in vitro Diagnostic Medical Device Technical File

CRP RAPID TEST
RAPG-CRP-002

The signature below certifies that this document has been reviewed and accepted for its accuracy.

	Signature	Position	Date
Approved by		Quality Manager	28/10/2021

1 BACKGROUND

C-reactive Protein (CrP) in a patient's sera has been found to be associated with acute infections, necrotic conditions and a variety of inflammatory disorders. There is a strong correlation between serum levels of CrP and the onset of the inflammatory process. Monitoring the levels of CrP in patient's sera indicates the effectiveness of treatment and the assessment of patient recovery. It is used in particular to differentiate bacterial infections from virus infections.

1.1 Test Principle

The Biopanda CRP Rapid Test is a qualitative, membrane based immunoassay for the detection of CRP in whole blood, serum or plasma. The membrane is pre-coated with specific capture antibodies in the test line region of the test. During testing, the whole blood, serum or plasma specimen reacts with the particle coated with specific antibodies. The mixture migrates laterally along the membrane chromatographically by capillary action to react with specific capture reagents on the membrane and generate a coloured line. The presence of this coloured line in the specific test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a coloured line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

1.2 Illustrations

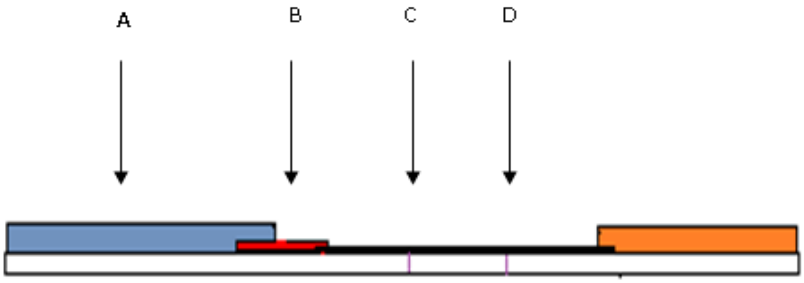

Figure 1: Test Principle

As shown in the illustration above, the specimen (A) migrates via capillary action along the membrane to react with the coloured conjugate (B). CRP antigen present in the specimen binds to the conjugate, forming a coloured antibody-antigen complex. The anti-CRP in the test zone (C) of the membrane captures any complexes that have formed. The formation of a visible coloured line in the test region indicates a positive result. The absence of a coloured line in the test zone suggests a negative result. In the control zone (D) of the membrane, immobilised reagents capture coloured conjugate regardless of test specimen composition. The resulting visible coloured band acts as the control line.

1.3 Precautions

- For professional in vitro diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to any testing.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Do not interchange or mix reagents from different lots.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded in accordance with local regulations.

1.4 Storage and Stability

Store the test at 2-30°C. Freezing must be avoided. The Biopanda CRP Rapid is stable for 24 months from the date of production when stored properly in unopened aluminium foil pouches with desiccant.

1.5 Specimen Collection and Preparation

- Before performing the test, please make sure that all components are brought to room temperature (15-30^{o}C). Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.
- Take a buffer tube out of the kit. Label it with patient's ID. Open the screw cap.

1.6 Standard Testing Procedure

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

Blood Sample Collection:

- Collect the specimen according to standard procedures.
- Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be used within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by finger stick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- EDTA-, citrate- or heparin blood can be used as well. Before performing the test, it has to be diluted accordingly with the supplied buffer.

Specimen Dilution/Stability

- With the capillary tube, aspirate 10 µl of blood. It is important that the capillary is filled end to end to ensure the correct volume of blood is taken.
- Place the end-to-end blood-filled capillary into the dilution buffer vial. Alternatively, the 10 µl of specimen can be added directly with the micro pipette into the dilution buffer vial.
- Close the vial and shake the sample vigorously for approximately 10 seconds so that sample and dilution buffer mix well. (See illustration)
- Let the diluted sample rest for approximately 1 minute.
- The diluted specimen can then be used immediately or stored for up to 8 hours.

1.7 Directions for Use

Bring tests, specimens, buffer, and/or controls to room temperature (15-30^{o}C) before use.

1. Remove the Test Cassette from its sealed pouch, and place it on a clean, level surface. For best results, the assay should be performed within one hour.
2. Open the tube with the diluted sample .Transfer 3 drops of mixed specimens to sample well. Start the timer.
3. Wait for the coloured lines to appear. The result should be read at 5 minutes. Do not interpret the results at 10 minutes.

