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| | **Category:** Lab Methodist, Lab Riley, Lab University | |
| | **Education: Level 1** | |
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# Procedure: Antigen Typing – Red Cell



**Reference # 24855**

# I. PURPOSE

To detail procedure for red cell antigen typing.

# II. SCOPE

This SOP addresses procedure for red cell antigen typing, documentation of results, and product labeling. This SOP is intended for all Transfusion Service scientists, Supervisors and Manager.

# III. EXCEPTIONS

Exceptions must be approved by a member of the QA unit.

# IV. DEFINITIONS

**QA UNIT:** Members include Medical Director, Director, Manager, Supervisors, and QA Coordinator.

# V. POLICY STATEMENTS

A. All units received from the donor center which have recently had their antigens reconfirmed as Negative before shipment do **NOT** need to be retyped for those antigens. The confirmed antigens will appear on tag attached to unit or on the face label.

B. Any unit from the donor center with only HISTORICAL donor antigens testing **will** be retyped for the antigens needed. There will be **NO** Reference Tag attached to unit.

C. Methods of Antigen Typing:

1. Tube (manual) Antigen typing (FDA approved)
2. Vision(automated) Antigen typing, FDA approved antigen typing, available for C, E, c, Rh phenotype (MTS Cards) and anti-K antisera.
3. RBC genotyping available from IUH Send Out Lab and is only used for patient samples.

When patient has been recently transfused in the last 90 days and/or direct anti-globulin test (IgG-DAT) is positive, the patient antigen typing results may be invalid. These samples may be forwarded for RBC genotyping or a microhematocrit cell separation must be completed and/or EGA-treatment before testing.

E. Antisera Controls will be performed once each day of use for each method of testing and for each lot number used.

F. For patients with specific demonstrable antibodies, the crossmatch **may** be used as a screening method for compatibility (BBT-002). This is referred to as Crossmatch-screening, see below for Cerner entry.

   a. If this method is used, then the compatible units will then be tested for the specific antigens (if antisera is available) and issued if confirmed antigen negative.

   b. Example: If a patient has anti-$Fy^a$, and the OR has called for immediate transfusion. One may complete a crossmatch screen in lieu of antigen typing to provide immediate compatible blood for the OR. After the units are released, then the units may be typed for $Fy^a$.

G. Charging for donor antigen typing should be completed only when the patient receives the antigen negative unit. We may screen units and have the units available for any patient. It is critical the charges for the antigen testing is completed when the product is crossmatched and provided to the patient. See Cener Entry, donor antigen section.

# VI. PRINCIPLE/BACKGROUND

None

# VII. MATERIALS

**Supplies, Equipment and Reagents** Listed in Package Insert

# VIII. SPECIMEN REQUIREMENTS

All patient samples must meet identification and collection criteria as outlined in Procedure: Requisition & Specimen Processing.

Donor Segments

# IX. PROCEDURE

A. Evaluate the sample to be tested

1. If the sample is from an un-transfused patient ( in the last 90 days) and the IgG-DAT is negative, then the patient may be tested by automated or tube antigen typing methods. Go to next step.
2. If the patient has been transfused in the last 90 days, then no serologic testing should be tested.
   a. The sample may be forwarded for RBC genotype testing.
   b. The sample may have an autologous red cell separation completed before antigen typing. See Autologous Red Cell Separation .
3. If the sample is from an un-transfused patient but the patient has a positive IgG-DAT, then the patient cannot be tested with all antisera. IgG-DAT positive samples may be tested with monoclonal antisera, but not any antisera which requires an AHG method.

a. One may omit serologic patient antigen typing which requires AHG method.

b. This patient sample may be forwarded for RBC genotype testing.

c. The sample may require treatment before completing testing with AHG antisera. This method required is Procedure: EDTA Glycine Acid - EGA Kit.

4. Multiple methods may be used for antigen typing based on what is the goal of the testing:
   a. If screening donor units for C, E, c, Rh phenotype, or K and adequate RBC volume is available, then one may use automated antigen screening.
   b. If donor units are needed to be screened for other antigen specificities than C, E, c, Rh phenotype, or K, then manual antigen screening is most appropriate.
   c. If testing an un-transfused patient sample, one may use automated antigen screening and/or manual antigen screening.

