Clinical Study Report of HCV Rapid Test

Ref.: IHC-402

	Name	Department	Signature	Date
Prepared by	Bubble Fei	R&D	Bubble Fei	2022.05.17
Reviewed by	Smile Jiang	R&D	Smile Jiang	2022.05.17

Digitally signed by Jighili Tatiana
Date: 2024.11.08 17:04:48 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Content

1. Summary

490 HCV positive specimens and 1544 HCV negative specimens confirmed by HCV Test and clinical Symptoms were used in clinical study. HCV Reagent Kit (CMIA) as the reference method for the HCV Test. The result shows the HCV Rapid Test has a high restive sensitivity and high relative specificity when tested with the 2034 specimen

2. Background

Hepatitis C is a liver disease caused by the hepatitis C virus (HCV) that causes acute and chronic infection[1,2]. Hepatitis C Virus (HCV) is a small, enveloped, positive-sense, single-stranded RNA Virus. HCV is now known to be the major cause of parenterally transmitted non-A, non-B hepatitis. Antibody to HCV is found in over 80% of patients with well-documented non-A, non-B hepatitis. An estimated 71 million people had chronic hepatitis C infection worldwide in 2015.[3]

Conventional methods fail to isolate the virus in cell culture or visualize it by electron microscope. Cloning the viral genome has made it possible to develop serologic assays that use recombinant antigens. Compared to the first generation HCV EIAs using single recombinant antigen, multiple antigens using recombinant protein and/or synthetic peptides have been added in new serologic tests to avoid nonspecific cross-reactivity and to increase the sensitivity of the HCV antibody tests.

The HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid test to qualitatively detect the presence of antibody to HCV in a whole blood, serum or plasma specimen. The test utilizes colloid gold conjugate and recombinant HCV proteins to selectively detect antibody to HCV in whole blood, serum or plasma. The recombinant HCV proteins used in the test kit are encoded by the genes for both structural (nucleocapsid) and non-structural proteins.

3. Objective

Do clinical studies of HCV Rapid Test with the HCV positive specimens and negative specimens which confirmed with HCV Rapid Test

4. Materials

- HCV Rapid Test Cassette

Lot: HCV19110006-T

Lot: HCV19110007-T

- Negative specimens:

  1544 negative whole blood, plasma and serum specimens: 1000 specimens collected from blood donations, 209 specimens collected from the hospitalized case, 200 specimens collected from the pregnant women. 135 specimens collected from the potentially interfering specimens.

- Positive specimens:

  490 positive whole blood, plasma and serum specimens collected from the hospitalized case.

5. Method

HCV Rapid Test: Totally 2034 Whole blood/Serum/Plasma samples collected from individuals, and then tested with EIA or CMIA, Alltest HCV Rapid Test cassette respectively.

6. Operation Method

Operation method can be referred to package insert provided in the kits.

7. Test Results

Table: Clinical Study Summary Result for HCV

Study Site: BIOMEX GmbH								
Sample Status	Sample Anti-HCV Status	Comparator Method	Serum/Plasma Specimen			Whole Blood Specimen		
			Specimen Number	Alltest Product Result		Specimen Number	Alltest Product Result	
				Positive	Negative		Positive	Negative
HCV positive sample	Positive	CMIA	349	349	0	/	/	/
Clinical(hospital) sample	Negative	CMIA	/	/	/	100	0	100
Blood donors	Negative	CMIA	900	0	900	100	0	100

Study Site: Kenya National HIV Reference Laboratory								
Sample Status	Sample Anti-HCV Status	Comparator Method	Serum/Plasma Specimen			Whole Blood Specimen		
			Specimen Number	Alltest Product Result		Specimen Number	Alltest Product Result	
				Positive	Negative		Positive	Negative
HCV positive sample	Positive	EIA	2	2	0	46	46	0
Clinical (hospital) sample	Negative	EIA	6	0	6	103	0	103

Study Site:Aisa lab Medical Diagnostic Laboratory								
Sample Status	Sample Anti-HCV Status	Total Specimen Number	Serum/Plasma Specimen			Whole Blood Specimen		
			Specimen Number	Alltest Product Result		Specimen umber	Alltest Product Result	
				Positive	Negative		Positive	Negative
HCV Genotype sample	Positive	93	93	93	0	/	/	/

Note: 93 HCV Genotype sample contains Genotype1,2,3,4,5,6. Genotype 1-4 each genotype has 21 samples. Genotype 5 has 6 samples. Genotype 6 has 3 samples.

Study Site: Inhouse study				
Sample Status	Sample	Total	Serum/Plasma Specimen	Whole Blood Specimen

	Anti-HCV Status	Specimen Number	Specimen Number	Alltest Product Result		Specimen umber	Alltest Product Result	
				Positive	Negative		Positive	Negative
HCG positive sample	Negative	200	200	0	200	/	/	/
Interference Substance sample	Negative	135	135	0	135	/	/	/

8. Summary

Method			HCV Rapid Test Cassette (Whole Blood/Serum/Plasma)		Agreement
Predicated Test (EIA or CMIA)	Result		Positive	Negative	
	Positive	HCV	397	0	>99.9% (397/397)
		Genotypes 1,2,3,4,5,6	93	0	>99.9% (93/93)
		Total	490	0	>99.9% (490/490)
	Negative	Blood Donation	0	1000	>99.9% (1000/1000)
		Clinical Negative	0	209	>99.9% (209/209)
		Pregnant Woman	0	200	>99.9% (200/200)
		Interference Substance	0	135	>99.9% (135/135)
		Total	0	1544	>99.9% (1544/1544)
Total Result			490	1544	>99.9% (2034/2034)

Sensitivity: 100% (95%Cl*=99.4%-100%)
Specificity: 100% (95%CI*=99.8%-100%)
Accuracy: 100% (95%CI*=99.9%-100%) *Confidence Intervals

9. Conclusion

The relative sensitivity of HCV Rapid Test was 99.9%, the relative specificity was 99.9% compare with EIA or CMIA result.

10. References

1.World Health Organization. New recommendations in the updated WHO guidelines for the screening, care and treatment of persons with chronic hepatitis C infection. Geneva: WHO; 2016. http://www.who.int/hepatitis/publications/hepatitis-c-guidelines-2016/en/.

2.Lavanchy D. The global burden of hepatitis C. Liver Int. 2009;29(s1):74–81.
3. World Health Organization. Global Hepatitis Report, 2017. Geneva; 2017.
http://www.who.int/hepatitis/publications/global-hepatitis-report2017/en/. Accessed 6 Oct 2017.