



Premier Medical Corporation Private Limited

Document No.: TR-PI05FRC-RT

Title: Test Report for Real Time Shelf Life Stability Testing

Revision: AF

Effective Date: 2021-04-15

Document type: Test Report (FM-QC-22)

Department: QC

Page 1 of 11

Review Due Date: 2023-04-14

Product Name First Response® HIV 1-2.O Card Test (Version 2.0)

Record No.: RC-QC-09

Sr. No. 20Month of Stability Study: July 2021

Sampling Details

Lot No.	77H0119S	Time duration	23 months
Mfg. Date	2019-08	Sampled Qty.	48 Tests
Exp. Date	2021-07	Storage Temp.	1-8°C
Date of Testing	2021-07-29		30 ± 2°C

Specimens Panel Details

Description of specimens used	Specimen Quantity
Negative Human Serum Specimens	02
Negative Whole Blood Specimens	02
HIV-1 Positive Serum Specimens	04
HIV-2 Positive Serum Specimens	04

(All) Assay Procedure

Precautions: Treat all the specimens as potentially infectious and use gloves while testing.
Bring the test device, assay buffer and specimens to room temperature prior to testing.
Before starting the assay procedure, label the test device with the Lot No. and specimens ID.

Sr. No.	Test Procedure
1.	Take out required number of test devices.
2.	Slowly add 1 drop (10 µL) of serum / plasma or 2 drops (20 µL) of whole blood specimen into the specimen well using the specimen transfer device / micropipette.
3.	Add one drop (35 µL) of assay buffer into the specimen well.
4.	Observe for development of colored lines in the results window.
5.	Interpret test results at 15 minutes. Do not interpret after 25 minutes.
6.	There should be clear background and both control line and test lines were clearly distinguishable.
7.	Check the control line, test line and background clearance visually. Record the result in the report within 15 minute time period. If background is cleared, mention C (Clear) on test report and if it is not cleared, mark abnormalities or issues affecting interpretation, such as poor blood clearance (i.e. Red background, Incomplete clearing and Red background obscuring test line), should be recorded NC (Not Cleared) in the report. Refer Table **Background Clearance Acceptance Criteria.



Digitally signed by Chirtoacă Iurie
Date: 2022.10.28 17:21:18 EEST
Reason: MoldSign Signature
Location: Moldova





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****Background Clearance Acceptance Criteria**

Acceptance Criteria	Rejection Criteria
1. If the background is clear and Control Line and/or Test Line is clearly visible, then test is accepted. 2. If the background is little hazy but the Control Line and/or Test Line is clearly visible, then the test is accepted 3. If the background is clear above Control Line and/or Test Line within stipulated time, then test is accepted. 4. If backflow of test does not cover Control Line and/or Test Line, then test is accepted	1. If the flow of specimen and colloidal gold covered the Control Line and makes it invisible but Test Line is visible then test is not accepted. 2. If the background is not clear up to Control Line within stipulated time but Test Line is visible, then test is not accepted. 3. When either colloidal gold/plasma/serum/ whole blood do not allow to interpret the result after completion of stipulated time then test is not accepted. 4. If Specimen Back flow covered Control Line and make it invisible and/or the Test Line is visible, then result is invalid and not accepted. 5. If the background is not clear above Control Line and/or Test Line, then test is not accepted.

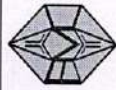
Note: Here Control Line is visible means all components/reagents has cleared reading window, crossed Control Line during flow towards absorbent pad.

Intact assay buffer bottle volume	Volume in ml		Sufficient volume : Yes / No	
	1-8°C	30 ± 2°C	1-8°C	30 ± 2°C
2.5 ml filled bottle for 25 Tests : Minimum 1.7 ml	2.5	2.5	Yes	Yes
2.5 ml filled bottle for 30 Tests : Minimum 2.0 ml	NA	NA	NA	NA

Remark: 0 day testing results will be noted down in 1-8°C column. The 30±2°C will be marked as not applicable/strike off.

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Experiment: 01

Reader 1: Tested & Read By: Nikhil Pawar

Sign & Date: (Signature) 2021-07-29

3. Functional / Performance Testing

3.1. Specificity

Negative Human Serum Specimens

Sr. No.	Specimen ID : PMC NHS	Criteria	Stored at (1-8 °C)					Stored at (30 ± 2 °C)				
			Color Line Intensity					Color Line Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	251	-Ve	4	0	0	C	-Ve	4	0	0	C	-Ve
2	252	-Ve	4	0	0	C	-Ve	4	0	0	C	-Ve

Negative Whole Blood Specimens

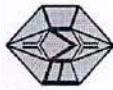
Sr. No.	Specimen ID : PMC NWB	Criteria	Stored at (1-8 °C)					Stored at (30 ± 2 °C)				
			Color Line Intensity					Color Line Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	2426	-Ve	4	0	0	C	-Ve	4	0	0	C	-Ve
2	2427	-Ve	4	0	0	C	-Ve	4	0	0	C	-Ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background, NC: - Not clear background.

Note: 0 to 4 = Color line intensity by using WHO color chart Prototype: C.



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3.2.	Sensitivity											
HIV-1 Positive Serum Specimens												
Sr. No.	Specimen ID : PMC H1	Criteria	Stored at (1-8 °C)					Stored at (30 ± 2 °C)				
			Color Line Intensity					Color Line Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	205 (1:640)	+Ve	4	0	2	C	+ve	4	0	2	C	+ve
2	205 (1:1280)	+Ve	4	0	1	C	+ve	4	0	1	C	+ve
3	205 (1:2560)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	214	+Ve	4	0	3	C	+ve	4	0	3	C	+ve
HIV-2 Positive Serum Specimens												
Sr. No.	Specimen ID : PMC H2	Criteria	Stored at (1-8 °C)					Stored at (30 ± 2 °C)				
			Color Line Intensity					Color Line Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	086 (1:160)	+Ve	4	2	0	C	+ve	4	2	0	C	+ve
2	086 (1:320)	+Ve	4	1	0	C	+ve	4	1	0	C	+ve
3	086 (1:640)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	146	+Ve	4	3	0	C	+ve	4	3	0	C	+ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

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Experiment: 01

Reader 2: Read By: Shreyashi KhatSign & Date: 2021-07-29

3.1.	Specificity	Negative Human Serum Specimens												
Sr. No.	Specimen ID : PMC NHS	Criteria	Stored at (1-8 °C)						Stored at (30 ± 2 °C)					
			Color Line Intensity						Color Line Intensity					
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result		
1	251	-Ve	4	0	0	C	-ve	4	0	0	C	-ve		
2	252	-Ve	4	0	0	C	-ve	4	0	0	C	-ve		
Negative Whole Blood Specimens														
Sr. No.	Specimen ID : PMC NWB	Criteria	Stored at (1-8 °C)						Stored at (30 ± 2 °C)					
			Color Line Intensity						Color Line Intensity					
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result		
1	2426	-Ve	4	0	0	C	-ve	4	0	0	C	-ve		
2	2427	-Ve	4	0	0	C	-ve	4	0	0	C	-ve		

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

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3.2.	Sensitivity											
HIV-1 Positive Serum Specimens												
Sr. No.	Specimen ID : PMC H1	Criteria	Stored at (1-8 °C)				Stored at (30 ± 2 °C)					
			Color Line Intensity				Color Line Intensity					
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	205 (1:640)	+Ve	4	0	2	C	+ve	4	0	2	C	+ve
2	205 (1:1280)	+Ve	4	0	1	C	+ve	4	0	1	C	+ve
3	205 (1:2560)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	214	+Ve	4	0	3	C	+ve	4	0	3	C	+ve
HIV-2 Positive Serum Specimens												
Sr. No.	Specimen ID : PMC H2	Criteria	Stored at (1-8 °C)				Stored at (30 ± 2 °C)					
			Color Line Intensity				Color Line Intensity					
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	086 (1:160)	+Ve	4	2	0	C	+ve	4	2	0	C	+ve
2	086 (1:320)	+Ve	4	1	0	C	+ve	4	1	0	C	+ve
3	086 (1:640)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	146	+Ve	4	3	0	C	+ve	4	3	0	C	+ve

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Experiment: 02

Reader 2: Tested & Read By: Shreyashi KhotSign & Date: SRK 2021-07-29

3.1.	Specificity	Negative Human Serum Specimens												
Sr. No.	Specimen ID : PMC NHS	Criteria	Stored at (1-8 °C)						Stored at (30 ± 2 °C)					
			Color Line Intensity						Color Line Intensity					
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result		
1	251	-Ve	4	0	0	C	-ve	4	0	0	C	-ve		
2	252	-Ve	4	0	0	C	-ve	4	0	0	C	-ve		
Negative Whole Blood Specimens														
Sr. No.	Specimen ID : PMC NWB	Criteria	Stored at (1-8 °C)						Stored at (30 ± 2 °C)					
			Color Line Intensity						Color Line Intensity					
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result		
1	2426	-Ve	4	0	0	C	-ve	4	0	0	C	-ve		
2	2427	-Ve	4	0	0	C	-ve	4	0	0	C	-ve		

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

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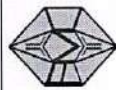
3.2. Sensitivity												
HIV-1 Positive Serum Specimens												
Sr. No.	Specimen ID : PMC H1	Criteria	Stored at (1-8 °C)				Stored at (30 ± 2 °C)					
			Color Line Intensity				Color Line Intensity					
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	205 (1:640)	+Ve	4	0	2	C	+ve	4	0	2	C	+ve
2	205 (1:1280)	+Ve	4	0	1	C	+ve	4	0	1	C	+ve
3	205 (1:2560)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	214	+Ve	4	0	3	C	+ve	4	0	3	C	+ve
HIV-2 Positive Serum Specimens												
Sr. No.	Specimen ID : PMC H2	Criteria	Stored at (1-8 °C)				Stored at (30 ± 2 °C)					
			Color Line Intensity				Color Line Intensity					
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	086 (1:160)	+Ve	4	2	0	C	+ve	4	2	0	C	+ve
2	086 (1:320)	+Ve	4	1	0	C	+ve	4	1	0	C	+ve
3	086 (1:640)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	146	+Ve	4	3	0	C	+ve	4	3	0	C	+ve

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Experiment: 02

Reader 1: Read By: Nikhil PawarSign & Date: 2021-07-29

3.1. Specificity												
Negative Human Serum Specimens												
Sr. No.	Specimen ID : PMC NHS	Criteria	Stored at (1-8 °C)					Stored at (30 ± 2 °C)				
			Color Line Intensity					Color Line Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	251	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
2	252	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
Negative Whole Blood Specimens												
Sr. No.	Specimen ID : PMC NWB	Criteria	Stored at (1-8 °C)					Stored at (30 ± 2 °C)				
			Color Line Intensity					Color Line Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	2426	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
2	2427	-Ve	4	0	0	C	-ve	4	0	0	C	-ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

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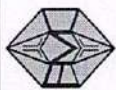
3.2.	Sensitivity											
HIV-1 Positive Serum Specimens												
Sr. No.	Specimen ID : PMC H1	Criteria	Stored at (1-8 °C)					Stored at (30 ± 2 °C)				
			Color Line Intensity					Color Line Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	205 (1:640)	+Ve	4	0	2	C	+ve	4	0	2	C	+ve
2	205 (1:1280)	+Ve	4	0	1	C	+ve	4	0	1	C	+ve
3	205 (1:2560)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	214	+Ve	4	0	3	C	+ve	4	0	3	C	+ve
HIV-2 Positive Serum Specimens												
Sr. No.	Specimen ID : PMC H2	Criteria	Stored at (1-8 °C)					Stored at (30 ± 2 °C)				
			Color Line Intensity					Color Line Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	086 (1:160)	+Ve	4	2	0	C	+ve	4	2	0	C	+ve
2	086 (1:320)	+Ve	4	1	0	C	+ve	4	1	0	C	+ve
3	086 (1:640)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	146	+Ve	4	3	0	C	+ve	4	3	0	C	+ve

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Observations:

After 23 months duration testing, no significant changes were observed in this lot when stored at $1-8^{\circ}\text{C}$ and $30 \pm 2^{\circ}\text{C}$ for its performance of the test movement, background clearance, specificity and sensitivity.

NA

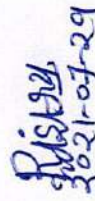
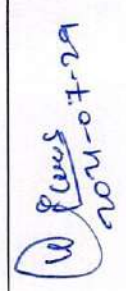
Conclusion:

Based on the obtained results, it can be concluded that no deterioration occurred to the test devices of the lot when tested with the specimens. Test devices showed equivalent performance when stored at $1-8^{\circ}\text{C}$ and $30 \pm 2^{\circ}\text{C}$. The assay buffer volume remained in sufficient quantity to test entire kit when stored at both temperatures.

WIEC (P)
2021-07-29

Moreover, background Moreover, background clearance profiles observed with whole blood / serum specimens were found acceptable without any background noise at 23 months stability testing.

NA

Responsibility	Tested by		Reviewed By	Approved By
	Reader 1	Reader 2		
Signature & Date	 2021-07-29	 2021-07-29	 2021-07-29	 2021-07-29
Designation	Officer-QC / Executive QC / Sr. Executive QC	Officer QC / Executive QC / Sr. Executive QC	Asst. Manager QC / Manager QC	Sr. Manager QA

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Product Name First Response® HIV 1-2.O Card Test (Version 2.0)

Record No.: RC-QC-09

Sr. No. 1020

Month of Stability Study: May 2021

Sampling Details

Lot No.	77H01195	Time duration	21 months
Mfg. Date	2019-08	Sampled Qty.	48 Tests
Exp. Date	2021-07	Storage Temp.	1-8°C
Date of Testing	2021-05-29		30 ± 2°C

Specimens Panel Details

Description of specimens used	Specimen Quantity
Negative Human Serum Specimens	02
Negative Whole Blood Specimens	02
HIV-1 Positive Serum Specimens	04
HIV-2 Positive Serum Specimens	04

(All) Assay Procedure

Precautions: Treat all the specimens as potentially infectious and use gloves while testing.
Bring the test device, assay buffer and specimens to room temperature prior to testing.
Before starting the assay procedure, label the test device with the Lot No. and specimens ID.

