MOLECULAR LABORATORY DIAGNOSTICS IN THE SERVICE OF REPRODUCTIVE HEALTH

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INTRODUCTION AND GOALS

Effective and high-quality laboratory medical services play a crucial role in comprehensive understanding of a patient's clinical profile, enabling more effective prevention, accurate diagnosis, targeted treatment, and informed reproductive planning. Equally important aspect is flexibility in laboratory services, characterized by key components highlighted in Figure 1. Laboratories often face a trade-off between quality and speed of reporting. Our goal was to eliminate this compromise by providing highly accurate and reliable results while significantly enhancing service flexibility.

Since 2019, the Genetic department at Poliklinika Breyer has progressively implemented a range of molecular diagnostic tests focused on reproductive health, alongside already established biochemistry, microbiology and cytology departments and laboratories (Figure 2). We present data on the efficacy of our HPV and STI testing for patients in care of their reproductive health, highlighting the importance of delivering accurate results quickly and minimizing the need for resampling.

MATERIALS AND METHODS

To support the integration of assays illustrated in Figure 2, the following common procedures and standards are implemented: specialized laboratory space design, personnel training, new tests validation, daily quality control procedures and evaluation of specimen transport media. The Genetic Department team at Poliklinika Breyer is highly experienced in a wide range of molecular techniques (Figure 3) and currently includes 10 members.

The success of on-site analyses was evaluated by the percentage of samples requiring repeated analysis and specimen resampling. Samples for STI and HPV testing were collected between September 2022 and December 2024. DNA was isolated using an automated system, with spin-columns applied as a more sensitive method in cases of low DNA concentration. All analyses were performed using qPCR on various sample types, such as genital swabs immersed in the specimen transport and storage medium, urine or ejaculate. Data processing was conducted in Excel.

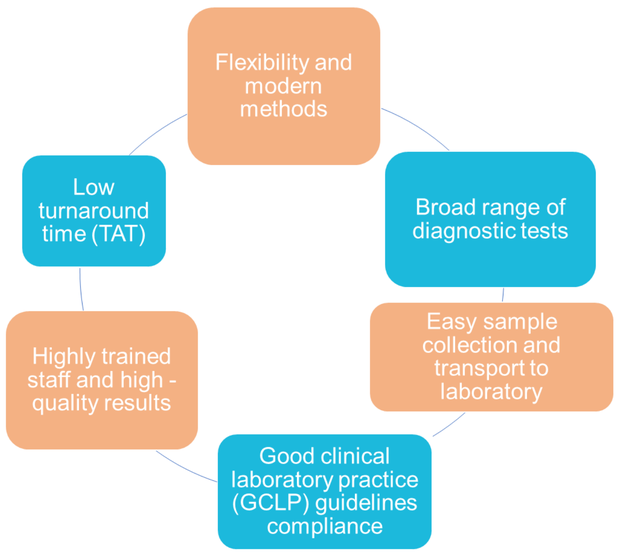

Figure 1. Components of laboratory service that guarantee high-quality and timely reports.

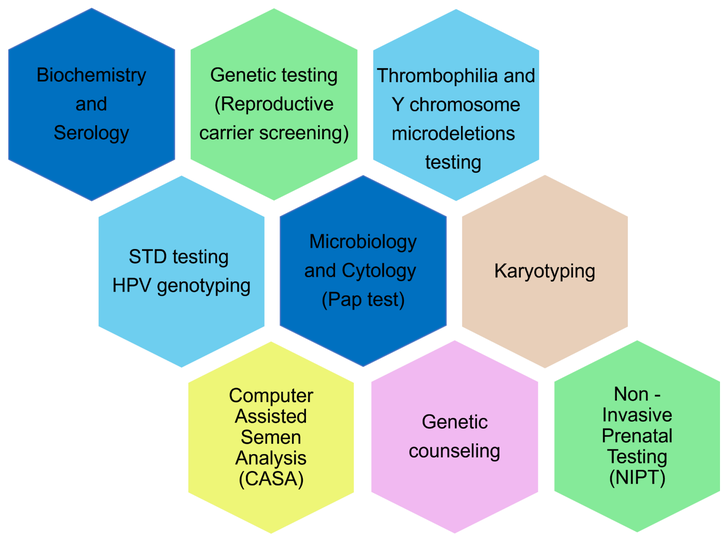

Figure 2. Reproductive health and pregnancy testing available in Poliklinika Breyer.