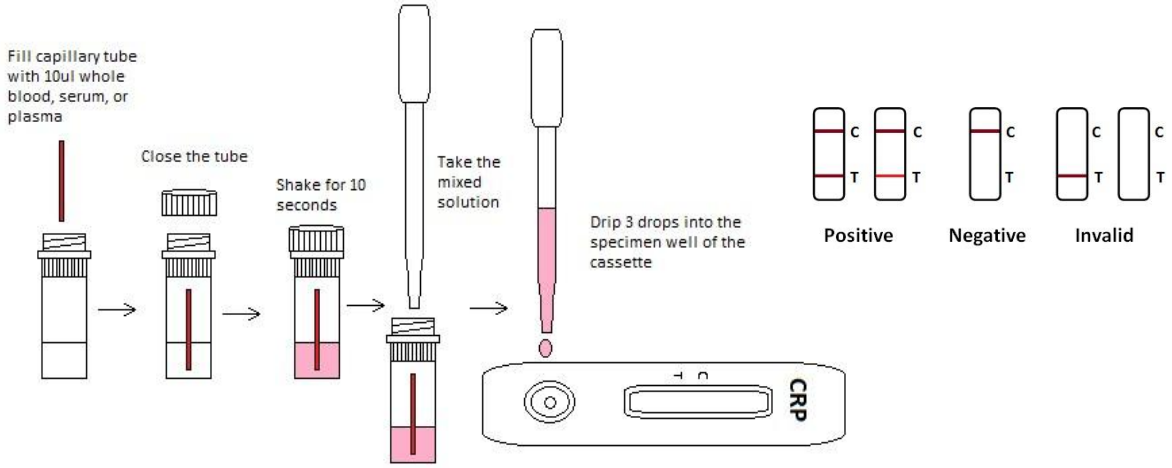

Figure 2: Interpretation of Results

1.8 Interpretation of Results

POSITIVE:* Two lines appear. One coloured line should be in the control line region (C) and another apparent coloured line should be in the test line region (T).

*NOTE: The intensity of the colour in the test line region (T) will vary depending on the concentration of CRP antigen present in the specimen. Therefore, any shade of colour in the test line region (T) should be considered positive.

NEGATIVE: One coloured line appears in the control line region (C). No line appears in the test line region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

1.9 Quality Control

Internal procedural controls are included in the test. A coloured line appearing in the control region (C) is an internal valid procedural control. It confirms sufficient specimen volume and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

1.10 Limitations

1. The Biopanda CRP Rapid Test is for professional in vitro diagnostic use, and should only be used for the qualitative detection of C - reactive protein.
2. This test will only indicate the qualitative level of CRP in the specimen and should not be used as the sole criteria for evaluating inflammatory conditions.
3. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. High concentrations of CRP may produce a dose hook effect, resulting in incorrect interpretation of CRP levels. High dose hook effect has not been observed with this test up to 2,000 mg/L of CRP.
5. The hematocrit of the whole blood should be between 25% and 65%.

1.11 Description of Test Methods

1.11.1 General remarks

The Quality Control department performs testing according to written procedures. Testing equipment is checked prior to use and calibrated at scheduled frequencies.

1.11.2 Receiving inspection and control of raw materials

A sample batch of each raw material (chemicals, packaging and labelling) is inspected/tested (where applicable) for suitability and functionality. Primary packaging is inspected for correct dimensions, cleanliness and suitability. Only QC “APPROVED” raw material is employed for production.

1.12 Composition of Product

A) Mouse anti-CRP for capture	B) Mouse anti-CRP for detection
C) Mouse IgG	D) Goat anti-mouse IgG
E) Adhesive plastic backing	F) Label pad
G) Absorbant pad	H) Sample pad
I) NC membrane	J) Desiccant (in pouch)

1.13 Manufacturing Procedure

- Coat the gold conjugated mouse anti-CRP, and mouse IgG on the label pad.
- Use the sprayer to dispense goat anti-mouse IgG and mouse anti-CRP onto the membrane.
- Assemble the membrane, label pad, absorbent pad, sample pad, and strip label on the plastic backing.
- Use the cuter to cut the plastic backing into strips of selected size.
- Test the strips according to the QC procedure and release the finished product.

