Indiana University Health

Origination:	*04/2013*
Effective:	*03/2019*
Last Approved:	*02/2019*
Last Revised:	*02/2019*
Next Review:	*02/2021*
Owner:	*Heather Vaught: Dir-Transfusion Medicine-Lab*
Area:	*Lab - Blood Bank*
Tag:	*Manual: Galileo Neo*
Applicability:	*Indiana University Health Pathology Laboratory*

Antigen Testing on NEO

PURPOSE:

To provide instruction for performing antigen testing on the NEO.

SCOPE:

This SOP addresses procedure for performing red cell antigen typing using NEO automated equipment and documentation of results. Testing can be performed on patient or donor samples. This SOP is intended for all transfusion service MT-I, MT-II, Technical Coordinators and Manager that have been trained to perform testing on the NEO.

EXCEPTIONS:

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

DEFINITIONS:

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

POLICY STATEMENTS:

1. Antisera validated for antigen typing: anti-C, anti-c, anti-E, anti-e, and anti-K
2. All reagents/samples should be at room temperature before testing
3. Quality control (QC) testing is required before antigen typing can be performed.
4. If possible, antisera vials used for antigen typing and control testing on the NEO will be kept separate from Tube testing Antisera vials until volume is insufficient for automated testing

PRINCIPLE/BACKGROUND:

None

MATERIALS:

NEO	MLA Pipettes (*calibrated)*

NEO specimen racks	MLA Pipette Tips
NEO strip carriers	PC with Cerner Software
CMT test strips	Bar-coded Antisera Labels
SELECT test strips	Antisera Dilution Labels
corQC Extend Complete Kit*	Phosphate Buffered Saline (PBS)
*corQC Extend 1,2,3 and 4	Lavender Tube Closures (rubber)
*corQC Standard (ST)	Antisera (Bar-coded vials)--Anti-C, Anti-c,
Specimen Diluent	Anti-E, Anti-e, Anti-K
12x75mm tubes	Appropriate Antisera to Prepare Dilutions

SPECIMEN REQUIREMENTS:

Anticoagulated patient or donor sample (See SOP BBGN-009)

All patient samples must meet identification and collection criteria as outlined in Requisition & Specimen Processing SOP BBT- 011.

PROCEDURE:

1. NEO (automated) Antigen Testing
    1. FDA approved Antigen Typing (see sections 2.0 - 4.0)
        1. C
        2. Little c
        3. E
        4. Little e
        5. K
    2. Antigen Assays on NEO (see table below)

Antigen to be Tested	Assay(s) on NEO	Strip Selection
C	Ag_C RH2, Ag_CcEe, CEK Antigen	CMT Strip
Little c	Ag_c RH4, Ag_CcEe	CMT Strip
E	Ag_E RH3, Ag_CcEe, CEK Antigen	CMT Strip
Little e	Ag_e RH5, Ag_CcEe	CMT Strip
Kell (K)	Ag_Kell, CEK Antigen	CMT Strip

2. Quality Control of Reagents (FDA approved Antigen Typing: C, Little c, E, Little e, & K)
    1. Place carrier with full plate of unused **CMT strips (from Echo)** into loading tower of NEO.
    If performing QC for both "CcEe" and "Kell" assays — **NEO will require two full carriers of unused CMT strips (one per assay)**.
    2. Close tower door allowing NEO to identify plates.
    3. Select **Maintenance** icon from NEO Main Menu Bar
    4. Select "**Rh Phenotyping QC**" and/or "**Kell Phenotyping QC**" from the Maintenance Action List

1. To select Both assays: Click the multiple line navigation button ☰ to allow marking of multiple tasks.
2. Select each task by pressing the screen lines on the touch screen monitor. The lines are highlighted in blue as they are selected.

5. Press **Continue** to access the **Resource Overview** window
6. Select assay(s) on the **Resource Overview** window to determine if any additional resources are required.
    1. In large container reagent rack, load large Specimen Diluent bottle into the reagent bay using the Resource Overview Window—'Reagents' Tab.
    2. In separate reagent rack, load required QC and antisera reagents into the reagent bay or sample bay using the Resource Overview Window—'Reagents' or 'Controls' Tab (depending on which rack is used).
7. Verify all 12 CMT strips are available using 'Plates' Tab in Resource Overview window.
8. Select "**START**" when all resource requirements are satisfied
9. " QC_CcEe Report" and "QC_Kell Report" should print when test completed showing all testing qualified
   Note: If QC fails, the test has to be repeated until all testing is qualified.
10. Document on the Neo Daily Maintenance Record (BBGN-F001) when the QC is valid.
11. Discard the used CMT strips and use remaining CMT strips on Echo or use on NEO for additional donor and/or patient antigen testing.

