

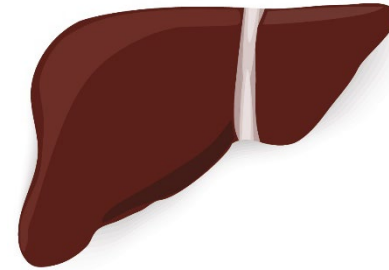


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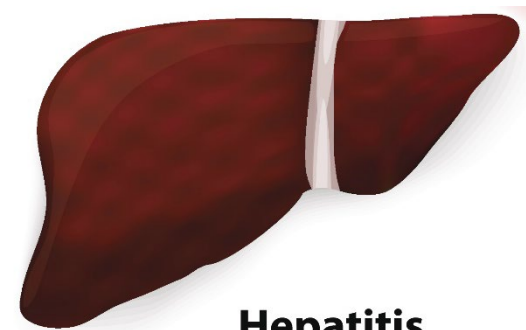
ABON[™] Hepatitis Product Training

What is Hepatitis?

- **Hepatitis** is a medical condition defined by the inflammation of the liver and characterized by the presence of inflammatory cells in the tissue of the organ
- There are 6 viruses known to affect the liver and cause Hepatitis: HAV, HBV, HCV, HDV (Delta), Hepatitis E virus (HEV) and HGV.
- Hepatitis A and E are typically caused by ingestion of contaminated food or water.
- Hepatitis B, C and D are typically caused by contact with contaminated blood or body fluids.
- There are two chronic and serious forms
 - Hepatitis B
 - Hepatitis C



Normal liver



Hepatitis

Hepatitis-Major Etiologies

1. Viral infections
2. Cytotoxic drugs
3. Cytomegalovirus (CMV)
4. Autoimmunity
5. Alcohol

Hepatitis Symptoms

- Hepatitis symptoms include:
 - Fatigue
 - Flu-like symptoms
 - Dark urine
 - Pale stool
 - Abdominal pain
 - Loss of appetite
 - Jaundice
 - Weight Loss

Many people feel no symptoms, and may be infected for years without knowing it.

Hepatitis B Virus

Hepatitis B-Diagnosis

Serologic markers

- **HBsAg:** indicate the person is infectious
- **HBsAb:** indicate recovery and immunity from Hepatitis B virus infection
- **HbeAg:** Virus copy
- **HBeAb:** Virus stop copy
- **HBcAb:** ever infected or on going
- **HBcAg:** Hepatitis B Virus Core Antigen, almost no free HBcAg

ABON Hepatitis B Product-HBsAg

Parameter	Description			
Intended Use	Detection of HBsAg (Hepatitis B Surface antigens) in human serum or plasma or whole Blood			
Format	Immunochromatographic Lateral Flow	Principle	Double Antibody Sandwich	
Chromogen	Latex	Antibodies	Highly purified antibodies to HBsAg	
Line Sescription	Line No.	Line Name	Description	
	Line 1	Test Line (T)	Coat with anti-HBsAg Antibodies, detect HBsAg	
	Line 2	Control Line (C)	To serve as a procedural control	
Test Format	Device		Strip	
Catalog No.	IHBsg-302 (Chromogen: Gold)	IHBsg-402	IHBsg-301	IHBsg-401
Sensitivity	>99.0%	98.99% (97.93%-99.59%)	>99.0%	99.0%(97.2%-99.8%)
Specificity	96.7%	99.87% (99.67%-99.97%)	97.0%	99.9%(99.3%-100%)
Accuracy	98.3%		98.5%	99.64%(99.07%-99.90%)
Pack	40 Tests	40 Tests	50 Tests	50 Tests

