Beaumont Laboratory
Royal Oak

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ANTIGEN TYPING POLICIES

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Purpose

The purpose of this document is to provide policies relating to antigen typing of patient and donor units. This document is to be used in conjunction with P605, *Antigen Typing Procedures.*

Scope

- Antigen testing is performed on patient's red blood cells (RBCs) to aid in the confirmation of antibody (ies) identified in the patient's plasma. With rare exception, when an alloantibody is present in a patient's plasma, the corresponding antigen is absent from the patient's RBCs.
- RBC donor units are typed for the antigen(s) corresponding to the patient's clinically significant antibody (ies) prior to crossmatch, to help ensure recipient-donor compatibility. For these patients, donor units must be negative for the antigen(s) corresponding to the patient's clinically significant antibody (ies).
- Patients with sickle cell disease and thalassemia shall be transfused with RBCs that are partially matched to their own phenotype. This is done in an attempt to prevent alloimmunization to the highly antigenic C, E, and K RBC antigens in this frequently transfused population. Refer to P606A, *Policies Specific to Patients with Sickle Cell Disease and Thalassemia.*
- Neonatal RBCs may be antigen typed to assess the risk of Hemolytic Disease of the Newborn (HDN) when the mother has unexpected antibodies. Refer to P506, *Hemolytic Disease of the Newborn Survey*, for additional information.
- A complete phenotype shall be performed on patients with 3 or more identifiable antibodies and patients with a detectable warm autoantibody. A phenotype is not required if the antibody cannot be identified; i.e., antibodies that are too weak to identify (TWTI). See the *Policies* section, *Policies for Patients with 3 or More Identifiable Antibodies or Detectable Warm Autoantibodies.*
- If a patient has anti- Le^a or anti-Le^b, then the patient's RBCs should be typed for both Le^a and $Le^{b.}$ Generally, the patient's RBCs should be negative for both antigens.
- If Anti-N is detected, then the patient's RBCs should be typed for N, S, and s. Refer to P620*, Interpretation of Antibody Investigations* for additional information.
- Note that if a patient has Anti-D, weak D testing is not indicated.

Forms

- Patient Antibody Card
- *Unit Antigen Label*
- F-332, *Reagent Receipt Log*
- *F-606a, Phenotypically Match Unit Tag*
- *F-606b, Manual Billing Adjustment Form*
- F-618b, *Phenotype / Downtime Patient Antigen Typing Worksheet*

- F-620, *Special Studies Worksheet*

Definitions / Acronyms

- **BBCDM:** Blood Bank Computer Documentation Manual.
- **Clinically significant antibody:** An antibody that:
  - is known to cause Hemolytic Disease of the Newborn or shortened survival of antigen positive RBCs, and
  - requires transfusion of antigen negative red cells, and
  - is usually IgG and best detectable with antihuman globulin (AHG).
- **Clinically insignificant antibody:** An antibody that:
  - does not cause shortened red cell survival of antigen positive RBCs, and
  - does not require transfusion of antigen negative red cells, and
  - is usually IgM and reacts best below 37C.
- **Rare anti-sera:** An anti-sera that is not readily available commercially due to factors such as extreme cost or technological production difficulties.
- **BHS-RO:** Beaumont Health System, Royal Oak.

Policies

Antigen Typing Policies Relating to the Patient's Transfusion History

- Before antigen typing a patient's RBCs, the technologist should obtain a patient history as described in P625, *Obtaining Patient Histories*. Antigen typing should not be documented to the patient's permanent records unless a history has been obtained.
- Samples of patients who have been transfused with red blood cells within the preceding 90 days cannot be accurately antigen typed. The RBCs circulating in their body and being tested may be a combination of their own cells and transfused cells. If applicable, refer to the policy *Antigen Typing Procedures Performed by Reference Laboratories.*

Antigen Typing Policies Relating to a Positive Direct Antiglobulin Test (DAT) and/or Positive Autocontrol

In some cases, antigen testing cannot be performed if the DAT and/or the autocontrol is positive; e.g., if the reagent requires an indirect antiglobulin test. Refer to the policy *Inert Control Requirements for Positive Antigen Results.*

Antigen Typing Methods

- **C, E, c, and e:**
  - The preferred method is by the Rh gel card method as described in Table 605-1: *Antigen Typing by the Rh Gel Card Method using the MTS™ Individual (Monoclonal) Cards or the MTS™ Monoclonal Rh Phenotype Cards*.
  - The alternate method is by the tube method as described in Table 605- 3: *Antigen Typing by the Tube Method.*
- **Fy^a, Fy^b, Kell, S, and s:**
  - The preferred method is by the IgG gel card method as described in Table 605-2: *Antigen Typing by the IgG Gel Card Method –using Bottled Reagent Antisera derived from a Human Source that Requires an IAT*. Reagents for these antigens that are derived from a human source and that require an IAT phase have been validated at this facility.
  - Based on the validation performed at this facility, there is no alternate method for typing for Fy^a and Fy^b, or s. For Kell and S, the tube method may be used for

reagents that are not derived from a human source or that do not require an IAT phase.