Sr. No.	Test Procedure
1.	Take out required number of test devices.
2.	Slowly add 1 drop (10 µL) of serum / plasma or 2 drops (20 µL) of whole blood specimen into the specimen well using the specimen transfer device / micropipette.
3.	Add one drop (35 µL) of assay buffer into the specimen well.
4.	Observe for development of colored lines in the results window.
5.	Interpret test results at 15 minutes. Do not interpret after 25 minutes.
6.	There should be clear background and both control line and test lines were clearly distinguishable.
7.	Check the control line, test line and background clearance visually. Record the result in the report within 15 minute time period. If background is cleared, mention C (Clear) on test report and if it is not cleared, mark abnormalities or issues affecting interpretation, such as poor blood clearance (i.e. Red background, Incomplete clearing and Red background obscuring test line), should be recorded NC (Not Cleared) in the report. Refer Table **Background Clearance Acceptance Criteria.

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****Background Clearance Acceptance Criteria**

Acceptance Criteria	Rejection Criteria
1. If the background is clear and Control Line and/or Test Line is clearly visible, then test is accepted. 2. If the background is little hazy but the Control Line and/or Test Line is clearly visible, then the test is accepted 3. If the background is clear above Control Line and/or Test Line within stipulated time, then test is accepted. 4. If backflow of test does not cover Control Line and/or Test Line, then test is accepted	1. If the flow of specimen and colloidal gold covered the Control Line and makes it invisible but Test Line is visible then test is not accepted. 2. If the background is not clear up to Control Line within stipulated time but Test Line is visible, then test is not accepted. 3. When either colloidal gold/plasma/serum/ whole blood do not allow to interpret the result after completion of stipulated time then test is not accepted. 4. If Specimen Back flow covered Control Line and make it invisible and/or the Test Line is visible, then result is invalid and not accepted. 5. If the background is not clear above Control Line and/or Test Line, then test is not accepted.

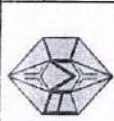
Note: Here Control Line is visible means all components/reagents has cleared reading window, crossed Control Line during flow towards absorbent pad.

Intact assay buffer bottle volume	Volume in ml		Sufficient volume : Yes / No	
	1-8°C	30 ± 2°C	1-8°C	30 ± 2°C
2.5 ml filled bottle for 25 Tests : Minimum 1.7 ml	NA	NA	NA	NA
2.5 ml filled bottle for 30 Tests : Minimum 2.0 ml	2.5	2.5	Yes	Yes

Remark: 0 day testing results will be noted down in 1-8°C column. The 30±2°C will be marked as not applicable/strike off.

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Premier Medical Corporation Private Limited			Document No.: TR-PI05FRC-RT	
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Experiment: 01

Reader 1: Tested & Read By: Nikhil Pawar

Sign & Date: NP 2021-05-29

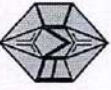
3. Functional / Performance Testing												
3.1. Specificity												
Negative Human Serum Specimens												
Sr. No.	Specimen ID : PMC NHS	Criteria	Stored at (1-8 °C)					Stored at (30 ± 2 °C)				
			Color Line Intensity					Color Line Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	251	-Ve	4	0	0	C	-Ve	4	0	0	C	-Ve
2	252	-Ve	4	0	0	C	-Ve	4	0	0	C	-Ve
Negative Whole Blood Specimens												
Sr. No.	Specimen ID : PMC NWB	Criteria	Stored at (1-8 °C)					Stored at (30 ± 2 °C)				
			Color Line Intensity					Color Line Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	1876	-Ve	4	0	0	C	-Ve	4	0	0	C	-Ve
2	1877	-Ve	4	0	0	C	-Ve	4	0	0	C	-Ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

Note: 0 to 4 = Color line intensity by using WHO color chart Prototype: C.



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3.2. Sensitivity													
HIV-1 Positive Serum Specimens													
Sr. No.	Specimen ID : PMC H1	Criteria	Stored at (1-8 °C)					Stored at (30 ± 2 °C)					
			Color Line Intensity					Color Line Intensity					
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	
1	205 (1:640)	+Ve	4	0	2	C	+ve	4	0	2	C	+ve	
2	205 (1:1280)	+Ve	4	0	1	C	+ve	4	0	1	C	+ve	
3	205 (1:2560)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve	
4	214	+Ve	4	0	3	C	+ve	4	0	3	C	+ve	
HIV-2 Positive Serum Specimens													
Sr. No.	Specimen ID : PMC H2	Criteria	Stored at (1-8 °C)					Stored at (30 ± 2 °C)					
			Color Line Intensity					Color Line Intensity					
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	
1	086 (1:160)	+Ve	4	2	0	C	+ve	4	2	0	C	+ve	
2	086 (1:320)	+Ve	4	1	0	C	+ve	4	1	0	C	+ve	
3	086 (1:640)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve	
4	146	+Ve	4	3	0	C	+ve	4	3	0	C	+ve	

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

Note: 0 to 4 = Color line intensity by using WHO color chart Prototype: C.



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Document type: Test Report (FM-QC-22)

Experiment: 01

Reader 2: Read By: Shreyashi khatSign & Date: 2021-05-29

3.1.	Specificity											
Negative Human Serum Specimens												
Sr. No.	Specimen ID : PMC NHS	Criteria	Stored at (1-8 °C)				Stored at (30 ± 2 °C)					
			Color Line Intensity				Color Line Intensity					
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	251	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
2	252	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
Negative Whole Blood Specimens												
Sr. No.	Specimen ID : PMC NWB	Criteria	Stored at (1-8 °C)				Stored at (30 ± 2 °C)					
			Color Line Intensity				Color Line Intensity					
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	1876	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
2	1877	-Ve	4	0	0	C	-ve	4	0	0	C	-ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

Note: 0 to 4 = Color line intensity by using WHO color chart Prototype: C.

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3.2. Sensitivity												
HIV-1 Positive Serum Specimens												
Sr. No.	Specimen ID : PMC H1	Criteria	Stored at (1-8 °C)					Stored at (30 ± 2 °C)				
			Color Line Intensity					Color Line Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	205 (1:640)	+Ve	4	0	2	C	+ve	4	0	2	C	+ve
2	205 (1:1280)	+Ve	4	0	1	C	+ve	4	0	1	C	+ve
3	205 (1:2560)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	214	+Ve	4	0	3	C	+ve	4	0	3	C	+ve
HIV-2 Positive Serum Specimens												
Sr. No.	Specimen ID : PMC H2	Criteria	Stored at (1-8 °C)					Stored at (30 ± 2 °C)				
			Color Line Intensity					Color Line Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	086 (1:160)	+Ve	4	2	0	C	+ve	4	2	0	C	+ve
2	086 (1:320)	+Ve	4	1	0	C	+ve	4	1	0	C	+ve
3	086 (1:640)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	146	+Ve	4	3	0	C	+ve	4	3	0	C	+ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

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Experiment: 02

Reader 2: Tested & Read By: Shreyashi KhotSign & Date: SRK2021-05-29

3.1.	Specificity	Negative Human Serum Specimens												
Sr. No.	Specimen ID : PMC NHS	Criteria	Stored at (1-8 °C)						Stored at (30 ± 2 °C)					
			Color Line Intensity						Color Line Intensity					
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result		
1	251	-Ve	4	0	0	C	-ve	4	0	0	C	-ve		
2	252	-Ve	4	0	0	C	-ve	4	0	0	C	-ve		
Negative Whole Blood Specimens														
Sr. No.	Specimen ID : PMC NWB	Criteria	Stored at (1-8 °C)						Stored at (30 ± 2 °C)					
			Color Line Intensity						Color Line Intensity					
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result		
1	1876	-Ve	4	0	0	C	-ve	4	0	0	C	-ve		
2	1877	-Ve	4	0	0	C	-ve	4	0	0	C	-ve		

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

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3.2.	Sensitivity											
HIV-1 Positive Serum Specimens												
Sr. No.	Specimen ID : PMC H1	Criteria	Stored at (1-8 °C)				Stored at (30 ± 2 °C)					
			Color Line Intensity				Color Line Intensity					
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	205 (1:640)	+Ve	4	0	2	C	+ve	4	0	2	C	+ve
2	205 (1:1280)	+Ve	4	0	1	C	+ve	4	0	1	C	+ve
3	205 (1:2560)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	214	+Ve	4	0	3	C	+ve	4	0	3	C	+ve
HIV-2 Positive Serum Specimens												
Sr. No.	Specimen ID : PMC H2	Criteria	Stored at (1-8 °C)				Stored at (30 ± 2 °C)					
			Color Line Intensity				Color Line Intensity					
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	086 (1:60)	+Ve	4	2	0	C	+ve	4	2	0	C	+ve
2	086 (1:320)	+Ve	4	1	0	C	+ve	4	1	0	C	+ve
3	086 (1:640)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	146	+Ve	4	3	0	C	+ve	4	3	0	C	+ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

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Experiment: 02

Reader 1: Read By: Nikhil PawarSign & Date: np 2021-05-29

3.1.	Specificity	Negative Human Serum Specimens												
Sr. No.	Specimen ID : PMC NHS	Criteria	Stored at (1-8 °C)						Stored at (30 ± 2 °C)					
			Color Line Intensity						Color Line Intensity					
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result		
1	251	-Ve	4	0	0	C	-ve	4	0	0	C	-ve		
2	252	-Ve	4	0	0	C	-ve	4	0	0	C	-ve		
Negative Whole Blood Specimens														
Sr. No.	Specimen ID : PMC NWB	Criteria	Stored at (1-8 °C)						Stored at (30 ± 2 °C)					
			Color Line Intensity						Color Line Intensity					
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result		
1	1816	-Ve	4	0	0	C	-ve	4	0	0	C	-ve		
2	1817	-Ve	4	0	0	C	-ve	4	0	0	C	-ve		

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background, NC: - Not clear background.

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3.2.	Sensitivity											
HIV-1 Positive Serum Specimens												
Sr. No.	Specimen ID : PMC H1	Criteria	Stored at (1-8 °C)					Stored at (30 ± 2 °C)				
			Color Line Intensity					Color Line Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	205 (1:640)	+Ve	4	0	2	C	+ve	4	0	2	C	+ve
2	205 (1:1280)	+Ve	4	0	1	C	+ve	4	0	1	C	+ve
3	205 (1:2560)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	214	+Ve	4	0	3	C	+ve	4	0	3	C	+ve
HIV-2 Positive Serum Specimens												
Sr. No.	Specimen ID : PMC H2	Criteria	Stored at (1-8 °C)					Stored at (30 ± 2 °C)				
			Color Line Intensity					Color Line Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	086 (1:160)	+Ve	4	2	0	C	+ve	4	2	0	C	+ve
2	086 (1:320)	+Ve	4	1	0	C	+ve	4	1	0	C	+ve
3	086 (1:640)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	146	+Ve	4	3	0	C	+ve	4	3	0	C	+ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

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Observations:

After 21 months duration testing, no significant changes were observed in this lot when stored at $1-8^{\circ}\text{C}$ and $30 \pm 2^{\circ}\text{C}$ for its performance of test movement, background clearance, specificity and sensitivity.

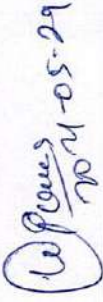
NA

Conclusion:

Based on the obtained results, it can be concluded that no deterioration occurred to the test devices of the lot when tested with the specimens. Test devices showed equivalent performance when stored at $1-8^{\circ}\text{C}$ and $30 \pm 2^{\circ}\text{C}$. The assay buffer volume remained in sufficient quantity to test entire kit when stored at both temperatures.

Moreover, background clearance profiles observed with whole blood / serum specimens were found acceptable without any background noise at 21 months stability testing

NA

Responsibility	Tested by		Reviewed By	Approved By
	Reader 1	Reader 2		
Signature & Date	 2021-05-29	 2021-05-29	 2021-05-29	 2021-05-29
Designation	Officer-QC / Executive QC / Sr. Executive QC	Officer QC / Executive QC / Sr. Executive QC	Asst. Manager QC / Manager QC	Sr. Manager QA

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Review Due Date: 2021-04-14

Product Name

First Response® HIV 1-2.O Card Test (Version 2.0)

Document ID: RC-QC-09

Sr. No. 20Month of Stability Study: Feb-2021

Sampling Details

Lot No.	<u>77H01195</u>	Duration Time	<u>18 months</u>
Mfg. Date	<u>2019-08</u>	Sampled Qty.	<u>48 Tests</u>
Exp. Date	<u>2021-07</u>	Store at	<u>1-8°C & 30 ± 2°C</u>
Date of Testing	<u>2021-02-25</u>		

Specimens Panel Details

Description of Specimens Used	Specimens Quantity
Negative Human Serum Specimens	<u>02</u>
Negative Whole Blood Specimens	<u>02</u>
HIV – 1 Positive Serum Specimens	<u>04</u>
HIV – 2 Positive Serum Specimens	<u>04</u>

(All) Assay Procedure

Precautions: Treat all the specimens as potentially infectious and use gloves while testing.

Bring the test device, assay buffer and specimens to room temperature prior to testing.

Before starting the assay procedure, label the test device with the LOT No. and specimens ID.

