Beaumont Laboratory
Royal Oak

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RECEIPT OF CRITICAL REAGENTS, MATERIALS AND REVIEW OF MANUFACTURERS' PRINTED MATERIALS

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Purpose

- To provide policies and procedures that are to be applied when receiving critical reagents in the Blood Bank.
- To provide policies and procedures for reviewing manufacturers' printed materials for reagents that are received.
- To provide directions for completing F-332, *Reagent Receipt Log*.

Introduction

Refer also to P331, *Inventory of Reagents and Critical Materials.*

The process of receiving reagents into the Blood Bank inventory consists of the following:

- Initialing and time-stamping the dock receipt traveler.
- Before filing the invoice, the Blood Bank employee will verify that the correct reagents and quantities were received (refer to P331).
- Documentation of F-332, *Reagent Receipt Log.*
- Placement of "Reagent Received / Date" sticker on each reagent vial or box of reagents as described in the policy *Use of the "Received / Date" Sticker*.
- Reviewing the corresponding manufacturer's inserts for reagents that are received for potential revisions.
- Visual inspection of all reagent shipments.
- Performing quality control (QC); see the policy *Quality Control of Reagents upon Receipt.*
- Registering and opening the reagents into the Blood Bank computer system as described in the *Computer Documentation Manual (CDM) / Reagents & Quality Control*.
- Unpacking the reagents from the delivery box and placing them in the correct location in the Blood Bank.

Manufacturers provide their customers with various printed materials to ensure quality is not compromised and that products are used as recommended. The laboratory must have a procedure to assure that the most current manufacturers' inserts are in use. The Blood Bank maintains several reference binders in which the current manufacturer's inserts are stored. When changes to an insert are noted, the appropriate Standard Operating Procedures (SOPs) are updated as necessary.

Definitions

- **Critical material:** A good or supply used in the collection, preservation, storage, preparation, or testing of blood components that directly affects quality or patient safety.

- **Receipt traveler:** A Beaumont document that is brought to the Blood Bank by the dock delivery personnel; usually includes price and quantity.

- **Invoice:** The itemized document for Blood Bank reagents or supplies that is provided by the supplier; includes quantities and sometimes includes prices.

- **Reference numbers:** A general term for the revision date and other numbers that are printed on manufacturers' inserts and packaging supplies. The Blood Bank uses these references numbers to help determine whether a manufacturer has revised the insert for a reagent.

- **MT Lead:** Medical Technologist Lead.

- **Designee:** Employee trained

Policies

All reagents are considered critical materials, as they are a good or supply used in the testing of blood components that directly affects quality or patient safety.

Documentation of the *Reagent Receipt Log*

All reagents that are received from the manufacturer must be documented on F-332, *Reagent Receipt Log*. Directions for documenting this log are located in the *Procedure* section of this document. Generally, all reagents should be documented on this log; items that are considered reagents are included in the policy *Quality Control of Reagents upon Receipt.* Note that it is not necessary to document supplies or any items not listed in the policy *Quality Control of Reagents upon Receipt* on the *Reagent Receipt Log*.

Visual Inspection of the Reagents and Materials

Each shipment of reagents must be visually inspected at the time of receipt. A satisfactory visual inspection of the shipment is documented in the computer by marking the "Receipt Criteria Met" box as the reagents are registered; refer to the CDM flows for registering reagents. Unsatisfactory visual inspection includes:

- Broken vials, incorrect volume, leakage, or damaged shipping boxes
- Reagents were shipped at inappropriate temperatures / conditions, noncompliance with any directions supplied by the manufacturer on the shipping container, etc.
- Gel cards that are lying on their side (instead of upright) when they are received or that appear damaged.
- Solutions that are cloudy, contain particulate matter, leaking or not properly sealed.

Note that as described throughout the SOPs each individual vial, gel card, etc. will also be visually inspected at the time of testing as part of routine QC testing.

