6TH EDITION OF FACT-JACIE STANDARDS
A QUICK SUMMARY

BHS JACIE Day, 6 March 2015
Eoin McGrath
JACIE Operations Manager
CONTENTS

- Review process
- Sources of information
- Selection of main changes and developments
- Questions
Cellular Therapy Standards Committee
6th Edition Development Process

INCLUSIVE AND COLLABORATIVE

Standards Committee
- 4 Subcommittees
- 12 Countries Represented
- 46 Members

Reviews
- Public Comments
- Legal Consultation
- FACT and JACIE Board Approval

In-Person Steering Committee Meetings
- London Kick-off Meeting in June 2013
- Grapevine Draft Review in February 2014

INTENSIVE

Duration of Commitment
- 1 Year
- 3 Months
- 26 Days
- = 483 Days

Number of Teleconferences
- 15 Steering
- 31 Clinical
- 21 Collection
- 23 Processing
- = 90 Meetings

Volunteer Hours
- Based on Quorum
- 117 Meeting Hours/Member
- = 922 Hours

Intangibles: Editing Standards, Drafting Guidance, Reviewing Meeting Materials, Researching Topics, and In-house Staff Support
- On web site
- Check the exact differences between each standard.
- Yellow indicates a change
- The change in text is underlined.
- Available from JACIE web site
SCOPE

6TH EDITION

- INTERNATIONAL STANDARDS FOR HEMATOPOIETIC CELLULAR THERAPY PRODUCT COLLECTION, PROCESSING, AND ADMINISTRATION

5TH EDITION

- INTERNATIONAL STANDARDS FOR CELLULAR THERAPY PRODUCT COLLECTION, PROCESSING, AND ADMINISTRATION
<table>
<thead>
<tr>
<th>Clinical</th>
<th>Collection Marrow</th>
<th>Collection Apheresis</th>
<th>Processing</th>
</tr>
</thead>
<tbody>
<tr>
<td>B1 General</td>
<td>CM1 General</td>
<td>C1 General</td>
<td>D1 General</td>
</tr>
<tr>
<td>B2 Clinical Unit</td>
<td>CM2 Marrow Collection Facility</td>
<td>C2 Apheresis Collection Facility</td>
<td>D2 Processing Facility</td>
</tr>
<tr>
<td>B3 Personnel</td>
<td>CM3 Personnel</td>
<td>C3 Personnel</td>
<td>D3 Personnel</td>
</tr>
<tr>
<td>B4 Quality Management</td>
<td>CM4 Quality Management</td>
<td>C4 Quality Management</td>
<td>D4 Quality Management</td>
</tr>
<tr>
<td>B6 Allogeneic and Autologous Donor Selection, Evaluation, and Management</td>
<td>CM6 Allogeneic and Autologous Donor Evaluation and Management</td>
<td>C6 Allogeneic and Autologous Donor Evaluation and Management</td>
<td>D6 Equipment, Supplies, and Reagents</td>
</tr>
<tr>
<td>B7 Recipient Care</td>
<td>CM7 Coding and Labeling of Cellular Therapy Products</td>
<td>C7 Coding and Labeling of Cellular Therapy Products</td>
<td>D7 Coding and Labeling of Cellular Therapy Products</td>
</tr>
<tr>
<td>B8 Clinical Research</td>
<td>CM8 Process Controls</td>
<td>C8 Process Controls</td>
<td>D8 Process Controls</td>
</tr>
<tr>
<td>B9 Data Management</td>
<td>CM9 Cellular Therapy Product Storage</td>
<td>C9 Cellular Therapy Product Storage</td>
<td>D9 Cellular Therapy Product Storage</td>
</tr>
<tr>
<td>CM10 Cellular Therapy Product Transportation and Shipping</td>
<td>C10 Cellular Therapy Product Transportation and Shipping</td>
<td>D10 Cellular Therapy Product Transportation and Shipping</td>
<td></td>
</tr>
<tr>
<td>D11 Distribution and Receipt</td>
<td>D12 Disposal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>B10 Records</td>
<td>CM11 Records</td>
<td>C11 Records</td>
<td>D13 Records</td>
</tr>
<tr>
<td>CM12 Direct Distribution to Clinical Program</td>
<td>C12 Direct Distribution to Clinical Program</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Basic tenets for compliance with these Standards include, but are not limited to:

• A.2.1  Where applicable laws and regulations include more stringent requirements than these Standards, those laws and regulations supersede the Standards. Conversely, when these Standards are more stringent than applicable laws and regulations, the Standards must be followed.

