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THE FIRST CANADIAN EXPERIENCE WITH THE AFIRMA® GENE EXPRESSION CLASSIFIER TEST

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Thyroid nodules are common and often benign, although prove to be malignant upon surgical pathology in 5–15% of cases. When assessed with ultrasound-guided fine-needle aspiration (USFNA), 15–30% of the nodules yield an indeterminate result. The Afirma® gene expression classifier (AGEC) was developed to improve management of indeterminate thyroid nodules (ITNs) by classifying them as “benign” or “suspicious.” Objectives were (1) to assess the performance of the AGEC in two Canadian academic medical centres, (2) to search for inter-institutional variation and (3) to compare AGEC performance in Canadian versus American institutions. We undertook a retrospective cohort study of patients with indeterminate cytopathology (Bethesda Class III or IV) as per USFNA who underwent AGEC testing. We reviewed patient demographics, cytopathological results, AGEC data and, if the patient underwent surgery, results from their final pathology. In total, 202 patients with Bethesda Class III or IV thyroid nodules underwent AGEC testing, 114 in Montreal, Quebec and 88 in St. John’s, Newfoundland. Among the nodules sent for testing, 53% (60/114) in Montreal and 32% (28/88) in St. John’s returned as “benign.” None of these patients underwent surgery. On the other hand, 47% (54/114) nodules in Montreal and 54% (48/88) in St. John’s were found to be “suspicious,” for a total of 102 specimens. To date, 73 of these patients have undergone surgery. Both in Montreal and St. John’s, the final pathology yielded malignant thyroid disease in approximately 50% of the specimens categorized as “suspicious.” Since 2013, no patients diagnosed with a benign nodule as per AGEC testing was found to harbor a malignant thyroid

nodule on follow-up. Molecular analysis is increasingly used in the management of indeterminate thyroid nodules. This study highlights the experience of two Canadian centres with AGECC testing. We found inter-institutional variability in the rate of nodules returning as “benign,” however we found similar rates of confirmed malignancy in nodules returning as “suspicious.” According to the literature, results for AGECC testing in two Canadian institutions align with results reported in American centres.