

	► Standard Operating Procedure ◀
Section: Data Management	Version: FINAL Initials: AD
Title: 3.0 PERCH Study ID Scheme	Revision Date: 01 Sep 2011

1. Definitions:

- 1.1 CRF: Case Report Form
- 1.1 Cryolabels: Synthetic labels designed for bio-medical research tubes/vials. Cryolabels used for PERCH must exhibit permanent adhesion to polypropylene tubes and be able to withstand temperatures as low as -196° C. They must also be resistant to multiple freeze-thaw cycles.
- 1.2 Participant ID: A unique ID associated with any child who is screened to be a PERCH participant. The ID is maintained after enrollment.
- 1.3 Sample ID: A unique ID associated a body fluid/specimen, stored aliquot, isolate or nucleic acid extract. The participant ID is embedded in the sample ID.
- 1.4 Study Participant: A PERCH case, control or HIV-positive control

2. Purpose / Background:

- 2.1 PERCH participant and sample IDs must be standardized according to the scheme described in this SOP in order to be entered in the PERCH EMMES data system.
- 2.2 To prevent transcription errors, all ID labels should be barcoded and scanned into the data entry system.

3. Scope / Applicability:

- 3.1 This SOP is applicable to all study sites.

4. Roles / Responsibilities

- 4.1. *[Site specific]*

5. Prerequisites / Supplies Needed:

- 5.1 Barcode Label making software (NiceLabel Express or equivalent and FreezerPro or equivalent)
- 5.2 Paper Labels for specimen collection containers, log books and paper CRFs.
- 5.3 Cryolabels for samples that will be stored in a freezer

6. Safety/Risk Assessment:

- 6.1 N/A

7. Procedural Steps

7.1 Participant IDs:

Each child screened for PERCH will be assigned a unique participant ID. The ID is maintained for that child if they are enrolled in the study. If a child is screened and/or enrolled in the study more than once,

she will be assigned a unique participant ID for each screening/enrollment episode. A participant ID may never be used more than once.

Note: If sites have an existing participant ID numbering scheme that they want to maintain in addition to the PERCH ID, they can include it in the PERCH database by entering it on the appropriate field of CRF 01, 01A or 01B. However, the PERCH ID will be the primary ID that is used to enter, edit and search data within the data system.

ID format: Participant IDs are 6 digits in length. The first digit is the site-specific identification letter. The following 5 digits will be sequential numbers [AXXXXX].

Example: Z00001, B00520, G45530, etc.

Site letter IDs have been assigned as follows:

Site*	Unique Letter ID
Kenya	K
Gambia	G
Mali	M
Zambia	Z
South Africa	S
Thailand – Nahkom Phanom	N
Thailand – Sa Kaeo	T
Bangladesh – Matlab	B
Bangladesh - Dhaka	D

Assigning Participant IDs: Participant IDs may be assigned in any order. There is no distinction between participant IDs used for cases and controls. This allows the laboratory to be blinded to case vs. control status and to community control vs. HIV control status.

Barcode Label Printing: Participant ID barcode labels can be created with any labeling software the site chooses to use. If using the NiceLabel Express software, refer to SOP 3.1 “Barcode Labels with NiceLabel Express”.

An example of a barcoded participant ID label is shown below:



7.2 Sample IDs:

Sample IDs are used to identify any specimen collected or any sample stored in the laboratory. Sample IDs are also used to identify chest x-ray images. The sample ID is an 8 digit ID with a hyphen separating the first six digits from a two digit suffix. The first six digits are the participant ID. The two digit suffix is the sample code. [AXXXXX-XX]

Each sample that could possibly be collected or store for PERCH has a pre-assigned code. Please see Appendix A for a complete list of the sample ID codes. All sites must adhere to the sample codes described in this SOP to enter data into the EMMES system.

Barcode Label Printing:

- Sample ID labels that are generated for *specimen collection containers, log books, and paper CRFs* may be printed on paper using the NiceLabel Express or equivalent software of the sites' choosing. See SOP 3.1 "Barcode Labels with NiceLabel Express" for instructions.

An example of a barcoded participant ID label is shown below:



- Sample ID labels that are generated for *stored samples (i.e. samples that are stored in a freezer)* must be printed on cryolabels using FreezerPro or equivalent software. See SOP 2.13 "Barcode Labels with FreezerPro" for instructions.
8. Quality Assurance / Quality Control
 - 7.1 Each site should have a system in place to ensure that each participant ID is used only once. The EMMES data entry system will assist with this for sites using electronic data capture at enrollment (vs. paper CRFs). It will not allow the same ID to be entered for two different patients.
 9. Record Management:
 - 8.1 N/A
 10. References:
 - 9.1 SOP 3.1 Barcode Labels with NiceLabel Express
 - 9.2 SOP 2.14 Barcode Labels with FreezerPro

SOP REVISIONS:

1 September 2011:

- Appendix A was correct to reflect additional sample ID codes, as well as CXR codes

SOP 3.0 Appendix A. PERCH Sample ID Codes

Note: All specimens and isolates (stored samples) will be identified by the participant ID (6-digit number) followed by a two digit sample code

Sample Type	Specimen Collection Container Code
Chest X-rays	
Anterior-Posterior or Posterior-Anterior chest xray	AP
Lateral chest xray	LT
Decubitus chest xray	DC
Blood	
Blood Culture Bottle*	1A
Blood Culture Isolates	10,11,12
<i>Second Blood Culture Bottle -If applicable for clinical reasons</i>	<i>1G</i>
<i>Second Blood Culture Bottle Isolates -If applicable</i>	<i>19, 25, 26</i>
Plain Tube	1B
Serum Aliquot 1	13
Serum Aliquot 2	14
Serum Aliquot 3 (if available)	A1
Serum Aliquot 4 (if available)	B1
Serum Aliquot 5 (if available)	C1
Serum Aliquot 6 (if available)	D1
Stored Blood Clot	15
Case Admission EDTA Tube #1	1C
Case Admission EDTA Tube #2*	1D
Control EDTA Tube **	1E
Control EDTA Tube #2 (For Thailand only - CBC)	1F
Malaria Slide- selected sites	1H
HIV Rapid Test- selected sites	1I
Dried Blood Spot (for HIV PCR, selected sites)	1J
Extracted NA from blood	16
EDTA blood aliquot 1	17
EDTA blood aliquot 2	18
EDTA Aliquot 3 (if available)	E1
EDTA Aliquot 4 (if available)	F1
EDTA Aliquot 5 (if available)	G1
EDTA Aliquot 6 (if available)	H1
Case 30 day convalescent plain tube	2A
30d serum aliquot 1	21
30d serum aliquot 2	22
30d serum aliquot 3	23
30d serum aliquot 4	24
30d serum aliquot 4 (if available)	A2
30d serum aliquot 5 (if available)	B2
30d serum aliquot 6 (if available)	C2
Case 30 day EDTA tube for CD4 testing	2B