3. Typing **Patient** Samples (FDA approved Typing: C, Little c, E, Little e, & K)
    1. Select **Start Run Assistant**
    2. Select **Load Samples**
    3. Load samples in appropriate Sample rack in designated lane on NEO (See SOP BBGN-009)
    4. Select appropriate assay(s) for each sample (see Table section 1.3)
    5. Press "**Done**"
    6. Select **Load Resources** and supply required resources making sure proper strip assignment has been made (See SOP BBGN-009)

       Note: See Table section 1.3 for proper strip selection
    7. Highlight assay(s) from **Resource Overview** window and select "**START**"
    8. Cerner Entry
        1. **Department Order Entry**, order 'Rh Phenotype' test or 'Ag Typing, RBC' for patient testing, whichever is appropriate.
        2. **Result Entry**
            1. **Phase Box:** Select > Rh Phenotype or Patient Ag Type
            2. **Cell Box:** Select > Rh Phenotype or Patient Ag Testing
            3. Enter results in RT phase for Rh and Kell typings

4. Interpret Results and Verify

9. Documentation
    1. Maintain the NEO result sheet with the patient investigation.

4. Typing **Donor** Samples (FDA approved Typing: C, Little c, E, Little e, & K)
    1. Donor sample preparation
        1. Obtain segment from donor unit to be tested
        2. Place bar-coded donor unit # on 12x75mm tube
        3. Empty segment into appropriately labeled tube
    2. Select **Start Run Assistant**
    3. Select **Load Samples**
    4. Load samples in Donor rack and place on NEO (See SOP BBGN-009)
    5. Select appropriate assay(s) for each sample (see Table section 1.3)
    6. Press "**Done**"
    7. Select **Load Resources** and supply required resources making sure proper strip assignment has been made (See SOP BBGN-009)

       Note: See Table section 1.3 for proper strip selection
    8. Highlight assay(s) from **Resource Overview** window and select "**START**"
    9. Cerner
        1. **Department Order Entry,** order BB Bill (Ag test) to charge patient using accession add-on
        2. **Result Entry**, enter the number of antigen tests performed and verify to charge patient for testing
        3. **Correct Inventory** > Special Testing
            1. Add antigen negative results to donor unit in Cerner
            2. Positive results should **not** be added to donor units in Cerner
    10. Documentation
        1. If applicable, complete the Donor Antigen Typing Label (see SOP BBT-010)
        2. Maintain the NEO result sheet (See SOP BBT-010) until the results are entered into Cerner.

APPENDICES/ATTACHMENTS/FORMS/LABELS:

Neo Daily Maintenance Record, BBGN - F001

REFERENCES/CITATIONS:

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

Policy #:

BBGN– 013

Attachments:

Image 01

Approval Signatures

Step Description	Approver	Date
Laboratory Director	Xiao-Ming Yin: Director	02/2019
Blood Bank Division Director	Daniel Smith: Division Director	02/2019
Blood Bank Medical Director	Nguyet Le: Staff Physician	02/2019
Supervisors (QA Unit)	Tracie Ingle: Supervisor-Lab	02/2019
Supervisors (QA Unit)	Evangeline Miguel	02/2019
Supervisors (QA Unit)	Jayanna Slayten: Supervisor-Lab	02/2019
Director	Heather Vaught: Dir-Transfusion Medicine-Lab	02/2019

Applicability

Indiana University Health Pathology Laboratory

Current Status: *Scheduled*

PolicyStat ID: *5955220*

Origination:	*02/2002*
Effective:	*03/2019*
Last Approved:	*02/2019*
Last Revised:	*02/2019*
Next Review:	*02/2021*
Owner:	*Heather Vaught: Dir-Transfusion Medicine-Lab*
Area:	*Lab - Blood Bank*
Tag:	*Manual: Blood Bank Testing*
Applicability:	*Indiana University Health Pathology Laboratory*

Indiana University Health

Antigen Typing – Red Cell

PURPOSE:

To detail procedure for red cell antigen typing.