• A2.2  Applicant organizations are responsible for providing verifiable documentation of evidence of compliance with these Standards.

• A2.3  Standards related to services not provided by the applicant do not apply to the applicant organization. The burden to demonstrate that a requirement is not applicable rests with the applicant organization.
OUTCOME ANALYSIS

- (B4.7, C4.7, D4.7)

- Outcome analysis must include evaluation of individual cellular therapy product data and aggregate data for each type of cellular therapy product and/or recipient type.

- Clinical Programs must compare one-year survival to national or international outcome data, and should achieve survival rates within expected ranges.
The sixth edition requires that organizations be actively implementing ISBT 128 coding and labeling technologies.

The 5th edition required organizations to have a plan for ISBT 128 coding and labeling technology implementation. “Actively implementing” could be demonstrated by registration with ICCBBA, identification or creation of appropriate product codes, label designs, label validation, and/or use of scanned information.

Barcoding - verification now may be conducted by two qualified people or by one qualified person using a validated process.

(CM7, C7, D7, APPENDIX II, APPENDIX III)
CONTINUING EDUCATION

- 10 hours per annum
- Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation and apheresis.
- Affects key personnel (directors, attending physicians, quality managers, and designated pharmacists)
ACCREDITATION OF TECHNIQUES USED FOR CHIMERISM TESTING

• Requires accreditation of the *techniques* used in chimerism.

• EFI and other organizations provide external laboratory accreditation and quality assurance in chimerism testing.

• Rationale

  • Clinical decisions regarding the pace of withdrawal of post-transplant immunosuppression and/or subsequent administration of donor lymphocytes based on chimerism results may have potentially life-threatening consequences with respect to GVHD, relapse risk, or graft failure.

  • Chimerism testing may be performed with a variety of methods and interlaboratory variability may be significant.

  • (B2.12)
CLINICAL PROGRAM PERSONNEL (B3)

• Pharmacists (B3.8)
  • Pharmacist requirements relate to those who perform services for the transplant program.
  • Pharmacists must be licensed to practice and limited to a scope of practice within the parameters of their training and licensure.
  • Training: overview of hematology/oncology patient care, therapeutic drug monitoring, monitoring for and recognizing drug/drug and drug/food interactions and making necessary modifications, and recognition of medications that require adjustment for organ dysfunction.
  • Pharmacists should be involved in the development of guidelines or SOPs related to pharmaceutical management of transplant recipients.
  • Designated transplant pharmacists (i.e., those who have a leadership role or routine involvement in the care of transplant recipients) must meet continuing education requirements.
New sections were added to B3 Personnel to include all key providers in a Clinical Program.

- Physicians-in-Training (B3.4)
- **Mid-level practitioners** are now referred to as **Advanced Practice Providers/Professionals**, or APPs. (B3.5)

- Consulting specialists must now also include
  - Ophthalmology
  - obstetrics/gynecology
  - dermatology. (B3.9)
BACKUP COVERAGE OF STAFF (CM3.3.2, C3.4.1, D3.4.1)

- Facilities were often found to have minimal staff that was only sufficient should no staff members be absent.
- To provide sufficient coverage should staff members become unavailable, facilities must have a minimum of one designated trained individual with an identified trained backup.
DONORS
A donor advocate shall be available to represent allogeneic donors who are minors or who are mentally incapacitated, as those terms as defined by applicable laws.
A pregnancy test shall be performed for all female donors with childbearing potential within seven (7) days prior to starting the donor mobilization regimen and, as applicable, within seven (7) days prior to the initiation of the recipient’s preparative regimen.
The Clinical Program must have written criteria for selection of allogeneic donors who are
- elderly
- minors.

Informed consent and donor evaluation now must be obtained by a health care professional who is not the primary health care professional overseeing care of the recipient.
- This was only a recommendation in the 5th edition.

The informed consent process must inform the donor of the policy for cellular therapy product discard or disposal.
DONOR SELECTION, EVALUATION, & MANAGEMENT

- Written order from a physician specifying the timing and goals of collection and processing is now also included in the clinical standards.

- Clinical Programs must have a policy for anti-HLA antibody testing for mismatched donors and recipients.

