MEMORANDUM

Date: August 4th, 2026

To: Dr. Nicole Chau (BC Cancer)
Dr. Tony Ng (BC Cancer & Vancouver General Hospital)

From: Dr. Stephen Yip, Medical Director – Cancer Genetics & Genomics Laboratory

RE: Test Update: Rapid BRAF (codon 600) Testing Workflow for Anaplastic Thyroid Carcinoma

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Effective immediately, the Cancer Genetics and Genomics Laboratory (CGL) is implementing a new rapid testing workflow for *BRAF* V600 (or codon 600) mutations in patients with Anaplastic Thyroid Carcinoma (ATC) using the Idylla™ BRAF Mutation Test. This initiative is designed to facilitate the prompt initiation of targeted therapy with dabrafenib and trametinib for patients harboring actionable mutations, addressing the critical need for speed in managing this aggressive disease.

Clinical Rationale

ATC is a rare but exceptionally aggressive form of thyroid cancer. Characterized by rapid progression and high morbidity, most patients present with stage IV disease. Standard chemotherapy typically yields a median overall survival (OS) of only 6 months. Without targeted intervention, the median survival for locally advanced or metastatic ATC is approximately 4–5 months, with a 1-year survival rate of just 20%.

Data from the **ROAR trial** (a phase II basket study) has established a new standard of care for the 20–50% of ATC patients whose tumors harbor the *BRAF* V600 mutations. Key outcomes from this study include:

- **Overall Response Rate (ORR):** 56%
- **Median Overall Survival (OS):** 14.5 months
- **12-Month OS Rate:** 51.7%

Given these clinical gains, rapid molecular identification is paramount to improving patient outcomes.

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How has testing changed?

To minimize the typical 2-week turnaround time (TAT) associated with the current amplicon-based NGS ("Focus panel") assay, CGL has adopted an "Idylla-First" logic. This rapid molecular assay allows for the identification of *BRAF* V600 mutations within days.

What is detected by the Idylla™ BRAF Mutation Test?

Testing for *BRAF* codon 600 variants (including wildtype) will be performed using the Idylla™ BRAF Mutation Test which has been specifically designed to detect the following codon 600 variants at limit of detection (LOD) of 1% mutant in wildtype background. Note that different mutations can result in amino acid alterations of BRAF codon 600 and these are all considered "BRAF codon 600 variants" and represent a POSITIVE finding as listed in the top 6 variants below:

- V600E (c.1799T>A)
- V600E2 (c.1799_1800delinsAA)
- V600D (c.1799_1800delinsAT, c1799_1800delinsAC)
- V600K (c.1798_1799delinsAA)
- V600R (c.1798_1799delinsAG)
- V600M (c.1798G>A)
- Wildtype (c.1799T)

Who qualifies for testing?

Testing is indicated for adults who meet the following criteria:

- Confirmed or suspected diagnosis of Anaplastic Thyroid Carcinoma.
- Disease is unresectable or metastatic.

How is the test ordered?

Testing can be ordered using the CGL Solid Tumour Molecular Requisition, found on the Requisition page.

What sample is required?

FFPE Tissue Block: 15µm section(s)

- Minimum tumour content is 30%

H&E Stained Slide: tumour region circled

- Include the tumour content and cellularity of the circled region provided in the Specimen section of the requisition

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Where and how does the sample get sent?

Further information: https://cancergeneticslab.ca/guidelines/specimens/#Shipping

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Ship at room temperature.

How will the test be reported?

- **Positive** – A *BRAF* V600 variant was detected (These can be BRAF V600E/D (c.1799T>A) or BRAF V600K/R/M (c.1798G>A).
- **Negative** – No *BRAF* variants were detected with the Idylla™ BRAF Mutation test.
- **Fail** – The Idylla™ BRAF Mutation test did not provide interpretable results. The most common reasons for this being the quantity and/or quality of DNA was insufficient to obtain a result from the tests or due to a cartridge/instrument failure.

Scenario	Clinical Action
Scenario A: **Positive Idylla ™ Result**	Reported expeditiously. To ensure immediate treatment initiation and preserve limited tissue for the patient, no further NGS testing is performed.
Scenario B: **Negative or Failed Idylla ™ Result**	The specimen is automatically reflexed to the Focus NGS panel to identify other potential actionable drivers, such as *RET* or *NTRK* alterations.

- For cases falling under **Scenario B**, the laboratory will issue an interim report acknowledging the Idylla™ result while the Focus NGS panel remains in progress.

What is the expected turnaround time (TAT) for results?

The anticipated TAT result is 4 calendar days from receipt of the sample in CGL.

How can I access the clinical report results for my patient?

The clinical report will be:

- Generated using the CGL SHIRE platform which is used for all CGL reporting

- Uploaded electronically to CAIS, CST Cerner and CareConnect
  - For CareConnect information on how to view the report or to request access, click here

Questions

Email: cancergeneticslab@bccancer.bc.ca

Website: cancergeneticslab.ca

References

1. Subbiah V, et al. Dabrafenib plus trametinib in patients with *BRAF* V600E-mutant anaplastic thyroid cancer: updated analysis from the phase II ROAR basket study. *Ann Oncol*. 2022.
2. American Thyroid Association (ATA) 2021 Guidelines.

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