Sr. No.	Test Procedure
1.	Take out required number of test device.
2.	Slowly add 1 drop (10 µL) of serum / plasma or 2 drops (20 µL) of whole blood specimens into the specimens well using the specimens transfer device / micropipette.
3.	Add one drop (35 µL) of assay buffer into the specimens well.
4.	Observe for development of colored bands in the results window.
5.	Interpret test results at 15 minutes. Do not interpret after 25 minutes.
6.	There should be clear background and both control line and test lines were clearly distinguishable.
7.	Check the control line, test line and background clearance visually. Record the result in the report within 15 minute time period. If background is cleared, mention C (Clear) on test report and if it is not cleared, mark abnormalities or issues affecting interpretation, such as poor blood clearance (i.e. Red background, Incomplete clearing and Red background obscuring test line), should be recorded NC (Not Cleared) in the report. Refer Table **Background Clearance Acceptance Criteria.

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****Background Clearance Acceptance Criteria**

Acceptance Criteria	Rejection Criteria
1. If the background is clear and Control Line and/or Test Line is clearly visible then test is accepted. 2. If the background is little hazy but the Control Line and/or Test Line is clearly visible then the test is accepted 3. If the background is clear above Control Line and/or Test Line within stipulated time then test is accepted. 4. If backflow of test does not cover Control Line and/or Test Line then test is accepted	1. If the flow of specimen and colloidal gold covered the Control Line and even make it invisible but Test Line is visible then test is not accepted. 2. If the background is not clear up to Control Line within stipulated time but Test Line is visible then test is not accepted. 3. When either colloidal gold/plasma/serum/ whole blood do not allow to interpret the result after completion of stipulated time then test is not accepted. 4. If Specimen Back flow covered Control Line and make it invisible and/or the Test Line is visible then result is invalid and not accepted. 5. If the background is not clear above Control Line and/or Test Line then test is not accepted.

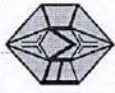
Note: Here Control Line is visible means all components/reagents has cleared reading window, crossed Control Line during flow towards absorbent pad.

Intact bottle assay buffer volume	Volume in ml		Sufficient volume Yes / No	
	1-8°C	30 ± 2°C	1-8°C	30 ± 2°C
2.5 ml filled bottle for 25 Test : Minimum 1.7 ml	NA	NA	NA	NA
2.5 ml filled bottle for 30 Test : Minimum 2.0 ml	2.6 ml	2.5 ml	Yes	Yes

Remark: 0 day testing results will be noted down in 1-8 °C column. The 30 ± 2 °C will be marked as not applicable/strike off.

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Experiment: 01

Reader 1: Tested & Read By: Nidhi S. Chaudhary

Sign & Date: 2021-02-25

3. Functional / Performance Testing												
3.1. Specificity:												
Negative Human Serum Specimens :												
Sr. No.	Specimens ID : PMC NHS	Criteria	Store at (1-8 °C)				Store at (30 ± 2 °C)					
			Colour Band Intensity				Colour Band Intensity					
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	251	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
2	252	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
Negative Whole Blood Specimens :												
Sr. No.	Specimens ID : PMC NWB	Criteria	Store at (1-8 °C)				Store at (30 ± 2 °C)					
			Colour Band Intensity				Colour Band Intensity					
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	0826	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
2	0827	-Ve	4	0	0	C	-ve	4	0	0	C	-ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background, NC: - Not clear background.

Footnotes: 0 to 4 = Color band intensity by using WHO color chart Prototype: C.



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3.2. Sensitivity:

HIV - 1 Positive Serum Specimens :

Sr. No.	Specimens ID : PMC H1	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	205 (1:640)	+Ve	4	0	2	C	+ve	4	0	2	C	+ve
2	205 (1:1280)	+Ve	4	0	1	C	+ve	4	0	1	C	+ve
3	205 (1:2560)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	214	+Ve	4	0	3	C	+ve	4	0	3	C	+ve

HIV - 2 Positive Serum Specimens :

Sr. No.	Specimens ID : PMC H2	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	086 (1:160)	+Ve	4	2	0	C	+ve	4	2	0	C	+ve
2	086 (1:320)	+Ve	4	1	0	C	+ve	4	1	0	C	+ve
3	086 (1:640)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	146	+Ve	4	3	0	C	+ve	4	3	0	C	+ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

Footnotes: 0 to 4 = Color band intensity by using WHO color chart Prototype: C.



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Premier Medical Corporation Pvt. Ltd.		Document No.: TR-PI05FRC-RT
Title: Test Report For Real Time Shelf Life Stability Testing		Revision : AE
Document type: Test Report (FM-QC-22)		Effective Date: 2019-04-15
Department: QC	Page 5 of 11	Review Due Date: 2021-04-14

Experiment: 01

Reader 2: Read By: Pooja K. Kuykhwaha

Sign & Date: Pooja K. Kuykhwaha
2021-02-25

3.1.	Specificity:	Negative Human Serum Specimens :										
Sr. No.	Specimens ID : PMC NHS	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	251	-Ve	u	0	0	C	-ve	u	0	0	C	-ve
2	252	-Ve	u	0	0	C	-ve	u	0	0	C	-ve
Negative Whole Blood Specimens :												
Sr. No.	Specimens ID : PMC NWB	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	0826	-Ve	u	0	0	C	-ve	u	0	0	C	-ve
2	0827	-Ve	u	0	0	C	-ve	u	0	0	C	-ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background, NC: - Not clear background.

Footnotes: 0 to 4 = Color band intensity by using WHO color chart Prototype: C.

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Review Due Date: 2021-04-14

3.2. Sensitivity:

HIV - 1 Positive Serum Specimens :

Sr. No.	Specimens ID : PMC H1	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/C)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/C)	Result
1	205(1:640)	+Ve	4	0	2	C	+ve	4	0	2	C	+ve
2	205(1:1280)	+Ve	4	0	1	C	+ve	4	0	1	C	+ve
3	205(1:2560)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	214	+Ve	4	0	3	C	+ve	4	0	3	C	+ve

HIV - 2 Positive Serum Specimens :

Sr. No.	Specimens ID : PMC H2	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/C)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/C)	Result
1	086(1:160)	+Ve	4	2	0	C	+ve	4	2	0	C	+ve
2	086(1:320)	+Ve	4	1	0	C	+ve	4	1	0	C	+ve
3	086(1:640)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	146	+Ve	4	3	0	C	+ve	4	3	0	C	+ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

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Document type: Test Report (FM-QC-22)

Experiment: 02

Reader 2: Tested & Read By: Pooja K. Kushwaha

Sign & Date:

Pooja K. Kushwaha
2021-02-25

3. Functional / Performance Testing

3.1. Specificity:

Negative Human Serum Specimens :

Sr. No.	Specimens ID : PMC NHS	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	251	-Ve	u	0	0	C	-ve	u	0	0	C	-ve
2	252	-Ve	u	0	0	C	-ve	u	0	0	C	-ve

Negative Whole Blood Specimens :

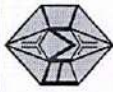
Sr. No.	Specimens ID : PMC NWB	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	0826	-Ve	u	0	0	C	-ve	u	0	0	C	-ve
2	0827	-Ve	u	0	0	C	-ve	u	0	0	C	-ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

Footnotes: 0 to 4 = Color band intensity by using WHO color chart Prototype: C.

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3.2. Sensitivity:												
HIV – 1 Positive Serum Specimens :												
Sr. No.	Specimens ID : PMC H1	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	205(1: 640)	+Ve	4	0	2	C	+ve	4	0	2	C	+ve
2	205(1: 1280)	+Ve	4	0	1	C	+ve	4	0	1	C	+ve
3	205(1: 2560)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	214	+Ve	4	0	3	C	+ve	4	0	3	C	+ve
HIV – 2 Positive Serum Specimens :												
Sr. No.	Specimens ID : PMC H2	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	086(1: 160)	+Ve	4	2	0	C	+ve	4	2	0	C	+ve
2	086(1: 320)	+Ve	4	1	0	C	+ve	4	1	0	C	+ve
3	086(1: 640)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	146	+Ve	4	3	0	C	+ve	4	3	0	C	+ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

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Experiment: 02

Reader 1: Read By: Nidhis Chauhan

Sign & Date: 2021-02-25

3.1. Specificity:		Negative Human Serum Specimens :										
Sr. No.	Specimens ID : PMC NHS	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	251	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
2	252	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
Negative Whole Blood Specimens :												
Sr. No.	Specimens ID : PMC NWB	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	0826	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
2	0827	-Ve	4	0	0	C	-ve	4	0	0	C	-ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

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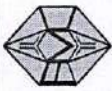
3.2. Sensitivity:												
HIV – 1 Positive Serum Specimens :												
Sr. No.	Specimens ID : PMC H1	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	205 (11.640)	+Ve	4	0	2	C	+ve	4	0	2	C	+ve
2	205 (11.280)	+Ve	4	0	1	C	+ve	4	0	1	C	+ve
3	205 (11.2560)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	214	+Ve	4	0	3	C	+ve	4	0	3	C	+ve
HIV – 2 Positive Serum Specimens :												
Sr. No.	Specimens ID : PMC H2	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	086 (11.160)	+Ve	4	2	0	C	+ve	4	2	0	C	+ve
2	086 (11.320)	+Ve	4	1	0	C	+ve	4	1	0	C	+ve
3	086 (11.640)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	146	+Ve	4	3	0	C	+ve	4	3	0	C	+ve

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Document type: Test Report

Observations:

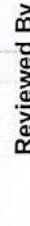
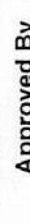
After 18 months duration testing, no significant changes were observed in this lot when stored at -18°C and $30 \pm 2^{\circ}\text{C}$ for its performance of the test movement, background clearance, specificity and sensitivity.

A
N

Conclusion:

Based on the obtained results, it can be concluded that no deterioration occurred to the test devices of the lot when tested with the specimens. Test devices showed equivalent performance when stored at -18°C and $30 \pm 1^{\circ}\text{C}$. The assay buffer volume remained in sufficient quantity to test entire kit when stored at both temperatures.

Moreover, background clearance profiles observed with whole blood / serum specimens were found acceptable without any background noise at 18 months stability testing.

Responsibility	Tested by		Reviewed By	Approved By
	Reader 1	Reader 2		
Signature & Date	 2021-02-25	 2021-02-25	 2021-02-25	 2021-02-25
Designation	Officer QC / Executive-QC / Sr-Executive-QC	Officer QC / Executive-QG / Sr-Executive-QG	Asst. Manager-QG/ Manager QC	Manager QA



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Document type: Test Report (FM-QC-22)

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Review Due Date: 2021-04-14

Product Name

First Response® HIV 1-2.O Card Test (Version 2.0)

Document ID: RC-QC-09

Sr. No. 20Month of Stability Study: Nov- 2020

Sampling Details

Lot No.	77H0119S	Duration Time	15 months
Mfg. Date	2019-08	Sampled Qty.	48 Tests
Exp. Date	2021-07	Store at	1-8°C & 30±2°C
Date of Testing	2020-11-27		

Specimens Panel Details

Description of Specimens Used	Specimens Quantity
Negative Human Serum Specimens	02
Negative Whole Blood Specimens	02
HIV – 1 Positive Serum Specimens	04
HIV – 2 Positive Serum Specimens	04

(All) Assay Procedure

Precautions: Treat all the specimens as potentially infectious and use gloves while testing.

Bring the test device, assay buffer and specimens to room temperature prior to testing.

Before starting the assay procedure, label the test device with the LOT No. and specimens ID.

Sr. No.	Test Procedure
1.	Take out required number of test device.
2.	Slowly add 1 drop (10 µL) of serum / plasma or 2 drops (20 µL) of whole blood specimens into the specimens well using the specimens transfer device / micropipette.
3.	Add one drop (35 µL) of assay buffer into the specimens well.
4.	Observe for development of colored bands in the results window.
5.	Interpret test results at 15 minutes. Do not interpret after 25 minutes.
6.	There should be clear background and both control line and test lines were clearly distinguishable.
7.	Check the control line, test line and background clearance visually. Record the result in the report within 15 minute time period. If background is cleared, mention C (Clear) on test report and if it is not cleared, mark abnormalities or issues affecting interpretation, such as poor blood clearance (i.e. Red background, Incomplete clearing and Red background obscuring test line), should be recorded NC (Not Cleared) in the report. Refer Table **Background Clearance Acceptance Criteria.

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Review Due Date: 2021-04-14

****Background Clearance Acceptance Criteria**

Acceptance Criteria	Rejection Criteria
1. If the background is clear and Control Line and/or Test Line is clearly visible then test is accepted. 2. If the background is little hazy but the Control Line and/or Test Line is clearly visible then the test is accepted 3. If the background is clear above Control Line and/or Test Line within stipulated time then test is accepted. 4. If backflow of test does not cover Control Line and/or Test Line then test is accepted	1. If the flow of specimen and colloidal gold covered the Control Line and even make it invisible but Test Line is visible then test is not accepted. 2. If the background is not clear up to Control Line within stipulated time but Test Line is visible then test is not accepted. 3. When either colloidal gold/plasma/serum/ whole blood do not allow to interpret the result after completion of stipulated time then test is not accepted. 4. If Specimen Back flow covered Control Line and make it invisible and/or the Test Line is visible then result is invalid and not accepted. 5. If the background is not clear above Control Line and/or Test Line then test is not accepted.