- **All other antigens (besides C, E, c, e, Fy^a, Fy^b, Kell, S, and s):** the required method is the tube method as described in Table 605- 3: *Antigen Typing by the Tube Method.*

Recording Test Results

- All unit antigen results are ordered and resulted in the computer as described in the *BBCDM / Special Studies / Unit Antigen Typing*. Quality control (QC), which is performed once per day of use per technologist for each antisera/methodology used, is also documented in the computer as described in the *BBCDM / Special Studies / Resulting the QC Rack*; QC results are documented only for phases tested.
- All patient antigen results are documented on either F-620, *Special Studies Worksheet* or F-618b, *Phenotype / Downtime Patient Antigen Typing Worksheet.* The results are then entered into the computer as described in the *BBCDM / Special Studies / Add/Delete/Edit/Display Patient Antigen Data.* The results are also documented on the *Patient Antibody Card.* Quality control (QC), which is performed once per day of use per technologist for each antisera/methodology used, is documented on F-620 or F-618b; QC results are documented only for phases tested. Note that patient antigen tests are not typically ordered by physicians and when recorded in this manner, they do not interface to the Hospital Information System (HIS). Note the exception for donor A1 subgroups and antigen results specifically ordered by the physician, below.
- Donor A1 Subgroups are specifically ordered by a physician for transplantation purposes. In addition, the patient's physician will occasionally order antigen results; e.g., on the partner of an obstetrical patient with antibodies to help assess the risk of HDN. These antigen results are ordered and resulted in the computer as described in the *BBCDM / Special Studies / Documentation of Donor A1 Subgroups and other Antigen Results Specifically Ordered by a Physician.* Note that when resulted in this manner, the results will interface to the HIS.

Patients with Unexpected Antibodies

- Once an unexpected antibody has been identified in a patient's plasma, the patient's RBCs should be tested for the corresponding antigen, if possible.
- If a clinically significant antibody is present in a patient's plasma, then the RBC donor units selected for transfusion should be negative for the antigen corresponding to the antibody. Refer to P118, *Policies for Providing Red Blood Cells to Patients with Unexpected Antibodies*, for additional information.
- The Blood Bank may not stock the anti-sera corresponding to a patient's antibody to a low incidence antigen. Refer to the applicable policy in section II of P118, *Providing Antigen Negative Units for Patients with Antibodies to Low Incidence Antigens.*

Phenotype for Patients with 3 or More Identifiable Unexpected Antibodies or Detectable Warm Autoantibodies

- A complete phenotype shall be performed on patients with 3 or more identifiable, unexpected antibodies or a detectable warm autoantibody. Examples follow:
  - *Anti-C, E, and K are identified in a patient's sample. A phenotype is indicated.*
  - *Anti-C, anti-E, and an antibody that is too weak to identify (TWTI) are detected. A phenotype is not indicated.*
- This phenotype should include Rh(D) testing and testing for the following eleven (11) antigens: C E c e K Fy^a Fy^b Jk^a Jk^b S and s

- The phenotype may be performed at BHS-RO, but it is often beneficial to send the patient sample out to a reference lab instead. Refer to the policy *Indications for Submitting a Sample to a Reference Laboratory for Molecular Genotyping.*

Indications for Submitting a Sample to a Reference Laboratory for Molecular Genotyping

It may be beneficial to send a sample to a reference laboratory for molecular genotyping instead of performing a phenotype at BHS-RO. Examples of these benefits include:

- Molecular genotyping extracts and tests genetic material from the patient's white blood cells, not the red blood cells. This allows the determination of the patient's genotype even if they have been recently transfused, or that have a positive DAT and/or autocontrol.
- Molecular genotypes provide more antigen results than if the phenotype was performed at BHS-RO due to the limited antisera availability.
- Molecular genotypes have the ability to detect antigen variants that may not be detectable during serologic testing.

