TUNISIE

HAMMAMET

du 28 au 30 sept. 2017

www.aframed2017.org

2e édition

AFRAMED

VIH / HÉPATITES

AFRAVIH

AFRAMED VIH/HÉPATITES
HAMMAMET, 28-30 SEPTEMBRE 2017

Atelier de Virologie

Tests de dépistage

JC Tardy (France)

N.Hannachi (Tunisie)

Qui dépister

World Health Organization

GUIDELINES
ON HEPATITIS B AND C TESTING

FEBRUARY 2017

Table 17.1. Potential populations and programmes for integration to promote hepatitis testing

Disease	High-risk groups and potential programme integration
Hepatitis B	• Infants of infected mothers (delivery units, maternal and child health [under-5 and immunization] clinics) • Children in endemic regions (maternal and child health [under-5 and immunization] clinics) • Sexual transmission in adults (STI and HIV clinics) • People who inject drugs (harm reduction and drug treatment services) • Health-care workers (occupational health)
Hepatitis C	• People who have received unsafe therapeutic injections/blood products (health promotion) • People who inject drugs (harm reduction and drug treatment services) • Men who have sex with men (STI and HIV clinics) • Health-care workers (occupational health)

HAUTE AUTORITÉ DE SANTÉ

SYNTHÈSE DE LA RECOMMANDATION EN SANTÉ PUBLIQUE

Réévaluation de la stratégie de dépistage de l'infection à VIH en France

Mars 2017

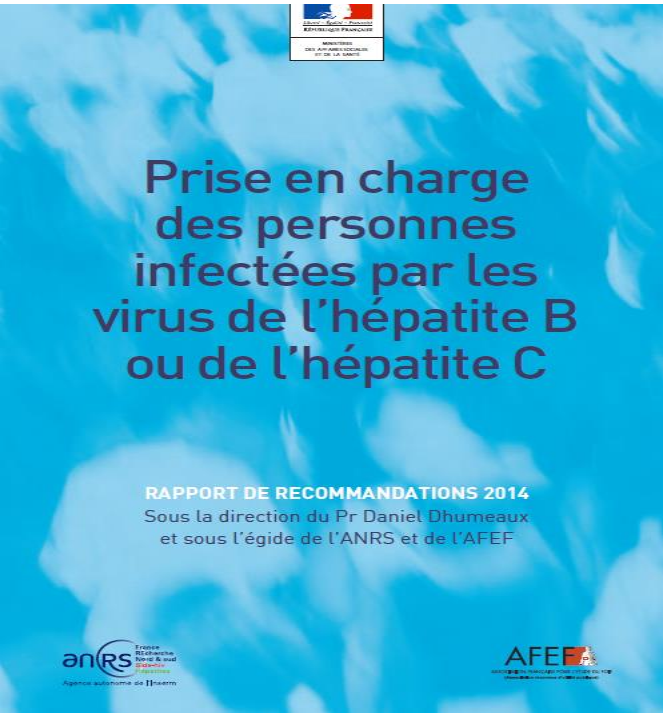
générale âgée de 15 à 70 ans « au moins une fois dans la vie » lors d'un recours aux soins, en dehors de toute notion d'exposition à un risque de contamination par le VIH. Elles préconisaient aussi le renforcement d'un dépistage ciblé et

Messages clés

- La priorité doit être accordée au dépistage de l'infection à VIH au sein des populations clés. Il convient ainsi de renforcer la fréquence du dépistage dans ces populations :
  - tous les 3 mois chez les HSH ;
  - tous les ans chez les UDI ;
  - tous les ans chez les personnes originaires de zones de forte prévalence de l'infection à VIH, notamment d'Afrique subsaharienne et des Caraïbes.

Qui dépister

France: ANRS /AFEF/HAS 2014



Recommandations

1. **Poursuivre une stratégie de dépistage ciblé des infections virales B et C en fonction des facteurs de risque de contamination** comme cela est actuellement recommandé, mais associer à cette stratégie une information de grande ampleur de la population générale et des médecins généralistes. Cette action pourrait s'inscrire dans le cadre du contrat d'objectifs et de moyens entre l'Union nationale des caisses d'assurance maladie et l'État et faire l'objet d'un objectif de santé publique proposé à chaque médecin.
2. **Élargir les stratégies de dépistage aux populations suivantes :**
   – hommes âgés de 18 à 60 ans,
   – femmes enceintes dès la première consultation prénatale,
   en évaluant régulièrement ces stratégies.
3. **Associer dans tous les cas la recherche des trois virus VHB, VHC et VIH,** compte tenu des similitudes épidémiologiques et de la possibilité et de l'intérêt de tests groupés.

World Health Organization

GUIDELINES
ON HEPATITIS B AND C TESTING

FEBRUARY 2017

Hépatite B

WHO TO TEST FOR CHRONIC HBV INFECTION

Testing approach and population	Recommendations*
General population testing	1. In settings with a ≥2% or ≥5%[1] HBsAg seroprevalence in the general population, it is recommended that all adults have routine access to and be offered HBsAg serological testing with linkage to prevention, care and treatment services. General population testing approaches should make use of existing community- or health facility-based testing opportunities or programmes such as at antenatal clinics, HIV or TB clinics. *Conditional recommendation, low quality of evidence*
Routine testing in pregnant women	2. In settings with a ≥2% or ≥5%%[1] HBsAg seroprevalence in the general population, it is recommended that HBsAg serological testing be routinely offered to all pregnant women in antenatal clinics[2], with linkage to prevention, care and treatment services. Couples and partners in antenatal care settings should be offered HBV testing services. *Strong recommendation, low quality of evidence*
Focused testing in most affected populations	3. In all settings (and regardless of whether delivered through facility- or community-based testing), it is recommended that HBsAg serological testing and linkage to care and treatment services be offered to the following individuals: • **Adults and adolescents from populations most affected by HBV infection[3]** (i.e. who are either part of a population with high HBV seroprevalence or who have a history of exposure and/or high-risk behaviours for HBV infection); • **Adults, adolescents and children with a clinical suspicion of chronic viral hepatitis[4]** (i.e. symptoms, signs, laboratory markers); • **Sexual partners, children and other family members, and close household contacts** of those with HBV infection[5]; • **Health-care workers:** in all settings, it is recommended that HBsAg serological testing be offered and hepatitis B vaccination given to all health-care workers who have not been vaccinated previously (*adapted from existing guidance on hepatitis B vaccination*[6]) *Strong recommendation, low quality of evidence*
Blood donors *Adapted from existing 2010 WHO guidance (Screening donated blood for transfusion transmissible infections[7])*	4. In all settings, screening of blood donors should be mandatory with linkage to care, counselling and treatment for those who test positive.

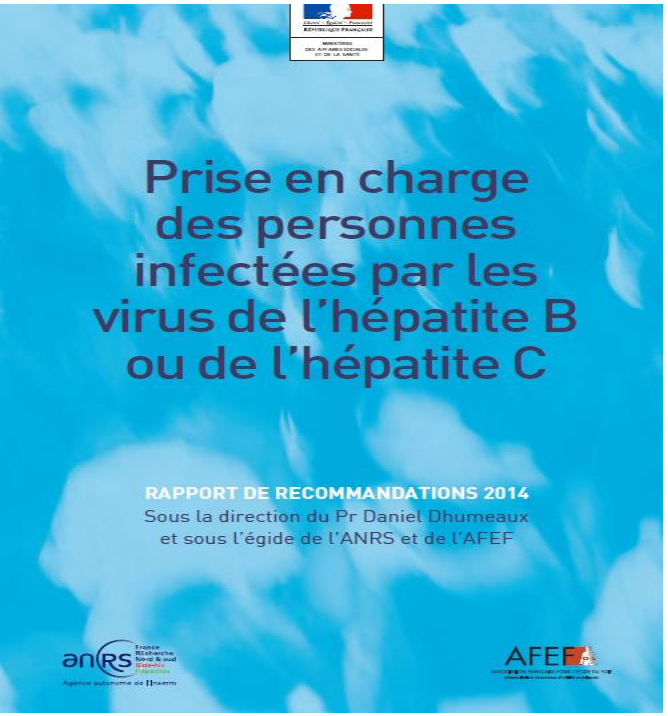
Hépatite C

WHO TO TEST FOR CHRONIC HCV INFECTION

Testing approach and population	Recommendations*
Focused testing in most affected populations	1. In all settings (and regardless of whether delivered through facility- or community-based testing), it is recommended that serological testing for HCV antibody (anti-HCV)[1] be offered with linkage to prevention, care and treatment services to the following individuals: • **Adults and adolescents from populations most affected by HCV infection**[2] (i.e. who are either part of a population with high HCV seroprevalence or who have a history of exposure and/or high-risk behaviours for HCV infection); • **Adults, adolescents and children with a clinical suspicion of chronic viral hepatitis**[3] (i.e. symptoms, signs, laboratory markers). *Strong recommendation, low quality of evidence* *Note: Periodic re-testing using HCV NAT should be considered for those with ongoing risk of acquisition or reinfection.*
General population testing	2. In settings with a ≥2% or ≥5%[4] HCV antibody seroprevalence in the general population, it is recommended that all adults have access to and be offered HCV serological testing with linkage to prevention, care and treatment services. General population testing approaches should make use of existing community- or facility-based testing opportunities or programmes such as HIV or TB clinics, drug treatment services and antenatal clinics[5]. *Conditional recommendation, low quality of evidence*
Birth cohort testing	3. This approach may be applied to specific identified birth cohorts of older persons at higher risk of infection[6] and morbidity within populations that have an overall lower general prevalence. *Conditional recommendation, low quality of evidence*

Quels marqueurs dépister?

France: ANRS /AFEF/HAS 2014



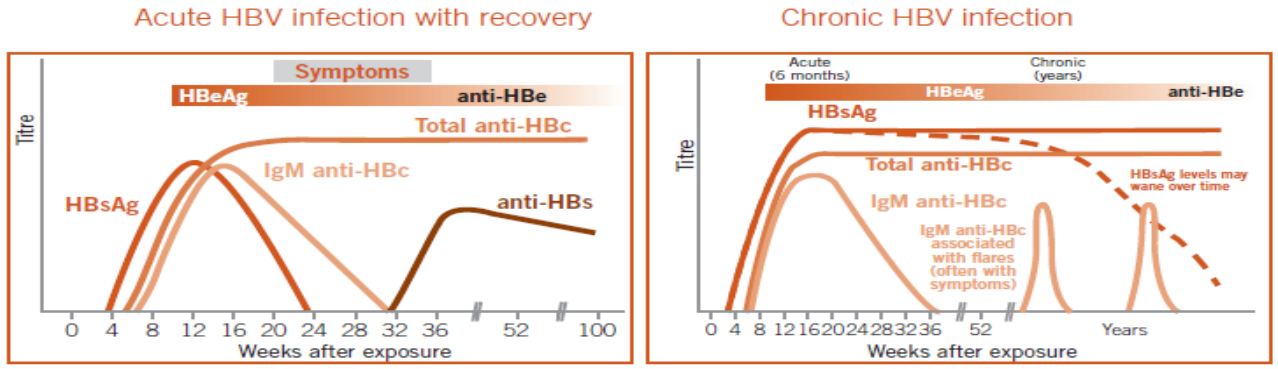
Recommandations

1. **Poursuivre une stratégie de dépistage ciblé des infections virales B et C en fonction des facteurs de risque de contamination** comme cela est actuellement recommandé, mais associer à cette stratégie une information de grande ampleur de la population générale et des médecins généralistes. Cette action pourrait s'inscrire dans le cadre du contrat d'objectifs et de moyens entre l'Union nationale des caisses d'assurance maladie et l'État et faire l'objet d'un objectif de santé publique proposé à chaque médecin.
2. **Élargir les stratégies de dépistage aux populations suivantes :**
   – **hommes âgés de 18 à 60 ans,**
   – **femmes enceintes dès la première consultation prénatale,**
   en évaluant régulièrement ces stratégies.
3. **Associer dans tous les cas la recherche des trois virus VHB, VHC et VIH,** compte tenu des similitudes épidémiologiques et de la possibilité et de l'intérêt de tests groupés.

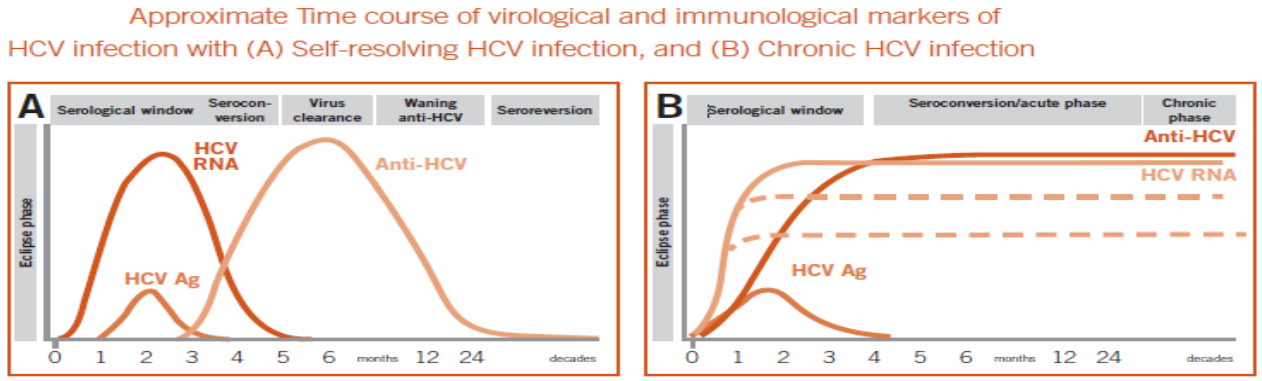
Quels marqueurs dépister?