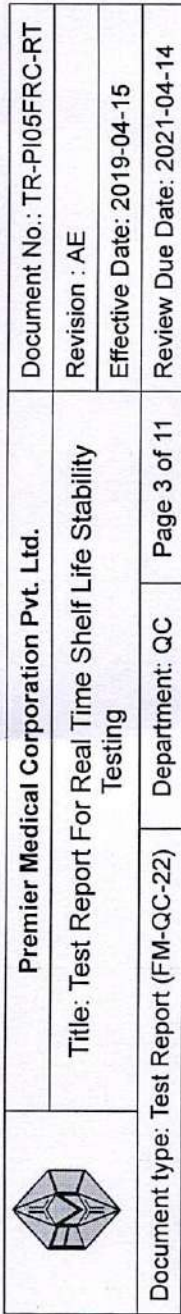
Note: Here Control Line is visible means all components/reagents has cleared reading window, crossed Control Line during flow towards absorbent pad.

Intact bottle assay buffer volume	Volume in ml		Sufficient volume Yes / No	
	1-8°C	30 ± 2°C	1-8°C	30 ± 2°C
2.5 ml filled bottle for 25 Test : Minimum 1.7 ml	NA	NA	NA	NA
2.5 ml filled bottle for 30 Test : Minimum 2.0 ml	NA	NA	NA	NA

Remark: 0 day testing results will be noted down in 1-8 °C column. The 30 ± 2 °C will be marked as not applicable/strike off.

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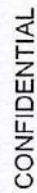


Reader 1: Tested & Read By: Rutuja N. Sawale

Sub 2020-11-27

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

Footnotes: 0 to 4 = Color band intensity by using WHO color chart Prototype: C.





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3.2. Sensitivity:

HIV - 1 Positive Serum Specimens :

Sr. No.	Specimens ID : PMC H1	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	205 (1:640)	+Ve	4	0	2	C	+ve	4	0	2	C	+ve
2	205 (1:1280)	+Ve	4	0	1	C	+ve	4	0	1	C	+ve
3	205 (1:2560)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	214	+Ve	4	0	3	C	+ve	4	0	3	C	+ve

HIV - 2 Positive Serum Specimens :

Sr. No.	Specimens ID : PMC H2	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	086 (1:160)	+Ve	4	2	0	C	+ve	4	2	0	C	+ve
2	086 (1:320)	+Ve	4	1	0	C	+ve	4	1	0	C	+ve
3	086 (1:640)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	146	+Ve	4	3	0	C	+ve	4	3	0	C	+ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

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Experiment: 01

Reader 2: Read By: Shreyashi khat

Sign & Date: Srk
2020-11-27

3.1.	Specificity:	Negative Human Serum Specimens :												
Sr. No.	Specimens ID : PMC NHS	Criteria	Store at (1-8 °C)						Store at (30 ± 2 °C)					
			Colour Band Intensity						Colour Band Intensity					
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result		
1	251	-Ve	4	0	0	C	-ve	4	0	0	C	-ve		
2	252	-Ve	4	0	0	C	-ve	4	0	0	C	-ve		
Negative Whole Blood Specimens :														
Sr. No.	Specimens ID : PMC NWB	Criteria	Store at (1-8 °C)						Store at (30 ± 2 °C)					
			Colour Band Intensity						Colour Band Intensity					
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result		
1	2576	-Ve	4	0	0	C	-ve	4	0	0	C	-ve		
2	2577	-Ve	4	0	0	C	-ve	4	0	0	C	-ve		

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

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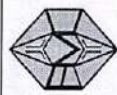
3.2.	Sensitivity:											
HIV – 1 Positive Serum Specimens :												
Sr. No.	Specimens ID : PMC H1	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	205 (1:1640)	+Ve	4	0	2	C	+ve	4	0	2	C	+ve
2	205 (1:1280)	+Ve	4	0	1	C	+ve	4	0	1	C	+ve
3	205 (1:2560)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	214	+Ve	4	0	3	C	+ve	4	0	3	C	+ve
HIV – 2 Positive Serum Specimens :												
Sr. No.	Specimens ID : PMC H2	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	086 (1:160)	+Ve	4	2	0	C	+ve	4	2	0	C	+ve
2	086 (1:320)	+Ve	4	1	0	C	+ve	4	1	0	C	+ve
3	086 (1:640)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	146	+Ve	4	3	0	C	+ve	4	3	0	C	+ve

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Experiment: 02

Reader 2: Tested & Read By: Shreyashi khat

Sign & Date: 2020-11-27

3. Functional / Performance Testing

3.1. Specificity:

Negative Human Serum Specimens :

Sr. No.	Specimens ID : PMC NHS	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	251	-Ve	4	0	0	C	-Ve	4	0	0	C	-Ve
2	252	-Ve	4	0	0	C	-Ve	4	0	0	C	-Ve

Negative Whole Blood Specimens :

Sr. No.	Specimens ID : PMC NWB	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	2576	-Ve	4	0	0	C	-Ve	4	0	0	C	-Ve
2	2577	-Ve	4	0	0	C	-Ve	4	0	0	C	-Ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background, NC: - Not clear background.

Footnotes: 0 to 4 = Color band intensity by using WHO color chart Prototype: C.

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3.2. Sensitivity:

HIV – 1 Positive Serum Specimens :

Sr. No.	Specimens ID : PMC H1	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	205 (1:640)	+Ve	4	0	2	C	+ve	4	0	2	C	+ve
2	205 (1:280)	+Ve	4	0	1	C	+ve	4	0	1	C	+ve
3	205 (1:2560)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	214	+Ve	4	0	3	C	+ve	4	0	3	C	+ve

HIV – 2 Positive Serum Specimens :

Sr. No.	Specimens ID : PMC H2	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	086 (1:160)	+Ve	4	2	0	C	+ve	4	2	0	C	+ve
2	086 (1:320)	+Ve	4	1	0	C	+ve	4	1	0	C	+ve
3	086 (1:640)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	146	+Ve	4	3	0	C	+ve	4	3	0	C	+ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

Footnotes: 0 to 4 = Color band intensity by using WHO color chart Prototype: C.

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Premier Medical Corporation Pvt. Ltd.		Document No.: TR-PI05FRC-RT
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Document type: Test Report (FM-QC-22)		Effective Date: 2019-04-15
Department: QC		Review Due Date: 2021-04-14
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Experiment: 02

Reader 1: Read By: Rutuja N. Sawale

Sign & Date: Sub 2020-11-02-24

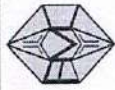
3.1.	Specificity:	Negative Human Serum Specimens :												
Sr. No.	Specimens ID : PMC NHS	Criteria	Store at (1-8 °C)						Store at (30 ± 2 °C)					
			Colour Band Intensity						Colour Band Intensity					
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result		
1	251	-Ve	4	0	0	C	-ve	4	0	0	C	-ve		
2	252	-Ve	4	0	0	C	-ve	4	0	0	C	-ve		
Negative Whole Blood Specimens :														
Sr. No.	Specimens ID : PMC NWB	Criteria	Store at (1-8 °C)						Store at (30 ± 2 °C)					
			Colour Band Intensity						Colour Band Intensity					
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result		
1	2576	-Ve	4	0	0	C	-ve	4	0	0	C	-ve		
2	2577	-Ve	4	0	0	C	-ve	4	0	0	C	-ve		

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background, NC: - Not clear background.

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3.2. Sensitivity:

HIV - 1 Positive Serum Specimens :

Sr. No.	Specimens ID : PMC H1	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	205 (1:640)	+Ve	4	0	2	C	+ve	4	0	2	C	+ve
2	205 (1:1280)	+Ve	4	0	1	C	+ve	4	0	1	C	+ve
3	205 (1:2560)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	214	+Ve	4	0	3	C	+ve	4	0	3	C	+ve

HIV - 2 Positive Serum Specimens :

Sr. No.	Specimens ID : PMC H2	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	086 (1:160)	+Ve	4	2	0	C	+ve	4	2	0	C	+ve
2	086 (1:320)	+Ve	4	1	0	C	+ve	4	1	0	C	+ve
3	086 (1:640)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	146	+Ve	4	3	0	C	+ve	4	3	0	C	+ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

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Document type:

Observations:

After 15 months, no significant changes in comparison with -8°C and $30 \pm 2^{\circ}\text{C}$ were observed in this lot for its performance of the test movement, background clearance, specificity and sensitivity.

NA

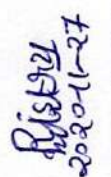
Conclusion:

Based on the results obtained, it is clear that there were no deterioration observed in the specimens tested. The test performance stored at -8°C as well as $30 \pm 2^{\circ}\text{C}$ showed equivalent results. The assay buffer volume remained in sufficient qty. at both storage temperature to test entire kit.

Moreover, background clearance profiles observed with whole blood / serum specimens was found acceptable, without any background noise at 15 months stability testing.

NA

NA

Responsibility	Tested by		Reviewed By	Approved By
	Reader 1	Reader 2		
Signature & Date	 2020-11-27	 2020-11-27	 2020-11-27	 2020-11-27
Designation	Officer QC / Executive QC-1 Sr. Executive QC	Officer QC / Executive QC-2 Sr. Executive QC	Asst. Manager QC / Manager QC	Manager QA

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Product Name

First Response® HIV 1-2.O Card Test (Version 2.0)

Document ID: RC-QC-09

Sr. No. 20Month of Stability Study: August-2020

Sampling Details

Lot No.	77H0119S	Duration Time	12 months
Mfg. Date	2019-08	Sampled Qty.	48 Tests
Exp. Date	2021-07	Store at	1-8°C & 30±2°C
Date of Testing	2020-08-28		

Specimens Panel Details

Description of Specimens Used	Specimens Quantity
Negative Human Serum Specimens	02
Negative Whole Blood Specimens	02
HIV - 1 Positive Serum Specimens	04
HIV - 2 Positive Serum Specimens	04

(All) Assay Procedure

Precautions: Treat all the specimens as potentially infectious and use gloves while testing.

Bring the test device, assay buffer and specimens to room temperature prior to testing.

Before starting the assay procedure, label the test device with the LOT No. and specimens ID.

Sr. No.	Test Procedure
1.	Take out required number of test device.
2.	Slowly add 1 drop (10 µL) of serum / plasma or 2 drops (20 µL) of whole blood specimens into the specimens well using the specimens transfer device / micropipette.
3.	Add one drop (35 µL) of assay buffer into the specimens well.
4.	Observe for development of colored bands in the results window.
5.	Interpret test results at 15 minutes. Do not interpret after 25 minutes.
6.	There should be clear background and both control line and test lines were clearly distinguishable.
7.	Check the control line, test line and background clearance visually. Record the result in the report within 15 minute time period. If background is cleared, mention C (Clear) on test report and if it is not cleared, mark abnormalities or issues affecting interpretation, such as poor blood clearance (i.e. Red background, Incomplete clearing and Red background obscuring test line), should be recorded NC (Not Cleared) in the report. Refer Table **Background Clearance Acceptance Criteria .

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****Background Clearance Acceptance Criteria**

Acceptance Criteria	Rejection Criteria
1. If the background is clear and Control Line and/or Test Line is clearly visible then test is accepted. 2. If the background is little hazy but the Control Line and/or Test Line is clearly visible then the test is accepted 3. If the background is clear above Control Line and/or Test Line within stipulated time then test is accepted. 4. If backflow of test does not cover Control Line and/or Test Line then test is accepted	1. If the flow of specimen and colloidal gold covered the Control Line and even make it invisible but Test Line is visible then test is not accepted. 2. If the background is not clear up to Control Line within stipulated time but Test Line is visible then test is not accepted. 3. When either colloidal gold/plasma/serum/ whole blood do not allow to interpret the result after completion of stipulated time then test is not accepted. 4. If Specimen Back flow covered Control Line and make it invisible and/or the Test Line is visible then result is invalid and not accepted. 5. If the background is not clear above Control Line and/or Test Line then test is not accepted.

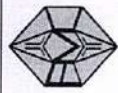
Note: Here Control Line is visible means all components/reagents has cleared reading window, crossed Control Line during flow towards absorbent pad.

Intact bottle assay buffer volume	Volume in ml		Sufficient volume Yes / No	
	1-8°C	30 ± 2°C	1-8°C	30 ± 2°C
2.5 ml filled bottle for 25 Test : Minimum 1.7 ml	NA	NA	NA	NA
2.5 ml filled bottle for 30 Test : Minimum 2.0 ml	2.5ml	2.5ml	yes	yes

Remark: 0 day testing results will be noted down in 1-8 °C column. The 30 ± 2 °C will be marked as not applicable/strike off.

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Experiment: 01

Reader 1: Tested & Read By: Pooja K. Kushwaha

Pooja Kushwaha

Sign & Date: 2020-08-28

3. Functional / Performance Testing

3.1. Specificity:

Negative Human Serum Specimens :

Sr. No.	Specimens ID : PMC NHS	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	251	-Ve	u	0	0	C	-ve	u	0	0	C	-ve
2	252	-Ve	u	0	0	C	-ve	u	0	0	C	-ve

Negative Whole Blood Specimens :

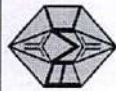
Sr. No.	Specimens ID : PMC NWB	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	1776	-Ve	u	0	0	C	-ve	u	0	0	C	-ve
2	1777	-Ve	u	0	0	C	-ve	u	0	0	C	-ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

Footnotes: 0 to 4 = Color band intensity by using WHO color chart Prototype: C.