2 PERFORMANCE CHARACTERISTICS

2.1 Sample Correlation

The Biopanda CRP Rapid Test has been evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals. ELISA served as the reference method for the Biopanda CRP Rapid Test. The specimen was considered positive if ELISA results were positive. The specimen was also considered negative if the ELISA results were negative.

Table: Sample Correlation Results

Method		**ELISA**		**Total Results**
CRP Rapid Test	Results	Positive	Negative	
	Positive	29	3	32
	Negative	1	197	198
Total results		30	200	230

Relative Sensitivity: 96.7% (95%CI: *82.8%-99.9%)
Relative Specificity: 98.5% (95%CI: *95.7%-99.7%)
Overall accuracy: 98.3% (95%CI: *95.6%-99.5%) *Confidence Intervals

Conclusion: A clinical study was conducted on a total of 230 specimens. The Biopanda tests were compared in parallel with ELISA, and the total conformity rate between the Biopanda CRP Rapid Test and ELISA was 98.3%.

2.2 Interfering Substances

Analytes were spiked into negative plasma and serum pools (ELISA confirmed) and middle positive plasma and serum specimens (ELISA confirmed) at the concentrations listed. The specimens were tested in triplicate on three different lots of test with visual interpretations occurring at 5 minutes after specimen application.

Table: Interfering Substance

Analytes	Conc.	CRP14060001-T											
		Serum						Plasma					
		Negative			CRP middle			Negative			CRP middle		
Ascorbic acid	2g/dl	-	-	-	+	+	+	-	-	-	+	+	+
Hemoglobin	1000mg/dl	-	-	-	+	+	+	-	-	-	+	+	+
Gentisic acid	20mg/dl	-	-	-	+	+	+	-	-	-	+	+	+
Oxalic acid	60mg/dl	-	-	-	+	+	+	-	-	-	+	+	+
Bilirubin	1000mg/dl	-	-	-	+	+	+	-	-	-	+	+	+
Acetylsalicylic Acid	20mg/dl	-	-	-	+	+	+	-	-	-	+	+	+
Acetaminophen	20mg/dl	-	-	-	+	+	+	-	-	-	+	+	+

Creatin	200mg/dl	-	-	-	+	+	+	-	-	-	+	+	+
Albumin	2000mg/dl	-	-	-	+	+	+	-	-	-	+	+	+
Caffeine	20mg/dl	-	-	-	+	+	+	-	-	-	+	+	+
Analytes	Conc.	CRP14060002-T											
		Serum						Plasma					
		Negative			CRP middle			Negative			CRP middle		
Ascorbic acid	2g/dl	-	-	-	+	+	+	-	-	-	+	+	+
Hemoglobin	1000mg/dl	-	-	-	+	+	+	-	-	-	+	+	+
Gentisic acid	20mg/dl	-	-	-	+	+	+	-	-	-	+	+	+
Oxalic acid	60mg/dl	-	-	-	+	+	+	-	-	-	+	+	+
Bilirubin	1000mg/dl	-	-	-	+	+	+	-	-	-	+	+	+
Acetylsalicylic Acid	20mg/dl	-	-	-	+	+	+	-	-	-	+	+	+
Acetaminophen	20mg/dl	-	-	-	+	+	+	-	-	-	+	+	+
Creatin	200mg/dl	-	-	-	+	+	+	-	-	-	+	+	+
Albumin	2000mg/dl	-	-	-	+	+	+	-	-	-	+	+	+
Caffeine	20mg/dl	-	-	-	+	+	+	-	-	-	+	+	+
Analytes	Conc.	CRP14060003-T											
		Serum						Plasma					
		Negative			CRP middle			Negative			CRP middle		
Ascorbic acid	2g/dl	-	-	-	+	+	+	-	-	-	+	+	+
Hemoglobin	1000mg/dl	-	-	-	+	+	+	-	-	-	+	+	+
Gentisic acid	20mg/dl	-	-	-	+	+	+	-	-	-	+	+	+
Oxalic acid	60mg/dl	-	-	-	+	+	+	-	-	-	+	+	+
Bilirubin	1000mg/dl	-	-	-	+	+	+	-	-	-	+	+	+
Acetylsalicylic Acid	20mg/dl	-	-	-	+	+	+	-	-	-	+	+	+
Acetaminophen	20mg/dl	-	-	-	+	+	+	-	-	-	+	+	+
Creatin	200mg/dl	-	-	-	+	+	+	-	-	-	+	+	+
Albumin	2000mg/dl	-	-	-	+	+	+	-	-	-	+	+	+
Caffeine	20mg/dl	-	-	-	+	+	+	-	-	-	+	+	+

Conclusion: No substances showed any interference with the test. There were no differences observed between the three lots at 5 minutes.

