Sanquin
Blood Supply

Creating a productive Screening Laboratory

John Jongerius
Head of screening Laboratory, Sanquin, Amsterdam

RESEARCH | DIAGNOSTICS | PHARMACEUTICALS

Creating a productive screening laboratory
centralization screening

- **2006: implementation of centralized screening (CS) under consideration**

- **Major motives**
  - **To establish uniformity in testing**
  - **To improve the efficiency and cost effectiveness of donation screening**
  - **To avoid high investments for new NAT**
  - **To anticipate on future developments**
    - **open EU market**

Creating a productive screening laboratory

Greenfield calculations

- **22 different models, taking into account:**
  - **Screening in 1, 2 or 4 locations**
  - **Working hours in one or two shifts**
  - **Implementation of a new NAT (pools of 6)**
  - **Costs:**
    - **materials / equipment / maintenance**
    - **staff**
    - **automation**
    - **housing**
    - **general**
    - **transportation**
    - **investments**

Creating a productive screening laboratory

Greenfield calculations

- **Most efficient model**
  - **1 central screening laboratory, two shifts**
    - **~ 50% less**
      - **staff**
      - **major lab devices**
      - **maintenance**
      - **lab space**

- **Approval for implementation of CS:**
  - **Sanquin**
  - **Sanquin Employees Council**
  - **Trade Unions**
  - **Ministry of Health**

Creating a productive screening laboratory
history

- **2007**
  - **Centralization process started**
- **2008**
  - **Centralization completed**
    - **NSS**
- **2009**
  - **NSS moved into a new building**

Creating a productive screening laboratory
blood samples

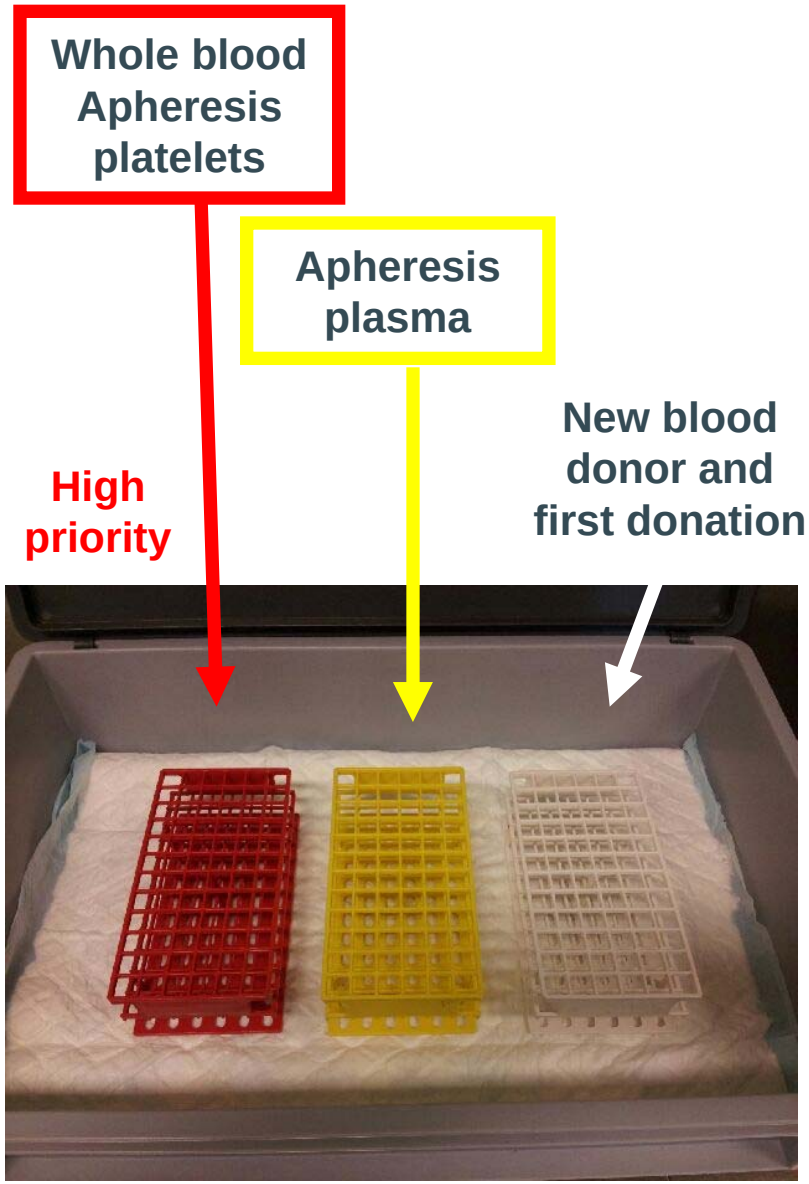
- **Blood samples to be tested**
  - **Thu-Fri : ~ 12.000**
  - **Sat : ~ 6.000**