Ag HBs

En dehors d'un contexte suspect

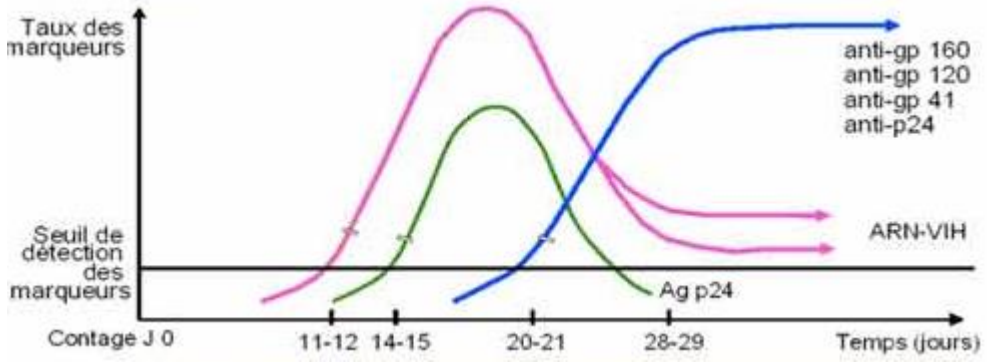


Ac anti-HCV
Marqueur de contact



Age > 18 Mois
(Anticorps maternels)

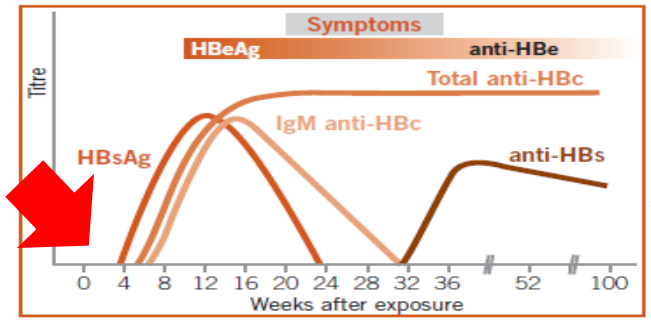
Ac anti-VIH1/VIH2



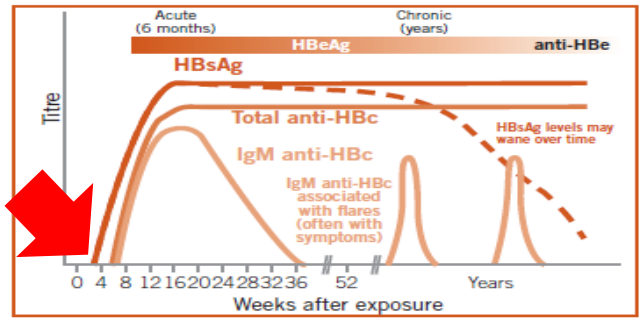
Quels marqueurs dépister?

Fenêtre sérologique virologique

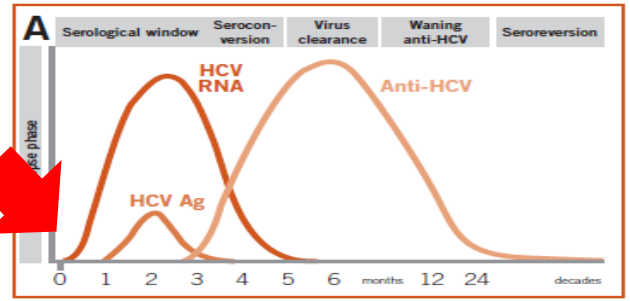
Acute HBV infection with recovery

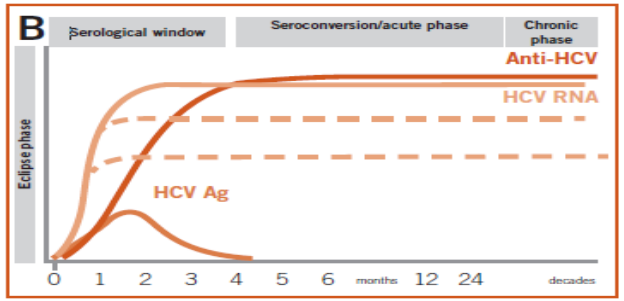


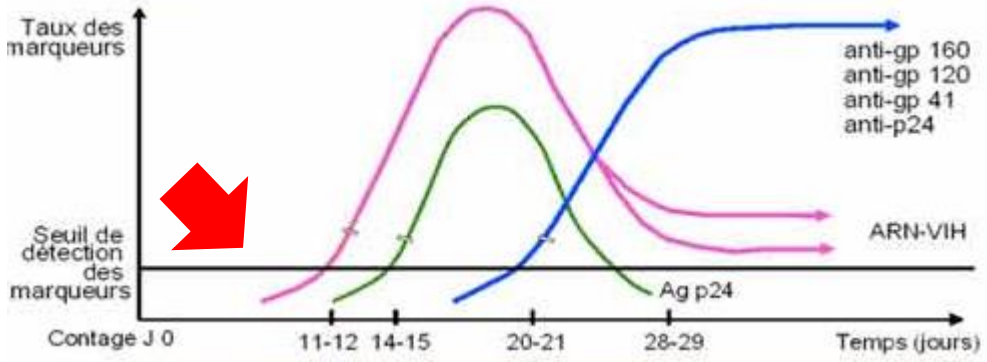
Chronic HBV infection



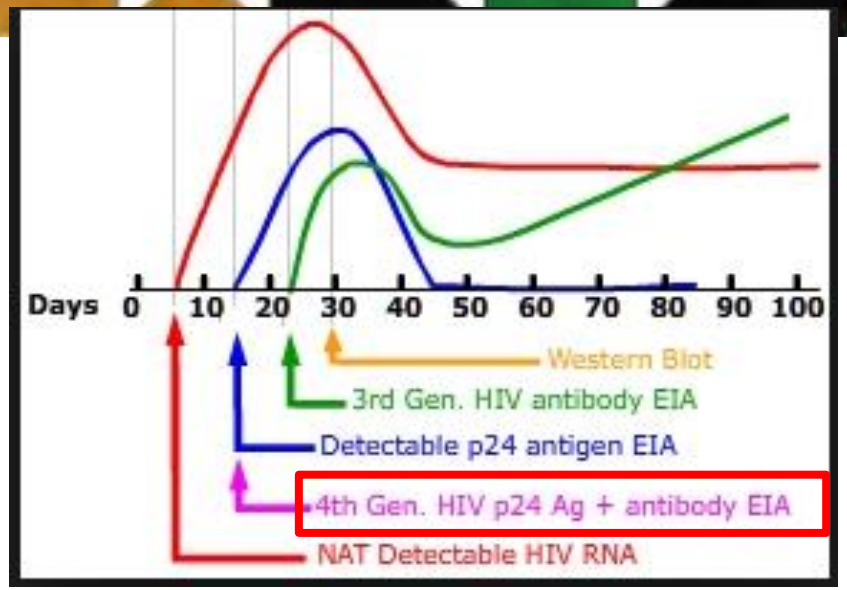
Approximate Time course of virological and immunological markers of HCV infection with (A) Self-resolving HCV infection, and (B) Chronic HCV infection



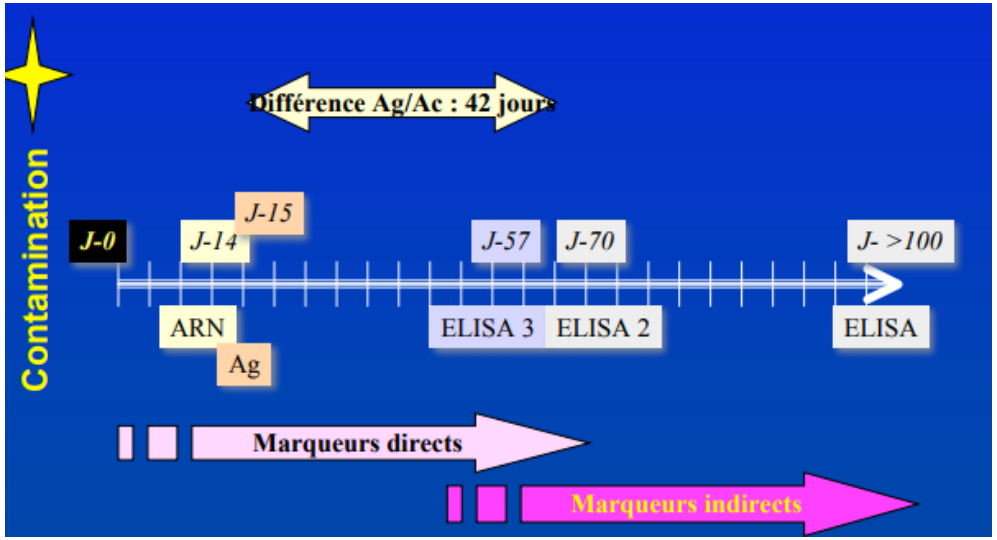




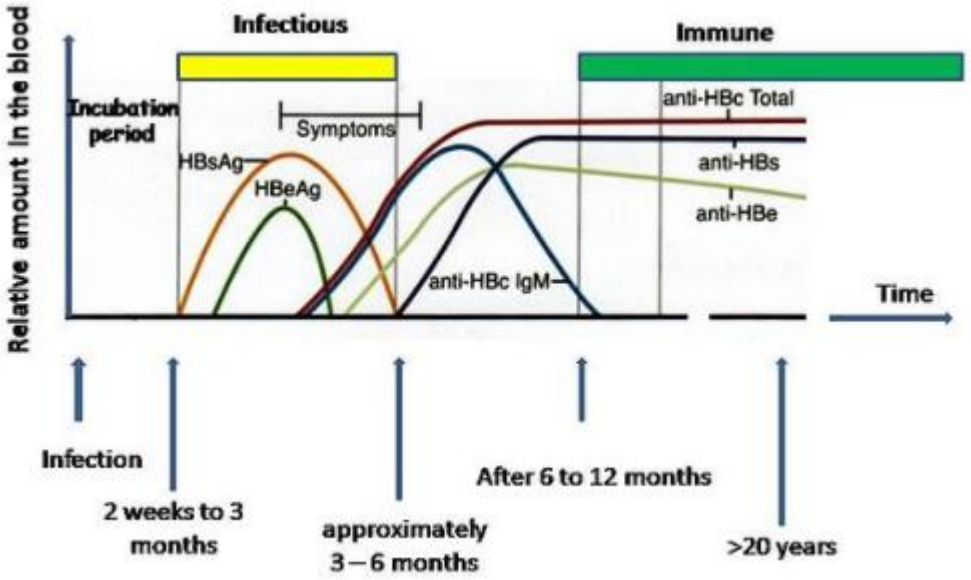
EIA 1.0			c-100-3	
EIA 2.0	c22-3		c-100-3	
EIA 3.0 CIA	c22-c	c33-c	c-100-3	NS5
RIBA 2.0	c22-3	c33-c 5-1-1	c-100-3	
RIBA 3.0	c22-p	c33-c	c-100-p	NS5



4ième génération Ag HCV + Ac anti-HCV



Ag HBs
Sensibilité :
0.13 UI/ ml



ELSEVIER

Available online at www.sciencedirect.com
SCIENCE DIRECT®

Transfusion Clinique et Biologique 11 (2004) 26–32

TRANSFUSION CLINIQUE ET BIOLOGIQUE

www.elsevier.com/locate/tracli

EUROSAT 2003

Should HBV DNA NAT replace HBsAg and/or anti-HBc screening of blood donors?

Le DGV ne devrait-il pas remplacer la recherche d'Ag HBS et/ou d'anti HBC dans le dépistage du virus de l'hépatite B, chez les donneurs de sang?

Michael P. Busch *

Original Article

Asian Journal of Transfusion Science - Vol 9, Issue 1, January - June 2015

Automated nucleic acid amplification testing in blood banks: An additional layer of blood safety

Pragati Chigurupati, K. Srinivasa Murthy[1]

DOI: 10.7860/JCDR/2016/16981.7319

Review Article

Biotechnology Section

Automated Triplex (HBV, HCV and HIV) NAT Assay Systems for Blood Screening in India

Bilan du DGV VIH et VHC en France entre le 01/07/2001 et le 31/12/2014 *(37,0 millions de dons)*

	VIH		VHC	
	N	%	N	%
DGV + / Ac +	428	92,7	1 798	66,9
DGV + / Ac -	21 *	4,5	14 *	0,5
DGV - / Ac +	13 **	2,8	876	32,6
Total	462	100	2 571	100

* Dont 1 Anti-HBc + et 1 syph +
** 5 VIH-2,
1 VIH-1 groupe 0,
7 VIH-1 CV faibles

* 8 FS, dont 1 ALAT et 1 Anti-HBc+
1 immunosilencieux (4 mois)
5 non suivis

Source : InVS, INTS, EFS, CTSA

InVS INSTITUT DE VEILLE SANITAIRE

HAS
HAUTE AUTORITÉ DE SANTÉ

SYNTHÈSE DE LA RECOMMANDATION EN SANTÉ PUBLIQUE

Hépatite B

Place des tests rapides d'orientation diagnostique (TROD) dans la stratégie de dépistage de l'hépatite B

Juin 2016

Une stratégie de dépistage fondée sur la détection des trois marqueurs de l'infection par le virus de l'hépatite B

La stratégie de dépistage de l'hépatite B repose actuellement sur la détection des trois marqueurs de l'infection à VHB (Ag HBs, Ac anti-HBs, Ac anti-HBc) par un test Elisa réalisé à partir d'un prélèvement veineux.

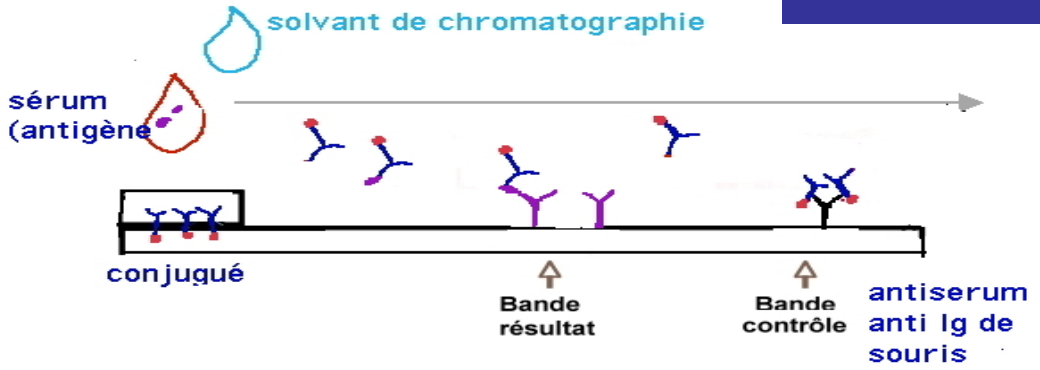
La recherche des trois marqueurs d'emblée présente l'avantage de permettre de déterminer le statut immunitaire exact de la personne dépistée et donc de répondre au double objectif du dépistage qui vise à identifier :

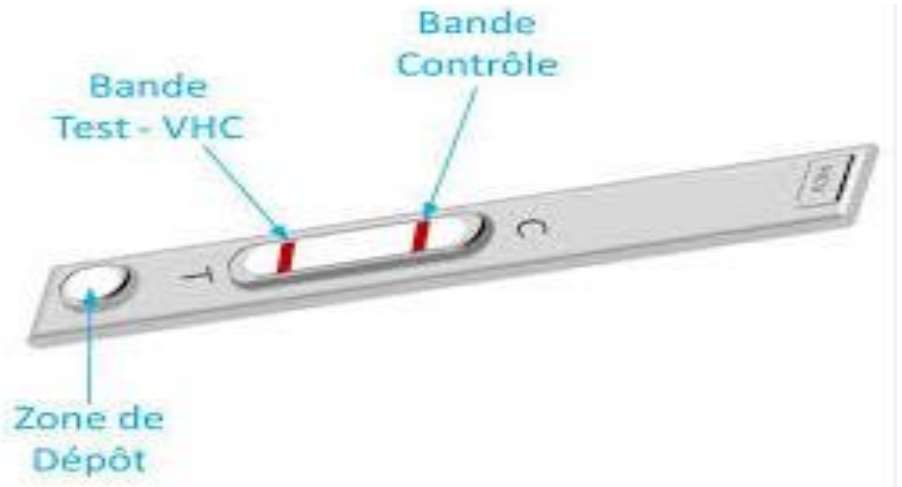
- les personnes atteintes d'une hépatite chronique pour permettre leur prise en charge précoce ;
- les personnes exposées au risque n'ayant jamais eu de contact avec le virus de l'hépatite B afin de leur proposer une vaccination.

