



*Lviv (Ukraine), 23 September 2015*

# Fully Automated Blood Transfusion laboratory: Strategy of an Italian Donor & Patient testing Hospital



AZIENDA  
OSPEDALIERO  
UNIVERSITARIA

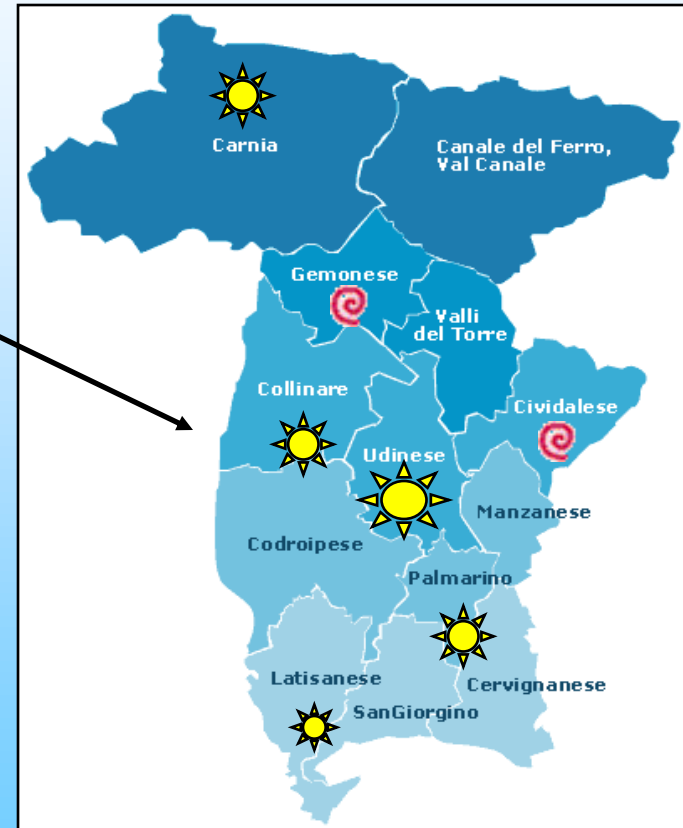


Santa Maria  
della Misericordia  
di Udine

**Dr Donatella Londero**

**Dept. Transfusion Medicine, AOU Udine, Italy**

# Department of Transfusion Medicine “Area Vasta Udinese”



SOC/SOS Department

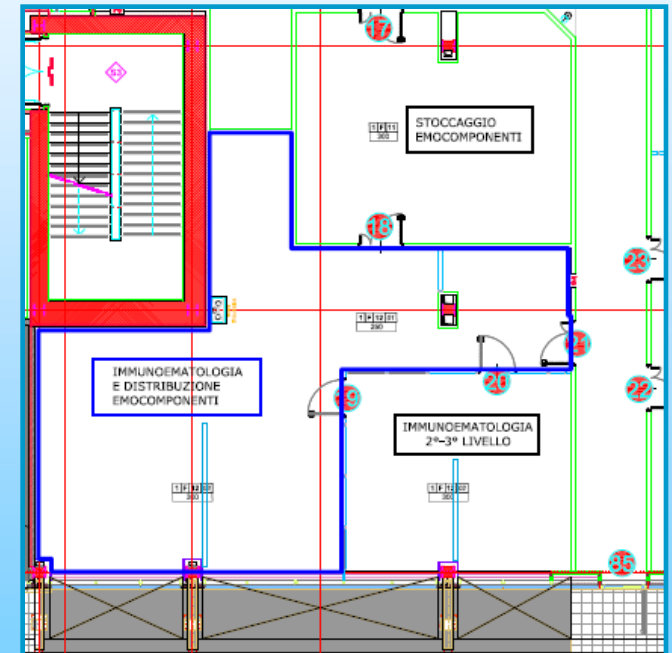


Sample collection points

# Immuno-haematology Laboratory



Dedicated Laboratory Area for Blood testing  
with access restricted to authorised personnel