Indications for submitting a sample to a reference laboratory for molecular genotyping include:

- The patient has 3 or more identifiable antibodies (not including non-specific antibodies).
- The patient has a Warm Autoantibody (WAA).
- The patient has sickle cell disease or thalassemia.

Do not submit a sample to a reference laboratory if the antigen typing is only being performed as part of a routine antibody investigation. For example:

Anti-E is identified in a routine antibody investigation on a patient who has been transfused recently. Do not submit a sample for E typing by reticulocyte separation. Instead, add the special instruction "Unable to Antigen Type" to the patient's Blood Bank computer record.

Refer to P621, *Submitting Samples to A Reference Laboratory* for additional information.

Patient and Unit Antigen Typing for Patients with Anti-U

For patients with suspected Anti-U or a historic record of Anti-U and for documentation of U unit antigen results refer to P606C, *Policies Specific to Patients with Anti-U***.**

Documentation of Antigen Results from Blood Suppliers, Reference Laboratories, or Antigen Screening at BHS

Generally, antigen types that are confirmed by the supplier will be documented as "official" results (not preliminary) under Inventory / Edit / Antigen, and antigen types that are unconfirmed by the supplier will be documented as preliminary, as described in the following table.

Antigen Result	Appropriate BHS Actions
Reference Lab **confirmed** donor units (testing was performed on current donation by reference lab)	• The antigen type does not need to be tested at BHS-RO. • Record the confirmed results; refer to the *BBCDM / Special Studies / Add/Delete/Edit/Display Unit Antigen Data;* e.g., add the LE antigen (little-e). • Confirmed antigen results may print on the reference lab unit face label or be labeled with a reference lab antigen label that is affixed to the unit. If the antigen results are printed directly on the unit face label, the BHS-RO *Unit Antigen Label* will also be documented and affixed to the unit; see the *Example: Labeling a Reference Lab Confirmed Donor Unit* following this table. • A reference lab may use unlicensed anti-sera to confirm antigen results if the anti-sera is rare.
Reference Lab **unconfirmed** donor units (testing was not performed on current donation by reference lab)	• If a patient requires antigen negative RBCs, these unconfirmed results must be tested and documented at BHS-RO as described in P605 and P606. • All unconfirmed antigen types that are not tested at BHS-RO will be documented as a preliminary result in the computer (e.g., P/KPA for preliminary Kpa antigen). • For unconfirmed antigens, the antigen results will not print on the reference lab unit face label. A preliminary reference lab antigen label will usually be affixed to the unit. If a preliminary reference lab antigen label is not affixed to the unit, the unconfirmed results will be documented on the yellow / preliminary side of a BHS-RO *Unit Antigen Label*; include a notation that the preliminary results were provided by a reference lab.
Reference Lab patient antigen results (including molecular)	• Document the reference lab results on the patient's antibody card and in the Blood Bank computer. Refer to the *BBCDM / Special Studies / Add/Delete/Edit/Display Patient Antigen Data.* It is not necessary to wait for the Final Reference Lab Report in order to document the antigen results. When the Final Reference Lab Report is received, verify that the results agree with the previously documented results. • The reference lab may send a preliminary report by fax or may telephone antigen results. • Add a comment to the patient's record indicating that we have a molecular report. • Save a copy of the molecular report in the Molecular Reports drawer, located at rounds. • Include a copy of the molecular report with the CABID, if indicated. • Refer to P621, *Submitting Samples to A Reference Laboratory* for additional information.
Molecular U results (patient or donor)	Refer to P606C, *Policies Specific to Patients with Anti-U.*
Antigen Screening at BHS-RO	The antigen results (positive and negative) of units screened at BHS-RO are documented as preliminary in the computer and will also be documented on the yellow / preliminary side of the unit antigen label. For additional information refer to P606D, *Preliminary Antigen Screening.*

Example: Labeling a Reference Lab Confirmed Donor Unit
A unit is ordered for a patient who has Anti-c, Anti-E, and Anti-Jka. The reference lab sends a unit that is confirmed (tested on the current donation) as c-negative, E-negative, Jka-negative, and M positive. These antigen results appear in very small font on the reference lab face label, but there is no reference lab antigen label that is affixed to the unit. The BHS-RO technologist will document a unit antigen label as follows:

- For confirmed negative antigens (c, E, and Jka), document the green side of the *Unit Antigen Label* by circling the negative antigen(s), and by writing the reference as the tester and as the cosigner.
- For confirmed positive antigens (M), document the yellow side of the unit antigen label by circling the positive antigen(s), documenting the result as "+", and by writing the reference lab as the tester.