2.3 Cross Reactivity

HBsAg+, HBsAb+, HBeAg+, HBeAb+, HBcAb+, HIV+, Syphilis+, HAMA+, RF+, MONO+, CMV+, Rubella+, TOXO+, H.pylori+ confounder specimens as confirmed by ELISA and clinical diagnosis were tested with the CRP Rapid Test. Results were read at 5 minutes after specimen application.

Table: Cross Reactivity Results

Confounder	Lot no.								
	CRP14060004-T			CRP14060005-T			CRP14060006-T		
	5mins			5mins			5mins		
HBsAg+	-	-	-	-	-	-	-	-	-
HBsAb+	-	-	-	-	-	-	-	-	-
HBeAg+	-	-	-	-	-	-	-	-	-
HbeAb+	-	-	-	-	-	-	-	-	-
HBcAb+	-	-	-	-	-	-	-	-	-
HIV+	-	-	-	-	-	-	-	-	-
H.pylori+	-	-	-	-	-	-	-	-	-
Syphilis+	-	-	-	-	-	-	-	-	-
HAMA+	-	-	-	-	-	-	-	-	-
RF+	-	-	-	-	-	-	-	-	-
MONO+	-	-	-	-	-	-	-	-	-
Rubella+	-	-	-	-	-	-	-	-	-
TOXO+	-	-	-	-	-	-	-	-	-
CMV+	-	-	-	-	-	-	-	-	-

Conclusion: There was no cross-reaction with the confounder specimens above at 5 minutes.

2.4 Between Day Reproducibility

Negative, CRP low positive, CRP middle positive and CRP high positive samples were run individually on ten separate days using the same lot of CRP rapid test. Results were read visually as positive or negative at 5 minutes and 10 minutes after specimen application.

Table: Between Day Test Results

Lot: CRP14060004-T

Day			1	2	3	4	5	6	7	8	9	10
Negative	**Serum**	**5mins**	10-	10-	10-	10-	10-	10-	10-	10-	10-	10-
		10mins	10-	10-	10-	10-	10-	10-	10-	10-	10-	10-
	Plasma	**5mins**	10-	10-	10-	10-	10-	10-	10-	10-	10-	10-
		10mins	10-	10-	10-	10-	10-	10-	10-	10-	10-	10-
CRP Low positive	**Serum**	**5mins**	10+	10+	10+	10+	10+	10+	10+	10+	10+	10+
		10mins	10+	10+	10+	10+	10+	10+	10+	10+	10+	10+
	Plasma	**5mins**	10+	10+	10+	10+	10+	10+	10+	10+	10+	10+
		10mins	10+	10+	10+	10+	10+	10+	10+	10+	10+	10+
CRP Middle positive	**Serum**	**5mins**	10+	10+	10+	10+	10+	10+	10+	10+	10+	10+
		10mins	10+	10+	10+	10+	10+	10+	10+	10+	10+	10+
	Plasma	**5mins**	10+	10+	10+	10+	10+	10+	10+	10+	10+	10+
		10mins	10+	10+	10+	10+	10+	10+	10+	10+	10+	10+
CRP high	**Serum**	**5mins**	10+	10+	10+	10+	10+	10+	10+	10+	10+	10+

positive		**10mins**	10+	10+	10+	10+	10+	10+	10+	10+	10+	10+
	plasma	**5mins**	10+	10+	10+	10+	10+	10+	10+	10+	10+	10+
		10mins	10+	10+	10+	10+	10+	10+	10+	10+	10+	10+

Conclusion: Test results for both serum and plasma were consistent over the ten day period.

2.5 Between Lot Reproducibility

Negative, CRP low positive, CRP middle positive and CRP high positive samples were run in replicates of ten on three separate lots of product. Results were read as positive or negative at 5 and 10 minutes after specimen application.

