# BLOOD COMPONENT NON-STANDARD MONOGRAPH
# PLATELETS FOR INTRAUTERINE TRANSFUSION, LEUCOCYTE DEPLETED

**REASON FOR ISSUE: Update to include ISBT 128 component codes, and label changes.**

| | |
|---|---|
| **Council of Europe Guide Monograph** | Platelets, Leucocyte Depleted for Intra-uterine Transfusion |
| **eProgesa Component Names** | Platelets for Intrauterine Transfusion, Leucocyte Depleted |
| **eProgesa Component Codes** | 12490, 12491, 12492, EA961V00, EA961VA0, EA961VB0, EA961VC0 |

*Platelets for Intrauterine Transfusion, Leucocyte Depleted (Aph, IUT, LD)* is a non-standard component that is not approved by Medsafe and is manufactured in response to a request for a specific patient from the treating clinician. *Platelets Aph, IUT, LD* are derived from a standard adult platelet component, suspended in additive solution and intended for use in intra-uterine transfusion. The component must meet a number of specific additional criteria as defined in section 3 of this monograph.

## 1. DEFINITION AND PROPERTIES:

*Platelets Aph, IUT, LD* is produced by secondary processing of *Platelets Apheresis PAS Leucocyte Depleted.* The primary component is suspended in additive solution and leucocyte depleted. This is then concentrated by centrifugation and removal of part of the supernatant plasma. *Platelets Aph, IUT, LD* must be produced from an RhD Negative and CMV antibody negative donor who has donated in the previous six months. The donation must be free of high titre anti-A and / or anti-B antibodies and compatible with maternal antibodies. The *Platelets Aph, IUT, LD* will be HLA / HPA compatible as clinically required. The component is irradiated prior to transfusion.

*Platelets Aph, IUT, LD* are resuspended to a final concentration determined by the requesting clinician in consultation with the NZBS TMS / MO. The concentration must be within the range defined in Table 1.

## 2. PREPARATION:

The primary platelet component *Platelets Apheresis PAS Leucocyte Depleted* is concentrated by centrifugation and subsequent removal of a defined volume of the supernatant solution so that the final platelet concentration meets the requirements identified by the requesting clinician within the specification defined in Table 1.

The component must be rested for a minimum of one hour after concentration before being released for transfusion and then transfused within six hours of the concentration process.

## 3. RELEASE REQUIREMENTS AND QUALITY CONTROL

### 3.1 mandatory Release Requirements

Mandatory release requirements are as indicated for the primary source component, with the following additional quality monitoring and clinical requirements:

**BLOOD COMPONENT NON-STANDARD MONOGRAPH**
**PLATELETS FOR INTRAUTERINE TRANSFUSION, LEUCOCYTE DEPLETED**

### 3.2 Quality Monitoring Requirements

**Table 1: Quality Monitoring Requirements for *Platelets Aph, IUT, LD***

| Parameter | Requirements | Frequency of control |
|---|---|---|
| Volume | 50-100mL | All units |
| Platelet Content | 2.0 – 4.0 x $10^{12}$ / L | |

1. User defined and within the range

### 3.3 Clinical Requirements

The requirements are identified in table 2.

The RhD status and High Titre anti-A and / or anti-B must be tested and the results must be negative in order to meet release requirements. The component must also meet the blood group requirements of the particular patient including, where appropriate HLA and / or HPA requirements and must have a negative CMV status in eProgesa.

**Table 2: Clinical Requirements for Platelets *Aph, IUT, LD***

| Parameter | Frequency of control | Requirements | Platelets for IUT |
|---|---|---|---|
| RhD Status | All units | Negative | Mandatory |
| High Titre anti-A and / or anti-B | All units | Negative | Mandatory |
| CMV antibody status | All units | Negative | Mandatory |
| HLA and / or HPA[1] | All units | Negative | As required |

1. HLA / HPA typing of the selected donor, not of the individual component

## 4. STORAGE AND TRANSPORT:

Storage and transport requirements are as defined for the source component. *Platelets Aph, IUT, LD* must be used within six hours of the secondary concentration process.

## 5. LABELLING:

Additional and / or amended labelling requirements to those of the source component are:

- Additional component information: irradiated, supernatant reduced etc. (as appropriate).
- The volume or weight of the blood component
- The platelet concentration x $10^{12}$ / L. The number of platelets x $10^{9}$ / unit may also be attached.
- The date and time of expiry

In addition, the following instructions are included:

- Use a standard transfusion set.

**BLOOD COMPONENT NON-STANDARD MONOGRAPH**
**PLATELETS FOR INTRAUTERINE TRANSFUSION, LEUCOCYTE DEPLETED**

## 6. WARNINGS:

As the fetus is at increased risk of graft versus host disease the component must be irradiated.

The rate of transfusion must be controlled to avoid excessive fluctuations in blood volume and possible bleeding after puncture must be monitored.

Adverse reactions: The general adverse reactions outlined in the relevant source monograph.

Note: although the component is given to the fetus, adverse reactions may also affect the mother.

In addition, the fetus is especially vulnerable to:

- CMV infection;
- Citrate toxicity;
- Transfusion-associated circulatory overload.