Dear {{TableStart:Case}}{{Contact Name: Salutation 1}} {{Contact Name: First Name 1}} {{Contact Name: Last Name 1}}{{TableEnd:Case}},

We are contacting you regarding the order you have placed for the Onco*type* DX® Prostate Cancer Assay for patient {{TableStart:Case}}{{Patient: Full Name 1}} (DOB: {{DOB\@ MM/dd/yyyy}}{{TableEnd:Case}}).

It appears that the patient has adenocarcinoma in \_\_\_ of \_\_\_ biopsy cores, and a Gleason score of \_+\_=\_\_ in \_\_\_/\_\_\_ cores and \_\_\_+\_\_\_=\_\_\_ in 2/12 cores, thereby placing the patient outside of our validation criteria for excessive cores and \_\_\_+\_\_\_\_.

The ODX GPS validation study cohort at UCSF included men with low volume NCCN Intermediate risk disease defined as GS 3 + 4 disease with up to 33% of all cores positive for any GS tumor, so the Genomic Prostate Score (GPS) has not been clinically validated in this particular setting. The likelihood of favorable pathology reported by the assay would likely not accurately reflect this patient’s risk.

As this patient falls outside of our validation criteria for both excessive cores and the presence of 4+3 disease, we are unable to proceed with testing and the patient’s sample will be returned to submitting pathology lab.

Best regards,

{{USER\_NAME}}

CE Team Member

Customer Service

Genomic Health, Inc.®

**Onco*type* DX® Prostate Cancer Assay**

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Fax:  650-362-6487