Point of care and dried blood spot HCV testing
- a practical introductory workshop

8th September, 2017
Hyatt regency on the Hudson,
Jersey City / New York,
United States.

Co-chairs
Dr Tanya Applegate
The Kirby Institute,
UNSW Sydney Australia

Dr Erika Castro Bataenjer
Centre Hospitalier Universitaire Vaudois
Lausanne, Switzerland
Scope of today’s workshop

• Increase awareness of point of care testing and sample collection

• Discuss principles, advantages, limitations

• Understand what tests are here, what tests are coming

• Share our experiences, lessons learned

• Practical demonstrations

• Open access guidance documents coming soon…..
Today’s workshop

1. Introduction to POC testing

2. Antibody testing using rapid diagnostic tests

3. HCV RNA testing using GeneXpert

4. Dried Blood Spots

5. Concluding remarks

- Followed by Orasure demonstration for those interested

Tanya Applegate
The Kirby Institute, UNSW Sydney, Australia

Jessie Schwartz
NYC Health Department, NY, USA

Francois Lamoury
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The HCV cascade of care

- Living with HCV Infection
- HCV Antibody Diagnosed
- HCV RNA Diagnosed
- Linked to HCV Care
- Liver Disease Assessed
- Initiated HCV Treatment
- Cure (SVR)

The HCV cascade of care

- Living with HCV Infection
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- HCV RNA Diagnosed
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- Initiated HCV Treatment
- Cure (SVR)

70M

<20% know their status
WHO 2030 HCV elimination goals

Target: 90% diagnosed

70M

Target: 80% treated
Increased access to diagnostics – our next challenge

Living with HCV Infection
HCV Antibody Diagnosed
HCV RNA Diagnosed
Linked to HCV Care
Liver Disease Assessed
Initiated HCV Treatment
Cure (SVR)

Prevention

Diagnostics

Drugs

$
Increased access to diagnostics – how?

Collaborative partnerships – everyone has a role
1. A quick introduction – point of care testing
How is testing for HCV done now?

Centralized testing

<table>
<thead>
<tr>
<th>Visit #1</th>
<th>Visit #2</th>
<th>Visit #3</th>
<th>Visit #4</th>
<th>Visit #5</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCV antibody (Physician)</td>
<td>Phlebotomy (Phlebotomist)</td>
<td>Receive diagnosis (Physician)</td>
<td>Phlebotomy (Phlebotomist)</td>
<td>Diagnosis (Physician)</td>
</tr>
</tbody>
</table>

- **Visit #1**: HCV antibody test (Physician)
- **Visit #2**: Phlebotomy (Phlebotomist)
- **Visit #3**: Receive diagnosis (Physician)
- **Visit #4**: Phlebotomy (Phlebotomist)
- **Visit #5**: Diagnosis (Physician)

**Central lab**

**Small labs**

**Clinics**

**Increased time, visits and loss of follow up**
How is testing for HCV done now?

Centralized testing

Visit #1
HCV antibody (Physician)

Visit #2
Phlebotomy (Phlebotomist)
Antibody test 1-2 weeks

Visit #3
Receive diagnosis (Physician)
Reflex RNA

Visit #4
Phlebotomy (Phlebotomist)
Central Lab
RNA test 1-2 weeks

Visit #5
Diagnosis (Physician)

Increased time, visits and loss of follow up
How can this be improved?

Centralized testing

Central lab → Clinics → Small labs

Decentralized services

Take the test to the patient

Outreach → Mobile services → Shelters

Drug and alcohol clinics → Community health centres

Primary health care / GPs

Prisons

NSP services

Sexual health

Take the test to the patient

Point of care testing

Test → Treat → Confirm cure
What are “point of care tests” (POCT) ?

A test performed near the patient that changes patient care

Benefits?

– Rapid, simple collection method (finger-prick, oral)
– Enables screening or diagnosis
– Facilitates single visit diagnosis and treatment
– Integration into a range of services
– Improves access for people using these services
The World Health Organization

ASSURED guidelines for POCTs

1. Affordable (for populations at risk)
2. Sensitive
3. Specific
4. User-friendly (simple to perform in a few steps with minimal training)
5. Rapid & Robust (results available in less than 30 minutes)
6. Equipment-free
7. Deliverable to those who need them

---

Remind me again…what is “sensitivity and specificity”?

