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FUJIFILM

Code No. 995-60701 CE

μTASWako DCP

Symbols in Product Labeling

REF	Catalog number		Consult instructions for use
IVD	In vitro diagnostics medical device		Use by (last day of the month)
CONT.	Contents of kit		Systemic health hazard
AC.	Accessory		Manufacturer
Adaptor	Adaptor		Temperature limitation
Holder	Holder		
LOT	Batch code		
EC REP	Authorized Representative in the European Community		
BL	Blank		
CAL	Calibrator		
CONTROL	Control		
CONC.	Assigned value		

Intended use

The μTASWako DCP Immunological Test System is an *in vitro* device that consists of reagents used with the μTASWako i30 Immunoanalyzer to quantitatively measure, by immunochemical techniques, des-γ-carboxy-prothrombin (DCP) in human serum. The device is intended for *in vitro* diagnostic use as an aid in the risk assessment of patients with chronic liver disease for development of hepatocellular carcinoma (HCC) in conjunction with other laboratory findings, imaging studies and clinical assessment.

Summary and explanation of the test

Prothrombin is a vitamin K dependent blood coagulation factor that is formed in the liver. It contains 10 γ-carboxy-glutamic acid (Gla) residues on its amino-terminal domain, which are synthesized from glutamic acid (Glu) residues by vitamin K dependent γ-glutamyl carboxylase in a posttranslational process[1,2,3]. In the case of deficiency of vitamin K or the ingestion of vitamin K antagonists (Warfarin sodium), DCP is found in patients.

DCP was reported by Liebman et al., in 1984 as a specific tumor marker that increases in patients with hepatocellular carcinoma (HCC)[4]. A number of reports have shown elevation in serum DCP levels in patients with HCC and liver cirrhosis[5,6]. Also, DCP does not correlate with AFP and AFP-L3%. DCP and AFP-L3% are considered complementary assays for assessing the risk of developing HCC[7,8]. When used in combination, a greater number of patients at risk of developing HCC were identified resulting in more treatment options for a larger number of patients.[7,8]

Principle of the method

The μTASWako DCP assay is an easy-to use system with all reagents in a single cartridge and each assay performed on a single, disposable ''chip'' using microfluidic electrophoretic separation[9]. After placing sample, reagent cartridge, Wash Solution and Chip Cassette in the instrument, the buffers, antibody solutions and sample are automatically dispensed into appropriate chip wells. The sample and Dye-Fab' solution are dispensed and form the primary immunocomplex (Dye-Fab'－DCP) in the well. Each solution is loaded into the microfluidic channel by vacuum. Voltage is applied to the chip and DNA-Fab' moves to anode and is concentrated by isotachophoresis. The concentrated DNA-Fab' reacts with the primary immunocomplex and forms the secondary immunocomplex (Dye-Fab'－DCP －DNA-Fab'). The secondary immunocomplex is further concentrated during isotachophoresis to the anode and is thereby separated from unbound Dye-Fab'.

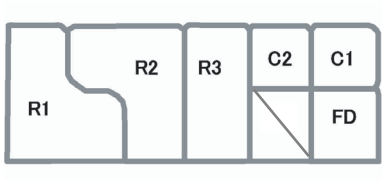
The concentrated secondary immunocomplexes are separated from unbound Dye-Fab' by capillary gel electrophoresis. The Dye-Fab'-labeled DCP is detected by laser-induced fluorescence. The concentration is proportional to the fluorescence. All reactions, separations and detection occur on a microfluidic chip.

Reagents

The μTASWako DCP kit contains a reagent cartridge and an adapter. The reagent cartridge contains the following buffers and antibodies for conducting 100 tests.