Creating a productive screening laboratory
blood samples before centralization

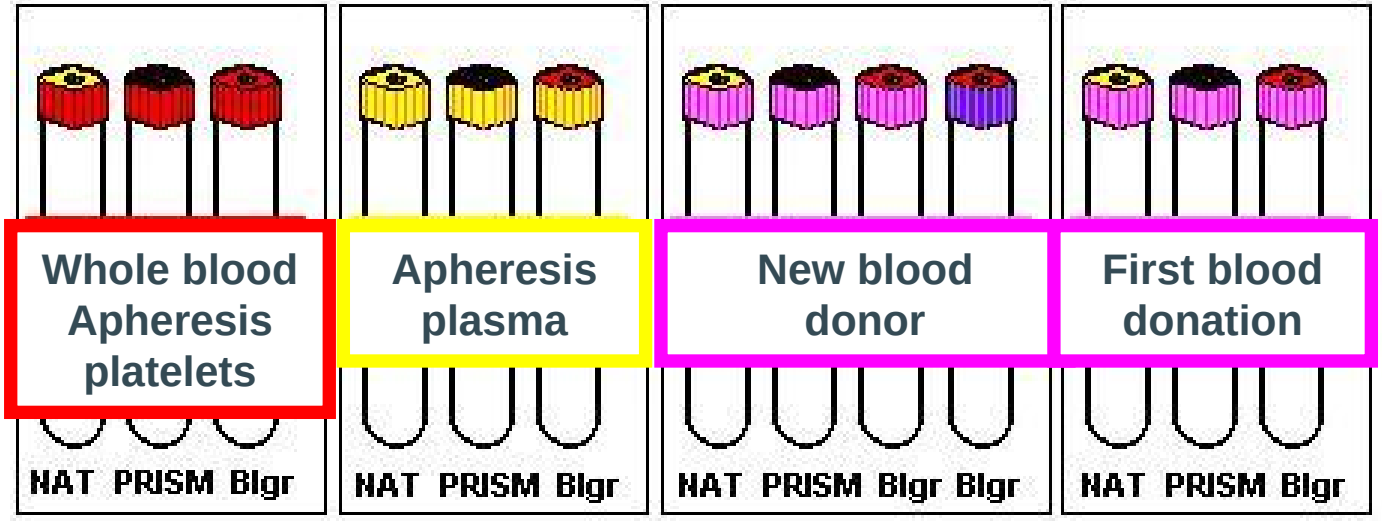
4 BB – 4 procedures for sample processing

- **Standardization**
- **Automation**
- **Implement time saving procedures for searching samples**

Simple but effective



Creating a productive screening laboratory
blood samples after centralization



High priority

Creating a productive screening laboratory
logistics after centralization

2

3

Priority / Stat

3a

4

5

23:00 – 03.00

Creating a productive screening laboratory
logistics after centralization

5a

Creating a productive screening laboratory
logistics after centralization

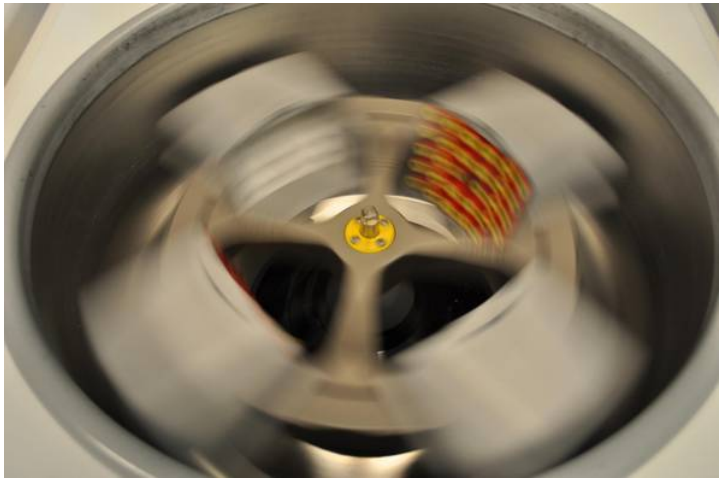
6a

6b

Creating a productive screening laboratory
logistics after centralization

6c

6d



6e

Creating a productive screening laboratory
logistics after centralization

6f

PVT

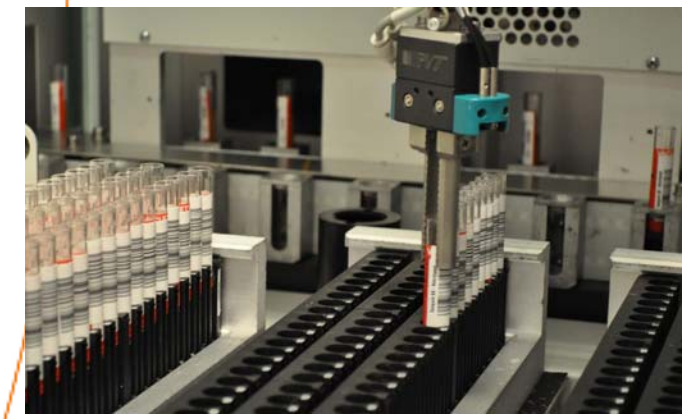
Creating a productive screening laboratory
logistics after centralization