Preliminary Antigen Results of Donor Units Tested at BHS
A unit with a preliminary negative antigen result may not be crossmatched for a patient who has the corresponding clinically significant antibody unless / until the unit has been tested and found to be antigen negative as described in P605, *Antigen Typing Procedures*. Antigen results of donor units tested at BHS-RO are considered preliminary in the following cases:

- For antigen positive donor units, if the inert control was not tested. Refer to the policy *Inert Control Requirements for Positive Antigen Results*.
- For antigen results that are obtained by screening as described P606D, *Preliminary Antigen Screening.*

Labeling Units Typed at BHS-RO
The results of all units tested at BHS-RO shall be documented in the Blood Bank computer and the *Unit Antigen Label* shall be affixed to the unit. This label is double sided.

- The green side is used for all antigen negative results (results that are not preliminary). The negative antigen result is circled and the donor unit number is documented using, if possible, a sticker from the unit with the donor number. This green side is initialed and dated by the technologist who antigen tests and tags the unit, as well as by the technologist who cosigns the unit.
- The yellow side is used for preliminary antigen results. For example, for positive unit antigen results or for results obtained by screening as described in P606D, *Preliminary Antigen Screening*. The preliminary antigen result is circled and the donor unit number is documented using, if possible, a sticker from the unit with the donor number. This yellow side is initialed and dated by the technologist who antigen tests and tags the unit. It is not necessary to cosign preliminary antigen results.

Cosigning Results of Antigen Negative Units
All antigen negative results (results that are not preliminary) must be cosigned; this is documented on the green side of the *Unit Antigen Label.* Cosigning should be performed by a different / second technologist than the one who originally tested and tagged the unit, if possible. The cosigner will perform the following:

- Verify that the negative unit antigen result recorded in the computer correlates with the negative unit antigen result recorded on the *Unit Antigen Label*.
- Verify that the donor unit number on the *Unit Antigen Label* correlates with the donor unit number on the unit's face label and in the computer.
- Verify that any preliminary negative results that have been documented were negative.

For example: A unit has been typed as K negative. The cosigning technologist should determine whether preliminary Kell results have been documented in Soft or on the unit antigen label. If preliminary Kell results have been documented, the preliminary Kell results must match the test-of-record Kell results (must be negative).If applicable, proceed as described in P606D, *Preliminary Antigen Screening / Appropriate Actions upon Detecting a Discrepancy between Preliminary and Test-of-Record Antigen Results.*

- Release the negative unit antigen result from the *Blood Bank Log* and review the corresponding quality control, as described in the *BBCDM / Special Studies / Cosigning Antigen Negative Units.*
- Investigate and correct any discrepancies before cosigning the *Unit Antigen Label.*
- Cosign (initial) and date the *Unit Antigen Label*, indicating that the above information has been verified and that the unit has been released from the *Blood Bank Log* in the computer.

Inert Control Requirements for Positive Antigen Results

Due to the potential for false positive reactions, most manufacturers' inserts recommend the use of an inert control when positive antigen results are obtained. For example, a monoclonal control may be tested when using the Rh individual or phenotype cards, a DAT may be performed as a control when antigen typing by the indirect antiglobulin tube method, etc. This inert control is expected to be non-reactive. Note that these controls are not required when the antigen result is negative (false positive results are not a concern in this case). Due to this potential for false positive results, the following policies apply:

- For <u>patient</u> samples with positive antigen results, the inert control must be tested if indicated by the manufacturer's insert or the policy *Appropriate Inert Controls.* If the patient antigen result is positive, and the inert control is positive or if the inert control is not tested, then the positive antigen result is invalid. The inert control result is documented on F-620, *Special Studies Worksheet* or F-618b, *Phenotype / Downtime Patient Antigen Typing Worksheet.* A copy of the policy *Appropriate Inert Controls* is included in the *Antigen Typing Job Aid* located in the Job Aids binder.
- For <u>donor</u> units with positive antigen results, this inert control will not be tested. Any antigen positive units will be considered and labeled as preliminary if the inert control is not tested. Note that it is not necessary to label antigen negative units as preliminary (false positive results are not a concern in this case). Refer to the policy *Labeling Units Typed at BHS-RO.*

Potential False Positivity if All Patient Antigen Results are Positive

If all of a patient's antigen types are positive by a given method, then the chance that the results are falsely positive is increased. This is especially true for AB positive patients, and if the DAT is positive. Therefore, if the patient's DAT is positive and all of the patient's antigen types are positive by a given method, do not interpret the results. Bring the case to rounds for consultation with the Medical Director. For example . . .