	NP/OP Swabs	
NP-STGG Vial	3A	
Stored STGG		30
Stored STGG - THY enriched growth		31
STGG Pneumo Isolates		32, 33, 34, 35
NP-OP VTM vial	3B	
VTM Aliquot 1		36
VTM Aliquot 2		37
VTM Aliquot 3		38
NP-OP Extracted NA		39

	Induced Sputum	
Induced Sputum Container	4A	
Induced Sputum aliquot 1		40
Induced Sputum aliquot 2		41
IS Extracted NA		42
Remaining specimen after sputasol digestion		43
IS culture isolates		44, 45, 46, 47
IS culture isolates continued		A4, B4, C4, D4
TB isolates		48, 49, 50
IS Gram Stained Slide		51
Second Induced Sputum Container	4B	
Second IS aliquot 1		52
Second IS isolate 2		53
Second IS TB isolates		54, 55, 56

	ETT Aspirate (Thailand and South Africa only)	
ETT Container	5A	
ETT aliquot 1		A5
ETT aliquot 2		B5
ETT Extracted NA		C5
Remaining specimen after sputasol digestion		D5
ETT culture isolates		E5, F5, G5, H5
ETT culture isolates continued		I5, J5, K5, L5
TB isolates		M5, N5, O5
ETT Gram Stained Slide		P5
Second ETT Container	5B	
Second IS aliquot 1		Q5
Second IS isolate 2		R5
Second IS TB isolates		S5, T5, U5

Gastric Aspirate

Gastric Aspirate Container	6A	
GA aliquot 1		60
GA aliquot 2		61
TB isolates		62, 63
<i>Second Gastric Aspirate Container, if applicable for clinical reasons</i>	6B	
<i>2nd GA aliquots, if applicable</i>		64, 65
<i>TB isolates from 2nd GA specimen, if applicable</i>		66, 67, 68
<i>Third Gastric Aspirate Container, if applicable for clinical reasons</i>	6C	
<i>3rd GA aliquots, if applicable</i>		69, A6
<i>TB isolates from 3rd GA specimen, if applicable</i>		B6, C6, D6
<i>4th GA aliquot, if applicable</i>	6D	
<i>TB isolates from 4th GA specimen, if applicable</i>		E6, F6, G6
<i>5th GA aliquot, if applicable</i>	6E	
<i>TB isolates from 5th GA specimen, if applicable</i>		H6, I6, J6

Urine

Urine Collection Container	7A	
Urine aliquot 1		70
Urine aliquot 2		71
Urine aliquot 3		72
Urine aliquot 4		73
Follow up (30 day) Urine Collection Container	7B	74
Second Urine aliquot 1		74
Second Urine aliquot 2		75
Second Urine aliquot 3		76
Second Urine aliquot 4		77

Pleural Fluid

Pleural Fluid Collection Container	8A	
PF Aliquot 1		80
PF Aliquot 2		81
PF Extracted NA		82
PF Culture Isolates		83, 84, 85
PF TB Isolates		86, 87, 88
<i>Second Pleural Fluid Collection Container-If applicable for clinical reasons</i>	8B	

Lung Aspirate

Lung Aspirate Collection Container	9A	
LA Specimen Aliquot 1		90
LA Specimen Aliquot 2		91

LA Extracted NA	92
LA Culture Isolates	93, 94, 95
LA TB isolates	96,97,98

* Some sites may use 1 EDTA tube rather than 2

** Note, this is the only control specimen with a different ID than the case specimen. It is because the control EDTA blood is treated slightly differently than the case EDTA blood in the lab. (No CBC, may have different Risk Factor Tests, Etc)

Post Mortem Specimens Please Refer To CRF 15

Only one sample - from right Lung	PR
Only one sample - from Left Lung	PL

Microbiology Core 1	M1
Mircobiology Core 2	M2
Microbiology Core 3	M3
Microbiology Core 4	M4
Microbiology Core 5	M5
Microbiology Core 6	M6

Post Mortem Microbiology culture isolates	PF, PG, PH, PI, PJ, PK, PL, PM, PN, PO, PQ, PR, PS, PT PU, PV, PW, PX, PY, PZ
Post Mortem TB Isolates	

RNA later sample 1	R7
RNA later sample 2	R8
RNA later sample 3	R9
RNA later sample 4	R10
Histology Core 1	H11
Histology Core 2	H12
Histology Core 3	H13
Histology Core 4	H14
Histology Core 5	H15
Frozen Tissue Sample 1	F16

Induced Sp	4A
Induced Sputum aliqu	40
Induced Sputum aliqu	41
IS Extracted NA	42
Remaining specimen :	43
IS culture isolates	44, 45, 46, 47
TB isolates	48, 49, 50
IS Gram Stained Slide	51
Second Inc	5A
Second IS aliquot 1	52
Second IS isolate 2	53
<u>Second IS TB isolates</u>	<u>54, 55, 56</u>



► **Standard Operating Procedure** ◀

Section: Data Management

Version: FINAL

Initials: AD

Title: 3.1 Creating Barcode Labels with NiceLabel Software

Revision Date: 20 July 2012

1. Definitions:

- 1.1 CRF: Case Report Form
- 1.2 Cryolabels: Synthetic labels designed for bio-medical research tubes/vials. CryoLabels used for PERCH must exhibit permanent adhesion to polypropylene tubes and be able to withstand temperatures as low as -196° C. They must also be resistant to multiple freeze-thaw cycles.
- 1.3 Database: the worksheets created in Excel to define the label fields
- 1.4 NiceLabel Express: Label making software
- 1.5 Participant ID: Unique identification code for a PERCH study participant, or anyone who is screened for enrollment in the study.
- 1.6 Records: A row in the Excel database. Each record is associated with a unique label.
- 1.7 Sample ID: Unique identification code for a study sample

2. Purpose / Background:

- 2.1 Barcoded study ID and sample ID labels are created to facilitate data entry and to prevent transcription errors. The ID scheme used at each site should follow that described in SOP 3.0 PERCH Study IDs. The NiceLabel Express software can be used to create paper barcoded participant ID and sample ID labels for use on the following:

- Paper CRFs
- Hospital Log Books
- Non-CRF study logs/forms
- Specimen Collection Containers

Note: NiceLabel Express software will not be used to create cryolabels for stored/frozen samples. Those will be created by FreezerPro or equivalent software.