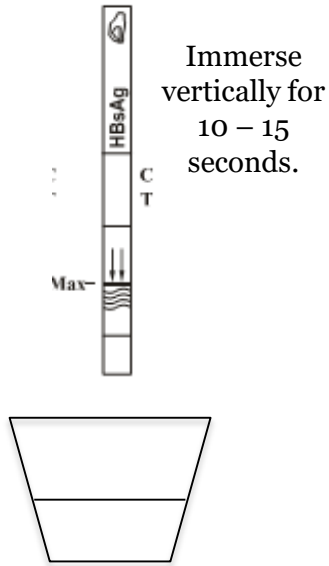
Focus, CE marked

Hepatitis B Product-Other HBV

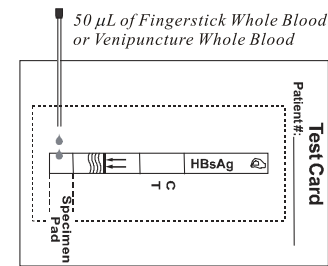
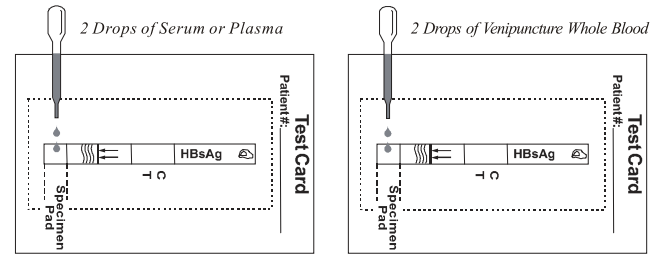
Name	Specimen	Format	Catalog No.	Sensitivity	Kit Size
One Step Hepatitis B Surface Antibody Test Device (Serum/Plasma)	Serum/Plasma	Device	IHBsb-302	100% (99.4%-100.0%)	40
One Step Hepatitis B Virus Combo Test Device (Serum/Plasma)	Serum/Plasma	Device	IHB-355	See insert	25

Hepatitis B Product Procedure

IHBsg-301



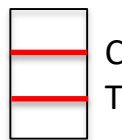
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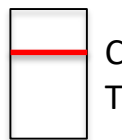
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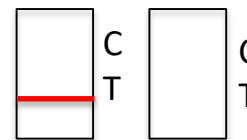
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Positive



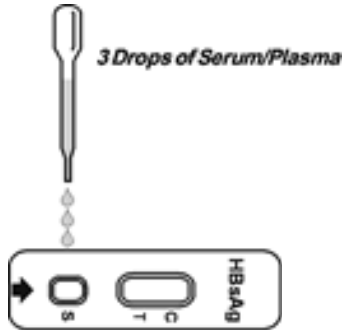
Negative



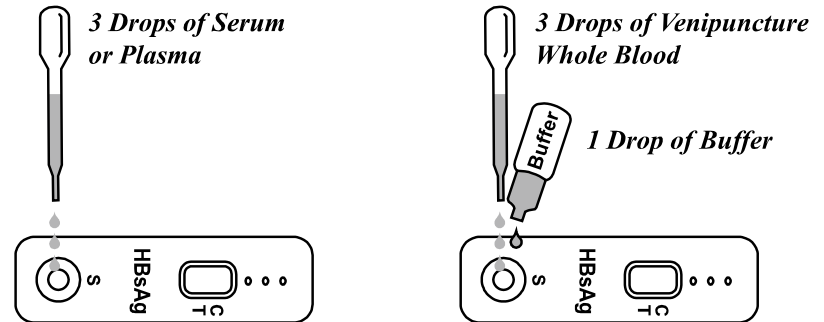
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Hepatitis B Product Procedure

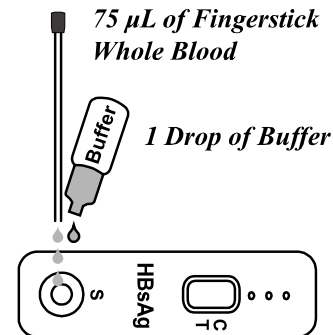
IHBsg-302



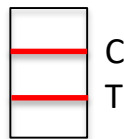
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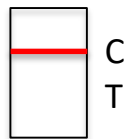
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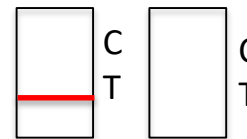
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Positive



