

myStage Dx
BREAST CANCER TEST RESULT

PATIENT

Patient Name	Jane Doe
Date of Birth	19 Aug. 1982
Sex at Birth	Female
Patient ID	NI64316009

ORDER

Date	16 Sep. 2024
Physician	Dr. Joe Schmoe
Institution	Hospital AB
Order ID	MSDX-129472

BASELINE CHARACTERISTICS

PR-positive cells	17%
Tumor Size	3mm
Grade	2
Positive Lymph Nodes	2

LOW RISK

OBSERVED GROUP AVERAGE DISTANT
RECURRENCE RATE

AT 5 YEARS

1.8% 95% CI
(0.7%, 7.1%)

AT 9 YEARS

4.6% 95% CI
(2.0%, 10.1%)

INTENDED PURPOSE

myStage Dx is an automated software intended for use in the prognosis by measuring the risk of relapse for patients with HR+/HER2- breast cancer that have undergone surgery. The result of myStage Dx is considered as qualitative.

This software is intended to be used in hospitals/health institutions by physicians specializing in oncology.

This medical device software uses clinicopathologic data and H&E (Hematoxylin and eosin) histological slides extracted from formalin fixed paraffin embedded tumor tissue obtained from a surgical resection specimens (vi) in order to produce a result of prediction : Low Risk or Not Low Risk of relapse.

These outputs are non autonomous and are intended to be used as a clinical interpretation for the physician.

This medical device software is developed using a machine learning model with a learning mechanism driven by the manufacturer and controlled externally. The result of the software is explained in the final report and can be comprehended. The medical device is considered as automated.

Reviewed by
Dr. Joe Schmoe
Laboratory Director

Review date /..../..

Sex assigned at birth refers to the classification of an individual as male or female, often based on physical characteristics at birth.

myStage Dx is a CE-IVDR in vitro diagnostic medical device. Availability, intended use and ordering workflow may vary by country. Please consult the applicable Instructions for Use.

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NOT LOW RISK

OBSERVED GROUP AVERAGE DISTANT
RECURRENCE RATE

AT 5 YEARS	AT 9 YEARS
11.0% 95% CI (8.6%, 14.0%)	23.0% 95% CI (19.6%, 27.0%)

INTENDED PURPOSE

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