3. Scope / Applicability:

- 3.1 This SOP is applicable to all study sites that will use NiceLabel Express software to create paper barcode labels for PERCH study participants.

4. Roles / Responsibilities

- 4.1. *[Site specific]*

5. Prerequisites / Supplies Needed:

- 5.1 NiceLabel Software with License Key

- 5.2 Printer (Laser Printer or Thermal Transfer Label Printer). **Note:** This SOP is written for use with a laser printer (recommended) but may be adapted for sites that wish to use a thermal transfer label printer.

6. Safety/Risk Assessment:

- 6.1 N/A

7. Procedural Steps

7.1 Software Installation

NiceLabel Express 5 Software must be installed on the computer before use. The license key is a code that allows activation of the software on one machine. The software may be installed with a CD, or by downloading it from the internet. For instructions on downloading and installing NiceLabel software from the internet, please see Appendix A.

If at some point a decision is made to un-install NiceLabel Express on one machine and transfer the license to another machine, go to the “help” menu, select “manage license” and select “deactivate license”. Follow the instructions and activate the license on the other machine.

7.2 Create an Excel Label Database

The NiceLabel software must pull ID codes from an external database. The simplest option is to create such a database in Excel (described below).

7.2.2. To create a Barcode Label Database:

7.2.2.1 Open a blank Excel Workbook

7.2.2.2 Save the Workbook with a name, e.g. “Barcode Labels”.

Participant ID Labels:

7.2.2.3 Assign a worksheet to be your Participant ID work sheet, and name it appropriately e.g. “Participant_IDs”

7.2.2.4 In cell A1, enter the title of the first variable field, “**Participant ID**”

7.2.2.5 In cell A2, enter the participant ID you will begin with - e.g. if you are site Z, enter Z00001 (Refer to SOP 3.0 “PERCH Study ID Scheme” if needed).

7.2.2.6 In cell A3, enter the next consecutive ID number.

7.2.2.7 Highlight cells A2 and A3. Place your cursor on the bottom right hand corner of cell A3 until you see a “+” sign appear. Hold down the left button on your mouse, and drag the cursor down. You may create as many consecutive IDs as you like. In this example, there are 100 unique IDs.

7.2.2.8 If you will print more than 1 label per participant, you must “tell” NiceLabel how many labels you want to print by creating a quantity variable in the database. To create the quantity variable, simply insert a column to the left or right of your Participant ID column. Label the column “**Quantity**”. Enter the number of labels that you want to be printed. Place your cursor on the bottom right hand corner of the cell until you see a “+” sign appear. Hold down the left

button on your mouse, and drag the cursor down the column so that the quantity value is populated for all of the unique participant IDs in your database.

	A	B
1	Participant ID	Quantity
2	Z00001	20
3	Z00002	20
4	Z00003	20
5	Z00004	20
6	Z00005	20
7	Z00006	20
8	Z00007	20
9	Z00008	20

7.2.2.9 **Note:** It is important to name the columns (variable fields) in your worksheet – this allows you to identify them from within the NiceLabel software.

7.2.2.10 This completes the participant ID worksheet. Make sure to save it.

Sample ID Labels:

7.2.2.11 Create a new worksheet in your existing Excel barcode database.

7.2.2.12 Name the worksheet appropriately, e.g. “Case Admission Sample IDs”

7.2.2.13 There are several sample types for PERCH. You only need to create barcode labels for the body fluids that are being collected at your site (See = Specimen Collection Container Code, in Appendix A of SOP 3.0).

7.2.2.14 In this example, the following specimen collection container codes are being included in the template (note, this is an example of a core set of admission specimens for cases. You should create separate worksheets for control specimens, follow up specimens, etc.):

- Blood Culture Bottle – 1A
- Plain Blood Tube – 1B
- EDTA Tube #1 – 1C
- EDTA Tube #2 -1D
- NP-STGG Vial – 3A
- NP-OP Vial – 3B
- Induced Sputum Container – 4A
- Urine Collection Container 7A

7.2.2.15 In row A, enter the variable title “**Participant ID**”. You will not be printing this field, but your excel database will need to reference it.

7.2.2.16 In row B, enter the variable title “**Sample ID**”.

7.2.2.17 In row C, enter the variable title “**Sample Name**”.

7.2.2.18 In row D, enter the variable title “**Quantity**”.

7.2.2.19 In the cell, A2, enter the code for the first participant ID, e.g. Z00001

7.2.2.20 In this example, there are 8 admission specimens being collected for each participant, so we need to create 8 rows for this participant. Create a formula =(A2) and apply it to cells A3 through A9. They should all be populated with the same participant ID. **Note:**

Populating the cells with this formula rather than copying and pasting will allow you to easily modify the worksheet for a different participant.

7.2.2.21 Click on the first empty cell under column B, cell B2. This should be the first sample ID column. We will use blood culture (xxxxxx-1A) as an example. Enter the following formula =A2&"-1A"). This will pull the participant ID from column A, and append the "1A" suffix to it. (**Note:** You must use the formula above to do this step. There are other ways to append a suffix to a value in Excel, but some will treat the suffix as text rather than a value, and thus not allow it to be imported to NiceLabel.)

7.2.2.22 Repeat the instructions above for the second available cell in the column, B3, which is the next sample type. Repeat for the rest of the specimens to be collected. Make sure you are appending the correct sample ID to the correct sample (see SOP 3.0 Appendix A).

7.2.2.23 In row C (sample name), write the names of the samples in text. The sample name should correspond to the sample ID in column B.

7.2.2.24 In column D (quantity), enter the number of labels you wish to print. In this example we are printing 8 copies of each label.