When testing with the Ortho BioClone tube reagents on a patient with a positive DAT, the following results were obtained DAT: C+ E+ c+ e+ Jk^a+ Jk^b +. Even if the bovine albumin control was negative, do not interpret the results, do not document the results in the computer or on the antibody card, and bring the case to rounds.

Appropriate Inert Controls

Antigen	Method	Appropriate Inert Controls (for positive patient antigen results)	*Code
C E c e	Preferred method is Table 605-1: *Antigen Typing by the **Rh Gel Card Method** using the MTS™ Individual (Monoclonal) Cards or the MTS™ Monoclonal Rh Phenotype Cards*	The MTS™ Monoclonal Control - typically tested on the Vision™ as part of the patient's ABO/Rh typing.	CGABO
		The MTS™ Monoclonal Control may be tested in parallel with the antigen testing.	CGLOT
		If the sample is found to be negative for *any* of the Rh antigens tested by the method in Table 605-1.	CAAN
		Negative gel autocontrol (tested as part of an antibody panel) or negative gel DAT (neonates).	CDATG
	Alternative method is Table 605- 3: *Antigen Typing by the **Tube Method**.*	Negative tube DAT.	CDATT
		Negative gel autocontrol (tested as part of an antibody panel) or negative gel DAT (neonates).	CDATG
		Negative bovine albumin control.	CALB
		If the sample is found to be negative for *any* of the Rh antigens tested by the method in Table 605-3.	CAAN
Fya Fyb Kell S s	Preferred method is Table 605-2: *Antigen Typing by **the IgG Gel Card Method** –using Bottled Reagent Antisera derived from a Human Source that Requires an IAT.*	Negative gel autocontrol- tested as part of an antibody panel.	CDATG
		Negative gel DAT (for example, on a neonatal sample)	CDATG
		If the sample is found to be negative for Fya, Fyb, Kell, S, or s when tested by the gel method Table 605-2.	CAANG
Kell S	Alternative method is Table 605- 3: *Antigen Typing by the **Tube Method**.*	Negative tube DAT.	CDATT
		Negative gel autocontrol- tested as part of an antibody panel.	CDATG
		For the Gamma Clone Anti-Kell tube reagent, the appropriate control is the Gamma Clone control (located in the ABO/Rh typing racks) * There is no computer code, add a comment to indicate that Gamma Clone control was used.	*
Jk^a Jk^b	Required method is Table 605- 3: *Antigen Typing by the **Tube Method**.*	Negative tube DAT.	CDATT
		Negative gel autocontrol- tested as part of an antibody panel.	CDATG
		Negative bovine albumin control.	CALB
		If the sample is found to be negative for either Jk^a or Jk^b when tested by the method in Table 605-3.	CAAN
All other antigens	Required method is Table 605- 3: *Antigen Typing by the **Tube Method**.*	Refer to the manufacturer's insert. Most inserts indicate that a negative DAT may be used to guard against false positive antigen results.	Varies
		If the sample is found to be negative for another antigen on the same manufacturer's insert.	CAAN
		In some cases, the manufacturer's insert does not require an inert control. In these cases, a positive antigen result is valid.	CNMFG

* The descriptions for these codes is included on the reverse side of F-618b, *Phenotype / Downtime Patient Antigen Typing Worksheet.*

Reagents / Antisera / Diluents / Gel Cards

- All reagents, anti-sera, and diluents must be visually inspected prior to use to ensure that the liquid is not discolored, turbid, or showing any signs of bacterial contamination.
- Each well of the gel card should have a clear liquid layer on top of the opaque gel. Do not use gel cards if:
  - The gel matrix is absent.
  - The liquid level in the microtube is at or below the top of the gel matrix.
  - They show signs of drying, discoloration, bubbles, crystals, or other artifacts.
  - Foil seals appear damaged or opened.
- The Rh individual and phenotype gel cards should be stored upright at 1°C to 8°C, and brought to room temperature before use.
- The IgG gel cards are stored upright between 2°C to 25°C and brought to room temperature before use.
- The quality control for IgG Gel Cards is located in the GEL DAT – GDAT rack
- The quality control for IgG and Coombs reagents are located in the 60 MIN NO LISS – RQ60M rack

Expiration Date of Reagents

All reagents, anti-sera, diluents, and gel cards must be used within the manufacturer's expiration date. Any exceptions must be approved by the Blood Bank Medical Director or designee, and may be used only if the positive and negative controls are tested and work as expected.