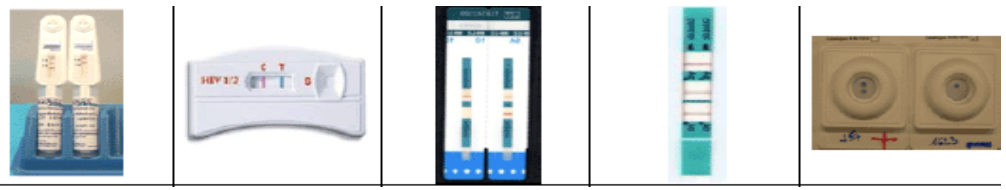
Si contexte suspect /évocateur → les 3 marqueurs (hépatite B occulte)

NON indiqué chez les donneurs de sang en Tunisie

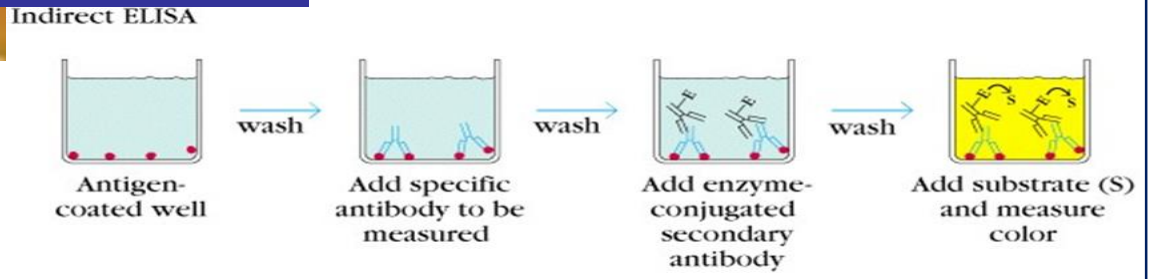
TROD ou EIA / CLIA

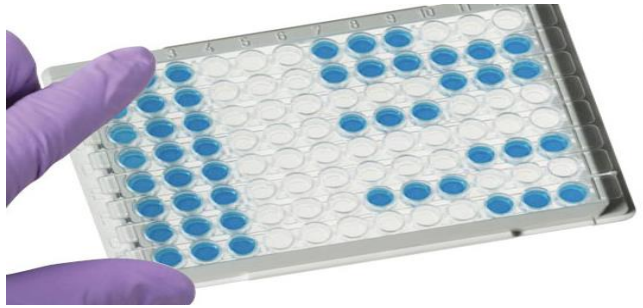






Immuno-chromatographie





enzyme immunoassay (EIA), chemoluminescence immunoassay (CLIA), electrochemoluminescence assay (ECL)

Review

CrossMark

EASL | JOURNAL OF HEPATOLOGY

Who to test and how to test for chronic hepatitis C infection – 2016 WHO testing guidance for low- and middle-income countries

Philippa J. Easterbrook*, on behalf of the WHO Guidelines Development Group **

Review

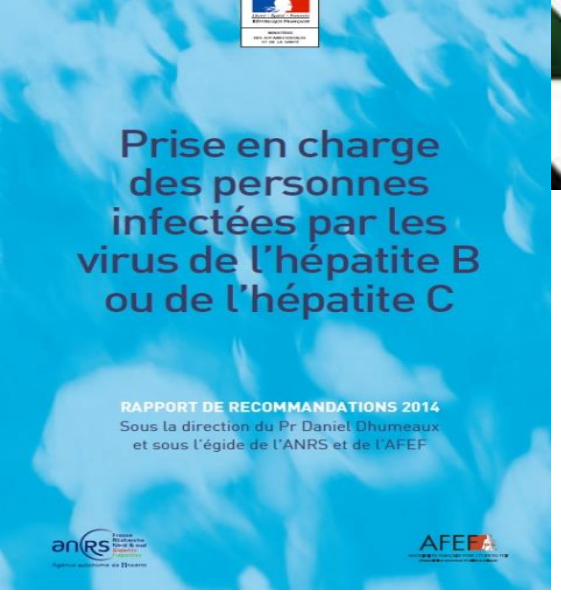
Table 4. Advantages and disadvantages of different assay formats [34].

	Advantages	Disadvantages
EIA, CLIA, ECL	• Superior clinical/diagnostic and analytical sensitivity/specificity • High throughput possible (>40 per day per operator) • High throughput greater when using automated immunoanalysers[a] • Objective, automated reading of results, but not for line blots or simple assays • Within-assay procedural quality control	• Requires laboratory facilities, equipment, e.g., EIA plate washers, readers, incubators or immunoanalyzers or random-access analyzers. • Requires trained laboratory technician • Reagents require refrigeration • Requires venepuncture to obtain specimen • Time to result ~3 hours and generally batched as one run if manual EIA
RDTs	• Accessible at the lowest level of the health care system (including community settings) • Does not specifically require laboratory facilities • May be carried out by trained lay-providers and healthcare workers, as well as laboratory technicians • Can be used with less-invasive specimens that do not require venepuncture such as capillary whole blood or oral fluid • If testing at or near to point-of-care, same day results are possible which may reduce individuals that are lost to follow-up and therefore do not receive their test results • Devices can be stored at 2 to 30 °C	• Lower clinical and analytical sensitivity/specificity • Less sensitive in certain populations such as immunosuppressed, and HIV positive individuals. • Ineffective within-assay quality control, i.e., most RDTs do not control for specimen addition • Lack of test kit external control reagents for quality control with most RDTs, but some exceptions, e.g., Oraquick • Stability at room temperature is impacted by environmental factors, e.g., heat, humidity, storage conditions • Subjective reading and interpretation of results • Requires manual transcription of testing results into laboratory logbook/testing register, partially mitigated by automated RDT readers

→Sensibilité/ Spécificité

→ Améliorer l'accès au dépistage

	TROD	IEA
Avantage	-Réalisable en tout lieu (lieux fréquentés par les populations cibles : à risque) -Stockage : température ambiante - Pas de matériel /structures supplémentaires -Facilité d'emploi - Formation facile du personnel - Acceptabilité > prélèvement veineux (moins invasive) -Rapidité du résultat : ↘ perdus de vue	- Sensibilité +++ (y compris en primo-infection) - Spécificité +++ - Automatisable / haut débit - Prix avantageux (kit hors matériel) - Traçabilité et enregistrement des résultats
Inconvénient	- manque de sensibilité : phases précoces de l'infection (≈3mois), immunodéprimés, VIH+ -Peu de tests validité CE/FDA (à cause de la spécificité /sensibilité) -Subjectivité de lecture - Pas de contrôle de qualité/c.externe - Problème d'élimination des déchets infectieux si en dehors des circuits de soins - Prix généralement élevé - Traçabilité des résultats: manuscrite	-Chaine du froid -Structures /personnel qualifié/matériel pour le prélèvement (local/infirmier /aiguilles/ tubes…) - Structures /personnel qualifié /matériel pour le test sérologique (local/technicien/réfrigérateurs/centrifugeuse/lecteur DO…) -Invasive (> trod) -Minimum 3h (svt>24h) pour le résultat Pour optimiser le cout : « passer en série » - Certains kits: Trop sensibles : plusieurs FP



Inconvénient TROD
SENSIBILITE+++ : Faux négatif?

La moindre sensibilité des TROD est expliquée par la nature des antigènes ou des anticorps utilisés, la liaison des antigènes et des anticorps à température ambiante et non à 37° C comme dans les tests EIA et la nature des matrices biologiques utilisées. Le temps de réaction (maximum 30 minutes) diminue également la sensibilité. La spécificité des TROD est bonne mais tout résultat positif doit être contrôlé par une méthode de référence.

7.4. Rationale for the recommendations on which assay to use

Use of EIAs. In settings where existing laboratory testing infrastructure is available and there is good access to laboratory services, EIAs were recommended as the preferred testing method for several reasons:

1. Although RDTs and EIAs for HBsAg had similar clinical sensitivity and specificity when compared to an EIA reference standard, the sensitivity of different RDTs was highly variable, and some RDTs had suboptimal sensitivity.
2. In HIV-infected individuals, clinical sensitivity of RDTs was poor (72.3%) and appears to be better for EIAs.
3. The analytical sensitivity is much higher for EIAs (50- to 100-fold higher). The benefit of more analytically sensitive assays with better limits of detection is that it improves detection in persons with primary infection, and in individuals in whom HBsAg levels are extremely low.
4. A confirmatory test using a neutralization step can be incorporated into laboratory-based EIAs.
5. Testing using laboratory-based EIAs can be automated and may be more appropriate and cost–effective in settings where there are many tests being performed per day (>40 per day per operator).

Key challenges to the use of RDTs include the limited availability of quality-assured RDTs for HBsAg detection, reduced analytical sensitivity compared to laboratory-based methods, and that very few HBsAg RDTs meet the analytical sensitivity (LoD 0.130 IU/mL) required by the European Union. However, overall, the Guidelines Development Group considered that the benefits of RDTs in terms of increased access would mitigate potential harms related to lower accuracy, especially if there was careful selection of RDTs that met minimum performance criteria.

Les TROD sont-ils recommandés pour le dépistage?

Draft For Consultation

World Health Organization

Global Health Sector Strategy on viral hepatitis, 2016–2021

Optimize diagnosis

New diagnostics technologies and approaches would improve viral hepatitis diagnosis and patient monitoring, especially for hard-to-reach priority populations. The required innovations include:

- Simplified and reliable diagnostics, including rapid diagnostic tests for diagnosing HBV and HCV infection.
- Point-of-care tests to measure HBV and HCV viral load (and HCV antigen) to guide treatment decisions.
- Simplified methods to reliably assess liver fibrosis and cirrhosis.

OMS EASL 2016

Review

CrossMark

EASL JOURNAL OF HEPATOLOGY

Who to test and how to test for chronic hepatitis C infection – 2016 WHO testing guidance for low- and middle-income countries

Philippa J. Easterbrook*, on behalf of the WHO Guidelines Development Group**

How to test – testing strategies

(i) The use of a single quality assured serological assay (either an immunoassay (EIA or CLIA) or rapid diagnostic test (RDT)) to detect HCV antibody that meets minimum performance standards is recommended.

(ii) RDTs are recommended in settings where there is limited access to laboratory infrastructure and testing, and/or populations where access to rapid testing would facilitate linkage to care and treatment.

(iii) Nucleic acid testing (NAT) technologies (either quantitative or qualitative detection of HCV RNA) is recommended as the preferred testing strategy to diagnose active HCV infection; but detection of core HCV antigen where the assay has comparable clinical sensitivity to NAT technologies, may be considered as an alternative.

(iv) The use of capillary whole blood dried blood spot (DBS) specimen collection for both HCV serological and NAT technologies may be considered to facilitate access to testing in certain settings where there are either no facilities or expertise to take venous blood samples; or in persons with poor venous access; or where quality-assured RDTs are not available or their use is not feasible.

EIA / CLIA ou TROD
Minimum de critères de performance

TROD Si accès labo limité
Et/ou soins/ttt facilités

Le diagnostic : PCR
+/- Ag VHC

HAS
HAUTE AUTORITÉ DE SANTÉ

RECOMMANDATION EN SANTÉ PUBLIQUE

Place des tests rapides d'orientation diagnostique (TROD) dans la stratégie de dépistage de l'hépatite C

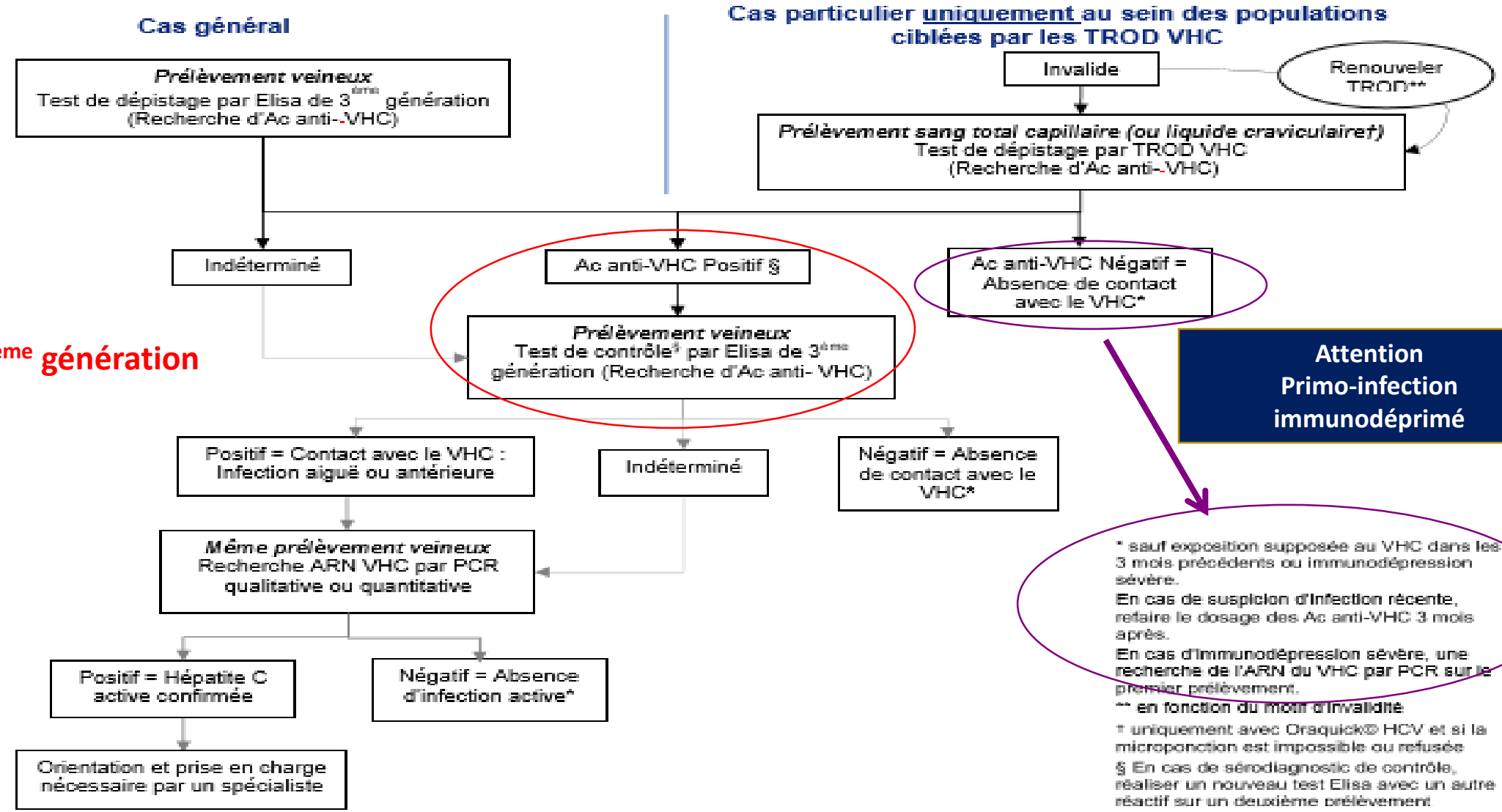
Date de validation par le collège : mai 2014

Hépatite C

Avis du groupe de travail HAS

Le dépistage de l'hépatite C repose sur la détection des Ac anti-VHC sériques par méthode immuno-enzymatique (Elisa de 3ème génération), qui reste la méthode de référence (cas général).
Compte tenu de leurs performances satisfaisantes et au regard de leurs avantages par rapport au dépistage classique, le groupe de travail a considéré que, pour certaines populations pour lesquelles ils apparaissent plus adaptés (cas particulier, cf. infra), les TROD pouvaient être utilisés en première intention, sous réserve d'une information éclairée des personnes à dépister sur leurs limites de sensibilité et spécificité et sur la confirmation diagnostique qui reste indispensable en cas de positivité et impose un prélèvement veineux.

