

BACKGROUND and TECHNOLOGY

The AutoBlot 3000H, produced by MedTec Inc., offers fully automated processing of Line Probe Assay (LiPA) strips from hybridization to color development. The automated processing of up to 20 tests in one run reduces the hands-on time by more than 60%.

The instrument has a small footprint and is easily programmable for up to 10 user-defined protocols.

AIM of STUDY

To compare the performance of the *Auto-LiPA* and the AutoBlot 3000H for the INNO-LiPA *CFTR* assays (INNO-LiPA *CFTR*17+Tn Update, INNO-LiPA*CFTR*19, INNO-LiPA *CFTR* Italian Regional) with regard to the intended use.



MATERIALS and METHODS

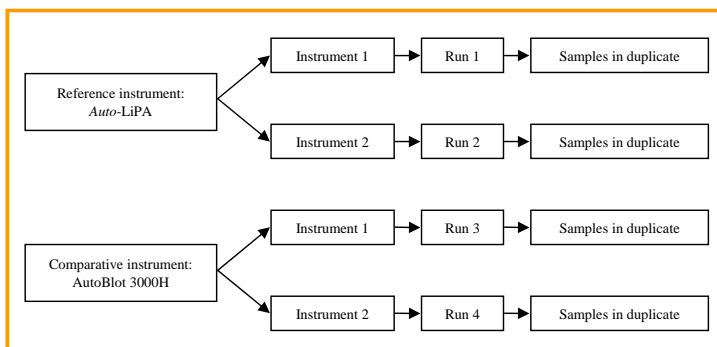
A panel of 15 samples (5 samples for INNO-LiPA *CFTR* Italian Regional, 10 samples for INNO-LiPA *CFTR*17+Tn Update and INNO-LiPA *CFTR*19) was selected so that the most prevalent mutations were covered, that the most critical probes were assessed, and that DNA concentrations close to the limit of the application range, were represented. This panel consists of real DNA samples, which were extracted from EDTA whole blood, dried blood spots and buccal brushes. Additionally one plasmid sample was tested for INNO-LiPA *CFTR*17+Tn Update and INNO-LiPA *CFTR*19.

The samples were tested in duplicate on two different instruments of each type. The sample position within each run was randomized. The *CFTR*17+Tn Update and *CFTR*19 strips were tested in the same and in separate troughs.

All tested strips were interpreted both visually and with LiRAS® for LiPA Cystic Fibrosis v2.00 software. Only OD values between 0.02 and 0.4 were included in the analysis.

Criteria:

- The genotyping result and band reactivity pattern must be identical on AutoBlot 3000H and *Auto-LiPA* for each sample. The plasmid sample is not intended as control for the intensity of the different probe lines.
- The % difference in mean OD values and the variance will be evaluated for both methods according to the QC specifications and the overall LiPA test variance.



RESULTS

For INNO-LiPA *CFTR*17+Tn Update and INNO-LiPA *CFTR*19, identical genotyping results and band reactivity patterns were obtained, both for strips tested in separate troughs or in the same trough, after processing on *Auto-LiPA* and AutoBlot 3000H. Twenty of the 240 strips (one AutoBlot run) were excluded from the results because of a manipulation error.

For INNO-LiPA *CFTR* Italian Regional, identical genotyping results and band reactivity patterns were obtained after processing on *Auto-LiPA* and AutoBlot 3000H.

The mean OD values of the results from the AutoBlot 3000H were generally lower (on average 19%) than those from *Auto-LiPA*, but the values were still well within the interpretation criteria. The overall variance on the AutoBlot 3000H was slightly higher in comparison to the *Auto-LiPA*, but the variance was still within the overall LiPA test variance.

CONCLUSIONS

Although the reactivities on the AutoBlot 3000H were weaker and slightly more variable than on the *Auto-LiPA*, the equivalence between both methods falls well within the postulated criteria.

Identical genotyping results and reactivity patterns were obtained for the INNO-LiPA *CFTR*17+Tn Update, INNO-LiPA *CFTR*19 and INNO-LiPA *CFTR* Italian Regional. Therefore, both *Auto-LiPA* and AutoBlot 3000H can be used with regard to the intended use.

Furthermore for AutoBlot 3000H, as is already the case for *Auto-LiPA*, equivalence was shown for strips tested in separate troughs or in the same trough.