# IE Laboratory activity

- **A)** Immunohaematological tests to perform at the time of each donation for the biological validation of blood components in accordance with national current regulatory requirements (Law n. 219/2005 and other directives)
- **B)** Pretransfusion testing to perform to each sample of RBC transfusion recipients in routine and urgent situations
- **C)** Immunohaematological investigations aimed at the diagnosis and prevention of any disease or condition likely to require a blood transfusion or administration of blood components, also including Molecular Typing



# Donors Activity- 2014

ABO Rh 1° Determination	ABO/Rh Control	Rh/Kell Phenotype	Antibody Screening	Molecular Typing	Total Tests
3231	47887	5475	3371	570	66009



COLLECTED	No.
<b>WHOLE BLOOD</b> (units collected)	36.138
<b>PRODUCTIVE APHERESIS</b> (procedure number)	11.680

# Transfusion Department Policy

- ▶ Type and screen and Computer crossmatch for patients with negative IAT
- ▶ Antibody identification, Antigen negative Units, Serological Crossmatch for patients with positive IAT

**Ricerche** Data prova Esito Sintesi anticorpi  
**anticorpali** 12-09-2015 11:53 **NEG**        ... Cat. **Trapianto**

Dati richiesta  
**Richiesta** Data arrivo Prevista trasf. Indicazione trasfusionale Reparto richiedente del  
 100055158 12-09-2015 10:53 12-09-2015 11:53 Altre indicazioni per globuli rossi PEDIATRIA CLINICA - Udin Ospedale di Udine

Elenco richieste  Unità da assegnare Data di assegnazione **15-09-2015 11:43**

Operatore **LONDERO DONATELLA** LETTURA BARCODE  Unità compatibili  Unità già assegnate ...

Dettaglio richiesta  
 Emocomponente richiesto **25 Emazie concentrate prefiltrate** Unità confermate 2 Unità assegnate 1 Modalità ass.T

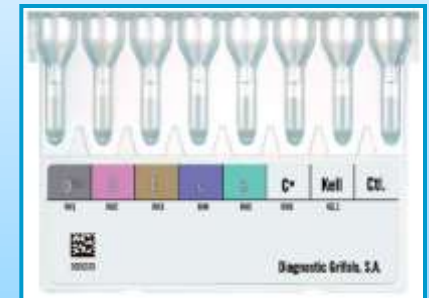
Unità compatibili  
 Struttura **0721** Sede **1** Frigoemoteca **UF2**

	CDM	Emc	Bag	Volume	Data scadenza	Us	St	Sp	Val	ABO	Rh	FtRh	Kell	Duffy	Kidd	Livello comp.
<input type="checkbox"/>	I070615.002394	25	01	259	02-10-2015 23:59	0	D		V	0	POS	CCDee	kk			1
<input type="checkbox"/>	I071115.166061	25	01	245	03-10-2015 23:59	0	D		V	0	POS	ccDEe	kk	Jka+b+		1
<input type="checkbox"/>	I071415.074302	25	01	270	03-10-2015 23:59	0	D		V	0	POS	CCDee	kk			1
<input type="checkbox"/>	I070615.062323	25	01	243	03-10-2015 23:59	0	D		V	0	POS	CcDee	kk			1
<input type="checkbox"/>	I071115.166076	25	01	247	03-10-2015 23:59	0	D		V	0	POS	CcDee	kk			1
<input type="checkbox"/>	I071415.074286	25	01	252	03-10-2015 23:59	0	D		V	0	POS	CCDee	kk			1
<input type="checkbox"/>	I070615.002554	25	01	272	05-10-2015 23:59	0	D		V	0	POS	ccDee	kk			1
<input type="checkbox"/>	I070615.062210	25	01	257	06-10-2015 23:59	0	D		V	0	POS	CcDee	kk			1

# Activity ► Blood requests

## New Patients

- Forward and Reverse ABO Typing
- Rh typing using 2 different anti-D (DVI+/-)
- Rh/Kell phenotyping for patients younger than 50y/old or multi-transfused
- Weak D antiglobulin test
- LISS/Coombs IAT at 37°C



