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National Transfusion Service of Slovakia chooses the Quadriga BeFree System, Enzygnost (ELISA) Assays

Case
Study



**National Transfusion Service
of Slovakia chooses the
Quadriga BeFree System,
Enzygnost (ELISA) Assays
for High Throughput and Extended Walkaway Time**

“With the Quadriga BeFree System and ELISA assays from Siemens, our operators simply load the reagents and samples in batch mode, walk away, and can focus on their other responsibilities.”

Dr. Monika Kračunova, head of the viral screening central laboratory,
National Transfusion Service of Slovakia



When the National Transfusion Service (NTS) of Slovakia decided several years ago to consolidate from nine laboratory testing facilities down to three, it needed to upgrade to a fast, high-throughput, and fully walkaway system for blood-donor screening. For more than a decade, NTS had used instrumentation from Abbott Laboratories, and it recognized that it was time for a change. Entering a new era of high-performance cost-effectiveness, the organization chose Quadriga BeFree® System with Enzygnost® (ELISA) assays from Siemens Healthineers.

Ensuring safety of the Slovakian blood supply

NTS is a nonprofit institution operating under a government commission to ensure the availability and safety of blood products to Slovakian patients. Formed in 2004, NTS serves a population of 5.5 million and, on a normal day, takes in 600 to 700 blood donations at 12 centers nationwide. The safety of donors and patients is its highest priority. NTS follows strict national guidelines covering the handling of tubes, transport and storage, infection-marker testing, blood-group serology, and primary-sample archiving.

In 2009, NTS began to renovate its blood-donation sites to make them more comfortable for donors. In addition, it launched an initiative to increase the cost efficiency of serological screening by reducing manufacturing of blood products from nine sites to three. The original nine manufacturing sites most recently had used Abbott AxSYM and Abbott ARCHITECT systems. NTS's drive to optimize workflows led it to choose the Quadriga BeFree System with Enzygnost assays.

Quadriga BeFree System delivers high productivity through automation

The Quadriga BeFree System provides fully automated processing of microtitration plates (MTP), with comprehensive quality management and a broad menu of assays for infectious-disease diagnostics. Composed of up to three BEP® III Systems and a sample processor, the Quadriga BeFree System loads samples



continuously in batch mode and processes them all the way through to result reporting and archiving; operators simply load and supervise, while the smart software demonstrates traceability of operational steps. Automated MTP processing generates up to 3000 results in an eight-hour shift with little or no manual intervention.

NTS chose the Quadriga BeFree System for its cost efficiency, high throughput, and archiving capabilities. The organization deployed a Quadriga BeFree System — composed of two BEP III Systems and the Freedom EVO automated sample-management module—in each of its three consolidated central labs. Blood samples from the 12 national blood-donation centers arrive in the central labs in batches throughout the day. In addition, NTS conducts regional blood drives every weekend in public places where potential donors congregate. Several times a year, NTS conducts special donation campaigns in alliance with the Slovak Red Cross. The organization's Quadriga BeFree Systems must operate reliably around the clock and easily handle demand peaks of 1500 samples a day at the three blood-products manufacturing sites. Of the 164,500 donations screened yearly, NTS screens 160,000 on these systems using Enzygnost assays.

