

ANI Biotech

CELIAC DISEASE TEST

3-028-000 / -200 / -400 / -410 / -420 / -401

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- marked for professional and home use since July 2005



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1. INTRODUCTION

The Biocard Celiac Disease tests manufactured by Ani Biotech Oy are disposable immunochromatographic tests for *in vitro* qualitative detection of the anti-tTG IgA antibodies associated with celiac disease. This document applies to test versions of Ani Biotech Oy; cat.no 3-028-000 / -400 / -410 / -420. These tests are meant for professional use, tests cat.no 3-028-200 / -401 are for home use.

1.1 Celiac Disease

Celiac disease (CD) is a serious, lifelong, gastrointestinal disorder that can cause a wide spectrum of clinical symptoms of diarrhea, abdominal distension, weight loss, malnutrition and skin disorders (Dermatitis herpetiformis) due to permanent intolerance to gluten, a complex mixture of storage proteins found in wheat, barley and rye. It was first described by Samuel Gee in 1888.

Celiac disease is characterized by inflammation of the small-intestinal mucosa that results from a genetically based immunologic intolerance to ingested gluten. The classic sprue syndrome of steatorrhea and malnutrition coupled with multiple deficiency states may be less common than more subtle and often monosymptomatic presentation of the disease. Diverse problems such as dental anomalies, short stature, osteopenic bone disease, lactose intolerance, infertility, and nonspecific abdominal pain among many others may be the only manifestations of celiac disease.

Studies have found the prevalence of CD to be highly variable from population to population and the true prevalence has been difficult to ascertain. The disparate criteria in diagnosing of CD are often the cause. If only the clinical criteria are used the incidence of CD is much lower compared with incidence established by serological methods. Using serological methods of diagnosis, the incidence of CD in the general population is app. 1 in 200. Several studies have shown that there is often a significant delay of many years between the initial appearance of symptoms and the diagnosis of celiac disease.

Several other diseases are associated with a high incidence with celiac disease. Celiac disease is particularly common in patients with type 1 diabetes, thyroid disease, Addison disease, osteopenic bone, Down syndrome, and rheumatologic complaints. It has been suggested that untreated celiac disease may predispose children to diabetes.

The diagnosis of celiac disease currently rests on the histologic demonstration of the characteristic lesion in the small intestine and the subsequent clinical response to the introduction of a gluten-free diet.

The treatment of celiac disease is lifelong avoidance of dietary gluten. Gluten-free diets are now readily achievable with appropriate professional instruction and community support.

