Status Scheduled PolicyStat ID 11808704

Beaumont

Origination	6/22/2022
Last Approved	6/7/2022
Effective	6/22/2022
Last Revised	6/7/2022
Next Review	6/6/2024
Document Contact	Kelly Sartor
Area	Laboratory-Blood Bank
Applicability	Dearborn, FH, Troy

Manual Operations When the Blood Bank Computer System is Unavailable

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

This document provides the Blood Bank staff with policies and worksheets that are to be used when the Blood Bank computer system is unavailable.

II. PRINCIPLE:

A. When the Blood Bank computer system is unavailable, a mechanism must be in place to retrieve historical data. The files containing this data must be current and contain relevant data to maintain patient safety when processing specimens and issuing blood products during downtime. During computer downtimes, this historical data is compared to the current records (test results obtained during the computer downtime).

B. All data that is normally entered into the system during standard operations is documented on downtime forms. The information recorded on these downtime forms is recouped when the system's functionality is restored.

III. SCOPE:

The processes described in this document are applicable only when the Blood Bank computer is unavailable. If the Blood Bank computer is available and the Epic/Beaker LIS systems are not available, then refer to Transfusion Medicine policy, Blood Bank Computer Downtime.

IV. DEFINITIONS/ACRONYMS:

A. LIS: Laboratory Information System

B. HIS: Hospital Information System

C. RBC: Red Blood Cell

V. POLICIES:

The following policies are applicable during Blood Bank computer downtimes:

A. **Manual Operations**

1. Each time Soft Bank goes down and the Blood Bank is forced to use manual operations (whether the downtime is scheduled or not), *Computer Downtime and Data Integrity Check Form* shall be initiated. All Transfusion Medicine policies and procedures remain in effect during computer downtimes, with the exceptions noted in this document. The processes, results, and interpretations that are normally documented when the computer is available will be instead documented on downtime forms.

B. **Historical Record Check / Accessing the SoftBank Backup Files / Documentation on the Patient's Downtime Worksheet**

1. The backup file of each patient must be accessed if a sample is triaged or tested or if blood is issued during the downtime. The *Patient Downtime Worksheet* will be answered "√ / Tech" to reflect that the backup file has been accessed.
2. In addition, the historical ABORh and any antibodies or messages will be documented on the patient's downtime form.
3. Any ABORh discrepancies must be investigated and corrected before a unit is issued for transfusion. If applicable, refer to Transfusion Medicine policy, Resolution of ABO and Rh Discrepancies.
4. In most cases, the backup file is accessed and the historical information is documented on the downtime form at the time a sample is triaged. In some cases, the Backup file will be accessed and the historical information will be documented on the downtime form at a time other than sample triage.
    a. *For example: The sample is triaged and the Type & Screen is completed while the computer is still available. Then a downtime occurs, and RBCs are requested. The crossmatching technologist does not find a downtime folder so he or she makes one, accesses the Backup file, and documents the Patient Downtime Worksheet. The technologist who issues the blood retrieves the downtime folder, sees that the backup files have already been accessed as indicated on the Patient Downtime Worksheet, and uses the information recorded on the worksheet to ensure that the blood product meets all of the requirements found in Transfusion Medicine procedure, Dispensing Blood Components.*

C. **Triage: Receiving Samples**

1. If Epic Beaker is operational, then all samples will be received in Beaker and extra accession labels will be printed. One label will be placed on the *Patient Downtime Worksheet* and another on the tab of the downtime folder. Extra labels will be printed and later used for each blood product that is selected for the patient.

2. If Epic Beaker is not operational so that accession labels cannot be generated by the system, then the Blood Bank shall use the Beaker downtime labels that will be provided by Clinical Pathology to label samples.
    a. Note that these labels include only accession numbers; therefore the patient's name and Medical Record Number (MRN) must be handwritten on the downtime folder, forms, and photocopies of components that are selected for the patient. Refer to Transfusion Medicine policy, Blood Bank Computer Downtime.

D. **Downtime Folders**

1. A downtime folder will be created for every patient sample received during downtime.
2. All paperwork for a given patient will be placed in the downtime folder, e.g., Epic shingle, downtime test requisition, instrument printouts, patient antibody workups/ cards (if applicable) etc.
3. The downtime folder will accompany the patient sample through the Blood Bank as testing is performed; it will be viewed each time that testing is performed or a component is processed or dispensed for the patient.
4. Any new special transfusion requests (as may be indicated on the shingle, downtime test requisition, or dispense form) will also be documented in the space provided on the *Patient Downtime Worksheet.*

E. **Vision™ Printouts**

1. Vision™ printouts will be added to the patient downtime folders and Vision™ interpretations will be recorded on the *Patient Downtime Worksheet.*
2. Use caution when documenting to make sure that the order numbers on the Vision™ printouts match the order numbers on the *Patient Downtime Worksheet* and that the printouts are placed in the folders belonging to the correct patients.

