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Blutspendedienst des Bayerischen Roten Kreuzes

Routine blood donor screening on a new NAT platform

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Introduction

According to the German guidelines all blood donations must be screened for transfusion-relevant viruses by nucleic acid amplification testing (NAT). In June 2022, a new high-throughput, fully automated NAT platform called *PoET Instrument* (GFE) running CE-IVD PCR-based assays was introduced. In this study, we used this new platform to test minipools of whole blood and apheresis donor plasma samples for the presence of HCV, HBV, HIV-1/-2, HAV and B19V.

Methods

NAT screening of the blood donations was performed in minipools of up to 96 EDTA-Plasma samples. On the *PoET Instrument* (Figure 1) three-times 1.3 ml plasma of each pool was extracted followed by PCR amplification (real-time RT-PCR) and detection. CE-IVD PCR assays (PoET HCV, PoET HBV, PoET HIV, PoET HAV, PoET B19V) were used. Analytical sensitivities (95% LoD) according to manufacturer information for detection of HCV, HBV, HIV, HAV and parvovirus B19 are listed in Table 1.

Table 1. Sensitivity (95 % LoD) for NAT-screening on the *PoET Instrument*

virus	reference material (WHO IS)	95 % LoD	confidence interval	95% LoD [IU/ml] in a pool with 96 samples
HCV	# 14/150	9.1	6.6 - 15	874
HBV	# 10/264	1.6	1.4 - 2.1	154
HIV-1	# 16/194	15	11 - 29	1,440
HIV-2	# 16/296	9.2	6.3 - 18	883
HAV	# 15/276	0.87	0.72 - 1.1	84
B19V	# 12/208	8.6	7.2 - 11	826

In a routine setting, up to 1,440 donor samples per run were tested for 5 viruses within 3.5 hours. Result evaluation was performed by the system (Calliope Management Software).

Results

Workflow

The routine NAT testing on the new platform *PoET Instrument* startet in June 2022. Daily NAT testing of up to 3,000 whole blood and apheresis donations was performed on three *PoET Instruments*. Initially, testing of all pools was performed within 3.5 h until 11 a.m. (Figure 2). Testing of secondary pools in order to identify positive samples and repeat testing were finished until 4 p.m.

Daily routine blood donor screening			
12:00 AM 12:30 AM 1:00 AM 1:30 AM 2:00 AM 2:30 AM 3:00 AM 3:30 AM 4:00 AM 4:30 AM 5:00 AM 5:30 AM	**Pooling**		
6:00 AM	Daily Maintenance	Daily Maintenance	Daily Maintenance
6:30 AM	Setup	Setup	Setup
7:00 AM 7:30 AM 8:00 AM 8:30 AM 9:00 AM 9:30 AM 10:00 AM	**PoET 1** 15 pools 1 trend control (HCV, HBV, HIV, HAV,B19V)	**PoET 2** 15 pools 1 trend control (HCV, HBV, HIV, HAV,B19V)	**PoET 3** 15 pools 1 trend control (HCV, HBV, HIV, HAV,B19V)
10:30 AM	**Release of results**	**Release of results**	**Release of results**
11:00 AM 11:30 AM	**Pooling** **(secondary pools: resolving positive pools, repetition pools)**		
12:00 PM	lunch break		
12:30 PM 1:00 PM 1:30 PM 2:00 PM 2:30 PM 3:00 PM	**PoET 1** up to 47 pools (secondary testing) 1 trend control	**PoET 2** up to 47 pools (scondary testing) 1 trend control	
3:30 PM	**Release of results**	**Release of results**	

Figure 2. Time schedule of routine blood donor screening

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Figure 1. *PoET Instrument* (GFE)

Results of Screening

From June 2022 to April 2023, a total of 526,276 donations in 7,174 pools were tested (Table 2). 99.8 % of the tested pools were tested valid. 0.2 % of the tested pools were initially invalid. In the period under consideration, 0.9 % of the pools (n=65) were initially reactive. Out of them, 33 pools (0.46 %) were tested confirmed reactive, while 0.45 % (n=32) of initially reactive pools could not be confirmed.

Table 2. Screening results

period	number of tested pools	rate of valid pools	rate of initial reactive pools	rate of confirmed positive pools	rate of not confirmed reactive pools
June 2022 - April 2023	7,174	99.8 %	0.9 %	0.46 %	0.45 %

Rates of invalid test results were very low with a highest rate of 0.09 % detecting B19V. Rates of reactive pools, for which the reactive results could not be confirmed, were also low. For HCV and HAV no false positive pools were observed. The highest rate of not confirmed reactive pools were obtained for HBV (0.24 %) (Table 3).

Table 3. Performance of PoET PCR assays

	HCV	HBV	HIV	HAV	B19V
Negative tested pools	99.92 %	99.47 %	99.72 %	99.94 %	99.84 %
Confirmed reactive pools	0.04 %	0.26 %	0.06 %	0.03 %	0.07 %
Initially reactive, not confirmed reactive pools	0%	0.24 %	0.17 %	0%	0.04 %
Invalid pools	0.04 %	0.03 %	0.06 %	0.03 %	0.04 %

System performance

In total 1,201 PCR plates in 749 runs were analyzed. 2.54 % (n=19) of started runs could not be finished due to an instrument error. Failed system controls led 11 times to an invalid PCR assay. Based on the tested plates 0.83 % PCR plates were affected by failed system controls.

Table 4. Failure rate of *PoET Instrument*

period	number of runs	failure rate of the instrument	failure rate of system controls
June 2022 - April 2023	749	2.54 %	0.83 %

Conclusions

Our experience with 10 months of testing demonstrates that the new *PoET* screening platform is a sensitive and robust system for routine infection screening of blood donors by NAT.

References

1) Manual PoET Instrument (GFE)