HOLOGIC

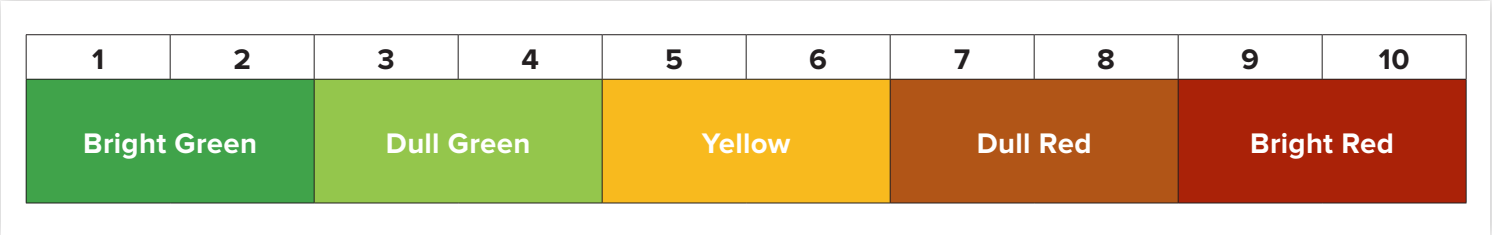
Understanding the Output of Genius AI® Detection PRO Solution

Objective

Genius AI Detection PRO solution is a concurrent reading assistive tool based on artificial intelligence technology to assist radiologists in the interpretation of mammograms. The purpose of this communication is to assist the users to interpret the quantitative outputs from cancer detection and characterization module of Genius AI Detection PRO solution.

Overview of Genius AI Detection PRO Solution Score

Genius AI Detection PRO solution analyzes mammograms and indicates findings that are suspicious of breast cancer. Each finding detected by Genius AI Detection PRO solution gets a score. A low score indicates a low level of suspicion, and a high score indicates high level of suspicion. This score ranges from 1 to 10; only findings with a score of 5-10 are displayed. Genius AI Detection PRO algorithm then assigns a score to each breast (left and right) based on highest score finding in that breast and overall score for a study is presented as maximum of the two breasts. In addition, Genius AI Detection PRO solution scores are grouped into color coded categories of green, yellow and red/ orange ranging from lowest to highest level of suspicion. The individual findings less than score of 5 are not displayed to the user.



Interpreting Genius AI Detection PRO Solution Score

Like any artificial intelligence-based system, Genius AI Detection PRO solution is not flawless in its ability to detect cancers. A bright green category does not indicate complete absence of cancer, only a low or very low level of suspicion, and bright red does not guarantee presence of cancer, only a high or very high level of suspicion. One way to understand a Genius AI Detection PRO solution score category is to compare how often a category is assigned to cases containing cancer compared to how often it is assigned to cases without cancer. In a fair and independent assessment, this comparison can be determined using a dataset that has not been involved in any way during training the Genius AI Detection PRO algorithm.

An illustration of the distribution of scores based on an enriched independent dataset of 3 US sites[1], simulated to reflect a screening distribution is shown in Figure 1. The figure shows the distribution of scores for cancer and non-cancer cases in this dataset, in bins of the 5 color coded categories. For the bar graph on the left representing cancers, the top bin with the highest suspicion category has a greater fraction of the cases than a bottom bin, representing lowest suspicion category. The reverse is true for the bar graph on the right representing non- cancers. The top bin representing the highest suspicion category has a much smaller fraction of the non-cancer cases than the bin with lowest suspicion category.