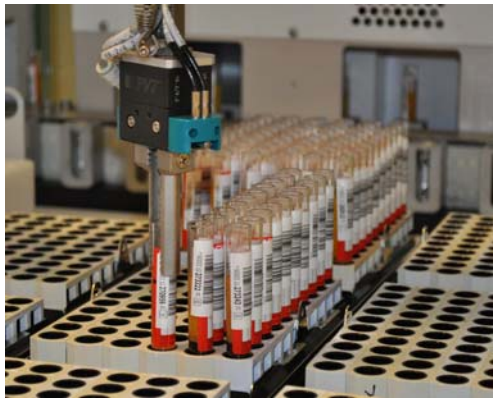
6g

NAT S201

PRISM

Olympus





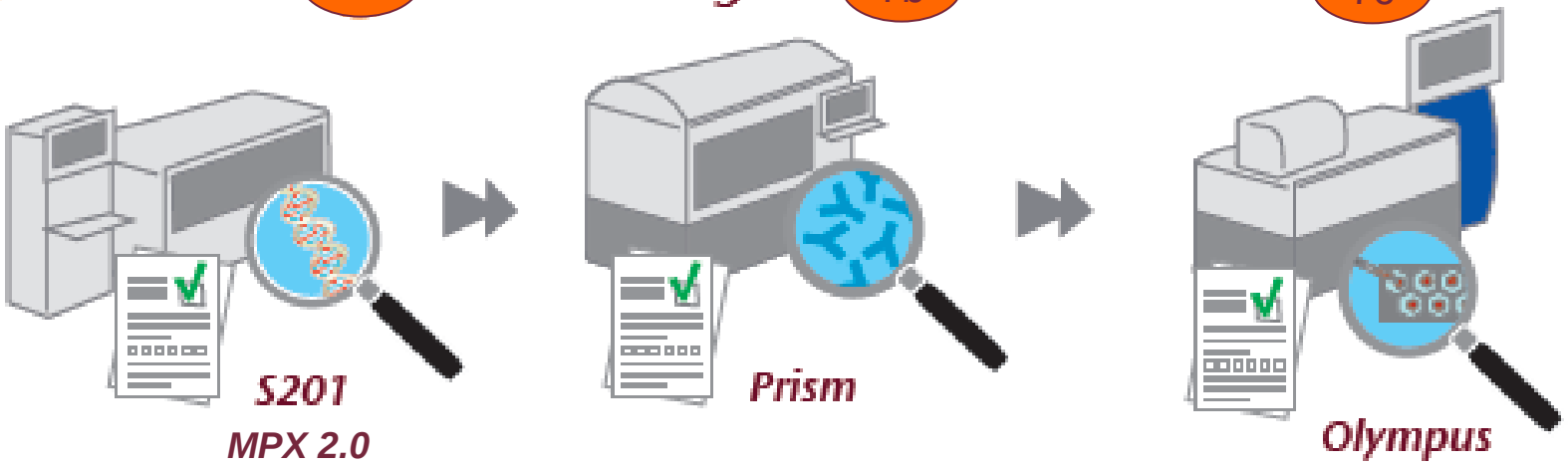
Creating a productive screening laboratory
logistics after centralization