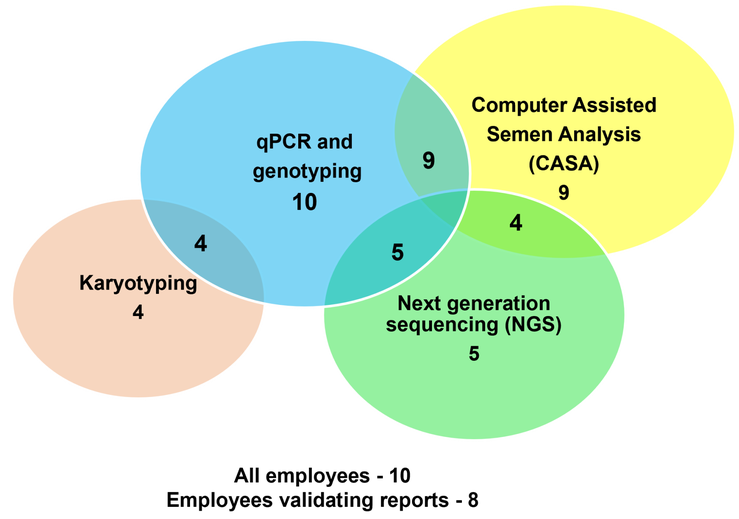

Figure 3. The distribution of Poliklinika Breyer Genetic department personnel's expertise in various molecular methods. In cases where there is an overlap, it signifies that certain staff members are trained to rotate across multiple workstations.

RESULTS

In the STI analyses, only 3 of 459 analyses required repetition. For HPV, just 5 of 221 analyses needed to be repeated. These repetitions were attributed to various factors, such as staff errors, equipment malfunctions and unsatisfactory quality control (Figure 4).

Among the 4890 STI samples analyzed, 18 required re-isolation using a more sensitive method. Of these, 13 were successfully processed, while in 5 cases a new sample had to be requested (Figure 5). Similarly, out of 1630 HPV samples, 13 required re-isolation; 6 were successfully analyzed, while 7 required resampling (Figure 6). The primary reason for failed analyses, whether requiring repetition or resampling, was poor sample quality (e.g., low DNA concentration, polymerase inhibition, or unidentified factors).

Overall, the success of on-site analyses was measured through two key performance indicators: repeat analysis rate and specimen resample frequency. Both metrics demonstrated high laboratory quality, as reflected in a very low proportion of repeated analyses and resampling (Figures 5 and 6).

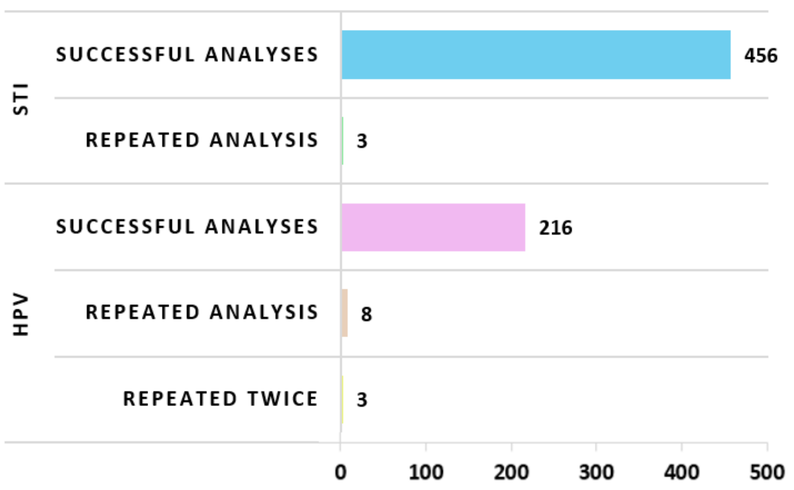

Figure 4. The graph shows the ratio of successful and unsuccessful analyses for STI and HPV testing, presented as the number of analyses. All analyses were successful after repetition.