Policies Relating to the Receipt Traveler and Invoice

- Receipt travelers should be initialed and time-stamped by the employee who accepts the shipment from the dock delivery personnel. One copy will be retained by the delivery personnel, the other copy should be placed in the shipping box. Any employee may accept a shipment. It is this employee's responsibility to place the shipment at the appropriate temperature, or to ask a technologist for assistance.
- The invoice that accompanies the shipment should be initialed and time-stamped by the Medical Technologist (MT) who opens the box in which the reagents were shipped. The

initials of the MT indicate that the visual inspection of the shipment is satisfactory; if the inspection is unsatisfactory then a variance report should be submitted.
- Once all steps of the procedure have been completed, the receipt traveler and invoice should be submitted to the Blood Bank clerk

Use of the "Received / Date" Sticker

The Blood Bank should be able to determine the date that any reagent was received. The "Received / Date" sticker will be affixed to reagents upon receipt.
- If multiple quantities are stored in a common box, then this sticker will be affixed to the storage box (e.g., gel cards).
- If reagents are removed from the box, then the sticker will be affixed to each individual reagent vial (e.g., reagent and typing sera, MTS diluents, etc.).

Manufacturers' Inserts Binder / Notecards

Reagent manufacturers must supply printed materials (inserts) which include storage requirements, testing procedures, etc. The Blood Bank maintains these inserts in the *Manufacturers' Inserts Binders.* The Blood Bank also maintains notecards along with many of the inserts in these binders. These notecards provide helpful information; e.g., acceptable inert controls, warnings that a test should not be centrifuged, warnings that a reagent should be tested only by the IgG gel card method, etc. These notecards are prepared and updated by a MT Lead.
- Only a MT Lead may place a notecard in the binder or revise a notecard.
- The reagent name and reference numbers shall be included on each notecard.
- As revisions to the insert are made by the manufacturer, the notecards must be updated as appropriate by a MT Lead.
- The notecards will be maintained electronically on the S: Drive as F-332a.
- Notecards should be removed from the binders only by a MT Lead.

Reference Numbers / Indicate whether an Insert has been Revised

The term *reference number* is a general term for the revision date and other numbers that are printed on manufacturers' inserts and packaging supplies. The Blood Bank documents the reference numbers on the *Reagent Receipt Log* and in the computer and uses these references numbers to help determine whether a manufacturer has revised the insert for a reagent.
- For <u>Ortho reagents,</u> the reference numbers include the revision date, the REF number, and/or the electronic number (the e number appears in the format e123456789_EN). These reference numbers appear on the reagent's box. Note that Ortho has not yet assigned both REF and e numbers to all reagents. Note also that Ortho does not typically send inserts with reagents, but may do so if a revision to the insert has recently been made. Ortho inserts include a text box in which the specific revisions are listed.
- For <u>Immucor / Gamma reagents</u>, the reference numbers include the Insert Code and the revision date, as they appear on the inserts that are routinely sent with the reagents. Revisions made by Immucor on an insert are typically underlined.
- For Bio-Rad reagents, the reference numbers include a REF number, the revision date, and another number listed on the insert before the revision date.
- For any other reagents, identify the applicable reference numbers / dates from the *Manufacturers' Inserts Binders*. These numbers / dates are usually highlighted.

Comparison of Reference Numbers when Reagents are Received

- Note that some manufacturers have recently discontinued the practice of sending inserts with reagents. Directions for viewing or printing manufacturer's inserts are located in the Ortho or Immucor/Gamma *Manufacturers' Inserts Binders*.
- The Blood Bank maintains printed copies of current manufacturers' inserts in the Ortho or Immucor/Gamma *Manufacturers' Inserts Binders*.
- For each reagent that is received by the Blood Bank, the reference number on the packaging must be compared to the reference number on the insert in the *Manufacturer's Insert Binder*. This comparison is documented on the *Reagent Receipt Log.* This comparison is also documented in the computer by marking the "Package Insert Reviewed" box as the reagents are registered; refer to the CDM flows for registering reagents.

