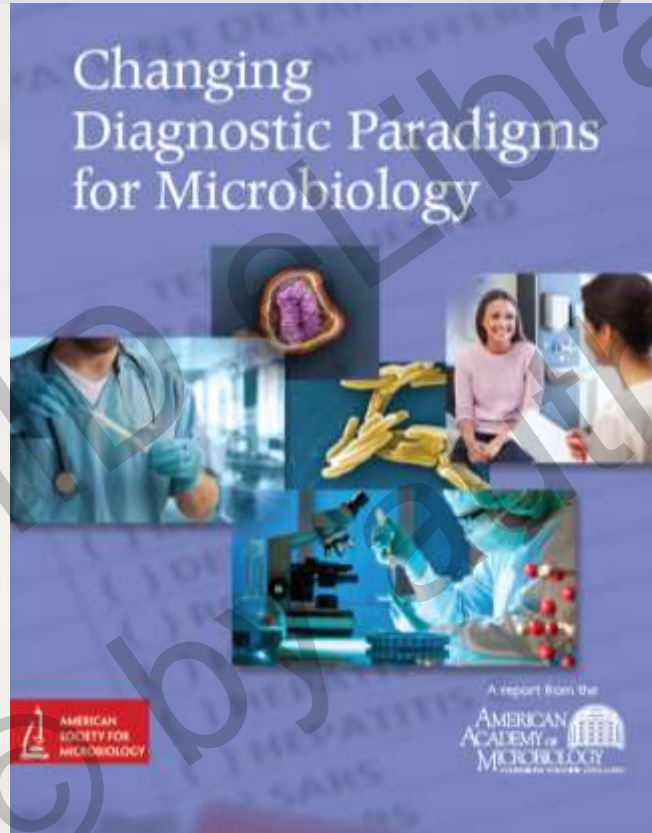
Review

Point-of-care testing: A position statement from the Canadian Society of Clinical Chemists

P.M. Yip^a, A.A. Venner^b, J. Shea^c, A. Fuezery^d, Y. Huang^e, L. Massicotte^f, N. Tetreault^g,
C. Tomalty^h, J.L.V. Shaw^{i,*}



POC Guidance



American Academy of Microbiology Report on POC Microbiology, 2017

POC Guidance



OS147

11:30 – 12:30

Hall R

1-Hour Oral Session

Workflow optimization: methodologies and applications

Chairs

Harald Seifert (Cologne, Germany),

François Vandenesch (Lyon, France)

00731

11:30

National guidelines for implementation of point of care testing for infectious diseases in Denmark

G. Lisby (Hvidovre, Denmark)*



73 microbiology laboratories participating in the IQMH Bacteriology Program:

1. Are any microbiology POC tests being used?

- Inpt: Yes (12%), No (77%), unsure (11%)
- Outpt: Yes (5%), No (77%), unsure (18%)

2. If no, are any POC devices being considered?

- Yes (7%), No (45%), unsure (45%), blank (3%)

3. Were you involved with decision to use POC?

- Yes (12%), No (77%), unsure (11%)



73 microbiology laboratories participating in the IQMH Bacteriology Program:

4. Rationale for bringing in POC?

- Improved TAT (45%), reducing abx use (25%), cost savings (10%)

5. Were in involved with choosing the specific device?

- Yes (60%), No (40%)

6. Was a verification study completed?

- Yes (60%), No (20%), Unsure (20%)



73 microbiology laboratories participating in the IQMH Bacteriology Program:

7. Is there an SOP?

- Yes (80%), No (20%)

8. Is there training?

- Yes (80%), No (20%)

9. Are there competency assessments?

- Yes (70%), No (20%), unsure (10%)



73 microbiology laboratories participating in the IQMH Bacteriology Program:

10. Is there ongoing validation?

- Yes (70%), No (20%), Unsure (10%)

11. Is there maintenance of the POC devices?

- Yes (10%), No (80%), Unsure (10%)

Challenges with Enforcement

- Accreditation requirements and guidelines must be enforced in order to assure POC testing
- Cannot readily be done through the laboratory
- Must reach all healthcare personnel who may be interested in using POC

Possible Solution

- **Consensus guidelines** provided to local professional bodies and hospitals and accreditation bodies
- **Recertification/reappointment requirement** to have documentation of use of POC tests with documentation of consultation with laboratory and registration for proficiency testing with distinct POC license issued



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