**Sensitivity**  = true positive result ++++

Ability to correctly identify those with the disease

**Specificity**  = true negative result ++++

Ability to correctly identify those without the disease
What tools might make it easier to get tested?

Visit #1
Rapid anti-HCV antibody test
(Health care worker)

#2
Phlebotomy
(Phlebotomist)

#3
Receive diagnosis
(Physician)

Central Lab
RNA test
1-2 weeks

Jessie Schwartz
What tools might make it easier to get tested?

Visit #1

Rapid anti-HCV antibody test
(Health care worker)

#2

Phlebotomy
(Phlebotomist)

Central Lab
Antibody test
1-2 weeks

#3

Receive diagnosis
(Physician)

Dried blood spot sample
(Health care worker)

Central Lab
Ab / reflex RNA test
1-2 weeks

Receive diagnosis
(Physician)

Tanya and Erika
What tools might make it easier to get tested?

Visit #1
Rapid anti-HCV antibody test
(Health care worker)

Visit #2
Phlebotomy
(Phlebotomist)

Visit #3
Receive diagnosis
(Physician)

Dried blood spot sample
(Health care worker)

Central Lab
Antibody test 1-2 weeks

Central Lab
Ab / reflex RNA test 1-2 weeks

POC HCV RNA and diagnosis
(Health care worker)

Francois Lamoury
Accessing quality tests – approvals and registration

- **Sample type** (eg. plasma, serum, whole blood, capillary, saliva, DBS)
- **Intended use** (screening, diagnosis, monitoring)

In country procurement, price negotiations and access

Jessie Schwartz, RN, MPH

Clinical Coordinator, Viral Hepatitis Program
New York City Health Department
HCV antibody testing using “Rapid Diagnostic Tests”

• Test kit detect antibodies to HCV (anti-HCV) produced by the body’s immune system – the majority of persons will develop antibodies within 8 weeks of exposure

• Kits can use blood or oral (not in the U.S.) specimens for diagnosis

• Hepatitis C viral testing to confirm infection is crucial; in NYC as many as 50% with a positive anti-HCV test do not have active infection
  – Natural clearance of virus (15-25%)
  – Successful treatment
  – False positives
# Many Rapid anti-HCV antibody Diagnostic Tests

<table>
<thead>
<tr>
<th>Test name</th>
<th>Manufacturer</th>
<th>Country</th>
<th>Certification</th>
</tr>
</thead>
<tbody>
<tr>
<td>SD Bioline HCV</td>
<td>Standard Diagnostics, Inc</td>
<td>South Korea</td>
<td>WHO; CE</td>
</tr>
<tr>
<td>OraQuick HCV Rapid Antibody Test</td>
<td>OraSure Technologies, Inc</td>
<td>USA</td>
<td>WHO, FDA; CE</td>
</tr>
<tr>
<td>HCV Card</td>
<td>Axiom Diagnostics</td>
<td>Germany</td>
<td>CE</td>
</tr>
<tr>
<td>ImmunoFlow HCV</td>
<td>Core Diagnostics</td>
<td>UK</td>
<td>CE</td>
</tr>
<tr>
<td>Hepa-Scan HCV card test</td>
<td>Bhat Biotech</td>
<td>India</td>
<td>CE</td>
</tr>
<tr>
<td>Toyo anti-HCV test</td>
<td>Türklab A.S.</td>
<td>Turkey</td>
<td>CE</td>
</tr>
<tr>
<td>Signal HCV</td>
<td>SPAN Diagnostics Ltd</td>
<td>India</td>
<td>CE</td>
</tr>
<tr>
<td>HCV TOP</td>
<td>BioSynex S.A.</td>
<td>France</td>
<td>CE</td>
</tr>
<tr>
<td>OneStep HCV Rapid Test</td>
<td>Span Biotech Ltd</td>
<td>China</td>
<td>CE</td>
</tr>
<tr>
<td>HCV Rapid Test</td>
<td>UAB Euro Genomas</td>
<td>Lithuania</td>
<td>CE</td>
</tr>
<tr>
<td>Hepatitis C Antibody Test</td>
<td>Artron Laboratories</td>
<td>Canada</td>
<td>CE</td>
</tr>
<tr>
<td>Diaquick HCV Cassette</td>
<td>Dialab GmbH</td>
<td>Austria</td>
<td>CE</td>
</tr>
<tr>
<td>MultiSure HCV</td>
<td>MP Biometicals,</td>
<td>Singapore</td>
<td></td>
</tr>
<tr>
<td>First Response HCV Card Test</td>
<td>Premier Medical Corporation Ltd</td>
<td>India</td>
<td></td>
</tr>
<tr>
<td>VEDA.LAB HCV</td>
<td>VEDA.LAB, Alençon</td>
<td>France</td>
<td></td>
</tr>
</tbody>
</table>