B. Automated Antigen Typing: Go to Vision: Automated Antigen Typing

C. Tube (manual) Antigen Typing:
   1. Perform Antigen typing of patient or donor samples following Manufacturer's Package Insert Instructions for the reagent, supplies and equipment necessary.
   2. Complete Quality Control testing for the reagent being following Package Insert.
      a. Positive controls should be heterozygous for the antigen being tested.
         1) There are exceptions to heterozygous based on the antisera. For example anti-Lea and anti-Leb.
         2) Always refer to the package insert to ensure correct cells are chosen for control.
      b. Negative controls should be negative for the specificity being tested,

   c. Evaluate the donor/patient and quality control testing
      a. Results for donors and patients should range from 0-4+.
      b. If unexpected mixed-field (dual population) is detected, then one should not assign the antigen phenotype.
         1) For example, if mixed-field is detected, 3+mf, then the patient should not be reported as positive.
         2) The patient sample may be forwarded for RBC Genotype testing or cell separation may be completed with antigen typing repeating.
      c. If the positive control or patient/donor antigen testing result is less than 1+, then the results are questionable.
         1) Refer to package insert for further problem-solving suggestions.
         2) Consult with BB management before assigning the donor or patient as positive for the antigen.

B. Documentation:

1. Record the results of patient and donor antigen typing and antisera control testing. Tube (manual) Testing.

   a. Record Quality Control results of quality control testing on the Antisera Quality Control Worksheet.. Attach a copy of the anagram for the cells used for QC..

   b. Record patient and donor and patient antigen testing on the Antigen Screening Worksheet (BBT-F105)

2. Labeling Donor Units

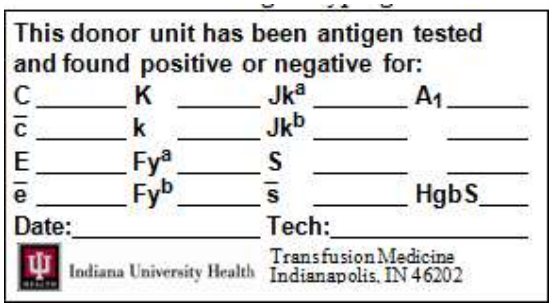
   a. Apply the "Donor Antigen Typing Label" to the front of a blank manila donor tag with corresponding donor identification number (DIN) sticker.

   b. Record **confirmed** interpretation of donor unit antigen typing on the "Donor Antigen Typing Label", including date tested and Tech initials performing test.

      i. Positive (Pos) and Negative (Neg) results.

      ii. When performing **additional** antigen testing for a unit with previously attached "Donor Antigen Typing Label": Record New antigen/s interpretation and New DATE/Tech Initials on same label.

Donor Antigen Typing label




C. Cerner Entry and Charging

1. Patient Antigen Typing

   a. **Department Order Entry,** Using Accession add-on > order Ag Typing RBC test for patient

   **b. Result Entry**

      1) **Phase Box:** Select > Patient Ag Type

      2) **Cell Box:** Select > Patient Ag Testing

         a) Insert additional rows by placing curser in open ID Field

         b) Click "Insert" icon located in top menu bar

         c) Select "Cell", then "OK"

         d) Cell Box: Select > Patient Ag Testing, then "OK"

         e) Repeat process for as many rows needed to result all antigentypings

      3) Enter Antigen Typing phase results

      4) Interpret Results and Verify

2. Donor Antigen Typing Result Entry for Units Received from Donor Center or Units Screened In-House

a. **Department Order Entry,** Using Accession add-on > order BB Bill (Ag test) to charge patient. The maximum charge for each BB Bill (Ag test) order is 20 typing. Need to order additional BB Bill (Ag test) orders as required.

b. **Result Entry,** enter the number of antigen tests performed and verify to charge patient for testing.

3. Donor Antigen Typing Cerner Entry for Units Received from Donor Center or Units Screened In-House

   a. **Go to Correct Inventory,** Using the units number add antigen negative results to donor unit in Cerner.

      i. Positive results should **not** be entered into Cerner for donor units.

      ii. Only negative results, because it is confusing to clinical team to have positive and negative results on the Transfusion Document.

   b. Go to ***Labeling Donor Units*** section, B. 2., for labeling of the units received from the donor center.

      i. All units from the donor center may or may not have a tag from the center or have negative antigens on the ISBT face label

      ii. There should be an IUH donor antigen manila tag attached. We add our manila tag for consistency for our clinical team.

