

mikrobiologiju i citologiju

# MOLECULAR LABORATORY DIAGNOSTIC IN SERVICE OF REPRODUCTIVE HEALTH

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#### **INTRODUCTION AND GOALS**

Effective laboratory services play a crucial role in early disease detection. Achieving this relies on the timely delivery of reports and maintaining the high quality of the essential components illustrated in Figure 1a.

Starting in 2019, the genetic department at Polyclinic Breyer embarked on a journey to incorporate new tests related to reproductive health, as indicated in Figure 1b, alongside our main biochemistry laboratory. Our primary objective was to enhance the precision and quality of laboratory reports while simultaneously enhancing the overall flexibility of our services. This applied to both the recently introduced tests and those that had been part of our laboratory service for many years.

#### MATERIALS AND METHODS

In all genetic laboratories in Breyer, following common procedures and standards are implemented: design and compliance of specialised laboratory spaces, laboratory staff training, daily quality control procedures, new tests validation, evaluation of specimen transport media, increasing the speed of analyses. The success of on-site analyses was evaluated by the percentage of repeated analyses and the number of resampled cases.

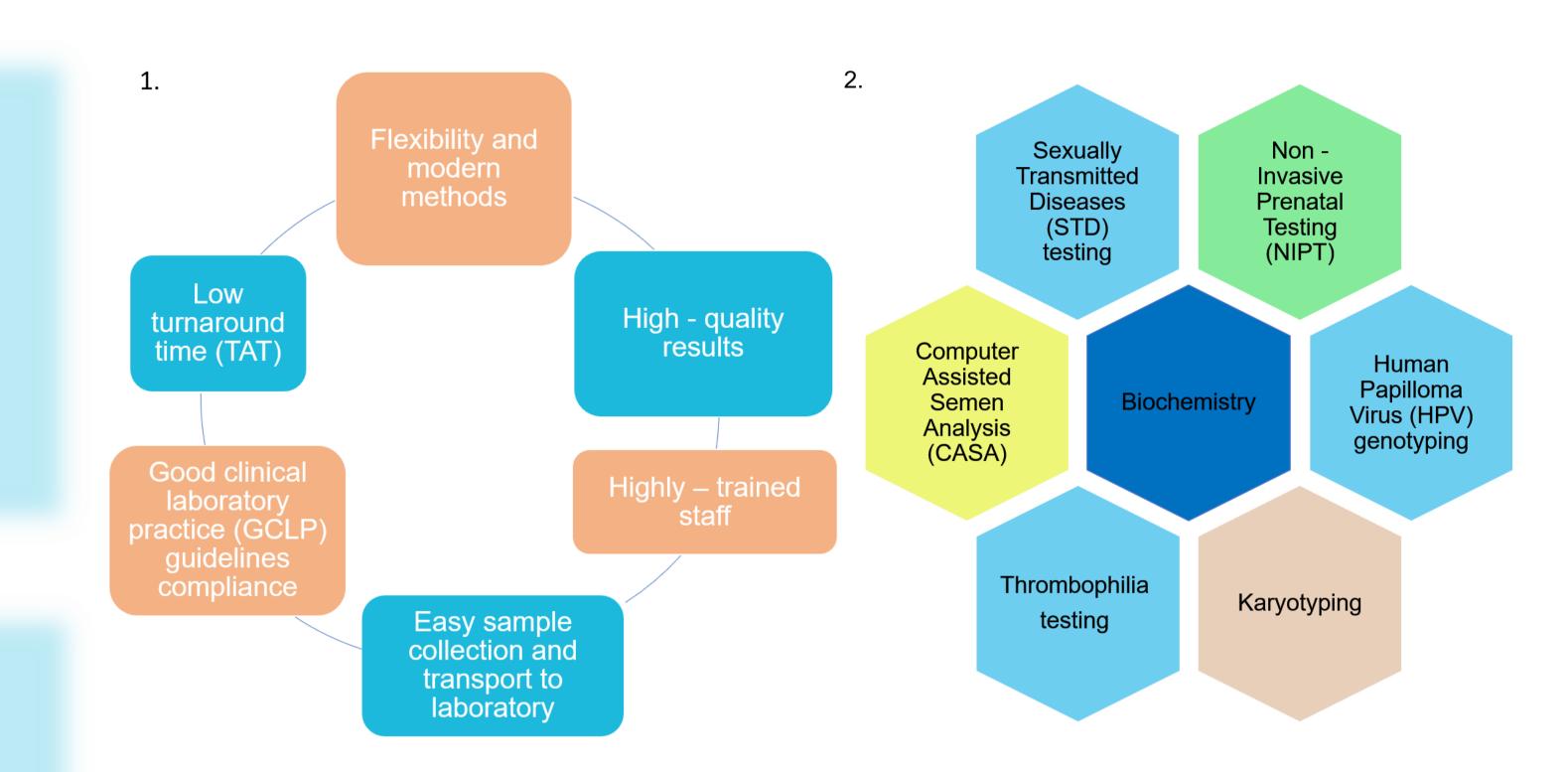
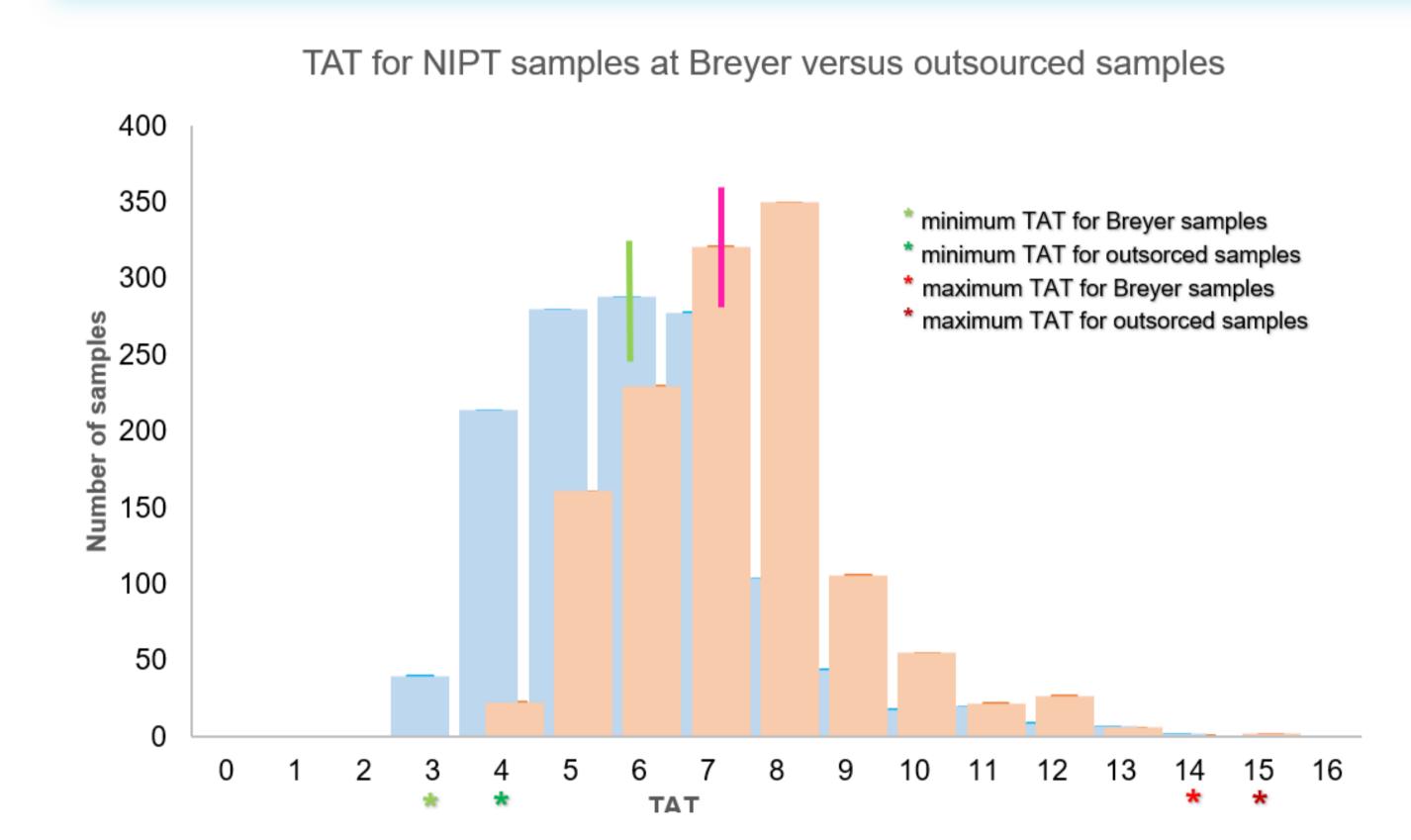


Figure 1. a) Components of laboratory service that guarantee high - quality and timely reports.

b) Reproductive health and pregnancy diagnostic testing performed in Breyer laboratories.

## **Turnaround time (TAT)**

Values of TAT for NIPT samples belonging to patients from Breyer in comparison to outsourced NIPT samples are following: minimum TAT 3 versus 4 days, maximum TAT 14 versus 15 days and mean TAT 6 versus 7 days (Figure 2).