Negative



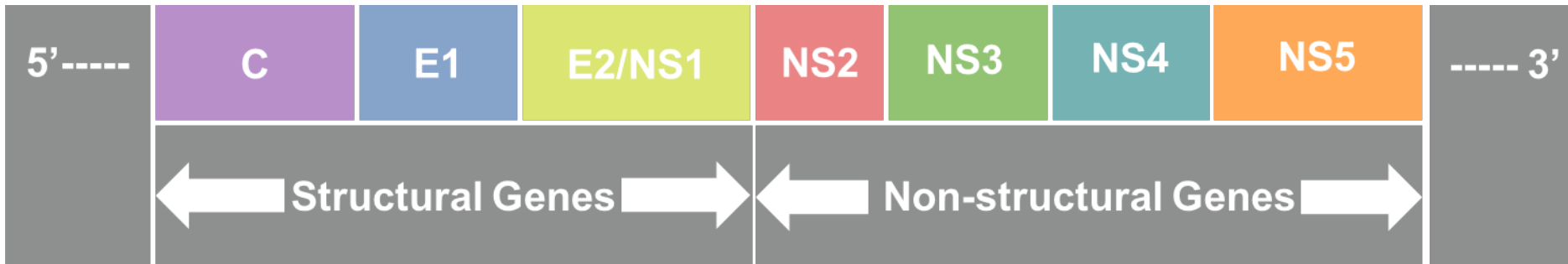
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Hepatitis C Virus

Hepatitis C Virus

Virus

- An envelope, single stranded positive sense RNA including:
 - Structural genes at the 5' end
 - Non-structural genes at the 3' end

