Viral Safety and Donor Qualification Statement

CytoPure™ Human Platelet Lysate — PLUS · XF · GI

1. Purpose and scope

This statement describes the donor eligibility criteria, screening, and infectious disease testing applied to the source material used to manufacture CytoPure™ human platelet lysate, and states what those controls do and do not establish. It applies to CytoPure™ PLUS, CytoPure™ XF, and CytoPure™ GI in all fill volumes.

This document is the authoritative source for the CytoPure™ donor testing panel. **Where other Cytologics documents refer to donor testing, they refer to this document rather than restating the panel.**

2. Source material

CytoPure™ is manufactured from human platelet units collected at U.S. Food and Drug Administration (FDA)-licensed and Association for the Advancement of Blood & Biotherapies (AABB)-accredited blood centers in the United States. Every unit was originally collected and released for use in patient transfusion, and met all donor eligibility criteria in force at the time of its collection.

Units are pooled across multiple donors during manufacture. Donor pools are typically greater than 300 individuals. Pooling is a consistency control, not a safety control. Each contributing unit is required to meet the applicable donor eligibility and infectious disease testing requirements before it is accepted as source material.

3. Donor eligibility and screening

Donors were screened using the Blood Donor History Questionnaire (DHQ) and accompanying educational materials — a screening document created by a coalition of regulatory, accrediting, and blood-collecting institutions including the Food and Drug Administration, Centers for Disease Control and Prevention, AABB, American Red Cross, and America's Blood Centers.

- Donor eligibility is determined by the collecting blood center under 21 CFR Part 630 before collection.
- Screening covers medical history, travel and residence history, medication history, and risk-associated behaviors, together with a physical assessment at the time of donation.
- Units from donors who do not satisfy every eligibility criterion are not released for transfusion and are therefore never available to Cytologics as source material.

4. Infectious disease testing panel

Every human donor of a platelet unit used in the manufacture of CytoPure™ was tested for the following agents, with negative or non-reactive results required for release. Testing is performed by the collecting blood center using FDA-authorized donor-screening assays.

Assay	Method	Result required for release
Syphilis		
Serologic test for syphilis (STS)	Serology	Negative / non-reactive
Hepatitis B		

Assay	Method	Result required for release
HBsAg	Serology	Negative / non-reactive
Anti-HBc	Serology	Negative / non-reactive
HBV NAT	Nucleic acid testing	Negative / non-reactive
Hepatitis C		
Anti-HCV (EIA)	Serology	Negative / non-reactive
HCV NAT	Nucleic acid testing	Negative / non-reactive
HIV		
Anti-HIV-1/2 (EIA), including HIV-1 subgroup O	Serology	Negative / non-reactive
HIV-1 NAT	Nucleic acid testing	Negative / non-reactive
HTLV		
Anti-HTLV-I/II (EIA)	Serology	Negative / non-reactive
West Nile virus		
WNV NAT	Nucleic acid testing	Negative / non-reactive
Chagas disease		
Anti-T. cruzi	Serology	Negative / non-reactive

Nucleic acid testing (NAT) may be performed on individual donations or in minipools, at the discretion of the collecting blood center, in accordance with the licensed assay's instructions for use.

5. Regulatory basis

The testing and eligibility requirements above are those applicable to blood and blood components intended for transfusion in the United States.

Reference	Applies to
21 CFR Part 610, Subpart E	Testing requirements for communicable disease agents in human blood and blood components.
21 CFR Part 630	Requirements for blood and blood components intended for transfusion, including donor eligibility determination.
21 CFR Part 606	Current good manufacturing practice for blood and blood components, applied by the collecting blood centers.
AABB Standards for Blood Banks and Transfusion Services	Accreditation standard applied by the collecting blood centers.

6. What these controls do not establish

No viral inactivation or viral removal step is performed during manufacture, and no viral clearance validation study has been conducted. Viral safety rests on the donor eligibility criteria, screening, and infectious disease testing described in sections 3 and 4, together with the regulatory framework governing collection of the source material.

Terminal gamma irradiation is applied to CytoPure™ GI as an additional processing step at an internal dose of 25–38 kGy. It has not been validated as a viral inactivation step, and CytoPure™ GI is subject to the same handling precautions as the other products in the family.

Handling As with any product of human origin, no testing regimen can entirely exclude the presence of infectious agents. CytoPure™ products should be handled as potentially infectious material using Biosafety Level 2 practices and containment as described in the current edition of Biosafety in Microbiological and Biomedical Laboratories (CDC/NIH).

7. Traceability and records

Unit-level identifiers for every contributing collection are recorded at receipt and retained, establishing traceability from a finished CytoPure™ lot back to the collections that produced it. Records are retained for 7 years. Lot numbers follow the convention described in CYT-QTS-031 (Quality and Testing Standards).

Cytologics does not receive, hold, or have access to personally identifying information for any donor. Donor identity remains with the collecting blood center.

Related documentation

This document is part of the CytoPure™ technical documentation library. Refer to the following companion documents:

- **CYT-COO-016** Certificate of Origin — CytoPure™ Human Platelet Lysate
- **CYT-TSE-002** TSE/BSE Risk Mitigation Statement
- **CYT-QTS-031** Quality and Testing Standards — CytoPure™ Human Platelet Lysate

IMPORTANT For research use only. Not for use in diagnostic or therapeutic procedures. Not for human or animal use. This product contains human-derived material and must be handled as potentially infectious; observe universal precautions and handle at Biosafety Level 2 or higher.

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