HIV RNA
HCV RNA
HBV DNA

HBsAg
a-HBcAg
a-HIV
a-HCV
a-HTLV

ABO
Rh(D)
C,c,E,e,K
Phenotyping other RBC-antigens
a-*Tp*

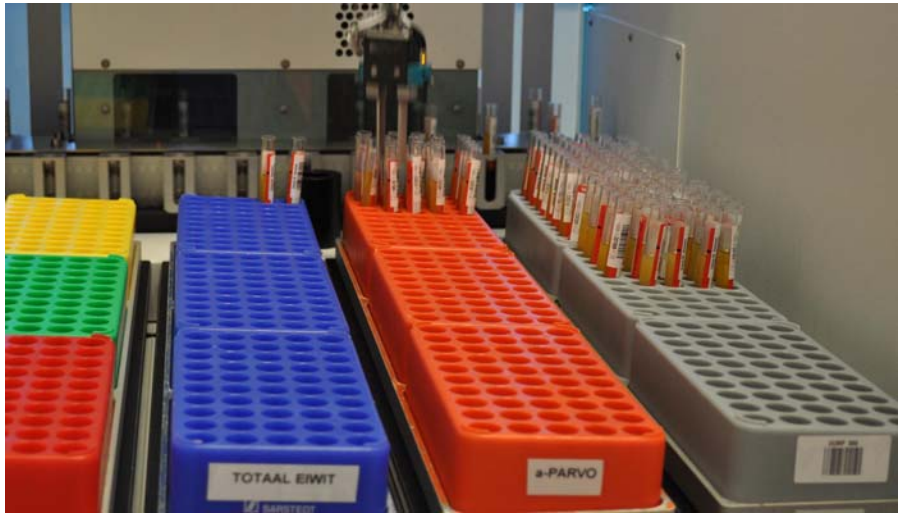
7a Screening 7b 7c



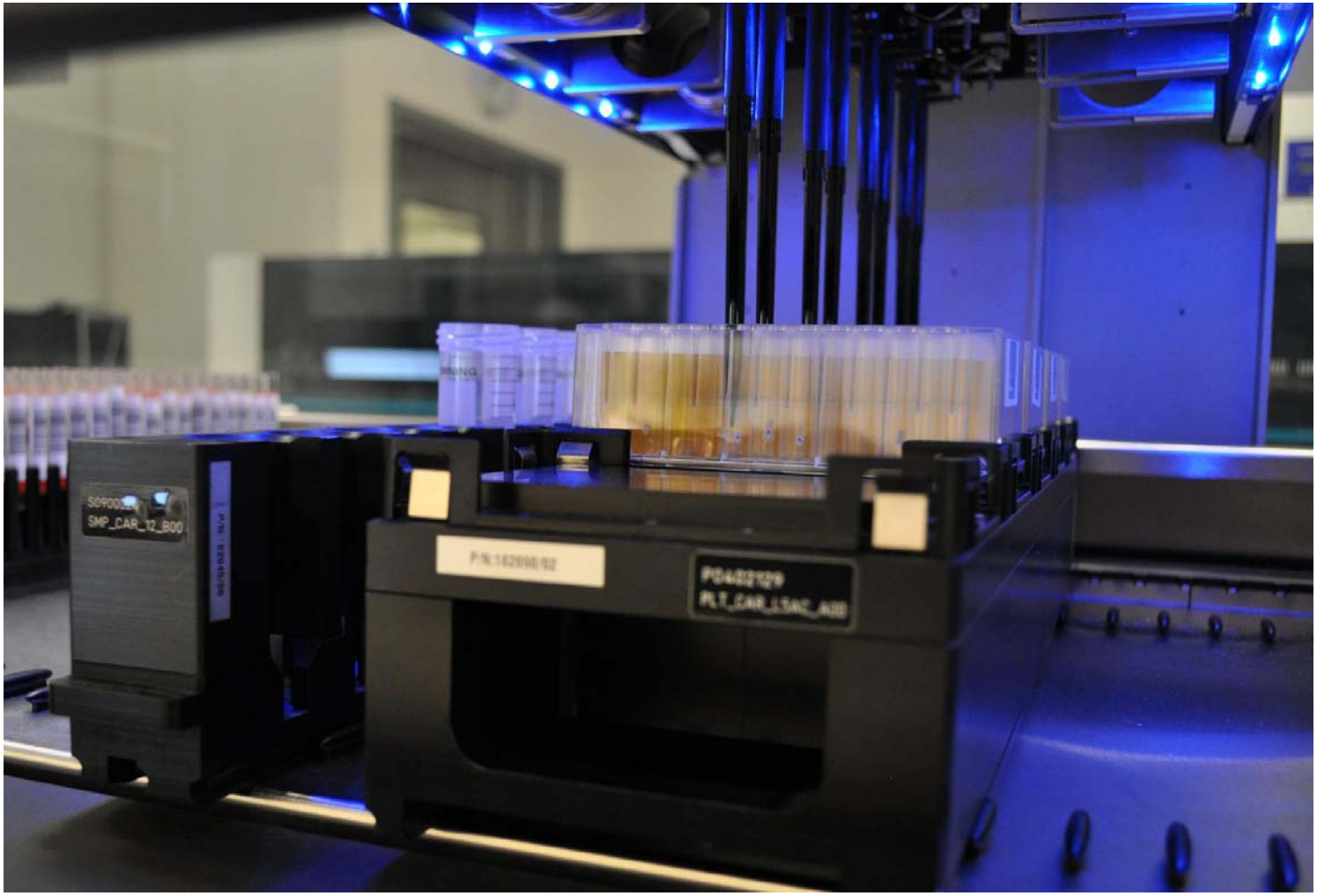
8x 5x 4x

Creating a productive screening laboratory
additional workflows

- **Sorting with PVT for:**
  - **Anti-Parvo B19**
  - **Total protein**
  - **Extended phenotyping**
  - **If necessary:**
    - **other tests**



