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Paper Poster Session IV

Improved diagnosis in enteric pathogens

"The utility of the NanoCHIP® gastrointestinal panel (GIP), a molecular-based test for simultaneous detection of gastrointestinal protozoan parasites and bacterial infections, in a community laboratory"

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Objectives. Infectious Gastroenteritis is a global health problem associated with extremely high morbidity and mortality rates. Accurate diagnosis is crucial to allow appropriate and timely treatment. Stool testing at the microbiology laboratory is currently a complex, time consuming and cumbersome process, demanding highly qualified personnel and application of a wide range of techniques. Thus, workload, lab space and turnaround time are high and costly. Savyon Diagnostics has recently finalized the development of a novel molecular-based diagnostic screening test for simultaneous detection of nine bacterial and protozoan parasitic pathogens tailored specifically according to the demands of a typical laboratory at community setting. The test was developed on Savyon proprietary NC400 NanoCHIP® molecular electronic microarray system. The bacterial panel includes *Salmonella*, *Shigella* and *Campylobacter spp.* The parasitic panel is composed of *Entamoeba histolytica*, *Entamoeba dispar*, *Giardia lamblia*, *Dientamoeba fragilis*, *Cryptosporidium spp.* and *Blastocystis spp.* The aim of this work is to demonstrate the utility of the NanoCHIP® GIP test for screening of gastro-enteric bacterial and parasitic pathogens in stool specimens in a typical laboratory at community setting.

Methods. Prospective and retrospective clinical studies were conducted at Meuhedet Health Services, Rosh Haayin Laboratory, Israel. Overall the evaluation included 196 samples received from symptomatic patients. The retrospective and the prospective studies included 46 and 150 samples, respectively. The DNA was extracted by the Bullet PRO® system (Diasorin), amplified by PCR and processed by the NanoCHIP® NC400 instrument (Savyon).

Results were compared to standard methods used routinely by the lab, i.e. culture and microscopy. Discrepant analysis was carried out by Diagenode RT-PCR assays (Mikrogen) and/or by sequencing.

Results. The NanoCHIP® GIP test results showed higher diagnostic yield relative to the conventional methods in all the pathogens composing the panel. The sensitivity in the retrospective study was 96-100% while the specificity 100%. The PPV in the prospective study was 99% while the NPV 100%. The Higher yield was demonstrated also in detection of mixed infections. Time to results was significantly reduced compared to the routine process.

Conclusions. The NanoCHIP® GIP test has demonstrated its utility in the community setting laboratory for reliable detection of bacterial and parasitic gastrointestinal infections and screening purposes. The test presents significant advantages compared to currently used methods, mainly in terms of minimal hands-on time, improved laboratory workflow, and potential assimilation as part of a fully automated process.