  Note that in some cases, two current inserts may appear in the binder for the same reagent; e.g., two lot numbers are currently in use and each lot number has different reference numbers.
- The reagent packaging must not be discarded until the reference numbers have been recorded on the *Reagent Receipt Log* and in the computer.
- If the reference number on the reagent packaging does not match the reference number on the insert in the *Manufacturer's Insert Binder,* the technologist must document sticker F-332b, *Revision Made to Manufacturer's Insert* and will affix this sticker on F-008c, *Communications and Daily Blood Bank Rounds Log*. This sticker must be documented for all manufacturers' revisions, no matter how insignificant the revision may seem. This sticker will alert a MT Lead or Designee to perform the actions described in ~~*MT Lead*~~ *Actions upon Revision to Manufacturer's Insert*. In some cases, it may be necessary to update the corresponding SOP or notecard. The technologist receiving the reagent has the option of whether to place the reagent in quarantine or not, and will mark the corresponding box on the *Reagent Receipt Log.*
  - ☐ Reagent NOT placed in quarantine; minor revision only. The technologist has determined the manner in which the insert has been revised and is comfortable to use the reagent consistent with standard operating procedures, despite the revision. For example, a revised logo on the insert.
  - ☐ Reagent placed in quarantine. The technologist may place the reagent in quarantine by affixing an orange *Quarantine* sticker to the reagent or box of reagents. A reagent should be placed into quarantine if the technologist has not determined the manner in which the insert has been revised, or is not comfortable to use the reagent consistent with standard operating procedures, due to the revision. For example, the entire test methodology has been revised. See the policy *Placement of Reagents into Quarantine.*

~~MT Lead~~ Actions upon Revision to Manufacturer's Insert

- Determine the nature of the revision to the insert.
- Determine whether the corresponding SOP and *Manufacturer's Insert Notecard* should be revised, and update the SOP and notecard as necessary.
- Place a copy of the revised insert in the *Manufacturer's Insert Binder.* Remove the previous version of the insert only if the all vials of the reagent corresponding to the previous insert are expired or exhausted.
- After each of these steps have been performed, the MT Lead / Designee will:

- Initial and date the *Reagent Receipt Log*.
- Initial and date the sticker (F-332b), which was placed on the *Communication Log.*
- If applicable, initiate QC testing of the reagent and remove the reagent from quarantine.
- The MT Lead / Designee will document F-332c, ~~*MT Lead*~~ *Review of Manufacturers' Revisions,* which is stored in the quality control folders.

Placement of Reagents into Quarantine

Reagents that have been received in the Blood Bank are considered to be in quarantine until all steps of the *Procedure* are complete. In addition, reagents shall be placed into quarantine in the following situations:

- If QC is required at the time of reagent receipt and the QC fails.
- If the visual inspection fails.
- The technologist *may* place a reagent into quarantine if the reference numbers on the reagent packaging do not match those in the current *Manufacturer's Insert Binder,* as described in the policy *Comparison of Reference Numbers when Reagents are Received.*

If a reagent is placed in quarantine, the following apply:

- The orange *Quarantine* sticker shall be affixed to the reagents by the receiving technologist.
- A variance report shall be submitted (unless the reason for placement of the reagent in quarantine is that the reference numbers do not match; in this case a MT Lead / Designee will take the actions described in the policy ~~*MT Lead*~~ *Actions upon Revision to Manufacturer's Insert).*
- The quarantined reagent should be stored at the appropriate temperature and conditions, as described by the manufacturer. For example, on the reagent quarantine shelf in the walk-in refrigerator, if applicable.

Unpacking Reagents / Moving to Storage Location in the Laboratory

- All reagents should be received into inventory as soon as possible after delivery from the supplier.
- Reagents should be left in the delivery box and should be stored at the temperature indicated by the manufacturer until all required steps of the *Procedure* have been completed. Once all steps have been completed, the reagents should be removed from the delivery boxes and placed in the correct reagent storage location.