F. **Quality Control**

1. Quality control (QC) of test reagents are performed and documented on applicable downtime QC forms as described in site specific Transfusion Medicine policies, *Quality Control of Blood Bank Reagents and Ortho Vision Analyzer QC.*

G. **ABORh Testing**

1. If the patient does not have a historical type in the Soft backup file, then both the ABORh test and the NPR test shall be performed.
2. If the patient has a historical type in the SoftBank backup file, then the ABORh test shall be performed as the NPR is not required. The ABORh test and the NPR may be performed by any of the following methods:
    a. Testing performed by the Ortho® Vision™ Analyzer.
        i. For any testing performed on the Vision™, a Show Order Report shall be printed and placed in the downtime folder. The ABO and Rh interpretation shall be documented on the *Patient Downtime*

Worksheet.

b. Testing Performed by the Tube Test Method.

i. The technologist will document the graded reactions on the *Patient Downtime Worksheet* accordingly and verify that the current ABORh matches the historical record (if applicable).

c. If both the ABORh test and the NPR test are indicated (because the patient does not have a historical type), then the same technologist should not perform both the ABORh and NPR if only manual methods are used.

i. The same technologist may perform both the ABORh and NPR on the Vision™.

H. **Crossmatching Red Blood Cells**

1. During computer downtimes, the Blood Bank will crossmatch all RBCs that are ordered by a patient's physician.
2. An immediate-spin crossmatch must be performed on all patients who require a crossmatch during the downtime, to assess ABO compatibility.
    a. If an electronic crossmatch was performed before the computer downtime, the unit may be issued and it is not necessary to also perform a serologic crossmatch during the downtime.
3. For patients with unexpected antibodies, an AHG (usually gel) crossmatch must also be performed in addition to the immediate-spin crossmatch.
    a. Note: a gel crossmatch by itself cannot be relied upon to assess ABO compatibility. See Transfusion Medicine policy, *Policies for the Providing RBCs for Patients with Unexpected Antibodies,* if applicable.
    b. *For example: During a computer downtime, a patient is found to have a positive antibody screen. Anti-E is identified. Both an immediate-spin and a gel crossmatch must be performed.*
    c. A photocopy of each RBC that is crossmatched for the patient shall be added to the downtime folder.
        i. If accession labels can be printed from Beaker, then a Beaker label can be placed on the photocopy of each RBC that is crossmatched for the patient.
        ii. If accession labels cannot be printed from Beaker, then the patient's name and MRN should be handwritten on each photocopy.
4. If the crossmatch is performed during the computer downtime, then the crossmatch tag must be handwritten with permanent ink (no gel pens).
5. Before crossmatching, the technologist will verify that the ABORh and/or NPR test results were completed, that the antibody screen was completed, and that an antibody investigation was performed, if applicable.
    a. Either the NPR or confirmatory type must be performed at the time of

crossmatch, by the technologist crossmatching the RBCs

I. **Confirmatory Type**

1. During computer downtimes, the patient's blood type must be verified at the time RBCs are crossmatched, by the technologist crossmatching the RBCs.
2. This requirement is met by either the NPR test or the **CONF** test.
    a. The **NPR** test may be performed at the same time that RBCs are crossmatched, by the same technologist crossmatching the RBCs.
    b. It is not necessary to also perform a **CONF** test if the **NPR** is done at the time RBCs are crossmatched, by the technologist crossmatching the RBCs.
    c. The **CONF** test consists of a tube forward typing with Anti-A, Anti-B, and the Ortho Bioclone® Anti-D reagent and shall be performed / repeated each time that the sample is retrieved from storage for crossmatching, and each time that a different technologist crossmatches RBCs. For example:
        i. A Type and Screen (TS) only was ordered on a patient with no historical record. The Blood Bank performs the ABORh and **NPR** and stores the sample in the refrigerator. RBCs are ordered several hours later. The **CONF** test must be performed at the time RBCs are crossmatched, by the technologist crossmatching the RBCs.
        ii. A technologist performs the **CONF** test, crossmatches 2 RBCs, and returns the sample to the refrigerator for storage. Several hours later, additional RBCs are requested. The same technologist retrieves the sample and must repeat the **CONF** test as the additional RBCs are crossmatched.
    d. If the sample is depleted due to multiple **CONF** tests, a new sample should be collected and a new TS should be performed on the new sample.
    e. SoftBank will NOT generate a warning during the computer recoup if the interpretation of the **CONF** test does not match the patient's previous / historical test results.
    f. The **CONF** test will be required when preparing platelets, plasma, or cryoprecipitate if compatibility testing was performed before the computer downtime.

