University of Washington Medical Center 1959 NE Pacific Street. Seattle, WA 98195 Transfusion Services Laboratory Policies and Procedures Manual	Original Effective Date: 10-28-2020 Revision Effective Date:	Number: PC-0087.01

TITLE: Visual Inspection of Blood Components at Northwest Campus

PURPOSE:
To provide instructions for visual inspection of blood components

LOCATION:
Northwest Lab Transfusion Support Service (TSS)

PRINCIPLE & CLINICAL SIGNIFICANCE:
Principle
Visual inspection is a major control point of manufacturing to ensure the safety, purity and potency of blood components.

Clinical Significance
Blood components are susceptible to damage during shipment and components not shipped and stored at the proper temperatures are at increased risk for bacterial contamination, hemolysis and other deleterious effects or may otherwise not function as expected and should be discarded to protect the potential recipient.

POLICIES:
- Blood components and blood component labels are visually inspected for acceptability at critical points from receipt to final disposition and these points are defined in standard operating procedure specific for the procedure/process being performed.
- Visual inspection at some critical points is documented electronically or manually. When required, documentation includes the following:
    - Date and time of inspection
    - Donor Identification Number (DIN)
    - Outcome of inspection
    - Action taken (QI form)
    - Identity of person performing inspection
- Blood components found visually unacceptable are quarantined electronically and physically until final disposition is determined.
    - A Quality Improvement (QI) form is initiated with the reason for quarantine and faxed to Montlake TSL manager for determination of final disposition – refer to SOP ***Quarantine and Final Disposition of Blood Components at Northwest Campus***

Quarantine Terminology	Meaning
Electronic Quarantine	Component is quarantine in the laboratory information system (SQ)
Physical Quarantine	Place in an appropriate storage device in a location labeled as ‘Quarantine’ and segregated from non-quarantined blood components

SPECIMEN REQUIREMENTS:
NA

REAGENTS/SUPPLIES/EQUIPMENT:

Reagents:	Supplies:	Equipment:
NA	NA	NA

QUALITY CONTROL:
NA

INSTRUCTIONS:

TABLE of CONTENTS

Inspecting the Component Label and Bag

<table>
<tr><th>STEP</th><th>ACTION</th></tr>
<tr><td>1</td><td>Verify the component label (ISBT label) is legible and includes:
One Donor Identification Number (and aliquot number, if applicable)
In-date expiration date/time
Component name and E code
Attributes and/or processing if applicable
ABO/Rh label</td></tr>
<tr><td>2</td><td>Inspect the blood containers for leaks, breaks or tears

NOTE: Light pressure may be applied to the unit.</td></tr>
<tr><td>3</td><td>Inspect the following for presence of blood or plasma which may indicate inadequate closure or sealing
Bag seams
Port areas</td></tr>
<tr><td>4</td><td><table><tr><th>If component is</th><th>Verify</th></tr><tr><td>Thawed plasma or cryoprecipitate</td><td>Port areas are free of moisture</td></tr><tr><td>RBC component</td><td>Presence of at least one integrally attached segment at the time of issue for transfusion</td></tr></table></td></tr>
<tr><td>5</td><td><table><tr><th>If component is</th><th>Verify</th></tr><tr><td>Irradiated</td><td>Verify indicator window on the Rad-Sure indicator film is BLACK, obscuring the word “NOT” NOTE: RadSure labels may not be present on all irradiated components due to transfer of product from primary container following irradiation</td></tr></table></td></tr>
<tr><td>6</td><td><table><tr><th>If label and/or bag are</th><th>Go to</th></tr><tr><td>Acceptable</td><td>Next section</td></tr><tr><td>Unacceptable</td><td>Results Reporting in Sunquest</td></tr></table></td></tr>
</table>

Verify Color and Consistency of Contents

<table>
<tr><th>STEP</th><th>ACTION</th></tr>
<tr><td>1</td><td>Verify component is acceptable in appearance

<table>
<tr><th>Component</th><th>Unacceptable Appearance</th></tr>
<tr><td>All components</td><td>• Blood or plasma observed in the ports at the sealing sites in tubing
• Leaks or cracks in the bag or tubing
• Murky, dark purple, brown in color (contamination should be expected if observed)
• Grossly lipemic plasma (pronounced milky appearance) is usually considered unsuitable for transfusion
• Foreign object</td></tr>
<tr><td>Red cell components and segments</td><td>• Hemolysis:
o Segments appear much lighter in color than red cells in bags
o Zone of hemolysis observed just about the cell mass (less opaque, pink plasma)
• Visible clots and/or aggregates: Dark purple to very dark burgundy masses that do not disperse easily by gently manipulation of change in temperature

EXCEPTIONS:
o A green hue from light-induced changes in bilirubin pigments is not cause for rejection
o White particulate matter generally described as one of the following: white specks, fatty material, crystalline material waxy appearing globs - refer to Blood Component Visual Inspection Guide, AABB/AARC</td></tr>
<tr><td>Plasma, Cryoprecipitate Granulocytes</td><td>• Hemolysis: pink to red in color
• Visible clots: a thick whitish, opaque mass that does not disperse easily by gentle manipulation or change in temperature
o Opacity prevents inspection for clots or fibrin strands
• Signs of unexpected thawing if components are frozen