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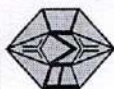
3.2. Sensitivity:												
HIV – 1 Positive Serum Specimens :												
Sr. No.	Specimens ID : PMC H1	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	205 (1: 640)	+Ve	4	0	2	C	+ve	4	0	2	C	+ve
2	205 (1: 1280)	+Ve	4	0	1	C	+ve	4	0	1	C	+ve
3	205 (1: 2560)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	214	+Ve	4	0	3	C	+ve	4	0	3	C	+ve
HIV – 2 Positive Serum Specimens :												
Sr. No.	Specimens ID : PMC H2	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	086 (1: 160)	+Ve	4	2	0	C	+ve	4	2	0	C	+ve
2	086 (1: 320)	+Ve	4	1	0	C	+ve	4	1	0	C	+ve
3	086 (1: 640)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	146	+Ve	4	3	0	C	+ve	4	3	0	C	+ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

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		Effective Date: 2019-04-15		Review Due Date: 2021-04-14

Experiment: 01

Reader 2: Read By: Rutuja N. Sawale

Sign & Date: _____

2020-08-28

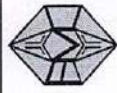
3.1.	Specificity:											
Negative Human Serum Specimens :												
Sr. No.	Specimens ID : PMC NHS	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	251	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
2	252	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
Negative Whole Blood Specimens :												
Sr. No.	Specimens ID : PMC NWB	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	1776	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
2	1777	-Ve	4	0	0	C	-ve	4	0	0	C	-ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background, NC: - Not clear background.

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3.2. Sensitivity:

HIV – 1 Positive Serum Specimens :

Sr. No.	Specimens ID : PMC H1	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	205 (1:640)	+Ve	4	0	2	C	+ve	4	0	2	C	+ve
2	205 (1:1280)	+Ve	4	0	1	C	+ve	4	0	1	C	+ve
3	205 (1:2560)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	214	+Ve	4	0	3	C	+ve	4	0	3	C	+ve

HIV – 2 Positive Serum Specimens :

Sr. No.	Specimens ID : PMC H2	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	086 (1:160)	+Ve	4	2	0	C	+ve	4	2	0	C	+ve
2	086 (1:320)	+Ve	4	1	0	C	+ve	4	1	0	C	+ve
3	086 (1:640)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	146	+Ve	4	3	0	C	+ve	4	3	0	C	+ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

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Experiment: 02

Reader 2: Tested & Read By: Rutuja N. Sawale

Sign & Date:  2020-08-28

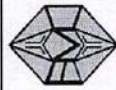
3. Functional / Performance Testing									
3.1. Specificity:									
Negative Human Serum Specimens :									
Sr. No.	Specimens ID : PMC NHS	Criteria	Store at (1-8 °C)				Store at (30 ± 2 °C)		
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	B.C. at 15 min. (C/NC)
1	251	-Ve	4	0	0	C	-ve	4	0
2	252	-Ve	4	0	0	C	-ve	4	0
Negative Whole Blood Specimens :									
Sr. No.	Specimens ID : PMC NWB	Criteria	Store at (1-8 °C)				Store at (30 ± 2 °C)		
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	B.C. at 15 min. (C/NC)
1	1776	-Ve	4	0	0	C	-ve	4	0
2	1777	-Ve	4	0	0	C	-ve	4	0

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

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3.2. Sensitivity:

HIV - 1 Positive Serum Specimens :

Sr. No.	Specimens ID : PMC H1	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	205 (1:640)	+Ve	4	0	2	C	+ve	4	0	2	C	+ve
2	205 (1:1280)	+Ve	4	0	1	C	+ve	4	0	1	C	+ve
3	205 (1:2560)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	214	+Ve	4	0	3	C	+ve	4	0	3	C	+ve

HIV - 2 Positive Serum Specimens :

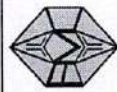
Sr. No.	Specimens ID : PMC H2	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	086 (1:160)	+Ve	4	2	0	C	+ve	4	2	0	C	+ve
2	086 (1:320)	+Ve	4	1	0	C	+ve	4	1	0	C	+ve
3	086 (1:640)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	146	+Ve	4	3	0	C	+ve	4	3	0	C	+ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

Footnotes: 0 to 4 = Color band intensity by using WHO color chart Prototype: C.

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Premier Medical Corporation Pvt. Ltd.		Document No.: TR-PI05FRC-RT
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Document type: Test Report (FM-QC-22)		Effective Date: 2019-04-15
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Experiment: 02

Reader 1: Read By: Pooja K. Kushwaha

Pooja Kushwaha
Sign & Date: 2020-08-28

3.1.	Specificity:	Negative Human Serum Specimens :										
Sr. No.	Specimens ID : PMC NHS	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	251	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
2	252	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
Negative Whole Blood Specimens :												
Sr. No.	Specimens ID : PMC NWB	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	1776	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
2	1777	-Ve	4	0	0	C	-ve	4	0	0	C	-ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background, NC: - Not clear background.

Footnotes: 0 to 4 = Color band intensity by using WHO color chart Prototype: C.

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3.2.		Sensitivity:										
HIV – 1 Positive Serum Specimens :												
Sr. No.	Specimens ID : PMC H1	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	205(1:640)	+Ve	4	0	2	C	+ve	4	0	2	C	+ve
2	205(1:1280)	+Ve	4	0	1	C	+ve	4	0	1	C	+ve
3	205(1:2560)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	214	+Ve	4	0	3	C	+ve	4	0	3	C	+ve
HIV – 2 Positive Serum Specimens :												
Sr. No.	Specimens ID : PMC H2	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	086(1:160)	+Ve	4	2	0	C	+ve	4	2	0	C	+ve
2	086(1:320)	+Ve	4	1	0	C	+ve	4	1	0	C	+ve
3	086(1:640)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	146	+Ve	4	3	0	C	+ve	4	3	0	C	+ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

Footnotes: 0 to 4 = Color band intensity by using WHO color chart Prototype: C.



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Observations:

After 12 months, no significant changes in comparison with $1-8^{\circ}\text{C}$ and $30\pm 2^{\circ}\text{C}$ were observed in this lot for its performance of the test movement, background clearance, specificity and sensitivity.

NA

Conclusion:

Based on the results obtained, it is clear that there were no deterioration observed in the specimens tested. The test performance stored at $1-8^{\circ}\text{C}$ as well as $30\pm 2^{\circ}\text{C}$ showed equivalent results. The assay buffer volume remained in sufficient qty. at both storage temperature to test entire kit.

Moreover, background clearance profiles observed with whole blood / serum specimens was found acceptable, without any background noise at 12 months stability testing.

NA

Responsibility	Tested by		Reviewed By	Approved By
	Reader 1	Reader 2		
Signature & Date	Twissalugh 2020-08-28	Sub 2020-08-28	Ristora 2020-08-28	W. J. J. J. 2020-08-28
Designation	Officer QC / Executive QC / Sr. Executive QC	Officer QC / Executive QC / Sr. Executive QC	Asst. Manager QC / Manager QC	Manager QA

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Product Name

First Response® HIV 1-2.O Card Test (Version 2.0)

Document ID: RC-QC-09

Sr. No. 20Month of Stability Study: May - 2020

Sampling Details

Lot No.	77H01195	Duration Time	09 months
Mfg. Date	2019-08	Sampled Qty.	48 Tests
Exp. Date	2021-07	Store at	1-8°C & 30±2°C
Date of Testing	2020-05-26		

Specimens Panel Details

Description of Specimens Used	Specimens Quantity
Negative Human Serum Specimens	02
Negative Whole Blood Specimens	02
HIV - 1 Positive Serum Specimens	04
HIV - 2 Positive Serum Specimens	04

(All) Assay Procedure

Precautions: Treat all the specimens as potentially infectious and use gloves while testing.

Bring the test device, assay buffer and specimens to room temperature prior to testing.

Before starting the assay procedure, label the test device with the LOT No. and specimens ID.

Sr. No.	Test Procedure
1.	Take out required number of test device.
2.	Slowly add 1 drop (10 µL) of serum / plasma or 2 drops (20 µL) of whole blood specimens into the specimens well using the specimens transfer device / micropipette.
3.	Add one drop (35 µL) of assay buffer into the specimens well.
4.	Observe for development of colored bands in the results window.
5.	Interpret test results at 15 minutes. Do not interpret after 25 minutes.
6.	There should be clear background and both control line and test lines were clearly distinguishable.
7.	Check the control line, test line and background clearance visually. Record the result in the report within 15 minute time period. If background is cleared, mention C (Clear) on test report and if it is not cleared, mark abnormalities or issues affecting interpretation, such as poor blood clearance (i.e. Red background, Incomplete clearing and Red background obscuring test line), should be recorded NC (Not Cleared) in the report. Refer Table **Background Clearance Acceptance Criteria.

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****Background Clearance Acceptance Criteria**

Acceptance Criteria	Rejection Criteria
1. If the background is clear and Control Line and/or Test Line is clearly visible then test is accepted. 2. If the background is little hazy but the Control Line and/or Test Line is clearly visible then the test is accepted 3. If the background is clear above Control Line and/or Test Line within stipulated time then test is accepted. 4. If backflow of test does not cover Control Line and/or Test Line then test is accepted	1. If the flow of specimen and colloidal gold covered the Control Line and even make it invisible but Test Line is visible then test is not accepted. 2. If the background is not clear up to Control Line within stipulated time but Test Line is visible then test is not accepted. 3. When either colloidal gold/plasma/serum/ whole blood do not allow to interpret the result after completion of stipulated time then test is not accepted. 4. If Specimen Back flow covered Control Line and make it invisible and/or the Test Line is visible then result is invalid and not accepted. 5. If the background is not clear above Control Line and/or Test Line then test is not accepted.

Note: Here Control Line is visible means all components/reagents has cleared reading window, crossed Control Line during flow towards absorbent pad.

Intact bottle assay buffer volume	Volume in ml		Sufficient volume Yes / No	
	1-8 °C	30 ± 2 °C	1-8 °C	30 ± 2 °C
2.5 ml filled bottle for 25 Test : Minimum 1.7 ml	NA	NA	NA	NA
2.5 ml filled bottle for 30 Test : Minimum 2.0 ml	2.5 ml	2.5 ml	Yes	Yes

Remark: 0 day testing results will be noted down in 1-8 °C column. The 30 ± 2 °C will be marked as not applicable/strike off.

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Experiment: 01

Reader 1: Tested & Read By: Pooja K. kushwah

Pooja k
Sign & Date: 2020-05-26

3. Functional / Performance Testing									
3.1. Specificity:									
Negative Human Serum Specimens :									
Sr. No.	Specimens ID : PMC NHS	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)	
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	HIV-2	HIV-1
1	246	-Ve	4	0	0	C	-ve	0	0
2	247	-Ve	4	0	0	C	-ve	0	0
Negative Whole Blood Specimens :									
Sr. No.	Specimens ID : PMC NWB	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)	
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	HIV-2	HIV-1
1	1051	-Ve	4	0	0	C	-ve	0	0
2	1052	-Ve	4	0	0	C	-ve	0	0

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background, NC: - Not clear background.

Footnotes: 0 to 4 = Color band intensity by using WHO color chart Prototype: C.



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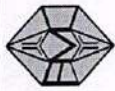
3.2.	Sensitivity:											
HIV – 1 Positive Serum Specimens :												
Sr. No.	Specimens ID : PMC H1	Criteria	Store at (1-8 °C)				Store at (30 ± 2 °C)					
			Colour Band Intensity				Colour Band Intensity					
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	203(1:640)	+Ve	4	0	2	C	+ve	4	0	2	C	+ve
2	203(1:1280)	+Ve	4	0	1	C	+ve	4	0	1	C	+ve
3	203(1:2560)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	162	+Ve	4	0	3	C	+ve	4	0	3	C	+ve
HIV – 2 Positive Serum Specimens :												
Sr. No.	Specimens ID : PMC H2	Criteria	Store at (1-8 °C)				Store at (30 ± 2 °C)					
			Colour Band Intensity				Colour Band Intensity					
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	034(1:160)	+Ve	4	2	0	C	+ve	4	2	0	C	+ve
2	034(1:320)	+Ve	4	1	0	C	+ve	4	1	0	C	+ve
3	034(1:640)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	050	+Ve	4	3	0	C	+ve	4	3	0	C	+ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

Footnotes: 0 to 4 = Color band intensity by using WHO color chart Prototype: C.



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Experiment: 01

Reader 2: Read By: Nidhis Chaudhary

Sign & Date: _____

3.1. Specificity:

Negative Human Serum Specimens :

Sr. No.	Specimens ID : PMC NHS	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	246	-Ve	L	0	0	C	-ve	L	0	0	C	-ve
2	247	-Ve	L	0	0	C	-ve	L	0	0	C	-ve

Negative Whole Blood Specimens :

Sr. No.	Specimens ID : PMC NWB	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	1051	-Ve	L	0	0	C	-ve	L	0	0	C	-ve
2	1052	-Ve	L	0	0	C	-ve	L	0	0	C	-ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

Footnotes: 0 to 4 = Color band intensity by using WHO color chart Prototype: C.

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3.2. Sensitivity:												
HIV – 1 Positive Serum Specimens :												
Sr. No.	Specimens ID : PMC H1	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	203 (1:640)	+Ve	4	0	2	C	+ve	4	0	2	C	+ve
2	203 (1:1280)	+Ve	4	0	1	C	+ve	4	0	1	C	+ve
3	203 (1:2560)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	162	+Ve	4	0	3	C	+ve	4	0	3	C	+ve
HIV – 2 Positive Serum Specimens :												
Sr. No.	Specimens ID : PMC H2	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	034 (1:160)	+Ve	4	2	0	C	+ve	4	2	0	C	+ve
2	034 (1:320)	+Ve	4	1	0	C	+ve	4	1	0	C	+ve
3	034 (1:640)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	050	+Ve	4	3	0	C	+ve	4	3	0	C	+ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

Footnotes: 0 to 4 = Color band intensity by using WHO color chart Prototype: C.