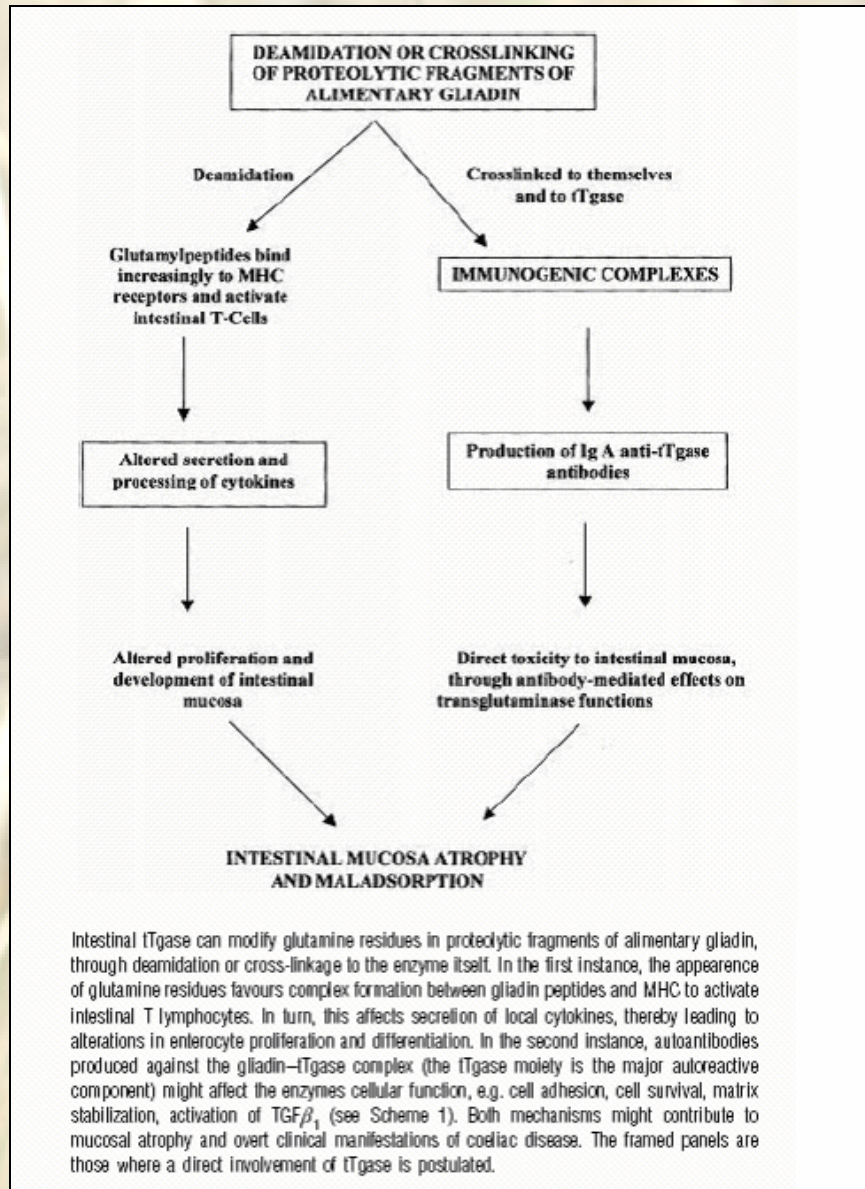


Figure 2: Possible roles of tTG in the pathogenesis of intestinal mucosal atrophy in celiac disease

1.3 Sensitivity of Biocard™ Celiac Disease

Sensitivity of Biocard™ Celiac Disease was studied with 149 clinical samples and the results were compared to the biopsy proven clinical diagnosis. The cut-off of Biocard™ Celiac Disease test is 5 U/ml.

Clinical diagnosis			
		+	-
Biocard™	+	78	7
Celiac Disease	-	3	61

Biocard™ Celiac Disease test showed sensitivity and specificity of 96,3 % and 89,7 %, respectively.

Accordance of different test versions was studied. The stick test showed similar sensitivity and specificity when tested with 64 clinical samples.

Clinical diagnosis			
		+	-
Biocard™	+	30	4
Celiac Disease	-	2	28

Stick

Biocard™ Celiac Disease stick test showed sensitivity and specificity of 93,8 % and 87,5 %, respectively. The accuracy of the test was 90,6 %, and the accordance to the slide version was 96,9 %.

2. PRINCIPLE OF THE TEST

Biocard™ Celiac Disease test is a rapid immunochromatographic test that detects the anti-tTG IgA antibodies from a blood sample. If the sample contains anti-tTG IgA antibodies these will bind with the gold labelled anti-hIgA antibodies (mouse IgG) and the tTG (derived from the lysis of red blood cells in the dilution buffer). tTG will then bind the complex to the stationary protein line (test line) forming a visible, red line. The test also contains an integrated control system consisting of stationary anti-mouse IgG antibody line that binds labelled mouse IgG (anti-hIgA) that has not bind with anti-tTG IgA and a red control line shows the proper functioning of the test.

The control line always becomes red provided that the test device is properly functioning and the testing procedure is performed according to the instructions for use: this serves as an internal functional control.

3. TEST VERSIONS

Cat. no. 3-028-000 is a slide version where the gold conjugate is located in a filter laminated in the test strip. See Figure 3 below.

