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M041

Comparability of selected assays on COBAS pure integrated solutions under routine-like conditions

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Background-aim

The novel cobas® pure integrated solutions system (Roche Diagnostics International Ltd, Rotkreuz, Switzerland) is a serum work area laboratory analyzer, comprising two analytical units: a clinical chemistry (CC) unit including ion selective electrodes (ISE) (cobas c 303) and an immunochromatography (IC) unit (cobas e 402). In a multicenter study, we assessed the comparability of the cobas pure integrated solutions system versus respective routine analyzers at four sites under routine-like conditions. Here, we report the comparability to routine non-Roche analyzers from one site in Seoul, Republic of Korea.

Methods

The study was conducted at five sites in Switzerland, Germany, and the Republic of Korea, from Sep to Dec 2020. At four sites, method comparison experiments using routine leftover samples evaluated comparability of the cobas pure integrated solutions system with respective routine analyzers. At three sites, the routine analyzers were Roche (cobas INTEGRA 400 plus, cobas e 411, cobas pro, and cobas 8000), and at one site (Seoul) were non-Roche analyzers (Beckman Coulter AU5822 Clinical Chemistry Analyzer, Abbott Alinity I, and Siemens ADVIA Centaur). There were 20 method comparisons vs. non-Roche methods. In total, 20 selected analytes covering CC (ALB, ALP, AST, CA, CHOL, CREA, CRP, GLUC, MG, PHOS, TP, UA, UREA), ISE (Cl, K, Na), and IC (CEA, TSH, FOL, Vit. B12) were assessed. Passing/Bablok regression analyses were carried out: slopes, intercepts, and correlations for method comparisons were calculated.

Results

Nearly 7000 result pairs were included in the analysis. For ISE, the bias at the medical decision point between cobas pure integrated solutions and Beckman Coulter AU5822 varied between 1% deviation (Cl, Na) and 4% (K). CC assay bias varied from 0% (CA) to 22% deviation (CRP). The IC method comparison regression analysis yielded slopes from 0.99 (CEA) to 1.28 (FOL).

Conclusions

The results of this study demonstrate that the cobas pure integrated solutions system is comparable to Beckman Coulter AU5822 Clinical Chemistry Analyzer ISE and CC results. CEA and TSH method comparisons to Abbott Alinity I and Vit. B12 and FOL comparisons to Siemens ADVIA Centaur have shown that differences in methods and reference ranges must be observed for comparison.

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M042

Simultaneous detection of respiratory infectious diseases using immunoprecipitation and liquid chromatography-tandem mass spectrometry

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Background-aim

With recent emergences in new infectious diseases and their variants, there is a need to develop a faster and more specific analytical tool to detect different respiratory infectious diseases such as SARS-CoV-2 or influenza viruses. Not only their symptoms are similar at early stages, but also, they are both enveloped viruses with several common biological properties, often leading to challenges in disease identification.

Among different viral components, nucleocapsid protein or nucleoprotein (NP) is highly conserved, less post-translational modifications possessed, and mostly specific for each infectious disease virus type. Therefore, targeting NP could be more advantageous to the method development, achieving much simpler and robust method with minimal subsequent modifications.

This study describes a targeted approach for simultaneous detection of NPs from different respiratory infectious diseases using immunoprecipitation (IP) and liquid chromatography-tandem mass spectrometry (LC-MS/MS). Multiple viruses, SARS-CoV-2, influenza virus A and B types, respiratory syncytial virus, and human coronavirus (HCoV-229E), were selected to show that this method can distinguish different disease viruses.

Methods

Sample collected via nasopharyngeal swabs in viral transport media was directly subjected to IP using Thermo Scientific™ Pierce™ MS-Compatible IP Kit (Streptavidin). The IP purified samples were then digested using SMART Digest™ Trypsin Kits and analyzed by Thermo Scientific™ Vanquish™ MD HPLC system hyphenated to Thermo Scientific™ TSQ Altis MD mass spectrometer. Data processing was performed using TraceFinder™ LDT software 1.0.

Results

Combining IP and LC-MS/MS resulted in a highly targeted approach with the high sensitivity and specificity. The method detected sub tens to hundreds amol of peptides on LC column. Also, it simplified the overall sample preparation process eliminating prior protein precipitation and post sample clean-up. Since the NPs mostly remain unchanged or less modified regardless of variants, the method doesn’t need tremendous alterations once established.

Conclusions

This targeted approach can be applied to other enveloped viruses’ detection. Automated IP method is available with KingFisher system so it could lead to a faster turn-around time and higher throughput of the method.

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