- Records required for donor eligibility determination must be in English or translated into English when crossing international borders.

- Standards throughout the document explicitly reference requirements for incomplete donor eligibility determination in addition to ineligible donors.
NEW REQUIRED ANALYSES

- Clinical Programs:
  - Acute GVHD grade within one hundred (100) days after transplantation.
  - Chronic GVHD grade within one (1) year after transplantation.
  - Central venous catheter infection.

- Apheresis Collection and Processing Facilities:
  - Time to engraftment measured by ANC and platelet count.
D9.2.2 There shall be a written stability program that evaluates the viability and potency of cryopreserved cellular therapy products, minimally annually.
STABILITY PROGRAMME

- There were many questions surrounding how stability studies must be performed and how they could be applied to early phase cellular therapy products.

- The Standards Committee felt that this requirement is appropriate, but added guidance that includes examples of how to perform stability studies and clarification that stability studies can be in development for early phase products that do not yet have a definitive potency marker.
QUALITY MANAGEMENT
NEW CLINICAL SOPS

- Donor screening, testing, eligibility determination, selection, and management
- Management of donors who require central venous access
- Administration of ABO-incompatible products to include a description of the indication for and processing methods to be used for red cell or plasma reduction
- Duration and conditions of cellular therapy product storage and indications for disposal
- Hygiene and use of personal protective equipment
NOW INCLUDED IN PART C

- SOP for Administration of blood products.
- All equipment with a critical measuring function shall be calibrated against a traceable standard, if available. Where no traceable standard is available, the basis for calibration shall be described and documented.
- Review and approval of the validation plan, results, and conclusion by the Facility Director or designee and the Quality Manager or designee.
- The Clinical Program shall inform the Collection Facility and Processing Facility of donor test results or if any testing was not performed.
AUDITS

- Most required audits must now be performed **annually**.
  - Audits do not need to have the same objective every year.
  - Different points of processes can be audited.
MANAGE ERRORS ETC.

- Documentation shall include a description of the event, the involved individuals and/or cellular therapy products, when the event occurred, when and to whom the event was reported, and the immediate actions taken.

- Cumulative files of errors, accidents, biological product deviations, serious adverse events, and complaints shall be maintained.

- Cumulative files shall include written investigation reports containing conclusions, follow-up, corrective actions, and a link to the record(s) of the involved cellular therapy products.
RECIPIENT CARE (B7)

- Previously titled, “Therapy Administration,” but now contains all requirements related to the care of the transplant recipient.

- Recipient informed consent must be obtained and documented by a licensed health care professional familiar with the proposed therapy, and this process must provide information regarding the risks and benefits.

- Records must be made concurrently with each step of recipient care in such a way that all steps may be accurately traced, and must identify the person immediately responsible for each significant step (including dates and times).

- Specific references to “chemotherapy” were replaced with references to the “preparative regimen” to encompass all regimens.
RECIPIENT CARE (B7)

- Barcoding: The verification now may be conducted by two qualified people or by one qualified person using a validated process.

- The recipient’s medical record of the administered cellular therapy product must include the product’s unique identifier, initiation and completion times of administration, and any adverse events related to administration.

- Standard of care has evolved in the assessment of recipients for evidence of acute and chronic GVHD, need for vaccinations, and post-transplant late effects.
  - Allogeneic recipients must be assessed regularly for evidence of acute and chronic GVHD using an established staging and grading system.
  - There must be policies and procedures in place for allogeneic recipient post-transplant vaccination schedules and indications.
MINIMUM NUMBER OF MARROW COLLECTION PROCEDURES (CM1.5)

- The minimum number remains at a minimum average of one (1) collection procedure per year within the accreditation cycle.

- This requirement applies to a single team of collectors and support staff. When different teams are used at different sites, the minimum number of procedures must be performed at each of those sites.

- The guidance also emphasizes that marrow collectors with little experience must be supervised appropriately to build and maintain competency.
APHERESIS EQUIPMENT (C8.3)

- Must be inspected for cleanliness prior to each use and verified daily to be in compliance with the maintenance schedule prior to use.
- Calibration must be performed according to a traceable standard and, when out of calibration, there must be a defined process for action for cellular therapy products collected since the last calibration.
· Marrow and Apheresis Collection Facility records must identify the person immediately responsible for each significant step (including dates and times). (CM8.15.1, C8.16.1)

· Marrow Collection Facilities must also control storage areas to prevent mix-ups, deterioration, contamination, cross-contamination, and improper release or distribution of products. (CM9.1)
  · Cellular therapy products are always undergoing some process, and temporary holding until they are picked up by another facility is considered storage.