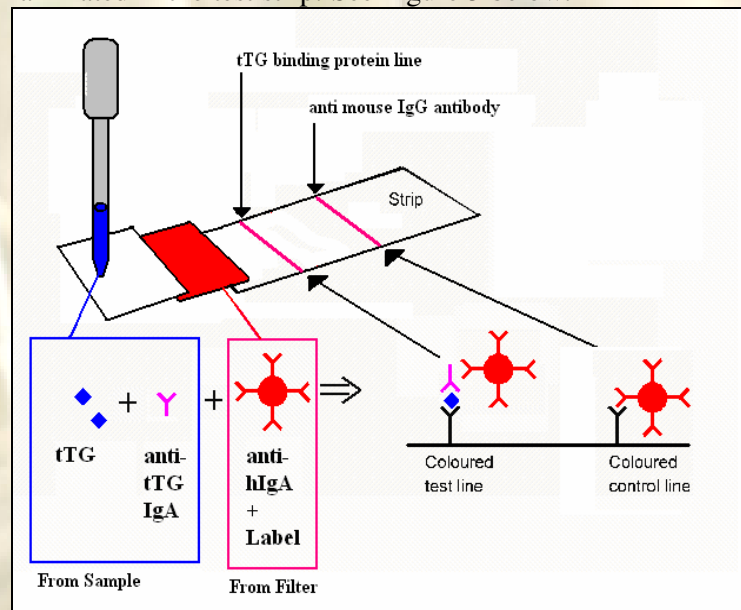


Figure 3: Test principle, cat. no. 3-028-000

Principle of the Celiac Disease test, cat. no. 3-028-000. Conjugate filter contains the label reagent, i.e. antibody labelled with red gold particles. Sample dissolves the label mixture and migrates to the zone of immobilized protein and antibody lines. If the sample contains anti tTG IgA antibodies a coloured test line will form.

Biocard Celiac Disease test kit cat.no 3-028-000 contains the following components:

- 10 aluminium sachets containing a test card and a pipette
- 10 sterile automatic lancets for obtaining a blood sample
- 10 plastic vessels with a 10 microlitre glass capillary
- 10 alcohol-soaked swabs
- 10 tubes containing 0,5 ml sample buffer
- 1 package leaflet with instructions for use.

In stick version 3-028-400 there is no plastic housing. The stick version is placed directly in the sample dilution buffer vial.

Biocard Celiac Disease stick test kit cat.no 3-028-410 contains the following components:

- 10 aluminium sachets containing a test stick
- 10 sterile automatic lancets for obtaining a blood sample
- 10 plastic vessels with a 10 microlitre glass capillary
- 10 alcohol-soaked swabs
- 10 tubes containing 0,5 ml sample buffer
- 1 package leaflet with instructions for use.

Biocard Celiac Disease stick test kit cat.no 3-028-420 contains the following components:

20 aluminium sachets containing a test stick
20 sterile automatic lancets for obtaining a blood sample
20 plastic vessels with a 10 microlitre glass capillary
20 alcohol-soaked swabs
20 tubes containing 0,5 ml sample buffer
1 package leaflet with instructions for use.

The test versions for home use (3-028-200 and 3-028-401) contain the test and sampling accessories (capillar, lancet, dilution buffer tube and a plaster). Version 3-028-200 contains also pipette for sample application.

All test versions are delivered with detailed instructions for use.

4. RESULT INTERPRETATION

Test result is negative if the coloured test line is not visible and the control line is visible.

Test result is positive if test line is visible and control line is visible.

If the control line is not visible the test is inconclusive, whether or not the test line is visible. A new test must be performed.

The test result can be interpreted after 5 minutes. After 10 minutes the test should not be interpreted anymore.

Positive:

The test indicates that there are anti-tTG antibodies in the blood sample. The detection of these antibodies indicates with a high probability an existing celiac disease.

Negative:

The test indicates that there are no anti-tTG antibodies in the tested blood. An existing celiac disease can virtually be ruled out. If gastrointestinal complaints are present, further medical investigation is necessary.

Anti-tTG IgA antibody titers diminish with the institution of gluten free diet, often within weeks and by 6 months may be undetectable. Therefore Biocard™ Celiac Disease test may be used for monitoring the effects of gluten free diet.

The incidence of IgA deficiency in CD patients is 2 – 3 %. Patients with IgA deficiency can not be diagnosed with Biocard™ Celiac Disease test.

5. PERFORMANCE CHARACTERISTICS

5.1 Sensitivity and specificity

Sensitivity of Biocard™ Celiac Disease was studied with 149 clinical samples and the results were compared to the biopsy proven clinical diagnosis. The cut-off of Biocard™ Celiac Disease test is 5 U/ml.