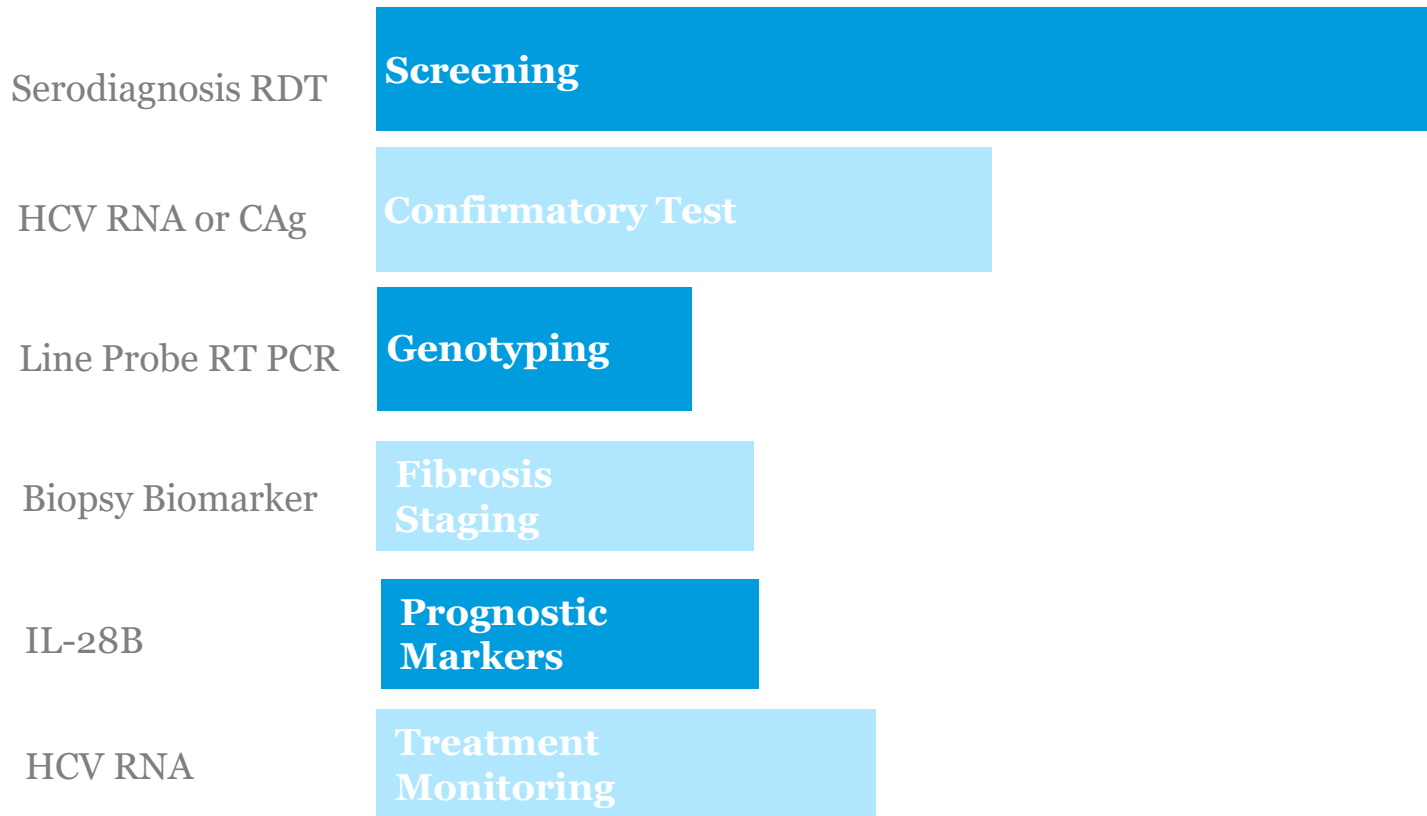


Hepatitis C

- 130-150 million people globally have chronic Hepatitis C infection ⁵
- 350,000-500,000 die each year from Hepatitis C-related liver disease ⁵
- Of those with chronic HCV infection, the risk of cirrhosis of the liver is 15-30% within 20 years ⁵
- There is NO vaccine against HCV
- An early diagnosis in the course of the disease can:
 - Increase the chances of successful treatment
 - Increase impact of essential lifestyle changes
 - Limit cross-infection

The HCV Diagnosis Continuum

The Hepatitis C Virus is a complex organism and treatment modalities are varied.