	A	B	C	D
1	Participant ID	Sample ID	Sample Name	Quantity
2	Z00001	Z00001-1A	Blood Culture	8
3	Z00001	Z00001-1B	Plain Blood Tube	8
4	Z00001	Z00001-1C	EDTA Tube #1	8
5	Z00001	Z00001-1D	EDTA Tube #2	8
6	Z00001	Z00001-3A	NP STGG Swabs	8
7	Z00001	Z00001-3B	NP-OP Swabs	8
8	Z00001	Z00001-4A	Induced Sputum	8
9	Z00001	Z00001-7A	Urine	8
10	Z00001	Z00001-2A	30day Plain Tube	8
11	Z00001	Z00001-2B	30day EDTA Tube	8

7.2.2.25 You have now created the information NiceLabel needs to print a set of sample labels for a single participant. You have two options at this point:

- **If you will be printing labels for one participant at a time** (for example, as soon as you learn that a participant has been enrolled, you print a set of labels for that participant):
 - You can open the excel template each time you are ready to print and modify the participant ID. Simply enter the participant ID for the samples you want to print in **cell A2** (first participant ID in upper left hand corner). ***Because all formulas are tied to this cell, all of the fields will automatically be updated.***
 - *****Important --- DO NOT rename the Excel filename after updating participant IDs. If you rename the file, NiceLabel will not be able to find it.**
- **If you will be printing labels for several participants at a time:**
 - Open your template. Highlight the complete set of labels you have created for a single participant. Hover your cursor over the bottom right corner of the highlighted area. Drag down through the number of rows

you want to be populated. You can populate as many fields as needed, creating as many participant “label sets” as you want.

- It is easiest to use the “drag and drop” method to create records for only as many labels as you want to print at one time, and then repeat the process the next time you are ready to print labels. In NiceLabel you will choose the “print all records” option. Alternatively, you can select which records to print from within the NiceLabel software. (e.g. you can select to print IDs 40-80 from a list of 1-100) – however, this may be much more time consuming.
- *****Important --- DO NOT rename the Excel filename after updating participant IDs. If you rename the file, NiceLabel will not be able to find it.**

7.2.3 Create a participant ID label template in Nice Label:

7.2.3.1 Open the NiceLabel software on your computer.

7.2.3.2 The “Welcome Wizard” window will open. Select “**create a new label**”, then click “**finish**”.

7.2.3.3 You must now select a default printer for your labels. Choose your printer from the list of options, then click “**next**”. (Your printer must already be mapped to your computer to complete this step).

7.2.3.4 Choose the label stock type that you will use. In this example, we will use Avery US, stock type 5167. You should use the label stock type that your site prefers to use. Then click “**next**”.

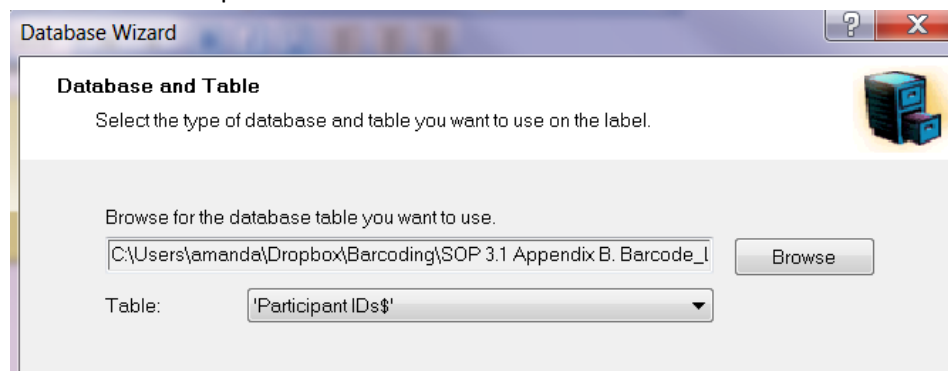
7.2.3.5 Choose portrait or landscape orientation. In this example, we will choose “**portrait**”. Click “**next**”.

7.2.3.6 You will now see a screen showing a preview of your label sheet, along with a description of their dimensions. Click **Finish**.

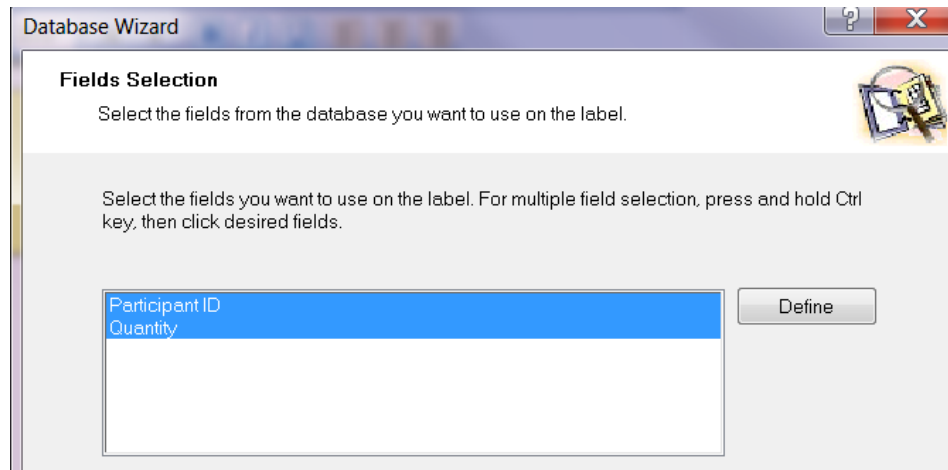
7.2.3.7 You are now in the label editing window. The only label you will be editing is the white label. Ignore the greyed-out labels.

7.2.3.8 Now it’s time to import data from your label database. Go to the **Database** menu, and select “**Create Database Connection**”.

7.2.3.9 Browse for your Excel barcode label ID database in the location where you saved it. The “Table” dropdown menu will allow you to select the appropriate worksheet. In this case, select the “Participant ID” worksheet. Click “next”.