J. **Product Modification (Thawing Plasma and Cryoprecipitate, Dividing and Preparing Aliquots, Irradiation)**

1. Make a photocopy of the pre-modified face label of the blood product.
    a. Do not cover the original product description on this photocopy because it is needed for barcode scanning / recouping data when the system's functionality is restored.
2. Modified components will be labeled with a new product description label that can

be found in the binder in the downtime bin along with a job aid that allows the user to determine the correct post-modification code/sticker based on the pre-modification code.

3. Product modifications for Thawing or Irradiation will documented on the *Downtime Product Modification* Form.
4. Product divisions or aliquots will be documented on the routine *Blood Product Division/Aliquot Preparation Log.*

K. **Platelet, Plasma, and Cryoprecipitate Preparation for Patients**

1. A photocopy of each product that is selected for the patient shall be added to the patient's downtime folder.
2. If accession labels can be printed from the Beaker, then a Beaker label will be placed on the photocopy of each product that is selected for the patient.
3. If accession labels cannot be printed from Beaker, then the patient's name and MRN should be handwritten on each photocopy.
4. The patient's blood type must be determined / tested during the downtime and be documented on the *Patient Downtime Worksheet.*
5. If compatibility testing was performed before the computer downtime, then the **CONF** test must be performed.
6. It is not necessary to perform more than one **CONF** on a sample for the purposes of providing additional platelets, plasma, or cryoprecipitate.
7. If a platelet, plasma, or cryoprecipitate is requested during a computer downtime, then a Blood Bank sample from the current admission must be available to be retrieved from storage for the **CONF** test.
    a. If the patient does not have a sample available in storage for retrieval (i.e. time has exceeded maximum specimen retention), then a new sample should be collected. It may be necessary to emergency issue components in this case.

L. **Dispensing Blood Components**

1. When dispensing blood components, the technologist will adhere as closely as possible to Transfusion Medicine policy, Dispensing Blood Components.
    a. Consistent with normal operations, the crossmatch tag is documented when the component is dispensed with the date and time of issue (time stamp), visual Inspection (circle "OK" if appropriate), issuing technologist's initials, etc.
    b. During computer downtimes the technologist who issues a component must verify that all required compatibility testing is complete and that the component meets the patient's special transfusion requirements.
    c. The photocopy of each dispensed unit (with the patient's accession label or handwritten name and MRN) will be stapled to F-1564, Blood Bank Product Dispense Form and to the copy of F-1566, Record of Transfusion, and returned to the downtime folder.

M. **Antibody Problems / Investigations**

1. If any new antibodies are detected or if any additional transfusion requirements are needed based on the investigation, document these on the *Patient Downtime Worksheet* and the patient's antibody panels/card (if applicable) so that they may be recouped later.

N. **Antigen Typing**

1. In the case of a Blood Bank computer system downtime the *Antigen Typing Downtime Form* is used to document unit antigen typing. Refer to Transfusion Medicine policy, *Antigen Typing* for further information.
2. All antigen typing data performed during downtime will be recouped in the computer system when available.

O. **Processing Units**

1. *Downtime Unit Receipt and Processing Worksheet* will be used to receive the units into inventory and to document confirmatory testing of RBCs.
2. Two photocopies of each unit will be made: one will be attached to the *Downtime Unit Receipt and Processing Worksheet* and the other will trail the unit through the Blood Bank during the downtime.
3. A copy of the invoice will be stapled to *Downtime Unit Receipt and Processing Worksheet* so that data can be recouped once the computer system becomes available.

P. **Suspected Reaction Evaluations**

1. The *Suspected Transfusion Reaction Evaluation Form* is used whenever a patient is suspected to have a transfusion reaction. Routinely, a technologist will document the clerical checks on this form, while the sample evaluation and testing is documented in the Blood Bank computer system. During a blood bank computer downtime, the evaluation, testing and instructions from Medical Director will be documented on the form and recouped when the computer system is available.

