



Date: July 20, 2020
To: Oncologists and Laboratory Services Personnel
From: Laboratory Medicine Advisory Committee
Re: Prosigna™ Delisting, modified OncotypeDx™ request process

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Key Message:

- Prosigna™ tests will stop July 23, 2020 as the number of tests/yr is insufficient to maintain testing.
- OncotypeDx™ (*Exact Sciences Corp*) will be the sole breast cancer molecular test available to Medical Oncologists to assist in chemotherapy decisions for a particular breast cancer patient.
- Pre-approval of Oncotype Dx tests will no longer be required.
- Test requests will use the current breast molecular request form until an updated form is available.
- Test requests must be faxed to the biomarker lab that performed the original biomarker testing.
- Eligible patients for testing must be hormone receptor positive, HER2 negative, with a nodal status that is negative, or positive for only isolated tumour cell clusters or micrometastatic disease. Patients with macrometastatic nodal disease are not currently eligible; however, guidance in this population will be re-evaluated once the results of the RxPONDER trial have been reported.
- The test is extremely expensive, and the updated form will include further recommendations on appropriate testing.

Why this is important:

- Starting July 23, 2020, Oncologists will need to be aware of the test menu and process changes to ensure streamlined handling of test requests.

Action Required:

- Medical Oncologists approved to order Oncotype Dx will no longer require pre-approval but will fax the Breast Molecular Request Form directly to the original biomarker lab in Calgary (403-291-2931, attention Dr. Sienko) or Edmonton (780-429-2819, attention Dr. Bigras).

Inquiries and feedback may be directed to:

	Edmonton & North Zone	Calgary, Red Deer, South Zone
For clinical questions on the appropriate use of OncotypeDx testing	Dr. Karen King 780-432-8343	Dr. Nancy Nixon 403-521-3688
For laboratory questions on tissue handling and result reporting	Dr. Gilbert Bigras 780-432-8445	Dr. Hua Yang 403-944-4056

This bulletin has been reviewed and approved by:

Dr. Carolyn O'Hara, Chief Medical Laboratory Officer (Interim), Alberta Precision Laboratories