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FDA studies for OncAlert® cancer test commences

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The study will enroll up to 1,000 patients with sites located in the United States as well as internationally.

Vigilant Biosciences, Inc., a leading innovator and developer of solutions that aid in the early detection and intervention of oral/oropharyngeal cancer, announced the launch and first patient enrollment for clinical studies of its OncAlert® point-of-care qualitative assay in support of its registration submission to the Food and Drug Administration (FDA).

Vigilant Biosciences' initial FDA clinical study is designed to validate performance and evaluate implementation of the OncAlert RAPID point-of-care qualitative assay into the standard of care paradigm for patients presenting with increased clinical risk for oral/oropharyngeal cancer. The study will enroll up to 1,000 patients with sites located in the United States as well as internationally.

Part of the funding support Vigilant Biosciences will receive for the study will come from Renaissance Health Service Corporation, the parent organization for an extensive family of affiliated companies specializing in dental insurance and administration, technology, claims clearinghouse, and dental practice management services.

The OncAlert Oral Cancer product line, includes the OncAlert Oral Cancer RAPID Test and the OncAlert Oral Cancer LAB Test, both CE Marked and available in select markets outside the United States.