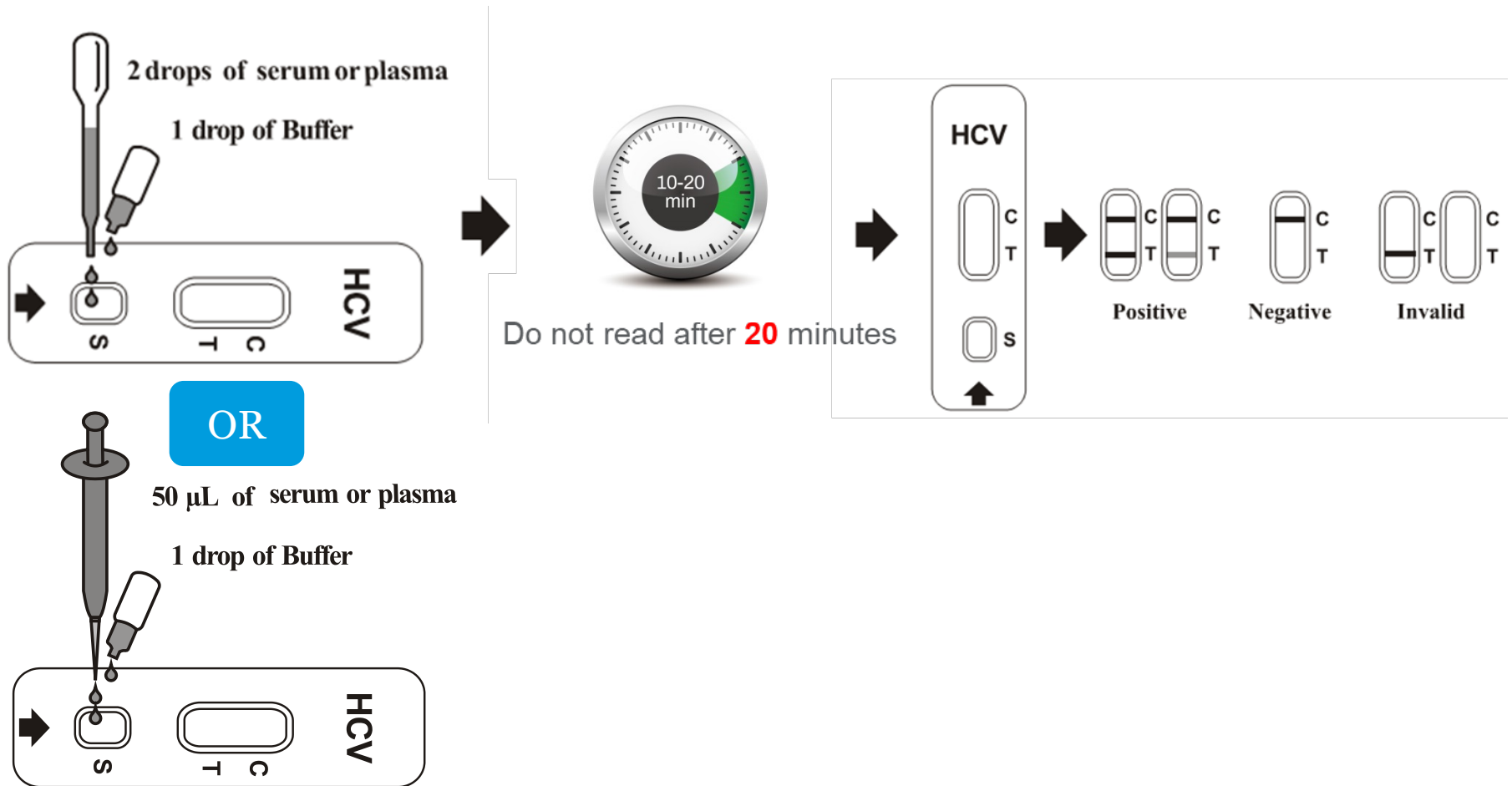


ABON™ HCV Test (Serum/Plasma) Brief Information

Parameter	Description		
Product Name	Hepatitis C Virus Rapid Test Device (Serum/Plasma)		
Intended Use	Detection of anti-HCV antibodies		
Cat. No.	IHC-302	Pack	40 Tests
Format	Immunochromatographic Lateral Flow Assay		
Detection Principle	Double Sandwich Antigen		
Test Time	10-20 min		
Performance Characteristics	Sensitivity	>99.53% (99.53%-100%)*	Specificity 99.78% (99.36%-99.95%)*

*95% Confidence Interval

Hepatitis C Virus Rapid Test Device (Serum/Plasma)



Hepatitis C Virus Rapid Test Device (Serum/Plasma)

Method		Commercial Rapid Test		Total Results
		Positive	Negative	
HCV Test Device	Results			
	Positive	630	3	633
	Negative	0	1367	1367
Total Results		630	1370	2000

Sensitivity:>99.53%(99.53%-100.0%)*

Specificity:99.78%(99.36%-99.95%)*

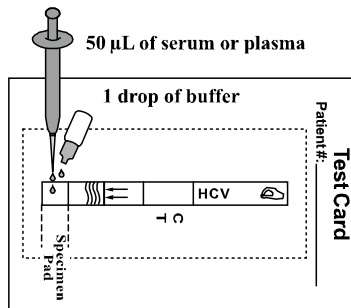
Accuracy:99.85%(99.56%-99.97%)*

* 95% Confidence Interval

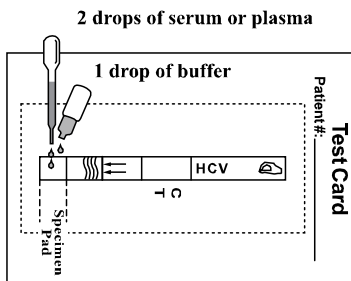
Hepatitis C Product-Other HCV

Name	Specimen	Format	Catalog No.	Sensitivity	Test Per Kit
Hepatitis C Virus Rapid Test Strip (Serum/Plasma)	Serum/Plasma	Strip	IHC - 301	> 99.53% (99.53%-100.0%)*	50

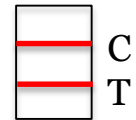
*95% Confidence Interval



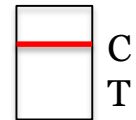
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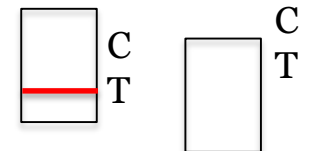
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Positive



