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# Observational study of real world clinical performance of microrna molecular profiling for cancer of unknown primary (CUP).

Sub-category:

[Genomic and Epigenomic Biomarkers](#)

Category:

Tumor Biology

Meeting:

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Abstract No:

e22173

Citation:  
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Publication-only abstracts (abstract number preceded by an "e"), published in conjunction with the 2013 Annual Meeting **but not presented at the Meeting**, can be found online only.

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### [Abstract Disclosures](#)

Abstract:

**Background:** Molecular profiling of CUP may effectively identify the underlying tumor type and potentially influence treatment decisions and outcomes. A microRNA (miR) array has been shown in concordance studies at leading academic centers to perform well in correctly identifying the tumor of origin in CUP. This series of consecutive referrals tested in a CLIA-laboratory extends these findings to the real world clinical setting. **Methods:** MicroRNA was isolated from 258 consecutive specimens referred to Rosetta Genomics, analyzed on a 64 miR-based array, and interpreted for any of 42 specific tumor types as previously described. The laboratory medical director routinely collected follow-up information on correlation of test prediction with other clinical information, pathology findings, supplemental IHC, treatment response, and clinical course as well as physician perception of relevance and utility of test result. This information was scored categorically into 3 classes of concordance depending on agreement with clinical and/or pathological data. The composite data was de-identified and analyzed for assessment of overall test performance in this real world clinical setting. **Results:** Of 258 specimens submitted 90% were paraffin embedded tissue (FFPE). Sufficient tumor material was received in 217 (85%) cases, of which 192 (88%) were successfully processed and reported with a mean TAT of 7 days. The most common result was colorectal (12%), followed by breast (10.4%), upper body squamous cell (7.3%), ovarian (6.8%), and biliary tract/pancreatic (6.8%); and the remaining 109 cases (57%) represented 30 additional tumor types. Overall the concordance with the clinical and/or pathological best final diagnosis was 86%, and when the reporting algorithm yielded a single diagnosis (51% of cases) the concordance was 89%. Clinical utility as measured by consideration of a shift in therapy or significantly increased decisional certainty for therapy was observed in approximately 70% of the cases. **Conclusions:** MicroRNA analysis in CUP cases performs comparably in the real world setting to that previously reported in academic studies and adds information of value to the management of patients.

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