**The T&S sample validity period depends on the patient's transfusion and obstetric history:**

- **72-hour** expiry time for patients transfused in the 3 months preceding pretransfusion sample collection or for currently pregnant patients
- **60 days** expiry time for patients who does not have a history of transfusion or pregnancy



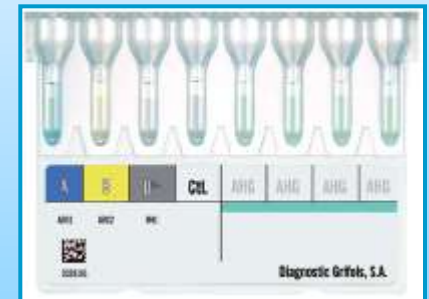
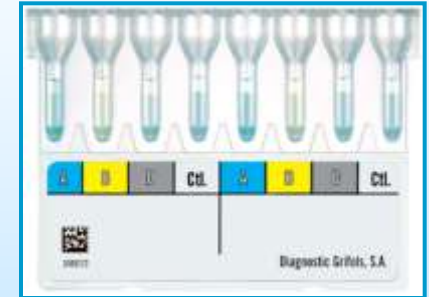
# Activity ► Blood requests

## Known Patients with valid T&S

- ABO/Rh control on RBCs using anti-A, anti-B, anti-D reagents

## Known Patients with invalid T&S

- ABO/Rh control on RBCs using anti-A, anti-B, anti-D reagents
- Rh/Kell phenotype (if not known)
- Antibody screening



In all cases, when IAT is positive or a patient is known to be immunised, the laboratory must **identify antibody specificity** (or confirm it) and perform **serological crossmatching** by the LISS-IAT method, using compatible donor's RBC, antigen negative, very often **extensive typed** by molecular biology.

# Transfusion Activity-2014

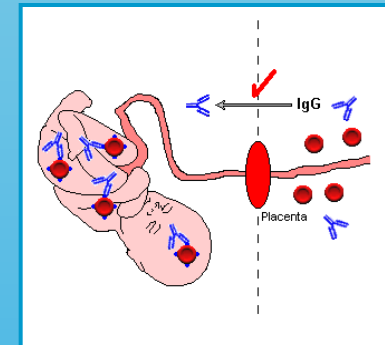
Type&Screen	ABO/Rh Control	ABO Rh 1° Determination	Serological Crossmatch	Total Tests
8691	3899	1212	1904	15706

TRANSFUSED	No.
Transfused ERYTHROCYTES (units)	25.797
Transfused PLATELET CONCENTRATIONS (units)	3.414
PLASMA for clinical use	1.602

# Activity ► Specialised Diagnostic Profiles

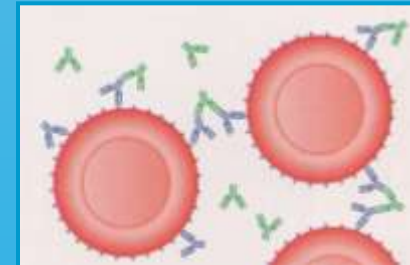
**Immunohaematological investigations aimed at the diagnosis and prevention of the HDN:**

- Maternal/Neonatal serological and molecular typing
- Fetomaternal hemorrhage detection
- IAT, DAT
- Elution of maternal Ab
- Titration of Haemagglutinins



**Investigations in cases of Alloimmunization including:**

- Antibody screening/Identification/Titration
- Elution/Adsorption methods
- Serological/Molecular Extensive Typing on recipients and Blood Units



# Activity ► Specialised Diagnostic Profiles

## Immunohaematological investigations aimed at the Study of autoimmune haemolytic disorders:

- Direct Antiglobulin test
- Cold reactive Autoagglutinins identification and titer
- Autoadsorption/Elution
- Paroxysmal Cold Hemoglobinuria Test
- ABO/RH molecular Typing




## Immunohaematological investigations aimed at the Study of Immune Platelet Disorders:

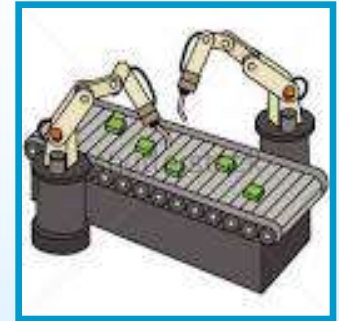
- Platelet Antibody Assays (solid phase red cell adherence; ELISA)
- Anti-PF4/heparin antibody test
- Pre-transfusion Platelet Crossmatching
- Molecular Typing of Platelet Specific Antigens

