Developing the production process of Anti-hAFP and Anti-hCGβ microtiter plates

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1 Introduction

Human alpha-fetoprotein (hAFP) and free β-subunit of human chorionic gonadotropin (hCGβ) are used as biomarkers in prenatal screening of chromosomal abnormalities [1] (Fig. 1).

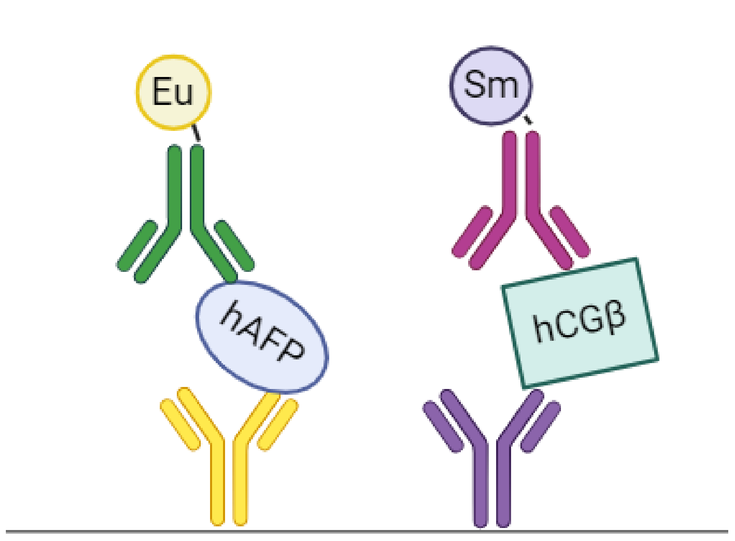

Figure 1. Illustration of the assay using the microtiter plates. hCGβ can also be detected alone. Europium (Eu) and Samarium (Sm) are used as labels.

The production of the plates is currently done in the old production line which is less automatized and more prone to breakage than the new production line. The process is described below in figure 2.

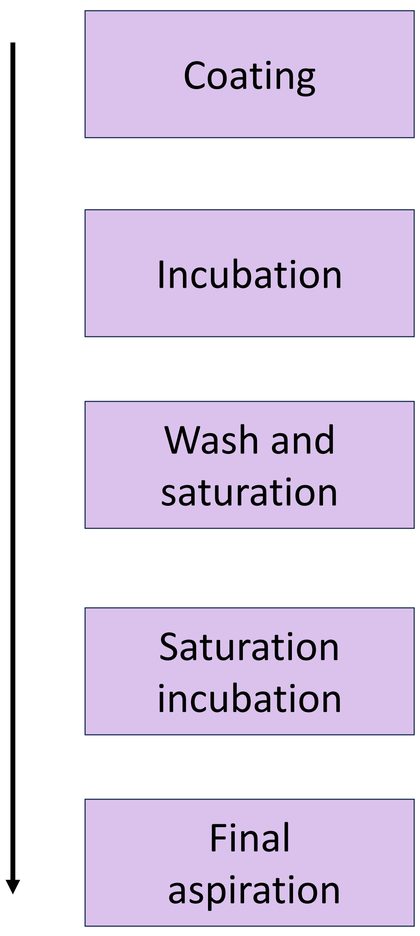

Figure 2. Overview of the production process of the microtiter plates.

The aim of the project is to transfer the production to the new production line, optimize production parameters and test the effect of longer saturation incubation times.

2 Methods

The production batch

- Testing and optimizing production parameters (table 1)
- The parameters will be the distance of the aspiration needle (DAN) and the aspiration time

Table 1. Production sub-batches and parameters for the first production batch. DAN is abbreviation for distance of the aspiration needle.

Sub-batch	DAN (wash)	DAN (final aspiration)	Aspiration time (final aspiration)
1	Max.	Min.	Fast
2	Min.	Max.	Fast
3	Min.	Min.	Normal
4	Max.	Max.	Normal

3 Results

The production batch was successfully manufactured in the new production line. Results from sub-batch 4 are still in progress. (Fig. 3-5)