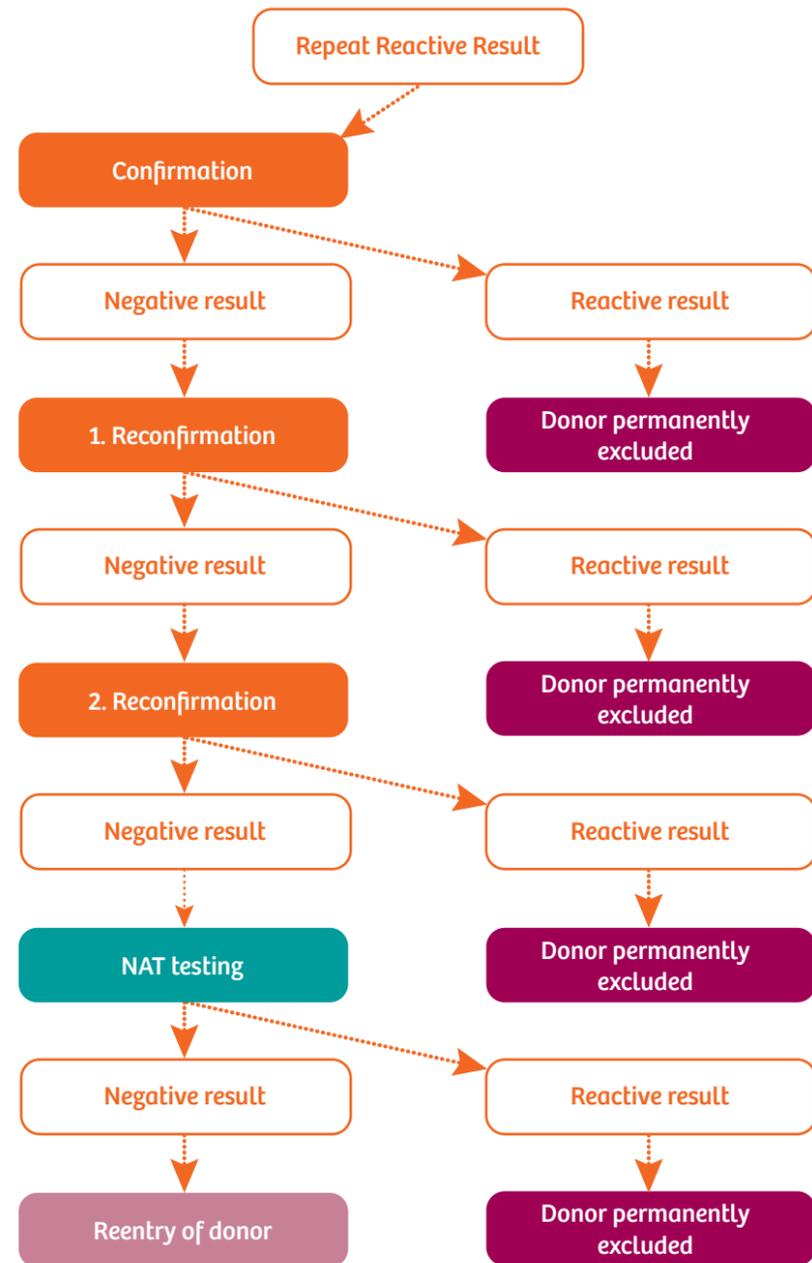
“Here we see the big advantage of the Quadriga BeFree System,” says Dr. Monika Kračunova, head of the NTS viral screening central laboratory. “We can load all samples at once after the delivery to the lab. Our operators just load the reagents and the samples in a batch mode, walk away, and can focus on their other responsibilities. The processing of microtitration plates runs automatically and doesn't require additional technician time.”

Archiving capability satisfies critical requirement

The Slovak government mandates 10 years' archiving of donor primary samples for look-back purposes. The Quadriga BeFree System's 96-well bar-coded microtitration plates make it simple to satisfy that requirement. Technicians simply load samples on the sample-management module and press a button to begin processing. The archiving is handled by the Quadriga BeFree System, with plasma volume of 800 µl of each sample automatically archived at the end of the day. A report is printed, and each of the 96 samples is dispensed in a specific well on the MTP. NTS stores the MTP plates in an archive freezer and can track and identify samples whenever look-back is requested. The process meets the applicable safety standards, with human error minimized because of automated sample handling.

“Our storage capacities are very limited, but deep well plates are spacious and free up space in our lab,” Dr. Kračunova says. “The archive feature is a standout feature of the Quadriga BeFree System, and a real benefit to NTS.”





Enzygnost (ELISA) assays speed end-to-end results

NTS examines all blood donations for blood-group serology and infection markers using the following Enzygnost assays: HIV Integral 4, HBsAg 6.0, Anti-HBc monoclonal, Anti-HCV 4.0, and Syphilis. Initially reactive samples are tested again, and if still considered reactive after retesting, the sample is clarified according to a confirmation method (see sidebar). NTS conducts all of its blood-donor serology screening, and manufacturing of blood preparations in strict accordance with regulations issued by the Ministry of Health of the Slovak Republic. An audit by Slovakia's State Institute for Drug Control and an independent inspection by Grifols, S.A., are held every second year. Grifols, a world supplier of plasma-derived

products, uses blood from NTS and conducts nucleic acid test (NAT) testing on samples; over three years, all samples showed concordant results in NAT compared to ELISA screening. NAT testing of blood-donor samples is not mandatory in Slovakia at present, but NTS plans to implement it in the near future.