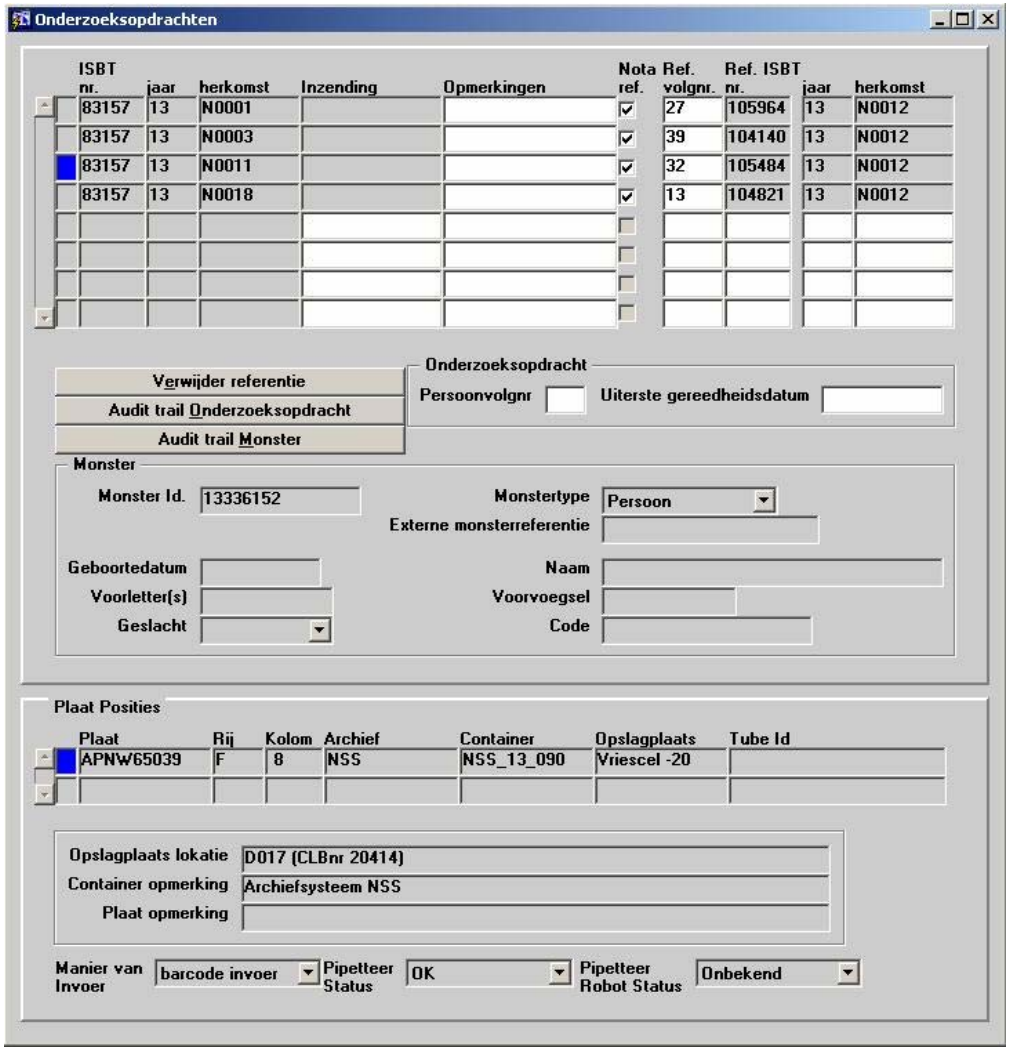
Creating a productive screening laboratory
additional workflows