**Figure 2.** TAT for 1304 NIPT samples drawn at Breyer (blue) versus 1304 outsourced samples (orange). TAT is calculated as the time in days from the day of sampling (venipuncture) to the day of report delivery. Mean of 6 days for Breyer TAT is marked by green vertical line, while mean of 7 days for outsourced samples with pink vertical line. Minimum and maximum TAT is represented by asterisk (\*) on the graph. Statistics were generated using non - personal and non - medical data.

### Assessment of success rate

An essential indicator of laboratory service quality is the remarkably low percentage of analyses requiring repetition, as depicted in Figure 4. In the case of STD analyses, only three analyses required repetition. For HPV analyses, out of a total of 88 conducted, only five needed to be repeated. Instances of repetition were caused by variety of factors, including staff errors, equipment malfunctions, poor sample quality, and unsatisfactory quality control.

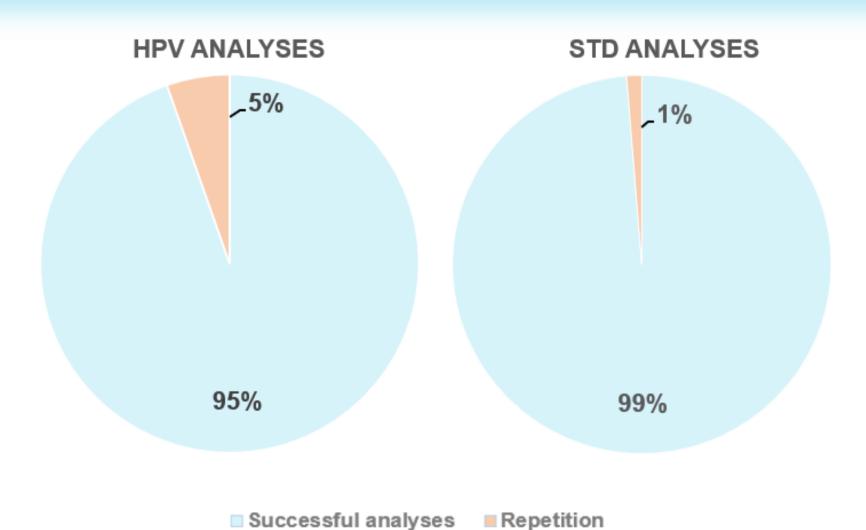
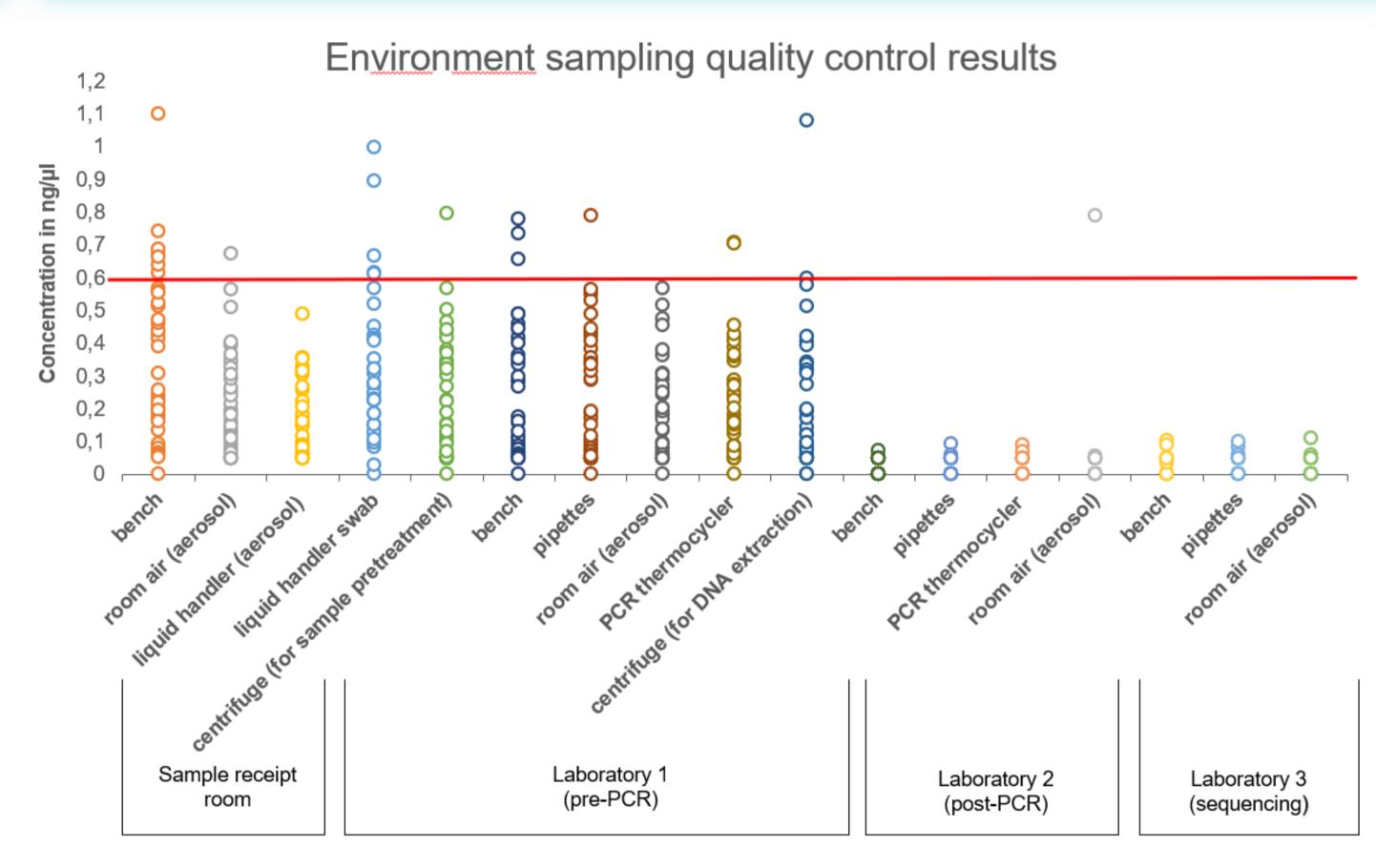