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Experiment: 02

Reader 2: Tested & Read By: Nidhi S. Chaudhary

Sign & Date: _____

3. Functional / Performance Testing

3.1. Specificity:

Negative Human Serum Specimens :

Sr. No.	Specimens ID : PMC NHS	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	246	-Ve	L ₄	0	0	C	-ve	L ₄	0	0	C	-ve
2	247	-Ve	L ₄	0	0	C	-ve	L ₄	0	0	C	-ve

Negative Whole Blood Specimens :

Sr. No.	Specimens ID : PMC NWB	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	1051	-Ve	L ₄	0	0	C	-ve	L ₄	0	0	C	-ve
2	1052	-Ve	L ₄	0	0	C	-ve	L ₄	0	0	C	-ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background, NC: - Not clear background.

Footnotes: 0 to 4 = Color band intensity by using WHO color chart Prototype: C.

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3.2. Sensitivity:												
HIV – 1 Positive Serum Specimens :												
Sr. No.	Specimens ID : PMC H1	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	203 (1:640)	+Ve	4	0	2	C	+ve	4	0	2	C	+ve
2	203 (1:1280)	+Ve	4	0	1	C	+ve	4	0	1	C	+ve
3	203 (1:2560)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	162	+Ve	4	0	3	C	+ve	4	0	3	C	+ve
HIV – 2 Positive Serum Specimens :												
Sr. No.	Specimens ID : PMC H2	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	034 (1:160)	+Ve	4	2	0	C	+ve	4	2	0	C	+ve
2	034 (1:320)	+Ve	4	1	0	C	+ve	4	1	0	C	+ve
3	034 (1:640)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	050	+Ve	4	3	0	C	+ve	4	3	0	C	+ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

Footnotes: 0 to 4 = Color band intensity by using WHO color chart Prototype: C.

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Review Due Date: 2021-04-14

Experiment: 02

Reader 1: Read By: Pooja K. Loughwaha

Sign & Date: Pooja Loughwaha
2020-05-26

3.1. Specificity:

Negative Human Serum Specimens :

Sr. No.	Specimens ID : PMC NHS	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	246	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
2	247	-Ve	4	0	0	C	-ve	4	0	0	C	-ve

Negative Whole Blood Specimens :

Sr. No.	Specimens ID : PMC NWB	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	1051	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
2	1052	-Ve	4	0	0	C	-ve	4	0	0	C	-ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background, NC: - Not clear background.

Footnotes: 0 to 4 = Color band intensity by using WHO color chart Prototype: C.

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3.2. Sensitivity:

HIV - 1 Positive Serum Specimens :

Sr. No.	Specimens ID : PMC H1	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	203(1:640)	+Ve	4	0	2	C	+ve	4	0	2	C	+ve
2	203(1:1280)	+Ve	4	0	1	C	+ve	4	0	1	C	+ve
3	203(1:2560)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	162	+Ve	4	0	3	C	+ve	4	0	3	C	+ve

HIV - 2 Positive Serum Specimens :

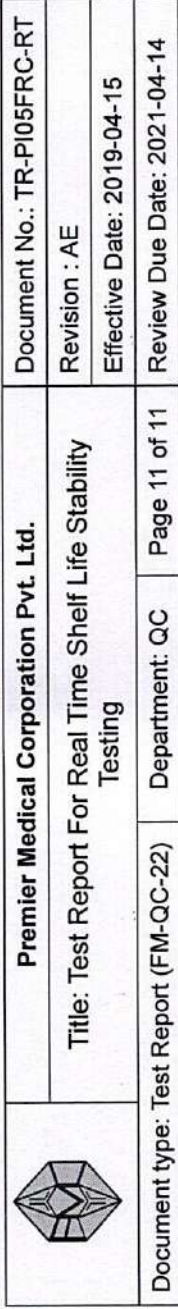
Sr. No.	Specimens ID : PMC H2	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	034(1:160)	+Ve	4	2	0	C	+ve	4	2	0	C	+ve
2	034(1:320)	+Ve	4	1	0	C	+ve	4	1	0	C	+ve
3	034(1:640)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	050	+Ve	4	3	0	C	+ve	4	3	0	C	+ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

Footnotes: 0 to 4 = Color band intensity by using WHO color chart Prototype: C.

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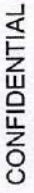




Observations:
After 09 months no significant changes in comparison with $1-8^{\circ}\text{C}$ and $30 \pm 2^{\circ}\text{C}$ were observed in this lot for its performance of the test movement background clearance specificity and sensitivity.

Conclusion:
Based on the results obtained it is clear that there were no deterioration observed in the specimens specimens tested. The test performance stored at $1-8^{\circ}\text{C}$ as well as $30 \pm 2^{\circ}\text{C}$ showed equivalent results. The assay buffer volume remained in sufficient qty. at both storage temperature to test entire kit.

Responsibility	Tested by		Reviewed By	Approved By
	Reader 1	Reader 2		
Signature & Date	Twinklugh 2020-05-26	 2020-05-26	 2020-05-26	 2020-05-26
Designation	Officer QC / Executive-QC / Sr-Executive-QC	Officer QC / Executive-QC / Sr-Executive-QC	Asst. Manager QC / Manager QC	Manager QA





Premier Medical Corporation Pvt. Ltd.

Document No.: TR-PI05FRC-RT

Title: Test Report For Real Time Shelf Life Stability Testing

Revision : AE

Effective Date: 2019-04-15

Document type: Test Report (FM-QC-22)

Department: QC

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Review Due Date: 2021-04-14

Product Name

First Response® HIV 1-2.O Card Test (Version 2.0)

Document ID: RC-QC-09

Sr. No. 20Month of Stability Study: Feb - 2020

Sampling Details

Lot No.	77H01195	Duration Time	06 months
Mfg. Date	2019-08	Sampled Qty.	48 Tests
Exp. Date	2021-07	Store at	1-8°C & 30±2°C
Date of Testing	2020-02-25		

Specimens Panel Details

Description of Specimens Used	Specimens Quantity
Negative Human Serum Specimens	02
Negative Whole Blood Specimens	02
HIV - 1 Positive Serum Specimens	04
HIV - 2 Positive Serum Specimens	04

(All) Assay Procedure

Precautions: Treat all the specimens as potentially infectious and use gloves while testing.

Bring the test device, assay buffer and specimens to room temperature prior to testing.

Before starting the assay procedure, label the test device with the LOT No. and specimens ID.

Sr. No.	Test Procedure
1.	Take out required number of test device.
2.	Slowly add 1 drop (10 µL) of serum / plasma or 2 drops (20 µL) of whole blood specimens into the specimens well using the specimens transfer device / micropipette.
3.	Add one drop (35 µL) of assay buffer into the specimens well.
4.	Observe for development of colored bands in the results window.
5.	Interpret test results at 15 minutes. Do not interpret after 25 minutes.
6.	There should be clear background and both control line and test lines were clearly distinguishable.
7.	Check the control line, test line and background clearance visually. Record the result in the report within 15 minute time period. If background is cleared, mention C (Clear) on test report and if it is not cleared, mark abnormalities or issues affecting interpretation, such as poor blood clearance (i.e. Red background, Incomplete clearing and Red background obscuring test line), should be recorded NC (Not Cleared) in the report. Refer Table **Background Clearance Acceptance Criteria.



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****Background Clearance Acceptance Criteria**

Acceptance Criteria	Rejection Criteria
1. If the background is clear and Control Line and/or Test Line is clearly visible then test is accepted. 2. If the background is little hazy but the Control Line and/or Test Line is clearly visible then the test is accepted 3. If the background is clear above Control Line and/or Test Line within stipulated time then test is accepted. 4. If backflow of test does not cover Control Line and/or Test Line then test is accepted	1. If the flow of specimen and colloidal gold covered the Control Line and even make it invisible but Test Line is visible then test is not accepted. 2. If the background is not clear up to Control Line within stipulated time but Test Line is visible then test is not accepted. 3. When either colloidal gold/plasma/serum/ whole blood do not allow to interpret the result after completion of stipulated time then test is not accepted. 4. If Specimen Back flow covered Control Line and make it invisible and/or the Test Line is visible then result is invalid and not accepted. 5. If the background is not clear above Control Line and/or Test Line then test is not accepted.

Note: Here Control Line is visible means all components/reagents has cleared reading window, crossed Control Line during flow towards absorbent pad.

Intact bottle assay buffer volume	Volume in ml		Sufficient volume Yes / No	
	1-8°C	30 ± 2°C	1-8°C	30 ± 2°C
2.5 ml filled bottle for 25 Test : Minimum 1.7 ml	NA	NA	NA	NA
2.5 ml filled bottle for 30 Test : Minimum 2.0 ml	2.6 ml	2.6 ml	yes	yes

Remark: 0 day testing results will be noted down in 1-8 °C column. The 30 ± 2 °C will be marked as not applicable/strike off.



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Document type: Test Report (FM-QC-22) Department: QC Page 3 of 11 Review Due Date: 2021-04-14

Experiment: 01

Reader 1: Tested & Read By: Jojoia k. kushwahaSign & Date: Jojoia k. kushwaha
2020-02-25

3. Functional / Performance Testing

3.1. Specificity:

Negative Human Serum Specimens :

Sr. No.	Specimens ID : PMC NHS	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	246	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
2	247	-Ve	4	0	0	C	-ve	4	0	0	C	-ve

Negative Whole Blood Specimens :

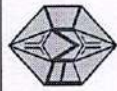
Sr. No.	Specimens ID : PMC NWB	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	0426	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
2	0427	-Ve	4	0	0	C	-ve	4	0	0	C	-ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background, NC: - Not clear background.

Footnotes: 0 to 4 = Color band intensity by using WHO color chart Prototype: C.



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3.2. Sensitivity:

HIV - 1 Positive Serum Specimens :

Sr. No.	Specimens ID : PMC H1	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	203 (1:640)	+Ve	4	0	2	C	+ve	4	0	2	C	+ve
2	203 (1:1280)	+Ve	4	0	1	C	+ve	4	0	1	C	+ve
3	203 (1:2560)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	162	+Ve	4	0	3	C	+ve	4	0	3	C	+ve

HIV - 2 Positive Serum Specimens :

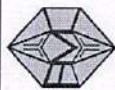
Sr. No.	Specimens ID : PMC H2	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	034 (1:160)	+Ve	4	2	0	C	+ve	4	2	0	C	+ve
2	034 (1:320)	+Ve	4	1	0	C	+ve	4	1	0	C	+ve
3	034 (1:640)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	050	+Ve	4	3	0	C	+ve	4	3	0	C	+ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

Footnotes: 0 to 4 = Color band intensity by using WHO color chart Prototype: C.



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Review Due Date: 2021-04-14

Experiment: 01

Reader 2: Read By: Nidhi S. Chaudhary

Sign & Date: 2020-02-25

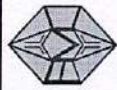
3.1.	Specificity:											
Negative Human Serum Specimens :												
Sr. No.	Specimens ID : PMC NHS	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	246	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
2	247	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
Negative Whole Blood Specimens :												
Sr. No.	Specimens ID : PMC NWB	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	0426	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
2	0427	-Ve	4	0	0	C	-ve	4	0	0	C	-ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

Footnotes: 0 to 4 = Color band intensity by using WHO color chart Prototype: C.



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3.2. Sensitivity:

HIV - 1 Positive Serum Specimens :

Sr. No.	Specimens ID : PMC H1	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	203 (1:640)	+Ve	4	0	2	C	+ve	4	0	2	C	+ve
2	203 (1:1280)	+Ve	4	0	1	C	+ve	4	0	1	C	+ve
3	203 (1:2560)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	162	+Ve	4	0	3	C	+ve	4	0	3	C	+ve

HIV - 2 Positive Serum Specimens :

Sr. No.	Specimens ID : PMC H2	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	034 (1:160)	+Ve	4	2	0	C	+ve	4	2	0	C	+ve
2	034 (1:320)	+Ve	4	1	0	C	+ve	4	1	0	C	+ve
3	034 (1:640)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	050	+Ve	4	3	0	C	+ve	4	3	0	C	+ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

Footnotes: 0 to 4 = Color band intensity by using WHO color chart Prototype: C.



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Review Due Date: 2021-04-14

Experiment: 02

Reader 2: Tested & Read By: Nidhis Chandra

Sign & Date: 2020-05-25

3. Functional / Performance Testing

3.1. Specificity:

Negative Human Serum Specimens :

Sr. No.	Specimens ID : PMC NHS	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	246	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
2	247	-Ve	4	0	0	C	-ve	4	0	0	C	-ve

Negative Whole Blood Specimens :

Sr. No.	Specimens ID : PMC NWB	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	0426	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
2	0427	-Ve	4	0	0	C	-ve	4	0	0	C	-ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background, NC: - Not clear background.

Footnotes: 0 to 4 = Color band intensity by using WHO color chart Prototype: C.



