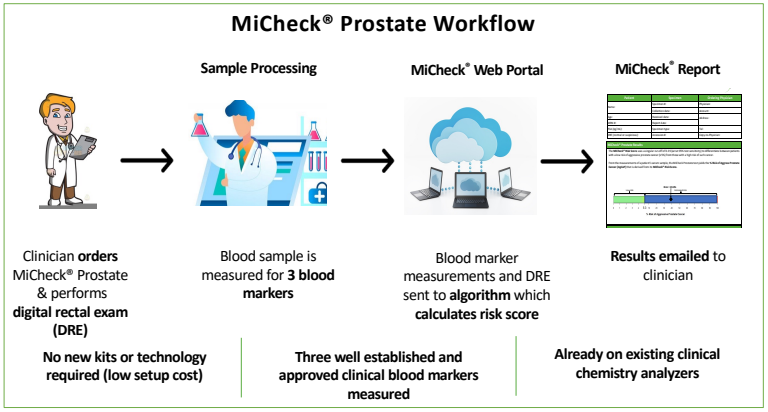
Abstract 229: MiCheck® Prostate Blood Test for Aggressive Prostate Cancer Designed for the Clinical Lab Setting

Authors: Neal D Shore[1], Christopher M Pieczonka[2], R Jonathan Henderson[1], James L Bailen[1], Daniel R Saltzstein[1], Raoul S Concepcion[1], David Gillatt[3], Manish Patel[3], Daniel W Chan[4], Douglas H Campbell[5], Yanling Lu[5], Thao Ho-Le[5], Niantao Deng[5] and Bradley J Walsh[5]

[1]CUSP LLC Research Consortium, Annandale VA,[2] Associated Medical Professionals, Syracuse New York, [3]Faculty of Medical and Health Sciences, Macquarie University, Sydney Australia,[4]Center for Biomarker Discovery and Translation, Department of Pathology, Johns Hopkins University School of Medicine, Baltimore MD, [5]Minomic International Ltd, Sydney Australia

Background

- Clinicians want a more accurate diagnostic test to identify patients for prostate biopsy
- Such a test should detect aggressive prostate cancer (Gleason ≥3+4) with high sensitivity and be simple to implement in clinical practice
- Widespread adoption of the test will be facilitated by using standard clinical chemistry analyzers (e.g. Cobas, Architect) for measurement of serum samples and a workflow tailored to existing clinical lab practice



Methods

- 314 serum samples collected in the MiCheck-01 US clinical trial were measured using Luminex Multiplex kits, Abbott Architect and Beckman Coulter systems to identify serum markers for algorithm development
- Logistic regression models were developed to maximize detection of aggressive prostate cancer (CaP)
- Samples were later re-tested on an Abbott Architect system and correlated with the results obtained from the mixed platforms
- A second set of 79 serum samples was collected in Australia from Macquarie University Hospital (MUH) and measured using the Abbott Architect system
- The combined US/Australia sample set was used for further algorithm development and validation

MiCheck® Prostate is an algorithm that incorporates three protein markers and one clinical factor to identify aggressive prostate cancer

Author Contact: brad.walsh@minomic.com

Results

- Initial algorithm development using the MiCheck-01 clinical samples was performed using analyte values from Luminex, Architect and Beckman Coulter platforms. The mixed-platform model identified one clinical factor (DRE) and three serum markers that detected aggressive cancer (Table 1).
- Measurement of all three markers on the Abbott Architect platform showed high correlation between analyte values across different measurement platforms, and consistent algorithm performance (Figure 1)
- Despite the platform used, sensitivity and specificity remained consistent, and specificity was higher than alternative blood marker diagnostic tests

Table 1

Mixed-Platform Model				Model based on Abbott Architect			
AUC	Sensitivity	Specificity	NPV	AUC	Sensitivity	Specificity	NPV
0.82	95%	48%	94%	0.82	95%	47%	94%

- Additional algorithm development and validation was performed using a combination of the 314 MiCheck-01 clinical samples and 79 samples collected in Australia.

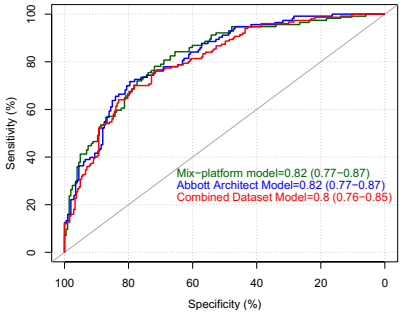


Figure 1. ROC curves obtained using either **(A)** MiCheck-01 clinical trial samples measured on mixed platforms (green curve), **(B)** MiCheck-01 samples measured on a standard Abbott Architect platform (blue curve) or **(C)** the combined MiCheck-01 and Australian sample set measured on the Abbott Architect platform (red curve). **There are no statistically significant differences between the three ROC curves (P>0.5).**

- Consistent performance was obtained in the Combined Dataset Model (Table 2) and in both individual sample sets.

Table 2

Combined Dataset Model (n=393)			Combined Model Applied to MiCheck -01 US (n=314)		**Combined** Model Applied to MUH (n=79)	
AUC	Sensitivity	Specificity	Sensitivity	Specificity	Sensitivity	Specificity
0.80	95%	43%	96%	42%	92%	45%

Future Directions for Research

- MiCheck® Prostate will be available in the US in 2022
- Additional clinical studies should be considered to investigate the relevance of specificity compared to similar blood tests