(1) Electrophoresis Buffer (R1) 5.4 mL
105 mmol/L Tris buffer, pH 7.9
(2) Electrophoresis Buffer (R2) 4.4 mL
42 mmol/L Tris buffer, pH 8.0
(3) Electrophoresis Buffer (R3) 2.6 mL
79 mmol/L Tris buffer, pH 7.1
(4) Labeled Antibody Solution (C1) 0.77 mL
80 mmol/L Good's buffer, pH 6.0
204 nmol/L Anion-conjugated anti human DCP antibody (mouse monoclonal antibody) (DNA-Fab' (DCP))
(5) Labeled Antibody Solution (C2) 0.92 mL
27 mmol/L Good's buffer, pH 5.8
707 nmol/L Fluorescent dye labeled anti human prothrombin antibody (mouse monoclonal antibody) (Dye-Fab' (prothrombin))
(6) Fluorescent Dye Solution (FD) 1.4 mL
50 mmol/L Good's buffer, pH 6.0

Store the reagent cartridge at 2－10℃ (Do not freeze).



Reagent allocation in the reagent cartridge

Accessory

Adapter (Reagent cartridge opener) 1 piece

Warning and precautions

Precautions for assay

(1) For *in vitro* diagnostic use.
(2) Not to be used internally in humans or animals.
(3) Store the reagents under the specified conditions. Do not use reagents past the expiration date stated on the reagent cartridge label or more than 30 days past the opening of the cartridge.

(4) The presence of precipitates in the reagents or values of control sera outside the manufacturer's acceptable range may be an indication of reagent degradation.
(5) Do not use the reagents described above for any purpose other than described herein.
(6) Do not use the reagents described above in any procedures other than those described herein. Performance cannot be guaranteed if the reagents are used in other procedures.
(7) Do not use reagents that were frozen. Such reagents may give false results.
(8) After opening reagents, place the reagents onto the instrument immediately. Once the reagents are opened, they must be stored on the μTASWako i30.
(9) Do not use the cartridge, the adapter and other materials in the kit for any purpose other than those described herein.
(10) Operate the instrument according to the Instruction Manual.
(11) Do not reuse chips or sample cups.
(12) Calibration material is sold separately. For the usage of calibration material, refer to its package insert.
(13) It is recommended that specimen collection be carried out in accordance with CLSI Document M29-A3 and other national safety regulations. No known test method can offer complete assurance that human blood samples will not transmit infection. Therefore, all blood derivatives should be considered potentially infectious.
(14) FDA UDI (Unique Device Identification) is on the box. Keep box until reagent is finished.

Precautions for protection from hazards

(1) If the reagents come in contact with mouth, eye, or skin, wash the exposed area immediately with plenty of water. Consult a physician if necessary.
(2) μTASWako Wash Solution is 0.5 mol/L NaOH, pH 11 or higher. If the reagent comes in contact with the mouth, eye, or skin, wash off immediately with plenty of water. Consult a physician if necessary.
(3) All serum samples, and apparatuses that may be contaminated with serum, should be treated with caution to avoid infection.

This product contains components classified as follows according to the European Regulation :

Hazard designation of product

Danger

Mixture containing :

5-Chloro-2-methyl-2H-isothiazol-3-one [EC No 247-500-7] and 2-Methyl-2H-isothiazol-3-one [EC No 220-239-6] (3:1), Heparin lithium salt.

Information pertaining to particular dangers for man and environment

Hazard statement

May cause an allergic skin reaction.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statement

Wear protective gloves/protective clothing/eye protection/face protection.
If exposed or concerned : Call a doctor.

Precautions for disposal

(1) Dispose of reagents according to your local or national regulations.
(2) Wear lab protective gear when disposing of the waste liquid, used chips and sample cups to avoid infection.

Limitations of the procedure

(1) Heterophilic antibodies in human serum can react with the immunoglobulins included in the assay components causing interference with *in vitro* immunoassays. Samples from patients routinely exposed to animals or animal serum products can demonstrate this type of interference potentially causing an anomalous result. The μTASWako DCP has been formulated to minimize the risk of the interference ; however, potential interactions between rare sera and ingredients can occur. For diagnostic purposes, the results obtained from this assay should always be used and interpreted in conjunction with the clinical examination, patient medical history, and other findings.
(2) It is recommended that this assay be used in conjunction with imaging studies for clinical diagnosis.
(3) DCP producing tumors other than HCC can show elevated values of DCP.
(4) Liver disease caused by other etiologies such as alcohol liver disease, hemachromatosis, Wilson's disease, autoimmune hepatitis and steatohepatitis have not been studied with this assay. The results obtained from this assay should always be used in combination with the clinical examination, patient medical history, and other findings.
(5) Medication containing vitamin K preparations may cause a negative bias on the DCP values.
(6) Medication containing vitamin K antagonist or antibiotic may cause a positive bias on the DCP values.