Q. **Data Recoup**

1. Once the system's functionality is restored, all test results, new special transfusion requirements, antibodies, etc. that were recorded on downtime forms will be recouped in the computer.
2. When possible, the actual date and time that the testing or process was performed will be recouped, and the name of the technologist who performed the test or process will be added as a comment.
3. The recouping technologist will initial the corresponding downtime form(s) with his or her initial, the date, and the time of recoup.

R. **Data Integrity Check**

1. After each Soft Bank downtime and after the Soft Bank's functionality has been restored, the Blood Bank shall perform a data integrity check.
2. This check shall be performed immediately after the restoration and will be

documented on Transfusion Medicine form, *Computer Downtime and Data Integrity Check Form*.

3. The pre-downtime and post-downtime ABORh, antibodies, and special messages of four patients will be compared between the Soft Backup file and the live version of SoftBank.
    a. These four patients will be identified from recent documented antibody investigations and shall include one patient of each of the four ABO types (A, B, O, and AB).
    b. Two patients should be Rh(D) positive and two should be Rh(D) negative.
    c. *The Computer Downtime and Data Integrity Check Form* is documented with the start and end time of the downtime, whether the downtime was scheduled, and the data integrity check / comparisons of these four patients.
    d. If the data from the two sources does not match, the cause must be investigated immediately. If the cause cannot be determined immediately, the Blood Bank must remain on downtime and the Medical Director and/or the supervisor must be notified immediately. Completed forms are stored in designated file/binder.

S. **Saving Downtime Records**
All downtime records including downtime forms, product photocopies, crossmatch tags, dispense forms, the Data Integrity Check Forms, and all other forms will be stored in the supervisor's office following document retention policies.

VI. SUPPLIES:

A. All supplies that are required during computer downtimes are found in the designated Downtime Supplies bin located in the department.

VII. REFERENCES:

1. AABB, *Technical Manual*, current edition.
2. AABB, *Standards for Blood Banks and Transfusion Services*, current edition
3. College of American Pathologists, *Transfusion Medicine Checklist*, current edition.

Attachments

Computer Downtime Data Integrity Form

Downtime Crossmatch Worksheet

Downtime RhIG Evaluation Worksheet

Downtime Unit Receipt and Processing Worksheet

Patient Downtime Worksheet

Approval Signatures

Step Description	Approver	Date
	Jeremy Powers: Chief, Pathology	6/7/2022
	Vaishali Pansare: Chief, Pathology	6/6/2022
	John Pui: Chief, Pathology	6/3/2022
	Ryan Johnson: OUWB Clinical Faculty	6/3/2022
Policy and Forms Steering Committe (if needed)	Kelly Sartor: Supv, Laboratory	6/3/2022
Policy and Forms Steering Committe (if needed)	Gail Juleff: Project Mgr Policy	6/3/2022
	Karrie Torgerson: Supv, Laboratory	6/3/2022
	Teresa Lovins: Supv, Laboratory	5/27/2022
	Kelly Sartor: Supv, Laboratory	5/27/2022
	Kelly Sartor: Supv, Laboratory	5/27/2022

Beaumont HEALTH

Beaumont Laboratory

Computer Downtime and Data Integrity Check Form

		Technologist
Start time / date of the computer downtime		
End time / date of the computer downtime		
Was the downtime scheduled? (Yes or No)		

Patient's Name and MRN	Data obtained from Soft Live (Attach a screen print from Patient / Edit / Messages)				Does data from Soft Backup File match data from Soft Live? (Yes or No)	Tech
	ABO	*Rh	**Antibodies	**Special Messages		
	A					
	B					
	O					
	AB					

*Two of these patients should be Rh(D) positive and two should be Rh(D) negative

** The screen print may be used to document the antibodies and special messages.

The data integrity check shall be performed immediately after the functionality of the computer system has been restored. If the data from the Soft Backup file and Soft Live does not match, the cause must be investigated immediately. If the cause cannot be determined immediately, the Blood Bank must remain on downtime and the Medical Director or the Supervisor must be notified immediately.

Document the following only if the data from the Soft Backup file and Soft Live does not match.	
Date and time of notification / tech	
Who was notified	
Appropriate course of action:	

Beaumont HEALTH

Beaumont Laboratory

Patient

Label

DOWNTIME CROSSMATCH WORKSHEET

	Unit Number	BPC	Type of Specimen	Type of XM	IS	37	AHG	CC	Gel	Comp Y/N	Tech	Date	Entered in SOFT	Notes
Ex	13FX12345	RU3	Auto absorp	60 min NL	NI	0	0	2+	NI	Y	JS	1/1/16	Y	ABO of unit/ Antigen type / notes
1														
2														
3														
4														
5														
6														
7														
8														
9														
10														
11														
12														
AC														