· Cellular therapy products must be transported or shipped to the Processing Facility in a validated container. (CM10.3, C10.3)
Apheresis collection performed in outpatient units must be in a designated area with appropriate location and adequate space and design to minimize the risk of airborne microbial contamination. (C2.1.2)

Apheresis Collection Facility Directors and Medical Directors must have performed or supervised a minimum of 5- previously 4- collection procedures in the 12 months preceding initial accreditation and a minimum average of 5 collection procedures per year within the accreditation cycle. (C3.1.4, C3.2.4)

Extracorporeal photopheresis (ECP) requirements are now also included in the apheresis section.
Part D was reorganized to separate the Process Controls section into more manageable sections of like requirements.

New sections:
- Equipment, Supplies, and Reagents
- Cellular Therapy Product Transportation and Shipping
- Distribution and Receipt.
OTHER PROCESSING FACILITY CHANGES

- Processing Facility Directors and Medical Directors - minimum of two years of postgraduate training and practical and relevant experience for the scope of activities carried out in the facility.
  - Some regions of the world may have degrees that are equivalent to the doctoral degree. If a Processing Facility Director has such a degree, significant and compelling information regarding the degree requirements must be submitted to demonstrate equivalency. (D3.1.1, D3.2.1).

- Policies and procedures on the management of cellular therapy products with positive microbial culture results must also address the identification of individuals authorized to approve release, including the Processing Facility Medical Director at a minimum. (D4.9.4)
OTHER PROCESSING FACILITY CHANGES

• Records of identification codes of personnel with methods to link the name and/or signature to the identification codes is no longer required because of improvements in recordkeeping.

• Alarm systems shall have audible and visible signals or other effective notification methods.
LABELS
# Cellular Therapy Product Labeling

<table>
<thead>
<tr>
<th>Element</th>
<th>6th</th>
<th>6th</th>
<th>6th</th>
<th>6th</th>
<th>5th</th>
<th>5th</th>
<th>5th</th>
<th>5th</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unique numeric or alphanumeric identifier</td>
<td>AF</td>
<td>AF</td>
<td>AF</td>
<td>AF</td>
<td>AF</td>
<td>AF</td>
<td>AF</td>
<td>AF</td>
</tr>
<tr>
<td>Proper name of product</td>
<td>AF</td>
<td>AF</td>
<td>AF</td>
<td>AF</td>
<td>AF</td>
<td>AF</td>
<td>AF</td>
<td>AF</td>
</tr>
<tr>
<td>Product attributes</td>
<td>AT</td>
<td>AC</td>
<td>AC</td>
<td>AT</td>
<td>AT</td>
<td>AT</td>
<td>AT</td>
<td>AT</td>
</tr>
<tr>
<td>Recipient name and/or identifier</td>
<td>AT</td>
<td>AT</td>
<td>AT</td>
<td>AT</td>
<td>AF</td>
<td>AT</td>
<td>AT</td>
<td>AT</td>
</tr>
<tr>
<td>Identity and address of collection facility or donor registry</td>
<td>AT</td>
<td>AC</td>
<td>AC</td>
<td>AT</td>
<td>AT</td>
<td>AT</td>
<td>AT</td>
<td>AT</td>
</tr>
<tr>
<td>Date, time collection ends, and (if applicable) time zone</td>
<td>AT</td>
<td>AC</td>
<td>AC</td>
<td>AT</td>
<td>AT</td>
<td>AT</td>
<td>AT</td>
<td>AT</td>
</tr>
<tr>
<td>Approximate volume</td>
<td>AT</td>
<td>AT</td>
<td>AT</td>
<td>AT</td>
<td>AT</td>
<td>AT</td>
<td>AT</td>
<td>AT</td>
</tr>
<tr>
<td>Name and quantity of anticoagulant and other additives</td>
<td>AT</td>
<td>AT</td>
<td>AT</td>
<td>AT</td>
<td>AT</td>
<td>AT</td>
<td>AT</td>
<td>AT</td>
</tr>
</tbody>
</table>