SCOPE:

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

EXCEPTIONS:

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

DEFINITIONS:

QA UNIT: Members include Medical Director, Manager, Supervisors, and QA Coordinators

POLICY STATEMENTS:

1. 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.
2. 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.
3. Methods of Antigen Typing:
    1. Tube (manual) Antigen typing (FDA approved)
    2. NEO (automated) Antigen typing (See SOP BBGN-013), FDA approved antigen typing (C, little c, E, little e, and Kell Antigens)
    3. RBC genotyping is available from IUH Molecular Lab and is only used for patient samples.
4. When patient has been recently transfused in the last 90 days and/or direct anti-globulin test (DAT) is positive, the patient antigen typing results may be invalid. These samples may be forwarded for RBC genotyping.

5. If possible, antisera vials used for antigen typing and control testing on the NEO will be kept separate from Tube testing Antisera vials to aid in lot control.
6. Antisera Controls will be performed once each day of use for each method of testing and for each lot number used.
    1. If quality control is not completed and results are released, then this should be investigated and will be reported to the FDA (see SOP BBQA-005)
7. Any attached tag indicating antigen testing results must match the original testing.
    1. If the antigens on the attached manila Donor Antigen Typing Label do not match the testing or Cerner Transfusion Form (discovered on audit) AND the unit leaves the Blood Bank, then this would be considered loss of control of a mis-branded product. It may be reported to the FDA (see SOP BBQA-005).
    2. Each case will be reviewed on a case-by-case basis.
8. 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.
    1. 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.
    2. 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.
    3. After the units are released, then the units may be typed for Fy^a.

PRINCIPLE/BACKGROUND:

None

MATERIALS:

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

SPECIMEN REQUIREMENTS:

All patient samples must meet identification and collection criteria as outlined in Requisition & Specimen Processing SOP BBT- 011.

Donor Segments

PROCEDURE:

1. Evaluate the sample to be tested
    1. If the patient has been transfused in the last 90 days, then no serologic testing should be tested. The sample may be forwarded for RBC genotype testing.
    2. If the sample is from an untransfused patient but the patient has a positive IgG-DAT, then the patient

cannot be tested with all antisera. DAT positive samples may be tested with monocloncal antisera, but not any antisera which requires an AHG method. This sample may be forwarded for RBC genotype testing.

3. If the sample is from an untransfused patient and the IgG-DAT is negative, then the patient may be tested by automated or tube antigen typing methods. Go to next step.

2. Decide which type of method should be used for antigen typing
    1. If screening donor units for C, E, c, e, or K and adequate RBC volume is available, then used automated antigen screening.
    2. If donor units are needed to be screened for other antigen specifcites than C, E, c, e, or K, then manual antigen screening is appropriate.
    3. If testing patient sample, one may use automated antigen screening or manual antigen screening.
3. Automated Antigen Typing: Go to SOP BBGN-13, Antigen Typing on Neo.
4. Tube (manual) Antigen Typing: (FDA approved method)
    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 (follow Package insert)
        b. Negative controls should be negative for the specificity being tested (follow package insert)
    3. 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. For example if mixed-field is detected, 3+mf, then the patient should not be reported as positive. The patient sample should be forwarded for RBC Genotype testing, if applicable.
        c. If the positive control or patient/donor antigen testing result is less than 1+, then the results are questionable. Consult with BB management before assigning the donor or patient as positive for the antigen.
5. Documentation:
    1. Record the results of patient and donor antigen typing and antisera control testing.
        1. Tube (manual) Testing
            1. Record Quality Control results of quality control testing on the "Antisera Quality Control Worksheet". (Form # BBT-F008).
            2. Record patient antigen testing on the Antibody Workup Form (BBT-F004)
            3. Record donor unit antigen testing on Donor Unit Antigen Screening Worksheet (BBT-F105)
        2. Neo Testing (see SOP BBGN-013)
            1. For donor unit antigen testing, **maintain the printout** the NEO result sheet(s) for FDA approved antigen typing (C, Little c, E, Little e, and K).
            2. After the unit is labeled in step 2, the NEO printout may be discarded.

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.