Plasma archive: 2 years: <- 20°C

Creating a productive screening laboratory

searching for archived plasma samples

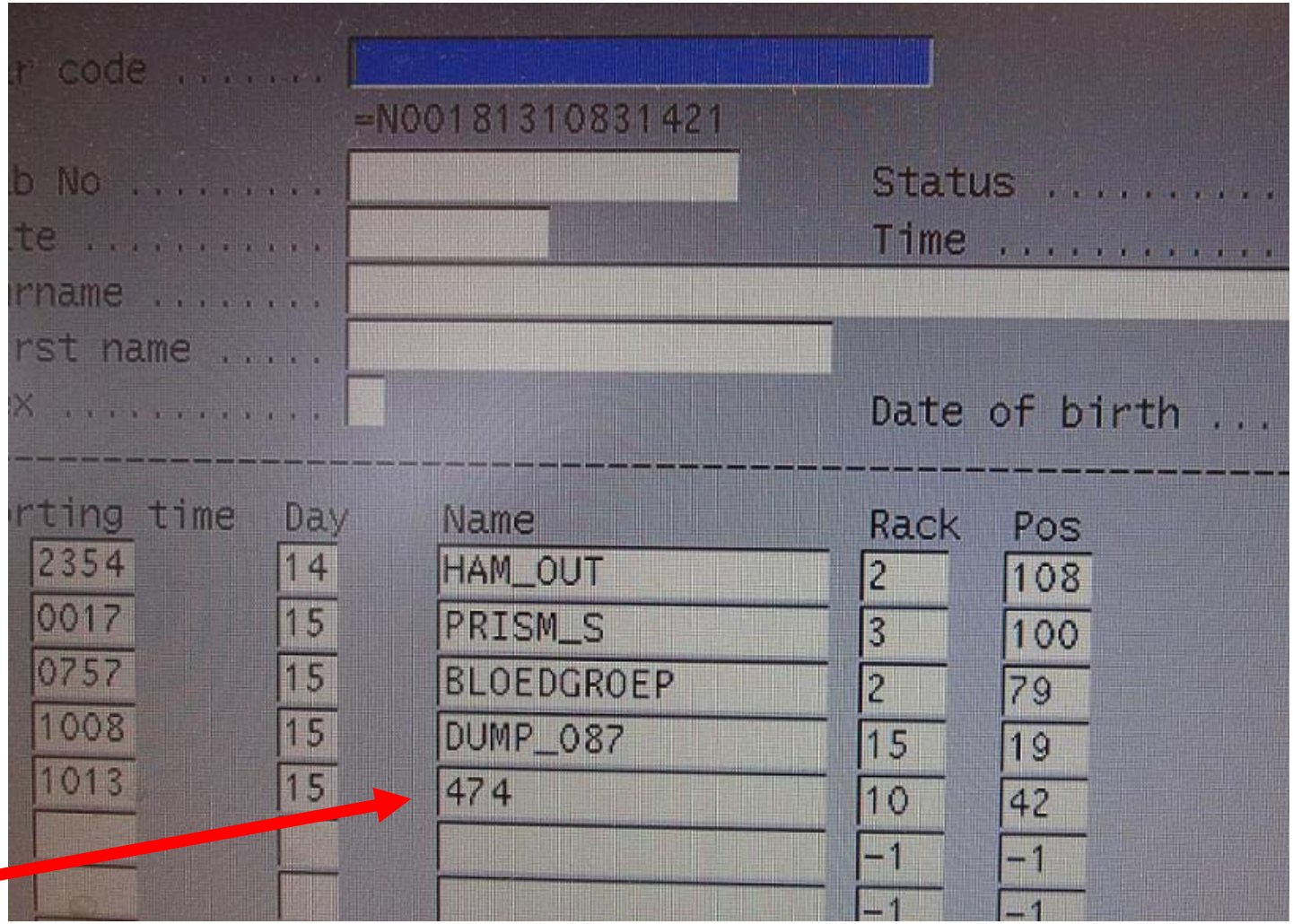


Creating a productive screening laboratory
additional workflows

Sample tube archive: storage time 1 week: 4-8 °C

Creating a productive screening laboratory

searching for archived sample tubes



Creating a productive screening laboratory
automation: BIS and LIMS

Day 1 after blood collection at ~7:00
before the availability of results

LIMS

NSS

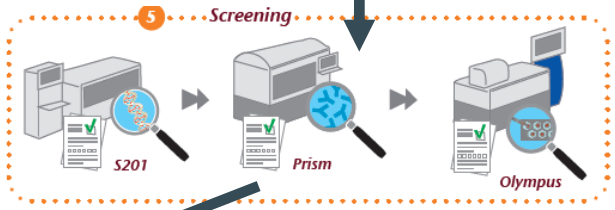
BIS

BB

Creating a productive screening laboratory
automation: BIS and LIMS

(Re)testing required

Searching samples



Lab results

LIMS
NSS

Authorization

day 1 after whole blood collection before 14:00

Release components

BIS
BB

Creating a productive screening laboratory

additional (re)testing: searching sample tubes

Resultaten bij onderzoeksopdracht: N0011-13-83157

Bepalings resultaat	Omschrijving	Grensw. ind	Ruwe waarde	Waarde	Eenheid	Classificatie	Code	Opm
6000	HBsAg ChGLIA kwal.		4	4		negatief		
6001	anti-HCV ChGLIA kwa		4	4		negatief		
6002	anti-HIV ChGLIA kwal		4	4		negatief		
6003	anti-HTLV ChGLIA kw		4	4		negatief		
6004	anti-HBc ChGLIA kwa		4	4		negatief		
6005	PRISM positie						33_25	
6007	aHBc historisch		4	4		negatief		
6010	HBsAg ChGLIA S/CO		.33	0.33	S/CO			
6011	anti-HCV ChGLIA S/C		.05	0.050	S/CO			
6012	anti-HIV ChGLIA S/C(		.19	0.19	S/CO			
6013	anti-HTLV ChGLIA S/		.25	0.25	S/CO			
6014	anti-HBc ChGLIA S/C		1.66	1.66	S/CO			
7000	ABD		1	1		A pos		
7001	Olympus positie						B0057	
7005	TPHA		4	4				
7015	Grote C		1	1				
7020	Kleine c		1	1				
7025	Grote E		1	1				
7030	Kleine e		1	1				
7035	Grote K		4	4				

