Registration File of

Celiac Rapid Test

(Whole Blood/Serum/Plasma)

OCEA-402

Version: 03

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1 BACKGROUND

Celiac disease (CD) is an immune-mediated systemic disorder triggered by gluten consumption, occurring in genetically predisposed individuals.[1~3] It is caused by a permanent intolerance to gluten and specifically to its proteic fragment called gliadine. The ingestion of such protein for in people with genetic predisposition, induce a severe injury of the intestinal mucosa that is histologically characterized by one hyperplasia of cryptas with total or subtotal atrophy of the intestinal microvilli. Though the definitive diagnosis of the celiac disease is based in characteristic histological changes observed in intestinal biopsies, the serological tests, such as the detection of antibodies anti-tTG and anti-endomysium, represent methods of analyses cheaper and less invasive to the detection of the disease.

Celiac Rapid Test is a immunochromatographic tests designed for the detection of IgA antibody against transglutaminase in whole blood, serum or plasma. The transglutaminase is the principal auto-antigen recognised by the antiendomisial antibodies.

1.1 Test Principle

The Celiac Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative membrane-based immunoassay for the detection of IgA antibodies to human tTG in whole blood, serum, or plasma. During testing, the specimen reacts with tTG antigen-conjugated in the test cassette. The gold antigen conjugate will bind to anti-tTG antibody in the specimen, which in turn will bind with anti-human IgA coated on the membrane. The mixture migrates upward on the membrane, the anti-human IgA on the membrane will bind the antibody-antigen complex causing a colored line to form in the test line region of the test. The intensity of the color will vary depending upon the amount of antibody present in the sample. The appearance of colored line in the test region should be considered as positive result. To serve as a procedural control, a colored 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

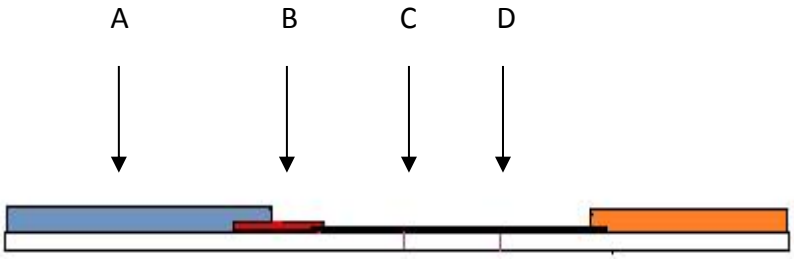

Figure 1: Test Principle

As shown in illustration above, the specimen (A) migrates via capillary action along the membrane to react with the gold conjugate (B). Celiac IgA antibodies present in the specimen binds to the conjugate and form a colored antibody-antigen complex. The anti-human IgA immobilized in the test zone of the membrane captures the test region (C). The formation of a visible colored line in the test region indicates a positive result (C). The absence of a colored line in the test zones suggests a negative result. In the control zone of the membrane, immobilized reagents capture colored conjugate regardless of test specimen composition. The resulting visible colored band (D) confirms control line.

1.3 Performance and Specification

The Celiac Rapid Test Cassette (Whole Blood/Serum/Plasma) is a lateral flow chromatographic immunoassay for the detection of IgA antibody against tissue transglutaminase in human whole blood, serum, or plasma. The test utilizes a combination of tissue Transglutaminase coated colored particles for the detection of IgA antibody against transglutaminase in human whole blood, serum, or plasma.

1.4 Precautions

- For professional in vitro diagnostic use only. Do not use beyond the expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.

1.5 Storage and Stability

The kit can be stored at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

1.6 Specimen Collection and Preparation

- The Celiac Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood, serum or plasma.
- To collect Fingerstick Whole Blood Specimens:
- Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
- Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Add the Fingerstick Whole Blood specimen to the test cassette by using a dropper or micropipette measuring 20µL. The dropper provided with the test dispenses approximately 20µL in one drop even if more blood is aspirated in the dropper.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Test should be performed immediately after specimen collection. Do not leave the 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 run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

- If specimens are to be shipped, they should be packed in compliance with local regulations for transportation of etiologic agents.
- EDTA K2, Heparin sodium, Sodium citrate and Potassium oxalate can be used as the anticoagulant for collecting the specimen.

1.7 Standard Testing Procedure

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

- Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within 1 hour.
- Place the cassette on a clean and level surface.
- To use a dropper: Hold the dropper vertically, draw the specimen about 1cm above the upper end of the nozzle as shown in illustration blew, transfer 1 drop of the serum/plasma (approximately 10µl) or 2 drops of the whole blood (approximately 20µl) to the specimen well (S) of the test cassette, then add 2 drops of buffer (approximately 80µl) and start the timer.
- To use a micropipette: Pipette and dispense 10µl of serum/plasma or 20µl of whole blood to the specimen well (S) of the test cassette, then add 2 drops of buffer (approximately 80µl) and start the timer.
- Wait for the colored line(s) to appear. Read result at 10 minutes. Do not interpret the result after 20 minutes.

Note: It is suggested not to use the buffer beyond 6 months after opening the vial.

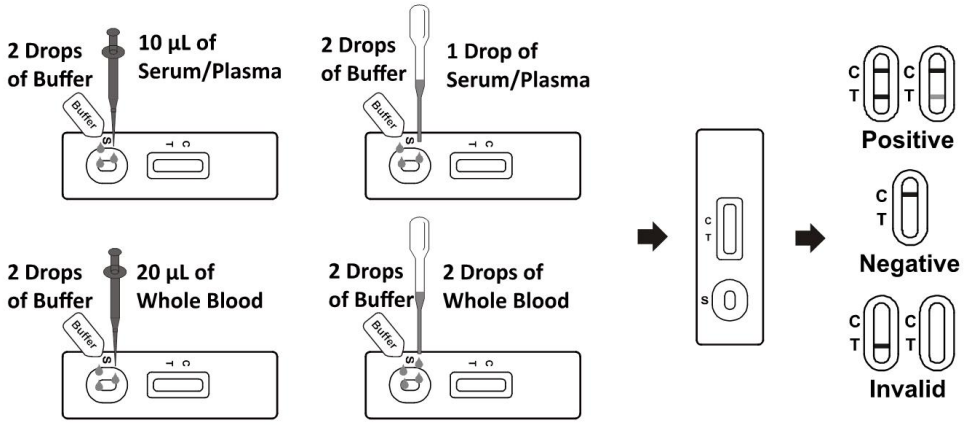

Figure 2: Interpretation of Results

1.8 Interpretation of Results

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

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

NEGATIVE: One colored line appears in the control region (C). No apparent colored line appears in the test 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 cassette. 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 colored line appearing in the control region (C) is an internal positive 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

