

TECHNICAL BULLETIN:

Auto-LiPA versus AutoBlot 3000H for INNO-LiPA HPV Genotyping Extra



BACKGROUND and TECHNOLOGY

The AutoBlot 3000H, produced by MedTec Inc., offers fully automated processing of DNA strips from hybridization to color development. The automated processing of up to 20 strips 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 protocols at 4 different temperatures.

AIM of STUDY

To compare the performance of the *Auto-LiPA* and the AutoBlot 3000H with the INNO-LiPA HPV Genotyping *Extra* assay, with regard to the intended use.



MATERIALS and METHODS

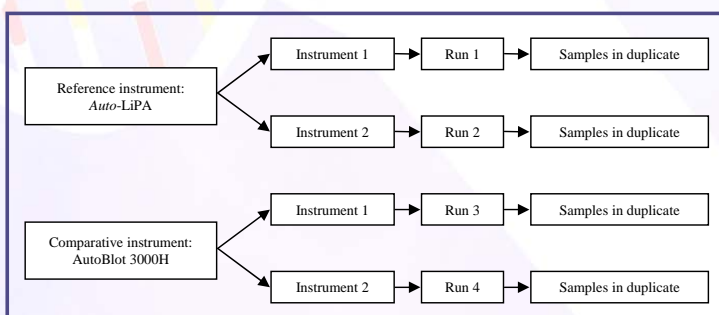
A panel of 9 plasmid samples was selected so that the most prevalent high-risk genotypes (HPV types 16, 18, 31, 45, and 52) were covered, that the most critical probes (probes prone to false-positive- or false-negative reactions) were assessed, and that a range of probe reactivity levels was represented.

The samples were tested in duplicate on two instruments of each type. The sample position within each run was randomized. For each assay method, one run was performed on each instrument.

Criteria:

All strips were interpreted both visually and with LiRAS® for LiPA HPV v1.00. Only the bands with an OD lower than 0.4 were included in the analysis.

- The AutoBlot 3000H method should have no influence on the genotyping or line pattern of the samples.
- The difference in mean OD values should lie within $\pm 10\%$ for both methods.
- The variance on the AutoBlot 3000H should not exceed the variance on *Auto-LiPA*.



RESULTS

All genotype results were concordant. Three of the 72 strips were excluded from the calculations because of a manipulation error.

There were 3 samples that showed differences in line patterns between the different runs. All such cases were borderline (pos-neg). The false-positive reactions were not systematically present in any of the methods used.

The data confirmed that the OD values of the AutoBlot 3000H were lower than those of the reference method, but the values were still above the QC specifications and far above the cut-off for negative-positive.

The overall variance and standard deviation on the AutoBlot 3000H was lower than the variance on the *Auto-LiPA*, the reference method.

CONCLUSIONS

Although the reactivities for the INNO-LiPA HPV Genotyping *Extra* on the AutoBlot 3000H are slightly weaker than on *Auto-LiPA*, the equivalence between both methods falls well within the postulated criteria. The variance of the AutoBlot 3000H is lower than that of the reference method.

As both assay methods give the same genotyping result, the INNO-LiPA HPV Genotyping *Extra* assay can be used on both the *Auto-LiPA* and AutoBlot 3000H.