Instruments

The μTASWako DCP kit is designed to be used with the automated analyzer ''μTASWako i30''. Refer to the Instruction Manual for a description of instrument operation and specifications.

Specimen collection and preparation

(1) Use serum as a specimen.
(2) If immediate analysis is not possible, store specimen at −80℃. DCP concentration in serum is stable for 4 years frozen at −80℃. DCP in serum is stable up to 3 weeks at −20℃. DCP in serum is stable for 1 week at 4℃.

Procedure for μTASWako i30

Materials supplied

Refer to the section entitled ''Reagents''.

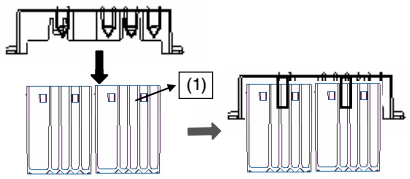
Materials required but not supplied (purchased separately)

μTASWako i30
μTASWako DCP Calibrator Set
μTASWako DCP Control L
μTASWako DCP Control H
μTASWako Wash Solution
μTASWako Chip Cassette
Sample Cup S
Pure Water

Reagent preparation

Reagents : Use as supplied. Unopened reagents are stable until expiration date printed on the label when stored at 2−10℃. Opened reagents can be used for 30 days on the μTASWako i30.

The unopened reagent cartridge is sealed with aluminum film. At the time of use, the adapter is placed on top of the reagent cartridge with the needle side downward then the aluminum seal is punctured by pressing the adapter through the cartridge completely. Lay the reagent cartridge on a flat surface when you open the reagent cartridge. Access holes are made by the needles and are used as passages for the pipetting probe. Seven access holes are observed on the reagent cartridge when above procedure is properly conducted. Do not remove the adapter after seal has been broken. Place the reagent cartridge onto the μTASWako i30 instrument according to the μTASWako i30 Instruction Manual. Store the reagent cartridge in the instrument.

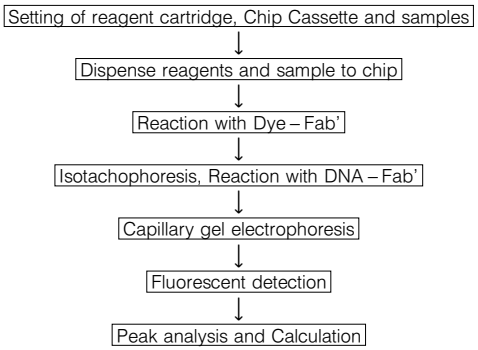


Set an adapter on a reagent cartridge and fit into socket (1).

Test procedure

Refer to ''μTASWako i30 Instruction Manual'' for the details of assay procedure.

Reaction Outline



Calibration

Calibration is required when reagent cartridge is opened. Calibration curve is automatically produced in the μTASWako i30 by plotting fluorescence intensity of the immunocomplex peak area vs. DCP concentrations of the calibrators. The calibration curve is stable for 30 days. For a detailed description on the calibration, refer to Section 4.2 ''Calibration Operation'' of the Instruction Manual.

Quality control

A quality control program is recommended for all clinical laboratories. Daily analysis using Wako's μTASWako DCP Controls L and H is recommended for monitoring the performance of the procedure. The values obtained for the controls should fall within 15% for DCP across upper reportable range (≥ 1 ng/mL) from the assigned values or within 20% for DCP across lower reportable range (< 1 ng/mL) from the assigned values.

Results

The final results are automatically calculated and printed out or sent out to the host computer. The results are reported as a concentration of DCP. Refer to Section 4.11 ''Checking Test Results'' of the Instruction Manual for the information on the calculation procedure and printout format.