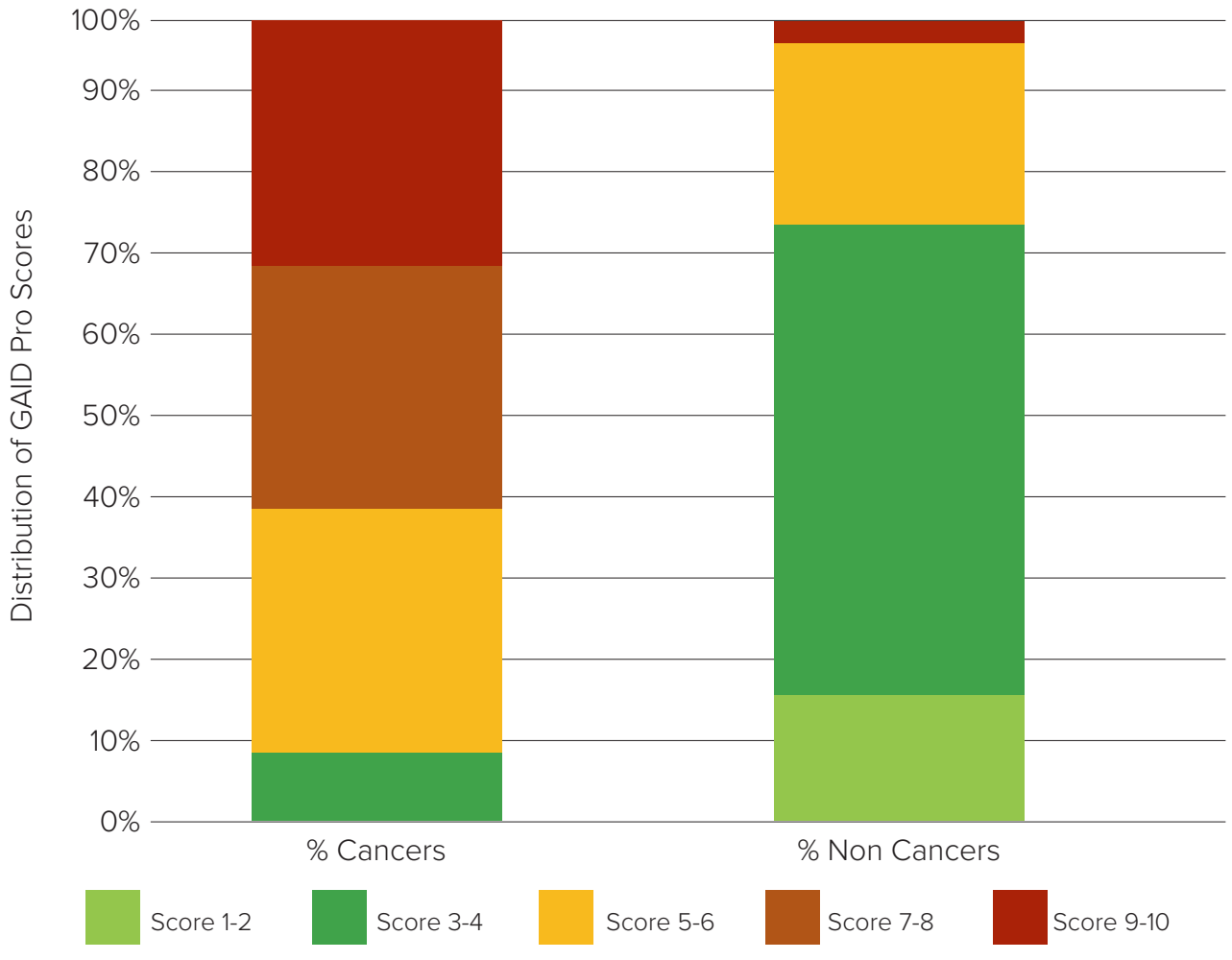
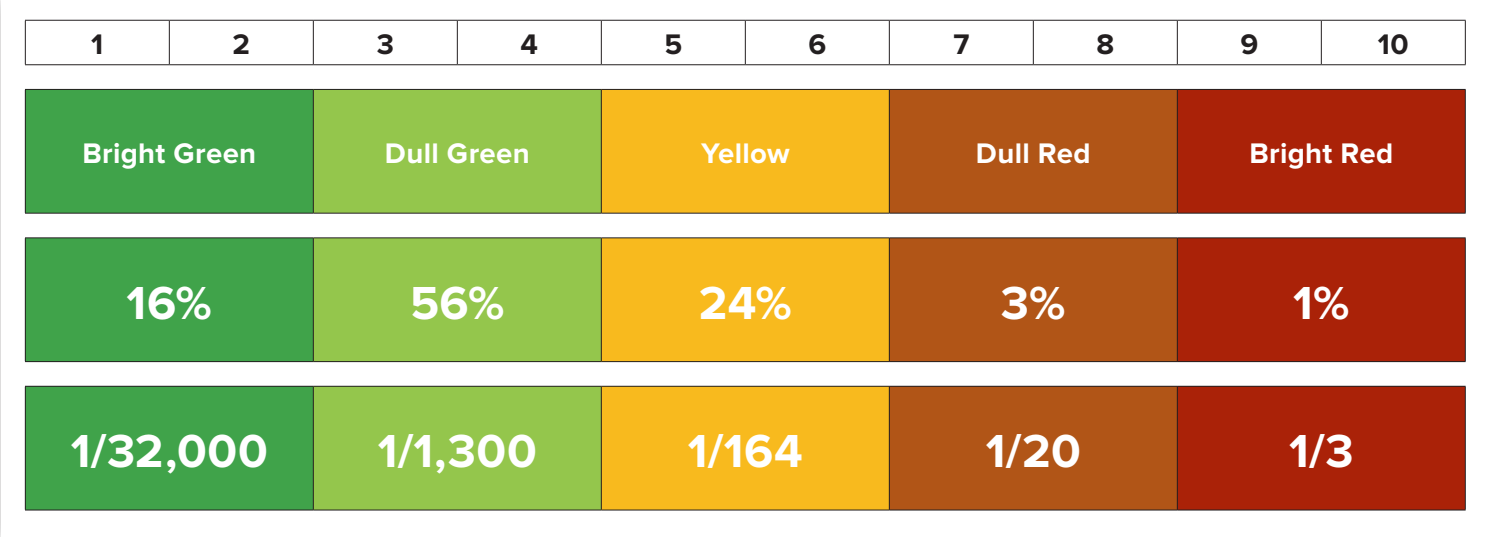