- The Celiac Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. The test should be used for the detection of tTG antibodies in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in tTG antibody concentration can be determined by this qualitative test.
- The Celiac Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of tTG antibodies in the specimen and should not be used as the sole criteria for the diagnosis of Celiac.
- A negative test result does not preclude the possibility of exposure to or infection with celiac disease.
- A negative result can occur if the quantity of tTG IgA present in the specimen is below the detection limits of the assay, or the tTG IgA that are detected are not present during the stage of disease in which a sample is collected.
- If the symptom persists, while the result from Celiac Rapid Test Cassette (Whole Blood/Serum/Plasma) is negative, it is recommended to collect the sample again from the patient few days later or test with an alternative test method.
- The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.
- 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 labeling) 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) Goat anti-rabbit IgG B) Rabbit IgG

C) Anti-human IgA
D) Tissue Transglutaminase antigen
E) Membrane
F) Absorbent pad
G) Adhesive plastic backing
H) Plastic Cassette
I) Label pad
J) Sample pad
K) Desiccant
L) Buffer
O) Package insert
P) Droppers

1.13 Manufacturing Procedure

- Coat the gold conjugated tissue Transglutaminase antigen and rabbit IgG on the label pad.
- Use the sprayer to dispense goat anti-rabbit IgG and anti-human IgA onto the membrane.
- Assemble the membrane, label pad, absorbent pad and sample pad on the plastic backing.
- Use the cutter to cut the plastic backing into strips of selected size.
- Lay the strip into the plastic cassette, pack the cassette and a desiccant packet into a pouch and seal the pouch.
- Test the cassette according to the QC procedure and release the finished product.

2 PERFORMANCE CHARACTERISTICS

2.1 Sample Correlation

The Celiac Rapid Test Cassette (Whole Blood/Serum/Plasma) has been compared with a leading commercial celiac test using clinical specimens. The results show that the relative sensitivity of the Celiac Rapid Test Cassette (Whole Blood/Serum/Plasma) is 96.7%, and the relative specificity is 98.6%

Table: Clinical Study Result

Method		**Commercial Celiac Test**		**Total Results**
Celiac Rapid Test Cassette (Whole Blood/Serum/Plasma)	Results	Positive	Negative	
	Positive	58	2	60
	Negative	2	138	140
Total Results		60	140	200

Relative sensitivity: 96.7% (95%CI*: 88.5%~99.6%)

Relative specificity: 98.6% (95%CI*: 94.9%~99.8%)

Accuracy: 98.0% (95%CI*: 95.0%~99.5%) *Confidence Intervals

2.2 Detection level determination

The detection level determination study was conducted by testing anti-Tissue transglutaminase IgA Antibody clinically positive samples. Negative plasma was used as diluent, and a series of different ratios ranging from 1:1 to 1:800 were tested with the rapid test. Test the diluted specimens with 3 lots of Celiac Rapid Test(Whole Blood/Serum/Plasma) according to package insert.

Table-Detection level determination result

Specimens	**OCEA-402**								
	CLA19040001-T			CLA19040002-T			CLA19040003-T		
	10min			**10min**			**10min**		
1:1	+	+	+	+	+	+	+	+	+
1:2	+	+	+	+	+	+	+	+	+
1:4	+	+	+	+	+	+	+	+	+
1:20	+	+	+	+	+	+	+	+	+
1:200	+	+	+	+	+	+	+	+	+
1:400	+	+	+	+	+	+	+	+	+
1:600	+	-	-	+	+	-	-	-	+
1:800	-	-	-	-	-	-	-	-	-

Note: “+”mean positive result, “-”mean negative result.

Conclusion: The Celiac Rapid Test(Whole Blood/Serum/Plasma) could detect out antibodies to anti-Tissue transglutaminase IgA with a ratio of as low as 1:400.

2.3 Interfering Substance

Analytes were spiked into negative whole blood, serum and plasma pools, Celiac middle positive at the concentrations listed. The specimens were tested in triplicate with visual interpretations occurring at 10 minutes after specimen application. Results are presented in Table below.

Table: Interfering Substances Results

Analytes	Conc.	CLA19040001-T																	
		Whole Blood						Serum						Plasma					
		Negative			Middle Positive			Negative			Middle Positive			Negative			Middle Positive		
Ascorbic Acid	2000mg/dl	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Gentisic Acid	20mg/dl	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Creatin	200mg/dl	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Oxalic Acid	60mg/dl	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Bilirubin	1000mg/dl	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Acetaminophen	20mg/dl	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Albumin	2000mg/dl	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Caffeine	20mg/dl	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Acetylsalicylic Acid	20mg/dl	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Hemoglobin	1000mg/dl	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Analytes	Conc.	CLA19040002-T																	
		Whole Blood						Serum						Plasma					
		Negative			Middle Positive			Negative			Middle Positive			Negative			Middle Positive		
Ascorbic Acid	2000mg/dl	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Gentisic Acid	20mg/dl	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Creatin	200mg/dl	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Oxalic Acid	60mg/dl	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Bilirubin	1000mg/dl	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Acetaminophen	20mg/dl	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Albumin	2000mg/dl	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Caffeine	20mg/dl	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Acetylsalicylic Acid	20mg/dl	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Hemoglobin	1000mg/dl	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Analytes	Conc.	CLA19040003-T																	
		Whole Blood						Serum						Plasma					
		Negative			Middle Positive			Negative			Middle Positive			Negative			Middle Positive		
Ascorbic Acid	2000mg/dl	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Gentisic Acid	20mg/dl	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Creatin	200mg/dl	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Oxalic Acid	60mg/dl	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Bilirubin	1000mg/dl	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Acetaminophen	20mg/dl	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Albumin	2000mg/dl	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+

Caffeine	20mg/dl	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Acetylsalicylic Acid	20mg/dl	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+
Hemoglobin	1000mg/dl	-	-	-	+	+	+	-	-	-	+	+	+	-	-	-	+	+	+

Note: "-" mean negative result, "+" mean positive result

Conclusion: No substances showed any interference with the test. There were no obvious differences among the 3 lots of products at 10 minutes.