Antigrams for Antibody Screens and Panels

When Selectogen sets, Surgiscreen sets and antibody panels are received they should be documented on the *Reagent Receipt Log,* delivered into Soft, and imported into the Antigen Plus program as described in P631, *Using the Antigen Plus Program*. One copy of each antigram will be initialed and dated by the receiving technologist. Several copies of each initialed / dated antigram will be made. The antigrams are distributed / managed as follows:

- One copy of each antigram will be placed in the *Panels to be Imported into Antigen Plus* folder, located in the bottom right drawer at the problem workstation. Refer to the P631 policy *Importing New Panels and Screen Cells.*
- One copy of each antigram will be placed in the applicable *Ortho* or *Immucor/Gamma Antibody Screens and Panels* reference binder.

- Several copies of each antigram will be placed in the Special Studies forms drawer, to be used for patients' antibody investigations. If there are antigrams from a previous lot in the Special Studies forms drawer, paper clip the new copies to keep them separated.
- After the antibody screen or panel has expired, the antigram should be removed from the Special Studies forms drawer.
- After the antibody screen or panel has been discarded (the last 3 lots of each screen/panel type are kept), the antigram should be removed from the reference binder.

Registering and Opening Reagents in the Blood Bank Computer System

Some reagents are registered and opened in the Blood Bank computer system upon receipt or upon physically opening the reagent, while other reagents aren't brought into the Blood Bank computer system. Use the following table to determine if a reagent is brought into the Blood Bank computer system.

Reagents are registered and opened in the Blood Bank computer system as described in the CDM flow *Registering Reagents*.

Table 332-1: Registering and Opening Reagents in the Blood Bank Computer System

Reagent / Supply	Registered / Opened in the Computer?	When to Register / Open in the Computer
• 0.8% Panels • 0.8% Selectogens • 3% Affirmagens • 3% Panels • 3% Surgiscreens • A_2 Cells • ABO/Rh Tube Type Reagents • AHG Reagents • Anti-IgG Gel Cards • Antisera • Check Cells • DAT Reagents • Diluent 2 • Fetal Cell Screen Kit • LISS • Rh Gel Cards • RhIG (as a supply)	Yes	Upon Receipt
• AlbaQ-Chek Kits • Hgb S Controls • Hgb S Solubility Kit • Saline Cubes • 7% Bovine Albumin (BSA)	Yes	Upon Opening Each Individual Reagent
• 0.8% Affirmagens • ~~7% Bovine Albumin (BSA)~~ • 22% Bovine Albumin • ABD/Reverse Gel Cards • Anti-D Gel Cards • Control Gel Cards • Diluent 2 Plus • DTT Reagent • Eluate Kit • Irradiation Indicators • PGD Reagents • WARM Reagent • Buffered Gel Cards	No	NA

Quality Control of Reagents upon Receipt

QC for some reagents is required at the time of receipt; for other reagents QC is not required at the time of receipt but QC may be required to test in parallel with testing of patient and donor samples. Use the following table to determine whether QC testing is required at the time of receipt and, if applicable, the location where the QC is documented.

Notes: If QC is documented in a rack in the computer, refer to the CDM flow *Documentation of Reagent QC upon Receipt*. Make a printout of the rack as described in the CDM flow *Making a Printout of a Soft QC Rack* and attach the printout to the *Reagent Receipt Log.*