	Clinical diagnosis	
	+	-
Biocard™	+ 78	7
Celiac Disease	- 3	61

Biocard™ Celiac Disease test showed sensitivity and specificity of 96,3 % and 89,7 %, respectively.

Accordance of different test versions was studied. The stick test showed similar sensitivity and specificity when tested with 64 clinical samples.

	Clinical diagnosis	
	+	-
Biocard™	+ 30	4
Celiac Disease	- 2	28

Stick

Biocard™ Celiac Disease stick test showed sensitivity and specificity of 93,8 % and 87,5 %, respectively. The accuracy of the test was 90,6 %, and the accordance to the slide version was 96,9 %.

5.2 Comparative studies

The sensitivity and specificity of the Biocard Celiac Disease test was studied at the Pediatric Research Centre and Dept. of Internal Medicine, University of Tampere.

In series 1 and 2 the results presented consist of the Biocard Celiac Disease test (3-028-000) result, the Celikey (anti tTG IgA EIA) test result, EMA test result, and the final diagnosis based on biopsy. In Celikey and EMA results a result under 5 is considered as a negative.

SERIES 1					
	Sample	Biopsy proven Diagnosis	Biocard	Celikey	EMA
	1	CD	pos	99,5	200
	10	CD	pos	70,6	1000
	12	CD	pos	50,1	200
	13	CD	pos	100	5
	14	CD	pos	100	2000
	18	CD	pos	100	4000
	22	CD	pos	34,3	50
	23	CD	pos	51,6	200
	26	CD	weak pos	45,2	500
	30	CD	pos	98,9	500
	34	CD	pos	22,7	100
	38	CD	pos	94,4	1000
	43	CD	weak pos	72,6	4000
	44	CD	pos	56,4	1000
	46	CD	pos	55,7	1000
	47	CD	pos	38,1	500
	48	CD	pos	100	4000
	49	CD	pos	65	200
	52	CD	pos	100	500
	53	CD	neg	100	2000
	54	C	neg	0,3	<5
	55	C	neg	0,8	<5
	56	C	weak pos	0,6	<5
	57	C	neg	0,7	<5
	58	C	neg	1,2	<5
	60	C	neg	0,5	<5
	61	C	pos	0,6	<5
	62	C	neg	0,8	<5
	66	C	weak pos	0,7	<5
	67	C	neg	0,7	<5
	68	C	neg	1,4	<5
	69	C	neg	0,7	<5
	70	C	neg	0,3	<5
	71	C	neg	0,5	<5
	72	C	neg	0,5	<5
	73	C	neg	1,3	<5
	74	C	neg	1,4	<5
	75	C	neg	0,5	<5
	78	C	neg	0,8	<5
	411	C	neg	1,1	<2,5
	434	C	neg	0,3	<2,5
	436	C	neg	1,3	<2,5

continued	478	C	neg	0,8	<2,5
	479	C	neg	1,5	<2,5
	498	C	neg	0	<2,5
	500	CD	pos	52,4	80
	504	C	neg	0,1	<2,5
	506	C	neg	0,2	<2,5
	508	C	neg	1,2	<2,5
	510	C	neg	0,1	<2,5
	511	C	neg	0,4	<2,5
	513	C	neg	0,2	<2,5
	516	C	neg	0,7	<2,5
	517	C	weak pos	2,8	<2,5
	522	CD	pos	136,2	80
	523	C	neg	0,3	<2,5
	524	CD	pos	140,1	160
	525	C	neg	0	<2,5
	527	C	neg	0,1	<2,5
	529	C	neg	0,9	<2,5
	532	CD	pos	134,2	160
	543	C	pos	3,5	<2,5
	546	C	neg	0,6	<2,5
	547	C	neg	0	<2,5
	550	CD	pos	58,2	20
	551	C	neg	0,4	<2,5
	553	CD	pos	207,3	160
	554	C	neg	0	<2,5
	555	C	neg	0,1	<2,5
	576	CD	pos	204,9	160
	579	CD	pos	316,5	320
	580	CD	pos	319	320
	581	CD	pos	372	320
	582	CD	pos	172,1	80
	591	CD	pos	300,7	1280
	594	CD	pos	282,7	160
	598	C	neg	0,1	<2,5
	599	CD	pos	23,9	10
	700	CD	pos	101	160
	714	C	neg	0,1	<2,5
	720	C	neg	0,1	<2,5
	743	C	neg	0,1	<2,5
	765	CD	pos	122,6	80
	766	CD	pos	157,9	1280
	774	CD	pos	153,9	320
	783	CD	pos	186,8	640
	784	CD	neg	36,9	20
	785	CD	pos	83,9	40
	786	CD	pos	151,5	40
	788	CD	pos	144,2	320
	789	CD	pos	121,5	80
	792	CD	pos	7,6	10