Algorithme de dépistage de l'hépatite C au sein des populations à risque ciblées (ANAES 2001)

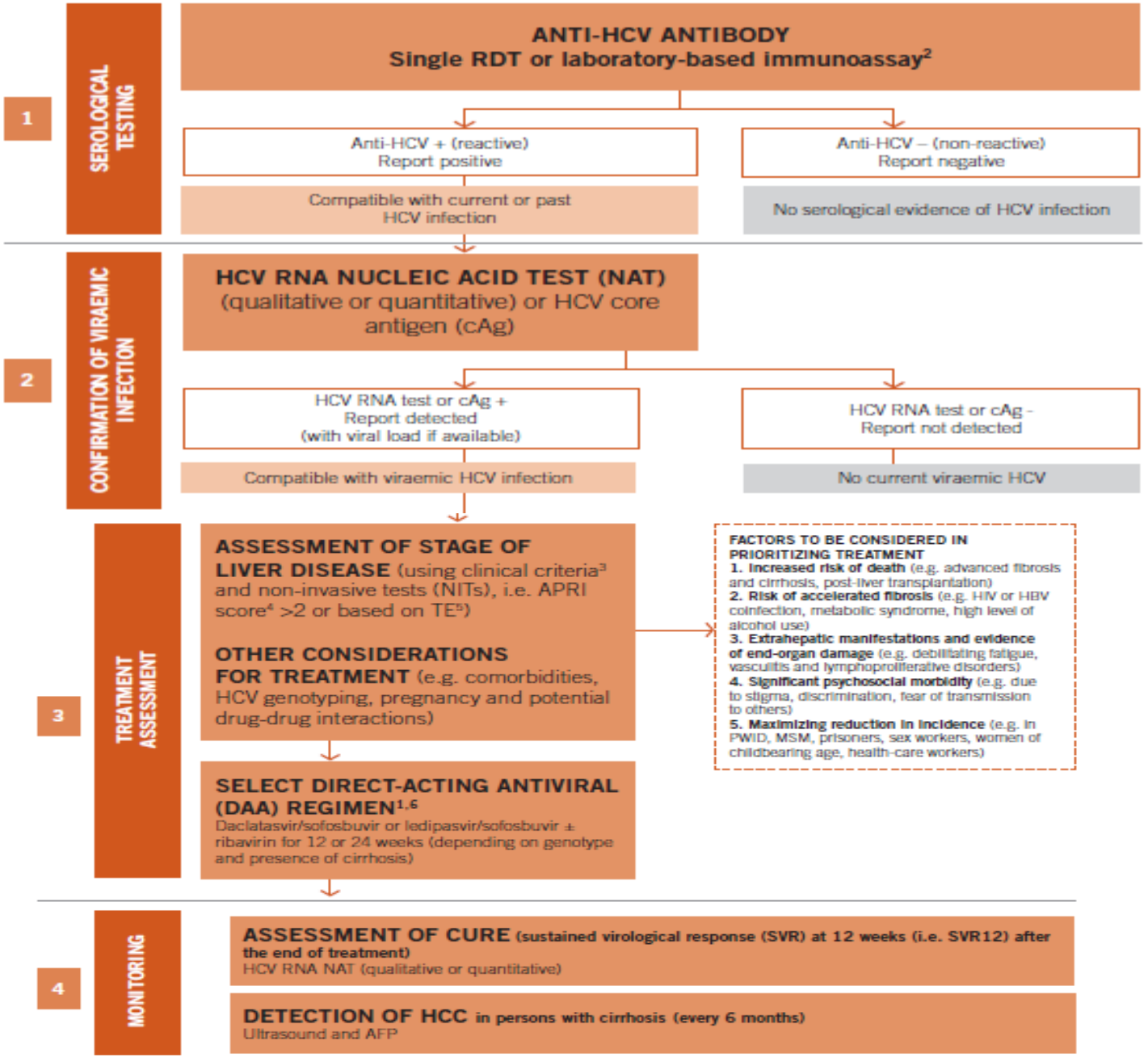


World Health Organization

GUIDELINES ON HEPATITIS B AND C TESTING

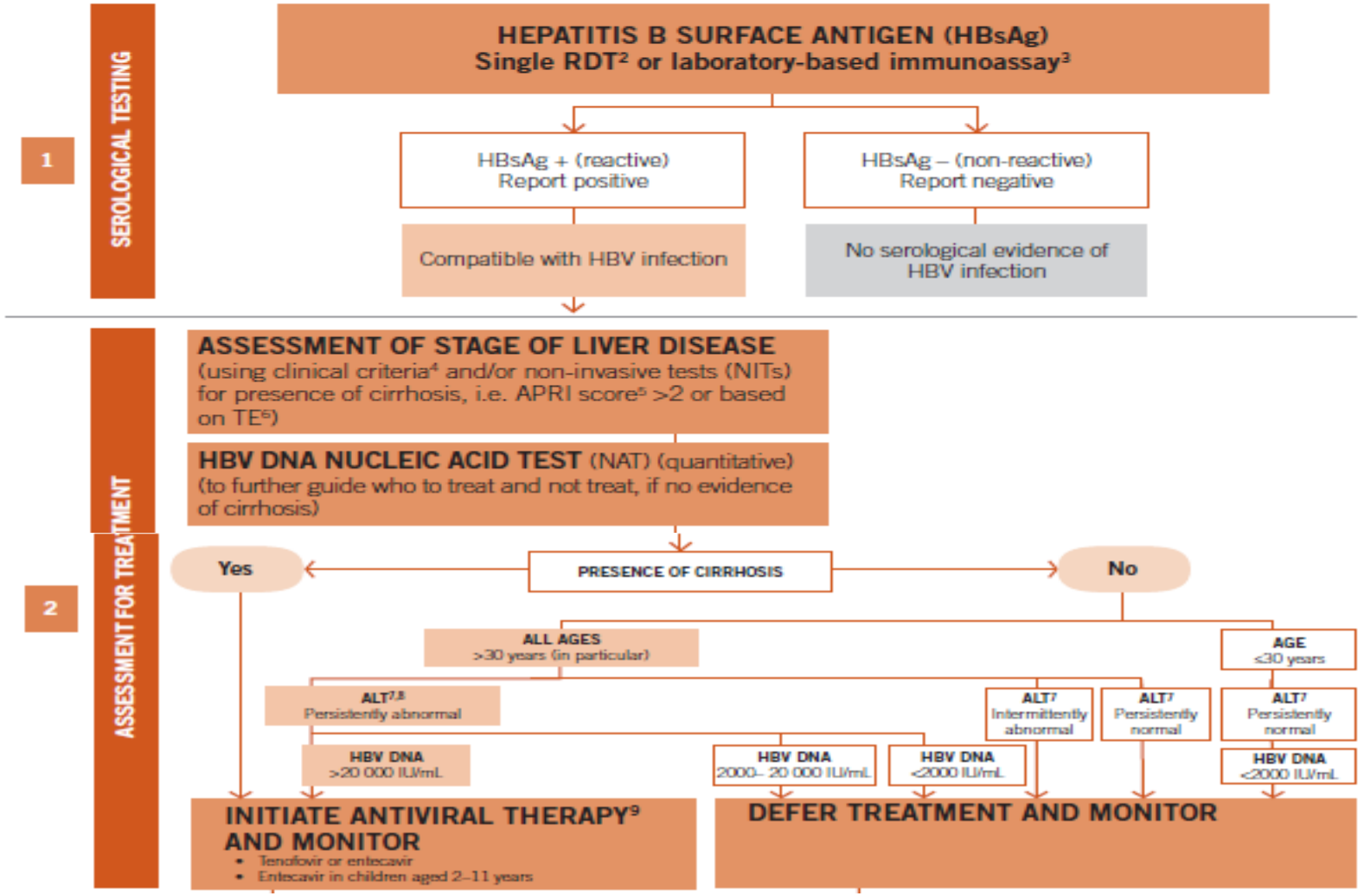
FEBRUARY 2017

FIG.3. Summary algorithm for diagnosis, treatment and monitoring[1] of chronic HCV infection



SUMMARY ALGORITHMS

FIG.2. Summary algorithm for diagnosis, treatment and monitoring[1] of chronic HBV infection



• Quels critères d'un bon TROD?

A	= Prix attractif (*Affordable*)
S	= Sensible (*Sensitive*)
S	= Spécifique (*Specific*)
U	= Facilité d'utilisation en un minimum d'étapes (*User-friendly*)
R	= Robuste et rapide (*Robust and rapid*)
E	= Sans équipement spécifique (*Equipment-free*)
D	= À disposition de tous ceux qui en ont besoin (*Deliverable*)

Oms 2003 : l'idéal

- **Bon marché**
- **Spécifique**
- **Sensible**
- **Résultat en moins de 30min**
- **Facile à réaliser**
- **Maximum de 3 à 4 étapes,**

-température ambiante,

- **par du personnel formé soignants ou non**
- **directement auprès des personnes exposées**
- **hors des structures classiques de dépistage**
- **Sans matériel spécifique (centrifugeuse, tubes)**

World Health Organization

List of in vitro diagnostics eligible to tender for procurement by WHO in 2016 (including WHO prequalified in vitro diagnostics)

Laboratory evaluation acceptance criteria for serology assays:

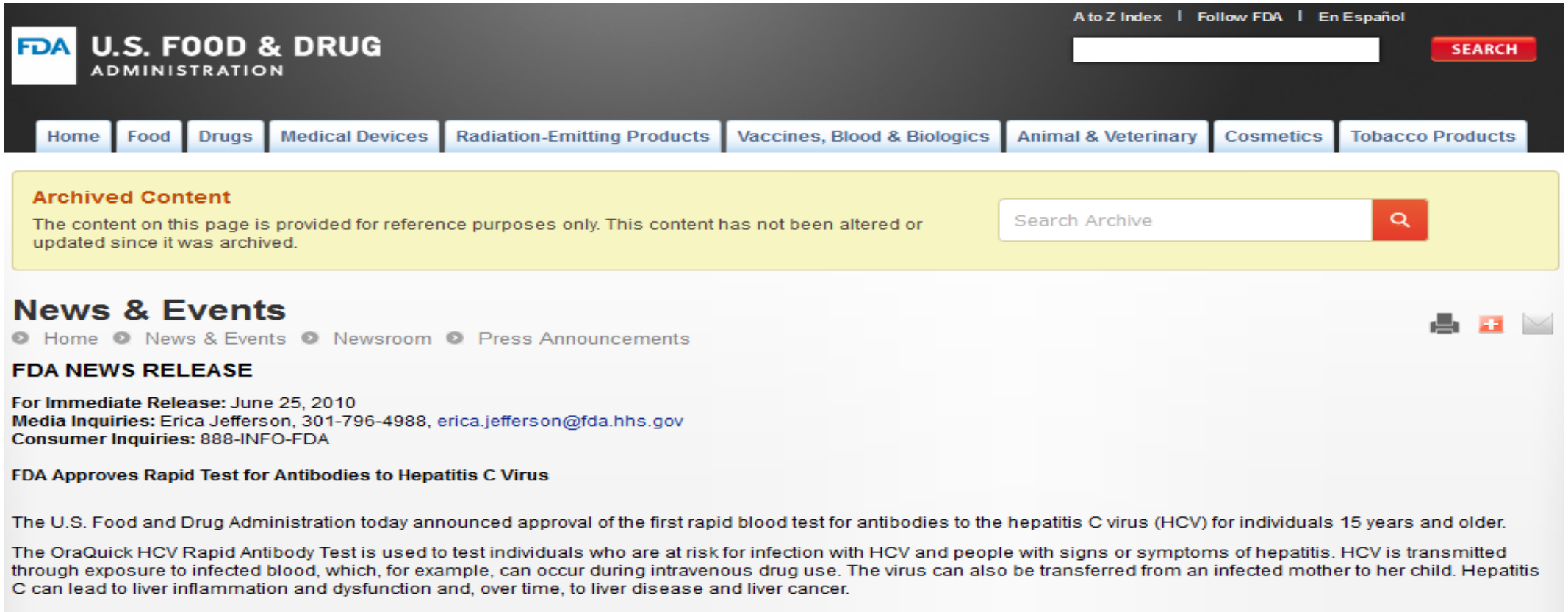
Analyte	EIAs	Simple assays/rapid diagnostic tests
anti-HIV-1/2 and/or HIV-1 p24 Ag	Initial sensitivity: **100%** Final specificity: **≥ 98%**	Initial sensitivity: **≥ 99%** Final specificity: **≥ 98%** Inter-reader variability: **≤5%** Invalid rate: **≤5%**
anti-HCV	Initial sensitivity: **100%** Final specificity: **≥ 98%**	Initial sensitivity: **≥ 98%** Final specificity: **≥ 97%** Inter-reader variability: **≤5%** Invalid rate: **≤5%**
HBsAg	Initial sensitivity: **100%** Final specificity: **≥ 98%**	Initial sensitivity: **100%** Final specificity: **≥ 98%** Inter-reader variability: **≤5%** Invalid rate: **≤5%**

List of diagnostics eligible to tender for procurement by WHO in 2016 (including WHO prequalified diagnostics)

Manufacturer Assay name (Country of manufacture)	Product code	No. of tests per kit	Initial sensitivity	Final specificity	Shelf life/ storage temp	Analyte	Specimen type	Comments	WHO PQDx status (PQ Public Report)
HCV Rapid Diagnostic Tests (RDTs)									
N/A									

Manufacturer Assay name (Country of manufacture)	Product code	No. of tests per kit	Initial sensitivity	Final specificity	Shelf life/ storage temp	Analyte	Specimen type	Comments	WHO PQDx status (PQ Public Report)
HBsAg Rapid Diagnostic Tests (RDTs)									
N/A									

Marquage FDA



FDA U.S. FOOD & DRUG ADMINISTRATION

A to Z Index | Follow FDA | En Español

SEARCH

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

Archived Content

The content on this page is provided for reference purposes only. This content has not been altered or updated since it was archived.

