

SD BIOLINE HCV Versus HCV Rapid Test Strip (DiaSpot[®]): A Comparative Study Of Rapid Screening Tests For Viral Hepatitis C

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Abstract

Rapid screening tests (RDTs) for infections are proliferating in Africa. In Cameroon, there are about ten viral hepatitis C (HVC) RDTs. Among these tests, some like SD BIOLINE HCV are prequalified by the WHO and others are not, like HCV Rapid Test Strip (DiaSpot[®]). The objective of this study was to compare and evaluate the performance of SD BIOLINE HCV and HCV Rapid Test Strip (DiaSpot[®]). 50 samples were selected at the Douala military hospital. Among these samples, 22 were positive and 28 were negative in the anti-HCV ELISA test (AUTOBIO DIAGNOSTICS CO., LTD). SD BIOLINE HCV and HCV Rapid Test Strip (DiaSpot[®]) were used to search for HCV antibodies in the serum of 50 patients. For each RDT, the sensitivity, specificity, Negative Predictive Value (NPV) and Positive Predictive Value (PPV) were calculated. HCV Rapid Test Strip (DiaSpot[®]) showed sensitivity, specificity, NPV and PPV equal to 100%, 82.14%, 100% and 81.48% respectively. And SD BIOLINE HCV presented 100% value for sensitivity, specificity, NPV and PPV. The reproducibility of SD BIOLINE HCV on 15 patients was 100%.

Conclusion: According to our study, the SD BIOLINE HCV and HCV Rapid Test Strip TDRs (DiaSpot[®]) exhibit excellent sensitivities. According to the operational criteria, although SD BIOLINE HCV is superior, both RDTs are appropriate for screening for viral hepatitis C.

1. Introduction

Rapid detection tests (RDTs) for infections are proliferating in Africa, because of their relatively accessible cost and their simplicity of use. In Cameroon, we have counted about ten commercialized RDTs for viral hepatitis C screening, all of which have not been pre-certified by organizations such as the World Health Organization (WHO), the Food and Drug Administration (FDA) or the European Community. Although there is a proliferation of non-certified RDTs, there are tests that have been prequalified by the WHO, such as SD BIOLINE HCV [1, 2]. Indeed, according to the WHO, the SD BIOLINE HCV test meets the criteria to classify it among the tests that can be used as

a screening test for viral hepatitis C. Finding ourselves in a context where the prevalence of viral hepatitis C is relatively high [3], and where two types of tests circulate, namely prequalified tests or certified by learned societies and others not, it seemed appropriate to us to conduct a comparative study to evaluate the effectiveness of two TDRs marketed in the city of Douala, namely the pre-qualified TDR SD BIOLINE HCV and HCV Rapid Test Strip (DiaSpot[®]) not pre-qualified by the WHO.

2. Methodology

The HCV Rapid Test Strip (DiaSpot[®]), and SD BIOLINE HCV whose characteristics are detailed in the table below were selected for our study.

Table 1. Characteristics of two rapid HCV tests

	HCV Rapid Test Strip	SD BIOLINE HCV Test
Mark	DiaSpot [®]	Standard Diagnosis Inc*
Packaging/ storage	Box of 50 strips (2-30°C)	Box of 30 Cassettes (4-30°C)
Country of origin	China	Republic of de Korea
Batch (Expiry Date)	HCV-S210401 (04/2024)	02BDG018A (04-06-2023)
Sensitivity	99.00%	99.3%
Specificity	98.60%	94.4%
Precision	99.30%	/

*

Note: The name of the test has changed from SD BIOLINE HCV to BIOLINE HCV. The manufacturer's name has also from Standard Diagnostics Inc to Abbott Diagnostics Korea Inc. However it is the SD BIOLINE HCV version that we used in this study.

50 samples from the blood bank and the cardiology department were selected at the Douala military hospital from April 2022 to May

2022. Of these samples, 22 were positive and 28 were negative to the anti-HCV ELISA test (AUTOBIO DIAGNOSTICS CO., LTD). (See table 2). Each RDT was used to search for hepatitis C antibodies in the serum of 50 patients. To ensure impartiality, the tests were carried out blindly. Here, only the principal investigator was aware of the positive and negative results of the HCV EIA test considered here as the standard

Table 2. Characteristics of the tests used as standard

Anti-HCV ELISA	
Mark	AUTOBIO DIAGNOSTICS CO.,LTD
Packaging/ storage	Box of 96 tests (2-8°C)
Country of origin	China
Batch (Expiry Date)	25K23-M66 (24/10/2022)/E0320
Negative specificity	100%
Positive specificity	100%

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On EPI INFO 7, Sensitivity, specificity, positive predictive value (PPV) and negative predictive

value (NPV) were calculated from contingency tables whose formulas are as follows:

Sensitivity (Se)

$$Se = \frac{\text{True positive}}{\text{False negative} + \text{True positive}}$$

Specificity (Sp)

$$Sp = \frac{\text{True negative}}{\text{True negative} + \text{False positive}}$$

Negative predictive value (NPV)

$$NPV = \frac{\text{True negative} \times 100}{\text{True negative} + \text{False negative}}$$

Positive predictive value (PPV)

$$PPV = \frac{\text{True positive} \times 100}{\text{True positive} + \text{False positive}}$$

For the HCV BIOLINE SD RDT, the negative and positive reproducibility test was also performed on 10 and 5 samples respectively. Based on the operationality criteria, a score out of 40 was

established for each RDT in order to know whether they are Very appropriate (score >30), appropriate (Score between 23 and 30) or inappropriate (score <30) for screening for viral hepatitis C.

3. Result and discussion

3.1. Socio-demographic characteristics

Our samples came from 50 patients, 27 of whom were women, i.e. 54% with a sex ratio of 1.17 in favor of women (See table 1). 44%, i.e. 22 patients came from the Littoral region (See table 2). The majority of patients were Catholic with a

proportion of 45.65% (See table 3). Half of our study population had never been tested for viral hepatitis C (See table 4), and the most represented professional activity in our population was University students with a proportion of 36.73% (See table 5). The average age was 37.84 ± 18.83 years (See table 6), average height was 1.66 ± 0.09 meter (See table 7) and the average mass of 65.86 ± 13.28 Kilogram (See table 8).

Table 1. Distribution of the study population by gender

Gender	Frequency	Percentage
Female	27	54.00%
Male	23	46.00%
TOTAL	50	100.00%

Table 2. Distribution of the study population by region

Region	Frequency	percentage
Center	8	16.00%
East	3	6.00%
Littoral	22	44.00%
North	2	4.00%
West	7	14.00%
South	8	16.00%
TOTAL	50	100.00%

Table 3. Distribution of the study population by religion

Religion	Frequency	percentage
Catholic	21	45.65%
Muslim	2	4.35%
Protestant	19	41.30%
Jehovah Witnesses	4	8.70%
TOTAL	46	100.00%



Table 4. Distribution of the study population by HCV test history

Have you ever done an HCV test?	Frequency	percentage
No	25	50.00%
Yes	25	50.00%
TOTAL	50	100.00%

Table 5. Distribution of the study population by profession

Occupation	Frequency	percentage
Driver	4	8.16%
Hairdresser	1	2.04%
Trader	2	4.08%
Accountant	2	4.08%
Secondary student	4	8.16%
Teacher	3	6.12%
University student	18	36.73%
Nurse	2	4.08%
Biomedical engineer	1	2.04%
Delivery man	1	2.04%
Housewife	5	10.20%
Lecturer	1	2.04%
Retired	5	10.20%
TOTAL	49	100.00%

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Table 6. Age of the study population

	Age (years)
N	50
Mean	37,84
Variance	354,8718
Standard deviation	18,838
Minimum	11
25%	26
Median	30
75%	48
Maximum	85
Mode	27

Table 7. Size on meters of the study population

	Height (meter)
N	50
Mean	1,66
Variance	0,0088
Standard deviation	0,0937
Minimum	1,42
25%	1,58
Median	1,67
75%	1,73
Maximum	1,83
Mode	1,58

Table 8. The mass in kilogram of the study population

	Mass (Kilogram)
N	50
Mean	65,86
Variance	176,3678
Standard deviation	13,2804
Minimum	35
25%	54
Median	67
75%	73
Maximum	96
Mode	50

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3.2. Frequency of HCV test according to the tests used

Depending on the test used, we obtained a frequency of 44%, 54% and 44% respectively for the anti-HCV ELISA test (AUTOBIO DIAGNOSTICS CO., LTD). HCV Rapid Test Strip (DiaSpot[®]) and SD BIOLINE HCV (See table 9).

3.2. Calculation of sensitivity, specificity, positive

and negative predictive value of each rapid test.

- HCV Rapid Test Strip (DiaSpot[®]): In our study, the sensitivity, specificity, NPV and PPV of the test were 100%, 82.14%, 100% and 81.48% respectively (See figure 1).