Positive and Negative Controls / Valid Graded Reactions

Appropriate positive and negative controls for antigen typings must be tested once per day of use per technologist for each antisera/methodology used.

- The reaction strength of the positive control must be 2+ or greater. If the reaction strength of the positive control is not 2+ or greater, then the quality control (QC) is considered to be failing.
- The negative control must be non-reactive. If the negative control is reactive (any strength) then the QC is considered to be failing.

Failing QC: Positive and Negative Controls do not React as Expected

If the QC fails, then all of the patient and donor samples and the positive and negative controls for that batch must be repeated with the same lot numbers (if possible). If the QC fails after this repeat testing then:

- Place the applicable anti-sera or Rh gel cards in quarantine; order additional anti-sera or gel cards, if necessary.
- If possible, repeat all testing with a new lot number.
- Patient and donor antigen typing results may not be released unless quality control is valid.
- Notify the manager by documenting all failed QC in a variance (even if the QC passes upon repeat).

Appropriate Test Cell for Antigen Positive Control

Anti-sera / gel card	Appropriate Test Cell for the Antigen Positive Control
anti-C	R1r (C+c+)
anti-E	R2r (E+e+)
anti-c	R1r (C+c+)
anti-e	R2r (E+e+)
anti-K	Kk
anti-Fya or anti-Fyb	Fy(a+b+)
anti-Jka or anti-Jkb	Jk(a+b+)
anti-S or anti-s	Ss
anti-M or anti-N	MN
anti-Lea	Le(a+b-)
anti-Leb	Le(a-b+)
anti-P_1	P_1 +weak (if available)
anti-C^w	C^w+
anti-A_1	A_1 cell for positive control; A2 cell for negative control

Valid Graded Reactions of Patient and Donor Samples

- To interpret the antigen typing result of a patient or donor sample as negative, the test must be non-reactive.
- To interpret the antigen typing result of a patient sample as positive, the reaction strength must be 2+or greater, and the inert control must be non-reactive.
- To interpret the antigen typing result of a donor sample as positive, any reactivity shall be interpreted as positive. However, if the reaction strength is less than 2+ (is weak+ or 1+), a variance shall be completed and submitted to the QA.

Invalid Graded Reactions of Patient or Donor Samples

- Weak+ or 1+ reactions on patient samples are considered invalid.
- All weak+ or 1+ reactions observed on patient or donor samples shall be documented in a variance. The Medical Director or designee will then determine whether additional investigation is needed.

Requirement to Consider an Antigen's Prevalence when Antigen Typing Units

When antigen typing donor units, the technologist should consider the antigen's prevalence in the general population, which may be obtained from the AABB *Technical Manual*, for the following purposes:

- To estimate the number of units that should be tested to find the desired number of antigen negative units. For example:
  The prevalence of the Jk^a antigen in the general population is approximately 77%. Therefore, the percentage of Jk^a negative donors is approximately 23%. The technologist types 10 units and should expect to find 2 Jk^a negative units.
- To verify that the antigen's prevalence observed in the units tested roughly corresponds to the antigen's prevalence in the general population. For example:
  A technologist types 20 units for Jk^a and observes that 17 of them are Jk^a negative and 3 are Jk^a positive. The technologist should repeat this testing, because the antigen's prevalence that is observed in the tested units (15%) does not roughly correspond to the antigen's prevalence in the general population (77%).

Policies Relating to Antigen Typing by the IgG Gel Card Method using Bottled Reagent Anti-sera derived from a Human Source that Requires an IAT (Table 605-2: Fy^a, Fy^b, S, s, and K)

The technologist must review the manufacturer's insert for the reagent being used before antigen typing for Fy^a, Fy^b, S, s, or K by the IgG gel method described in Table 605-2. The procedure described in Table 605-2 has been validated at BHS-RO, and may therefore be used, only if typing for Fy^a, Fy^b, S, s, or K with a reagent that is derived from a human source and that requires an IAT (indirect antiglobulin test).