Search Archive

News & Events

Home › News & Events › Newsroom › Press Announcements

FDA NEWS RELEASE

For Immediate Release: June 25, 2010
Media Inquiries: Erica Jefferson, 301-796-4988, erica.jefferson@fda.hhs.gov
Consumer Inquiries: 888-INFO-FDA

FDA Approves Rapid Test for Antibodies to Hepatitis C Virus

The U.S. Food and Drug Administration today announced approval of the first rapid blood test for antibodies to the hepatitis C virus (HCV) for individuals 15 years and older.

The OraQuick HCV Rapid Antibody Test is used to test individuals who are at risk for infection with HCV and people with signs or symptoms of hepatitis. HCV is transmitted through exposure to infected blood, which, for example, can occur during intravenous drug use. The virus can also be transferred from an infected mother to her child. Hepatitis C can lead to liver inflammation and dysfunction and, over time, to liver disease and liver cancer.

The OraQuick HCV Rapid Antibody → le seul approuvé FDA

Advantages and Disadvantages of FDA-Approved HIV Assays Used for Screening, *by test category*

Test Category [a]	HIV Sreening Tests	Run Time	Instrument	Report Ag and Ab separately	Detects IgG	Detects IgM	Uses whole blood specimens	Uses oral fluid specimens	Uses dried blood spot specimens	Least complex[b] CLIA category	External quality control not required in each run
Nucleic acid laboratory test	Aptima HIV-1 RNA Qualitative Assay[c]	>3 hours	semi-automated							high	
Ag/Ab laboratory test	Architect HIV Ag/Ab Combo Assay	<30 mins	automated		✓	✓				moderate	✓
	ADVIA Centaur HIV Ag/Ab Combo (CHIV) Assay	<1 hour	automated		✓	✓				moderate	✓
	BioPlex 2200 HIV Ag-Ab	45 mins	automated	✓	✓	✓				moderate	✓
	GS HIV Combo Ag/Ab EIA	>3 hours	semi-automated		✓	✓				high	
Ag/Ab rapid test	Determine HIV-1/2 Ag/Ab Combo	20 mins	single-use	✓	✓	✓	✓			waived	✓
Ab laboratory test	ADVIA Centaur HIV 1/O/2 Enhanced (EHIV) Assay	<1 hour	automated		✓	✓				moderate	
	Vitros Anti-HIV 1+2	<1 hour	automated		✓	✓				moderate	✓
	GS HIV-1/2 Plus O	>3 hours	semi-automated		✓	✓				high	
Ab rapid test	INSTI HIV-1/HIV-2 Antibody Test	<2 mins	single-use		✓	✓	✓			waived	✓
	Uni-Gold Recombigen HIV	10 mins	single-use		✓	✓	✓			waived	✓
	HIV 1/2 STAT-PAK	15 mins	single-use		✓		✓			waived	✓
	SURE CHECK HIV 1/2 Assay	15 mins	single-use		✓		✓			waived	✓
	OraQuick ADVANCE Rapid HIV-1/2 Antibody Test	20 mins	single-use		✓		✓	✓		waived	✓
	DPP HIV-1/2 Assay	≤40 mins	single-use		✓		✓	✓		waived	✓
	Reveal G4 Rapid HIV-1 Antibody Test	<2 mins	single-use		✓		✓			moderate	✓

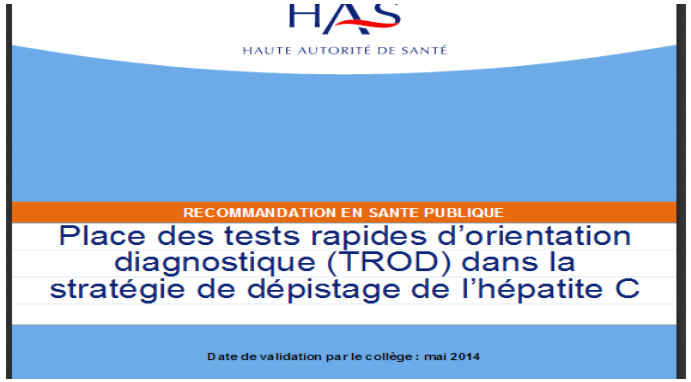
CS280729-B

Marquage CE

2014

Les TROD VHC

A ce jour, trois TROD disposent d'un marquage de la Commission européenne (CE) pour le dépistage de l'infection à VHC : (a) OraQuick® HCV rapid antibody test (OraSure Technologies, PA, USA), (b) TOYO® anti-HCV test (Turklab, Izmir, Turkey) et (c) Labmen HCV test (Turklab, Izmir, Turkey).



4. Conclusions et avis du groupe de travail

4.1 Evaluation des performances des tests

4.1.1 Conclusions sur les performances des TROD

Les performances retrouvées dans les études menées par les fabricants des TROD de l'infection VHC commercialisés en France depuis 2011 respectent les spécifications techniques communes européennes. Les TROD VHC présentent une bonne sensibilité clinique ainsi qu'une très bonne spécificité clinique, la plupart du temps supérieure à 99%, voire 99,5%.

Le contrôle de marché réalisé par l'ANSM a conclu à la conformité des tests Oraquick® HCV et Toyo® HCV vis-à-vis des critères d'acceptabilité établis et à la non-conformité du test signal® HCV qui a depuis été retiré du marché français. Le test Multisure® HCV, commercialisé plus récemment, n'a pu être inclus dans ce contrôle de marché

Les performances des TROD retrouvées dans la littérature à partir d'études menées par des équipes indépendantes des fabricants de TROD apparaissent très satisfaisantes mais variables d'un test à l'autre.

ANSM : Agence Nationale de sécurité du Médicament et des produits de santé

Apport des Tests Rapides d'Orientation Diagnostique (*TROD*) au Diagnostic et Dépistage

Stéphane Chevaliez

Centre National de Référence des Hépatites Virales B, C et delta
Département de Virologie, Bactériologie-Hygiène, Mycologie-Parasitologie
& INSERM U955
Hôpital Henri Mondor
Université Paris-Est Créteil

Tests Rapides Disposant du Marquage CE IVD pour la Détection des Anti-VHC

	Oraquick® HCV	Toyo® HCV	Labmen® HCV	Multisure HCV	Assure® HCV	First Response HCV
Manufacturer	Orasure	Türklab	Türklab	MP Diagnostics	MP Diagnostics	Premier Medical Corporation Ltd
Specimen type	**oral fluid, whole blood,** serum, plasma	**whole blood,** serum, plasma	**whole blood,** serum, plasma	**whole blood,** serum, plasma	**whole blood,** serum, plasma	**whole blood** serum, plasma
Volume required (µL)	40 (oral fluid) 20	30	10	25	50	35
Time to read (min)	20	15	15	15	15	20

http://www.pathexo.fr/docfiles/09_chevaliez.pdf

Place des tests rapides d'orientation diagnostique (TROD) dans la stratégie de dépistage de l'hépatite B

Juin 2016

Tableau 2. Caractéristiques des trousses rapides d'orientation diagnostique (Ag HBs) ayant obtenu le marquage CE

Nom du test	Fabricant / distributeur	Principe	Antigènes utilisés	Matrices	Délai lecture résultats (en minutes)
Vikia® HBs Ag	bioMérieux, France / bioMérieux, France	Immunochroma-tographie à flux latéral	Ag HBs	Sérum, plasma, **sang total (capillaire)**	15-30 (< 60 minutes)
DRW-HBs Ag® V2.0 assay	Diagnostics for the Real World™, USA / Oxoid-Thermo-Fisher	Immunochroma-tographie à flux latéral	Ag HBs	Sérum, plasma (citrate, EDTA ou héparine)	30 (< 35 minutes)
Toyo HBs Ag test®	Turklab, Turquie / -	Immunochroma-tographie à flux latéral	Ag HBs	Sérum, plasma, **sang total (capillaire)**	5-15
First res ponse® HBs Ag	Premier Medical Corporation Ltd, Inde / Nephrotek, France	Immunochroma-tographie à flux latéral	Ag HBs	Sérum, plasma (citrate, EDTA ou héparine) **sang total (capillaire)**	20 (< 30 minutes)

Ann Intern Med. 2012;157:558-566.

REVIEW | Annals of Internal Medicine

Accuracy of Rapid and Point-of-Care Screening Tests for Hepatitis C

A Systematic Review and Meta-analysis

Sushmita Shivkumar, MSc; Rosanna Peeling, PhD; Yalda Jafari, MSc; Lawrence Joseph, PhD; and Nitika Pant Pai, MD, MPH, PhD

Table 2. **Test Specifications**

Test (Reference)	Manufacturer	Time to Result, *min*	Antigen Used	Specimen Required for Testing	Volume Required for Testing	Storage Temperature, °C	Shelf Life, *mo*	Test Type
OraQuick HCV Rapid Antibody Test (19)	OraSure Technologies, Bethlehem, Pennsylvania	20–40	Core, NS3, NS4	Oral fluid, whole blood, serum, plasma	1 drop	2–30	NA	POCT
Dual Path Platform test (19)	Chembio Diagnostic Systems, Medford, New York	15–30	Core, NS3, NS4, NS5	Oral fluid, whole blood, serum, plasma	NA	NA	24	POCT
Multiplo Rapid HIV/HCV Antibody Test (19)	MedMira, Halifax, Nova Scotia, Canada	3	Core, NS3	Whole blood, serum, plasma	1 drop	2–30	NA	POCT
SD Bioline HCV (25)	Standard Diagnostics, Yongin, Korea	5–20	Core, NS3, NS4, NS5	Whole blood, serum, plasma	10–20 μL	2–30	18	POCT
Hexagon HCV (26)	Human Diagnostics Worldwide, Wiesbaden, Germany	5–20	Core, NS3, NS4, NS5	Whole blood, serum, plasma	NA	15–30	NA	POCT
Genedia HCV Rapid LF (24)	Green Cross Medical Science, Yongin, Korea	20–30	Core, NS3, NS4, NS5	Whole blood, serum, plasma	10–20 μL	2–30	18	POCT
Anti-HCV Ab rapid test (32)	Tema Ricerca, Bologna, Italy	3	NA	Whole blood	1 drop	NA	NA	POCT
SM-HCV Rapid Test (30)	SERO-Med Labor Spezialitaten, Pollenfeld, Germany	3	Core, NS3, NS4	Whole blood, serum	30–40 μL	2–8; after opening, should be stored at <30	NA	POCT
Bioeasy HCV Test (6)	Bioeasy Diagnóstica, Belo Horizonte, Minas Gerais, Brazil	10	Core, NS3, NS4, NS5	Whole blood, serum, plasma	10 μL	2–30	NA	POCT
Advanced Quality One Step HCV Test (23)	Bionike, San Francisco, California	6	NA	Serum, plasma	4 μL	2–30	18	RDT
SeroCard HCV (23)	Trinity Biotech, Bray, Ireland	19		Serum, plasma, whole blood	80 μL	2–8	16	RDT
Diagnos HCV Bi-Dot (23)	J. Mitra, New Delhi, India	3	Core, NS3, NS4, NS5	Serum, plasma	NA	2–8	15	RDT
HCV Tri-Dot (23)	J. Mitra, New Delhi, India	5	Core, NS3, NS4, NS5	Serum, plasma	45 μL	2–8	12	RDT
HCV Spot (23)	MP Biomedicals, Santa Ana, California	10	NA	Serum, plasma	45 μL	2–25	6–8	RDT

Pas : sang total!

REVIEW | Annals of Internal Medicine

Accuracy of Rapid and Point-of-Care Screening Tests for Hepatitis C

A Systematic Review and Meta-analysis

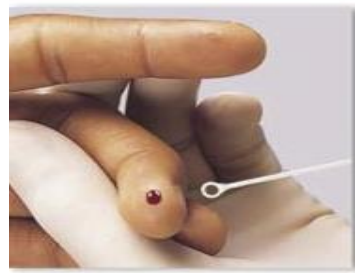
Sushmita Shivkumar, MSc; Rosanna Peeling, PhD; Yalda Jafari, MSc; Lawrence Joseph, PhD; and Nitika Pant Pai, MD, MPH, PhD

Table 4. **Results of Meta-analysis, by Specimen Subgroup**

Subgroup	Pooled Sensitivity (95% CI), %	Pooled Specificity (95% CI), %	Positive LR (95% CI)	Negative LR (95% CI)	DOR (95% CI)
Oral fluid POCTs	97.1 (94.7–98.4)	98.2 (92.2–99.6)	54.8 (11.9–251.4)	0.03 (0.01–0.06)	1870.9 (263.9–13 263.6)
Whole blood and finger-stick POCTs	98.9 (94.5–99.8)	99.5 (97.5–99.9)	208.7 (38.3–1136.6)	0.01 (0.002–0.06)	19 438.6 (858.4–440 169.7)
Serum and plasma POCTs	98.9 (96.8–99.6)	99.7 (99.3–99.9)	342.7 (140.5–836.4)	0.01 (0.004–0.03)	33 800.4 (5862.3–194 885.2)
Serum and plasma RDTs	98.4 (88.9–99.8)	98.6 (94.9–99.6)	68.4 (19.1–246.2)	0.02 (0.002–0.12)	4135.2 (517.5–33 042.1)

DOR = diagnostic odds ratio; LR = likelihood ratio; POCT = point-of-care test; RDT = rapid diagnostic test.