Table 332-2: Quality Control of Reagents upon Receipt

Reagent	Examples	Is QC Required at Time of Receipt?	Location of QC Documentation
Tube testing ABO/Rh reagents	Anti-A, Anti-B, Anti-D, Rh control, reverse cells	Yes	RQ3rack in Soft
AlbaQ-Chek® Kit vials	AlbaQ-Chek® Kit vials	No	NA
Vision reagents (except Anti-D / Control gel cards)	IgG and ABO/Rh gel cards, MTS Diluent 2 Plus, MTS Diluent 2, Affirmagen and Selectogen cells	Yes	Attach Vision printout to the *Reagent Receipt Log*
A_2 Cells	A_2 Cells	NA	NA
Antisera or gel cards for antigen typing	Anti-C, Anti-Fya, Anti-A1, Rh gel cards, Anti-D gel cards, MTS™ Control cards, Buffered gel cards	No	NA
Surgiscreen cells and LISS	Surgiscreen cells and LISS	Yes	RQLIS rack in Soft
Antiglobulin and DAT reagents	Polyspecific, IgG, and C3 antiglobulin, check cells	Yes	RQDAT rack in Soft
Ortho Panel A 0.8%	Ortho Panel A 0.8%	No, upon opening	Problems Clipboard
All other reagents	Fetal cell screen, other panels, sickle cell testing, warm autoantibody removal medium (WARM), eluate kit, Pan Genera Detection (PGD) , 22% bovine albumin, DTT, 7% BSA	No	NA
Supplies	Glycerolyte solution~~, 7% BSA,~~ syringes, Rh Immune Globulin, etc.	No	NA
Codabar Labels	Refer to P333, *Approval of Blood Product Labels.*		

RECEIPT OF CRITICAL REAGENTS, MATERIALS AND REVIEW OF MANUFACTURERS' PRINTED MATERIALS

Forms

- F-332, *Reagent Receipt Log.* Note that directions for documenting this log are located in the *Procedure* section of this document.
- *F-332a, Manufacturers' Insert Notecards;* stored electronically on the S: Drive. These notecards are placed in the *Manufacturers' Inserts binders* by a MT Lead.
- F-332b, *ALERT: Revision Made to Manufacturer's Insert* sticker. This sticker is affixed to the *Communication Log* when a manufacturer's insert has been revised (no matter how insignificant the revision may seem), to alert a MT Lead / Designee of the revision. Copies of this sticker are stored *Reagent Inventory* binder
- F-332c, ~~*MT Lead*~~ *Review of Manufacturers' Revisions*
- F-008c, *Communication and Daily Blood Bank Rounds Log*
- See also the forms listed in P331, *Inventory of Reagents and Critical Materials.*

Reference Binders / Folders

- *Manufacturers' Inserts Binders*
- Immucor/Gamma and Ortho Antibody Screens and Panels
- The *Reagent Inventory* binder located near the crossmatch assist workstation. This binder includes a table of contents; many forms are stored in this binder including the forms listed in this SOP and the forms listed in P331, *Inventory of Reagents and Critical Materials.*
- *Manufacturers' Inserts Revision History folder.* This folder is stored in the office of the SOP MT Lead, and includes F-332c, ~~*MT Lead*~~ *Review of Manufacturers' Revisions.*

Procedure: Reagent Receipt and Documentation of F-332, *Reagent Receipt Log*

1. Document the following on F-332, *Reagent Receipt Log*:
   - Current date and initials of technologist receiving the reagent
   - Reagent name (e.g., Anti-A, reverse cells, fetal cell screen kit, etc.)
   - Reagent manufacture (e.g., Ortho, Immucor/Gamma, BioRad, etc.)
   - Reagent Lot Number
   - Reagent expiration date

2. Document the quantity of reagents received; include a description of the quantity. For example: x number of vials, y number of boxes of gel cards, etc. Also document the log with a check mark to indicate that the quantity received matches the quantity from the invoice. If the quantity received does not match the quantity from the invoice, then investigate the discrepancy and take appropriate actions (for example, submit a variance).

3. Visually inspect the shipment of reagents. Document the visual inspection as S (satisfactory) or U (unsatisfactory). If the visual inspection is unsatisfactory, place the reagent in quarantine and document a variance.
   - For example: an unsatisfactory inspection would include broken vials, leakage, or damaged shipping boxes; reagents that were not shipped at appropriate temperatures / conditions; visible contamination; non-compliance with any directions supplied by the manufacturer on the shipping container, etc.
   - Refer to the Reagents/QC CDM / *Placement of a Reagent into Quarantine.*

4. Document the reference numbers from the box / packaging.
   - For Ortho document the revision date, REF number, and the e number.
   - For Immucor/Gamma document the insert code and the revision date.
   - For Bio-Rad reagents document the REF number, the revision date, and the number listed on the insert before the revision date.
   - For any other reagents, identify the applicable reference numbers / dates from the *Manufacturers' Inserts Binders* and identify these numbers / dates on the incoming box / packaging.