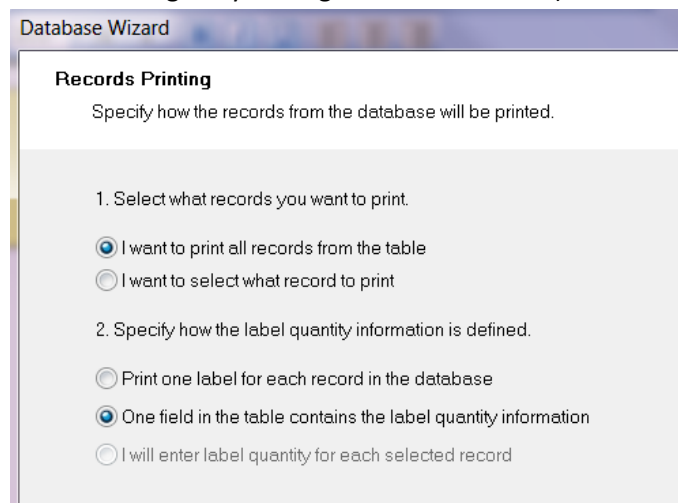


7.2.3.10 **Field Selection Screen:** Two fields should appear: the “Participant ID” field and the “Quantity” field. Select both fields, and then click “**Next**”

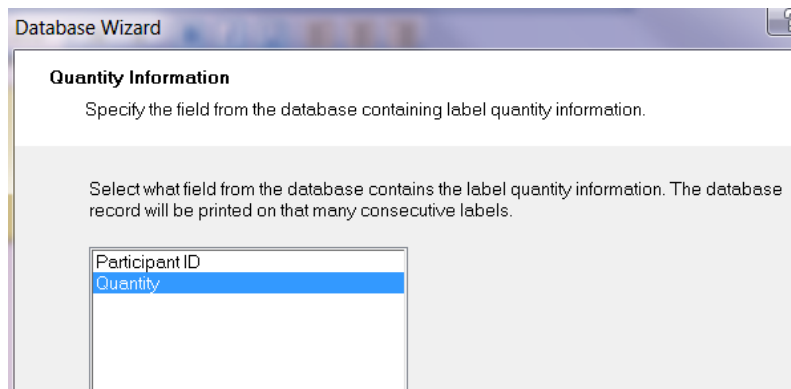


7.2.3.11 **Records Printing:** Under “1. select what records you want to print”, click “**I want to print all records from the table**” if you will print labels for all participants in your database. Alternatively, click “I want to select what record to print” if you want to print labels for a subset of patients/records. Under “2. Specify how the label quantity information is defined”, select “**One field in the table contains the label quantity information**”. Then click “**next**”.

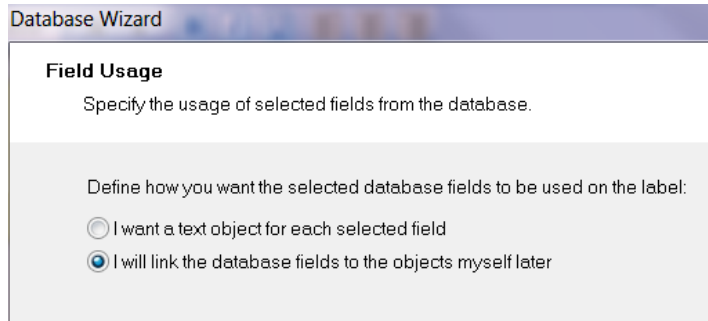
- (Note: Even though the software appears to give you the option to manually enter the number of quantities to print, you cannot do this. That can only be done in Nice Label Pro, an upgraded version of the software. In NiceLabel Express, you must choose to print either one label per participant or the number of labels that you have defined in the quantity field of your database. To change the number of labels, simply change the value in the quantity column of your Excel database. You don’t need to change any settings within NiceLabel.)



7.2.3.12 **Quantity Information:** Select the “Quantity” field. Click next.



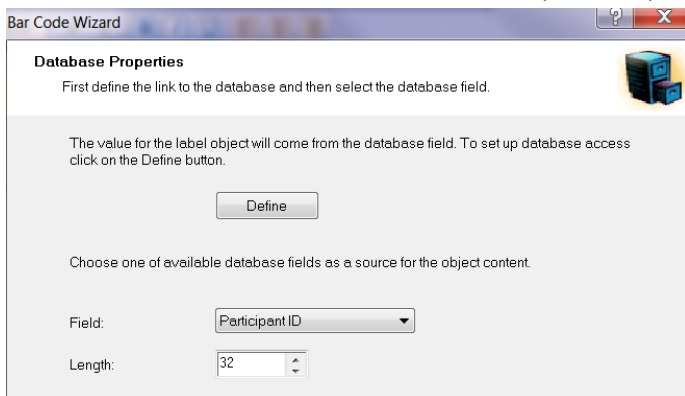
7.2.3.13 **Field Usage:** Select **“I will link the database fields to the objects myself later”**. Click **“Finish”**.



7.2.3.14 Once you click finish, you will be taken back to the label editing window. You are now ready to begin making labels. Click the downward facing arrow next to the word **“Text”** on the left side menu. Select **Fixed Text**.

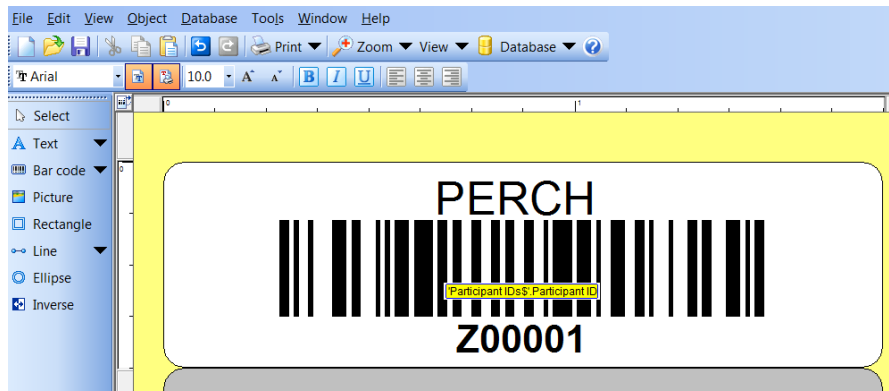
7.2.3.15 Your cursor will have an **“A”** attached to it. Click on the un-shaded white label in the upper left corner of your template. The text wizard box will appear. Type **“PERCH”** in the text box. Click Finish. The word PERCH will appear on the label. You can position and resize the text box later. You can also modify the font, size and style of the text using the toolbar above.

7.2.3.16 Click the downward facing arrow next to the word **“Bar code”** on the left side menu. Choose **“new database field”**. Your cursor will have a small barcode attached to it. Click on the label where you just entered the PERCH text field. The Bar Code Wizard box will appear. The field should say **“Participant ID”**. Click **Finish**.



7.2.3.17 A barcode image will now appear on your label. Using your cursor, resize the text box and the barcode field on the label until they both fit.

You now have both fields in your label – the PERCH study name, and the participant barcode with human-readable text at the bottom. Resize and reposition the items to your liking..



7.2.3.18 You are now ready to print. Go to file -> Print. The choices you selected in the database connection process will determine what appears in the print dialog box. If you selected “I want to print all records from the table” and “one field in the table contains the label quantity information” everything is automated at this point – just click print. If you did not select those options, you will have to manually select the records that you want to be printed.