Matrice : Sang total / sérum /Plasma +++ > liquide craviculaire



REVIEW | Annals of Internal Medicine

Accuracy of Rapid and Point-of-Care Screening Tests for Hepatitis C

A Systematic Review and Meta-analysis

Sushmita Shivkumar, MSc; Rosanna Peeling, PhD; Yalda Jafari, MSc; Lawrence Joseph, PhD; and Nitika Pant Pai, MD, MPH, PhD

Table 1—Continued

Test*	Sensitivity (95% CI), %	Specificity (95% CI), %
HCV Spot	97.6 (87.4–99.9)	92.6 (87.3–96.3)
HCV Spot	90.9 (58.7–99.8)	97.9 (94.8–99.4)
Anti-HCV Ab Rapid test	100 (92.9–100)	98 (89.4–99.9)
Diagnos HCV Bi-Dot	87.5 (71–96.5)	100 (99.9–100)
SM-HCV Rapid Test	98 (93–99.8)	100 (96.2–100)
Advanced Quality One Step HCV Test	97.1 (89.8–99.6)	96.3 (92.5–98.5)
SeroCard HCV	98.5 (92.1–100)	100 (98.1–100)
HCV Tri-Dot	100 (94.7–100)	91.5 (86.6–95.1)
HCV Spot	100 (94.7–100)	93.7 (89.2–96.7)
HCV Tri-Dot, 4th Generation	100 (94.7–100)	98.9 (96.2–99.9)
Genedia HCV Rapid LF	98.5 (92.1–100)	98.4 (95.4–99.7)
SD Bioline HCV	96.9 (89.5–99.6)	100 (98.1–100)
SM-HCV Rapid Test	83.5 (75.2–89.9)	100 (95.9–100)
HCV Tri-Dot	99.3 (95.5–100)	99.0 (98.5–99.4)
Hexagon HCV	87.7 (80.3–93.1)	93.6 (82.5–98.7)
HCV Spot	0 (0–11.6)	100 (88.4–100)
HCV Spot	22.2 (2.8–60)	96.4 (92.7–98.5)
Bioeasy HCV Test	100 (88.4–100)	92.7 (80.1–98.5)
OraQuick HCV Rapid Antibody Test	99.2 (95.5–100)	100 (99.2–100)
OraQuick HCV Rapid Antibody Test	100 (97.0–100)	100 (99.2–100)
OraQuick HCV Rapid Antibody Test	100 (97.0–100)	100 (99.2–100)
OraQuick HCV Rapid Antibody Test	100 (97–100)	99.8 (98.8–100)
OraQuick HCV Rapid Antibody Test	100 (97–100)	99.8 (98.8–100)
OraQuick HCV Rapid Antibody Test	98.1 (96.9–99.0)	99.6 (99.2–99.9)
OraQuick HCV Rapid Antibody Test	99.7 (99.9–100)	99.9 (99.5–100)
OraQuick HCV Rapid Antibody Test	99.7 (99–100)	99.9 (99.6–100)
OraQuick HCV Rapid Antibody Test	99.9 (99.3–100)	99.9 (99.5–100)
OraQuick HCV Rapid Antibody Test	99.9 (99.3–100)	99.9 (99.6–100)
Dual Path Platform test	97.8 (96.1–98.7)	99.8 (99–100)
Multiplo Rapid HIV/HCV Antibody Test	88.3 (85.3–90.7)	99.8 (99–100)
OraQuick HCV Rapid Antibody Test	99.3 (98.1–99.7)	99.5 (98.4–99.8)
Dual Path Platform test	91.2 (85.6–94.8)	81.6 (68.6–90)
OraQuick HCV Rapid Antibody Test	94.7 (90.8–97)	92.1 (83.8–96.3)
Dual Path Platform test	92.2 (87.5–95.2)	97.7 (92–99.4)
	94 (90.6–96.2)	97.1 (91.8–99)
Multiplo Rapid HIV/HCV Antibody Test	78.9 (74.6–82.7)	83.3 (71–91.5)
OraQuick HCV Rapid Antibody Test	92.2 (87.5–95.2)	97.2 (90.9–99.3)
	97.4 (94.1–98.9)	98.6 (92.9–99.8)
OraQuick HCV Rapid Antibody Test	93.9 (87.1–97.7)	99.5 (98.1–99.9)

Cruz et al. BMC Infectious Diseases (2015) 15:548
DOI 10.1186/s12879-015-1249-5

BMC Infectious Diseases

RESEARCH ARTICLE Open Access

Evaluating HBsAg rapid test performance for different biological samples from low and high infection rate settings & populations

Accuracy metrics (point estimates and 95%CIs) of three rapid tests compared to results of HBsAg One® and ETI-MAK-4®, enzyme immunoassays

Manufacturer	TP	FN	TN	FP	Sensitivity	Specificity	PPV	NPV	K (CI%)
HBsAg non-reactive/HBsAg reactive ($n = 393$)									
Vikia HBsAg®	101	2	290	0	98.06 % (93.16–99.76)	100.00 % (98.74–100.00)	100.00 % (96.42–100.00)	99.32 % (97.54–99.92)	98.68 % (96.85–100.00)
Imuno-Rápido HBsAg®	98	5	287	3	95.15 % (89.03–98.40)	98.97 % (97.01–99.79)	97.03 (91.58–99.38)	98.29 % (96.05–99.44)	94.7 % (91.07–98.33)
HBsAg teste rápido®	96	7	287	3	93.20 % (86.51–97.22)	98.97 % (97.01–99.79)	96.97 % (91.39–99.37)	97.62 % (95.16–99.04)	93.34 % (89.26–97.42)

Research Article

EASL EUROPEAN ASSOCIATION FOR THE STUDY OF THE LIVER | JOURNAL OF HEPATOLOGY

Performance of rapid tests for detection of HBsAg and anti-HBsAb in a large cohort, France

Table 1. Classification probabilities comparing rapid HBsAg tests compared to ELISA.

	HBsAg serology ELISA		AUC (95% CI)	Se	Sp	PPV	NPV
	Positive	Negative					
VIKIA®	(n = 85)	(n = 3843)	0.982 (0.962-1.000)	96.5	99.9	97.6	99.9
Positive	82	2					
Negative	3	3841					
DETERMINE™	(n = 47)	(n = 2425)	0.968 (0.933-1.000)	93.6	100.0	100.0	99.9
Positive	44	0					
Negative	3	2425					
QUICK PROFILE™	(n = 84)	(n = 3838)	0.951 (0.919-0.983)	90.5	99.7	88.4	99.8
Positive	76	10					
Negative	8	3828					

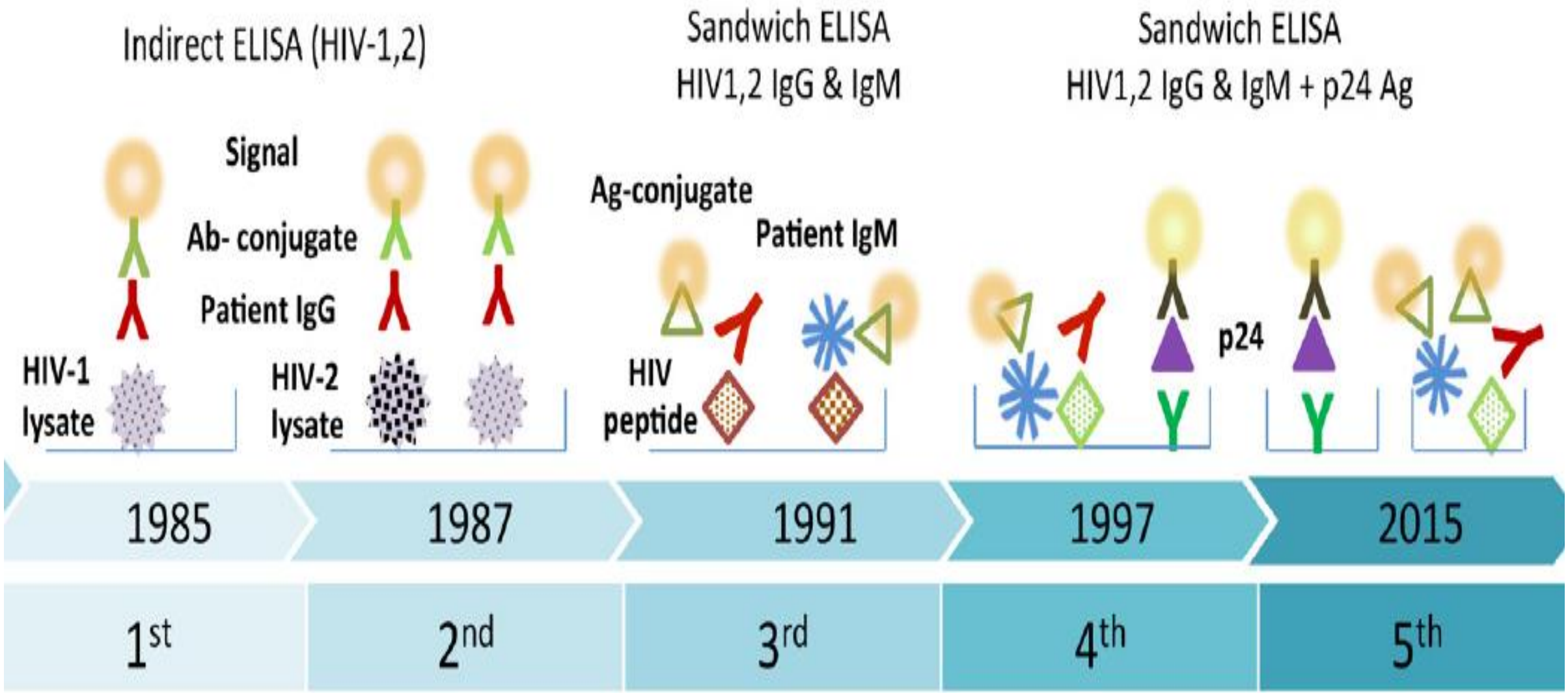
Rapid Point-of-Care First-Line Screening Tests for Hepatitis B Infection: A Meta-Analysis of Diagnostic Accuracy (1980–2010)

Table 2. Pooled sensitivity and specificity

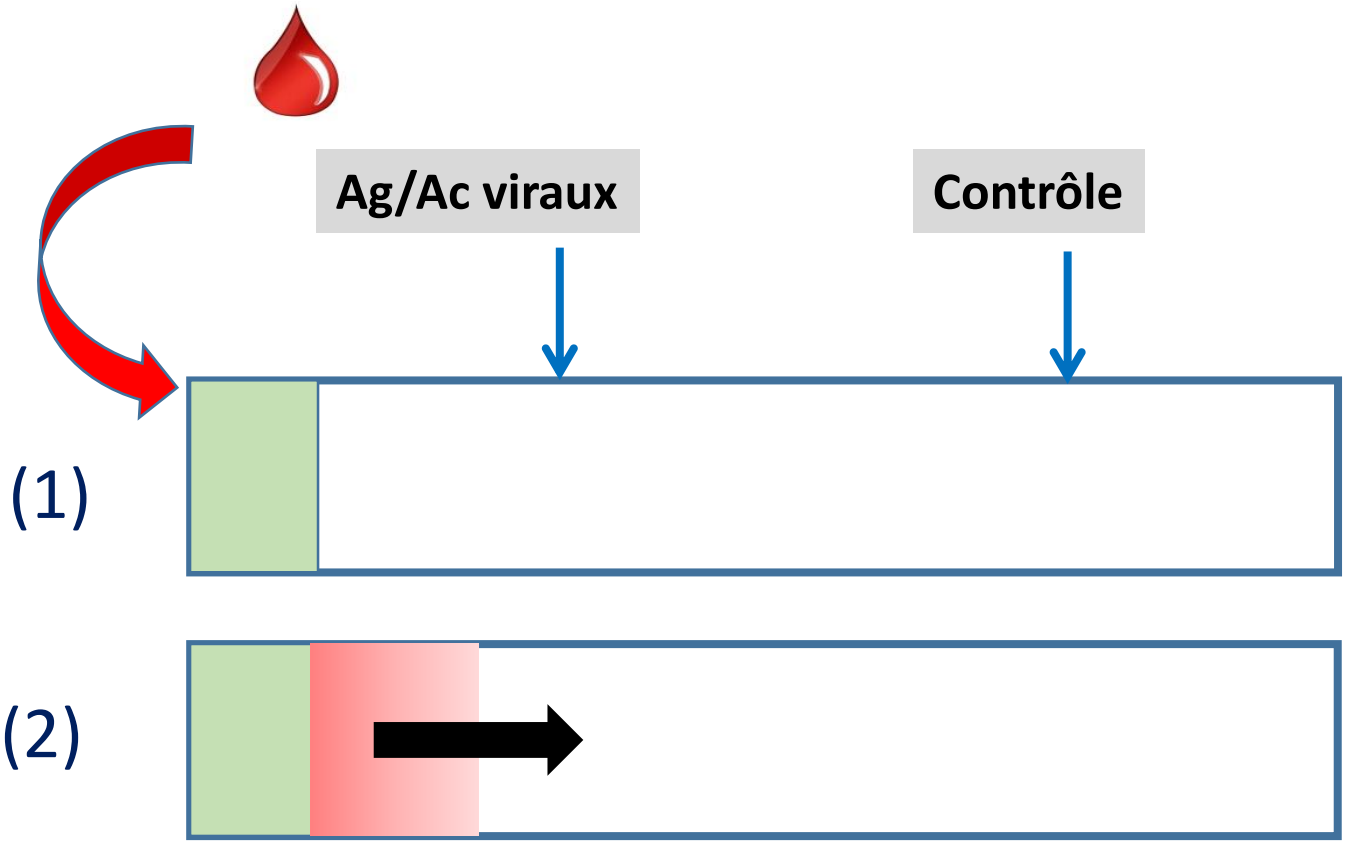
	Assuming perfect reference standard		Assuming imperfect reference standard	
Subgroup	**Sensitivity (95% CrI)**	**Specificity (95% CrI)**	**Sensitivity (95% CrI)**	**Specificity (95% CrI)**
HBsAg tests	94.7% (93.7–95.6%)	99.4% (99.2–99.6%)	94.8% (90.1–98.2%)	99.5% (99.1–99.9%)
Determine – HbsAg	97.6% (96.3–98.6%)	99.7% (99.2–99.9%)	98.2% (94.7–99.9%)	99.96% (99.3–100%)
Binax – HBs/eAg	97% (95.6–98%)	99.7% (99.5–99.9%)	95.5% (88.9–99.4%)	99.8% (99.3–100%)
Anti-HBsAg tests	92.7% (89.7–95%)	87.4% (83.5–90.7%)	93.2% (85.1–98.5%)	93.1% (81.9–99.9%)

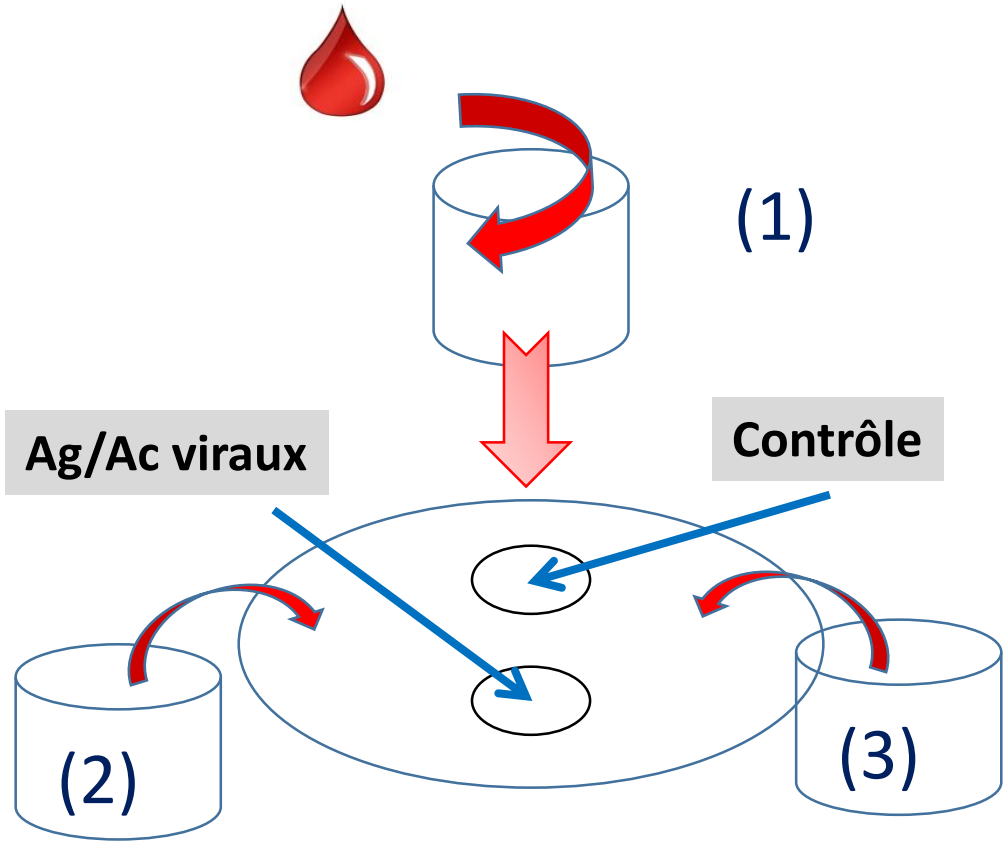
Anti-HbsAg, antibody to Hepatitis B surface antigen; CrI, credible interval; HBsAg, Hepatitis B surface antigen; HBeAg: Hepatitis B e Ag.