Reportable range

The reportable range of DCP concentration is 0.1－950 ng/mL. When the value exceeds 950 ng/mL, marks H! or HH! appears on the screen of μTASWako i30 and on paper printout. Dilute the sample with ''Blank'' in the μTASWako Calibrator Set to 950 ng/mL or less, re-assay and multiply an obtained result by dilution factor. The dilution factors are approximately 20-fold for H! and 200-fold for HH!. Refer to Section 4.11.3 ''How to Check Printed Test Results'' of the Instruction Manual for detailed information on the marks.

Expected values

Less than 7.5 ng/mL (In-house data).

Performance characteristics

Dilution Recovery

The accuracy was demonstrated by the recovery study. The results of recovery (%) ranged from 94.0% to 111.6%.

Sample.	Sample Series A (ng/mL)	Sample Series B (ng/mL)	After mixed Sample Series (A:B=9:1 mixed) Expected Value (ng/mL)	Obtained Value (ng/mL)	Recovery (%)
1	0.20	2.10	0.39	0.38 0.38	97.4 97.4
2	0.20	9.80	1.16	1.09 1.12	94.0 96.6
3	0.20	73.10	7.49	7.15 7.18	95.5 95.9
4	0.20	893.90	89.57	94.87 95.82	105.9 107.0
5	0.20	3639.00	364.08	374.13 376.92	102.8 103.5
6	7.80	9.80	8.00	8.12 8.17	101.5 102.1
7	7.80	73.10	14.33	14.13 13.82	98.6 96.4
8	7.80	893.90	96.41	96.87 99.88	100.5 103.6
9	7.80	3639.00	370.92	392.40 391.92	105.8 105.7
10	7.80	7565.60	763.58	782.87 809.56	102.5 106.0
11	100.84	893.90	180.15	183.26 181.28	101.7 100.6
12	100.84	3639.00	454.66	438.91 430.21	96.5 94.6
13	100.84	7565.60	847.32	924.94 945.39	109.2 111.6
14	307.19	893.90	365.86	357.92 362.80	97.8 99.2
15	307.19	1866.60	463.13	467.82 481.47	101.0 104.0
16	307.19	3639.00	640.37	667.58 671.57	104.2 104.9

Precision

[Within-run precision]

Within-run precision studies were performed for the DCP assay over the reportable range using 4 serum samples and 2 levels of controls. The results of CV% for each sample measured in 21 replicates ranged from 1.1% to 6.7%. This study was conducted in accordance with CLSI EP5-A2.

No.	Replicate	Mean (ng/mL)	SD (ng/mL)	CV (%)
Serum 1	21	0.18	0.012	6.7
Serum 2	21	1.05	0.017	1.6
Serum 3	21	6.70	0.076	1.1
Serum 4	21	914.98	14.039	1.5
Control L	21	1.00	0.018	1.8
Control H	21	22.63	0.256	1.1

[Total precision]

Total precision studies were performed for the DCP assay over the reportable range using 7 pooled human serum samples and 2 levels of controls. Three samples (5, 6 and 7) were pooled human serum samples near the clinical decision point and were prepared without spiking with analyte. The results of CV%, measured over 21 days, for all samples ranged from 1.3% to 7.9%. This study was conducted in accordance with CLSI EP5-A2.

No.	Number of assay days	Mean (ng/mL)	ST (ng/mL)	CV (%)
Serum 1	21	0.19	0.015	7.9
Serum 2	21	1.04	0.035	3.4
Serum 3	21	6.70	0.135	2.0
Serum 4	21	917.94	14.847	1.6
Serum 5	21	6.91	0.24	3.5
Serum 6	21	7.22	0.21	2.9
Serum 7	21	7.57	0.23	3.0
Control L	21	1.05	0.024	2.3
Control H	21	22.74	0.303	1.3

Linearity

The assay was verified to be linear for the reportable ranges of 0.1－950 ng/mL according to CLSI EP6-A.