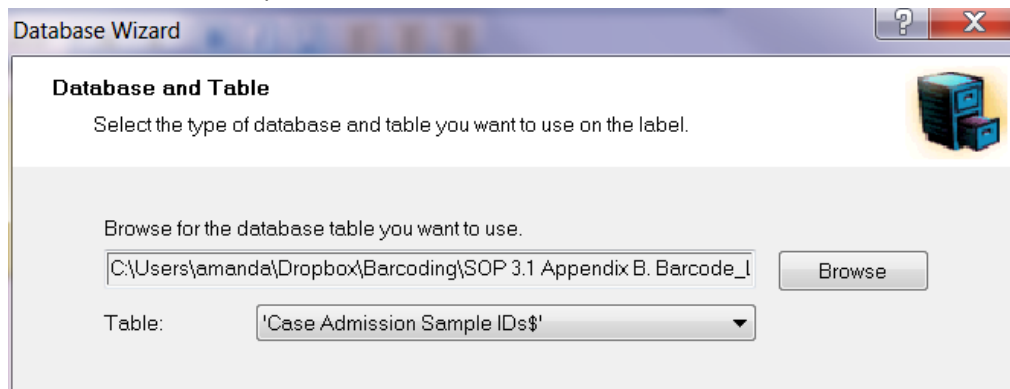
7.2.3.19 Print a test sheet of labels to make sure all of the text is aligned well within the label borders. Do a test with the barcode scanner to assure that the barcode can be read.

7.2.4 Create a sample ID label template in Nice Label

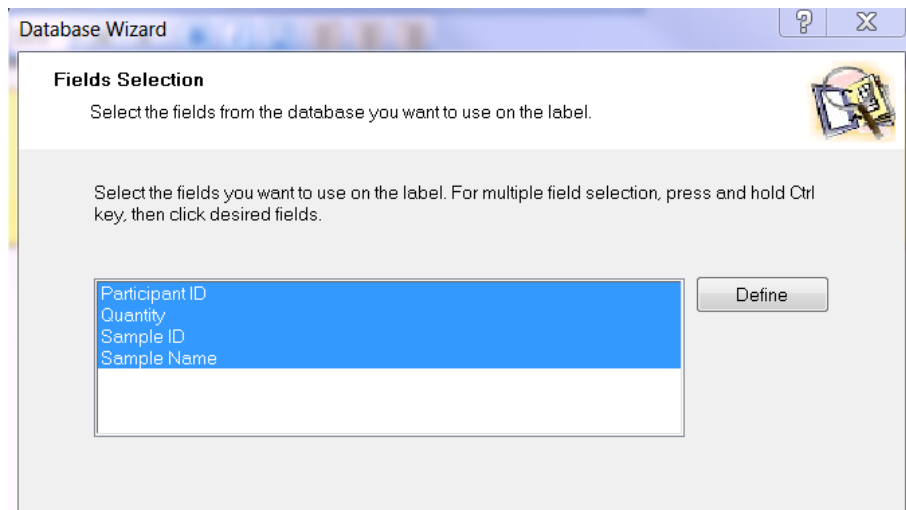
7.2.4.1 Repeat steps 7.2.3.1 through 7.2.3.7 above.

7.2.4.2 Go to the **Database** menu, and select “**Create Database Connection**”.

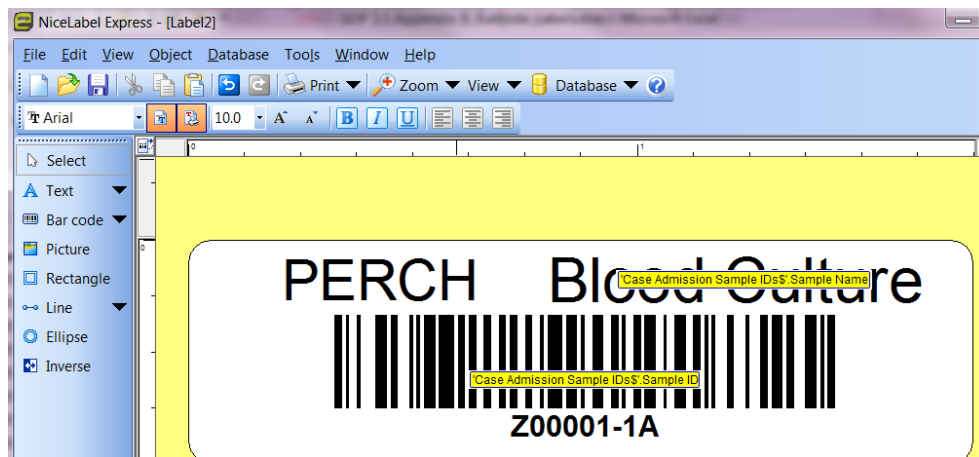
7.2.4.3 Browse for your barcode label ID database in the location where you saved it. The “Table;” dropdown menu will allow you to select the appropriate worksheet. In this case, select the “Case Admission Sample ID” worksheet.



7.2.4.4 **Field Selection Screen:** Select the Sample ID, Sample Name and Quantity variables. Do not select the participant ID variable.



- 7.2.4.5 **Records Printing:** (1) Select “I want to print all records from the table” (alternatively, you can go through the manual step of selecting which records to print – this is what to select in a situation where you only want to print a few labels for a participant rather than the whole set). (2) Select “One field in the table contains the label quantity information”.
- 7.2.4.6 **Quantity Information:** Select the field titled “Quantity” and click “Next”.
- 7.2.4.7 **Field Usage:** Select “I will link the database fields to the objects myself later”
- 7.2.4.8 Click “finish”.
- 7.2.4.9 Once you click finish, you will be taken back to the label editing window. You are now ready to begin making labels. Click the downward facing arrow next to the word “**Text**” on the left side menu. Select **Fixed Text**. Your cursor will have an “A” attached to it. Click on the un-shaded label in the upper left corner. The text wizard box will appear. Type “PERCH” in the text box. You can modify font style and size as you like. Click Finish. The word will appear on the label. You can position and resize the text box later. You can use the editing toolbar to change the font, style and size of the text.
- 7.2.4.10 Click the downward facing arrow next to the word “**Text**” on the left side menu once again. This time, select “new database field”. When you click on the label, the Text Wizard dialog box will pop up. Select the “Sample Name” field. Click next and then click finish. Ignore the prefix and suffix boxes. The sample name for the first record will appear on the label. You can position and resize the text box later. You can use the editing toolbar to change the font, style and size of the text.
- 7.2.4.11 Click the downward facing arrow next to the word “**Bar code**” on the left side menu. Choose “**new database field**”. Your cursor will have a small barcode attached to it. Click on the label where you just entered the PERCH text field. The Bar Code Wizard box will appear. The field should say “Sample ID”. Click **Finish**.
- 7.2.4.12 A barcode image will now appear on your label. Using your cursor, resize the text box and the barcode field on the label until they both fit.
- 7.2.4.13 You now have all three fields in your label – the PERCH study name, the sample type, and the sample barcode with human-readable text at the bottom. Resize and reposition the items to your liking.



