

ΤΜΗΜΑ ΓΕΝΕΤΙΚΗΣ ΚΑΙ ΜΟΡΙΑΚΗΣ ΒΙΟΛΟΓΙΑΣ
ΕΛΕΓΧΟΣ ΠΟΛΥΓΟΝΙΔΙΑΚΗΣ ΕΚΦΡΑΣΗΣ ENDPREDICT (Κωδ. Εξέτασης 34171)

CSVD

Αριθμός Πιστοποιητικού Νο: 356-05, ΕΛΟΤ EN ISO 15189:2012

Ημερομηνία Απάντησης: 16-11-2021
Ονοματεπώνυμο:
Κωδικός Δείγματος:
Έτος Γεννήσεως:
Βιολογικό Δείγμα: **Κύβος Παραφίνης (Προσκομισθέν δείγμα)**
Ημερομηνία Παραλαβής Δείγματος: 15-11-2021
Κωδικός Κύβου προς εξέταση: 20851/21
Παθολογοανατομική εκτίμηση κύβου εξέτασης: >30% περιεκτικότητα σε καρκινικά κύτταρα

ΑΠΟΤΕΛΕΣΜΑ:

EP Score: 9.2	Tumor Size (Μέγεθος όγκου): pT1c	Nodal status (Αριθμός διηθημένων λεμφαδένων): pN0
EPclin Score: 3.9		EPclin Class: High Risk
Αρχικό πλάνο θεραπείας:	10ετής πιθανότητα μετάστασης (με 5ετή ενδοκρινική θεραπεία μόνο)	17%
	10ετές εκτιμώμενο απόλυτο όφελος χημειοθεραπείας	7%
Μακροπρόθεσμο πλάνο θεραπείας	5ετής – 15ετής πιθανότητα μετάστασης(χωρίς εμφάνιση μετάστασης μετά την 5ετία με ενδοκρινική θεραπεία μόνο χωρίς επικουρική χημειοθεραπεία)	13%

Ο EPclin αλγόριθμος λαμβάνει υπόψη του, το μέγεθος του όγκου και τον αριθμό των διηθημένων λεμφαδένων, για να βγάλει την προγνωστική τιμή και να υπολογίσει την πιθανότητα μετάστασης σε διάστημα [(10 ετών) – (5-15ετών)] σε ασθενείς που λαμβάνουν ορμονοθεραπεία για 5 έτη, καθώς επίσης υπολογίζει και το απόλυτο όφελος της χημειοθεραπείας στην 10ετία.

ΜΕΘΟΔΟΛΟΓΙΑ

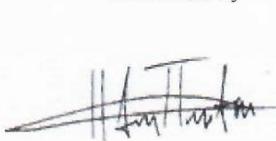
Το παραληφθέν δείγμα ιστού, μονιμοποιημένου σε παραφίνη (τομές 5mm έως 10mm, ανάλογα από την παθολογοανατομική εκτίμηση της ποσότητας των καρκινικών κυττάρων, η οποία πρέπει να είναι βάση των οδηγιών >30% σε καρκινικά κύτταρα), υπέστη διαδικασία απομόνωσης γενετικού υλικού RNA. Ποσότητα από το εκχυλισμένο γενετικό υλικό χρησιμοποιήθηκε προς πολυγονιδιακή εκλεκτική ενίσχυση αντίστροφης μεταγραφής της αλυσιδωτής αντίδρασης πολυμεράσης πραγματικού χρόνου (RT Real Time PCR), με χρήση αντιδραστηρίων SIVIDON DIAGNOSTICS-MYRIAD GENETICS, στον θερμοκυκλοποιητή VERSANT KPCR. Τα raw data της αντίδρασης επεξεργάζονται στο Endopredict Report generator CE πρόγραμμα της SIVIDON DIAGNOSTICS-MYRIAD GENETICS και εκτυπώνονται τα αποτελέσματα της εξέτασης με πλήρη ενημέρωση των παραμέτρων και των μαρτύρων όπως έχει σχεδιαστεί από την κατασκευάστρια εταιρεία.