Note – list is incomplete!
Two Rapid Diagnostic Tests are WHO prequalified

OraQuick HCV Rapid Antibody Test (OraSure Technologies, Inc)

- **WHO sample type**: oral fluid, fingerstick whole blood, venipuncture whole blood, plasma specimens (EDTA, sodium heparin, lithium heparin, and sodium citrate), and serum (serum separator tube (SST)).
- **CE-marked**: as above.
- **FDA-approved**: All samples except oral in US

SD Bioline (Standard Diagnostics, Inc)

- **WHO sample type**: human serum, plasma (heparin, EDTA and sodium citrate) or venous whole blood. (not fingerstick)
- **CE-marked and FDA-approved** – all samples (not fingerstick)
How to use a Rapid anti-HCV antibody Diagnostic Test

Collect blood or...

...oral sample

Insert device into or add buffer solution

Read results in 20-40 minutes
Hepatitis C in New York City

- Largest city in the United States

- Estimated that around 146,500 are living with chronic hepatitis C infection

- Up to 50% not aware of their status

- Highest rates in very high poverty neighborhoods

- Prevalence 71% in persons who inject drugs

- 1.2% increase in rates of newly reported HCV infection in adults aged 20-29 between 2005 - 2015

New York City Hepatitis C Care Cascade (2013)

- Current HCV infection: 146,500
- Aware of infection status: 73,250
- Referred to clinical evaluation: 58,600
- Eligible to be treated: 31,050
- Treated: 19,255
- Sustained virological response: 9,630
New York City Hepatitis C Care Cascade (2013)

Is this an appropriate goal for a Hep C rapid test program?
New York City Hepatitis C Care Cascade (2013)

Is this an appropriate goal for a Hep C rapid test program?

......Or is this??
NYC Hep C Peer Navigation

at Syringe Exchange Programs

• Part time peer navigators support people at risk or living with Hep C to complete Hep C testing, link or return to medical care, and prevent infection or re-infection

• Implemented at 15 NYC syringe exchange and harm reduction programs affiliated with Injection Drug User Health Alliance (IDUHA)
Demographics

Gender:
- 65% male
- 26% female
- 7% transgender

Race & ethnicity:
- 40% Latinx
- 33% Non-Hispanic Black

Age:
- 51% 30 – 50 years old
- 32% 51 – 71 years old
- 16% 29 years or younger

Psychosocial factors*:
- 74% mental health issue
- 65% homeless or unstably housed
- 61% have injected drugs

42% not aware of Hep C status at intake

*Source: IDUHA Citywide Evaluation Study, 2015 Report
NYC Hep C Peer Navigation Program

Implemented at 15 NYC syringe-exchange and harm reduction programs (all with rapid test programs)

Overall Program Outcomes: December 2014 – March 2017

* Hepatitis C education and prevention services provided
Tips - local implementation of Rapid HCV test programs

1. Set clear & measurable programmatic goals
2. Create a registry of hepatitis C patients & track health outcomes
3. Identify appropriate referral sites & providers for your client population
4. Provide active referrals (i.e. make appointments for clients) - do not expect clients to do this independently
5. Use a team-based approach – avoid isolating your hepatitis C testing programs
6. Coordinated mental health, substance use, and hepatitis treatment services can increase hepatitis C treatment uptake, adherence, and cure

Questions?