Tests rapides VIH



T.S Alexander ; Clin.Vacc.Immunol. 2016





Sérum , Plasma, Sang total, Salive

5 – 75 µl

5 – 30 mn

Sensitivity of Five Rapid HIV Tests on Oral Fluid or Finger-Stick Whole Blood: A Real-Time Comparison in a Healthcare Setting

	N 199*		Oraquick OF	Oraquick FSB	Vikia FSB	Determine FSB	Insti FSB	Determine 4G FSB
HIV-1 Subtype B	126	Positive (%)	**111** (88)	**119** (94)	**124** (97)	**118** (94)	**123** (97)	**96** (76)
		Negative	**15**	**7**	**2**	**5**	**1**	**5**
		Invalid	-	-	-	**3**	**2**	**25**
HIV-1 Subtype Non B**	58	Positive (%)	**51** (87)	**55** (94)	**57** (98)	**52** (89)	**58** (100)	**49** (84)
		Negative	**7**	**3**	**1**	**5**	-	**2**
		Invalid	-	-	-	**1**	-	**7**
HIV-2	6	Positive	**4**	**6**	**6**	**6**	**6**	**6**

194 HIV-1; 6 HIV-2

J.Pavie et al ; PLoS ONE 2010

Analyse de la sensibilité de 10 TROD au cours de la primo-infection par du VIH-1

Marie-Capucine Costes[1], Grégoire Chiarella[1], Emilie Guilleminault[1], Laurence Hermet[1], Laurence Kalkias[1], Bruno Le Labousse[1], Agnès Gautheret-Dejean[1,2]

[1]AP-HP, Hôpitaux Universitaires La Pitié Salpêtrière-Charles Foix, Service de Virologie, Paris, France

[2]Sorbonne Paris Cité, Université René Descartes Paris 5, UFR des Sciences Pharmaceutiques et Biologiques, Laboratoire de Microbiologie, Paris, France.

Hôpitaux Universitaires La Pitié-Salpêtrière - Charles Foix

UNIVERSITÉ PARIS DESCARTES SCIENCES PHARMACEUTIQUES ET BIOLOGIQUES

Nom de la trousse	Fabricant ou distributeur	Antigènes/Anticorps utilisés	Technologie
- Determine™ HIV-1/2 Ag/Ab Combo	Alere	gp41*,/**, gp36*,/**, anti-p24	IC
- INSTI™ HIV-1/HIV-2 Antibody Tests	Nephrotek	gp41*, gp36*	IF
- MULTISURE HIV Rapid Test	Nephrotek	gp120*, gp41*, gp36*, p24*	IC
- SURE CHECK® HIV 1/2	Nephrotek	gp120**, gp41**, gp36**	IC
- HIV 1/2 STAT-PAK® Assay	Nephrotek	gp120**, gp41**, gp36**	IC
- Exacto® TEST HIV PRO	All Diag	gp41*, gp36*	IC
- Genie™ Fast HIV 1/2	BioRad	gp120*, gp41*, gp36*	IC
- VIKIA® HIV 1/2	BioMérieux	gp41**, gp36**	IC
- HIVTOP® Ac 1&2	All Diag	gp41*, gp36*	IC
- FIRST RESPONSE® Test VIH 1-2.O CARTE	Nephrotek	gp41*, gp36*, p24*	IC

IC : Immunochromatographie ; IF : Immunofiltration

Journées Francophones Virologie 2016

	Volume (µL, matrice)	Différenciation VIH-1/VIH-2	Durée du test min-max (minutes)
- Determine™ HIV-1/2 Ag/Ab Combo	50 (S,P,ST)	non	20-30
- INSTI™ HIV-1/HIV-2 Antibody Tests	50 (S,P,ST)	non	immediat
- MULTISURE HIV Rapid Test	25 (S,P), 20 (ST)	oui	20-25
- SURE CHECK® HIV 1/2	2,5 (S,P),1 goutte (ST)	non	15-20
- HIV 1/2 STAT-PAK® Assay	5 (S,P,ST)	non	15
- Exacto® TEST HIV PRO	5 (S,P,ST)	non	10-20
- Genie™ Fast HIV 1/2	80 (S,P,ST)	non	10-30
- VIKIA® HIV 1/2	75 (S,P,ST)	non	30
- HIVTOP® Ac 1&2	25 (S,P), 50 (ST)	oui	10
- FIRST RESPONSE® Test VIH 1-2.O	10 (S,P), 20 (ST)	oui	15

CARTE

S : sérum ; P : plasma ; ST : sang total

	Nombre d'échantillons testés	Positif (%)	Négatif (%)	Invalide (%)
- Determine™ HIV-1/2 Ag/Ab Combo	75	56 (74,7)	2 (2,7)	17 (22,7)
- INSTI™ HIV-1/HIV-2 Antibody Tests	75	57 (76)	18 (24)	0 (0)
- MULTISURE HIV Rapid Test	75			
lecture visuelle		58 (77,3)	17 (22,7)	0 (0)
lecture automatique		56 (74,6)	19 (25,3)	0 (0)
- SURE CHECK® HIV 1/2	75	57 (76)	18 (24)	0 (0)
- HIV 1/2 STAT-PAK® Assay	75	57 (76)	18 (24)	0 (0)
- Exacto® TEST HIV PRO	75	69 (92)	6 (8)	0 (0)
- Genie™ Fast HIV 1/2	75	66 (88)	8 (10,7)	1 (1,3)
- VIKIA® HIV 1/2	75	61 (81,3)	12 (16)	2 (2,7)
- HIVTOP® Ac 1&2	75			
lecture visuelle		67 (89,3)	7 (9,3)	1 (1,3)
lecture automatique		68 (90,6)	7 (9,3)	0 (0)
- FIRST RESPONSE® Test VIH 1-2.O CARTE	47	39 (83)	8 (17)	0 (0)

Analyse de la sensibilité de **11 TROD** au cours de la **primo-infection** par du VIH-1

Nom	Fabricant Distributeur	Marquage	Ag/AC utilisé	Temps Lecture (mn)	Matrice Volume
HIV Combo	Alere	CE/OMS	gp41 / gp36	20-30	S,P,Sg : 50
Exacto TEST HIV PRO	BioSynex		gp41 / gp36	10-20	S,P,Sg : 5
Genie Fast HIV1/2	BioRad	CE	gp120 gp41 / gp 36	10-30	S,P,Sg : 80
HIV1/2 STAT-PAK	Nephrotek	CE/FDA OMS	gp41 / gp36	15	S,P,Sg : 5
INSTI	Biolytical Nephrotek	CE/FDA OMS	gp41 / gp36	Immédiat	S,P,Sg : 50
SURE CHECK	Nephrotek	FDA/OMS	gp120 gp41 / gp 36	15-20	S,P,Sg 1 goutte
VIKIA	bioMérieux	CE/OMS	gp41 / gp36	30	S,P,Sg : 75

Q.Beaulieu et al ; JNI 2017

Nom	Nombre échantillons	Positif (%)	Négatif (%)	Invalide (%)
HIV Combo	60	60 (**100**)	-	-
Exacto TEST HIV PRO	75	69 (92)	6 (8)	-
Genie Fast HIV1/2	75	66 (88)	8 (10,7)	1 (1,3)
HIV1/2 STAT-PAK	75	57 (76)	18 (24)	-
INSTI	75	57 (76)	18 (24)	-
SURE CHECK	75	57 (76)	18 (24)	-
VIKIA	75	61 (81,3)	12 (16)	2 (2,7)

Q.Beaulieu et al ; JNI 2017

Comparison of the New Alere HIV Combo with Alere Determine HIV-1/2 Ag/Ab Combo in Acute Primo and Established HIV Infections

Patient	Determine Alere HIV-1/2 Ag/Ab Combo Ref. Nr. 7D2646		New Alere HIV combo Ref.Nr. 7D2846		Abbott Architect i2000SR	NCR[1)]		
	anti-HIV-1 or HIV-2 Ab	p24 Ag	anti-HIV Ab	p24 Ag	anti-HIV-1/2 p24 Combo (cutoff S/CO <1)	HIV western blot	HIV RNA (copies/ml)	Clade
Anti HIV-1 antibodies								
1	pos	neg	pos	neg	632	HIV-1	363	A1
2	pos	neg	pos	neg	504	HIV-1	191024	A1
3	pos	neg	pos	neg	253	HIV-1	718	B
4	pos	neg	pos	neg	486	HIV-1	4044	B
5	pos	neg	pos	neg	919	HIV-1	29472	B
6	pos	neg	pos	neg	321	HIV-1	75720	B
7	pos	neg	pos	neg	678	HIV-1	92000	B
8	pos	very weak pos	pos	neg	1142	HIV-1	>10000000	B
9	pos	neg	pos	neg	873	HIV-1	23637	C
10	pos	neg	pos	neg	839	HIV-1	23700	CRF01_AE
11	pos	neg	pos	neg	633	HIV-1	26265	CRF01_AE
12	pos	neg	pos	neg	313	HIV-1	1379981	CRF01_AE
13	pos	neg	pos	neg	428	HIV-1	2537	CRF02_AG
14	pos	neg	pos	neg	613	HIV-1	282000	CRF02_AG
15	pos	neg	pos	neg	257	HIV-1	59572	D
Anti-HIV-2 antibodies								
16	pos	neg	pos	neg	83	HIV-2	PERT 911 nU RNA/ml = 17659 copies/ml	
17	pos	neg	pos	neg	-	HIV-2	under HAART	
p24-antigen only								
18	neg	very weak pos	neg	weak pos	49.1	no Ab	1808956	B
19	neg	very weak pos	very weak pos	pos	251	very weak pos HIV-1 Ab	1983752	B
20	neg	very weak pos	neg	pos	128	no Ab	>10000000	B
21	neg	**neg**	neg	**pos**	91	no Ab	>10000000	C
22	neg	**neg**	neg	**weak pos**	50.5	no Ab	>10000000	CRF01_AE
23	neg	**neg**	neg	**pos**	423	no Ab	>10000000	CRF02_AG

C.Ottiger et al ; Ann.Clin.Lab.Res.2015

Performance of serological and molecular tests within acute HIV infection

Test	NAAT positive N° reactives/total tested	Sensitivity% (95% CI)	NAAT negative N° reactives/total tested	Specificity% (95% CI)
Determine HIV1/2	2/33	**6.06** (0.92–20.26)	Not done	Not done
SD-Bioline HIV-1/2	4[a]/33	**12.12** (3.48–28.22)	Not done	Not done
Determine HIV1/2 Ag/Ab	3/35	**8.57** (1.80–23.06)	2/29	**93.10** (77.23–99.15)
SD-Bioline HIV Ag/Ab Combo	10/34	**29.41** (15.12–47.48)	0/35	**100** (89.90–100)
HIV Combo	6/35	**17.14** (6.56–33.65)	2/29	**93.10** (77.23–99.15)

HIV **p24 Ag** of the **Determine** HIV1/2 Ag/Ab assay and the HIV **Combo** assay has **no real added value** in the early detection of an HIV infection

The **new test HIV Combo test is in general slightly more sensitive** compared with the previous version

but **none of them** are precise in detecting Ag in the determination of acute infections

K.Fransen et al ; J.Clin.Virol. 2017

Diagnosing acute HIV infection at point of care: a retrospective analysis of the sensitivity and specificity of a fourth-generation point-of-care test for detection of HIV core protein p24

Table 1 Alere HIV-Combo point-of-care testing (POCT) results for detection of p24 antigen

Abbott Architect HIV Ag/Ab Combo assay results	Number tested	Alere HIV-Combo POCT results p24 antigen-positive
p24-positive serum	34	30 (88%)*
p24-negative plasma	30	0
p24-negative whole blood	20	0
HIV-negative serum	35	0

*This does not include the sample that was negative for p24 antigen when read at 20 min but positive when read at 40 min (delayed detection).