Επιστημονικός Υπεύθυνος



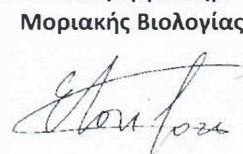
Χρήστος Κίττας
Καθηγητής,
Ιατρός Παθολογοανατόμος
Α.Μ.Κ.Α: 25084502878

Ο εκτελέσας



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Σελ. 1/1

Η αξιολόγηση των αποτελεσμάτων γίνεται από τον θεράποντα ιατρό με συνεκτίμηση της κλινικής εικόνας και του ιστορικού του ασθενούς. Δεν συνιστάται η αναπαραγωγή μεμονωμένων αποτελεσμάτων, αλλά όλης της έκθεσης.

Result Report

Created by: EndoPredict Report Generator®




EndoPredict®

Breast Cancer Prognostic Test

Sample name:

Note:

Report created: 2021-11-16 08:51 AM (CET)

12-Gene Molecular Score:	9.2	Result	
		EPclin Risk Score	EPclin Risk Class
Tumor size:	pT1c (>1cm but ≤2cm)	3.9	High
Nodal status:	all lymph nodes negative		

EndoPredict® Breast Cancer Prognostic Test is a gene expression assay for patients with ER-positive, HER2-negative early-stage breast cancer. From this genomic analysis, a 12-Gene Molecular Score is assigned. This score is combined with the two patient-specific factors, tumor size and nodal status, to calculate the EPclin Risk Score, from which the risks of distant recurrence (0 to 10 years and 5 to 15 years) with 5 years of adjuvant endocrine therapy alone and the estimated absolute benefit of chemotherapy (at 10 years) are determined. The EPclin Risk Class refers to the risk of distant recurrence with 5 years of adjuvant endocrine therapy alone.

Initial treatment planning	Likelihood of distant recurrence within years 0-10 For patients treated with 5 years of endocrine therapy alone	17%
	Absolute chemotherapy benefit at 10 years	7%
Long-term treatment planning	Likelihood of late distant recurrence within years 5-15 For patients with no recurrence after 5 years of endocrine therapy alone	13%

Authorized signature

Result Report

Created by: EndoPredict Report Generator®



EndoPredict®

Breast Cancer Prognostic Test

Sample name:

Note:

Report created: 2021-11-16 08:51 AM (CET)

12-Gene Molecular Score:



9.2

Result

Tumor size:

pT1c (>1cm but ≤2cm)

Nodal status:

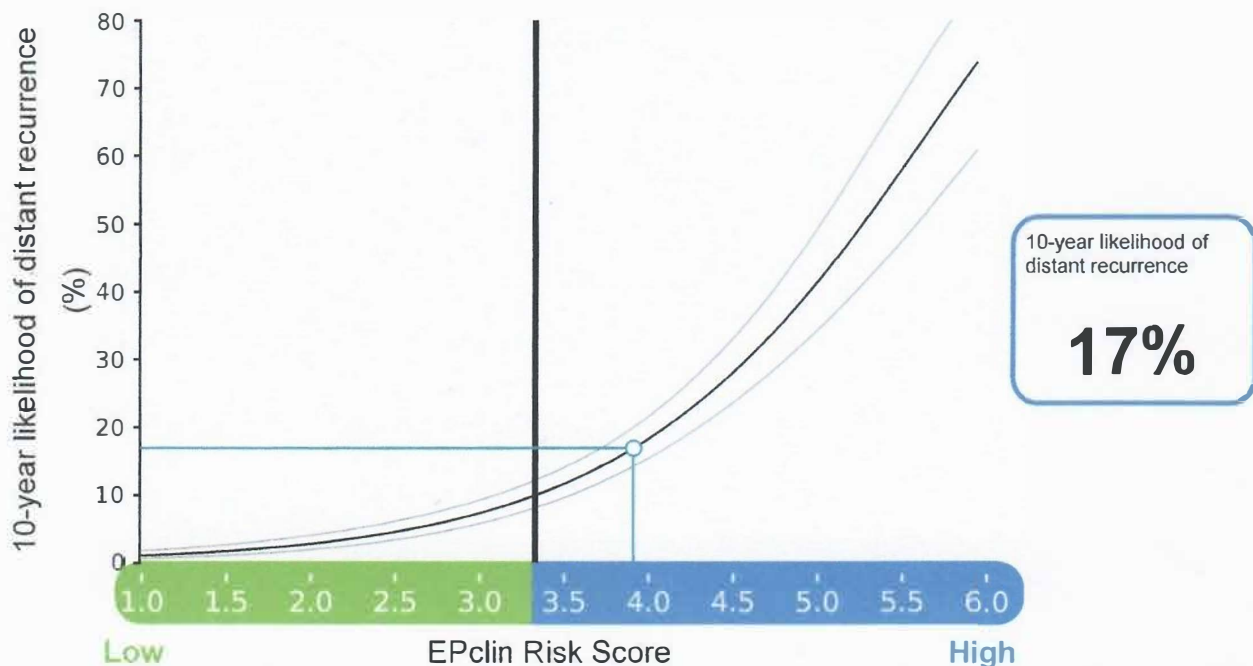
all lymph nodes
negative

EPclin
Risk Score
3.9

EPclin
Risk Class
High

Likelihood of distant recurrence within years 0-10

For patients treated with 5 years of endocrine therapy alone



Based on the clinical validation of the EndoPredict test in the ABCSG-6/-8 trials with 1,702 patients, the chart displays the relation of the EPclin Risk Score and estimated 10-year likelihood of distant recurrence after initial diagnosis for patients treated with 5 years of adjuvant endocrine therapy alone (Filipits et al., 2011).

Result interpretation: Based on the validation trials ABCSG-6/-8 and considering the two patient-specific factors tumor size and nodal status, an EPclin Risk Score of 3.9 is categorized as High and is associated with a 17% (95% CI: 14.3% - 20.1%) 10-year estimated likelihood of experiencing a distant recurrence when treated with 5 years of endocrine therapy alone.

Result Report

Created by: EndoPredict Report Generator®



EndoPredict®

Breast Cancer Prognostic Test

Sample name:

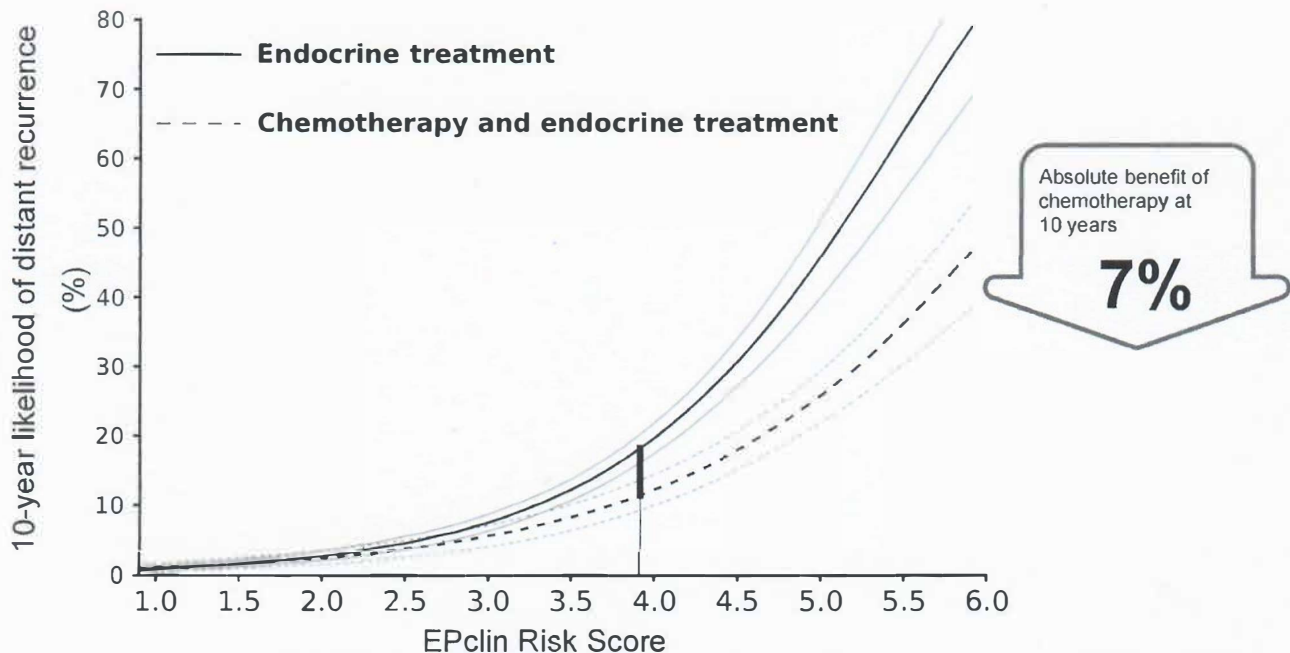
Note:

Report created: 2021-11-16 08:51 AM (CET)

12-Gene Molecular Score:	9.2	Result	
Tumor size:	pT1c (>1cm but ≤2cm)	EPclin Risk Score 3.9	EPclin Risk Class High
Nodal status:	all lymph nodes negative		

Absolute chemotherapy benefit at 10 years

5 years endocrine therapy alone versus chemotherapy plus 5 years endocrine therapy



Based on the clinical validation of the EndoPredict test in the ABCSG-6, ABCSG-8, TransATAC, GEICAM/2003-02, and GEICAM/9906 trials with 3,746 patients, the chart displays the relation of the EPclin Risk Score and 10-year estimated likelihood of distant recurrence after initial diagnosis for patients treated with 5 years of adjuvant endocrine therapy alone (ABCSG-6, ABCSG-8, TransATAC) or for patients treated with adjuvant chemotherapy (fluorouracil, epirubicin, and cyclophosphamide (FEC), or with FEC followed by weekly paclitaxel (FEC-P), or with fluorouracil, doxorubicin, and cyclophosphamide (FAC), or with FAC followed by weekly paclitaxel) in combination with 5 years of adjuvant endocrine therapy, respectively (GEICAM/2003-02, GEICAM/9906)(Sestak et al., 2019).

Result interpretation: Based on the validation trials ABCSG-6, ABCSG-8, TransATAC, GEICAM/2003-02, and GEICAM/9906 and considering the two patient-specific factors tumor size and nodal status, at 10 years an EPclin Risk Score of 3.9 is associated with an estimated 7% absolute benefit from chemotherapy, when used in combination with endocrine treatment, compared to endocrine treatment alone.

Result Report

Created by: EndoPredict Report Generator®



EndoPredict®
Breast Cancer Prognostic Test

Sample name:

Note:

Report created: 2021-11-16 08:51 AM (CET)

12-Gene Molecular Score:

9.2

0 5 10 15

Tumor size:

pT1c (>1cm but ≤2cm)

Nodal status:

all lymph nodes
negative

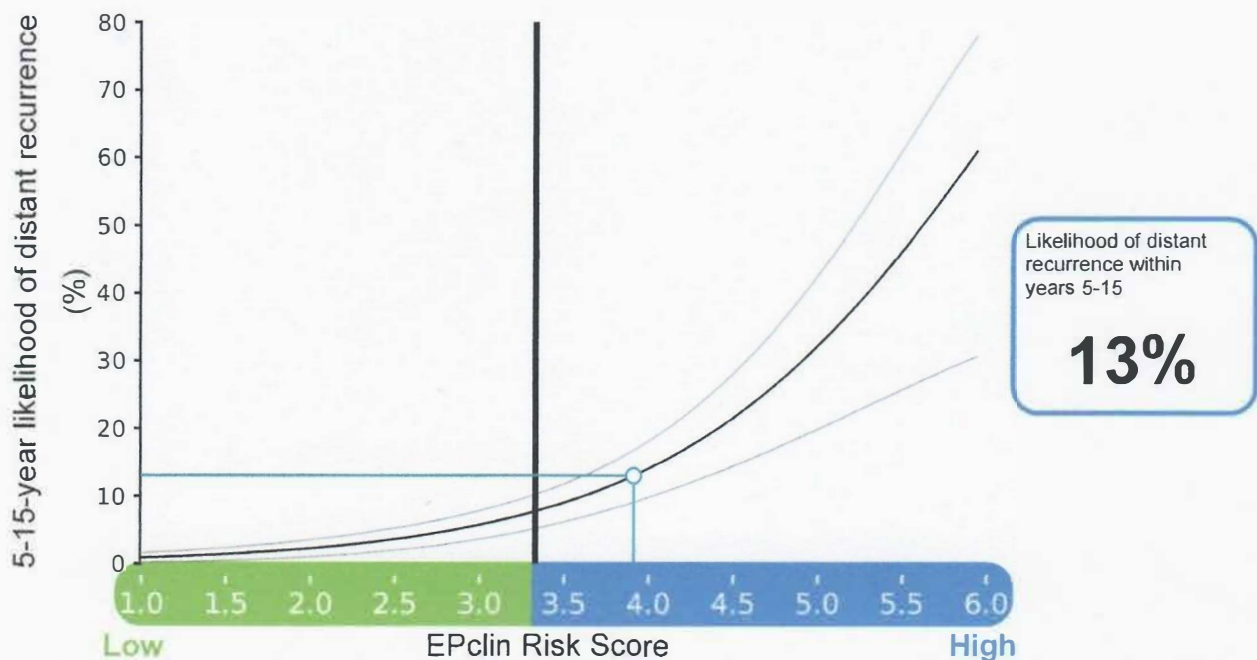
Result

EPclin
Risk Score
3.9

EPclin
Risk Class
High

Likelihood of late distant recurrence within years 5-15

For patients with no recurrence after 5 years of endocrine therapy alone



Based on the clinical validation of the EndoPredict test in the ABCSG-6/-8 trials with 1,386 patients, the chart displays the relation of the EPclin Risk Score and 5-15-year estimated likelihood of distant recurrence after initial diagnosis for patients who are distant recurrence-free after 5 years of endocrine therapy alone and who do not receive extended endocrine therapy (Filipits et al., 2019).

Result interpretation: Based on the validation trial ABCSG-6/-8 and considering the two patient-specific factors tumor size and nodal status, an EPclin Risk Score of 3.9 is categorized as High and is associated with a 13% (95% CI: 9.1% - 16.8%) estimated likelihood of experiencing a distant recurrence within 5-15 years of diagnosis. Estimates of distant recurrence at 15 years apply to patients who are distant recurrence-free after 5 years of endocrine therapy alone and who do not receive extended endocrine therapy.

Result Report

Created by: EndoPredict Report Generator®



EndoPredict®

Breast Cancer Prognostic Test

Sample name:

Note:

Report created: 2021-11-16 08:51 AM (CET)

Description of EndoPredict: Analysis is performed on RNA extracted from FFPE blocks of the primary resected tumor. This test utilizes quantitative RT-PCR to measure the expression of eight target genes, three normalization genes, and one control gene, from which a 12-Gene Molecular Score is calculated¹. The molecular data is then combined with patient-specific clinicopathologic features (tumor size and lymph node status) to generate an EPclin Risk Score, which is a more significant predictor of the 10-year risk of metastatic disease¹. The threshold differentiating "Low" and "High" risk EPclin Risk Scores was established during assay development and is pre-specified during testing of current samples.

Note: Therapeutic decisions made subsequent to testing should take into account all relevant patient-specific clinical parameters, including patient's age, overall health, etc. and the likelihood of severe side effects from chemotherapy. The EndoPredict test result has not been validated for patients treated prior to resection with systemic therapy (e.g. Chemotherapie or endocrine therapy) or radiation therapy or patients that do not meet the current inclusion criteria.

Risks may differ for individuals who do not meet the inclusion criteria. Reported recurrence risks assume that this patient will receive 5 years endocrine therapy (with or without localized radiation therapy) alone. If adjuvant chemotherapy is administered after resection, the reported 10-year likelihood of distant recurrence and the likelihood of late recurrence (years 5-15) will not reflect actual patient risks. This test result is invalid if the patient has already experienced a distant recurrence.

For more details on the test and the inclusion criteria please refer to the product manual.

Please contact Myriad Professional Support at EPsupport@myriadgenetics.eu to discuss questions regarding this result.