Contact:
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347-396-2627
Hepfree.nyc
3. HCV RNA testing on the GeneXpert

François Lamoury

Research Officer
Viral Hepatitis and Clinical Research Program
The Kirby Institute, UNSW Sydney
Xpert® HCV Viral Load assay

- Automated, self-contained, single use, random access
- European CE-IVD, WHO pre-qualified (plasma only)
- Single platform for integration (HIV, HPV, TB)
- Minimal training, fast (108min)
- Multiple configurations

- Not available in all countries
- Cost - pricing per test and platform access.
Method: Plasma versus finger-stick samples

**Venous whole blood**

- **Xpert® HCV Viral Load**
  - 1. Collect *venous whole blood* by venepuncture
  - 2. Centrifuge
  - 3. Load *1.2mL plasma* into Xpert® HCV Viral load cartridge
  - 4. Result in 108min ("fast")
    - WHO pre-qualified
    - CE - IVD marked
    - Not yet available in the US

**Finger-stick capillary blood**

- **Xpert® Fingerstick HCV Viral Load**
  - 1. Collect *100µL capillary blood* by finger-stick into a Minivette
  - 2. Load *100µL capillary blood* into Xpert® Fingerstick HCV Viral load cartridge
  - 3. Result in 58min ("rapid")
    - Research Use only
    - Not registered
    - Targeted availability 2018
### Examples

#### Lancet Types – Push Button Activated

| MiniCollect® safety | Lancet type: Blade and Needle options available. Blade Depth: - 1.8 mm (Green); - 1.8 mm (Purple); Needle gauge: - 22G penetration depth 2.2 mm (Orange) | Activation: Push button activation. Product Ref: C8054B www.inhsu.com
|--------------------|---------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

| Haemolancet Plux® | Lancet type: Blade and Needle options available. Blade Depth: - 1.8 mm (Green); - 1.8 mm (Purple) | Activation: Push button activation. Product Ref: HA8054B www.inhsu.com
|--------------------|---------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

#### Lancet Types – Contact Activated

| BD Microtainer® contact activated | Lancet type: Blade and Needle options available. Blade Depth: - 0.5 mm Blade Width: - 0.5 mm (Blue); - 1.0 mm (Green) | Activation: Contact activated. Product Ref: 380594 (Blue) www.bd.com/micronainer
|------------------------------------|---------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

| Medilance® Safety lancets | Lancet type: Blade and Needle options available. Blade Depth: - 0.5 mm Blade Width: - 0.5 mm (Yellow); - 1.0 mm (Green) | Activation: Contact activated. Product Ref: 380594 (Blue) www.medilance.com
|-----------------------------|---------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

| Sterilance® Lite 2 | Lancet type: Blade and needle options available. Blade Depth: - 1.8 mm (Green); Needle gauge: - 22G penetration depth 2.2 mm (Orange) | Activation: Push button activation. Product Ref: 56.10.002 www.pathtech.com.au
|---------------------|---------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

| Sterilance® press 2 | Lancet type: Blade and needle options available. Blade Depth: - 1.8 mm (Green) | Activation: Contact activated. Product Ref: 56.05.002 www.pathtech.com.au
|---------------------|---------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

#### Safety Lancets

| SARSTE® Safety | Lancet type: Blade and Needle options available. Blade Depth: - 1.8 mm (Green); - 1.8 mm (Purple) | Activation: Push button activation. Product Ref: 380594 www.medilance.com
|-----------------|---------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

| Curity™ Sheer Adhesive Bandage | Lancet type: Blade and Needle options available. Blade Depth: - 1.8 mm (Green); - 1.8 mm (Purple) | Activation: Push button activation. Product Ref: 380594 www.medilance.com
|-------------------------------|---------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

| Bremarphan® Skin Cleansing Swabs | Lancet type: Blade and Needle options available. Blade Depth: - 1.8 mm (Green); - 1.8 mm (Purple) | Activation: Push button activation. Product Ref: 380594 www.medilance.com
|----------------------------------|---------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

| Lab Bench Coat | Lancet type: Blade and Needle options available. Blade Depth: - 1.8 mm (Green); - 1.8 mm (Purple) | Activation: Push button activation. Product Ref: 380594 www.medilance.com
|-----------------|---------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

| Multigate® Sterile Cotton Balls | Lancet type: Blade and Needle options available. Blade Depth: - 1.8 mm (Green); - 1.8 mm (Purple) | Activation: Push button activation. Product Ref: 380594 www.medilance.com
|-------------------------------|---------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