Table: Between Lot Reproducibility Results (Serum)

Lot	Specimens	Negative		Low positive		Middle positive		High positive	
		5 min	10 min	5 min	10 min	5 min	10 min	5 min	10 min
CRP14060004-T	1	-	-	+	+	+	+	+	+
	2	-	-	+	+	+	+	+	+
	3	-	-	+	+	+	+	+	+
	4	-	-	+	+	+	+	+	+
	5	-	-	+	+	+	+	+	+
	6	-	-	+	+	+	+	+	+
	7	-	-	+	+	+	+	+	+
	8	-	-	+	+	+	+	+	+
	9	-	-	+	+	+	+	+	+
	10	-	-	+	+	+	+	+	+
CRP14060005-T	1	-	-	+	+	+	+	+	+
	2	-	-	+	+	+	+	+	+
	3	-	-	+	+	+	+	+	+
	4	-	-	+	+	+	+	+	+
	5	-	-	+	+	+	+	+	+
	6	-	-	+	+	+	+	+	+
	7	-	-	+	+	+	+	+	+
	8	-	-	+	+	+	+	+	+
	9	-	-	+	+	+	+	+	+
	10	-	-	+	+	+	+	+	+
CRP14060006-T	1	-	-	+	+	+	+	+	+
	2	-	-	+	+	+	+	+	+
	3	-	-	+	+	+	+	+	+
	4	-	-	+	+	+	+	+	+
	5	-	-	+	+	+	+	+	+

	6	-	-	+	+	+	+	+	+
	7	-	-	+	+	+	+	+	+
	8	-	-	+	+	+	+	+	+
	9	-	-	+	+	+	+	+	+
	10	-	-	+	+	+	+	+	+

Table: Between Lot Reproducibility Results (Plasma)

Lot	Specimens	Negative		Low positive		Middle positive		High positive	
		5 min	10 min	5 min	10 min	5 min	10 min	5 min	10 min
CRP14060004-T	1	-	-	+	+	+	+	+	+
	2	-	-	+	+	+	+	+	+
	3	-	-	+	+	+	+	+	+
	4	-	-	+	+	+	+	+	+
	5	-	-	+	+	+	+	+	+
	6	-	-	+	+	+	+	+	+
	7	-	-	+	+	+	+	+	+
	8	-	-	+	+	+	+	+	+
	9	-	-	+	+	+	+	+	+
	10	-	-	+	+	+	+	+	+
CRP14060005-T	1	-	-	+	+	+	+	+	+
	2	-	-	+	+	+	+	+	+
	3	-	-	+	+	+	+	+	+
	4	-	-	+	+	+	+	+	+
	5	-	-	+	+	+	+	+	+
	6	-	-	+	+	+	+	+	+
	7	-	-	+	+	+	+	+	+
	8	-	-	+	+	+	+	+	+
	9	-	-	+	+	+	+	+	+
	10	-	-	+	+	+	+	+	+
CRP14060006-T	1	-	-	+	+	+	+	+	+
	2	-	-	+	+	+	+	+	+
	3	-	-	+	+	+	+	+	+
	4	-	-	+	+	+	+	+	+
	5	-	-	+	+	+	+	+	+
	6	-	-	+	+	+	+	+	+
	7	-	-	+	+	+	+	+	+
	8	-	-	+	+	+	+	+	+
	9	-	-	+	+	+	+	+	+
	10	-	-	+	+	+	+	+	+

Conclusion: Test results were consistent between the 3 lots of test cassettes.

2.6 Accelerated Stability

Accelerated Stability of the CRP Rapid Test was evaluated using samples from 3 different lots. These were placed in an incubator with the temperature calibrated at 45°C and 55°C. Relative humidity (RH) was calibrated at around 60%. A series of stability tests were performed at 0, 7, 14, 21, 28, 35, 42, 56, 77, 84 days for 45°C. At 55°C, stability tests were performed at 0, 7, 14, 21, 28, 35, 42 days according to the Arrhenius Plot. Test cassettes were assayed using negative, CRP low positive, CRP middle positive and CRP high positive specimens. Testing at each specific time interval consisted of 3 replicates for each specimen. The tests were performed according to the package insert.