continued	795	C	weak pos	1,4	<2,5
	799	C	neg	0,1	<2,5
	808	CD	pos	67,5	40
	809	CD	pos	191,3	320
	810	CD	pos	152,6	320
	813	CD	pos	152,5	320
	828	C	neg	1,1	<2,5
	832	CD	pos	49,4	20
	844	CD	pos	45,7	20
	847	CD	pos	96,4	40
	852	CD	pos	136,3	40
	853	C	neg	1,2	<2,5
	854	C	neg	1	<2,5
	856	C	neg	1	<2,5
	862	CD	pos	112,2	40
	863	C	very weak pos	1,4	<2,5
	873	CD	pos	241,2	320

Series 2			
Sample	Celikey	Status	Biocard
528	0,2	C	-
531	0,1	C	-
540	0,1	C	-
541	0,8	C	-
545	0,7	C	-
705	0,1	C	-
793		C	-
798		C	-
800		C	-
815		C	-
830		C	-
831		C	-
849		C	-
851		C	-
505	22	CD	+
519	54,5	CD	+
536	27,9	CD	+
575	89,3	CD	++
577	23,6	CD	-
585	289,3	CD	++
586	55,2	CD	+
592	0,1	CD	+
609	193,5	CD	+
699	60,1	CD	+ weak
764	101	CD	++
781		CD	+
796		CD	++
833		CD	++

841		CD	++
846		CD	+
859	132	CD	++
876	100,4	CD	++
877	97,7	CD	+ weak
1086		CD	++
1091		CD	++
1092		CD	++
1094	94	CD	+
1095		CD	+
1097		CD	+
608	123,2	DH	+

5.3 Interfering substances

Effect of the rheumatoid factor was studied. The results are presented in a table below.

Sample	Result (Lot 4098)
Negative (221004) + Rf sera 675 (22.3.00)	-5 min, -(?) 10 min
Negative (221004)	-5 min, -(?) 10 min
Positive (201004, n:o 1) + Rf sera 675 (22.3.00)	+ 1.00 min
Positive (201004, n:o 1)	+ 1.00 min

Rheumatoid factor had no effect on the test result.

5.4 Reproducibility

5.4.1 In lot variation

In order to test in-lot variation three groups of tests were taken from lot 4098. These groups were tested with positive and negative samples. Three parallel tests / sample / group were run. The results are presented in a table below.

Sample	Lot / Group	Result
Negative	4098 / 1	-5 min / - (?) 10 min
Negative	4098 / 2	-5 min / - (?) 10 min
Negative	4098 / 3	-5 min / - (?) 10 min
Moderate Positive	4098 / 1	+ 1.00 min
Moderate Positive	4098 / 2	+ 1.00 min
Moderate Positive	4098 / 3	+ 1.00 min

No in-lot variation was detected.

5.4.2 Lot to lot variation

Lot-to-lot variation was studied with two lots. The results are presented in a table below.

Sample	Lot 4098	Lot 200904
Negative	-5 min / -(?) 10 min	-5 min / -(?) 10 min
Moderate positive	+ 50 s	+ 50 s
Strong positive	+ 40 s	+ 40 s

No lot-to-lot variation was detected.

5.4.3 Sample concentration

When only 5µl of moderate positive sample was added to the dilution buffer the test yielded correct results within reading time. If half full capillary is used the test yields correct results.

5.4.4 Amount of sample

Effect of the amount of the sample was studied. The results are presented in a table below.