   Refer to the policy *Reference Numbers.*

5. Compare the reference numbers on the reagent's packaging with the reference numbers on the insert in the *Manufacturer's Insert Binders*; and determine whether the reference numbers match. Mark the applicable box:
   - ☐ Reference numbers match
   - ☐ Reference numbers do NOT match

   Refer to the policy *Comparison of Reference Numbers when Reagents are Received.*

6. Perform step 6 only if the reference numbers DO NOT match.
   - Document F-332b, *Revision Made to Manufacturer's Insert* and affix this sticker on F-008c, *Communication and Daily Blood Bank Rounds Log*. This sticker must be documented for all manufacturers' revisions, no matter how insignificant the revision may seem. This sticker will alert a MT Lead / Designee to perform the actions described in ~~*MT Lead*~~ *Actions upon Revision to Manufacturer's Insert*.
   - The technologist receiving the reagent has the option of whether to place the reagent in quarantine or not, and will mark the corresponding box on the log.
     - ☐ Reagent NOT placed in quarantine; minor revision only
     - ☐ Reagent placed in quarantine. The technologist may place the reagent in quarantine by affixing an orange *Quarantine* sticker to the reagent.
   - A MT Lead or designee will complete the actions described in the policy ~~*MT Lead*~~ *Actions upon Revision to Manufacturer's Insert.* Place a copy of the revised insert in the *Manufacturer's Insert Binder*. Remove the previous version of the insert only if the all vials of the reagent corresponding to the previous insert are expired or exhausted.

7. Affix a *"Received / Date" sticker* to each supply or reagent; document the form with a check mark.

   Refer to the policy *Use of the "Received / Date" Sticker*.

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8. Register and open the reagent in the Blood Bank computer system, if applicable; document the form with a check mark or NA.

   Refer to the policy *Registering and Opening Reagents in the Blood Bank Computer System.*

   Refer to the Reagents/QC CDM / *Registering Reagents*. Remember to document the reference numbers in the Blood Bank computer system.

9. Perform QC testing, if indicated, and mark the applicable box on the *Reagent Receipt Log.* Attach a Vision or Soft printout of the QC, when QC is indicated. Indicate the new reagent that is being QC'd on the printout by highlighting or circling it.
   - ☐ Passed, Soft printout attached
   - ☐ Passed, Vision printout attached
   - ☐ Failed, quarantine, variance
   - ☐ QC NR (QC not required)

   - Refer to the policy *Quality Control of Reagents upon Receipt.*
   - Refer to the Reagents/QC CDM / *Making a Printout of a Soft QC Rack.*

10. Move the supplies or reagents to the correct storage location in the laboratory; document the form with a check mark.

11. Once all steps of this *Procedure* have been performed satisfactorily, the reagent is acceptable for use. Document the form with a check mark and the technologist's initials to indicate that the reagent is acceptable for use.

12. Document the *Reagent Receipt Log* with any applicable *Notes*.

Notes

Copies of the Job Aids *Obtaining Ortho Technical Documents Online* and *Obtaining Immucor/Gamma Technical Documents* are located in the applicable Manufacturers' Inserts Binders.

