workflow simplicity, and less chance for user error as compared to the GeneXpert system.

Abstract no: 196
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Performance of a molecular diagnostic, multicode based, sample-to-answer assay for the simultaneous detection of Influenza A, B and Respiratory Syncytial Viruses

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Introduction: Rapid diagnostics is required in cases with respiratory failure for clinical decision making regarding isolation and antiviral therapy. Techniques like immune-chromatographic test (ICT) and direct immunofluorescence assay (DFA) have lower sensitivities and specificities than molecular diagnostic assays, but have the advantage of quick turnaround times and ease-of-use. Here, we evaluated the performance of an automated, easy to use, sample-to-answer system, which performs an Influenza A/B virus (fluA/B), respiratory syncytial virus (RSV) and internal control multiplex RT-PCR of 1–12 samples within 2 h.

Methods: The analytical performance of the FluA/B/RSV assay on the ARIES (Luminex), a system using multicode technology (a probe-free real-time RT-PCR method with melting curve confirmation), was evaluated using published laboratory developed automated real-time RT-PCR assays (LDA) for fluA, fluB, RSV-A and RSV-B. Genotype inclusivity of the ARIES was tested using 16 avian (H1–H16) and 33 human fluA strains, 3 fluB strains and the two RSV (A/B) strains. Specificity was assessed using 40 high positive non-fluA/fluB/RSV-viruses and analytical sensitivity was compared to LDA assays by testing 0.5 log dilution series. The clinical performance was compared to both LDA + ICT (BinaxNOW influenza A/B and RSV test) + DFA using selected (pretreated), −80 °C stored, respiratory tract samples from 2006 until 2015 (retrospective) and prospective testing of original respiratory tract samples from December 2015 onwards.

Results: All fluA, fluB and RSVA/B strains tested for analytical performance evaluation were detected and no aspecific reactions were identified. ARIES FluA/B/RSV assay was 0.5 log less sensitive for fluA, 1 log for RSV-A, 2 logs for RSV-B and 2.5 logs for fluB compared to LDA. In total, 447 samples were included in the clinical performance evaluation, of which 15.4% tested positive for fluA, 9.2% for fluB and 26.0% for RSV, (RSV-A, 13.2% and RSV-B 12.9%) in both LDA and ARIES. Confirmed discrepant results were found in 11 samples (1 fluA, 4 fluB and 6 RSV-A), which tested positive in LDA and negative in ARIES (2%, LDA Ct values 28.8–36.0), resulting in an overall clinical sensitivity and specificity of 98.6% and 100% for fluA, 91.1% and 100% for fluB and 95.1% and 100% for RSV, respectively. If compared to the DFA ($n = 217$) and ICT ($n = 119$), ARIES detected 38 (17.5%; 4 fluA, 23 fluB, 11 RSV) and 32 (26.9%; 7 fluA, 3 fluB, 22 RSV) more samples respectively, all confirmed by LDA (Ct range 14.9–35.0). In terms of robustness, 2.2% cassettes failed during operation in clinical specimen, of which 90% was an undiluted bronchio-alveolar lavage, nose wash or sputum.

Conclusion: The ARIES influenza A/B/RSV assay is a specific and rapid molecular assay. Although analytically the ARIES is less sensitive for fluB, RSV-A and RSV-B than the LDA assays, the performance in clinical samples is comparable to LDA and better than those of the established rapid assays. Other respiratory samples than throat swabs can be analyzed by the ARIES, but need to be diluted prior analysis.

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Fully automated diagnosis of MERS-CoV infection in respiratory specimen on the IdyllaTM MDx Platform

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Background: Rapid diagnosis of MERS-CoV infection is essential for the successful clinical management and isolation of MERS patients. The prototype Idylla™ MERS assay is a RT-PCR based assay which generates highly sensitive, specific results with a minimal turn-around time. Two independent PCR assays, targeting different regions in the MERS-CoV genome, are combined to detect and at the same time confirm infection with MERS-CoV. The prototype Idylla™ MERS assay is a single-use cartridge that will be run in the fully automated Idylla™ MDx Platform. The cartridge contains all reagents and is capable of processing samples without any user manipulation, minimizing the possibility of errors in setup and decreasing the risk of infection or contamination. The aim of this work was to demonstrate the performance of the prototype Idylla™ MERS assay on the Idylla™ Platform.

Methods: Performance of the prototype Idylla™ MERS assay was assessed using serial dilutions of viral culture spiked in MERS-CoV negative clinical material. The performance of the prototype Idylla™ MERS assay was compared to a conventional RT-PCR kit in combination with extraction by the NucliSENS® easyMag®. In vitro transcribed MERS-CoV RNA was used to determine the LoD of the assay and to show reproducibility. Cross-reactivity was analysed using culture and clinical specimen positive of other respiratory pathogens. Additionally, an *in-silico* analysis was performed to prove the reactivity with all available MERS-CoV sequences and to exclude any cross-reactivity with organisms present in respiratory specimen or with the human genome.

Results: The prototype Idylla™ MERS assay demonstrated high sensitivity and specificity. The analysis of MERS-CoV viral culture showed the same sensitivity with the Idylla™ MERS assay as a conventional MERS RT-PCR kit in combination with NucliSENS® easyMag® extraction. No cross-reactivity with other pathogens or the human genome was observed *in-vitro* or *in-silico*. The *in-silico* reactivity analysis showed 100% identity in 98.31% of the available sequences for the MERS screening assay and 97.07% for the confirmatory assay. The remaining sequences only showed minor mismatches and we confirmed the binding capability of our assay by using plasmids containing the mismatches.