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3.2. Sensitivity:

HIV - 1 Positive Serum Specimens :

Sr. No.	Specimens ID : PMC H1	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	203 (1:640)	+Ve	4	0	2	C	+ve	4	0	2	C	+ve
2	203 (1:1280)	+Ve	4	0	1	C	+ve	4	0	1	C	+ve
3	203 (1:2560)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	162	+Ve	4	0	3	C	+ve	4	0	3	C	+ve

HIV - 2 Positive Serum Specimens :

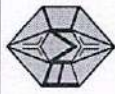
Sr. No.	Specimens ID : PMC H2	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	034 (1:160)	+Ve	4	2	0	C	+ve	4	2	0	C	+ve
2	034 (1:320)	+Ve	4	1	0	C	+ve	4	1	0	C	+ve
3	034 (1:640)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	050	+Ve	4	3	0	C	+ve	4	3	0	C	+ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

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Review Due Date: 2021-04-14

Experiment: 02

Reader 1: Read By: Pooja k. kushwahaSign & Date: Pooja k. kushwaha
2020-02-25

3.1.	Specificity:	Negative Human Serum Specimens :												
Sr. No.	Specimens ID : PMC NHS	Criteria	Store at (1-8 °C)						Store at (30 ± 2 °C)					
			Colour Band Intensity						Colour Band Intensity					
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result		
1	246	-Ve	4	0	0	C	-ve	4	0	0	C	-ve		
2	247	-Ve	4	0	0	C	-ve	4	0	0	C	-ve		
Negative Whole Blood Specimens :														
Sr. No.	Specimens ID : PMC NWB	Criteria	Store at (1-8 °C)						Store at (30 ± 2 °C)					
			Colour Band Intensity						Colour Band Intensity					
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result		
1	0426	-Ve	4	0	0	C	-ve	4	0	0	C	-ve		
2	0427	-Ve	4	0	0	C	-ve	4	0	0	C	-ve		

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

Footnotes: 0 to 4 = Color band intensity by using WHO color chart Prototype: C.



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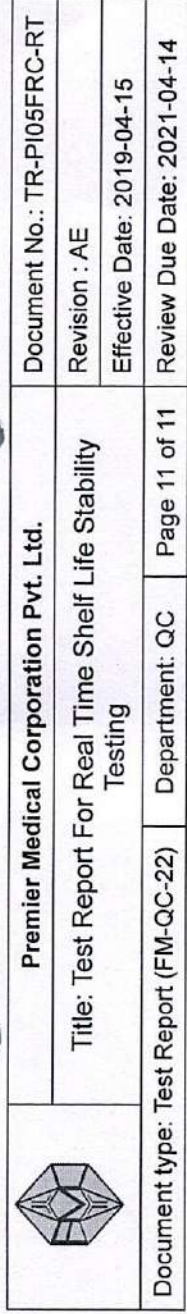
3.2.		Sensitivity:										
HIV – 1 Positive Serum Specimens :												
Sr. No.	Specimens ID : PMC H1	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	203 (1: 640)	+Ve	4	0	2	C	+ve	4	0	2	C	+ve
2	203 (1: 1280)	+Ve	4	0	1	C	+ve	4	0	1	C	+ve
3	203 (1: 2560)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	162	+Ve	4	0	3	C	+ve	4	0	3	C	+ve
HIV – 2 Positive Serum Specimens :												
Sr. No.	Specimens ID : PMC H2	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	034 (1: 160)	+Ve	4	2	0	C	+ve	4	2	0	C	+ve
2	034 (1: 320)	+Ve	4	1	0	C	+ve	4	1	0	C	+ve
3	034 (1: 640)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	050	+Ve	4	3	0	C	+ve	4	3	0	C	+ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

Footnotes: 0 to 4 = Color band intensity by using WHO color chart Prototype: C.



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After 6 months no significant changes in comparison with $1-8^{\circ}\text{C}$ and $30\pm 2^{\circ}\text{C}$ were observed in this lot for its performance of the test movement, background clearance, specificity and sensitivity.

Based on the results obtained it is clear that there were no deterioration observed in the specimens tested. The test performance stored at -18°C as well as $30 \pm 5^{\circ}\text{C}$ showed equivalent results. The assay buffer volume remained in sufficient qty. at both storage temperature to test entire kit.

Responsibility	Tested by		Reviewed By	Approved By
	Reader 1	Reader 2		
Signature & Date	Poojalekh 2020-02-25	Signature 2020-02-25	Poojalekh 2020-02-25	Poojalekh 2020-02-25
Designation	Officer QC / Executive QC / Sr-Executive QC	Officer QC / Executive QC / Sr-Executive QC	Asst. Manager QC / Manager QC	Manager QA

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Review Due Date: 2021-04-14

Product Name

First Response® HIV 1-2.O Card Test (Version 2.0)

Document ID: RC-QC-09

Sr. No. 20Month of Stability Study: Nov - 2019

Sampling Details

Lot No.	77H01195	Duration Time	03 months
Mfg. Date	2019-08	Sampled Qty.	48 Tests
Exp. Date	2021-07	Store at	1-8°C & 30±2°C
Date of Testing	2019-11-29		

Specimens Panel Details

Description of Specimens Used	Specimens Quantity
Negative Human Serum Specimens	02
Negative Whole Blood Specimens	02
HIV - 1 Positive Serum Specimens	04
HIV - 2 Positive Serum Specimens	04

(All) Assay Procedure

Precautions: Treat all the specimens as potentially infectious and use gloves while testing

Bring the test device, assay buffer and specimens to room temperature prior to testing.

Before starting the assay procedure, label the test device with the LOT No. and specimens ID.

Sr. No.	Test Procedure
1.	Take out required number of test device.
2.	Slowly add 1 drop (10 µL) of serum / plasma or 2 drops (20 µL) of whole blood specimens into the specimens well using the specimens transfer device / micropipette.
3.	Add one drop (35 µL) of assay buffer into the specimens well.
4.	Observe for development of colored bands in the results window.
5.	Interpret test results at 15 minutes. Do not interpret after 25 minutes.
6.	There should be clear background and both control line and test lines were clearly distinguishable.
7.	Check the control line, test line and background clearance visually. Record the result in the report within 15 minute time period. If background is cleared, mention C (Clear) on test report and if it is not cleared, mark abnormalities or issues affecting interpretation, such as poor blood clearance (i.e. Red background, Incomplete clearing and Red background obscuring test line). should be recorded NC (Not Cleared) in the report. Refer Table **Background Clearance Acceptance Criteria.

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Premier Medical Corporation Pvt. Ltd.

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Review Due Date: 2021-04-14

****Background Clearance Acceptance Criteria**

Acceptance Criteria	Rejection Criteria
1. If the background is clear and Control Line and/or Test Line is clearly visible then test is accepted. 2. If the background is little hazy but the Control Line and/or Test Line is clearly visible then the test is accepted 3. If the background is clear above Control Line and/or Test Line within stipulated time then test is accepted. 4. If backflow of test does not cover Control Line and/or Test Line then test is accepted	1. If the flow of specimen and colloidal gold covered the Control Line and even make it invisible but Test Line is visible then test is not accepted. 2. If the background is not clear up to Control Line within stipulated time but Test Line is visible then test is not accepted. 3. When either colloidal gold/plasma/serum/ whole blood do not allow to interpret the result after completion of stipulated time then test is not accepted. 4. If Specimen Back flow covered Control Line and make it invisible and/or the Test Line is visible then result is invalid and not accepted. 5. If the background is not clear above Control Line and/or Test Line then test is not accepted.

Note: Here Control Line is visible means all components/reagents has cleared reading window, crossed Control Line during flow towards absorbent pad.

Intact bottle assay buffer volume	Volume in ml		Sufficient volume Yes / No	
	1-8°C	30 ± 2°C	1-8°C	30 ± 2°C
2.5 ml filled bottle for 25 Test : Minimum 1.7 ml	NA	NA	NA	NA
2.5 ml filled bottle for 30 Test : Minimum 2.0 ml	2.6	2.5	YES	YES

Remark: 0 day testing results will be noted down in 1-8 °C column. The 30 ± 2 °C will be marked as not applicable/strike off.

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Premier Medical Corporation Pvt. Ltd.		Document No.: TR-PI05FRC-RT
Title: Test Report For Real Time Shelf Life Stability Testing		Revision : AE
Document type: Test Report (FM-QC-22)		Effective Date: 2019-04-15
Department: QC		Review Due Date: 2021-04-14
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Experiment: 01

Reader 1: Tested & Read By: Pooja K. Kugshwar

Sign & Date: Pooja K. Kugshwar
2019-11-29

3. Functional / Performance Testing

3.1. Specificity:

Negative Human Serum Specimens :

Sr. No.	Specimens ID : PMC NHS	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	246	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
2	247	-Ve	4	0	0	C	-ve	4	0	0	C	-ve

Negative Whole Blood Specimens :

Sr. No.	Specimens ID : PMC NWB	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	1951	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
2	1952	-Ve	4	0	0	C	-ve	4	0	0	C	-ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background, NC: - Not clear background.

Footnotes: 0 to 4 = Color band intensity by using WHO color chart Prototype: C.



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3.2. Sensitivity:

HIV - 1 Positive Serum Specimens :

Sr. No.	Specimens ID : PMC H1	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	203(1:640)	+Ve	4	0	2	C	+ve	4	0	2	C	+ve
2	203(1:1280)	+Ve	4	0	1	C	+ve	4	0	1	C	+ve
3	203(1:2560)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	162	+Ve	4	0	4	C	+ve	4	0	4	C	+ve

HIV - 2 Positive Serum Specimens :

Sr. No.	Specimens ID : PMC H2	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	034 (1:160)	+Ve	4	2	0	C	+ve	4	2	0	C	+ve
2	034 (1:320)	+Ve	4	1	0	C	+ve	4	1	0	C	+ve
3	034 (1:640)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	050	+Ve	4	3	0	C	+ve	4	3	0	C	+ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

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Review Due Date: 2021-04-14

Experiment: 01

Reader 2: Read By: Nidhis. Chandhara

Sign & Date: 2019-11-29

3.1.	Specificity:											
Negative Human Serum Specimens :												
Sr. No.	Specimens ID : PMC NHS	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	2416	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
2	247	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
Negative Whole Blood Specimens :												
Sr. No.	Specimens ID : PMC NWB	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	1951	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
2	1952	-Ve	4	0	0	C	-ve	4	0	0	C	-ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background, NC: - Not clear background.

Footnotes: 0 to 4 = Color band intensity by using WHO color chart Prototype: C.

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Review Due Date: 2021-04-14

3.2.	Sensitivity:
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HIV – 1 Positive Serum Specimens :

Sr. No.	Specimens ID : PMC H1	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	203(1640)	+Ve	4	0	2	C	+ve	4	0	2	C	+ve
2	203(11280)	+Ve	4	0	1	C	+ve	4	0	1	C	+ve
3	203(1-2560)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	162	+Ve	4	0	4	C	+ve	4	0	4	C	+ve

HIV – 2 Positive Serum Specimens :

Sr. No.	Specimens ID : PMC H2	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	034 (1.60)	+Ve	4	2	0	C	+ve	4	2	0	C	+ve
2	034 (1.320)	+Ve	4	1	0	C	+ve	4	1	0	C	+ve
3	034 (1.640)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	050	+Ve	4	3	0	C	+ve	4	3	0	C	+ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

Footnotes: 0 to 4 = Color band intensity by using WHO color chart Prototype: C.

Experiment: 02

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Reader 2: Tested & Read By: Nishith S. Chaudhari

Sign & Date: 2019-11-29

3. Functional / Performance Testing

3.1. Specificity:

Negative Human Serum Specimens :

Sr. No.	Specimens ID : PMC NHS	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	246	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
2	247	-Ve	4	0	0	C	-ve	4	0	0	C	-ve

Negative Whole Blood Specimens :

Sr. No.	Specimens ID : PMC NWB	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	1951	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
2	1952	-Ve	4	0	0	C	-ve	4	0	0	C	-ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background, NC: - Not clear background.

Footnotes: 0 to 4 = Color band intensity by using WHO color chart Prototype: C.

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3.2. Sensitivity:

HIV - 1 Positive Serum Specimens :

Sr. No.	Specimens ID : PMC H1	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	203 (1:640)	+Ve	4	0	2	C	+ve	4	0	2	C	+ve
2	203 (1:1280)	+Ve	4	0	1	C	+ve	4	0	1	C	+ve
3	203 (1:2560)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	162	+Ve	4	0	4	C	+ve	4	0	4	C	+ve

HIV - 2 Positive Serum Specimens :

Sr. No.	Specimens ID : PMC H2	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	034 (1:160)	+Ve	4	2	0	C	+ve	4	2	0	C	+ve
2	034 (1:320)	+Ve	4	1	0	C	+ve	4	1	0	C	+ve
3	034 (1:640)	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
4	050	+Ve	4	3	0	C	+ve	4	3	0	C	+ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

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Experiment: 02

Reader 1: Read By: Pooja K. Kushwaha

Sign & Date: Pooja K. Kushwaha
2019-11-29

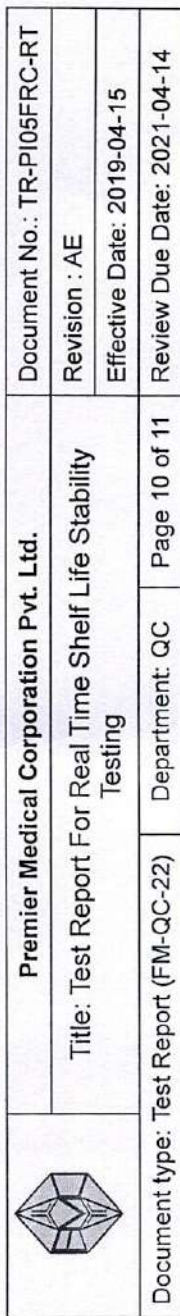
3.1. Specificity:		Negative Human Serum Specimens :										
Sr. No.	Specimens ID : PMC NHS	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	246	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
2	247	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
Negative Whole Blood Specimens :												
Sr. No.	Specimens ID : PMC NWB	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	1951	-Ve	4	0	0	C	-ve	4	0	0	C	-ve
2	1952	-Ve	4	0	0	C	-ve	4	0	0	C	-ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C. - Clear background, NC: - Not clear background.