References:

1. Filipits M, et al. A new molecular predictor of distant recurrence in ER-positive, HER2-negative breast cancer adds independent information to conventional clinical risk factors. Clin Cancer Res. 2011;17(18):6012-6020.
2. Sestak I, et al. Prediction of chemotherapy benefit by EndoPredict in patients with breast cancer who received adjuvant endocrine therapy plus chemotherapy or endocrine therapy alone. Breast Cancer Res Treat. 2019; 176(2):377-386.
3. Filipits M, et al. Prediction of Distant Recurrence using EndoPredict among Women with ER+, HER2- Node-Positive and Node-Negative Breast Cancer Treated with Endocrine Therapy Only. Clin Cancer Res. 2019; 25(13):3865-3872.

Summary Report

Created by: EndoPredict Report Generator®



EndoPredict

Breast Cancer Prognostic Test

Sample name:

Note:

User name:

Report created: 2021-11-16 08:48 AM (CET)

Test result

The test result is valid.

EPclin Risk Score: 3.9

EPclin Risk Class: High

Additional information

12-Gene Molecular Score: 9.2

Tumor size: pT1c

Nodal status: Negative



Tumor size

		pT1ab (≤1cm)	pT1c (>1cm but ≤2cm)	pT2 (>2cm but ≤5cm)	pT3 (>5cm)
Nodal status	all lymph nodes negative	EPclin: 3.6 High DRR: 12% (95% CI: 10% - 15%) CB: 4% (95% CI: 5% - 4%)	EPclin: 3.9 High DRR: 17% (95% CI: 14% - 20%) CB: 7% (95% CI: 7% - 7%)	EPclin: 4.3 High DRR: 23% (95% CI: 19% - 27%) CB: 10% (95% CI: 10% - 10%)	EPclin: 4.6 High DRR: 31% (95% CI: 26% - 36%) CB: 14% (95% CI: 13% - 15%)
	1 to 3 positive lymph nodes (incl. pN1mic)	EPclin: 4.2 High DRR: 22% (95% CI: 19% - 26%) CB: 9% (95% CI: 9% - 9%)	EPclin: 4.5 High DRR: 29% (95% CI: 25% - 35%) CB: 14% (95% CI: 13% - 14%)	EPclin: 4.9 High DRR: 39% (95% CI: 32% - 46%) CB: 19% (95% CI: 17% - 20%)	EPclin: 5.2 High DRR: 50% (95% CI: 41% - 59%) CB: 24% (95% CI: 22% - 26%)
	4 to 10 positive lymph nodes	EPclin: 4.8 High DRR: 37% (95% CI: 31% - 44%) CB: 18% (95% CI: 16% - 19%)	EPclin: 5.2 High DRR: 48% (95% CI: 39% - 57%) CB: 23% (95% CI: 21% - 25%)	EPclin: 5.5 High DRR: 60% (95% CI: 49% - 71%) CB: 29% (95% CI: 26% - 30%)	EPclin: 5.9 High DRR: 72% (95% CI: 59% - 84%) CB: 32% (95% CI: 30% - 32%)
	more than 10 positive lymph nodes	EPclin: 5.5 High DRR: 57% (95% CI: 47% - 68%) CB: 28% (95% CI: 25% - 29%)	EPclin: 5.8 High DRR: 70% (95% CI: 57% - 82%) CB: 32% (95% CI: 30% - 32%)	EPclin: 6.2 High DRR: 82% (95% CI: 68% - 92%) CB: 33% (95% CI: 33% - 30%)	EPclin: 6.5 High DRR: 91% (95% CI: 78% - 97%) CB: 30% (95% CI: 34% - 24%)
		EPclin: 3.6 High DRR: 12% (95% CI: 10% - 15%) CB: 4% (95% CI: 5% - 4%)	EPclin: 3.9 High DRR: 17% (95% CI: 14% - 20%) CB: 7% (95% CI: 7% - 7%)	EPclin: 4.3 High DRR: 23% (95% CI: 19% - 27%) CB: 10% (95% CI: 10% - 10%)	EPclin: 4.6 High DRR: 31% (95% CI: 26% - 36%) CB: 14% (95% CI: 13% - 15%)

DRR: Distant recurrence risk within years 0-10

CB: Absolute chemotherapy benefit at 10 years

Authorized signature