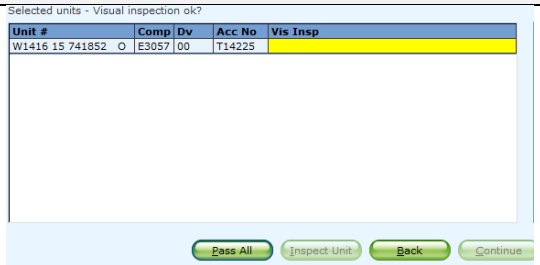
EXCEPTIONS:
o Green hue due to light-induced changes in bilirubin or pale green color due to birth control pills are acceptable and not cause for rejection
o Flocculent material that appears after thawing: describes as cloudy, fuzzy, or fluffy white precipitate that may have a tissue paper-like appearance. Can easily disperses by gentle manipulation or increase in temperature</td></tr>
</table>
</td></tr>
</table>

STEP	ACTION
	Platelets • Hemolysis: pink to red in color • Visible clots and/or aggregates: a thick whitish, opaque mass that does not disperse easily by gentle manipulation or change in temperature • Gross lipemia or icterus • No swirl noted **EXCEPTIONS** ○ White particulate matter generally described as one of the following: white specks, fatty material, crystalline material waxy appearing globs - refer to Blood Component Visual Inspection Guide, AABB/AARC ○ Pathogen reduced platelets
2	Go to Results Reporting in Sunquest

CALCULATIONS/INTERPRETATIONS/RESULTS REPORTING/NORMAL VALUES/CRITICAL VALUES

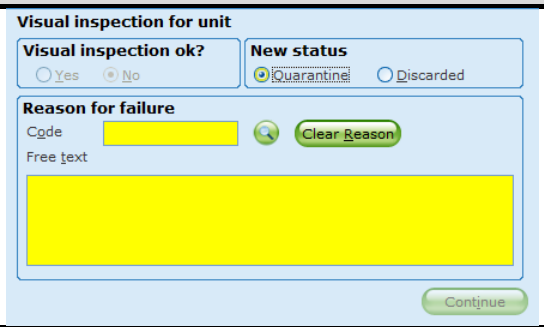
Interpretation
Any component not passing the visual inspection should not be issued for transfusion

Results Reporting in Sunquest

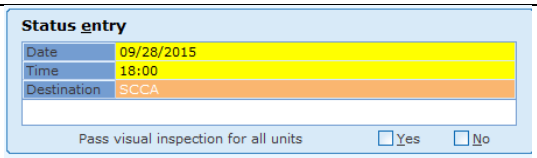
STEP	ACTION
1	Record the result of the visual inspection in the LIS **If**: **Issuing** to a patient **Then record at the following step**: 

If visual inspection is	Then answer the question "Select units-Viusal inspection ok?"
ACCEPTABLE	• Yes • Continue following SOP ***Issuing Blood Component at Northwest Campus***
UNACCEPTABLE	• No • Quarantine the component following SOP ***Quarantine and Final Disposition of Blood Components at Northwest Campus***

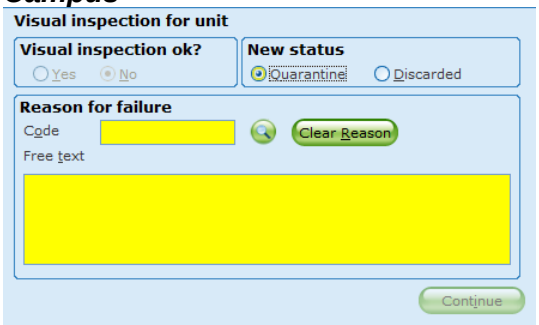
STEP	ACTION



Receiving , returning or **shipping**



If visual inspection is	Then answer the question "Pass Visual Inspection for all units"
ACCEPTABLE	• Yes • Refer to the appropriate SOP ○ ***Receiving Blood Components from Montlake at Northwest Campus*** ○ ***Returning Issued Blood Components to Inventory at Northwest Campus*** ○ ***Returning Blood Components to Montlake from Northwest Campus***
UNACCEPTABLE	• No Quarantine the component following SOP ***Quarantine and Final Disposition of Blood Components at Northwest Campus***



PROCEDURE NOTES/LIMITATIONS

- It is not possible to determine all possible adverse conditions through a visual inspection of the component and where indicated, additional testing will be incorporated into the process.

- Blood labels are electronically checked for accuracy when blood component are modified and relabeled.

REFERENCES:

- Technical Manual. Bethesda, MD: AABB Press, current edition
- Standards for Blood Banks and Transfusion Services. Bethesda, MD: AABB Press, current edition

RELATED DOCUMENTS:

FORM *Quality Improvement Form*
SOP *Receiving Blood Components from Montlake at Northwest Campus L*
SOP *Returning Blood Components to Montlake from Northwest Campus*
SOP *Quarantine and Final Disposition of Blood Components at Northwest Campus*
SOP *Issuing Blood Components at Northwest Campus*
SOP *Returning Issued Blood Components to Inventory at Northwest Campus*

APPENDIX:

NA

UWMC SOP Approval:

UWMC CLIA Medical Director	Mark H. Wener, MD	Date 10/20/20
Transfusion Service Manager	Nina Sen	Date 10/16/20
Compliance Analyst	Christine Clark	Date 10-16-2020
Transfusion Service Medical Director	Monica Pagano, MD	Date 10-19-2020

UWMC Biennial Review:

	Date
	Date