Table 9. Frequency of viral hepatitis C by test used

Anti-HCV ELISA (AUTOBIO DIAGNOSTICS CO., LTD).	Frequency	percentage
Negative	28	56.00%
Positive	22	44.00%
TOTAL	50	100.00%
HCV Rapid Test Strip (DiaSpot [®])	Frequency	percent
Non-reactive	23	46.00%
Reactive	27	54.00%
TOTAL	50	100.00%
SD BIOLINE HCV test	Frequency	percent
Non-reactive	28	56.00%
Reactive	22	44.00%
TOTAL	50	100.00%



Although the HCV Rapid Test Strip (DiaSpot[®]) has not been prequalified by the WHO, the FDA has validation from the European community (EC). It is clear that in our study this RDT has a sensitivity greater than 99%, a value recommended by the WHO for RDTs [4-9]. However, HCV Rapid Test Strip (DiaSpot[®]) has a

specificity of less than 99%. According to our study, this test is responsible for false positives in 5 patients. Based on the operational criteria (See table 10), the RDT HCV Rapid Test Strip (DiaSpot[®]) with a score of 30/40 is considered according to our study as an appropriate test for screening of viral hepatitis C.

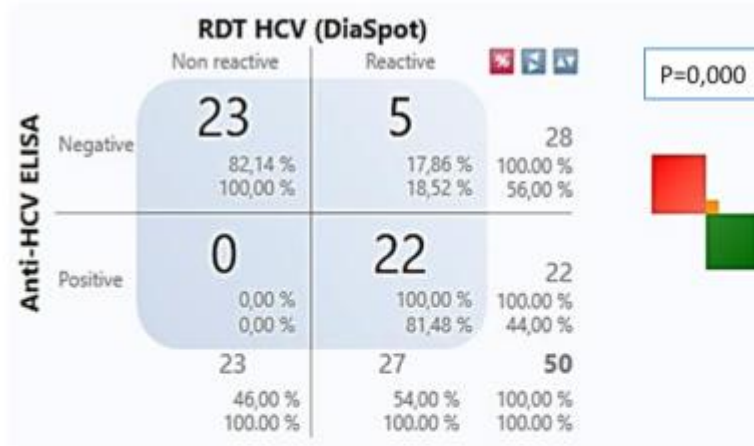


Figure 1. Cross-tabulation of the standard results based on HCV Rapid Test Strip (DiaSpot®)

Table 10. Operational characteristics of HCV Rapid Test Strip (DiaSpot®)

Criteria	Score	Test performance	Test score
<u>Sensitivity</u>			
100%	5		
98-100%	3	100%	5
< 98%	0		
<u>Specificity</u>			
> 98%	5		
95-98%	3	82.14%	0
< 95%	0		
<u>Incubation conditions</u>			
Ambient temperature	3	Ambient temperature	3
Outside ambient temperature	1		
<u>Lifespan</u>			
> 1 year	3		
6-12 months	2	> 1 year	3
< 6 months	1		
<u>Storage conditions</u>			
Ambient temperature (open kit)	5	Ambient temperature (open kit)	5
Ambient temperature (unopened kit)	2		
2-8°C	1		
<u>Cost of the test in XAF</u>			
< 1000	3		
1000-2000	2	17000	1
> 2000	1		
<u>Ease of use</u>			
Very simple	5		
Simple	3	Simple	3
Not easy	1		
<u>Speed of execution (1 test)</u>			
< 10 mins	3		
10-30 mins	2	15 mins	2
> 30 mins	1		
<u>Need Agitator/Scrubber</u>			
Not necessary	3	Not necessary	3
Necessary	1		
<u>Reading</u>			
Visual with interplay variability < 3%	5	Visual with interplay variability < 3%	5
Visual with interplay variability > 3%	3		
With a device	1		
TOTAL	40	/	30

Interpretation of the score:

The test is very suitable if the total score is > 30

The test is Appropriate if the total score is between 23 and 30

The test is inappropriate if the total score is < 23

Table 11. Operational characteristics of SD BIOLINE HCV

Criteria	Score	Test performance	Test score
<u>Sensitivity</u>			
100%	5		
98-100%	3	100%	5
< 98%	0		
<u>Specificity</u>			
> 98%	5	100%	5
95-98%	3		
< 95%	0		
<u>Incubation conditions</u>			
Ambient temperature	3	Ambient temperature	3
Outside ambient temperature	1		
<u>Lifespan</u>			
> 1 year	3	> 1 year	3
6-12 months	2		
< 6 months	1		
<u>Storage conditions</u>			
Ambient temperature (open kit)	5	Ambient temperature (open kit)	5
Ambient temperature (unopened kit)	2		
2-8°C	1		
<u>Cost of the test in XAF</u>			
< 1000	3		
1000-2000	2	28500	1
> 2000	1		
<u>Ease of use</u>			
Very simple	5		
Simple	3	Very simple	5
Not easy	1		
<u>Speed of execution (1 test)</u>			
< 10 mins	3		
10-30 mins	2	15 mins	2
> 30 mins	1		
<u>Need Agitator/Scrubber</u>			
Not necessary	3	Not necessary	3
Necessary	1		
<u>Reading</u>			
Visual with interplay variability < 3%	5	Visual with interplay variability < 3%	5
Visual with interplay variability > 3%	3		
With a device	1		
TOTAL	40	/	37