# Diagnostic Activity-2014

<b>Automated tests</b>	<b>No.</b>
ABO/Rh Patient Group	15806
Neonatal Group	1690
Ab screening	11866
Ab identification	505
Direct antiglobulin Test	1603
Anti-PLT Test	984
<b>Manual tests</b>	<b>No.</b>
Eluation/Adsorption	150
Cold Agglutinines Identification	40
FMH	119
Anti-PF4/heparin antibody test	159
Molecular Typing	94



**Automated sample processing equipment**



**Improvements to the safety of blood transfusion result from application of modern-day technology**

**Implementation of information technology systems**



# The Benefits of Automation

- Standardization of testing procedures
- Documentation and Traceability of all steps
- Decrease average Turn-around-time
- Ability to process more samples without increasing staff
- Interface with LIS (laboratory information systems)



# Equipment

There are two major methods used in automation:

- Gel column
- Microtiter plate technologies





# Our Strategy

## NEO-Immucor

- ▶ Use hemagglutination for antigens and solid phase red cell adherence assay for antiglobulin phase (Du, antibodies)
- ▶ Platform suited to process large batches with the same testing requirements (T&S; Platelet crossmatchnig; PLT antibody assays)
- ▶ High throughput and good turn-around time

**Donor Samples and  
Patient Routine samples**



# Our Strategy

## **ERYTRA/WADIANA-Grifols**

- ▶ Platform suited to process urgent samples, small batches or single samples with multiple diagnostic requirements (T&S; IAT, DAT, Antibody identification, Antigen Typing)
- ▶ Easy to perform, interchangeable depending on the workload