2.4 Cross Reactivity

Positive for anti-HAMA, RF, anti-HIV, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, anti-HCV, anti-Syphilis, anti-H.pylori, anti-CMV IgG, anti-CMV IgM, anti-Rubella IgG, anti-Rubella IgM, anti-TOXO IgG and anti-TOXO IgM specimens were tested with the Celiac Rapid Test Cassette. Results were presented in Table below.

Table: Cross Reactivity

Treatment	No.	OCEA-402					
		CLA19040001-T		CLA19040002-T		CLA19040003-T	
		10min	20min	10min	20min	10min	20min
3 anti-HAMA positive samples	1	-	-	-	-	-	-
	2	-	-	-	-	-	-
	3	-	-	-	-	-	-
3 anti-HIV positive samples	1	-	-	-	-	-	-
	2	-	-	-	-	-	-
	3	-	-	-	-	-	-
3 RF samples	1	-	-	-	-	-	-
	2	-	-	-	-	-	-
	3	-	-	-	-	-	-
3 HBsAg positive samples	1	-	-	-	-	-	-
	2	-	-	-	-	-	-
	3	-	-	-	-	-	-
3 HBsAb positive samples	1	-	-	-	-	-	-
	2	-	-	-	-	-	-
	3	-	-	-	-	-	-
3 HBeAg positive samples	1	-	-	-	-	-	-
	2	-	-	-	-	-	-
	3	-	-	-	-	-	-
3 HBeAb positive samples	1	-	-	-	-	-	-
	2	-	-	-	-	-	-
	3	-	-	-	-	-	-
3 HBcAb positive samples	1	-	-	-	-	-	-
	2	-	-	-	-	-	-
	3	-	-	-	-	-	-
3 anti-HCV positive samples	1	-	-	-	-	-	-
	2	-	-	-	-	-	-
	3	-	-	-	-	-	-
3 anti-H.pylori positive samples	1	-	-	-	-	-	-
	2	-	-	-	-	-	-
	3	-	-	-	-	-	-
3 Syphilis positive samples	1	-	-	-	-	-	-
	2	-	-	-	-	-	-
	3	-	-	-	-	-	-
3 anti-CMV IgG positive samples	1	-	-	-	-	-	-
	2	-	-	-	-	-	-
	3	-	-	-	-	-	-
3 anti-CMV IgM positive samples	1	-	-	-	-	-	-
	2	-	-	-	-	-	-

	3	-	-	-	-	-	-
3 anti-Rubella IgG positive samples	1	-	-	-	-	-	-
	2	-	-	-	-	-	-
	3	-	-	-	-	-	-
3 anti-Rubella IgM positive samples	1	-	-	-	-	-	-
	2	-	-	-	-	-	-
	3	-	-	-	-	-	-
3 anti-TOXO IgG positive samples	1	-	-	-	-	-	-
	2	-	-	-	-	-	-
	3	-	-	-	-	-	-
3 anti-TOXO IgM positive samples	1	-	-	-	-	-	-
	2	-	-	-	-	-	-
	3	-	-	-	-	-	-

Note: "-" mean negative result

Conclusion: There was no cross-reaction with the substance above.

2.5 Hematocrit Flex Study

Whole blood standards were prepared with type “O” red cell and Celiac standards at the hematocrit 25%, 40%, 50% and 65%. Low positive, middle positive, high positive and negative standard whole blood samples were performed individually at different hematocrit. Visual interpretations were recorded after specimen application.

Table: Results of Hematocrit Flex Study

OCEA-402	CLA19040001-T											
Sample / Hematocrit	High Positive			Middle Positive			Low Positive			Negative		
25%	+	+	+	+	+	+	+	+	+	-	-	-
40%	+	+	+	+	+	+	+	+	+	-	-	-
50%	+	+	+	+	+	+	+	+	+	-	-	-
65%	+	+	+	+	+	+	+	+	+	-	-	-
OCEA-402	CLA19040002-T											
Sample / Hematocrit	High Positive			Middle Positive			Low Positive			Negative		
25%	+	+	+	+	+	+	+	+	+	-	-	-
40%	+	+	+	+	+	+	+	+	+	-	-	-
50%	+	+	+	+	+	+	+	+	+	-	-	-
65%	+	+	+	+	+	+	+	+	+	-	-	-
OCEA-402	CLA19040003-T											
Sample / Hematocrit	High Positive			Middle Positive			Low Positive			Negative		
25%	+	+	+	+	+	+	+	+	+	-	-	-
40%	+	+	+	+	+	+	+	+	+	-	-	-
50%	+	+	+	+	+	+	+	+	+	-	-	-
65%	+	+	+	+	+	+	+	+	+	-	-	-

Note: “-” mean negative result, “+” mean positive result

Flowing and background: Four different hematocrit levels showed good flow characteristics and the control line appeared within 3mins. There was no background problem at read time even with the high hematocrit level.

Conclusion: There were no performance effects seen with the hematocrit levels testing. The Celiac Rapid Test showed good flow and no background problem between 25% and 65% hematocrit.

2.6 Anticoagulant Study

Collect 25 volunteers' blood with EDTA-K2, Heparin sodium, sodium citrate and potassium oxalate anticoagulant tube. Separate the whole blood and plasma from the specimen in anticoagulant tube, then spiked the celiac positive specimen into the plasma and whole blood, tested the 25 negative and positive spiked specimens with Celiac Rapid Test (Whole Blood/Serum/Plasma). The operation method refers to the package insert.