- **Modifiers now “attributes”**
- **Volume now “quantity”**

- **6th edition**
- **5th edition**
<table>
<thead>
<tr>
<th><strong>CELLULAR THERAPY PRODUCT LABELING</strong></th>
<th>6th edition</th>
<th>5th edition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Donor identifier and (if applicable) name</strong></td>
<td>AT AT AT</td>
<td>AT AT AT</td>
</tr>
<tr>
<td><strong>Recommended storage temperature range</strong></td>
<td>AT AT AT</td>
<td>AT AT AT</td>
</tr>
<tr>
<td><strong>Biohazard and/or Warning Labels</strong> (as applicable, see CM7.4.2, C7.4.2, D7.4.2.)</td>
<td>AT AT AT</td>
<td>AT AT AT</td>
</tr>
<tr>
<td><strong>As applicable:</strong></td>
<td></td>
<td>If applicable:</td>
</tr>
<tr>
<td><strong>Statement “NOT EVALUATED FOR INFECTIOUS SUBSTANCES”</strong></td>
<td>AT AT AT</td>
<td>AT AT AT</td>
</tr>
<tr>
<td><strong>Statement “WARNING: Advise Patient of Communicable Disease Risks”</strong></td>
<td>AT AT AT</td>
<td>AT AT AT</td>
</tr>
<tr>
<td><strong>Statement “WARNING: Reactive Test Results for [name of disease agent or disease]”</strong></td>
<td>AT AT AT</td>
<td>AT AT AT</td>
</tr>
<tr>
<td><strong>Identity and address of processing and distribution facility(ies)</strong></td>
<td>AC AC</td>
<td>AC AC</td>
</tr>
<tr>
<td><strong>Statement “Do Not Irradiate”</strong></td>
<td>AT AT</td>
<td>AT AT</td>
</tr>
<tr>
<td><strong>Expiration Date (if applicable)</strong></td>
<td>AC AC</td>
<td>AT AT</td>
</tr>
<tr>
<td><strong>Expiration Time (if applicable)</strong></td>
<td>AC AC</td>
<td>AC AT</td>
</tr>
<tr>
<td><strong>ABO and Rh of donor (if applicable)</strong></td>
<td>AC AC</td>
<td>AC AC</td>
</tr>
</tbody>
</table>
### Cellular Therapy Product Labeling

<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>RBC compatibility determination (if applicable)</td>
<td>RBC compatibility testing results (if applicable)</td>
</tr>
<tr>
<td>AT</td>
<td>Statement &quot;Properly Identify Intended Recipient and Product&quot;</td>
</tr>
<tr>
<td>AT</td>
<td>Statement indicating that leukoreduction filters should not be used.</td>
</tr>
<tr>
<td>AT</td>
<td>Statement &quot;FOR AUTOLOGOUS USE ONLY&quot; (if applicable)</td>
</tr>
<tr>
<td>AT</td>
<td>Statement &quot;FOR AUTOLOGOUS USE ONLY&quot; (if applicable)</td>
</tr>
<tr>
<td>AT</td>
<td>Statement “For Use By Intended Recipient Only” (if for allogeneic recipient)</td>
</tr>
<tr>
<td>AT</td>
<td>Statement “For Nonclinical Use Only” (if applicable)</td>
</tr>
<tr>
<td>AC</td>
<td>Date of distribution</td>
</tr>
</tbody>
</table>
# CELLULAR THERAPY PRODUCT LABELS FOR SHIPPING & TRANSPORT ON PUBLIC ROADS

<table>
<thead>
<tr>
<th>Element</th>
<th>Inner container document</th>
<th>Outer container label</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of distribution</td>
<td>AC</td>
<td>AC</td>
</tr>
<tr>
<td>Time of distribution, if appropriate</td>
<td>AC</td>
<td>AC</td>
</tr>
</tbody>
</table>

6th edition

<table>
<thead>
<tr>
<th>Element</th>
<th>Inner container document</th>
<th>Outer container label</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of distribution and time, if appropriate</td>
<td>AC</td>
<td>AF</td>
</tr>
</tbody>
</table>

5th edition

- Time and date separated into distinct items
- Element
  - Inner container document
  - Outer container label
DEFINITIONS