Attachments

- Job Aid, Obtaining Ortho Technical Documents Online
- Job Aid, Obtaining Immucor/Gamma Technical Documents

References

- AABB, *Technical Manual*, current edition
- College of American Pathologists; TRM 31227, *Package Inserts*
- College of American Pathologists; TRM.31241, *Reagent QC*

Authorized Reviewers

Chief, Pathology and Laboratory Medicine
Medical Director and/or Designee, Blood Bank
Manager/Supervisor, Blood Bank

RECEIPT OF CRITICAL REAGENTS, MATERIALS AND REVIEW OF MANUFACTURERS' PRINTED MATERIALS

Document Control

Location of Master: Master electronic file stored on the Beaumont Laboratory server under S:/
Master printed document stored in the *Transfusion Medicine Standard Operating Procedures Manual.*
Number of Controlled Copies posted for educational purposes: 0
Number of circulating Controlled Copies: 1
Location of circulating Controlled Copies: A copy of Table 332-1 and Table 332-2 are located on the reverse side of F-332, *Reagent Receipt Log.*

Document History

Signature	Date	Revision #		Related Documents Reviewed/ Updated
Prepared by: Jennifer Sarhan	03/30/2013	r00.00.00	The 300 series / Quality Control has been reorganized. This document (P332) and P333, Approval of Blood Product Labels replace P311 and Letter P311, Quality Control of Critical Supplies. P332 also replaces P319 Manufacturers' Printed Material Review & Insert Notebook Update.	
Validated by: Karrie Torgerson	06/27/2013			
Additional Review by: Heather Asiala	06/27/2013			
QA: Louisa Serafimovska	06/24/2013			
Supervisor: Judy Easter	06/12/2013			
Approved by: Peter Millward, MD	06/12/2013			
Approved by: Mark Kolins, MD	09/09/2013			
Reviewed by: (Signature)	**Date**	**Revision #**	**Modification**	**Related Documents Reviewed/ Updated**
Reviewed by: Peter Millward, MD	08/02/2013			
Reviewed by: Peter Millward, MD	09/09/2013			
Reviewed by: Peter Millward, MD	07/23/2014			
Reviewed by: Peter Millward, MD	03/09/2015			
Revised by: Ashley Wilson	10/07/2015	r00.01.00	Updated Visual Inspection information, added "Materials" to the SOP nap.	
QA: Anne Sepienza	10/09/2015			
Supervisor: Judy Easter	10/09/2015			
Approved by: Peter Millward, MD	10/09/2015			
Revised by: Ashley Wilson	12/14/2015	r00.01.01	Updated Panel A QC upon opening box.	
Approved by: Peter Millward, MD	01/11/2016			
Approved by: Peter Millward, MD	05/03/2017			
Revised by: Christopher Ferguson	12/01/2017	r00.02.00	MTS Diluent 2 now requires QC upon receipt like the rest of the Vision reagents. Added BSA to supplies. Changed "Provue" to "Vision". Updated header	
QA: Anne Sepienza	12/07/2017			
Supervisor: Billie Ketelsen	12/07/2017			
Approved by: Peter Millward, MD	12/07/2017			
Approved by: Elizabeth Sykes, M.D.	02/23/2018			

Document Control, Cont.

Signature	Date	Revision #	Modification	Related Documents Reviewed/ Updated
Approved by: Peter Millward, MD	02/26/2019			
Approved by: Craig Fletcher, MD	03/27/2019			
Revised by: Christopher Ferguson	01/30/2020	r00.03.00	Added chart to designate which reagents are brought into the computer system. Added anti-D and control gel cards to SOP. Removed F-331f from SOP. No longer keep copies of new/old inserts with F-332c. Updated job titles and authorized reviewers. Added statement about referencing manufacturers'' inserts other than Ortho/Immucor. Added statement to indicate which reagent is being QC'd on the QC printout.	
Manager: Billie Ketelsen	01/31/2020			
Approved by: Craig Fletcher, MD	02/10/2020			
Approved by: Craig Fletcher, MD	07/15/2020			
Revised by: Samantha Maynard	06/09/2020	r00.04.00	Added buffered gel cards to reagent lists, changed 7% BSA from a supply to a reagent to be QCed. Allowed reagent revisions to be reviewed by a designee as well, not just a MT Lead	
Manager:				
Approved by: Craig Fletcher, MD				