GENPATH

4Kscore
FINAL REPORT

DOCTOR

SAMPLE DOCTOR
123 Main St
Anytown, USA 12345
Acct #: **(1234)**
P:(123)456-7890

PATIENT

SAMPLE PATIENT
DOB:04/30/1938 **Age:**76 Y
Sex:M
Address:123 Main Street
Anytown, USA 12345
P: (123)456-7890

SAMPLE

Specimen ID: 123456789
Date Of Report: 04/19/2015
Date Collected: 04/18/2015
Time Collected: 00:00
Date Received: 04/18/2015
Time Received:

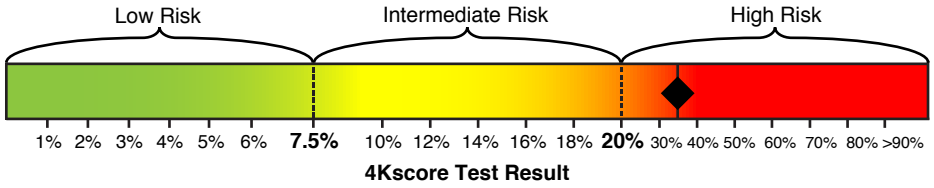
Interpretation

HIGH RISK

There is a **65%** probability that the patient will not have aggressive disease on a prostate biopsy.

4Kscore Test Results

4Kscore: **35%**



Clinical Information

Digital Rectal Exam (DRE): **Normal**

Prior Biopsy Status: **No Prior Biopsy**

Test Information

The 4Kscore result is the prediction of the individual's risk of aggressive prostate cancer of Gleason score 7 or higher if a prostate biopsy is performed.

The 4Kscore is calculated from the results of four immunoassays: Total PSA, Free PSA, Intact PSA, and Human Kallikrein-2 (hK2), plus patient age, reported DRE result, and history of prior negative biopsy.

Based on the 4Kscore US validation study, prostate biopsy should be considered in most men with a 4Kscore of 7.5% or higher. However, patient management should be based on clinical judgment and shared decision-making about undergoing biopsy.

In a landmark study by Stattin et al. 12,542 men were followed for up to 20 years in Västerbotten, Sweden to determine the risk of prostate cancer metastases. Men who had a suspicious PSA and a 4Kscore of 7.5% or less had a low risk (<1%) of having metastatic prostate cancer within 20 years.

References:

1. Parekh, DJ, Punnen S, Sjoberg DD, et al. Eur Urol. 2015 Sep;68(3):464-70.
2. Gupta A, Roobol J, Savage CJ, et al. Br J Cancer. 2010 Aug;103(5):708-14.
3. Stattin P, Vickers AJ, Sjoberg DD, et al. Eur Urol. 2015 Aug;68(2):207-13.

Note: This test was evaluated and its performance characteristics determined by BioReference Laboratories. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. BioReference Laboratories is certified under the Clinical Laboratory Improvement Act of 1988 (CLIA) as qualified to perform high complexity clinical testing.