Limit of Detection

The limit of detection (LoD) study was carried out consistent with CLSI EP17-A ''Protocols for Determination of Limits of Detection and Limits of Quantitation ; Approved Guideline'' (Vol. 24, No. 34, 2004). From the results, the LoD for DCP was found by calculation using the equation given in CLSI EP-17A (section 4.3.2) because data distributions were Gaussian. The LoD, the point at which the analytes are distinguished from blank, was found to be 0.042 ng/mL.

Interference testing

Potential interfering substances listed below were evaluated by determining recovery in the presence of known amounts of these substances. No significant effect from the potential interferents occurred. This study was conducted in accordance with CLSI EP7-A.

①Hemoglobin

Hemoglobin	(mg/dL)	0	193.3	386.6	579.9	773.2	966.5
DCP	(ng/mL)	4.81	4.83	4.84	4.88	4.82	5.12
	Recovery (%)	100.0	100.4	100.6	101.5	100.2	106.4

②Bilirubin

Bilirubin	(mg/dL)	0	7.5	15.0	22.5	30.0	37.5	74.9
DCP	(ng/mL)	5.00	4.97	4.83	4.75	4.66	4.66	4.70
	Recovery (%)	100.0	99.4	96.6	95.0	93.2	93.2	94.0

③Conjugated bilirubin

Conjugated bilirubin	(mg/dL)	0	8.4	16.8	25.3	33.7	42.1	84.2
DCP	(ng/mL)	5.36	5.25	5.10	5.06	5.07	4.73	4.65
	Recovery (%)	100.0	97.9	95.1	94.4	94.6	88.2	86.8

④Triglycerides

Triglycerides	(mg/dL)	0	45.2	90.4	135.6	180.8	226.0	452.0
DCP	(ng/mL)	5.83	5.91	5.87	5.91	5.81	5.82	5.99
	Recovery (%)	100.0	101.4	100.7	101.4	99.7	99.8	102.7

⑤Ascorbic acid

Ascorbic acid	(mg/dL)	0	10	20	30	40	50
DCP	(ng/mL)	6.42	6.70	6.60	6.81	7.01	6.98
	Recovery (%)	100.0	104.4	102.8	106.1	109.2	108.7

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⑥Rheumatoid factor

Rheumatoid factor	(IU/mL)	0	100	200	300	400	500
DCP	(ng/mL)	6.15	6.16	6.32	6.21	6.25	6.25
	Recovery (%)	100.0	100.2	102.8	101.0	101.6	101.6

⑦Acetaminophen

Acetaminophen	(mg/dL)	0	4	8	12	16	20
DCP	(ng/mL)	5.03	5.05	4.98	5.04	4.92	5.05
	Recovery (%)	100.0	100.4	99.0	100.2	97.8	100.4

⑧Ibuprofen

Ibuprofen	(mg/dL)	0	10	20	30	40	50
DCP	(ng/mL)	6.36	6.09	6.37	6.80	6.85	6.79
	Recovery (%)	100.0	95.8	100.2	106.9	107.7	106.8

⑨Acetylsalicylic acid

Acetylsalicylic acid	(mg/dL)	0	10	20	30	40	50
DCP	(ng/mL)	6.33	6.15	6.37	6.28	6.38	6.48
	Recovery (%)	100.0	97.2	100.6	99.2	100.8	102.4

⑩Vitamin B1

Vitamin B1	(mg/dL)	0	10	20	30	40	50
DCP	(ng/mL)	5.67	5.63	5.53	5.66	5.65	5.67
	Recovery (%)	100.0	99.3	97.5	99.8	99.6	100.0

⑪Vitamin B6

Vitamin B6	(mg/dL)	0	10	20	30	40	50
DCP	(ng/mL)	5.66	5.59	5.61	5.58	5.54	5.61
	Recovery (%)	100.0	98.8	99.1	98.6	97.9	99.1

⑫Vitamin B12

Vitamin B12	(mg/dL)	0	10	20	30	40	50
DCP	(ng/mL)	5.86	5.92	5.86	5.87	5.85	5.80
	Recovery (%)	100.0	101.0	100.0	100.2	99.8	99.0