Figure 4. STD and HPV analyses success rate.

### **RESULTS**

#### Quality control - environment testing

Over the period from January 2019 to July 2023, a total of 40 rounds of environmental sampling were conducted. Only in a mere 3.08% of the 680 measurements taken were the concentrations found to exceed the permissible limits, as illustrated in Figure 3.

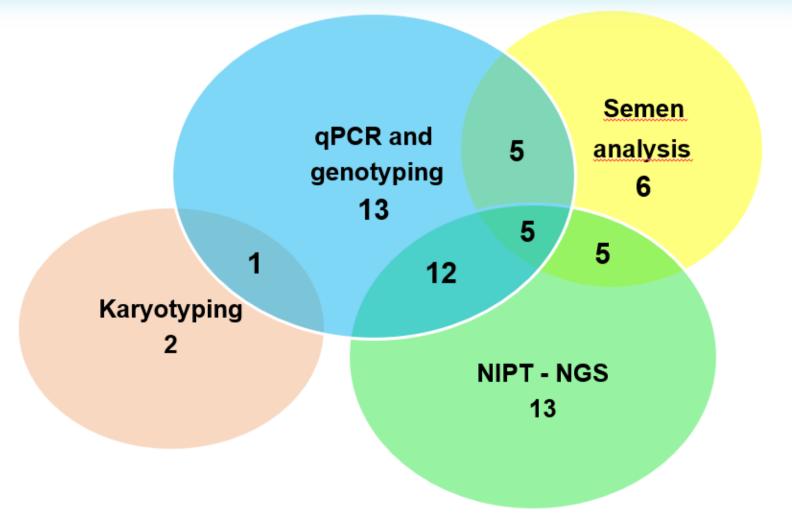


**Figure 3.** Environment sampling for quality control. Measured concentration for every sampling location in each round of environment testing (40 in total) is represented with its individual color. The red line represents the threshold for contamination detection (0,6 ng/ $\mu$ L). The swabs and aerosol samples underwent the same laboratory protocol as NIPT samples. Concentrations of DNA were measured with Qubit fluorometer.

#### Training, education and certification

The genetic department team at Breyer Polyclinic is well - versed and skilled in a variety of molecular techniques, as illustrated in Figure 5. An employee can acquire a certificate for their competency in conducting the next generation sequencing (NGS) protocol for NIPT analysis, which requires several months of training, due to the protocol's complex and highly technological nature.

Figure 5. The distribution of Breyer department personnel's genetic expertise in various molecular methods. In cases where there is an overlap, it signifies that certain staff members are to rotate across multiple trained workstations. Certificate confirms that staff is trained for sample pretreatment, automated DNA extraction, library DNA construction, quantification (microplate reader) and sequencing.



All employees - 16
Employees with certificate - 11
Employees validating reports - 6

## CONCLUSIONS

By implementing effective laboratory space design, continuous staff training, expanding in - house testing capabilities, and adopting real-time sample quality monitoring, the laboratory gained the ability to influence both the quality and timeliness of reporting. Additionally, investing in the validation of flexible specimen transport and storage solutions brings multiple advantages for patients, physicians, and diagnostic laboratories alike. The combined impact of these factors significantly enhances the speed and accuracy of disease diagnosis and treatment.

#### REFERENCE