7.2.4.14 You are now ready to print. Go to file -> Print. The choices you selected in the database connection process will determine what appears in the print dialog box. If you selected “I want to print all records from the table” and “one field in the table contains the label quantity information” everything is automated at this point – just click print. If you did not select those options, you will have to manually select the records that you want to be printed.

7.2.4.15 Print a test sheet of labels to make sure all of the text is aligned well within the label borders. Do a test with the barcode scanner to assure that the barcode can be read.

8. Quality Assurance / Quality Control

8.1 Each site should have a system in place to ensure that each participant ID is used only once. The EMMES data entry system will assist with this for sites using electronic data capture at enrollment (vs. paper CRFs). It will not allow the same ID to be entered for two different patients.

9. Record Management:

9.1 N/A

10. References:

10.1 SOP 3.0 PERCH ID Scheme

Appendix A. Downloading and Installing NiceLabel Express Software from the Internet

To use the ordered software edition, do the following:

1. Go to <http://www.nicelabel.com/Downloads/NiceLabel-Demo> and download a demo version of the NiceLabel software.
2. Install NiceLabel Express software on your desktop computer.
3. Activate the software: In the open ‘Manage License’ window, select the ‘Activate’ option and click on the ‘Next’ button.

Note: If you have closed NiceLabel after completing the installation, open NiceLabel again and click on the ‘Manage License’ button of the window prompt.

4. Follow the wizard.
5. When you have completed the activation process, register your NiceLabel version 5 software to receive automatic news updates and fast technical support services.
6. When you have completed the registration process, close and start NiceLabel software again.

Now you will be able to work with the full version of NiceLabel software!

To learn more about NiceLabel software, check the following links on our Web site:

www.nicelabel.com/downloads/dwld_manuals.php (NiceLabel Quick Start and User Guides)

www.nicelabel.com/support/support_tutorials.php (NiceLabel Tutorials)

Please read the following activation instructions prior to installing and registering NiceLabel software.

These editions of NiceLabel software are single seat licenses that are each protected by a unique serial number. This software is licensed to be installed on only one (1) PC at a time.

Installing the software on multiple PCs is a legal violation of the licensing agreement. Please see the NiceLabel CD for the software End user Licensing Agreement (EULA).

	► Standard Operating Procedure ◀
Section: Data Management	Version: FINAL Initials: AD
Title: 3.2 Creating Barcode Labels with FreezerPro Software	Revision Date: 07 Sep 2011

1. Definitions:

- 1.1 Cryolabels: Synthetic labels designed for bio-medical research tubes/vials. CryoLabels used for PERCH must exhibit permanent adhesion to polypropylene tubes and be able to withstand temperatures as low as -196° C. They must also be resistant to multiple freeze-thaw cycles.
- 1.2 FreezerPro: Specimen tracking software
- 1.3 Zebra GX430t Printer: 300dpi printer recommended for printing PERCH cryolabels
- 1.4 Participant ID: Unique identification code for a PERCH study participant, or anyone who is screened for enrollment in the study.
- 1.5 Sample ID: Unique identification code for a study sample

2. Purpose / Background:

- 2.1 To create barcode labeled cryolabels for stored/frozen samples. These cryolabels are designed to withstand long-term storage and extreme temperature conditions. They will allow PERCH samples to be used for future investigations on-site, or at collaborating laboratories. Barcoded labels are created to prevent transcription errors and to facilitate sample handling and management. The ID scheme used at each site should follow that described in SOP 3.0 PERCH Study IDs.

3. Scope / Applicability:

- 3.1 This SOP is applicable to all study sites that will use FreezerPro software to create cryovial barcode labels for PERCH study samples.

4. Roles / Responsibilities

- 4.1. *[Site specific]*

5. Prerequisites / Supplies Needed:

- 5.1 FreezerPro software
- 5.2 Thermal Transfer Label Printer such as the Zebra GX430t
- 5.3 Cryolabels such as the 0.88in x 1.75in (22.35mm x 44.45mm) ASTRO cryolabels provided by Partnered Print Solutions
- 5.4 Resin ribbon (Zebra 05095GS06407 or equivalent)

6. Safety/Risk Assessment:

6.1 N/A

7. Procedural Steps

7.1 Software Installation:

FreezerPro software must be installed on a networked server in order to be accessed from multiple computers. This installation process requires a free application called “VMware player”.

For help installing the software, please visit

http://www.ruro.com/support/installation/vm_player.html

For additional help, please contact support@ruro.com

Note: If you assign your copy of FreezerPro a visible IP address, anyone with the IP address and a password for your FreezerPro software may view your stored samples (e.g. an off-site investigator)

7.2 Printer Set up and Installation:

Please follow the instructions enclosed with your Zebra GX430t printer, or refer to **Appendix A**, the Zebra printer manual (Also available on their [website](#)) to set up your printer. After installing the labels and ribbon, your printer should look like this:



7.2 Network Configurations:

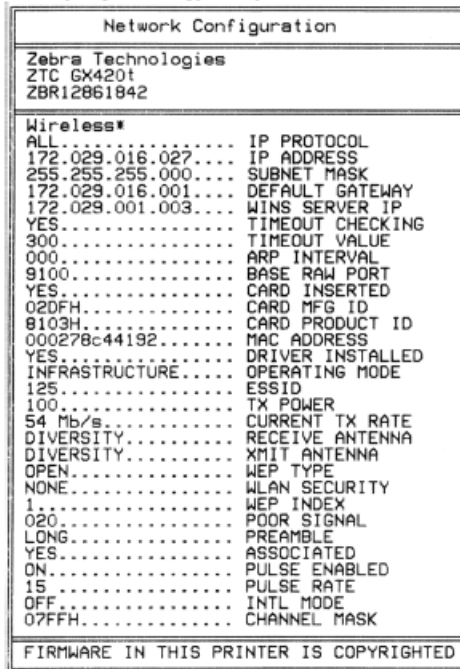
To work with FreezerPro, the printer should be connected with an Ethernet cable to the network (it should not be connected directly to the PC with the USB connector). When connected to the network, the printer will automatically pull an IP address. To see what IP address is being pulled, push down the feed button on top of the printer until a green light flashes once. The printer will print the network configurations, including the IP address.