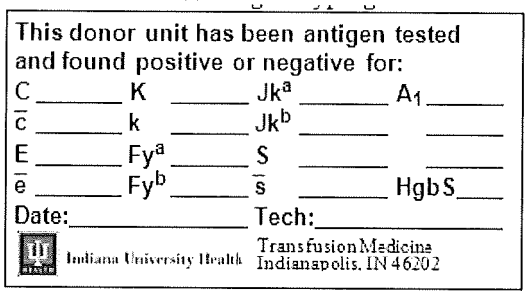
   b. Record **confirmed** interpretation of donor unit antigen typing on the "Donor Antigen Typing Label", including date tested and Tech initials performing test.

      i. Positive and Negative results from Tube method (FDA approved method)

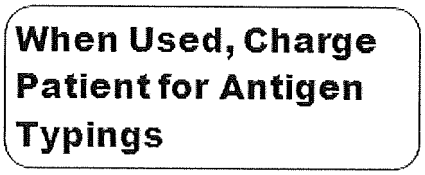
      ii. Positive and Negative results from Galileo or NEO FDA approved method (C, Little c, E, Little e, and K)

      iii. 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. If antigen typing donor units and **NOT** charging patient AT THIS TIME: Apply the sticker that reads **" When Used, Charge Patient for Antigen Typings"** to the front of the donor blood bag without obscuring or defacing any other parts of the existing label. (see below). Once antigens are charged, **Remove** sticker from donor unit.



6. Cerner

   1. Patient Antigen Typing

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

      2. **Result Entry**

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

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

            1. Insert additional rows by placing curser in open ID Field

            2. Click "Insert" icon located in top menu bar

            3. Select "Cell", then "OK"

            4. Cell Box: Select > Patient Ag Testing, then "OK"

5. Repeat process for as many rows needed to result all antigen typings

3. Enter Antigen Typing phase results
4. Interpret Results and Verify

2. Donor Antigen Typing
    1. **Department Order Entry,** Using Accession add-on > order BB Bill (Ag test) to charge patient. NOTE:The maximum charge for each BB Bill (Ag test) order is 20 typings. Need to order additional BB Bill (Ag test) orders as required.
    2. **Result Entry,** enter the number of antigen tests performed and verify to charge patient for testing.

        EXCEPTION: When using the Galileo or NEO to pre-screen donor units for antigen typing—only charge for the number of units that are confirmed by Tube (manual) method.
    3. **Correct Inventory** > Special Testing
        1. Add antigen negative results to donor unit in Cerner
        2. Positive results should **not** be attached to donor units in Cerner
3. Crossmatch Screening
    1. **Department Order Entry,** Using Accession add-on > order BB Bill (Ag Screen) to charge patient.

        NOTE: The maximum charge for each BB Bill (Ag Screen) order is 20. Need to order additional BB Bill (Ag Screen) orders as required.
    2. **Result Entry,** enter the number of units crossmatched and verify to charge patient for testing.

        NOTE: When charging patient for Crossmatch Screening, technologist must show documentation on Cerner Requisition by affixing DIN sticker with crossmatch interpretation results.
    3. Once Compatible donor units from Crossmatch Screening are confirmed antigen negative, patient will also need to be charged BB Bill (Ag test) for that testing (see section 3.2)

APPENDICES/ATTACHMENTS/FORMS/LABELS:

Antisera Quality Control Worksheet, BBT-F008

Donor Unit Antigen Screening Worksheet, BBT-F105

Antibody Workup Form, BBT-F004

REFERENCES/CITATIONS:

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

Policy #:

BBT - 010

Attachments:

 Image 01

 Image 02

Approval Signatures

Step Description	Approver	Date
Laboratory Director	Xiao-Ming Yin: Director	02/2019
Blood Bank Division Director	Daniel Smith: Division Director	02/2019
Blood Bank Medical Director	Nguyet Le: Staff Physician	02/2019
Supervisors (QA Unit)	Tracie Ingle: Supervisor-Lab	02/2019
Supervisors (QA Unit)	Evangeline Miguel	02/2019
Supervisors (QA Unit)	Jayanna Slayten: Supervisor-Lab	02/2019
Director	Heather Vaught: Dir-Transfusion Medicine-Lab	02/2019