Figure 1 Distribution of Genius AI Detection PRO solution scores for cancers and non-cancers in an independent dataset.

These distributions can be used to estimate how often a given score category will occur in a screening environment for both cancers and non-cancers, based on how many cancers and non-cancers are found in the general population. In the US, the average screening breast cancer rate is approximately 5.12 per thousand screened women.

Consider the top bin with the highest suspicion category (bright red, score 9-10). This bin contains about 33% of cancer cases in the dataset, and about 0.4% of non-cancer cases. In a population of 100,000 women and the cancer rate of 5.1/1000, there are on average 510 cancers and 99,490 non-cancers. In this population, one would expect on average to see about 168 cancers (33% x 510 cancers), and about 358 non-cancers (0.4% x 99,490) in score 9-10 category. Therefore, of the 526 cases with a score of 9-10, approximately 1 in every 3 of these cases with score 9-10 are cancers: 168/(358+168). One can do a similar analysis for other score bins, extrapolating from the observed dataset distributions, to estimate the expected numbers in a general screening environment, and therefore arrive at an estimate of the fraction of a given score that would be a cancer as shown in the graphic below.



The observed score distributions for cancer and non-cancer cases in a known dataset allow one to estimate the expected cancer fraction as a function of Genius AI Detection PRO solution score category. The likelihood of a patient's lesion being cancerous increases as the Genius AI Detection PRO solution score increases.

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References:
1. K240301 510(k) Summary. Manufactured by Therapixel and distributed by Hologic.
2. National Performance Benchmarks for Modern Screening Digital Mammography: Update from the Breast Cancer Surveillance Consortium. Lehman CD, Arao RF, Sprague BL, Lee JM, et al. Radiology. 2017 Apr;283(1):49-58.