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Function: Medical Director

Main expertise (1-2 lines): Donor screening, IT support of the blood supply

Epidemiology of viral hepatitis among blood donors in Hungary

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Overview

- Hungarian National Blood Transfusion Service (OVSz)
- Workflow
- Screening and confirmatory tests
- Screening and confirmatory algorithms
- Statistical data of the past years
- Summary

Hungarian National Blood Transfusion Service

- Governmental organization
- 1100 employes
- 5 production centers
- 18 territorial (county) blood banks
- 1 IA Screening Laboratory
- 1 NAT Screening Laboratory
- 1 Confirmatory Laboratory



Main activities

- Blood collection
- Component processing
- Laboratory testing of donors
- Component distribution
- Immunohematological testing of patients
- HLA testing of donors and patients
- Organ coordination
- Bone Marrow Registry

Number of IA Screening Laboratories

- Before 2000: 63
- 2000 (establishment of HNBTS): 26
- 2008 (designation of production centers): 6
- 2010 (unification of equipment park): 4
- 2011 (considerations of economies of scale): 2
- Since 2020 (fulfillment of infrastructure conditions): 1

Workflow

- Samples
 - IA
 - NAT
 - Blood group determination
- Administration
 - Each sample registered as item and the IT System is tracking them
- Transport
 - From collection sites to regional centers after collection
 - From Regional Centers to Laboratories during the night

Workflow

- IA Laboratory
 - Preanalytical activities
 - 7/7 days, 3 shifts (24/24)
 - Testing
 - 5/7 days, 2 shifts (16/24)
- NAT Laboratory
 - Preanalytical activities
 - 5/7days, 1 shift (8/24)
 - Testing
 - 3/7days, 2 shifts (10/24)

Screening tests

- IA (*ministerial decree*)
 - HIV Ab (in fact Ag/Ab)
 - HCV Ab
 - HBs Ag
 - HBc Ab (FT donors)
- MP-NAT (*contract with the fractionation center*)
 - HIV 1/2
 - HCV
 - HBV
 - HAV
 - Parvo B19 (quantitative test)

Abbreviations

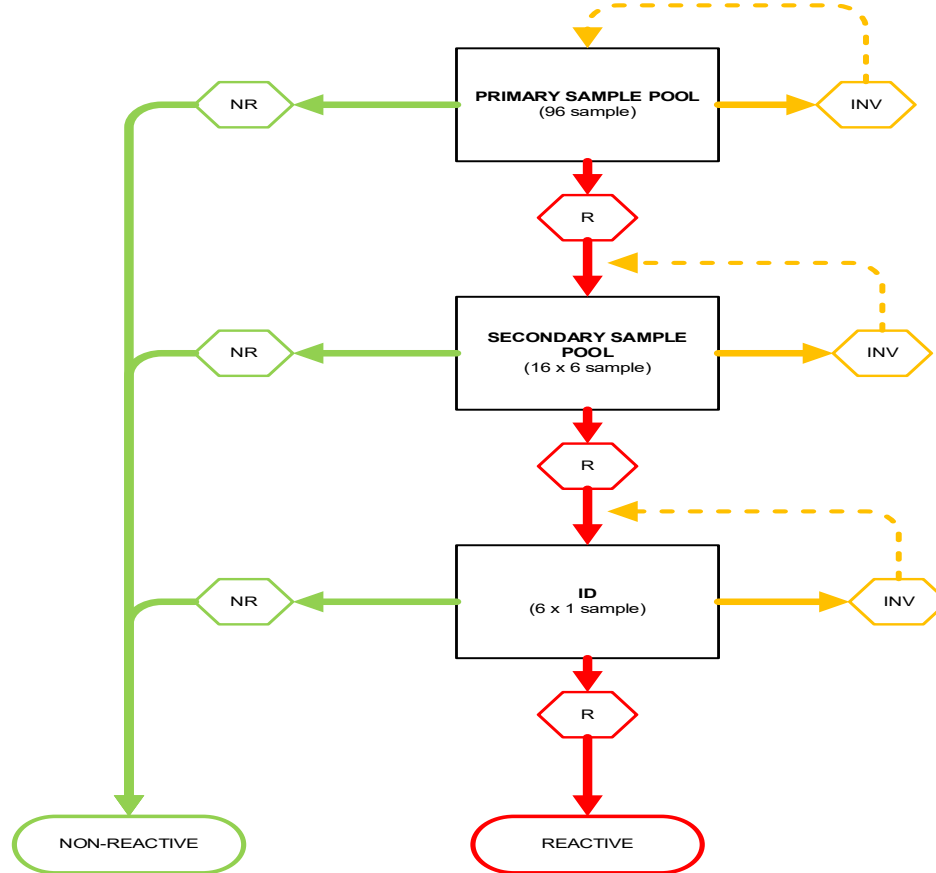
- FT: first time tested Donor
- IA: immunoassay
- MP-NAT: nucleic acid amplification test, from pooled (96 and 6) samples
- ID-NAT: nucleic acid amplification test, from a single sample
- LIA: line immunoassay
- NR: non-reactive result
- R: reactive result
- RR: at least 2 reactive results out of 3 measurements

