Product Name	First Response® HBsAg Card Test		
Lot. No.	81 C 03 22S	**Date of Testing**	2022-03-03
Mfg. Date	2022-03	**Sample Quantity**	210 Tests
Exp. Date	2024-02	**Page No.**	1 of 2

A) Appearance:

Sr. No.	Test	Specifications	Results
1.	Test Device	Printed "First Response HBsAg" Plastic cassettes containing strip coated with Monoclonal Antibodies specific to Hepatitis B surface antigen to detect it in infected human serum / plasma / whole blood.	Complies
2.	Assay Buffer	Clear colorless solution.	Complies

B) Testing Protocol:

Sr. No.	Test	Specifications	Results
1.	**Specificity:**		
	Check 100 test device with HBsAg negative serum / plasma / whole blood specimens.	HBsAg negative serum / plasma / whole blood specimens should give negative results for HBsAg test line.	Complies
2.	**Cross reactivity study (Analytical specificity):**		
2.1	Check 5 test device with HIV positive serum specimens.	HIV positive serum specimens should give negative results for HBsAg test line.	Complies
2.2	Check 5 test device with HCV positive serum specimens.	HCV positive serum specimens should give negative results for HBsAg test line.	Complies
2.3	Check 5 test device with Syphilis positive serum specimens.	Syphilis positive serum specimens should give negative results for HBsAg test line.	Complies
3.	**Analytical sensitivity:**		
3.1	Check 5 test device with End point dilution of HBsAg positive serum specimen.	Should give positive result up to 1:128, end point dilution of QC reference HBsAg positive serum specimen.	Complies
3.2	Check 5 test device with End point dilution of HBsAg positive plasma specimen.	Should give positive result up to 1:128, end point dilution of QC reference HBsAg positive plasma specimen.	Complies

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Sr. No.	Test	Specifications	Results
4.	**Diagnostic Sensitivity:**		
	Check 30 test device with HBsAg positive serum specimens.	QC reference HBsAg positive serum specimens should give positive results for HBsAg test line.	Complies
	Check 15 test device with HBsAg positive plasma specimens.	QC reference HBsAg positive plasma specimens should give positive results for HBsAg test line.	Complies
5.	**Repeatability:**		
5.1	Check 10 test device with HBsAg positive serum specimen.	Should be uniform result in terms of reaction time and color intensity of line in all test devices when tested with QC reference HBsAg positive serum specimen.	Complies
	Check 10 test device with HBsAg positive plasma specimen.	Should be uniform result in terms of reaction time and color intensity of line in all test devices when tested with QC reference HBsAg positive plasma specimen.	Complies
5.2	Check 10 test device with HBsAg negative serum specimen.	Should be uniform result in terms of reaction time and color intensity of line in all test devices when tested with QC reference HBsAg negative serum specimen.	Complies
	Check 10 test device with HBsAg negative plasma specimen.	Should be uniform result in terms of reaction time and color intensity of line in all test devices when tested with QC reference HBsAg negative plasma specimen.	Complies

We hereby certify that the device lot described above was visually and functionally inspected and found to comply with the device specification, prior to release for shipment. The lot is released.

Prepared By

2022-03-03

~~Sr. Executive QC / Asst. Manager QC~~ /
Sr. Manager QC

Authorized By

Bela
2022-03-03

Sr. Executive QA /
~~General Manager QA & RA~~