Table: Anticoagulant Study Result

EDTA-K2 Anticoagulant Tube												
No.	CLA19040001-T				CLA19040002-T				CLA19040003-T			
	Negative		Positive		Negative		Positive		Negative		Positive	
	Plasma	Whole Blood	Plasma	Whole Blood	Plasma	Whole Blood	Plasma	Whole Blood	Plasma	Whole Blood	Plasma	Whole Blood
1	-	-	+	+	-	-	+	+	-	-	+	+
2	-	-	+	+	-	-	+	+	-	-	+	+
3	-	-	+	+	-	-	+	+	-	-	+	+
4	-	-	+	+	-	-	+	+	-	-	+	+
5	-	-	+	+	-	-	+	+	-	-	+	+
6	-	-	+	+	-	-	+	+	-	-	+	+
7	-	-	+	+	-	-	+	+	-	-	+	+
8	-	-	+	+	-	-	+	+	-	-	+	+
9	-	-	+	+	-	-	+	+	-	-	+	+
10	-	-	+	+	-	-	+	+	-	-	+	+
11	-	-	+	+	-	-	+	+	-	-	+	+
12	-	-	+	+	-	-	+	+	-	-	+	+
13	-	-	+	+	-	-	+	+	-	-	+	+
14	-	-	+	+	-	-	+	+	-	-	+	+
15	-	-	+	+	-	-	+	+	-	-	+	+
16	-	-	+	+	-	-	+	+	-	-	+	+
17	-	-	+	+	-	-	+	+	-	-	+	+
18	-	-	+	+	-	-	+	+	-	-	+	+
19	-	-	+	+	-	-	+	+	-	-	+	+
20	-	-	+	+	-	-	+	+	-	-	+	+
21	-	-	+	+	-	-	+	+	-	-	+	+
22	-	-	+	+	-	-	+	+	-	-	+	+
23	-	-	+	+	-	-	+	+	-	-	+	+
24	-	-	+	+	-	-	+	+	-	-	+	+
25	-	-	+	+	-	-	+	+	-	-	+	+
Heparin sodium Anticoagulant Tube												
No.	CLA19040001-T				CLA19040002-T				CLA19040003-T			
	Negative		Positive		Negative		Positive		Negative		Positive	
	Plasma	Whole Blood	Plasma	Whole Blood	Plasma	Whole Blood	Plasma	Whole Blood	Plasma	Whole Blood	Plasma	Whole Blood
1	-	-	+	+	-	-	+	+	-	-	+	+
2	-	-	+	+	-	-	+	+	-	-	+	+
3	-	-	+	+	-	-	+	+	-	-	+	+
4	-	-	+	+	-	-	+	+	-	-	+	+
5	-	-	+	+	-	-	+	+	-	-	+	+

6	-	-	+	+	-	-	+	+	-	-	+	+
7	-	-	+	+	-	-	+	+	-	-	+	+
8	-	-	+	+	-	-	+	+	-	-	+	+
9	-	-	+	+	-	-	+	+	-	-	+	+
10	-	-	+	+	-	-	+	+	-	-	+	+
11	-	-	+	+	-	-	+	+	-	-	+	+
12	-	-	+	+	-	-	+	+	-	-	+	+
13	-	-	+	+	-	-	+	+	-	-	+	+
14	-	-	+	+	-	-	+	+	-	-	+	+
15	-	-	+	+	-	-	+	+	-	-	+	+
16	-	-	+	+	-	-	+	+	-	-	+	+
17	-	-	+	+	-	-	+	+	-	-	+	+
18	-	-	+	+	-	-	+	+	-	-	+	+
19	-	-	+	+	-	-	+	+	-	-	+	+
20	-	-	+	+	-	-	+	+	-	-	+	+
21	-	-	+	+	-	-	+	+	-	-	+	+
22	-	-	+	+	-	-	+	+	-	-	+	+
23	-	-	+	+	-	-	+	+	-	-	+	+
24	-	-	+	+	-	-	+	+	-	-	+	+
25	-	-	+	+	-	-	+	+	-	-	+	+

Sodium citrate Anticoagulant Tube

No.	CLA19040001-T				CLA19040002-T				CLA19040003-T			
	Negative		Positive		Negative		Positive		Negative		Positive	
	Plasma	Whole Blood	Plasma	Whole Blood	Plasma	Whole Blood	Plasma	Whole Blood	Plasma	Whole Blood	Plasma	Whole Blood
1	-	-	+	+	-	-	+	+	-	-	+	+
2	-	-	+	+	-	-	+	+	-	-	+	+
3	-	-	+	+	-	-	+	+	-	-	+	+
4	-	-	+	+	-	-	+	+	-	-	+	+
5	-	-	+	+	-	-	+	+	-	-	+	+
6	-	-	+	+	-	-	+	+	-	-	+	+
7	-	-	+	+	-	-	+	+	-	-	+	+
8	-	-	+	+	-	-	+	+	-	-	+	+
9	-	-	+	+	-	-	+	+	-	-	+	+
10	-	-	+	+	-	-	+	+	-	-	+	+
11	-	-	+	+	-	-	+	+	-	-	+	+
12	-	-	+	+	-	-	+	+	-	-	+	+
13	-	-	+	+	-	-	+	+	-	-	+	+
14	-	-	+	+	-	-	+	+	-	-	+	+
15	-	-	+	+	-	-	+	+	-	-	+	+
16	-	-	+	+	-	-	+	+	-	-	+	+
17	-	-	+	+	-	-	+	+	-	-	+	+
18	-	-	+	+	-	-	+	+	-	-	+	+
19	-	-	+	+	-	-	+	+	-	-	+	+
20	-	-	+	+	-	-	+	+	-	-	+	+
21	-	-	+	+	-	-	+	+	-	-	+	+
22	-	-	+	+	-	-	+	+	-	-	+	+
23	-	-	+	+	-	-	+	+	-	-	+	+

24	-	-	+	+	-	-	+	+	-	-	+	+
25	-	-	+	+	-	-	+	+	-	-	+	+

Potassium oxalate Anticoagulant Tube												
No.	**CLA19040001-T**				**CLA19040002-T**				**CLA19040003-T**			
	Negative		**Positive**		**Negative**		**Positive**		**Negative**		**Positive**	
	Plasma	Whole Blood	Plasma	Whole Blood	Plasma	Whole Blood	Plasma	Whole Blood	Plasma	Whole Blood	Plasma	Whole Blood
1	-	-	+	+	-	-	+	+	-	-	+	+
2	-	-	+	+	-	-	+	+	-	-	+	+
3	-	-	+	+	-	-	+	+	-	-	+	+
4	-	-	+	+	-	-	+	+	-	-	+	+
5	-	-	+	+	-	-	+	+	-	-	+	+
6	-	-	+	+	-	-	+	+	-	-	+	+
7	-	-	+	+	-	-	+	+	-	-	+	+
8	-	-	+	+	-	-	+	+	-	-	+	+
9	-	-	+	+	-	-	+	+	-	-	+	+
10	-	-	+	+	-	-	+	+	-	-	+	+
11	-	-	+	+	-	-	+	+	-	-	+	+
12	-	-	+	+	-	-	+	+	-	-	+	+
13	-	-	+	+	-	-	+	+	-	-	+	+
14	-	-	+	+	-	-	+	+	-	-	+	+
15	-	-	+	+	-	-	+	+	-	-	+	+
16	-	-	+	+	-	-	+	+	-	-	+	+
17	-	-	+	+	-	-	+	+	-	-	+	+
18	-	-	+	+	-	-	+	+	-	-	+	+
19	-	-	+	+	-	-	+	+	-	-	+	+
20	-	-	+	+	-	-	+	+	-	-	+	+
21	-	-	+	+	-	-	+	+	-	-	+	+
22	-	-	+	+	-	-	+	+	-	-	+	+
23	-	-	+	+	-	-	+	+	-	-	+	+
24	-	-	+	+	-	-	+	+	-	-	+	+
25	-	-	+	+	-	-	+	+	-	-	+	+

Note: "-" mean negative result, "+" mean positive result

Conclusion: The result showed no difference among different anticoagulant tube to collect whole blood specimens and plasma specimen in this study.

