# TRANSITIONING THE MICHECK® TEST FOR DETECTING AGGRESSIVE CAP INTO ROUTINE USE AS A LABORATORY DEVELOPED TEST

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**INTRODUCTION AND OVERALL GOAL:** A more accurate diagnostic test is still needed to enhance physician-patient decision-making regarding the need for a prostate biopsy, in conjunction with Prostate Specific Antigen (PSA) kinetics and/or the digital rectal examination (DRE). The MiCheck® test is a triage test to assist clinicians and patients in the decision to proceed to prostate biopsy. MiCheck® is a blood test which measures Glypican-1 protein levels and related signalling molecules while combining this information with both serum PSA and Digital Rectal Exam (DRE) status using an algorithm. Previous studies have demonstrated the potential clinical utility of the MiCheck® test in detection of aggressive prostate cancer. Minomic and its US based laboratory partner aim to make MiCheck® available as a laboratory developed test (LDT) in a CLIA-certified "high complexity" laboratory. Transitioning this test into routine clinical use involves a number of technical transfer steps in order to validate the test performance.

**SPECIFIC AIMS:** The specific aims were to firstly undertake technology transfer of the MiCheck® Luminex bead-based assay to a suitable CLIA-certified "high complexity" laboratory. Secondly, to compare the performance for each analyte with data originally obtained by Minomic from identical retrospective patient samples. Finally, to compare the MiCheck® test algorithm output from the LDT with the results previously obtained from the same subject samples to confirm that similar clinical outputs can be achieved.

**METHODS AND MATERIALS:**
Technical transfer of the assay and algorithm to the CLIA-certified laboratory involved establishing final assay manufacturing specifications, manufacturing of the Luminex kit with the selected panel of analytes, establishing reproducibility of the Luminex kit performance and determination of precision for the individual analytes in the test. MiCheck® test scores were calculated and compared to the MiCheck® values generated using the Minomic laboratory assay format. The algorithm performance was compared using the same samples previously tested based on the correlation and classification of patients.

**RESULTS:**
The assay format was modified and the multiplex kit was reformatted. The new format of the assay was optimized and internal controls were included for quality assurance of each step of the protocol. Following finalisation of assay format and its manufacturing specifications, correlation analyses were performed for each test analyte in the multiplex kit. 80 subject serum samples previously tested were evaluated using the expected final Luminex kits. High correlations ($r^2$>0.85) for analyte concentrations were observed. MiCheck® test scores generated using the new LDT kits showed very high correlation ($R^2$ = 0.99) when compared with previous results from the same subject samples.

**DISCUSSION AND CONCLUSIONS:**

These results demonstrate that the MiCheck® test could be successfully transferred and established in a CLIA-certified "high complexity" laboratory enabling routine availability to clinicians. Further studies contemplated include a larger study of over 300 patients and a "real world" study in which up to five large urology practices will submit prospective samples to enable additional clinical validation and, importantly, verification of test sample handling logistics and reporting formats.