Policies Relating to Antigen Typing by the Tube Method (Table 605-3)

- Before antigen typing by the tube method described in Table 605-3, *Special Antigen Typing by the Tube Method*, the technologist must review the applicable manufacturer's insert. The technologist must follow the policies, directions, inert control requirements, etc. in the manufacturer's insert. The procedure in Table 605-3 is intended to supplement the procedures found in the manufacturers' inserts.
- If the manufacturer's insert indicates that an indirect antiglobulin phase is required, then check cells must be used in all tubes in which the graded reaction is negative. The ~~strength of the~~ check cells must be positive (any strength) ~~2+ or greater~~. If the ~~strength of the~~ check cells reaction is not positive ~~is not 2+ or greater~~, then the results for that tube are considered invalid and must be repeated.
- All patient and donor cells must be washed and resuspended to 2% - 4% before testing, even if the manufacturer's insert has a statement such as "samples *may* be washed and resuspended prior to testing."

Policy to Document the "Open Date" on Each Vial of Reagent Antisera

As indicated in P332, *Receipt of Critical Reagents, Materials and Review of Manufacturers' Printed Materials*, a "Received / Date" sticker will be affixed to each vial of reagent antisera upon receipt. In addition, the open date and technologist's initials will be written on each vial when it is opened (when it is used for the first time).

Notes

1. The manufacturer's insert may be located in either the *Manufacturer's Insert Book* or through an online version; directions are located in the front of the binder.
2. In order to determine the correct manufacturer's insert, it may be necessary to reference F-332, *Reagent Receipt Log.* Compare the reagent lot number from the bottle of anti-sera with the reagent lot number recorded on F-332, and determine the reference number or identification number from F-332. The reference number or identification number is included on the applicable manufacturer's insert.
3. If a patient with antibodies needs blood quickly, it may save time to begin crossmatching the patient with several units that have not yet been antigen tested. If any of the units are compatible by this "screening" method, these units may then be antigen tested.
4. When antigen typing a unit for a patient, bill the patient in the Blood Bank computer system as described in *BBCDM / Special Studies / Unit Antigen Type/HgbS Billing*, or F-606b, *Manual Billing Adjustment Form* should be documented. On the unit antigen label, place an "x" under the applicable antigen to indicate that a patient has been billed for the antigen (so that more than one patient will not be billed for the unit antigen type).

References

AABB, *Technical Manual*, current edition.

Attachments

- P606A, *Policies Specific to Patients with Sickle Cell Disease and Thalassemia*
- P606B, *Antigen Typing Job Aid*
- P606C, *Patient and Unit Antigen Typing for Patients with Anti-U*
- P606D, *Preliminary Antigen Screening*
- Memo from Evelyn Rios, Technical Support Specialist, Ortho Clinical Diagnostics, June 28, 2012.

Authorized Reviewers

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

ANTIGEN TYPING POLICIES

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 Procedure Manual*.
Number of Controlled Copies posted for educational purposes: 0
Number of circulating Controlled Copies: 3
Location of circulating Controlled Copies: One copy of P606, Attachment B, *Antigen Typing Job Aid* is located in the Job Aids binder at the antibody problems workstation, and another copy is located in the Computer Documentation Manual. One copy of P606, Attachment C, *Policies Specific to Patients with Anti-U* (the flow from the *Procedure* section) is located in the Job Aids binder.

Document History

Signature	Date	Revision #	Modification	Related Documents Reviewed/ Updated
Revised by: Jennifer Sarhan	01/14/2013	r02.01.00		
Revisions Validated by: Heather Asiala	02/28/2013			
QA: Louisa Serafimovska	03/05/2013			
Supervisor: Judy Easter	03/05/2013			
Approved by: Peter Millward, MD	03/05/2013			
Revisions to r02.01.00 • Added *Policies Specific to Patients with Anti-U* to this document and added P606 Attachment C *Policies Specific to Patients with Anti-U.* • Revised the policy *Documentation of Antigen Typing Results Provided by Blood Suppliers and Reference Laboratories.* • In the table *Appropriate Inert Controls,* added CDATG for Rh typing by the gel card method.				
Reviewed by: (Signature)	**Date**	**Revision #**	**Modification**	**Related Documents Reviewed/ Updated**
Reviewed by: Peter Millward, MD	08/05/2013			
Revised by: Jennifer Sarhan	09/24/2013	r02.02.00		
Supervisor: Judy Easter	09/30/2013			
Approved by: Peter Millward, MD	09/30/2013			
Revisions to r02.02.00 • To the table on page 5, added the text "Confirmed antigen results print on the ARC face label; however, the font is very small. Therefore, the BHS *Unit Antigen Label* will also be documented and affixed to the unit; see the *Example: Labeling an ARC Conformed Donor Unit* following this table". Also added the example. • To the page 6 policy *Cosigning Results of Antigen Negative Units,* added "Verify that any preliminary negative results that have been documented were negative" and added the example. • Added note #3 (*Notes* section, page 11).				
Revised by: Jennifer Sarhan, QA	01/03/2014	r02.03.00	Page 11: added the *Policy to Document the "Open Date" on Each Vial of Reagent Antisera.*	
Supervisor: Judy Easter	01/03/2014			
Approved by: Peter Millward, MD	01/03/2014			