2.7 Negative Conversion Study

10 clinically proven negative samples were tested in duplicate, in test with and without temperature stressing (storing tests for two days at 4°C, 25°C, 45°C and -20°C prior to running tests) to evaluate possible conversion to positive results. The operators read the results at 10 and 20 minutes after sample addition.

Table: Negative Conversion Study Result

CLA19040001-T		**N1**	**N2**	**N3**	**N4**	**N5**	**N6**	**N7**	**N8**	**N9**	**N10**
4°C	10min	-	-	-	-	-	-	-	-	-	-
	20min	-	-	-	-	-	-	-	-	-	-
25°C	10min	-	-	-	-	-	-	-	-	-	-
	20min	-	-	-	-	-	-	-	-	-	-
45°C	10min	-	-	-	-	-	-	-	-	-	-
	20min	-	-	-	-	-	-	-	-	-	-
-20°C	10min	-	-	-	-	-	-	-	-	-	-
	20min	-	-	-	-	-	-	-	-	-	-
CLA19040002-T		**N1**	**N2**	**N3**	**N4**	**N5**	**N6**	**N7**	**N8**	**N9**	**N10**
4°C	10min	-	-	-	-	-	-	-	-	-	-
	20min	-	-	-	-	-	-	-	-	-	-
25°C	10min	-	-	-	-	-	-	-	-	-	-
	20min	-	-	-	-	-	-	-	-	-	-
45°C	10min	-	-	-	-	-	-	-	-	-	-
	20min	-	-	-	-	-	-	-	-	-	-
-20°C	10min	-	-	-	-	-	-	-	-	-	-
	20min	-	-	-	-	-	-	-	-	-	-
CLA19040003-T		**N1**	**N2**	**N3**	**N4**	**N5**	**N6**	**N7**	**N8**	**N9**	**N10**
4°C	10min	-	-	-	-	-	-	-	-	-	-
	20min	-	-	-	-	-	-	-	-	-	-
25°C	10min	-	-	-	-	-	-	-	-	-	-
	20min	-	-	-	-	-	-	-	-	-	-
45°C	10min	-	-	-	-	-	-	-	-	-	-
	20min	-	-	-	-	-	-	-	-	-	-
-20°C	10min	-	-	-	-	-	-	-	-	-	-
	20min	-	-	-	-	-	-	-	-	-	-

Note: "-" mean negative result

Conclusion: The results were consistent between tests with and without temperatures stress. In this experiment, none of the samples tested converted from negative to positive results in the 10-20 minutes reading time.

2.8 Between Day Reproducibility

Negative, low positive, middle positive and high positive specimens were run individually on ten separate days using the same lots of reagents and cassettes. Results were read at 10 and 20 minutes after specimen application. Results are presented in Table below.

Table: Between Day Reproducibility Result

OCEA-402			CLA19040001-T									
Day			1	2	3	4	5	6	7	8	9	10
Negative	1	10min	-	-	-	-	-	-	-	-	-	-
		20min	-	-	-	-	-	-	-	-	-	-
	2	10min	-	-	-	-	-	-	-	-	-	-
		20min	-	-	-	-	-	-	-	-	-	-
	3	10min	-	-	-	-	-	-	-	-	-	-
		20min	-	-	-	-	-	-	-	-	-	-
	4	10min	-	-	-	-	-	-	-	-	-	-
		20min	-	-	-	-	-	-	-	-	-	-
	5	10min	-	-	-	-	-	-	-	-	-	-
		20min	-	-	-	-	-	-	-	-	-	-
Low Positive	1	10min	+	+	+	+	+	+	+	+	+	+
		20min	+	+	+	+	+	+	+	+	+	+
	2	10min	+	+	+	+	+	+	+	+	+	+
		20min	+	+	+	+	+	+	+	+	+	+
	3	10min	+	+	+	+	+	+	+	+	+	+
		20min	+	+	+	+	+	+	+	+	+	+
	4	10min	+	+	+	+	+	+	+	+	+	+
		20min	+	+	+	+	+	+	+	+	+	+
	5	10min	+	+	+	+	+	+	+	+	+	+
		20min	+	+	+	+	+	+	+	+	+	+
Middle Positive	1	10min	+	+	+	+	+	+	+	+	+	+
		20min	+	+	+	+	+	+	+	+	+	+
	2	10min	+	+	+	+	+	+	+	+	+	+
		20min	+	+	+	+	+	+	+	+	+	+
	3	10min	+	+	+	+	+	+	+	+	+	+
		20min	+	+	+	+	+	+	+	+	+	+
	4	10min	+	+	+	+	+	+	+	+	+	+
		20min	+	+	+	+	+	+	+	+	+	+
	5	10min	+	+	+	+	+	+	+	+	+	+
		20min	+	+	+	+	+	+	+	+	+	+
High Positive	1	10min	+	+	+	+	+	+	+	+	+	+
		20min	+	+	+	+	+	+	+	+	+	+
	2	10min	+	+	+	+	+	+	+	+	+	+
		20min	+	+	+	+	+	+	+	+	+	+
	3	10min	+	+	+	+	+	+	+	+	+	+
		20min	+	+	+	+	+	+	+	+	+	+
	4	10min	+	+	+	+	+	+	+	+	+	+
		20min	+	+	+	+	+	+	+	+	+	+
	5	10min	+	+	+	+	+	+	+	+	+	+

		20min	+	+	+	+	+	+	+	+	+	+

Note: "-" mean negative result, "+" mean positive result

Conclusion: Test results were consistent over the ten days period.