Arrhenius Formula:
In K=-Ea/RT + In A
"K" mean Rate constant
"A" mean Arrhenius constant
"Ea" mean Activation energy
"R" mean Gas constant
"T" mean Temperature in Kelvin

Table: Timeline for Accelerated Stability Study

Day / Temp.	0day	7days	14 days	21 days	28 days	35 days	42 days	56 days	77 days	84 days
45°C	√	√	√	√	√	√	√	√	√	√
55°C	√	√	√	√	√	√	√	×	×	×

Table: 45°C Accelerated Stability Study Results

Day	Specimen	Lot no.								
		CRP14060004-T			CRP14060005-T			CRP14060006-T		
0	Negative	-	-	-	-	-	-	-	-	-
	Low positive	+	+	+	+	+	+	+	+	+
	Middle positive	+	+	+	+	+	+	+	+	+
	High positive	+	+	+	+	+	+	+	+	+
7	Negative	-	-	-	-	-	-	-	-	-
	Low positive	+	+	+	+	+	+	+	+	+
	Middle positive	+	+	+	+	+	+	+	+	+
	High positive	+	+	+	+	+	+	+	+	+
14	Negative	-	-	-	-	-	-	-	-	-
	Low positive	+	+	+	+	+	+	+	+	+

	Middle positive	+	+	+	+	+	+	+	+	+
	High positive	+	+	+	+	+	+	+	+	+
21	Negative	-	-	-	-	-	-	-	-	-
	Low positive	+	+	+	+	+	+	+	+	+
	Middle positive	+	+	+	+	+	+	+	+	+
	High positive	+	+	+	+	+	+	+	+	+
28	Negative	-	-	-	-	-	-	-	-	-
	Low positive	+	+	+	+	+	+	+	+	+
	Middle positive	+	+	+	+	+	+	+	+	+
	High positive	+	+	+	+	+	+	+	+	+
35	Negative	-	-	-	-	-	-	-	-	-
	Low positive	+	+	+	+	+	+	+	+	+
	Middle positive	+	+	+	+	+	+	+	+	+
	High positive	+	+	+	+	+	+	+	+	+
42	Negative	-	-	-	-	-	-	-	-	-
	Low positive	+	+	+	+	+	+	+	+	+
	Middle positive	+	+	+	+	+	+	+	+	+
	High positive	+	+	+	+	+	+	+	+	+
56	Negative	-	-	-	-	-	-	-	-	-
	Low positive	+	+	+	+	+	+	+	+	+
	Middle positive	+	+	+	+	+	+	+	+	+
	High positive	+	+	+	+	+	+	+	+	+
77	Negative	-	-	-	-	-	-	-	-	-
	Low positive	+	+	+	+	+	+	+	+	+
	Middle positive	+	+	+	+	+	+	+	+	+
	High positive	+	+	+	+	+	+	+	+	+
84	Negative	-	-	-	-	-	-	-	-	-
	Low positive	+	+	+	+	+	+	+	+	+
	Middle positive	+	+	+	+	+	+	+	+	+
	High positive	+	+	+	+	+	+	+	+	+

Table: 55°C Accelerated Stability Summary

Day	**Specimen**	**Lot no.**								
		CRP14060004-T			CRP14060005-T			CRP14060006-T		
0	Negative	-	-	-	-	-	-	-	-	-
	Low positive	+	+	+	+	+	+	+	+	+
	Middle positive	+	+	+	+	+	+	+	+	+
	High positive	+	+	+	+	+	+	+	+	+
7	Negative	-	-	-	-	-	-	-	-	-
	Low positive	+	+	+	+	+	+	+	+	+
	Middle positive	+	+	+	+	+	+	+	+	+
	High positive	+	+	+	+	+	+	+	+	+

14	Negative	-	-	-	-	-	-	-	-	-
	Low positive	+	+	+	+	+	+	+	+	+
	Middle positive	+	+	+	+	+	+	+	+	+
	High positive	+	+	+	+	+	+	+	+	+
21	Negative	-	-	-	-	-	-	-	-	-
	Low positive	+	+	+	+	+	+	+	+	+
	Middle positive	+	+	+	+	+	+	+	+	+
	High positive	+	+	+	+	+	+	+	+	+
28	Negative	-	-	-	-	-	-	-	-	-
	Low positive	+	+	+	+	+	+	+	+	+
	Middle positive	+	+	+	+	+	+	+	+	+
	High positive	+	+	+	+	+	+	+	+	+
35	Negative	-	-	-	-	-	-	-	-	-
	Low positive	+	+	+	+	+	+	+	+	+
	Middle positive	+	+	+	+	+	+	+	+	+
	High positive	+	+	+	+	+	+	+	+	+
42	Negative	-	-	-	-	-	-	-	-	-
	Low positive	+	+	+	+	+	+	+	+	+
	Middle positive	+	+	+	+	+	+	+	+	+
	High positive	+	+	+	+	+	+	+	+	+

Conclusion: The CRP Rapid Test was stable at 45°C for 84 days and at 55°C for 42 days. The data was plotted on an Arrhenius Plot and the shelf life of this product was determined to be at least 24 months from the date of manufacture.