Interpretation of the score:

The test is very suitable if the total score is > 30

The test is Appropriate if the total score is between 23 and 30

The test is inappropriate if the total score is <23

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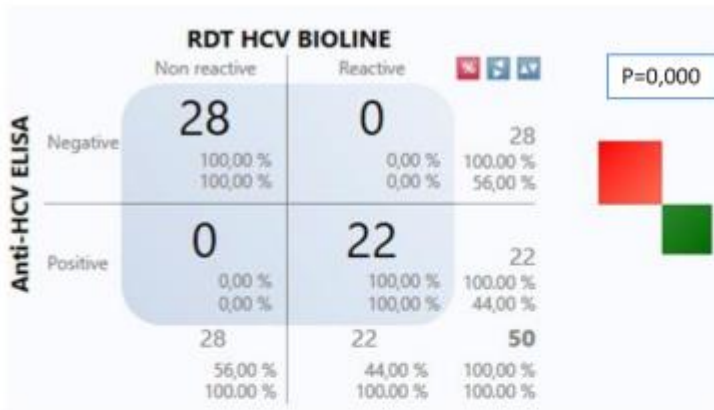


Figure 2. Cross-tabulation of the standard results based on SD BIOLINE HCV

Table 12. Reproducibility of the SD BIOLINE HCV rapid test

Test	SD BIOLINE HCV 1st LOT	SD BIOLINE HCV 2nd LOT	REPRODUCIBILITY
Reactive	10	10	10/10 (100%)
Non-Reactive	5	5	5/5 (100%)
Total	15	15	/

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Although both tests have in our study an identical sensitivity (See figure 3), the SD BIOLINE test has an excellent specificity which ranks it above HCV Rapid Test Strip (DiaSpot[®]). However, the cost of the HCV Rapid Test Strip (DiaSpot[®]) is more affordable (XAF 17,000) than the SD BIOLINE HCV test (XAF 28,500). Therefore, in a country with limited resources like Cameroon, the RDT HCV Rapid Test Strip (DiaSpot[®]) is more affordable and that is why it is one of the most used tests in Cameroon.

The fact that our study shows good sensitivity of the RDTs and good specificity of SD BIOLINE HCV should in no way suggest that we recommend replacing the ELISA HCV tests with RDTs. The diagnostic algorithms for the diagnosis of viral hepatitis C must be respected. In addition, it should be noted that the use of 50 samples may be a limitation to our study. Thus, with a larger sample size, and in another context like using frozen samples [10], one can find different sensitivity and specificity values.

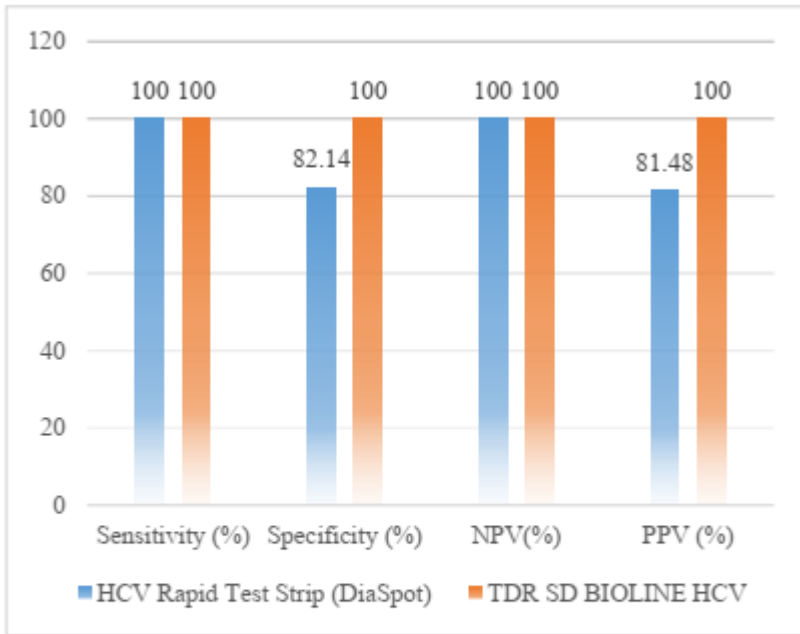


Figure 3. Comparative graph of the parameters of the two rapid screening tests for viral hepatitis C, HCV Rapid Test Strip (DiaSpot[®]) and SD BIOLINE HCV

4. Conclusion

SD BIOLINE HCV and HCV Rapid Test Strip TDRs (DiaSpot[®]) have excellent sensitivity. According to the operability criteria, they are appropriate for the screening of viral hepatitis C. However, these tests should not solely be used to confirm the diagnosis of viral hepatitis C. The application of national and international diagnostic algorithms must remain in place.

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