2.9 Between Lot Reproducibility

Negative, low positive, middle positive and high positive specimens were run in replicates of five in three separate lots of products. Results were read at 10 and 20 minutes after specimen application. Results were presented in Table below.

Table: Between Lot Reproducibility Results

CLA19040001-T								
Times	Negative		Low Positive		Middle Positive		High Positive	
	10 min	20 min	10 min	20 min	10 min	20 min	10 min	20 min
1	-	-	+	+	+	+	+	+
2	-	-	+	+	+	+	+	+
3	-	-	+	+	+	+	+	+
4	-	-	+	+	+	+	+	+
5	-	-	+	+	+	+	+	+
CLA19040002-T								
Times	Negative		Low Positive		Middle Positive		High Positive	
	10 min	20 min	10 min	20 min	10 min	20 min	10 min	20 min
1	-	-	+	+	+	+	+	+
2	-	-	+	+	+	+	+	+
3	-	-	+	+	+	+	+	+
4	-	-	+	+	+	+	+	+
5	-	-	+	+	+	+	+	+
CLA19040003-T								
Times	Negative		Low Positive		Middle Positive		High Positive	
	10 min	20 min	10 min	20 min	10 min	20 min	10 min	20 min
1	-	-	+	+	+	+	+	+
2	-	-	+	+	+	+	+	+
3	-	-	+	+	+	+	+	+
4	-	-	+	+	+	+	+	+
5	-	-	+	+	+	+	+	+

Note: “-” mean negative result, “+” mean positive result

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

2.10 Reading Time Flex Study

Negative, low positive, middle positive and high positive standards have been tested according to the directions for use in replicates of three. The test was rated as positive or negative at 3, 5, 10, 15, 20, 30minutes, 1 hour and 2 hours.

Table: Reading Time Flex Study Result

Time	CLA19040001-T											
	Negative			Low Positive			Middle Positive			High Positive		
3min	-	-	-	-	-	-	-	-	-	+	+	+
5min	-	-	-	-	-	-	+	+	+	+	+	+
10min	-	-	-	+	+	+	+	+	+	+	+	+
15min	-	-	-	+	+	+	+	+	+	+	+	+
20min	-	-	-	+	+	+	+	+	+	+	+	+
30min	-	-	-	+	+	+	+	+	+	+	+	+
1h	-	-	-	+	+	+	+	+	+	+	+	+
2h	-	-	-	+	+	+	+	+	+	+	+	+
Time	CLA19040002-T											
	Negative			Low Positive			Middle Positive			High Positive		
3min	-	-	-	-	-	-	-	-	-	+	+	+
5min	-	-	-	-	-	-	+	+	+	+	+	+
10min	-	-	-	+	+	+	+	+	+	+	+	+
15min	-	-	-	+	+	+	+	+	+	+	+	+
20min	-	-	-	+	+	+	+	+	+	+	+	+
30min	-	-	-	+	+	+	+	+	+	+	+	+
1h	-	-	-	+	+	+	+	+	+	+	+	+
2h	-	-	-	+	+	+	+	+	+	+	+	+
Time	CLA19040003-T											
	Negative			Low Positive			Middle Positive			High Positive		
3min	-	-	-	-	-	-	-	-	-	+	+	+
5min	-	-	-	-	-	-	+	+	+	+	+	+
10min	-	-	-	+	+	+	+	+	+	+	+	+
15min	-	-	-	+	+	+	+	+	+	+	+	+
20min	-	-	-	+	+	+	+	+	+	+	+	+
30min	-	-	-	+	+	+	+	+	+	+	+	+
1h	-	-	-	+	+	+	+	+	+	+	+	+
2h	-	-	-	+	+	+	+	+	+	+	+	+

Note: "-" mean negative result, "+" mean positive result

Conclusion: This study demonstrated the ability of the assay to give correct results with the prescribed read time of 10-20 minutes.

2.11 Specimen Volume Flex Study

Negative serum, negative plasma, negative whole blood, low positive spiked serum, low positive spiked plasma and low positive spiked whole blood specimen add into the sample well of Celiac Rapid Test with the following operation method, read the results at 10 minutes and 20 minutes, a suitable specimen volume should be validated in this study.

Method A- 10µl specimen+1 drop of buffer
Method B- 10µl specimen+2 drops of buffer
Method C- 10µl specimen+3 drops of buffer
Method D- 20µl specimen+1 drop of buffer
Method E- 20µl specimen+2 drops of buffer
Method F- 20µl specimen+3 drops of buffer

Table: Specimen Volume Flex Study Result

Method	Time	CLA19040001-T								
		Negative								
		Serum			Plasma			Whole Blood		
A	10min	-	-	-	-	-	-	-	-	-
	20min	-	-	-	-	-	-	-	-	-
B	10min	-	-	-	-	-	-	-	-	-
	20min	-	-	-	-	-	-	-	-	-
C	10min	-	-	-	-	-	-	-	-	-
	20min	-	-	-	-	-	-	-	-	-
D	10min	-	-	-	-	-	-	-	-	-
	20min	-	-	-	-	-	-	-	-	-
E	10min	-	-	-	-	-	-	-	-	-
	20min	-	-	-	-	-	-	-	-	-
F	10min	-	-	-	-	-	-	-	-	-
	20min	-	-	-	-	-	-	-	-	-
Method	Time	CLA19040002-T								
		Negative								
		Serum			Plasma			Whole Blood		
A	10min	-	-	-	-	-	-	-	-	-
	20min	-	-	-	-	-	-	-	-	-
B	10min	-	-	-	-	-	-	-	-	-
	20min	-	-	-	-	-	-	-	-	-
C	10min	-	-	-	-	-	-	-	-	-
	20min	-	-	-	-	-	-	-	-	-
D	10min	-	-	-	-	-	-	-	-	-
	20min	-	-	-	-	-	-	-	-	-
E	10min	-	-	-	-	-	-	-	-	-
	20min	-	-	-	-	-	-	-	-	-
F	10min	-	-	-	-	-	-	-	-	-
	20min	-	-	-	-	-	-	-	-	-
Method	Time	CLA19040003-T								
		Negative								
		Serum			Plasma			Whole Blood		
A	10min	-	-	-	-	-	-	-	-	-

