Celiac Rapid Test Cassette (Whole Blood/Serum/Plasma)

English

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A rapid test for a qualitative detection of IgA antibody to human tTG in human whole blood, serum or plasma.
For professional in vitro diagnostic use only.

INTENDED USE

The Celiac Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of IgA antibodies to human tTG in human whole blood, serum, or plasma as an aid in the diagnosis of celiac disease.

SUMMARY

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. The Celiac Rapid Test Cassette 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.

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.

REAGENTS

The test contains tTG antigen conjugated gold particles and anti-human IgA antibody coated on the membrane.

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 may adversely affect results.

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30 ℃). 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.

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 20 µL. The dropper provided with the test dispenses approximately 20 µL 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 ℃ for up to 3 days. For long-term storage, specimens should be kept below -20 ℃. Whole blood collected by venipuncture should be stored at 2-8 ℃ 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.

MATERIALS

Materials provided

- Test Cassettes
- Droppers
- Buffer
- Package Insert

Materials required but not provided

- Specimen Collection Container
- Centrifuge
- Micropipettes
- Timer
- Lancets (for fingerstick whole blood only)

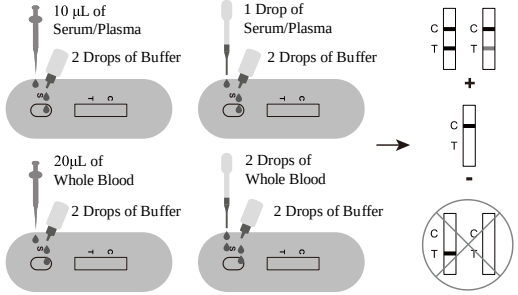
DIRECTIONS FOR USE

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

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within 1 hour.
2. Place the cassette on a clean and level surface.
- **Use a dropper**: Hold the dropper vertically, draw the specimen about 1cm above the upper end of the nozzle as shown in illustration below, transfer **1 drop of the serum/plasma (approximately 10 µL) or 2 drops of the whole blood (approximately 20 µL)** to the specimen well (S) of the test cassette, then add **2 drops of buffer (approximately 80 µL)** and start the timer.
- **Use a micropipette**: Pipette and dispense **10µL of serum/plasma or 20 µL of whole blood** to the specimen well (S) of the test cassette, then add **2 drops of buffer (approximately 80 µL)** and start the timer.

3. 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.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE: * **Two 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 antibodies 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 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.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal 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.

LIMITATIONS

1. 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 IgA antibody concentration can be determined by this qualitative test.
2. The Celiac Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of tTG IgA antibodies in the specimen and should not be used as the sole criteria for the diagnosis of Celiac.
3. A negative test result does not preclude the possibility of celiac disease.
4. A negative result can occur if the quantity of tTG IgA antibodies present in the specimen is below the detection limits of the assay, or the tTG IgA antibodies that are detected are not present during the stage of disease in which a sample is collected.
5. If the symptom persists, while the result from the 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.
6. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.
7. The hematocrit of the whole blood should be between 25% and 65%.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

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 95.0% and the relative specificity is 98.5%.

Method		Commercial Celiac Test		Total Results
Celiac Rapid Test Cassette (Whole Blood/Serum/Plasma)	Results	Positive	Negative	
	Positive	19	2	21
	Negative	1	128	129
Total Results		20	130	150

Relative sensitivity: 95.0% (95%CI*: 75.1%~99.9%)
Relative specificity: 98.5% (95%CI*: 94.6%~99.8%)
Accuracy:98.0%(95%CI*:94.3%~99.6%)
*Confidence Intervals

Precision

Intra-Assay

Within-run precision has been determined by using 5 replicates of four specimens: negative, low positive, middle positive and high positive. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 5 independent assays on the same four specimens: negative, low positive, middle positive and high positive. Three different lots of the Celiac Rapid Test Cassette (Whole Blood/Serum/Plasma) have been tested using these specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

The Celiac Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested by anti-HAMA, RF, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, anti-Syphilis, anti-HIV, anti-HCV, anti-*H. pylori*, anti-CMV IgG, anti-CMV IgM, anti-Rubella IgG, anti-Rubella IgM, anti-TOXO IgG and anti-TOXO IgM positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to celiac negative and positive specimens.

Gentisic Acid: 20 mg/dL	Caffeine: 20 mg/dL
Acetaminophen: 20 mg/dL	Ascorbic Acid: 2 g/dL
Creatin: 200 mg/dL	Hemoglobin: 1000 mg/dL
Oxalic Acid: 60 mg/dL	Acetylsalicylic Acid: 20 mg/dL
Albumin: 2 g/dL	Bilirubin: 1 g/dL

None of the substances at the concentration tested interfered in the assay.

BIBLIOGRAPHY

1. Roujon, P, Sarrat, A, Contin-Bordes, C, et al. (2013) Diagnostic sérologique de la maladie coeliaque. Pathologie Biologie 61: e39–346.
2. Husby, S, Koletzko, S, Korponay-Szabó, IR, et al. (2012) European society for pediatric gastroenterology, hepatology, and nutrition guidelines for the diagnosis of coeliac disease. Journal of Pediatric Gastroenterology and Nutrition 54: 136–160.
3. Malamut, G, Cellier, C (2010) Celiac disease. La Revue de Médecine Interne 31: 428–433.

INDEX OF SYMBOLS

IVD	*In vitro* diagnostic medical device
2°C 30°C	Temperature limit
	Do not use if package is damaged and consult instructions for use
REF	Catalogue number
Σ	Contains sufficient for <n> tests
	Use-by date
LOT	Batch code
	Manufacturer
	Do not re-use
	Consult instructions for use or consult electronic instructions for use
	Caution
EC REP	Authorized representative in the European Community

REF:OCEA-CT402
Number: CT6018855
Rev: 00
Date:11/03/2023