Diagnostics and biomarkers

OC - (8435) - MULTI-BIOMARKER TEST STRIP FOR POINT-OF-CARE SCREENING FOR ACTIVE TUBERCULOSIS: A FIVE COUNTRY MULTI-CENTER TEST EVALUATION

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Background: Inexpensive rapid screening tests that can be used at the point-of-care (POC) are vital to combat tuberculosis. Particularly, less invasive non-sputum-based biomarker tests for all TB forms can help controlling transmission. Availability of such tests would significantly accelerate and streamline diagnostic approaches, improve cost-efficiency and decrease unnecessary costly GeneXpert referrals.

Methods: Multi-biomarker test (MBT) devices measuring levels of selections of up to six serum proteins simultaneously on a single lateral flow (LF) strip were produced. The strip contains individual capture lines for a biomarker selection allowing discrimination of TB-patients from other respiratory diseases (ORD). Only biomarkers successfully evaluated with singleplex strips (single biomarker tests) were applied to the MBT device. Quantitative signals are recorded with a low-cost handheld reader compatible with the applied luminescent up-converting particle (UCP) label. Biomarker selection and algorithms used to distinguish potential-TB and ORD are flexible.

Results: Results obtained with MBT strips containing multiple test lines correlate well with singleplex LF strips. Using LF tests for 5 selected biomarkers a sensitivity of 94% and specificity of 96% could be achieved with a confirmed South-African selection of 20 TB and 31 non-TB samples. Patients were designated TB positive when scoring a value above the cutoff threshold for at least 3 out of 5 biomarkers. Serum samples of potential TB patients collected at five medical research institutes (Ethiopia, Namibia, South-Africa, The Gambia, Uganda) were tested locally with MBT strips comprised of CRP, SAA, IP-10, Ferritin, ApoA-I and IL-6 and results analyzed to obtain an overall pan-Africa applicable signature.

Conclusions: Evaluated POC applicable UCP-LF devices detecting serum biomarker signatures can help to distinguish active TB from ORD and as such can prioritize highest risk patients for further care. Ongoing prospective studies evaluate the MBT strip with fingerstick blood and don’t require a laboratory nor trained phlebotomists anymore.