3 RISK ASSESSMENT

Process step / component	Cause and effect of failure	S	O	D	RPN before	Preventative measure(s)	S	O	D	RPN after
Storage of kit outside of prescribed environmental conditions	Degradation of the components of the kits due to storage at incorrect temperature may lead to erroneous test results. Such degradation is not immediately obvious.	3	4	7	**84**	Label on the kit box as well as product instructions should clearly state the storage conditions. Lack of control line will indicate if test has degraded due to poor storage.	3	2	3	**18**
Use of kit past expiration date	Degradation of the components of the kit past their expiration date may lead to erroneous test results.	3	3	3	**27**	Label on the kit box and components clearly stating expiration date.	3	2	2	**12**
Reuse of kit	Test cassettes must not be reused.	5	3	2	**30**	“Do not re-use” symbol on kit box.	5	2	2	**20**
Use by unskilled operator	The kit is not for self testing and must be used by a trained laboratory technician. Misuse can cause erroneous test results.	5	3	3	**45**	Include a statement “For use by healthcare professionals”	5	2	3	**30**
Mislabelling of expiration date	Misinformation of user. User may dispose of unexpired test kit causing wastage, or may use an expired test kit causing erroneous test results.	6	3	5	**90**	Carefully inspect label and cross-reference against production records to ensure printed expiry date is 24 months from date of manufacture.	6	2	1	**12**
Mislabelling of lot numbers	Misinformation of user. Traceability not ensured.	2	3	5	**30**	Carefully inspect labels and cross-reference against production records.	2	2	1	**4**
Leakage of reagent bottles	Insufficient material to carry out test. Destruction of outer package.	5	3	5	**75**	Ensure all bottle lids are tight. Check each bottle for leaks by inverting and gently squeezing.	5	1	1	**5**
Foil pouch damaged	Humidity affects the test cassettes and causes degradation.	5	2	4	**40**	Inspect foil pouches and ensure vacuum seal integrity. Include a desiccant packet.	5	1	1	**5**
Antibody not properly coated on membrane	Caused by incorrect use of coating buffer, or insufficient coating time. Low or no reading. Difficult to visually confirm strips are properly	6	3	8	**144**	Ensure correct dilution of antibody is made according to manufacturing method. Ensure correct coating buffer is used. Assemble membrane into cassettes and seal the cassettes	6	1	2	**12**

Process step / component	Cause and effect of failure	S	O	D	RPN before	Preventative measure(s)	S	O	D	RPN after
	coated.					in a foil pouch with desiccant under vacuum. Carry out QC on membrane and ensure they meet batch release criteria.				
Use of incorrect antigen or antibody	Low or no reading and the test would not work.	5	3	4	**60**	Carefully check labels of antibody or antigen stock. Carry out QC to ensure batch release criteria are met.	5	2	1	**10**
Result read too early	Coloured lines on test strip may not be fully developed, could give misleading reading.	6	5	3	**90**	Ensure instructions clearly state to allow 5 minutes before reading results.	6	2	3	**36**
Result read too late	Coloured lines on test strip may begin to fade, giving misleading reading.	6	5	3	**90**	Ensure instructions clearly state not to read results after 10 minutes.	6	2	3	**36**

Declaration of Conformity

according to Directive 98/79/EC, on *in vitro* diagnostic medical devices

Manufacturer (Name, Address)	Biopanda Reagents Ltd Unit 14 Carrowreagh Business Park Carrowreagh Road Belfast, BT16 1QQ United Kingdom		
Product Details	Name	:	CRP Rapid Test (RAPG-CRP-002)
	Classification of products according to directive	:	Other IVDs (not under Annex II)
Applicable coordination standards	EN ISO 14971:2019 ISO 13485:2016 EN ISO 18113:2011 EN 13612:2002 EN 23640:2015 EN ISO 15223-1:2016		

Signatory representative declares herein the above mentioned device meets the basic requirements of the European Parliament and the Council's *in vitro* diagnostic medical devices directive: 98/79/EC Annex III.

This declaration of conformity is based on European Parliament and the Council's 98/79/EC directive Annex III.

28/10/2021

(place and date of issue)

Han Yan

(name and signature or equivalent marking of authorised person)