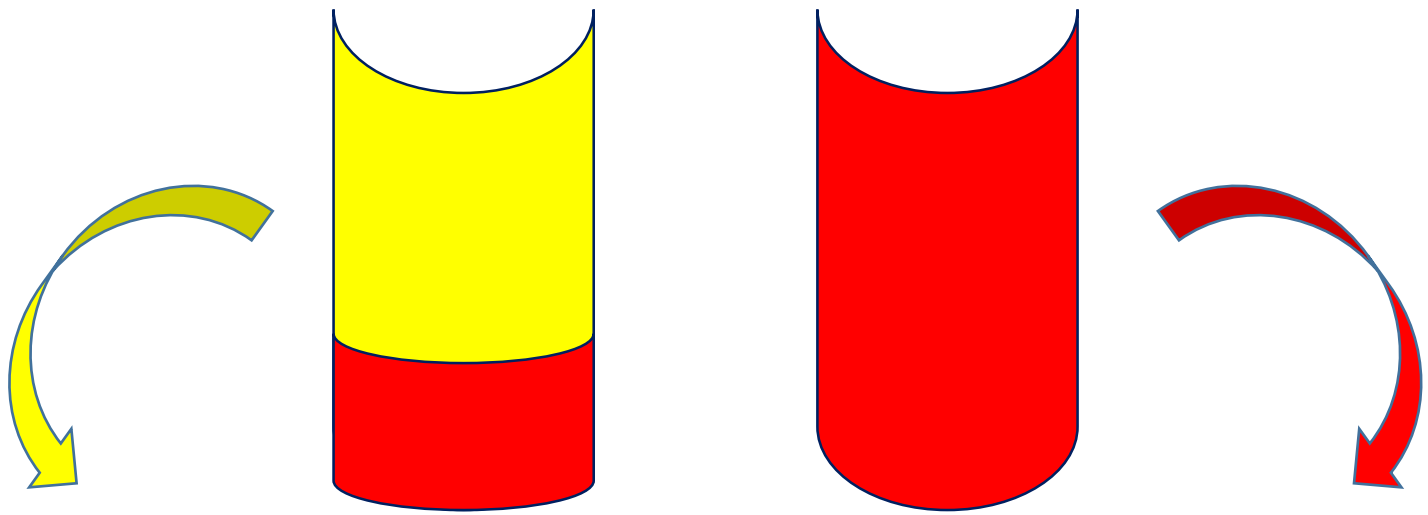
Overall the Alere HIV Combo POCT test demonstrated **88% sensitivity** and 100% specificity for detection of p24 antigen when read at **20 min** and **91%** sensitivity at **40 min**
The antibody portion of the test showed 100% sensitivity and specificity

The **mean p24 antigen** level, as detected by the VIDAS quantitative HIV p24 11 assay, was **279.6 pg/mL** (range 8.3– >400 pg/mL)
The p24 antigen levels for the **three false negative** cases were **8.3** pg/mL, **27.6** pg/mL and **>400 pg/mL** and for the delayed detection case 13.6 pg/mL

N.Fitzgerald et al ; Sex.Transm.Infect. 2017

Performance evaluation of the FDA-approved Determine™ HIV-1/2 Ag/Ab Combo assay using plasma and whole blood specimens

In 20 HIV-1 seroconversion panels,there was a **significant difference** between DC reactivity



Plasma (**91.1%**)

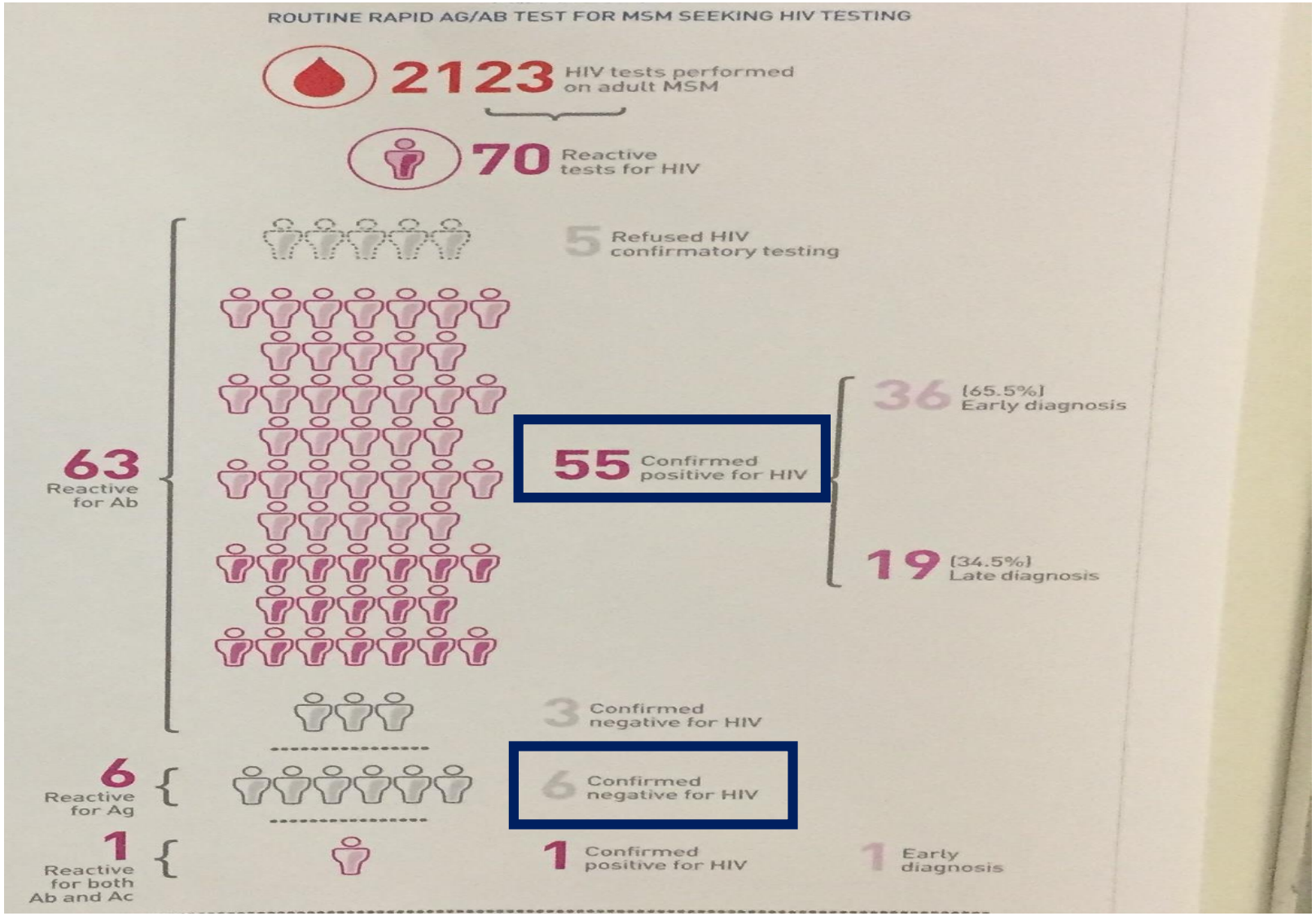
Whole blood (**56.4%**)

$p < 0.0001$

S.Masciotra et al ; J.Clin.Virol. 2017

MEN WHO HAVE SEX WITH MEN PRIMARY HIV INFECTION DETECTION AT CHECKPOINTLX, LISBON, PORTUGAL

Authors: L. M. Carvalho Rocha[1], A. S. Cabrita Martins[2], R. Guerreiro[1], J. Rojas[1], F. Ferreira[1], L. Verissimo[1], J. Brito[1], N. Pinto[1], M. L. G. P. Varandas Costa[3], D. Medina[1]
Institutions: [1]GAT Portugal, CheckpointLX, Lisbon, Portugal. [2]Northern Lisbon Hospital Center, Lisbon, Portugal. [3]Lisbon Nursing School, Community Health Nursing, Lisbon, Portugal



AC
3/58 (5,2%)
faux positifs

Ag
6/6 faux positifs

Au total
9/64
Faux positifs
(14%)

IAS Juillet 2017

The fourth generation Alere™ HIV Combo rapid test improves detection of acute infection in MTN-003 (VOICE) samples

Fourth generation HIV rapid tests use a lateral flow cassette to separately assay for both anti-HIV antibodies and p24 antigen, however **numerous studies** have demonstrated the United States Food and Drug Administration (FDA)-approved Alere Determine™ HIV-1/2 Ag/Ab Combo to be **insensitive** for detection of acute infection

In **February 2015**, Alere released a re-formulated fourth generation rapid test kit, the Conformité Européene (CE)-Marked **Alere™ HIV Combo**

Of **57** antibody-negative **pre-seroconversion** plasma samples with HIV RNA>20 copies/mL identified, **16** (**28%**) were reactive by CE-Marked **Alere™ HIV Combo** (1 Ab; 9 Ag; 6 Ag/Ab reactive) and **4** (**7%**) by **Alere Determine™** HIV-1/2 Ag/Ab Combo (2 Ab; 2 Ag; 0 Ag/Ab reactive) (p =0.0005)

E.Livant et al ; J.Clin.Virol. 2017

The effect of oral preexposure prophylaxis on the progression of HIV-1 seroconversion

D.Donnell et al ; AIDS 2017

Assessment of HIV Screening Tests for Use in Preexposure Prophylaxis Programs

C.Delaugerre et al ; JID 2017

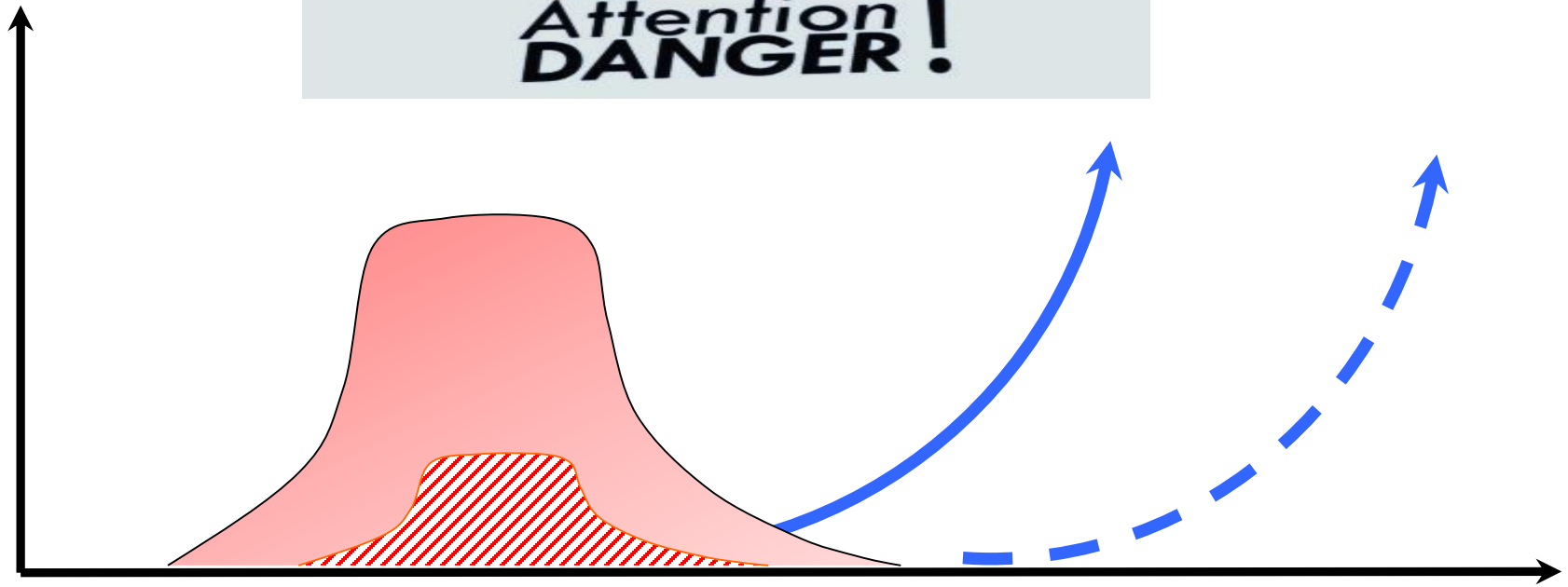
Sensitivity of 2 antigen/antibody immunoassays (**Architect and Bioplex**), 2 antibody-based rapid tests (**Vikia-HIV-1/2** and **Autotest-VIH**), and 1 antigen/antibody rapid test (**Alere HIV Combo**) for the diagnosis of HIV infection

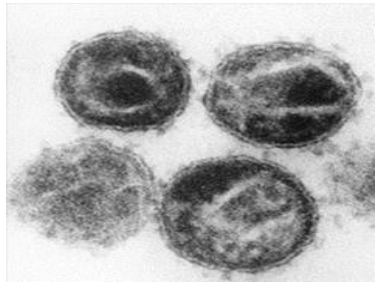
The sensitivities of the Architect and Bioplex assays were **83% and 82%**, respectively

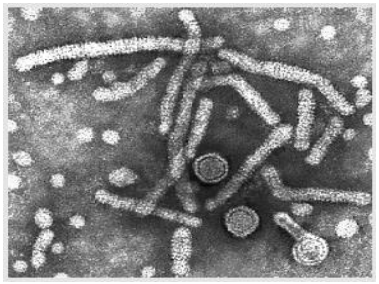
The sensitivities of the Vikia, Autotest, and Alere tests were **54%, 50%**, and **78%**

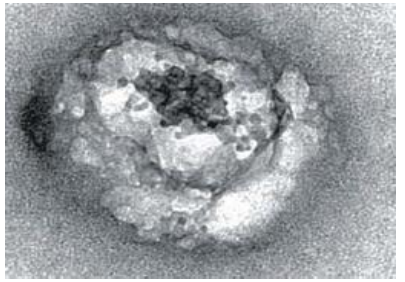
Les **autotests** et **tests rapides (TROD)** peuvent être pris en défaut pour le diagnostic de primo-infection: ils peuvent être négatifs en infection aiguë (Western blot négatif) et se positivent inconstamment en infection récente (Western blot indéterminé, ≤ 5 bandes)

Rapport Morlat 2016









Infections chroniques

25000

150000

75000

DÉPISTAGE COMMUNAUTAIRE PAR TESTS RAPIDES (TROD) VIH EN FRANCE SUR UNE PÉRIODE DE TROIS ANS, 2012-2014

De 2012 à 2014, environ **149 800** dépistages par **TROD** ont été réalisés par **60 associations**

31 700 en 2012

56 500 en 2013 (+28% par rapport à 2012)

61 600 en 2014 (+4% par rapport à 2013)

	2012	2013	2014	Total
	N	N	N	N
Personnes avec TROD positifs	332 (1,04%)*	486 (0,86%)	552 (0,90%)	1 370 (0,90%)
dont personnes connaissant déjà leur séropositivité	69	97	83	261
dont TROD positifs non confirmés en laboratoire (« faux positifs »)	ND	ND	12**	12
Nouvelles découvertes de séropositivité	263 (0,83%)	389 (0,69%)	457 (0,74%)	1 109 (0,74%)

457/6584 = **6,9%**

A. Sarr et al ; Bull Epidémiol Hebd. 2015

Test rapide pour la détection qualitative de l'**AgHBs**, des anticorps **anti-VHC** et des anticorps **anti-VIH**

TROD

Situation idéale

0 risque : **< 2 mois**

Pas de pré/post Prophylaxie

TROD NEGATIF

PAS D'INFECTION VIH

TROD

Situation idéale

0 risque : **< 2 mois**
Pas de pré/post
Prophylaxie

TROD NEGATIF
PAS D'INFECTION VIH

Situation « délicate »

Risque : **< 2 mois**
et/ou
pré/post prophylaxie

TROD NEGATIF
N'exclut pas
INFECTION VIH

MERCI


TUNISIE
HAMMAMET
du 28 au 30 sept. 2017
www.aframed2017.org
2e édition
AFRAMED
VIH / HÉPATITES
AFRAVIH