⑬Interferon α

Interferon α	(IU/mL)	0	600	1200	1800	2400	3000
DCP	(ng/mL)	6.22	6.43	6.31	6.35	6.36	6.31
	Recovery (%)	100.0	103.4	101.4	102.1	102.3	101.4

⑭Interferon β

Interferon β	(IU/mL)	0	600	1200	1800	2400	3000
DCP	(ng/mL)	6.14	6.23	6.08	6.16	6.17	6.34
	Recovery (%)	100.0	101.5	99.0	100.3	100.5	103.3

⑮Interferon γ

Interferon γ	(JRU/mL)	0	600	1200	1800	2400	3000
DCP	(ng/mL)	6.13	6.22	6.34	6.11	6.01	6.34
	Recovery (%)	100.0	101.5	103.4	99.7	98.0	103.4

Interference testing with high concentration of DCP samples.

Potential interfering substances listed below were evaluated by determining recovery in the presence of known amounts of these substances. No significant effect from the potential interferents occurred. This study was conducted in accordance with CLSI EP7-A.

①Hemoglobin

Hemoglobin	(mg/dL)	0	1060
DCP	(ng/mL)	125.9	124.3
	Recovery (%)	100.0	98.7

②Bilirubin

Bilirubin	(mg/dL)	0	75
DCP	(ng/mL)	108.2	118.4
	Recovery (%)	100.0	109.5

③Conjugated bilirubin

Conjugated bilirubin	(mg/dL)	0	80
DCP	(ng/mL)	106.9	101.7
	Recovery (%)	100.0	95.2

④Triglycerides

Triglycerides	(mg/dL)	0	452
DCP	(ng/mL)	135.4	135.3
	Recovery (%)	100.0	100.0

⑤Rheumatoid factor

Rheumatoid factor	(IU/mL)	0	500
DCP	(ng/mL)	159.9	161.7
	Recovery (%)	100.0	101.1

Correlation

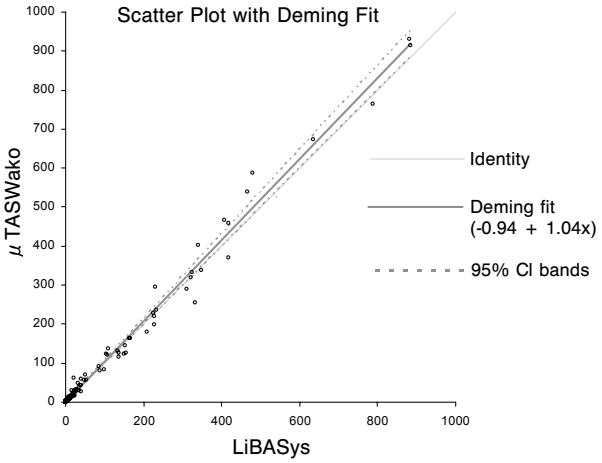
A comparison of the μTASWako DCP to a similar DCP assay (LBA DCP) was performed using μTASWako i30 and LiBASys, respectively. A comparison study of 200 samples from 100 patients was conducted by both instruments. In addition, 20 serum samples spiked with DCP to cover the upper part of the reportable range were studied.

Deming analysis shows acceptable correlation with and without spiked samples, as demonstrated in the correlation graphs given herein. Correlation #1 shows the Deming regression analysis of DCP values, with spiked samples, run on μTASWako i30 and LiBASys. Correlation #2 shows the Deming regression analysis of DCP values, without spiked samples.

Additionally, a calculation of an estimate of agreement is given to describe how often the μTASWako DCP test agrees with the comparative test, DCP assay (LBA DCP). Using the data from correlation #2 and the clinical cut-off value of 7.5 ng/mL, a concordance rate (overall agreement) of 95.5% is found.