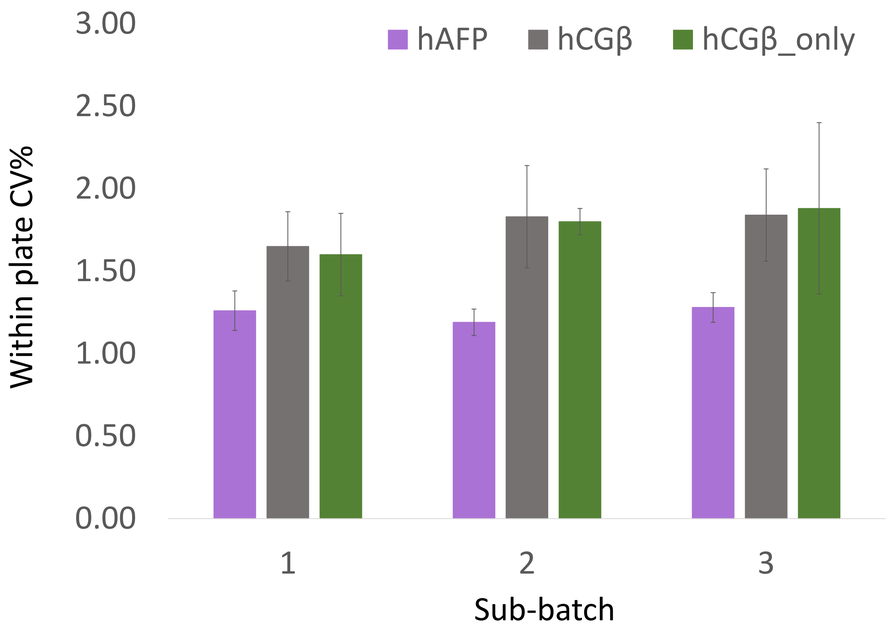

Figure 3. Results from homogeneity test.

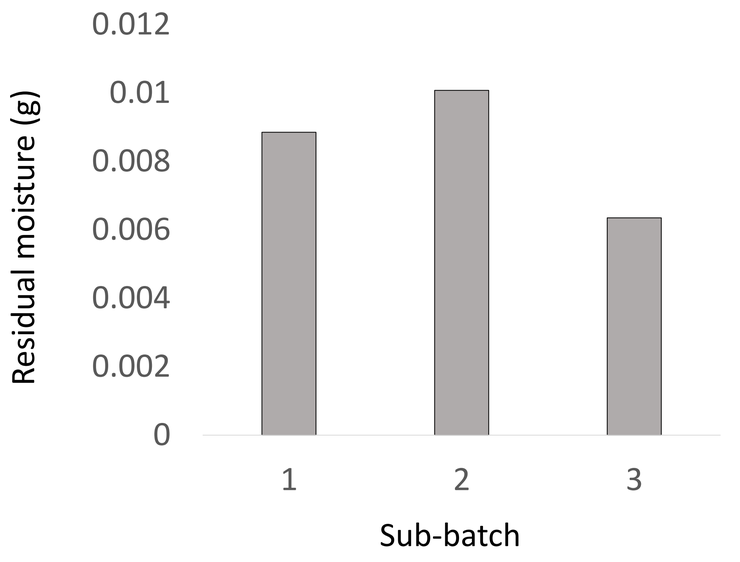

Figure 5. Residual moisture after the final aspiration.

The biggest difference was found in residual moisture. Other results are similar except differences in standard deviations are notable. Sub-batch 3 has the best results overall but more deviation than sub-batch 1. More tests are needed with the sub-batch 3 settings. Therefore, settings of sub-batch 1 were chosen as the most optimal.

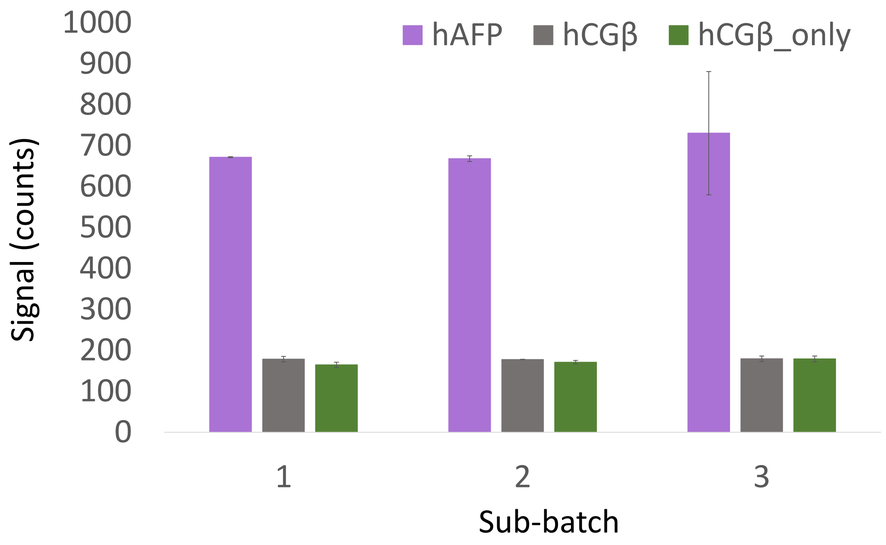

Figure 4. Results from background test. The signal was measured from a 0-calibrator.

4 Conclusions

The production in the new line was successful and the most optimal parameters were the settings of sub-batch 1.

The project continues with testing new saturation incubation times.

References:
[1] Guibourdenche et al. (2023) DOI: 10.3390/ijms24087669