### INHSU Sydney 2017

August 2017 - version 1.0
Xpert® Fingerstick HCV Viral Load assay

(Not available for diagnostic use)

Consumables
- Lab Bench coat
- SARSTEDT® Safety Lancet Super
- MULTIGATE® sterile Cotton Balls
- Curity™ Sheer Adhesive Bandage
- Minivette® POCT 100µl K3E
- BRIEMARPAK® Skin Cleansing Swabs
- Examination Gloves

Choice

Fingerstick capillary blood collection and sample loading

1. Lab Bench coat
2. SARSTEDT® Safety Lancet Super
3. MULTIGATE® sterile Cotton Balls
4. Curity™ Sheer Adhesive Bandage
5. Minivette® POCT 100µl K3E
6. BRIEMARPAK® Skin Cleansing Swabs
7. Examination Gloves
Demonstration of capillary blood by fingerstick and minivette collection for the GeneXpert
4. Dried Blood Spot sampling and testing

Tanya Applegate
Senior Lecturer
The Kirby Institute,
UNSW Sydney Australia

Erika Castro
Head of Internal Medicine in Addiction clinic
Centre Hospitalier Universitaire Vaudois
Lausanne, Switzerland
What are Dried blood Spots (DBS)?

Centralized testing

Decentralized services
What are the pros and cons of DBS?

<table>
<thead>
<tr>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>✔️ Linkage to care</td>
<td>✗ Low sample volume</td>
</tr>
<tr>
<td>✔️ Easy and inexpensive to collect</td>
<td>✗ Reduced sensitivity</td>
</tr>
<tr>
<td>✔️ No medical training required</td>
<td>✗ Analyte degradation can occur</td>
</tr>
<tr>
<td>✔️ Facilitate access</td>
<td>✗ Centralised testing in specialized lab</td>
</tr>
<tr>
<td>✔️ Self-collection possible at home</td>
<td>✗ Processing, storage</td>
</tr>
<tr>
<td>✔️ Reflex testing (no second test)</td>
<td>✗ Cost (?? country dependent)</td>
</tr>
<tr>
<td>✔️ RNA, Ab (including RDT), core antigen</td>
<td>✗ No registered tests for clinical use</td>
</tr>
</tbody>
</table>
How are dried blood spots collected?

Consumables

- Bench coat
- Safety Lancet
- Sterile Cotton Balls
- Adhesive Bandage
- Alcohol Cleansing Swabs
- Gloves
- Whatman® 903 protein saver card
- Humidity Indicator card
- Absorbent packets
- Whatman® Foil barrier bags

Fingerstick capillary dried blood spot collection

1. Wear gloves
2. Apply lancet
3. Prick finger
4. Collect drops
5. Dry spot
6. Apply pressure
7. Inspect drop
8. Transfer to card
9. Seal card
10. Store in appropriate packaging

Bench coat
Safety Lancet
Sterile Cotton Balls
Adhesive Bandage
Alcohol Cleansing Swabs
Gloves
Whatman® 903 protein saver card
Humidity Indicator card
Absorbent packets
Whatman® Foil barrier bags

How are dried blood spots collected?

- Whatman® 903 protein saver card
- Humidity Indicator card
- Absorbent packets
- Whatman® Foil barrier bags
Open access resources / videos – available soon

**HCV DRIED BLOOD SPOT (DBS) COLLECTION GUIDE**

1. **ASSEMBLE DBS CONSUMABLES**
   - Whatman® 903 protein saver card
   - Whatman® Foil barrier reusable bags
   - SARSTEDT® Safety Lancer Super
   - BRIEMLAP® Skin Cleaning Swabs
   - Clarant Humidity Indicator card
   - Minipak® absorbent packets
   - MULTIGATE® sterile Cotton Balls
   - Curity™ Sheer Adhesive Bandage
   - Examination Gloves
   - Lab Bench Coat