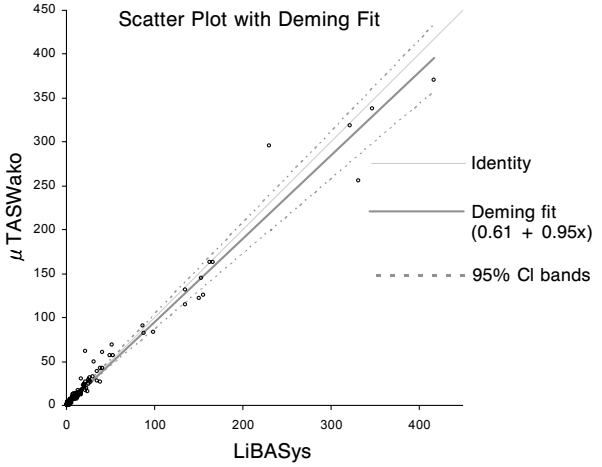
Correlation #1

Number	220	
Intercept	−0.94	95% CI (−2.09 to 0.21)
Slope	1.04	95% CI (1.00 to 1.08)



Correlation #2

Number	200	
Intercept	0.61	95% CI (−0.50 to 1.72)
Slope	0.95	95% CI (0.85 to 1.04)



DCP 2x2 Agreement

		LiBASys	
		≥ 7.5 ng/mL	< 7.5 ng/mL
μTASWako i30	≥ 7.5 ng/mL	77 (38.5%)	5 (2.5%)
	< 7.5 ng/mL	4 (2.0%)	114 (57.0%)

Percent positive agreement = 95.1%
Percent negative agreement = 95.8%
Overall agreement = 95.5%

Clinical Information Collected with LiBASys

Longitudinal data were collected on 441 subjects with liver disease from seven clinical sites. The study subjects consisted of 324 males and 117 females, with an average age of 52.6 years and ranged from 40 to 70 years. Serum was collected at an average interval of 138 days.

The study subjects were categorized into three groups based on biopsy, explanted liver histology and imaging results. Group A patients developed confirmed HCC during study and with lesions of at least 0.5 cm in diameter. Group B patients were suspected of possible HCC with lesions at least 0.3 cm in diameter and high DCP results. Group C patients did not have HCC. The risk of developing HCC among patients with an elevation of DCP at or above 7.5 ng/mL, and among patients without such an elevation is calculated, along with their 95% confidence interval using DCP results from Group A and Group C. The risk of developing HCC with an elevated DCP test result is 36.5%. The risk of developing HCC with a negative DCP test result is 7.6%. Their ratio is 4.8, indicating a 4.8 fold increase of developing HCC given an elevated DCP test result.

Group		A	C	Total	B
		HCC	No HCC		Suspicious*
DCP	≥7.5 ng/mL	19	33	52	7
	<7.5 ng/mL	20	244	264	64
Total		39	277	316	71

Relative risk : 4.8 (95% C.I. : 2.8–8.4)
Risk of HCC given DCP positive : 36.5% (95% C.I. : 23.5%–49.6%)
Risk of HCC given DCP negative : 7.6% (95% C.I. : 4.4%–10.8%)

*The patients categorized as ''Suspicious'' (far right column) were treated as a separate study group because no definitive diagnosis could be obtained from the physicians. However, for demonstrative purposes, these patients were included in the analysis to illustrate the effect of this regrouping on the relative risk calculations. The worst case and the best case scenarios are shown in the following two tables.

Best case scenario		HCC	No HCC	Total
DCP	≥7.5 ng/mL	19+7=26	33	59
	<7.5 ng/mL	20	244+64=308	328
Total		46	341	387

Relative risk : 7.2 (95% C.I. : 4.3–12.1)
Risk of HCC given DCP positive : 44.1% (95% C.I. : 31.4%–56.7%)
Risk of HCC given DCP negative : 6.1% (95% C.I. : 3.5%–8.7%)

Worst case scenario		HCC	No HCC	Total
DCP	≥7.5 ng/mL	19	33+7=40	59
	<7.5 ng/mL	20+64=84	244	328
Total		103	284	387

Relative risk : 1.3 (95% C.I. : 0.8–1.9)
Risk of HCC given DCP positive : 32.2% (95% C.I. : 20.3%–44.1%)
Risk of HCC given DCP negative : 25.6% (95% C.I. : 20.9%–30.3%)

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Ordering information

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Revision Date ; Nov. 7, 2019

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