	20min	-	-	-	-	-	-	-	-	-	
B	10min	-	-	-	-	-	-	-	-	-	
	20min	-	-	-	-	-	-	-	-	-	
C	10min	-	-	-	-	-	-	-	-	-	
	20min	-	-	-	-	-	-	-	-	-	
D	10min	-	-	-	-	-	-	-	-	-	
	20min	-	-	-	-	-	-	-	-	-	
E	10min	-	-	-	-	-	-	-	-	-	
	20min	-	-	-	-	-	-	-	-	-	
F	10min	-	-	-	-	-	-	-	-	-	
	20min	-	-	-	-	-	-	-	-	-	
Method	Time	CLA19040001-T									
		Low Positive									
		Serum			Plasma			Whole Blood			
A	10min	+	+	+	+	+	+	+	+	+	
	20min	+	+	+	+	+	+	+	+	+	
B	10min	+	+	+	+	+	+	+	+	+	
	20min	+	+	+	+	+	+	+	+	+	
C	10min	+	+	+	+	+	+	+	+	+	
	20min	+	+	+	+	+	+	+	+	+	
D	10min	+	+	+	+	+	+	+	+	+	
	20min	+	+	+	+	+	+	+	+	+	
E	10min	+	+	+	+	+	+	+	+	+	
	20min	+	+	+	+	+	+	+	+	+	
F	10min	+	+	+	+	+	+	+	+	+	
	20min	+	+	+	+	+	+	+	+	+	
Method	Time	CLA19040002-T									
		Low Positive									
		Serum			Plasma			Whole Blood			
A	10min	+	+	+	+	+	+	+	+	+	
	20min	+	+	+	+	+	+	+	+	+	
B	10min	+	+	+	+	+	+	+	+	+	
	20min	+	+	+	+	+	+	+	+	+	
C	10min	+	+	+	+	+	+	+	+	+	
	20min	+	+	+	+	+	+	+	+	+	
D	10min	+	+	+	+	+	+	+	+	+	
	20min	+	+	+	+	+	+	+	+	+	
E	10min	+	+	+	+	+	+	+	+	+	
	20min	+	+	+	+	+	+	+	+	+	
F	10min	+	+	+	+	+	+	+	+	+	
	20min	+	+	+	+	+	+	+	+	+	
Method	Time	CLA19040003-T									
		Low Positive									
		Serum			Plasma			Whole Blood			
A	10min	+	+	+	+	+	+	+	+	+	
	20min	+	+	+	+	+	+	+	+	+	
B	10min	+	+	+	+	+	+	+	+	+	

	20min	+	+	+	+	+	+	+	+	+
C	**10min**	+	+	+	+	+	+	+	+	+
	20min	+	+	3+	+	+	+	+	+	+
D	**10min**	+	+	+	+	+	+	+	+	+
	20min	+	+	+	+	+	+	+	+	+
E	**10min**	+	+	+	+	+	+	+	+	+
	20min	+	+	+	+	+	+	+	+	+
F	**10min**	+	+	+	+	+	+	+	+	+
	20min	+	+	+	+	+	+	+	+	+

Note: "-" mean negative result, "+" mean positive result

Conclusion: This study demonstrated the ability of the assay to give correct results with the prescribed specimen volume as following:

Serum/Plasma: 10µl+2 drops of buffer

Whole blood: 20µl+2 drops of buffer

2.12 Open Pouch Stability Study

Negative, low positive, middle positive, and high positive specimens which were run in triplicate using the Celiac Rapid Test which were opened pouch after 10 minutes, 20 minutes, 30 minutes, 1 hour, 1.5 hours and 2 hours at following condition. All results were read as positive or negative at 10 to 20 minutes after sample application.

Condition 1: Room temperature and high humidity (≥80%)

Condition 2: 45°C and normal humidity (≤60%)

Condition 3: 45°C and high humidity (≥80%)

Condition 4: Room temperature and normal humidity (≤60%)

Each specimen was tested in replicated of 3.

Table: Open Pouch Stability Study Results

Standard	Time after Open Pouch	Results of Condition 1								
		CLA19040001-T			CLA19040002-T			CLA19040003-T		
Negative	10min	-	-	-	-	-	-	-	-	-
	20min	-	-	-	-	-	-	-	-	-
	30min	-	-	-	-	-	-	-	-	-
	60min	-	-	-	-	-	-	-	-	-
	90min	-	-	-	-	-	-	-	-	-
	120min	-	-	-	-	-	-	-	-	-
Low Positive	10min	+	+	+	+	+	+	+	+	+
	20min	+	+	+	+	+	+	+	+	+
	30min	+	+	+	+	+	+	+	+	+
	60min	+	+	+	+	+	+	+	+	+
	90min	+	+	+	+	+	+	+	+	+
	120min	+	+	+	+	+	+	+	+	+
Middle Positive	10min	+	+	+	+	+	+	+	+	+
	20min	+	+	+	+	+	+	+	+	+
	30min	+	+	+	+	+	+	+	+	+
	60min	+	+	+	+	+	+	+	+	+
	90min	+	+	+	+	+	+	+	+	+
	120min	+	+	+	+	+	+	+	+	+
High Positive	10min	+	+	+	+	+	+	+	+	+
	20min	+	+	+	+	+	+	+	+	+
	30min	+	+	+	+	+	+	+	+	+
	60min	+	+	+	+	+	+	+	+	+
	90min	+	+	+	+	+	+	+	+	+
	120min	+	+	+	+	+	+	+	+	+
Standard	Time after Open Pouch	Results of Condition 2								
		CLA19040001-T			CLA19040002-T			CLA19040003-T		
Negative	10min	-	-	-	-	-	-	-	-	-
	20min	-	-	-	-	-	-	-	-	-
	30min	-	-	-	-	-	-	-	-	-
	60min	-	-	-	-	-	-	-	-	-
	90min	-	-	-	-	-	-	-	-	-
	120min	-	-	-	-	-	-	-	-	-
Low	10min	+	+	+	+	+	+	+	+	+