2. **PATIENT ASSESSMENT AND PREPARATION**
   - Ask patient to warm hands by rubbing together
   - Increase circulation by doing fist clenches
   - Massage to further help blood flow
   - Best practice is to use the middle ring finger of the non-dominant hand
   - Assess suitable fingers

3. **SITE CLEANING AND DISINFECTION**
   - Use 1st swab Clean the finger well moving in both directions
   - Use 2nd swab to disinfect in a single stroke

4. **PERFORMING FINGERSTICK AND DBS COLLECTION**
   - Do not touch the spots with bare fingers to avoid contamination
   - Open pre-labelled protein saver card. Do not touch the spots with bare fingers to avoid contamination
   - Position the hand flat on the surface
   - Show and explain to the patient that the lancet is unused then break seal
   - Determine the best site for taking the sample which is either side of the midline of the finger
   - Hold lancet firmly against finger on the side closest to the little finger and press the button
   - Wipe away the first blood drop
   - Apply gentle pressure and allow a drop of blood to form and fall onto the card. Continue until five spots are collected. DO NOT DAB FINGER ONTO THE CARD.
   - Stop blood flow by applying pressure for 5 minutes and place spot band on finger

5. **DRYING AND PACKING OF DBS FOR TRANSPORT**
   - Dry cards horizontally in a DBS drying rack for minimum 4 hrs or overnight
   - Close flap on DBS card insert into a sealable foil bag then add humidity indicator card + two absorbent packs. Apply pressure to ensure air is expelled from foil bag prior to sealing

6. **STORAGE OF DBS CARDS**
   - Sealed foil bags can be stored at room temperature away from sunlight and moisture in a cool, dry environment for up to 14 days before sending in standard postal envelope to a central reference laboratory

**References:**
   http://www.who.int/diagnostics_laboratory/docs/guidance/pm_module14.pdf
   http://apps.who.int/iris/bitstream/10665/75826/1/WHO_HIV_2012.30_eng.pdf?ua=1
What makes a good DBS?

Scoring DBS – valid / invalid

**Quantity**

DBS quantity encompasses both the number of DBS collected (i.e., number of DBS collected out of maximum of 5) and the amount of blood collected on the filter paper (i.e., whether the area was fully covered with blood, half, spotted etc.). This information must be recorded on the DBS receipt log and if necessary must be described on the "DBS quantity comment" section.

<table>
<thead>
<tr>
<th>DBS Quantity</th>
<th>Image</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><img src="image1.png" alt="Image" /></td>
<td>Sufficient</td>
</tr>
<tr>
<td></td>
<td><img src="image2.png" alt="Image" /></td>
<td>Insufficient</td>
</tr>
<tr>
<td>Front view</td>
<td><img src="image3.png" alt="Image" /></td>
<td>Not soaked through</td>
</tr>
</tbody>
</table>

**Quality**

DBS quality determines whether a DBS specimen is valid or invalid. The laboratory receiving the DBS specimen must classify whether a sample is considered valid or invalid. In the case that a specimen is classified as invalid, it is important that the reason for such classification is indicated. Please refer to the images below when recording the DBS specimen quality score. Use the scoring code indicated in this guide in filling out the DBS receipt log.

<table>
<thead>
<tr>
<th>DBS Quality score</th>
<th>Image</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td><img src="image4.png" alt="Image" /></td>
<td>Insufficient quantity for testing</td>
</tr>
<tr>
<td>2</td>
<td><img src="image5.png" alt="Image" /></td>
<td>Specimen is scratched or abraded</td>
</tr>
<tr>
<td>3</td>
<td><img src="image6.png" alt="Image" /></td>
<td>Specimen was not dry before mailing</td>
</tr>
<tr>
<td>4</td>
<td><img src="image7.png" alt="Image" /></td>
<td>Specimen is supersaturated</td>
</tr>
<tr>
<td>5</td>
<td><img src="image8.png" alt="Image" /></td>
<td>Specimen appears dilute, discoloured or contaminated</td>
</tr>
<tr>
<td>6</td>
<td><img src="image9.png" alt="Image" /></td>
<td>Specimen exhibit serum separating from cells may also appear as serum rings</td>
</tr>
<tr>
<td>7</td>
<td><img src="image10.png" alt="Image" /></td>
<td>Specimen appears to be clotted or layered</td>
</tr>
<tr>
<td>8</td>
<td><img src="image11.png" alt="Image" /></td>
<td>Specimen obtained with incorrect filter paper</td>
</tr>
<tr>
<td>9</td>
<td><img src="image12.png" alt="Image" /></td>
<td>No blood spot was added</td>
</tr>
</tbody>
</table>
Tips to improve DBS collection