4. Crossmatch Screening

   a. **Department Order Entry,** Using Accession add-on > order BB Bill (Ag Screen) to charge patient. The maximum charge for each BB Bill (Ag Screen) order is 20. Need to order additional BB Bill (Ag Screen) orders as required.

   b. **Result Entry,** enter the number of units crossmatched and verify to charge patient for testing. When charging patient for Crossmatch Screening, technologist must show documentation with crossmatch interpretation results.

   c. Once Compatible donor units from Crossmatch Screening are confirmed antigen negative, then donor units would be entered as antigen negative (see section above) using Correct Inventory and tagged per procedure.

      i. For example, if the patient has anti-K. We crossmatched **4 units** and 3 of 4 were compatible.

      ***ii.*** Under BB Bill (Ag Screen) we would charge the patient for **4 units** in ***Result Entry.***

      iii. The 3 compatible units, would be entered as K negative using ***Correct Inventory***, and crossmatch results entered per procedure and tagged with manila donor antigen tag as well as the Transfusion Document.

# X. APPENDICES/ATTACHMENTS/FORMS/ LABELS

Antisera Quality Control Worksheet, BBT-F008

Antigen Screening Worksheet, BBT-F105

# XI.REFERENCES/CITATIANS

Quality System, AABB/IU Health.
AABB Technical Manual, current edition.
AABB Standards, current edition.

## Policy #:

BBT – 010

Indiana University Health
Indianapolis, IN 46202

# Antisera Quality Control Worksheet

Form #: BBT F008.02
Manual:
Original Effective: 03/01/2012

| Date of Testing | | Supervisory Review/Date | |
|---|---|---|---|

| Daily QC of Antisera | | Anti-____ | | Anti-____ | | Anti-____ | | Anti-____ | | Anti-____ | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Lot # | | | | | | | | | | | |
| Expiration | | | | | | | | | | | |
| **Pos Control**, >1+ *For Pos control use heterozygous cells only | Cell Lot # Exp., Cell# | Lot# Exp | Cell # | Lot# Exp | Cell # | Lot# Exp | Cell # | Lot# Exp | Cell # | Lot# Exp | Cell # |
| | | **Result** | | **Result** | | **Result** | | **Result** | | **Result** | |
| **Neg Control** Neg | Cell Lot # Exp, Cell# | Lot# Exp | Cell # | Lot# Exp | Cell # | Lot# Exp | Cell # | Lot# Exp | Cell # | Lot# Exp | Cell # |
| | | **Result** | **Incubation** | **Result** | **Incubation** | **Result** | **Incubation** | **Result** | **Incubation** | **Result** | **Incubation** |
| Testing Tech/Peer Review | | Tech Initials | Peer Review | Tech Initials | Peer Review | Tech Initials | Peer Review | Tech Initials | Peer Review | Tech Initials | Peer Review |

| Daily QC of Antisera | | Anti-____ | | Anti-____ | | Anti-____ | | Anti-____ | | Anti-____ | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Lot # | | | | | | | | | | | |
| Expiration | | | | | | | | | | | |
| **Pos Control**, >1+ *For Pos control use heterozygous cells only | Cell Lot # Exp., Cell# | Lot# Exp | Cell # | Lot# Exp | Cell # | Lot# Exp | Cell # | Lot# Exp | Cell # | Lot# Exp | Cell # |
| | | **Result** | | **Result** | | **Result** | | **Result** | | **Result** | |
| **Neg Control** Neg | Cell Lot # Exp, Cell# | Lot# Exp | Cell # | Lot# Exp | Cell # | Lot# Exp | Cell # | Lot# Exp | Cell # | Lot# Exp | Cell # |
| | | **Result** | **Incubation** | **Result** | **Incubation** | **Result** | **Incubation** | **Result** | **Incubation** | **Result** | **Incubation** |
| Testing Tech/Peer Review | | Tech Initials | Peer Review | Tech Initials | Peer Review | Tech Initials | Peer Review | Tech Initials | Peer Review | Tech Initials | Peer Review |

**Reference # 24856**

**++ Please attach Antigram for control cells ++**

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