

**Novel microRNA-based assay demonstrates 92% agreement with diagnosis based on clinicopathologic and management data in a cohort of patients with carcinoma of unknown primary.**

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**Source**

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**Abstract**

**BACKGROUND:**

Cancer of unknown or uncertain primary is a major diagnostic and clinical challenge, since identifying the tissue-of-origin of metastases is crucial for selecting optimal treatment. MicroRNAs are a family of non-coding, regulatory RNA molecules that are tissue-specific, with a great potential to be excellent biomarkers.

**METHODS:**

In this study we tested the performance of a microRNA-based assay in formalin-fixed paraffin-embedded samples from 84 CUP patients.

**RESULTS:**

The microRNA based assay agreed with the clinical diagnosis at presentation in 70% of patients; it agreed with the clinical diagnosis obtained after patient management, taking into account response and outcome data, in 89% of patients; it agreed with the final clinical diagnosis reached with supplemental immunohistochemical stains in 92% of patients, indicating a 22% improvement in agreement from diagnosis at presentation to the final clinical diagnosis. In 18 patients the assay disagreed with the presentation diagnosis and was in agreement with the final clinical diagnosis, which may have resulted in the administration of more effective chemotherapy. In three out of four discordant cases in which supplemental IHC was performed, the IHC results validated the assay's molecular diagnosis.

**CONCLUSIONS:**

This novel microRNA-based assay shows high accuracy in identifying the final clinical diagnosis in a real life CUP patient cohort and could be a useful tool to facilitate administration of optimal therapy.