- Some changes to the definitions so pay attention to this section

<table>
<thead>
<tr>
<th>DEFINITIONS</th>
<th>5th</th>
<th>6th</th>
<th>CATEGORY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accompany: To go, be together with, or be available to the appropriate individual(s) electronically, but not affixed or attached. Written or printed information that must accompany a cellular therapy product must be in a sealed package with, or alternatively, be attached or affixed to, the cellular therapy product container.</td>
<td>Accompany: To go, be together with, or be available to the appropriate individual(s) electronically, but not affixed or attached. Written or printed information that must accompany a cellular therapy product must be in a sealed package with, or alternatively, be attached or affixed to, the cellular therapy product container.</td>
<td>No change from 5th ed.</td>
<td></td>
</tr>
<tr>
<td>Accreditation cycle: The period of time from the awarding of accreditation until its expiration as set, and subject to change, by FACT or JACIE. At publication of these Standards, this period is three (3) years for FACT-accredited programs and four (4) years for JACIE-accredited programs.</td>
<td>Accreditation cycle: The period of time from the awarding of accreditation until its expiration as set, and subject to change, by FACT or JACIE. At publication of these Standards, this period is three (3) years for FACT-accredited programs and four (4) years for JACIE-accredited programs.</td>
<td>No change from 5th ed.</td>
<td></td>
</tr>
<tr>
<td>Advanced Practitioner: Advanced Practitioner of Nursing; includes certified nurse anesthetist, nurse practitioner, certified nurse midwife, and clinical nurse specialist.</td>
<td>Advanced practice provider/professional: Physician Assistant, Nurse Practitioner, or other licensed Advanced Practitioner authorized by the applicable legal authority to provide primary patient care with physician oversight. Physician Assistants are formally trained and licensed or certified by the applicable authority to provide diagnostic, therapeutic, and preventive health care services with physician supervision. Advanced Nurse Practitioner includes certified nurse anesthetists, nurse practitioners.</td>
<td>Change from 5th ed.</td>
<td></td>
</tr>
</tbody>
</table>
### Shipping labels

**INNER & OUTER CONTAINER DOCUMENTS**

<table>
<thead>
<tr>
<th>Answers</th>
<th>Applicant's Self-assessment</th>
<th>%</th>
<th>Inspector's Assessment</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compliant</td>
<td>11</td>
<td>58%</td>
<td>10</td>
<td>53%</td>
</tr>
<tr>
<td>Partially compliant</td>
<td>1</td>
<td>5%</td>
<td>2</td>
<td>11%</td>
</tr>
<tr>
<td>Non-compliant</td>
<td>2</td>
<td>11%</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Not applicable</td>
<td>0</td>
<td>0%</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Uncompleted</td>
<td>5</td>
<td>26%</td>
<td>7</td>
<td>37%</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>19</strong></td>
<td><strong>100%</strong></td>
<td><strong>19</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

**Applicant's Self-assessment**
- Compliant: 58%
- Partially compliant: 5%
- Non-compliant: 0%
- Not applicable: 0%

**Inspector's Assessment**
- Compliant: 53%
- Partially compliant: 11%
- Non-compliant: 0%
- Not applicable: 0%

### PARTIAL LABELS

<table>
<thead>
<tr>
<th>Type of label</th>
<th>Standard</th>
<th>Cat.</th>
<th>Applicant's assessment</th>
<th>Source of evidence and explanatory text</th>
<th>Inspector's assessment</th>
<th>Inspector's Comments (support your answers with additional information)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Label at completion of collection</td>
<td>Unique numeric or alphanumeric identifier</td>
<td>AF</td>
<td>Compliant</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Label at completion of collection</td>
<td>Proper name of product</td>
<td>AF</td>
<td>Compliant</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Label at completion of collection</td>
<td>Recipient name and/or identifier</td>
<td>AT</td>
<td>Compliant</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Label at completion of collection</td>
<td>Identity and address of collection facility or donor registry</td>
<td>AT</td>
<td>Compliant</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Label at completion of collection</td>
<td>Date, time collection ends, and (if applicable) time zone</td>
<td>AT</td>
<td>Compliant</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Label at completion of collection</td>
<td>Approximate volume</td>
<td>AT</td>
<td>Compliant</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Label at completion of collection</td>
<td>Name and quantity of anticoagulant and other additives</td>
<td>AC</td>
<td>Compliant</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Label at completion of collection</td>
<td>Donor identifier and (if applicable) name</td>
<td>AT</td>
<td>Compliant</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Inspector: All items compliant?** Yes
That's all Folks!
Any Question?