Sample	Amount of sample	Result (lot 4098)
Moderate positive	2 drops	+ 50 s
Moderate positive	4 drops	+ 50 s
Moderate positive	6 drops	+ 50 s

Even if the amount of the sample is substantially lower or higher than the 3 drops mentioned in instructions for use, the test yields correct results.

5.5 Monitoring the effects of GFD

Suitability of Biocard Celiac Disease test in monitoring the effects of gluten free diet was studied at the Pediatric Research Centre and Dept. of Internal Medicine, University of Tampere. 11 blood samples of people on gluten free diet were studied with Biocard Celiac Disease test, EMA and Celikey.

Sample	Biocard	Celikey	EMA
1	neg	4,5	<5
2	neg	1,7	<5
3	neg	1,9	<5
4	neg	0,6	<5
5	neg	1,1	<5
6	pos	4,2	<5
7	neg	2,5	<5
8	pos	4,6	<5
9	neg	1,1	<5
10	neg	3	<5
11	neg	0,5	<5

All except three samples yielded negative results. The three positive samples were also close to borderline with Celikey. According to these results the Biocard Celiac Disease test is suitable for monitoring of the effects of gluten free diet

6. STORAGE AND SHELF LIFE

Shelf life is 18 months provided that the storage instructions (storage at RT, +2 ... +27 °C, for the test units and buffers) are followed.

7. STABILITY

7.1 Long term stability

No data of the long term stability of the Biocard Celiac Disease tests is currently available. Long term stability studies will be carried out as more lots are manufactured and as the first lots reach suitable age. At the moment the stability documentation relies on the data of the accelerated stability study

7.2 Transport simulations

The purpose of the transport simulation tests was to simulate the possible extreme conditions during the transportation. The tests were stored at +65 °C for 24, 48, 72 and 96 hours, at -20 °C for 24 and 48 hours and also first at -20 °C for 24 hours and after that at +65 °C for 24 and 48 hours. Tests were tempered at RT before opening the pouch and performing the test. The tests were performed and the results interpreted according to the instructions for use.

The results are presented in Table 3: Transport Simulations

Table 3: Transport Simulations
n = number of parallel tests

CAT. NO	3-027-000				LOT 200904			
Conditions	RT		+65 °C 48 h		+65 °C 72 h		+65 °C 96 h	
Sample	Result	n	Result	n	Result	n	Result	n
Negative 221004	-5 / -? 8	3	-5 / -? 8	3	-5 / -? 10	3	-5 / -10	3
Moderate positive 201004 no. 1	+ 50 s	3	+ 1.20	3	+1.20	3	+1.30	3
Strong Positive 201004 no. 4	+ 40 s	3	+ 1.00	3	+1.20	3	+1.10	3

CAT. NO	3-027-000				LOT 200904			
Conditions	- 20 °C 24 h		- 20 °C 48 h		- 20 °C 24 h +65 °C 24 h		- 20 °C 24 h +65 °C 48 h	
Sample	Result	n	Result	n	Result	n	Result	n
Negative 221004	-? 3-4/ +10	3	-? 4 / +10	3	-5 / -?10	3	-5 / -?10	3
Moderate positive 201004 no. 1	+50 s	3	+50 s	3	+ 1.20	3	+ 1.20	3
Strong Positive 201004 no. 4	+40 s	3	+40 s	3	+1.00	3	+1.20	3

The tests had kept their performance under simulated transport conditions and their sensitivity was unaltered. In the tests that were stored frozen (and not heat treated after that) the negative sample gave positive results. The lot 200904 is first validation lot and was adjusted slightly too sensitive.

7.3 Accelerated stability study

The tests were stored in +62 °C for 3, 5 and 7 days in order to simulate normal aging of the tests. Storage in +62 °C for 3, 5 and 7 days equals to storage in room temperature for 12, 18 and 24 months, respectively. The dilution buffer was stored under the same conditions as the tests. Tests were tempered at RT before opening the pouch and performing the test. The tests were performed and the results interpreted according to the instructions for use.