Negative

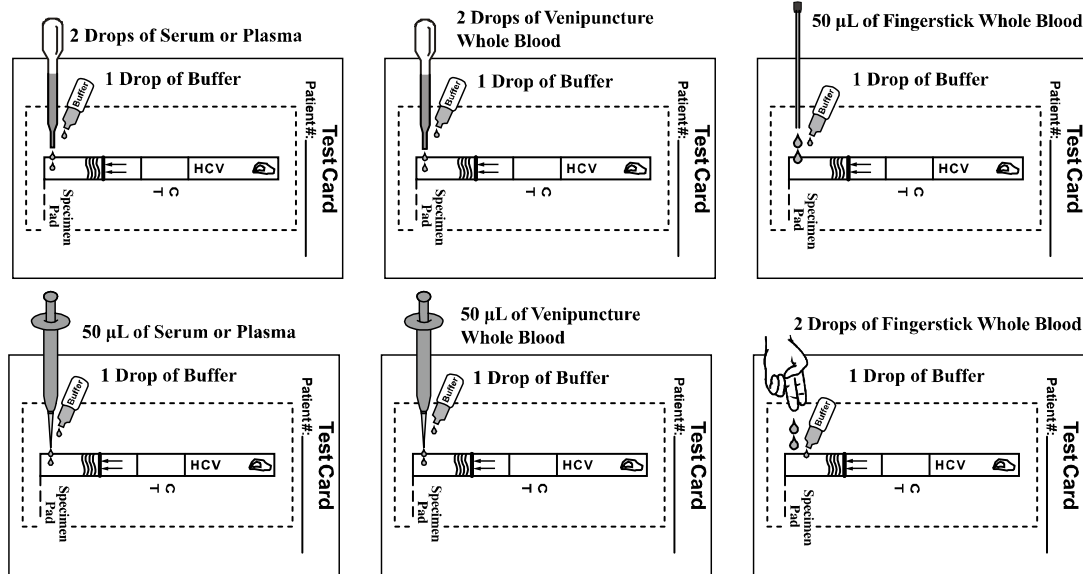


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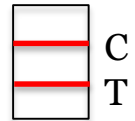
Hepatitis C Product-Other HCV

Name	Specimen	Format	Catalog No.	Sensitivity	Test Per Kit
Hepatitis C Virus Rapid Test Strip (Serum/Plasma)	Whole Blood/ Serum/Plasma	Strip	IHC - 401	> 99.53% (99.53%-100.0%)*	50

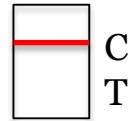
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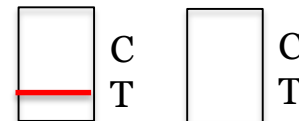
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Positive



Negative

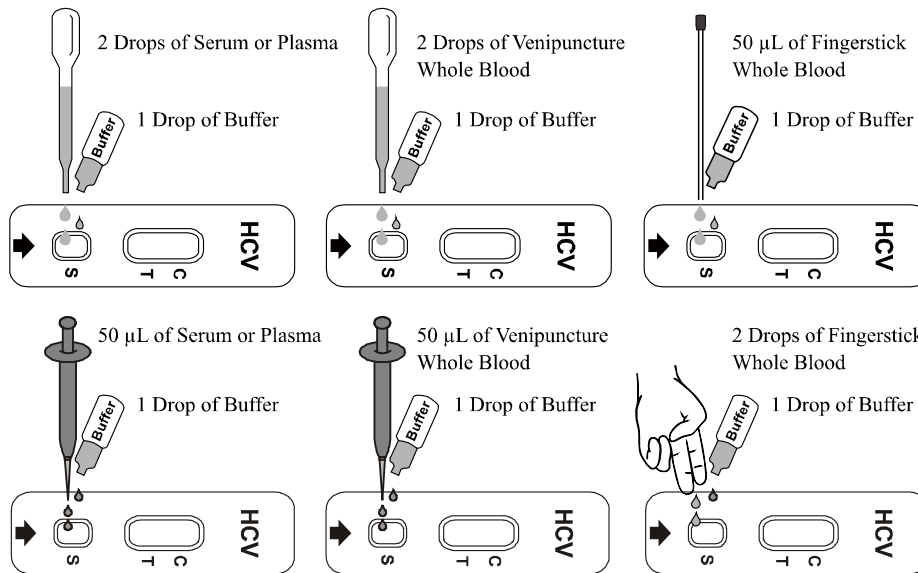


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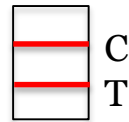
Hepatitis C Product-Other HCV

Name	Specimen	Format	Catalog No.	Sensitivity	Test Per Kit
Hepatitis C Virus Rapid Test Strip (Whole Blood/Serum/Plasma)	Whole Blood/ Serum/Plasma	Device	IHC - 402	> 99.53% (99.53%-100.0%)*	40

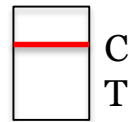
*95% Confidence Interval



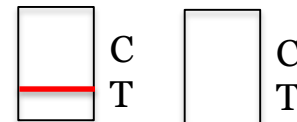
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Positive