Successful participation in external quality assessments is a condition of laboratory certification. NTS has passed and received certificates of hepatitis B, hepatitis C, HIV, and syphilis serology surveys.

If an unexpected result is found, Siemens Healthineers launches an investigation for verification of assay performance. "That gives us confidence in the assay we use," Dr. Kračunova says.

"I want to highlight the outstanding technical support we receive from Siemens. The field engineers react very quickly and fully understand how crucial testing for supplying hospitals with lifesaving blood products."

Dr. Kračunova says.

Results indicate excellent specificity with ELISA assays

Data collected over three years on the testing of approximately 305,000 blood-donor samples across the three sites indicates that the Siemens Healthineers ELISA assays delivered excellent retest reactivity (RR) specificity:

Assay Tested 2014–2016	Number of Tests*	RR Specificity (%)
Enzygnost HIV Integral 4	304,822	99.96
Enzygnost Anti-HCV 4.0	305,089	99.96
Enzygnost Syphilis	305,309	99.92
Enzygnost Anti-HBc monoclonal	304,812	99.90
Enzygnost HBsAg 6.0	305,059	99.83

*There were no NAT-only positive results (all NAT-positive results were detected in ELISA screening as well). Data provided by NTS.

Support ensures high performance

In addition to high-performing systems and assays, Siemens Healthineers provides NTS with extraordinary technical and application support, Dr. Kračunova says. For example, after several weeks of using the Quadriga BeFree System and Enzygnost reagents, an issue emerged with falsely reactive HBsAg samples. The root cause turned out to be poor water quality from an external source. To ensure high performance of the system and assays, Siemens Healthineers bore the cost of replacing the water-supply units. In general, their technicians are able to find root causes quickly via remote access to instruments and often can even fix problems remotely. When site visits are needed, the response is fast and effective to keep instruments in peak operational condition around the clock.

Also crucial to NTS success was the training Siemens Healthineers provided for laboratory technicians who operate the Quadriga BeFree System. "Thanks to

a patient approach during the implementation and training phase, our operators gained confidence," Dr. Kračunova says. "A lot of potential issues have been avoided. The technical and application support we receive from Siemens is extraordinary."

Leveraging Siemens Healthineers solutions, supplies, and support, NTS has successfully consolidated its laboratory testing facilities, optimized workflows, freed up technicians' time, cut costs, and ensured the safety of the blood supply to patients all over Slovakia. "Our laboratories need to run reliably, 24 hours a day, seven days a week —while meeting strict regulatory requirements," Dr. Kračunova says. "We succeed with confidence, supported by the high-throughput capacity of the Quadriga BeFree System, the reliability of ELISA assays, and outstanding service from Siemens."

Slovak National Transfusion Service (NTS) at a glance

- Population served: 5.5 million
- 12 regional sites; three have laboratory testing facilities
- 164,500 blood donations per year:
 - 160,000 whole blood
 - 4500 aphaeresis
- Produced and delivered to hospitals:
 - 158,000 red blood cell concentrates (RBC) per year
 - 19,000 platelets concentrates (PT) per year
- 160,000 of total 164,000 donations screened on Quadriga BeFree System with Enzygnost assays (ELISA)
- Each of the three central labs has a Quadriga BeFree System with the Freedom EVO automated sample-management module and two BEP III Systems

Tests performed

All blood donations are examined for blood-group serology and infection markers. Infection testing is carried out with the following Enzygnost tests: HIV Integral 4, HBsAg 6.0, anti-HBc monoclonal, anti-HCV 4.0, and Syphilis. All initially reactive samples are tested again in duplicate, and if still considered reactive after retesting, the sample must be clarified according to a confirmation method. (See Figure 1 showing algorithms for confirmation of each parameter.) The confirmation methods are:

- For HBsAg-reactive samples: an independent HBsAg confirmatory test
- For anti-HBc-reactive samples: an independent anti-HBc assay
- For anti-HCV-reactive samples: an independent HCV immunoblot assay
- For HIV-reactive samples: an independent ELISA HIV Ag/Ab assay and independent HIV immunoblot assay
- For syphilis-reactive samples: an independent VDRL assay, ELISA assay, immunoblot assay, and FTA Abs IgG assay
- Re-entry of a donor is possible only if confirmation tests performed at the National Reference Center are negative and the final result of an independent NAT assay is negative as well.