Applicability

Indiana University Health Pathology Laboratory

Indiana University Health
Indianapolis, IN 46202

Antisera Quality Control Worksheet

Form #: BBT F008
Manual: Testing
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 #
		Graded Result		Graded Result		Graded Result		Graded Result		Graded Result	
Neg Control Expected Result = 0	Cell Lot # Exp, Cell#	Lot# Exp	Cell #	Lot# Exp	Cell #	Lot# Exp	Cell #	Lot# Exp	Cell #	Lot# Exp	Cell #
		Graded Result		Graded Result		Graded Result		Graded Result		Graded Result	
Testing Tech/Peer Review		Tech	Peer Rev	Tech	Peer Rev	Tech	Peer Rev	Tech	Peer Rev	Tech	Peer Rev

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 #
		Graded Result		Graded Result		Graded Result		Graded Result		Graded Result	
Expected Result = 0	Cell Lot # Exp, Cell#	Lot# Exp	Cell #	Lot# Exp	Cell #	Lot# Exp	Cell #	Lot# Exp	Cell #	Lot# Exp	Cell #
		Result		Graded Result		Graded Result		Graded Result		Graded Result	
Testing Tech/Peer Review		Tech	Peer Rev	Tech	Peer Rev	Tech	Peer Rev	Tech	Peer Rev	Tech	Peer Rev

Indiana University Health

Indianapolis, IN 46202

Date of Testing_____

Form #: BBT – F105.00
Manual: Testing
Original Effective: NEW

Donor Unit Antigen Screening Worksheet

Supervisory Review/Date _____

Unit Number	C	E	c	e	K	Fy^a	Fy^b	Jk^a	Jk^b	M	N	S	s	Cerner Entry Y/N	Testing Tech	Peer Review
Antisera Lot Number and Expiration Date																
Is Antisera QC Completed? Y=Yes																

EXAMPLE

Indiana University Health
Indianapolis, IN 46202

Antisera Quality Control Worksheet

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

Date of Testing 2/28/19

Supervisory Review/Date

Daily QC of Antisera	Anti-K	Anti-____	Anti-____	Anti-____	Anti-____
Lot #	K1234				
Expiration	2020-01-01				
Pos Control, >=1+ *For Pos control use heterozygous cells only — Cell Lot # Exp., Cell#	Lot# 675421 Cell # 47 (3+) Exp 2019-03-15	Lot# Cell # Exp	Lot# Cell # Exp	Lot# Cell # Exp	Lot# Cell # Exp
	Graded Result 3+	Graded Result	Graded Result	Graded Result	Graded Result
Neg Control Expected Result = 0 — Cell Lot # Exp. Cell#	Lot# 675421 Cell # 9 Exp 2019-03-15	Lot# Cell # Exp	Lot# Cell # Exp	Lot# Cell # Exp	Lot# Cell # Exp
	Graded Result 0	Graded Result	Graded Result	Graded Result	Graded Result
Testing Tech/Peer Review	Tech JM / Peer Rev TMI	Tech / Peer Rev	Tech / Peer Rev	Tech / Peer Rev	Tech / Peer Rev

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# Cell # Exp	Lot# Cell # Exp	Lot# Cell # Exp	Lot# Cell # Exp	Lot# Cell # Exp
	Graded Result	Graded Result	Graded Result	Graded Result	Graded Result
Expected Result = 0 — Cell Lot # Exp. Cell#	Lot# Cell # Exp	Lot# Cell # Exp	Lot# Cell # Exp	Lot# Cell # Exp	Lot# Cell # Exp
	Result	Graded Result	Graded Result	Graded Result	Graded Result
Testing Tech/Peer Review	Tech / Peer Rev	Tech / Peer Rev	Tech / Peer Rev	Tech / Peer Rev	Tech / Peer Rev

Example

Indiana University Health
Indianapolis, IN 46202

Date of Testing 2/28/19

Form #: BBT – F105.00
Manual: Testing
Original Effective: NEW

Donor Unit Antigen Screening Worksheet

Supervisory Review/Date _____

Unit Number	C	E	c	e	K	Fy^a	Fy^b	Jk^a	Jk^b	M	N	S	s	Cerner Entry Y/N	Testing Tech	Peer Review
W040719654321					0									Y	jms	TMI
W040719754322					0									Y	jms	TMI
Antisera Lot Number and Expiration Date					K1234 2020-01-01											
Is Antisera QC Completed? Y=Yes					Y											