Beaumont HEALTH

Beaumont Laboratory

Downtime RhIG Evaluation Worksheet

Place mother's accession label here Name MRN DOB Order #	**Mother**	**Baby**
	B#:	**N#:**
	ABO/Rh:	Baby's Name:
	ABSC:	Baby's MRN:
	Antibodies:	Baby's ABO (if determined) :
	Notes:	Baby's Rh:
		DAT (if determined):
		Cord Blood Evaluation results: (if indicated)

Testing for Fetal Maternal Hemorrhage			
Fetal Cell Screen (FCS)	FCS Kit Mfg.:	FCS Pos Control Result:	Patient FCS Result:
	FCS kit Lot #:	FCS Neg Control result:	
	FCS Kit Exp. Date:	Tech / Date:	
Fetal RBC Assay	Sample sent to Flow Cytometry for Fetal RBC Assay, if indicated. Date / time / Tech:		Flow Cytometry Results (% fetal cells): **FMHA** Test Code: Y or N
Acid Elution/Kleihauer	Sample sent for Acid Elution Stain, if required by physician in lieu of Fetal RBC Assay Date / time / Tech:		Acid Elution Results (% fetal cells):

RhIG Evaluation

	*RhIG Eval code(s)	# Vials RhIG Indicated	RN Notified				RhIG Mfg.	RhIG Lot #	RhIG Exp. Date	# Vials Issued	Issue (D/T/Tech)	RhIG Eval Recouped (D/T/Tech)
			RN ID#	Tech	Date	Time						
RhIG Candidacy Report												

Reviewed by and acceptable: _____ Date: _____

Beaumont HEALTH

Beaumont Laboratory

Downtime Unit Receipt and Processing Worksheet

Invoice#	Receive D/T	Receiving Tech	Temperature:

Attach a copy of the invoice and a photocopy of each unit listed to this downtime form.

Visual Inspection (circle)	Unit Number	Product Code	RBC Testing (forward typing)							2 photocopies of product made (√)	Special Attributes/ Antigen Types / Notes	Recouped In SOFT Tech / Date / Time		
			A	B	D	Interp.	Testing Tech / Date / Time							
S U														
S U														
S U														
S U														
S U														
S U														
S U														
S U														
S U														
S U														
S U														
S U														
S U														

Reviewed by and acceptable: _____ Date: _____

Beaumont HEALTH

Beaumont Laboratory

Patient Downtime Worksheet

B#: _____

Place accession label here Name MRN DOB Order #	Current Order		Historical Record	
	☐ TS ☐ NPR ☐ Other:	☐ RBCs:_____ ☐ PLT: _____ ☐ FFP:_____ ☐ CRYO: ____	3 Soft Backups Files Accessed? (√ / Tech)	
			Historical ABO/Rh or NA	
			Historical Antibodies or NA	
			Historical Messages or NA	
			Last Sample Date or NA	
	New Special Requests		New Messages & Antibodies	Triage Recouped (Tech / Date)
	☐ IRR ☐ SKL neg ☐ Other:			

Test	QC Rack	A	B	DTT	D gel	DC	RA	RB	ABORh Interpretation (Interp)	Tech	Date /Time	Order #s on sample and Vision report match (√ or NA)	
ABORh													
NPR													

Test	QC Rack	Screen Cell I	Screen Cell II	ABSCR Interpretation	Addt'l Studies?	Tech	Date /Time	Current & Historical ABORh Match (√ or NA)	
ABSCR									

Test	QC Rack	Surgiscreen Cell 1			Surgiscreen Cell 2			Surgiscreen Cell 3			ABSCR Interpretation	Addt'l Studies?	Tech	Date /Time	Type & Screen Recouped (Tech / Date)	
		37C	AHG	CC	37C	AHG	CC	37C	AHG	CC						
ABSCR																

Test	QC Rack	Reagent	IS	RT	CC	Tube Interp	Saline Control
		Poly					
Tube DAT		IgG		NI			
		Comp					

Test	QC Rack	Gel DAT	Gel Interp	Tech	Date /Time	DAT Recouped (Tech / Date)	
Gel DAT							

Critical DAT called to: _____ at _____ on _____, Readback (circle): Yes or No, Tech_____,Date_____,Time_____

QC Rack	Unit #	Product Code	Gel	IS	RT	37	AG	CC	Interpretation (Comp or Inc)	Patient CONF type				Tech	Date / Time	XM Recouped (Tech / Date)
										A	B	D	ABO Rh			

Reviewed by and acceptable: _____ Date: _____