Conclusions: The fully automated prototype Idylla™ MERS assay requires less than 2 min of hands-on time for sample handling and provides results in less than 90 min without need for experienced staff or extensive training. Due to the integrated sample preparation the handling of the infectious material is reduced to an absolute minimum. The automated sample processing and RT-PCR and data analysis will lead to a sensitive and accurate calling of any MERS-CoV positive sample. The sample-to-result format of the pro-

totype Idylla™ MERS assay offers the possibility for point-of care or centralized laboratory testing.

Abstract no: 21
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Flexibility and full automation for clinical sample extraction – Performance evaluation of the new bioMérieux eMAG

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While molecular testing continues to play an increasingly important role in human diagnostics, Molecular Laboratories nowadays are confronted with numerous challenges resulting from more comprehensive test menus, consolidation of laboratory testing (including increased traceability), more stringent regulatory requirements, high throughputs and the need for rapid turnaround times. Sample preparation remains a key element in the laboratory workflow and requires processing of multiple human specimens and sample matrices, handling of different laboratory consumables, simultaneous extraction of DNA and RNA targets and coordination of eluates for downstream PCR analysis. Automation of sample extraction is a common need to master laboratory throughput and standardization whereas adaptation of automated solutions to complex workflow requirements remains a challenge. We present here results of the performance evaluation (e.g.: reproducibility, precision, LOD, carry-over, tests on different specimen types) of the new bioMerieux eMAG™ which provides full automation of sample extraction starting from primary tubes and using well established easyMAG® chemistry. Higher throughput, increased traceability and seamless integration into diagnostic laboratory's workflows have been primary design goals for this next generation platform while keeping the known flexibility of the easyMAG®.

Abstract no: 212
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Evaluation of the Beckman Coulter DxN VERIS Molecular Diagnostics System (DxN VERIS) for the determination of viral load in plasma from patients infected with either HBV or HIV-1

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Background: The recently launched DxN VERIS system is a fully-automated, random-access system for the determination of viral load in infected patients. The aim of this study was to assess the performance of the VERIS HCV and HIV-1 assays against the Roche COBAS AmpliPrep/COBAS TaqMan (CAP-CTM) system and assays which is in routine use in our laboratory.

Methods: For method comparison, the plasma from 167 HBV infected patients were selected for analysis on both platforms. Similarly for HIV-1, 188 plasma samples were selected for analysis on both the DxN VERIS and Roche CAP-CTM instruments. For patient monitoring, archived plasma samples from a number of patients covering four time points were analysed on both the DxN VERIS and Roche CAP/CTM systems.

Results: For the HBV method comparison, of the 167 specimens tested, 20 samples were "not-detected" on both systems, a further 32 samples were detected but not quantified on both systems (the VERIS HBV assay linear range is $10–10^9$ IU/mL, the Roche HBV v2 assay linear range is $20–1.71 \times 10^8$ IU/mL). Seven samples were quantified using the Roche HBV assay but "detected-not quantifiable" on the VERIS HBV assay. A further 11 samples were quantified using the VERIS HBV assay but were only detected and not quantifiable on the Roche HBV assay. Of the remaining 97 samples that gave results within the linear range of both assays, the correlation coefficient was determined to be 0.87 (Spearman, 95% CI 82.0–91.7). Passing-Bablok analysis illustrated an intercept value of −0.2898 with a slope of 0.939. The sample's tested ranged from 1.01–6.73 log IU/mL. Bland–Altman analysis demonstrated that there was a −0.45 log IU/mL bias on the VERIS HBV assay when compared with the Roche HBV assay. The overall profiles obtained for the patient monitoring analysis showed a good agreement between both methods. The HIV-1 data is still under analysis and will be presented later.

Conclusions: Method comparison between the VERIS HBV and Roche HBV assays demonstrated an overall concordance of 77%. There was a negative bias on the DxN VERIS system when compared with the Roche system for HBV. The VERIS HBV assay is a useful tool in the monitoring of HBV infected patients.

Abstract no: 220
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Performance evaluation of the Aptima® HIV-1 Quant Dx and Aptima® HBV Quant assays on the fully automated Panther in comparison to COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 and HBV tests

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Background: Quantification of HIV-1 RNA and HBV DNA viral load plays a central role in clinical management of HIV and HBV infected patients, before and during antiviral therapy.

The Hologic Aptima® HIV-1 Quant Dx and HBV Quant are quantitative assays, being developed on the fully automated Panther system. The assay is based on real-time Transcription Mediated Amplification (TMA) technology.

Methods: *HIV*: 191 plasma samples (94 prospective and 97 retrospective) from HIV-infected patients were tested for Aptima® HIV-1 Quant Dx Assay, based on HIV viral load, as determined by routine testing using COBAS®TaqMan® HIV-1 test.

Reference panels: BioQcontrol P0043HIV-RNA, Qnostics HIV-1, HIV1 50904 and S1003 HIV-RNA DOM 046200047 were used to assess sensitivity, reproducibility and linearity.

HBV: 200 plasma or sera samples (100 prospective and 100 retrospective) from HBV-infected patients were tested for Aptima® HBV Quant Assay, based on HBV viral load, as determined by routine testing using COBAS®TaqMan® HBV test.

Reference panels: Qnostics 14038 HBV, BioQC control P0041 HBV DNA and Hologic panel were tested to assess sensitivity, reproducibility and linearity.

Cross contamination was evaluated (for both HBV and HIV) by testing 5 consecutive runs of 15 samples, composed of Hologic high and low positive control, and negative samples (Hologic diluent).