Negative



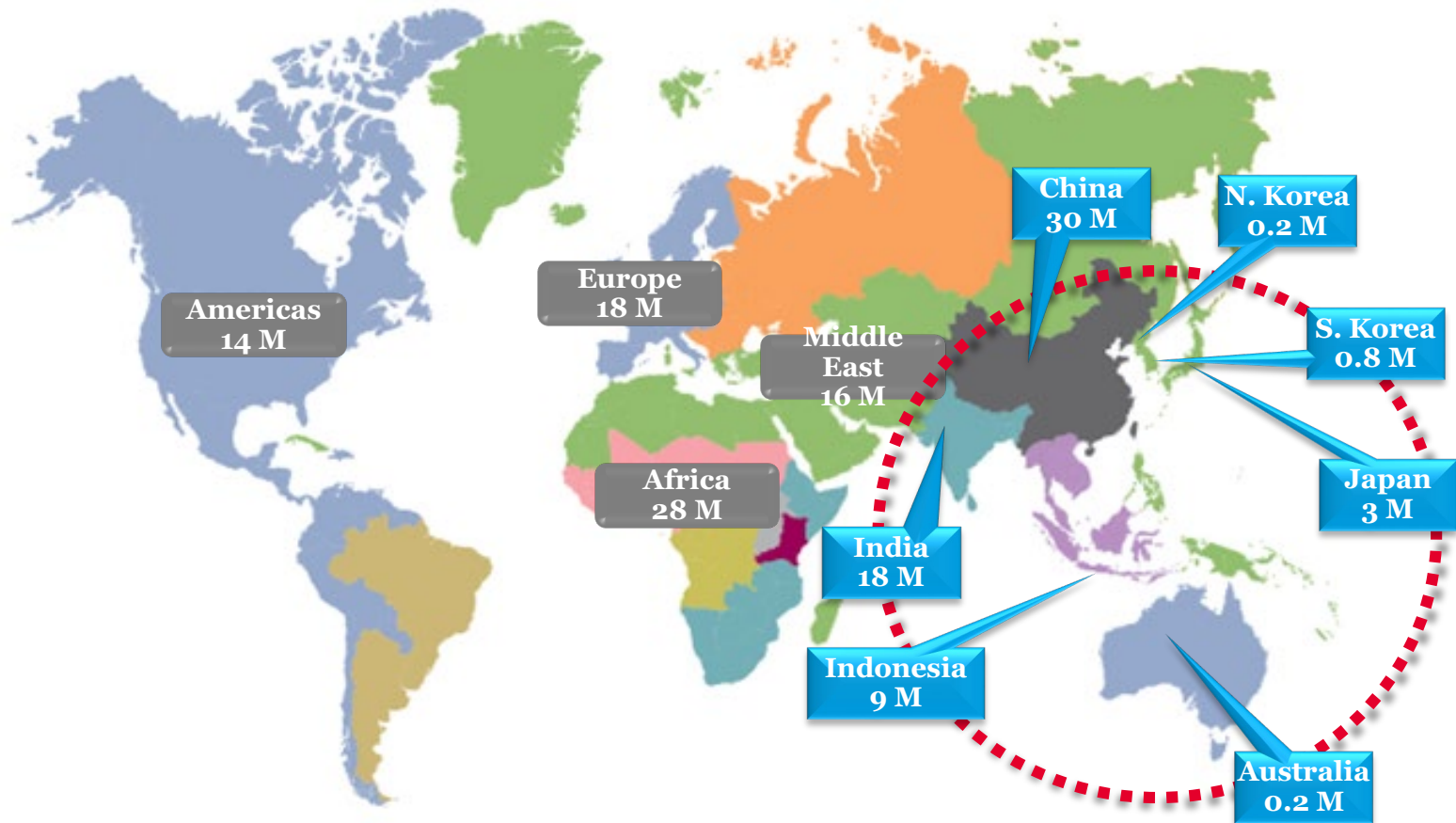
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Hepatitis

Hepatitis C Incidence

According to recent estimates, more than 185 million people globally have been infected with Hepatitis C, of whom 350,000 die each year.⁶

Estimated number of chronically infected individuals (2010)⁶



References

1. World Health Organization (WHO) What is hepatitis [Online] <https://www.who.int/features/qa/76/en/> Accessed 4 December 2018
2. Healthline [Online] <https://www.healthline.com/health/hepatitis#symptoms> Accessed 4 December 2018
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