IA screening algorithm

1+2 measurements („A” „B” „C”)

- „A” NR >> IA NR >> MP-NAT screening
- „A” R >> „B” and „C” must be performed
- „B” and „C” NR >> IA NR >> MP-NAT screening
- „B” and/or „C” R >> IA RR
 - Rejection of components
 - Deferral of the donor
 - Starting of the confirmatory process

MP-NAT screening algorithm



Confirmatory algorithms

HCV

- ID-NAT
- LIA
 - PCR R >> permanent deferral
 - PCR NR >> LIA
 - LIA R >> permanent deferral
 - LIA NR >> temporary deferral (until another IA screening supplier)

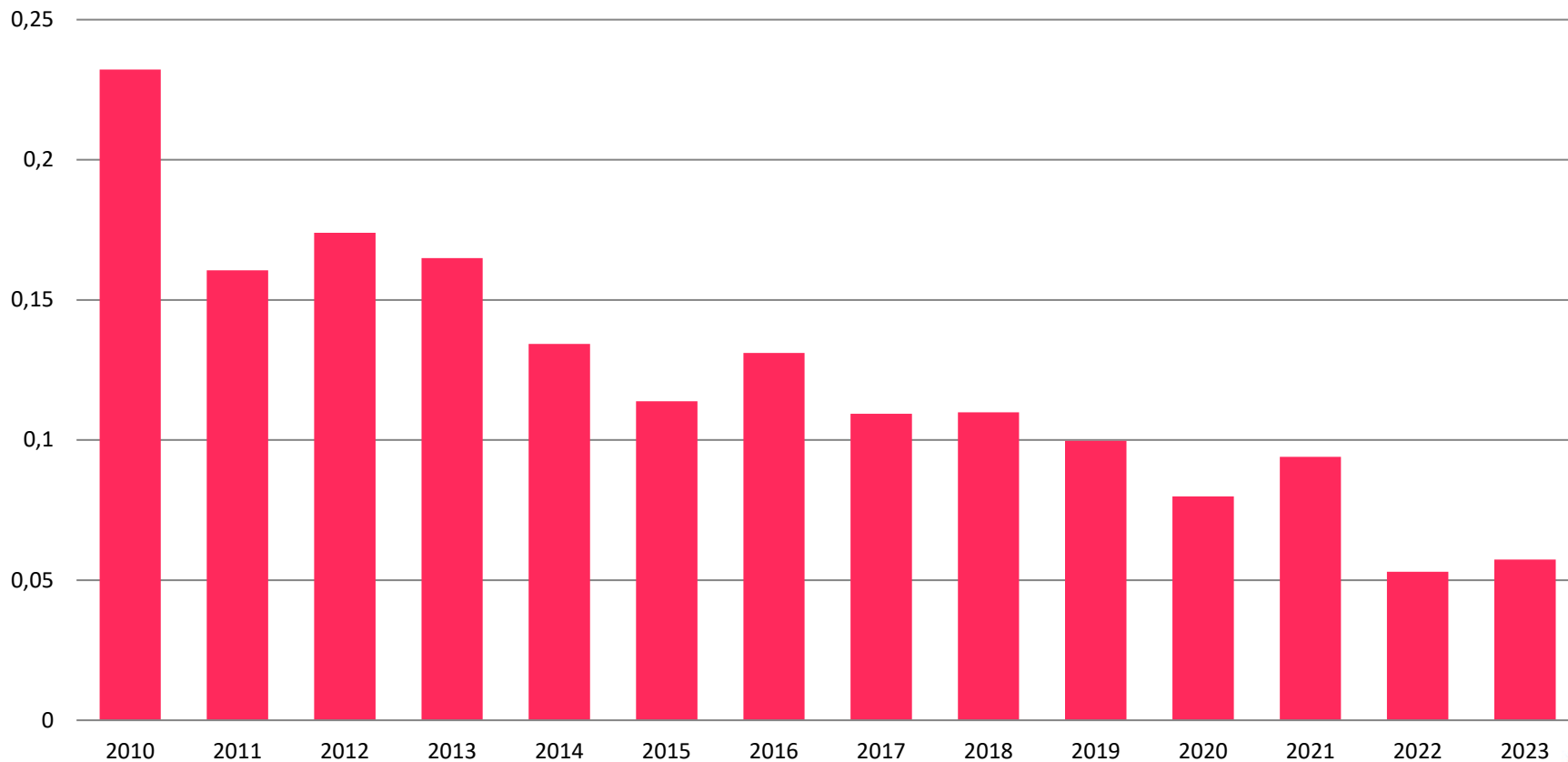
HBV

- ID-NAT
- HBsAg Confirmatory test
 - PCR R >> permanent deferral
 - PCR NR >> HBsAg Confirmatory
 - HBsAg Confirmatory R >> permanent deferral
 - HBsAg Confirmatory NR >> temporary deferral (until another IA screening supplier)