- The best place middle or 4th finger
  - Non-dominant hand

- Prick the finger on the side (not on the pad).
  - Nearest the little finger (to help the next steps)

- Let the blood accumulate until a drop forms.
  - You can encourage blood flow
    - “To milk or not to milk?”

- Let the blood drop where possible
DBS collection demonstration
How are DBS stored and tested?

**Storage**
1. Intact card (Research)
2. Punch / elute (Service provider)
   - Foil bag
   - Eluate stored
   - Drawers
   - -70 freezer

**Testing**
1. Punch
2. Elute
   - HCV RNA assays (research use only)
   - Panther system (Hologic)
   - m2000sp/rt (Abbott)
   - AmpliPrep / COBAS Taqman (Roche)
HCV RNA quantification on DBS

A concept of proof in Swiss settings
Disclosure

This study was co-sponsored with an unrestricted grant of Gilead.
HCV RNA quantification on DBS – A Swiss study

Nested projects 2018

Multicenter Validation 2017

Local DBS lab standard 2016

- Expand virologic applications
- Run monitoring surveys
- Compare external HCV RNA plasma standards to local DBS lab standard
- Integrate DBS HCV RNA analysis to local lab standards as a routine test
A Swiss case study – why?

Why HCV screening with DBS in tertiary referral hospital?
A Swiss case study - background

The need of optional blood collection strategies for people who inject drugs with difficult venous

- Poor vascular health consecutive to years of intravenous drug injection is a common constraint.

- Routine limb vein puncture can become a barrier for screening and treatment of HCV infection.
Hepatitis C Virus RNA quantitation using DBS

Erika Castro, Rachel Mamin, Cyril Andre, Lorenza Oprandi

HCV RNA quantification:

COBAS® AmpliPrep/COBAS® TaqMan® HCV Quantitative Test v2.0.
Conclusions

- We found a positive and strong correlation of patient’s DBS and plasma/EDTA HCV viremia values.

- In this dataset EDTA plasma RNA average was 5.16 log (range: 1.17 - 6.85) with a limit detection value of 1.17 log (≤15 IU/mL).

- DBS RNA detection limit was 2.69 log (480 IU/mL).
HCV RNA quantification on DBS:
A proof of concept in Swiss settings

Small dataset...to argue for quantitative use.
HCV RNA quantification on DBS:
A proof of concept in Swiss settings

Nested projects
2018
- Expand virologic applications
- Run monitoring surveys

Multicenter Validation
2017
- Compare external HCV RNA plasma standards to novel DBS lab standard

Local DBS lab standard
2016
- Integrate DBS HCV RNA testing to local lab standards as a routine test

HCV RNA quantification on DBS:
A proof of concept in Swiss settings
HCV RNA quantification on DBS:
A proof of concept in Swiss settings

1. CHUV: DBS central lab + Addiction medicine clinic
2. Unité de traitement des addictions, Dr Laurianne Mer.
3. Fondazione Epatocentro Ticino, Dr Alberto Morighia.
A Cost-Effectiveness Analysis of Increasing Hepatitis C Virus Screening in People Who Inject Drugs in Switzerland Using Rapid Antibody Saliva and Dried Blood Spot Testing

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- Cost-effective due to the increased screening uptake via rapid saliva and DBS testing instead of venipuncture.

- The proposed test package is less expensive than venipuncture.

- Would likely increase the number of diagnoses and result in a greater number of PWID initiating treatment.
6. Closing remarks

Point of care testing strategies can globally:

- Scale-up HCV screening/monitoring in LMIC and HIC
- Improve linkage to care
- Be adapted to settings’ needs
- Enhance collaborative partnerships
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Orasure for providing training today

Thanks in advance……Abbott, Hologic and Roche for pushing DBS registration!
Orasure demonstration – for those who are keen.