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3.2. Sensitivity:												
HIV – 1 Positive Serum Specimens :												
Sr. No.	Specimens ID : PMC H1	Criteria	Store at (1-8 °C)						Store at (30 ± 2 °C)			
			Colour Band Intensity						Colour Band Intensity			
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (CNC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/N/C)	Result
1	203 (I: 640)	+Ve	+	0	2	C	+ve	+	0	2	C	+ve
2	203 (I: 1280)	+Ve	+	0	1	C	+ve	+	0	1	C	+ve
3	203 (I: 2560)	-Ve	+	0	0	C	-ve	+	0	0	C	-ve
4	162	+Ve	+	0	+	C	+ve	+	0	+	C	+ve

Sr. No.	Specimens ID : PMC H2	Criteria	Store at (1-8 °C)						Store at (30 ± 2 °C)					
			Colour Band Intensity						Colour Band Intensity					
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/N/C)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/N/C)	Result		
1	034 (1:160)	+Ve	+	2	0	C	+ve	+	2	0	C	+ve		
2	034 (1:320)	+Ve	+	1	0	C	+ve	+	1	0	C	+ve		
3	034 (1:640)	-Ve	+	0	0	C	-ve	+	0	0	C	-ve		
4	050	+Ve	+	3	0	C	+ve	+	3	0	C	+ve		

Footnotes: 0 to 4 = Color band intensity by using WHO color chart Prototype: C.



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Observations:

After 3 months no significant changes in comparison with $1-8^{\circ}\text{C}$ and $30\pm 2^{\circ}\text{C}$ were observed in this lot for its performance of the test movement background clearance, specificity and sensitivity.

NA
Bojaleugh
2019-11-29

Conclusion:

Based on the results obtained it is clear that there were no deterioration observed in the specimens tested. The test performance stored at $1-8^{\circ}\text{C}$ as well as $30\pm 2^{\circ}\text{C}$ showed equivalent results. The assay buffer volume remained in sufficient qty at both storage temperature to test entire kit.

Moreover background clearance profiles observed with whole blood / Serum specimens was found acceptable without any background noise at 3 months stability testing.

Responsibility	Tested by		Reviewed By	Approved By
	Reader 1	Reader 2		
Signature & Date	Bojaleugh 2019-11-29	 2019-11-29	 2019-11-29	 2019-11-29
Designation	Officer QC / Executive QC / Sr-Executive QC	Officer QC / Executive QC / Sr-Executive QC	Asst. Manager QC / Manager QC	Manager QA



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Review Due Date: 2021-04-14

Product Name

First Response® HIV 1-2.O Card Test (Version 2.0)

Document ID: RC-QC-09

Sr. No. 20Month of Stability Study: Aug-2019

Sampling Details

Lot No.	77H01195	Duration Time	0 day
Mfg. Date	2019-08	Sampled Qty.	24 Test
Exp. Date	2021-07	Store at	NA
Date of Testing	2019-08-27		

Specimens Panel Details

Description of Specimens Used	Specimens Quantity
Negative Human Serum Specimens	02
Negative Whole Blood Specimens	02
HIV - 1 Positive Serum Specimens	04
HIV - 2 Positive Serum Specimens	04

(All) Assay Procedure

Precautions: Treat all the specimens as potentially infectious and use gloves while testing.

Bring the test device, assay buffer and specimens to room temperature prior to testing.

Before starting the assay procedure, label the test device with the LOT No. and specimens ID.

Sr. No.	Test Procedure
1.	Take out required number of test device.
2.	Slowly add 1 drop (10 µL) of serum / plasma or 2 drops (20 µL) of whole blood specimens into the specimens well using the specimens transfer device / micropipette.
3.	Add one drop (35 µL) of assay buffer into the specimens well.
4.	Observe for development of colored bands in the results window.
5.	Interpret test results at 15 minutes. Do not interpret after 25 minutes.
6.	There should be clear background and both control line and test lines were clearly distinguishable.
7.	Check the control line, test line and background clearance visually. Record the result in the report within 15 minute time period. If background is cleared, mention C (Clear) on test report and if it is not cleared, mark abnormalities or issues affecting interpretation, such as poor blood clearance (i.e. Red background, Incomplete clearing and Red background obscuring test line), should be recorded NC (Not Cleared) in the report. Refer Table **Background Clearance Acceptance Criteria .

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****Background Clearance Acceptance Criteria**

Acceptance Criteria	Rejection Criteria
1. If the background is clear and Control Line and/or Test Line is clearly visible then test is accepted. 2. If the background is little hazy but the Control Line and/or Test Line is clearly visible then the test is accepted 3. If the background is clear above Control Line and/or Test Line within stipulated time then test is accepted. 4. If backflow of test does not cover Control Line and/or Test Line then test is accepted	1. If the flow of specimen and colloidal gold covered the Control Line and even make it invisible but Test Line is visible then test is not accepted. 2. If the background is not clear up to Control Line within stipulated time but Test Line is visible then test is not accepted. 3. When either colloidal gold/plasma/serum/ whole blood do not allow to interpret the result after completion of stipulated time then test is not accepted. 4. If Specimen Back flow covered Control Line and make it invisible and/or the Test Line is visible then result is invalid and not accepted. 5. If the background is not clear above Control Line and/or Test Line then test is not accepted.

Note: Here Control Line is visible means all components/reagents has cleared reading window, crossed Control Line during flow towards absorbent pad.

Intact bottle assay buffer volume	Volume in ml		Sufficient volume Yes / No	
	1-8°C	30 ± 2°C	1-8°C	30 ± 2°C
2.5 ml filled bottle for 25 Test : Minimum 1.7 ml	2.6 ml	NA	Yes	NA
2.5 ml filled bottle for 30 Test : Minimum 2.0 ml	NA	NA	NA	NA

Remark: 0 day testing results will be noted down in 1-8 °C column. The 30 ± 2 °C will be marked as not applicable/strike off.

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Experiment: 01

Reader 1: Tested & Read By: Pooja K. KeshwahaSign & Date: Pooja Keshwaha
2019-08-27

3. Functional / Performance Testing

3.1. Specificity:

Negative Human Serum Specimens :

Sr. No.	Specimens ID : PMC NHS	Criteria	Store at (1-8 °C)				Store at (30 ± 2 °C)			
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1
1	246	-Ve	4	0	0	C	-ve			
2	247	-Ve	4	0	0	C	-ve			

Negative Whole Blood Specimens :

Sr. No.	Specimens ID : PMC NWB	Criteria	Store at (1-8 °C)				Store at (30 ± 2 °C)			
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1
1	1201	-Ve	4	0	0	C	-ve			
2	1202	-Ve	4	0	0	C	-ve			

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background, NC: - Not clear background.

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3.2. Sensitivity:

HIV - 1 Positive Serum Specimens :

Sr. No.	Specimens ID : PMC H1	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)					
			Colour Band Intensity					Colour Band Intensity					
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	
1	203(1:640)	+Ve	4	0	2	C	+ve						
2	203(1:1280)	+Ve	4	0	1	C	+ve						
3	203(1:2560)	-Ve	4	0	0	C	-ve						
4	162	+Ve	4	0	4	C	+ve						

HIV - 2 Positive Serum Specimens :

Sr. No.	Specimens ID : PMC H2	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)					
			Colour Band Intensity					Colour Band Intensity					
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	
1	034(1:160)	+Ve	4	2	0	C	+ve						
2	034(1:320)	+Ve	4	1	0	C	+ve						
3	034(1:640)	-Ve	4	0	0	C	-ve						
4	050	+Ve	4	3	0	C	+ve						

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background, NC: - Not clear background.

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Experiment: 01

Reader 2: Read By: Nidhi S. Chaudhary

Sign & Date: 2019-08-27

3.1. Specificity:

Negative Human Serum Specimens :

Sr. No.	Specimens ID : PMC NHS	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	246	-Ve	4	0	0	C	-ve			4	0	-ve
2	247	-Ve	4	0	0	C	-ve			4	0	-ve

Negative Whole Blood Specimens :

Sr. No.	Specimens ID : PMC NWB	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	1201	-Ve	4	0	0	C	-ve			4	0	-ve
2	1202	-Ve	4	0	0	C	-ve			4	0	-ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background, NC: - Not clear background.

Footnotes: 0 to 4 = Color band intensity by using WHO color chart Prototype: C.



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Test Report (FM-QC-22)

Document type:

3.2. Sensitivity:

HIV - 1 Positive Serum Specimens :

Sr. No.	Specimens ID : PMC H1	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)					
			Colour Band Intensity					Colour Band Intensity					
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	
1	203 (1:640)	+Ve	4	0	2	C	+ve				N/A		
2	203 (1:1280)	+Ve	4	0	1	C	+ve				Not		
3	203 (1:2560)	-Ve	4	0	0	C	-ve				2019-08-27		
4	162	+Ve	4	0	4	C	+ve						

HIV - 2 Positive Serum Specimens :

Sr. No.	Specimens ID : PMC H2	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)					
			Colour Band Intensity					Colour Band Intensity					
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	
1	034(1:160)	+ve	4	2	0	C	+ve				N/A		
2	034(1:320)	+ve	4	1	0	C	+ve				Not		
3	034(1:640)	-ve	4	0	0	C	-ve				2019-08-27		
4	50	+ve	4	3	0	C	+ve						

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

Footnotes: 0 to 4 = Color band intensity by using WHO color chart Prototype: C.

Experiment: 02



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Premier Medical Corporation Pvt. Ltd.

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Reader 2: Tested & Read By: Nishi S. ChaudharySign & Date: 2019-08-27

3. Functional / Performance Testing

3.1. Specificity:

Negative Human Serum Specimens :

Sr. No.	Specimens ID : PMC NHS	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	246	-Ve	4	0	0	C	-ve					
2	247	-Ve	4	0	0	C	-ve					

Negative Whole Blood Specimens :

Sr. No.	Specimens ID : PMC NWB	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	1201	-Ve	4	0	0	C	-ve					
2	1202	-Ve	4	0	0	C	-ve					

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

Footnotes: 0 to 4 = Color band intensity by using WHO color chart Prototype: C.

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3.2. Sensitivity:

HIV - 1 Positive Serum Specimens :

Sr. No.	Specimens ID : PMC H1	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)					
			Colour Band Intensity					Colour Band Intensity					
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	
1	203 (1:640)	+Ve	4	0	2	C	+ve						
2	203 (1:1280)	+Ve	4	0	1	C	+ve						
3	203 (1:2560)	-Ve	4	0	0	C	-ve						
4	162	+Ve	4	0	4	C	+ve						

HIV - 2 Positive Serum Specimens :

Sr. No.	Specimens ID : PMC H2	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)					
			Colour Band Intensity					Colour Band Intensity					
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	
1	034 (1:160)	+Ve	4	2	0	C	+ve						
2	034 (1:320)	+Ve	4	1	0	C	+ve						
3	034 (1:640)	-Ve	4	0	0	C	-ve						
4	050	+Ve	4	3	0	C	+ve						

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background, NC: - Not clear background.

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Review Due Date: 2021-04-14

Experiment: 02

Reader 1: Read By: Pooja k. kushwahaSign & Date: Pooja k. kushwaha
2019-08-27

3.1. Specificity:

Negative Human Serum Specimens :

Sr. No.	Specimens ID : PMC NHS	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	246	-Ve	4	0	0	C	ve	4	0	0	C	ve
2	247	-Ve	4	0	0	C	ve	4	0	0	C	ve

Negative Whole Blood Specimens :

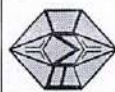
Sr. No.	Specimens ID : PMC NWB	Criteria	Store at (1-8 °C)					Store at (30 ± 2 °C)				
			Colour Band Intensity					Colour Band Intensity				
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result
1	1201	-Ve	4	0	0	C	ve	4	0	0	C	ve
2	1202	-Ve	4	0	0	C	ve	4	0	0	C	ve

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

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3.2. Sensitivity:		HIV – 1 Positive Serum Specimens :												
Sr. No.	Specimens ID : PMC H1	Criteria	Store at (1-8 °C)						Store at (30 ± 2 °C)					
			Colour Band Intensity						Colour Band Intensity					
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result		
1	203(1:640)	+Ve	4	0	2	C	+ve							
2	203(1:1280)	+Ve	4	0	1	C	+ve							
3	203(1:2560)	-Ve	4	0	0	C	-ve							
4	162	+Ve	4	0	4	C	+ve							
HIV – 2 Positive Serum Specimens :														
Sr. No.	Specimens ID : PMC H2	Criteria	Store at (1-8 °C)						Store at (30 ± 2 °C)					
			Colour Band Intensity						Colour Band Intensity					
			Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result	Control Line	HIV-2	HIV-1	B.C. at 15 min. (C/NC)	Result		
1	034(1:160)	+Ve	4	2	0	C	+ve							
2	034(1:320)	+Ve	4	1	0	C	+ve							
3	034(1:640)	-Ve	4	0	0	C	-ve							
4	050	+Ve	4	3	0	C	+ve							

Abbreviation: - Ve: Negative, + Ve: Positive, B.C. - Background Clearance, C: - Clear background; NC: - Not clear background.

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Observations:

After today, no significant changes observed in this lot for its performance of the test movement background clearance specificity and sensitivity.

NA
Rajalugh
2019-08-27

Conclusion:

Moreover, background clearance profiles observed with whole blood / serum specimens was found acceptable without any background noise at today testing.

NA
Rajalugh
2019-08-27

Responsibility	Tested by		Reviewed By	Approved By
	Reader 1	Reader 2		
Signature & Date	Rajalugh 2019-08-27	Rajalugh 2019-08-27	Rajalugh 2019-08-27	Rajalugh 2019-08-27
Designation	Officer QC / Executive QC / Sr-Executive QC	Officer QC / Executive QC / Sr-Executive QC	Asst. Manager QC / Manager QC	Manager QA

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