Verdunning

Reden ongeldig

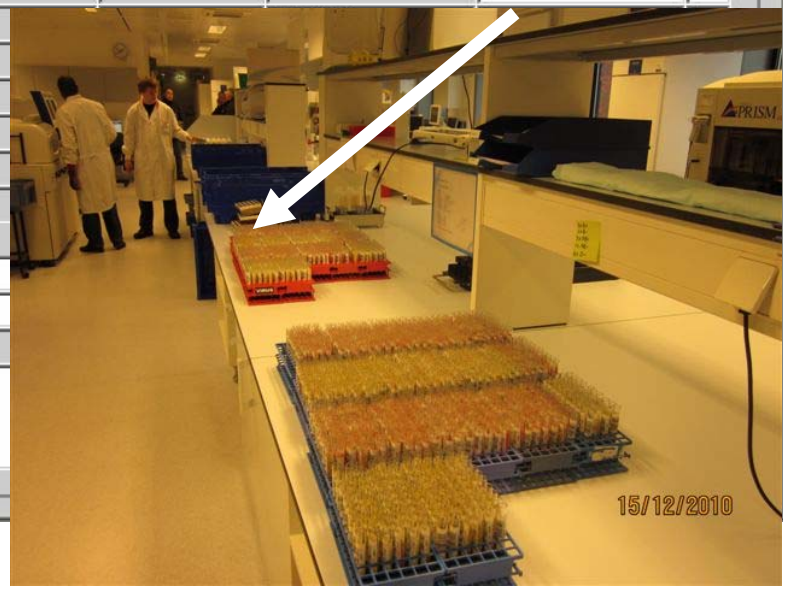
Type: Bepaald

Ruwe ondergrens

Meettijdstip: 03-05-2013 09:05:2

Ondergrens

Opmerkingen



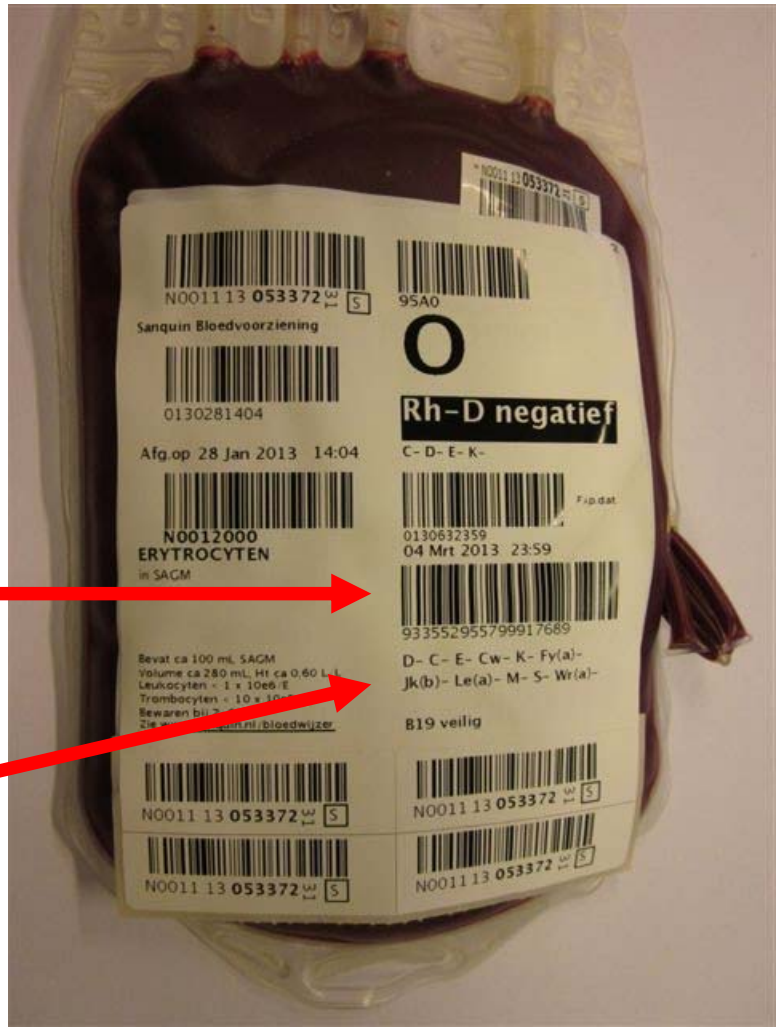
Creating a productive screening laboratory
extended RBC phenotyping

- Target % set for 22 antigens
  - C c E e C^w K k
  - Fy^a Fy^b Jk^a Jk^b S s
  - M N Le^a Le^b P_1
  - Kp^a Lu^a Wr^a Co^b