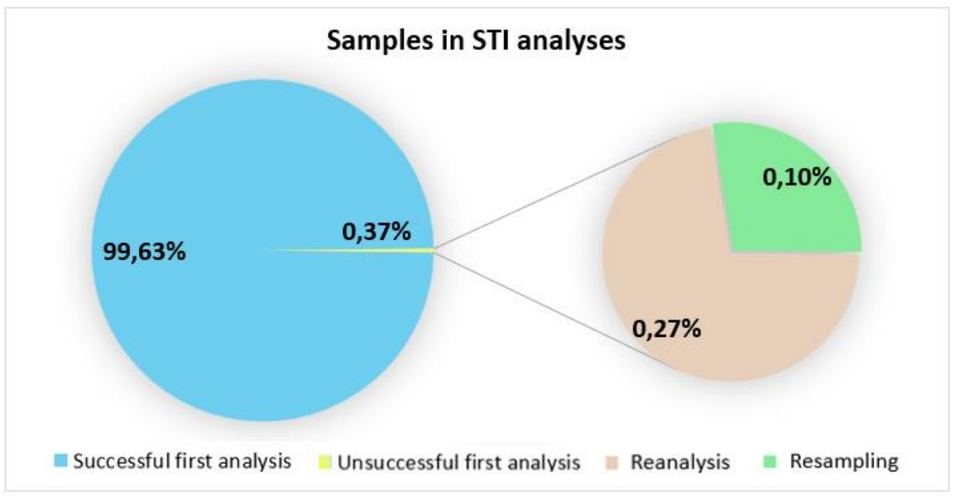

Figure 5. The chart shows the success rate of STI sample analyses in percentages. The left part of the pie chart illustrates the proportion of successfully and unsuccessfully analyzed samples. The right part shows the breakdown of samples successfully analyzed after reanalysis or resampling.

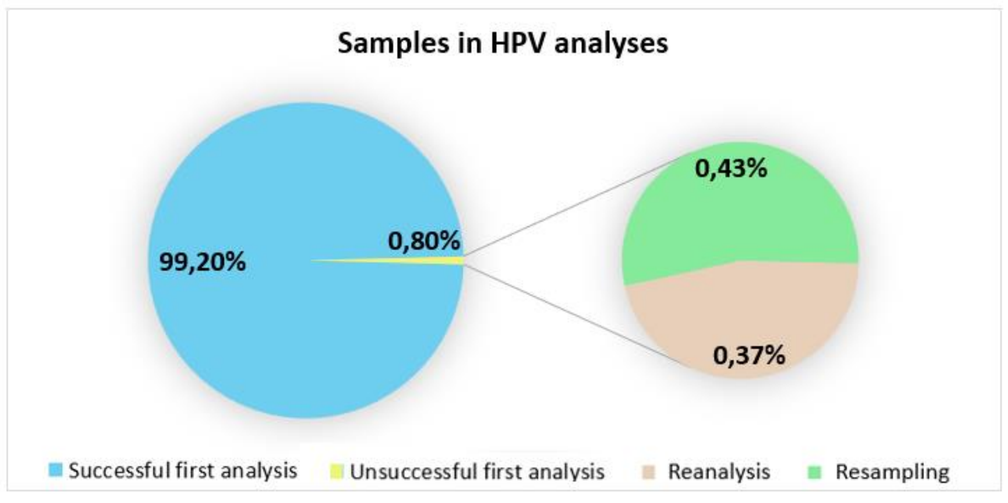

Figure 6. The chart shows the success rate of HPV sample analyses in percentages. The left part of the pie chart illustrates the proportion of successfully and unsuccessfully analyzed samples. The right part shows the breakdown of samples successfully analyzed after reanalysis or resampling.

CONCLUSIONS

Optimized laboratory design, continuous staff training, expanded in-house testing, and real-time sample quality monitoring improved both quality and turnaround time. All patients were successfully tested for STI and HPV, with only a minimal need for resampling. Additionally, investing in the validation of flexible specimen transport and storage media provided clear benefits for patients, physicians and diagnostic laboratory. When compared with manufacturer-provided performance metrics, our laboratory demonstrated lower rates of repeat analyses and resampling. Moreover, our on-site turnaround times rank among the fastest in the Croatian market, supporting quicker and more accurate diagnosis and treatment.

REFERENCE

Laboratory design and maintenance. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs). Licence: CC BY - NC - SA 3.0 IGO.