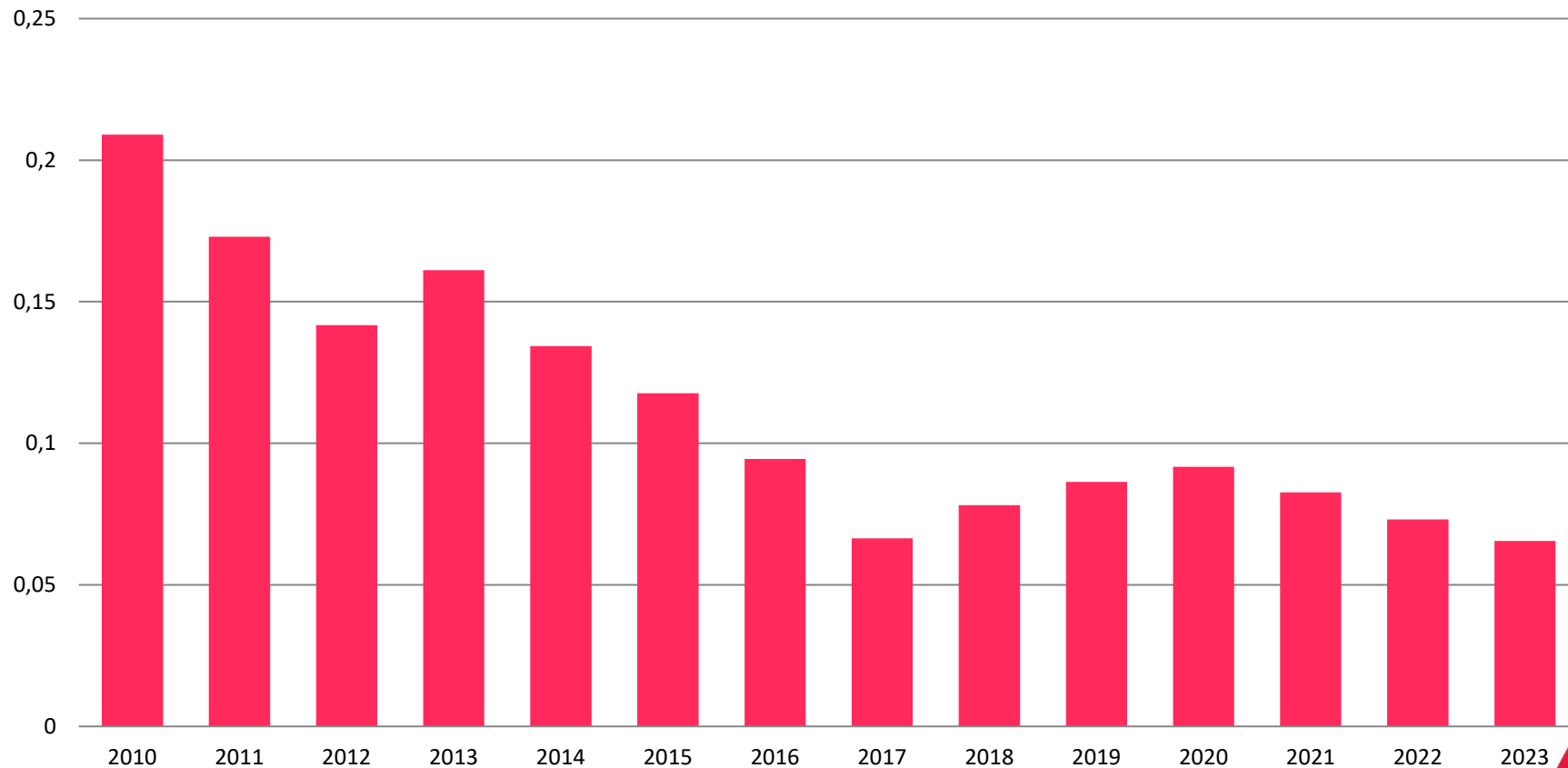
Confirmed positive FT Donors

Year	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	Total
FT Donors	51683	56667	55751	53978	53597	51822	51863	46652	47334	45153	33801	35096	39662	36623	659682
HCV	132	110	130	116	107	81	100	62	63	61	32	40	34	26	1094
HCV%	0,26%	0,19%	0,23%	0,21%	0,20%	0,16%	0,19%	0,13%	0,13%	0,14%	0,09%	0,11%	0,09%	0,07%	0,17%
HBV	113	101	89	91	77	65	53	35	43	48	32	31	31	28	837
HBV%	0,22%	0,18%	0,16%	0,17%	0,14%	0,13%	0,10%	0,08%	0,09%	0,11%	0,09%	0,09%	0,08%	0,08%	0,13%
a-HBc	1984	1558	1358	1201	1036	956	846	720	634	763	436	455	423	406	12776
a-HBc%	3,84%	2,75%	2,44%	2,22%	1,93%	1,84%	1,63%	1,54%	1,34%	1,69%	1,29%	1,30%	1,07%	1,11%	1,94%