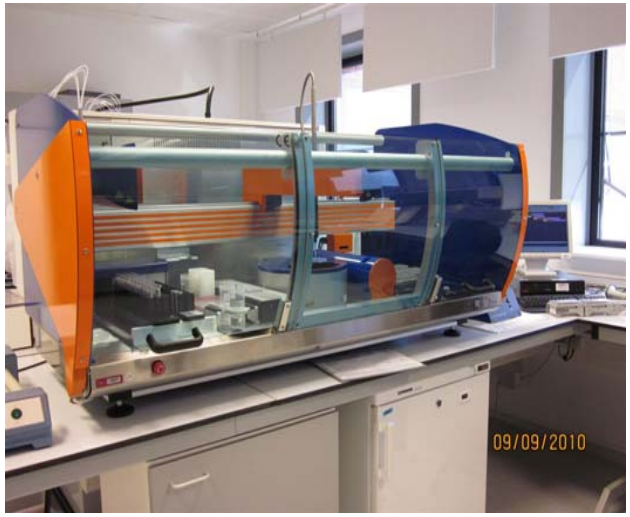
- AIM
  - Direct availability from stocks
    - BB
    - hospitals
  - No retesting required by BB
    - no delay

Creating a productive screening laboratory
extended RBC phenotyping

- **Example**
  - **At least 12% of Group O and A RBC donors must be Fy(a-) on two different occasions = validated negative**
  - **Negative and positive results are presented in barcode**
  - **Validated negative results are printed eye readable on the RBC label**



Creating a productive screening laboratory
extended RBC phenotyping



- 2012
  - Target % achieved for 19/22 antigens
    - % for k, N and Le^a below target

- end 2014
  - Target % achieved for 21/22 antigens
    - % for k ????

Creating a productive screening laboratory
look back: results

- Savings: ~ € 7 million / year
- ~ 30 FTE needed for screening of ~ 930.000 donations / year
- EBA benchmark 2011:
  - NSS is the most efficient screening laboratory in Europe
    - ~ 32.000 equivalent units/FTE/year

Creating a productive screening laboratory

look back: major challenges of centralization process

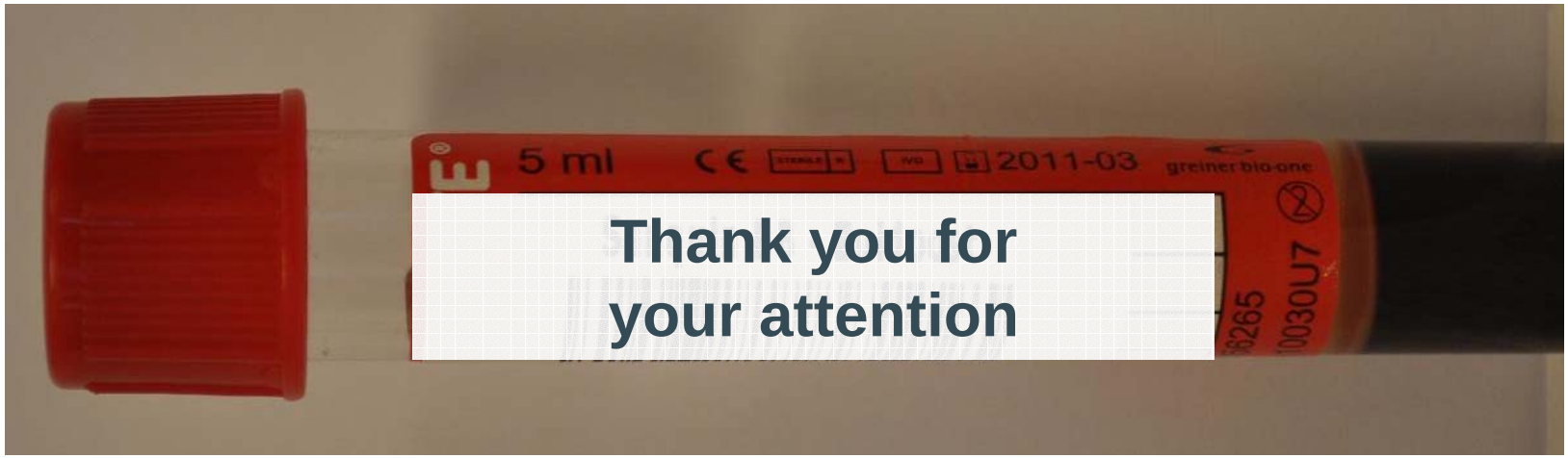
- Propagation of the message
- Dealing with distress / disbelief among staff
- Premature closure of labs involved
  - Recruitment and training of new employees
  - Working in a limited space (2007 lab)
- Realization of a new laboratory
- Set up of a new logistic system
  - Sample tubes
    - implementation of collection sets
    - transportation
    - pre and post analytical processes
  - Processes within the lab

Creating a productive screening laboratory

look back: major challenges of centralization process

- Implementing new NAT system
  - Including HBV NAT
- Validation / documentation
  - Due to removal of equipment
  - New equipment and processes
- Automation of the laboratory processes
- Arranging back-up facilities
  - Intermediate solution:
    - BB Nijmegen
    - DRK Frankfurt, Germany
  - Final solution:
    - 2009 BB Leuven, Belgium

Creating a productive screening laboratory



John Jongerius
j.jongerius@sanquin.nl