The results are presented in Table 4: Accelerated Stability

Table 4a: Accelerated Stability 3-028-000

n = number of parallel tests

CAT. NO 3-027-000			LOT 200904					
Conditions	RT		+62 °C 3 days*		+62 °C 5 days*		+62 °C 7 days*	
Sample	Result	n	Result	n	Result	n	Result	n
Negative 221004	-5 / -?8	3	-5 / -?7	3	-5 / -?7	3	-5 / -?7	3
Moderate positive 201004 no. 1	+50 s	3	+1.00	3	+1.00	3	+1.20	3
Strong Positive 201004 no. 4	+40 s	3	+50 s	3	+1.00	3	+1.00	3

Table 4b: Accelerated Stability 3-028-400

n = number of parallel tests

CAT. NO 3-028-400			LOT 5014					
conditions	RT		+62 °C 3 days		+62 °C 5 days		+62 °C 8 days	
Sample	Result	n	Result	n	Result	n	Result	n
436 celikey 1,3 EMA <2,5	-10	3	-10	3	-10	3	-10	3
579 Celikey 316,5 EMA 320	+ 1,30	3	+1,30	3	+1,50	3	+1,50	3
no 3, Unkari Celikey 24 ½ diluted (Celikey 12)	+2,00	3	+2,20	3	+2,30	3	+4,00 weak 5 clear 8	3
no 3, Unkari Celikey 24 ¼ diluted (Celikey 6)	+/- 5 +7	1	+? 7,30 +9	1	h7 +9	1	h?8 +10 weak	1
Test has kept (Y/N)	Y		Y		Y		Y	
	migration 1,40-1,50		migration 1,40-1,50		migration 1,50-2,00		migration 2,00-2,10	

According to the data obtained, the test keeps well for at least 7 days in the temperature of 62 °C, which equals to 24 months storage in room temperature. During this time the sensitivity of the test remains good and the migration of the test reagent does not significantly slow down. This leaves a safety margin of 6 months to the promised shelf-life of 18 months. The lot 200904 is first validation lot and was adjusted slightly too sensitive

7.4 In-use stability

The in-use stability of Celiac Disease tests is not necessary to study, as the test comprises of the pouched test devices only. Tests are meant to be used right after opening the pouch, which is mentioned in the instructions for use. Sample dilution buffer keeps well as can be seen in the results of accelerated stability study.

Stability of the diluted sample was studied. Samples were tested at 0,2,4 and 24 hours from the dilution. Samples were stored in room temperature. Results are presented in a table below.

Sample	Time (h)	Result
Negative 221004	0	-5 / -10
Negative 221004	2	-5 / -?10
Negative 221004	4	-5 / -?10
Negative 221004	24	-5 / -10
Moderate positive 201004 no. 1	0	+50 s
Moderate positive 201004 no. 1	2	+1.00
Moderate positive 201004 no. 1	4	+1.00
Moderate positive 201004 no. 1	24	+1.00

The samples may be stored in room temperature for 24 hours without losing the performance of the test

8. WARNINGS AND LIMITATIONS

- ❖ If the instructions for use are not followed in detail, outcome of the test may be false. Do not reuse tests or accessories.
- ❖ A final diagnosis should in principle only be made in conjunction with the clinical symptoms and further laboratory data.
- ❖ Use only whole blood samples, tTG derived from red blood cells is needed for the proper functioning of the test.
- ❖ General laboratory procedures and precautions shall be followed in the handling and disposal of samples and used materials.
- ❖ Do not use the test after the expiry date.
- ❖ Do not use the test if the aluminium sachet is damaged or broken accessories.
- ❖ After the aluminium sachet has been opened, the test should be carried out within the next 10 minutes.
- ❖ Do not mix reagents or tests from different lots.
- ❖ The sample buffer contains 0.09 % sodium azide. Avoid contact with the skin. Do not swallow!
- ❖ The incidence of IgA deficiency in CD patients is 2 – 3 %. Patients with IgA deficiency can not be diagnosed with Biocard™ Celiac Disease test.

9. REFERENCES

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Biocard™ Celiac Disease Test

A rapid, simple and reliable immunochromatographic test for the qualitative detection of anti-tTG antibodies from a fingertip blood sample.

CE *marked for professional and home use since July 2005*