**Urgent/Routine Pre-transfusion Samples**  
**IE Diagnostic Activity**



# Blood Group Testing Area



# Urgency Testing Area



# Distribution of Blood Components Area



# IE Diagnostic Area



# Molecular Testing Area



# Storage Area





# Irradiation Area

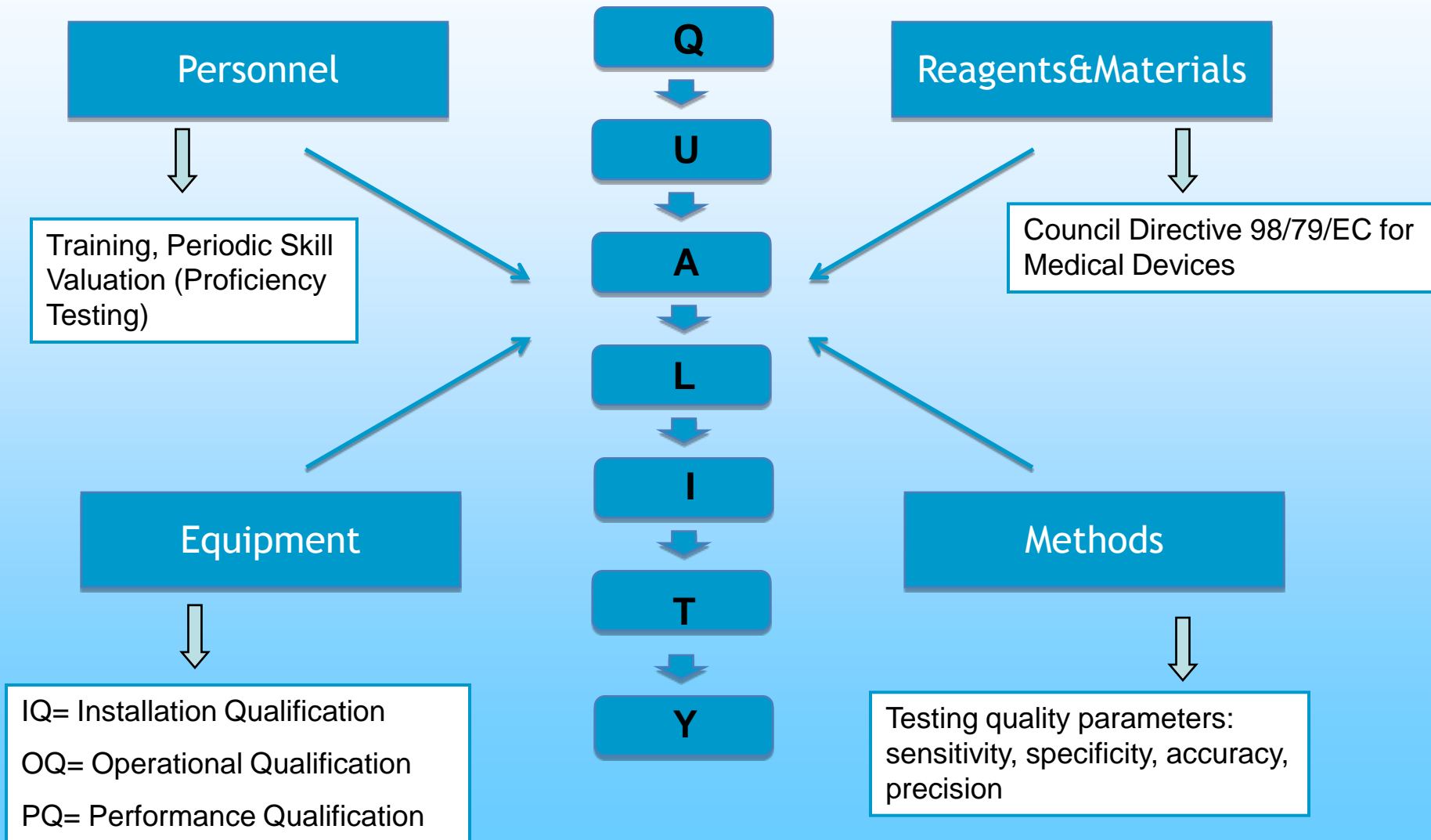


# Validation Master Plan of the Process

- **Identification of the requirements and process steps**
- **Risk-assessment**
- **Validation activities:**
  - Qualification of premises and space
  - Qualification of equipments
  - Qualification of materials
  - Qualification of personnel
  - Validation of the analytical methods

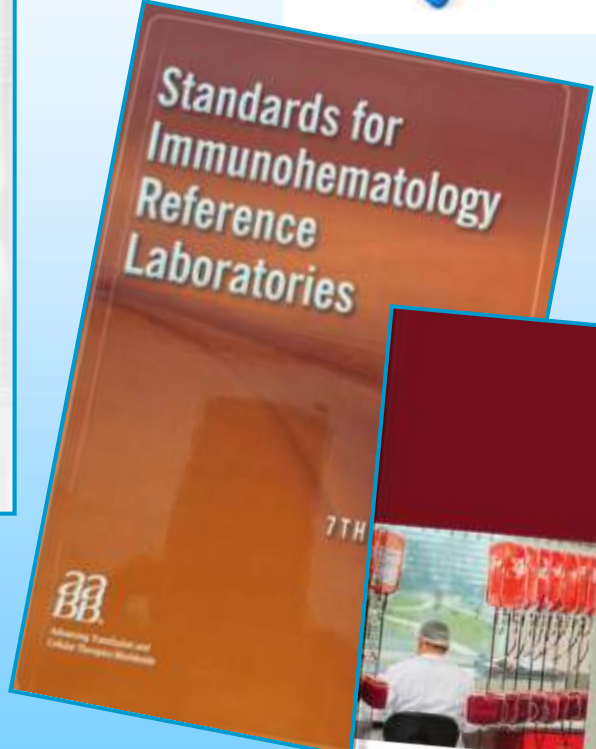


# Validation of Analytical Process



COMMISSION DIRECTIVE 2005/62/EC  
of 30 September 2005

implementing Directive 2002/98/EC of the European Parliament and of the Council as regards  
Community standards and specifications relating to a quality system for blood establishments  
(Text with EEA relevance)





**Thank you for your attention**