MicroRNAs (miRNAs) constitute a class of small cellular RNAs (typically 19-23 nt) that function as post-transcriptional regulators of gene expression. Current estimates indicate that more than one third of the cellular transcriptome is regulated by miRNAs, although they are relatively few in number (less than 2000 human miRNAs). The high relative stability of miRNA in a range of biofluid sample types, and the ability of miRNA expression profiles in biofluids to accurately classify different disease states have positioned miRNA quantification as a promising new tool for a wide range of diagnostic applications. Furthermore miRNAs have been shown to be actively exported from tissues into the circulation with the development of pathology, through a variety of mechanisms including exosome and microvesicle transport, and complexing with RNA binding proteins or HDL.

To facilitate discovery and clinical development of miRNA-based biomarkers in biofluids, we developed an LNA™-based miRNA PCR platform with unparalleled sensitivity and robustness. The platform uses a single RT reaction to profile human miRNAs and thus allows high-throughput profiling of miRNAs from important clinical sources without the need for pre-amplification.

Using the LNA™ PCR system, we have profiled thousands of biofluid samples. An extensive QC system has been implemented in order to secure technical excellence and reveal any unwanted bias in the dataset. We will present our approaches to data normalization and studies of pre-analytical variables such as hemolysis.