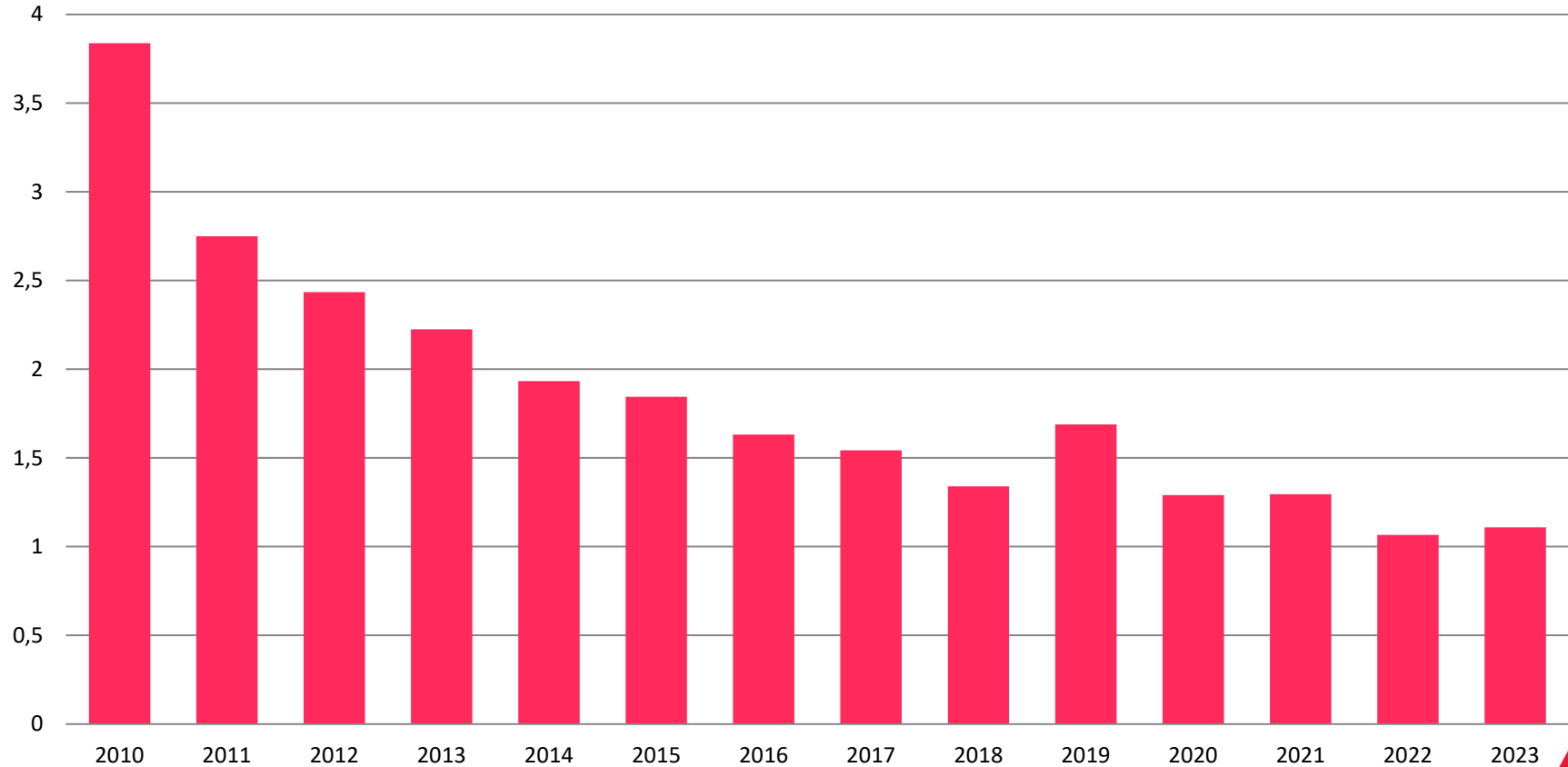
Confirmed HCV positive FT Donors (%)



Confirmed HBV positive FT Donors (%)



Anti-HBc reactive FT Donors (%)



HCV confirmatory statistics

Year	2019	2020	2021	2022	2023	Total
FT Donors	45153	33801	35096	39662	36623	190335
NAT positive	20	20	22	9	15	86
NAT positive%	0,04%	0,06%	0,06%	0,02%	0,04%	0,05%
LIA positive	7	7	11	12	6	43
LIA positive%	0,02%	0,02%	0,03%	0,03%	0,02%	0,02%
LIA indeterminate	24	17	7	12	9	69
LIA indeterminate%	0,05%	0,05%	0,02%	0,03%	0,02%	0,04%

Summary

- Modern technologies can only be used economically above a given test number
- The centralization of laboratory tests was a process of several years, the safety of the supply and blood products was always the primary consideration, but economic aspects also appeared as a serious motivating factor.
- Centralization would not have been possible without a unified donor database
- The unified algorithm would not have been possible without centralization of testing

Thank you very much
for your kind attention