Positive	20min	+	+	+	+	+	+	+	+	+
	30min	+	+	+	+	+	+	+	+	+
	60min	+	+	+	+	+	+	+	+	+
	90min	+	+	+	+	+	+	+	+	+
	120min	+	+	+	+	+	+	+	+	+
Middle Positive	10min	+	+	+	+	+	+	+	+	+
	20min	+	+	+	+	+	+	+	+	+
	30min	+	+	+	+	+	+	+	+	+
	60min	+	+	+	+	+	+	+	+	+
	90min	+	+	+	+	+	+	+	+	+
	120min	+	+	+	+	+	+	+	+	+
High Positive	10min	+	+	+	+	+	+	+	+	+
	20min	+	+	+	+	+	+	+	+	+
	30min	+	+	+	+	+	+	+	+	+
	60min	+	+	+	+	+	+	+	+	+
	90min	+	+	+	+	+	+	+	+	+
	120min	+	+	+	+	+	+	+	+	+
Standard	Time after Open Pouch	Results of Condition 3								
		CLA19040001-T			CLA19040002-T			CLA19040003-T		
Negative	10min	-	-	-	-	-	-	-	-	-
	20min	-	-	-	-	-	-	-	-	-
	30min	-	-	-	-	-	-	-	-	-
	60min	-	-	-	-	-	-	-	-	-
	90min	-	-	-	-	-	-	-	-	-
	120min	-	-	-	-	-	-	-	-	-
Low Positive	10min	+	+	+	+	+	+	+	+	+
	20min	+	+	+	+	+	+	+	+	+
	30min	+	+	+	+	+	+	+	+	+
	60min	+	+	+	+	+	+	+	+	+
	90min	+	+	+	+	+	+	+	+	+
	120min	+	+	+	+	+	+	+	+	+
Middle Positive	10min	+	+	+	+	+	+	+	+	+
	20min	+	+	+	+	+	+	+	+	+
	30min	+	+	+	+	+	+	+	+	+
	60min	+	+	+	+	+	+	+	+	+
	90min	+	+	+	+	+	+	+	+	+
	120min	+	+	+	+	+	+	+	+	+
High Positive	10min	+	+	+	+	+	+	+	+	+
	20min	+	+	+	+	+	+	+	+	+
	30min	+	+	+	+	+	+	+	+	+
	60min	+	+	+	+	+	+	+	+	+
	90min	+	+	+	+	+	+	+	+	+
	120min	+	+	+	+	+	+	+	+	+
Standard	Time after Open Pouch	Results of Condition 4								
		CLA19040001-T			CLA19040002-T			CLA19040003-T		
Negative	10min	-	-	-	-	-	-	-	-	-
	20min	-	-	-	-	-	-	-	-	-

	30min	-	-	-	-	-	-	-	-	-
	60min	-	-	-	-	-	-	-	-	-
	90min	-	-	-	-	-	-	-	-	-
	120min	-	-	-	-	-	-	-	-	-
Low Positive	10min	+	+	+	+	+	+	+	+	+
	20min	+	+	+	+	+	+	+	+	+
	30min	+	+	+	+	+	+	+	+	+
	60min	+	+	+	+	+	+	+	+	+
	90min	+	+	+	+	+	+	+	+	+
	120min	+	+	+	+	+	+	+	+	+
Middle Positive	10min	+	+	+	+	+	+	+	+	+
	20min	+	+	+	+	+	+	+	+	+
	30min	+	+	+	+	+	+	+	+	+
	60min	+	+	+	+	+	+	+	+	+
	90min	+	+	+	+	+	+	+	+	+
	120min	+	+	+	+	+	+	+	+	+
High Positive	10min	+	+	+	+	+	+	+	+	+
	20min	+	+	+	+	+	+	+	+	+
	30min	+	+	+	+	+	+	+	+	+
	60min	+	+	+	+	+	+	+	+	+
	90min	+	+	+	+	+	+	+	+	+
	120min	+	+	+	+	+	+	+	+	+

Note: "-" mean negative result, "+" mean positive result. In condition 1 and condition 3, the test line intensity will be decreased after opening the pouch for 90 minutes.

Conclusion: Results above indicated best results of Celiac will be got within 1 hour after opening the pouch.

2.13 Accelerated Stability Study

Accelerated stability of the Celiac Rapid Test (Whole Blood/Serum/Plasma) was evaluated using samples from three different batches. These were placed in an incubator with the temperature calibrated at 45°C and 55°C. Relative humidity (RH) calibrated at about 60%. A series of stability tests were performed at 0, 7, 14, 21, 28, 35, 42, 56, 77, 84, 105, 126, 147, 168 days for 45°C. About 55°C, some performance study would be tested at 0, 7, 14, 21, 28, 35, 42, 56, 77 days according to Arrhenius Plot. See Table in below. Test cassettes were assayed using negative, low positive, middle positive and 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. Results are presented in Table below.

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: Time Line for Accelerated Stability Study

Day / Temp.	0	7	14	21	28	35	42	56	77	84	105	126	147	168
45°C	√	√	√	√	√	√	√	√	√	√	√	√	√	√
55°C	√	√	√	√	√	√	√	√	√	/	/	/	/	/

Table: 45°C Accelerated Stability Summary

Day	Specimen	OCEA-402								
		CLA19040001-T			CLA19040002-T			CLA19040003-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	+	+	+	+	+	+	+	+	+
105	Negative	-	-	-	-	-	-	-	-	-
	Low positive	+	+	+	+	+	+	+	+	+
	Middle positive	+	+	+	+	+	+	+	+	+
	High positive	+	+	+	+	+	+	+	+	+
126	Negative	-	-	-	-	-	-	-	-	-
	Low positive	+	+	+	+	+	+	+	+	+
	Middle positive	+	+	+	+	+	+	+	+	+
	High positive	+	+	+	+	+	+	+	+	+
147	Negative	-	-	-	-	-	-	-	-	-
	Low positive	+	+	+	+	+	+	+	+	+
	Middle positive	+	+	+	+	+	+	+	+	+
	High positive	+	+	+	+	+	+	+	+	+
168	Negative	-	-	-	-	-	-	-	-	-
	Low positive	+	+	+	+	+	+	+	+	+
	Middle positive	+	+	+	+	+	+	+	+	+
	High positive	+	+	+	+	+	+	+	+	+

Note: "-" mean negative result, "+" mean positive result

Table: 55°C Accelerated Stability Summary

Day	**Specimen**	**OCEA-402**								
		CLA19040001-T			CLA19040002-T			CLA19040003-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	+	+	+	+	+	+	+	+	+

Note: "-" mean negative result, "+" mean positive result

Conclusion: The Celiac Rapid Test (Whole Blood/Serum/Plasma) was stable at 45°C for 168 days and at 55°C for 84 days. These data were 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 BIBLIOGRAPHY

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01	2022.02.18	/	N/A
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