Document Control, continued

Signature	Date	Revision #	Modification	Related Documents Reviewed/ Updated
Revised by: Jennifer Sarhan, QA	08/05/2014	r02.04.00		
Additional review by: Laurie Nelson	08/07/2014			
Supervisor: Judy Easter	08/07/2014			
Approved by: Peter Millward, MD	08/07/2014			
Revisions to r02.04.00: • In the Scope section, added to type for N, S, and s if Anti-N is detected. • Added reference to F-606, *Manual Billing Adjustment Form*. • Added the policy *Potential for False Positivity if all Patient Antigen Results are Positive*. • To the Appropriate Inert Control table, added "For the Gamma Clone Anti-Kell tube reagent, the appropriate control is the Gamma Clone control." • Added *Note* # 4 at the end of the document, RE: F-606, *Manual Billing Adjustment Form.*				
Revised by: Ashley Wilson	03/19/2015	r02.04.01	Added IgG Gel card, IgG and Coombs reagent quality control locations.	
Approved by: Peter Millward, MD	03/19/2015			
Revised by: Ashley Wilson	09/28/2015	r02.05.00	Removed references to the ARC, added "and/or" to alert techs that a positive DAT or autocontrol stops IAT phase testing at BHS, updated to BHS.	
QA: Anne Sepienza	10/22/2015			
Supervisor: Judy Easter	09/30/2015			
Approved by: Peter Millward, MD	09/30/2015			
Revised by: Ashley Wilson	11/19/2015	r02.05.01	Specified antigen typing policy: "transfused red blood cells within 90 days"	
Approved by: Peter Millward, MD	11/24/2015			
Revised by: Ashley Wilson	04/13/2016	r02.06.00	Updated instructions for new Cw reagent.	
QA: Anne Sepienza	04/20/2016			
Supervisor: Judy Easter	04/20/2016			
Approved by: Peter Millward, MD	04/20/2016			
Revised by: Ashley Wilson	06/06/2016	r02.07.00	Added instruction to initial yellow antigen tags attached to Appleton Units.	
QA: Anne Sepienza	06/08/2016			
Supervisor: Judy Easter	06/08/2016			
Approved by: Peter Millward, MD	06/08/2016			
Approved by: Peter Millward, MD	05/08/2017			
Approved by: Elizabeth Sykes, MD	02/22/2018			
Approved by: Peter Millward, MD	02/26/2019			
Approved by: Craig Fletcher, MD	05/21/2019			

Document Control, continued

Signature	Date	Revision #	Modification	Related Documents Reviewed/ Updated
Revised by: Christopher Ferguson	07/15/2019	r02.08.00	Antigen testing QC is now only required once per day of use, per technologist instead of with each batch. Removed unlicensed Anti-Cw antisera policy section. Added Anti-S tube testing as an alternate method. Updated BHS action for reference lab unit antigen testing. Updated authorized reviewer titles. Updated SOP names that are references within the document. Updated IgG gel card QC location to GDAT rack. Updated template and format.	
QA: Anne Sepienza	07/30/2019			
Manager: Billie Ketelsen	07/22/2019			
Approved by: Craig Fletcher, MD	09/03/2019			
Revised by: Christopher Ferguson	05/04/2020	r02.09.00	Check cells are only added to AHG results that are negative instead of negative or less that 2+. Molecular reports are no longer submitted to the MD every time. Instead, they are included in the CABID if one is being performed. Removed QA from authorized reviewer.	
Manager: Billie Ketelsen	05/05/2020			
Approved by: Craig Fletcher, MD	05/06/2020			
Approved by: Craig Fletcher, MD	07/02/2020			
Reviewed by: Samantha Maynard	09/08/2021	r02.10.00	Any strength check cells are acceptable.	
Manager:				
Approved by: Craig Fletcher, MD				

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