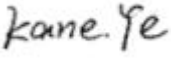
Clinical Study Report of Celiac Rapid Test

Ref.: OCEA-402

	Name	Department	Signature	Date
Prepared by	Kane Ye	R&D		2024.03.29
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Content

1. Summary

We analyzed the Celiac Rapid Test (Whole Blood/Serum/Plasma) at different clinical specimens, as described below.
Totally 60 Tissue Transglutaminase IgA positive specimens and 140 Tissue Transglutaminase IgA negative specimens with clinical symptoms and asymptomatic were used in this clinical study. Tissue Transglutaminase Ab IgA ELISA test served as the reference method for the Celiac Rapid Test Cassette (Whole Blood/Serum/Plasma). The result shows the Celiac Rapid Test Cassette has a high restive sensitivity and high relative specificity when tested with the 200 specimens.

2. 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 protein fragment called gliadin. 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 an 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 antonomasia antibodies.

3. Objective

Do clinical studies of Celiac Rapid Test Cassette with the Tissue Transglutaminase IgA positive specimens and negative specimens which confirmed with Tissue Transglutaminase Ab IgA ELISA Test.

4. Materials

- Celiac Rapid Test (Whole Blood/Serum/Plasma)
- 60 Celiac IgA positive specimens
- 140 Celiac IgA negative specimens
- Tissue Transglutaminase Ab IgA ELISA

5. Method

Totally 200 specimens and collected from different individuals with suspected Celiac Totally 200 specimens and collected from different individuals with suspected Celiac Disease, then tested with Tissue Transglutaminase Ab IgA ELISA and Celiac rapid test respectively.

6. Operation Method

Operation method can be referred to package insert provided in the kits.

7. Test Results

Table: Summary Result

Method		ELISA		Total
		Positive	Negative	
Celiac Rapid Test Cassette (Whole Blood/Serum/Plasma)	Positive	58	2	60
	Negative	2	138	140
Total		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 interval

8. Conclusion

The relative sensitivity of Celiac Rapid Test Cassette (Whole Blood/Serum/Plasma) was 96.7% (95%CI*: 88.5%~99.6%), the relative specificity was 98.6% (95%CI*: 94.9%~99.8%) compare with Tissue Transglutaminase Ab IgA ELISA Test result when tested with the specimens.

9. References

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.