- *If the ink is too faint to read, push the feed button on top of the printer until it flashes 6 times, then release. It will print labels in incrementally darker shades. When it reaches the desired darkness, press the feed button on top of the printer once. The print darkness is now set. Try to print the network settings again.*
- *If the network information is printing off the label, push the feed button on top of the printer until it flashes 5 times. It will print an image in increasing sizes. When it reaches the desired size, press the button on top of the printer once. Try to print the network settings again.*

According to the manual, the full network configuration manual will look like this:

Printer Network Configuration Status Label

G-Series™ printers with the ZebraNet® Internal Wireless Print Server option on-board print an additional printer configuration status label for information needed to establish and trouble shoot network printing. The following printout is printed with the ZPL ~WL command.



The regular printout of the configuration status label has some of the printer's network settings

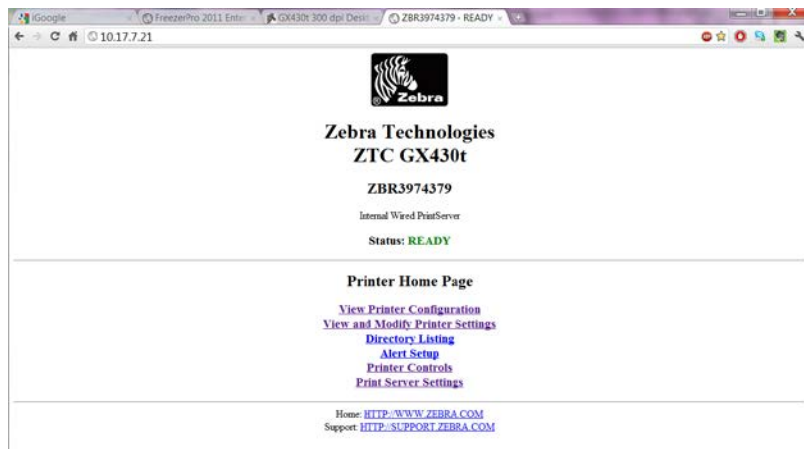
However, with ASTRO labels loaded in the printer, you may get an image that looks like this:

```
Network Co
Zebra Technologies
ZTC GX430t
ZBR3974379

Internal Wireds
All .....
010.017.007.021
255.255.255.000
010.017.007.001
010.015.070.074
YES .....
300 .....
900 .....
9100 .....
00074d3cafeb
```

The IP address can be found here: in this case, it's 010.017.007.021

7.2.1 Once you have the IP address for the printer, enter it into your web browser. You should see a screen that looks like this:



7.2.2. Click “View and Modify Printer Settings”. It will ask for a password. The password is “1234”.

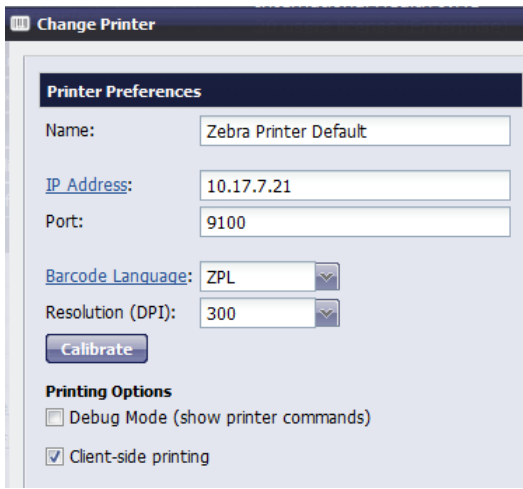
7.2.3. Click the “Access Granted” link, and then Click “View and modify printer settings”. Under “General set up”, make sure Darkness is set somewhere between 24.0 and 28.0, and speed is set at 2 IPS (the lowest speed). Print mode should be “tear off”. Under “Media Setup”, make sure the media type is non-continuous, the sensor type is “mark”, print method is “thermal transfer”, print width is 288, and maximum length is 11700.

7.3 Configuring the printer in FreezerPro

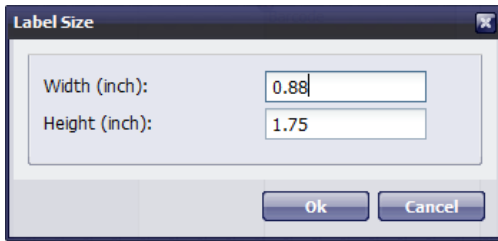
7.3.1 Enter your FreezerPro address in your web browser and log in to the software.

7.3.2. Expand the “System Preferences” menu on the left side of the console. Double click on “Barcode Printers”. There should be a default printer already entered into the system. Click the edit button to edit the settings of this default printer. (Note: you will have to individually set up each printer that you wish to sync with FreezerPro. E.g. if you have one FreezerPro license but are using two printers, each will have to be set up individually within the software).

7.3.3. Edit the printer settings as shown below, using the appropriate IP address. Port 9100 must always be selected, and always make sure to select the “client side printing” option. Then click the “calibrate” button.



7.3.4 You will need to edit the label size. On the label template, click “edit label”, click the label size link, and enter the following dimensions:



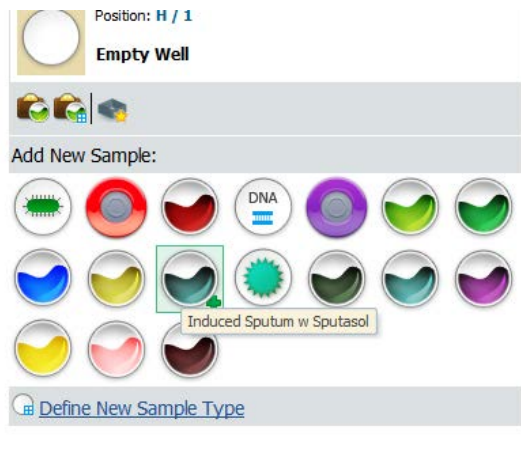
7.3.5. Print a test label. Don’t worry about editing the label template for now – you can use the default template as a test to see if the printer is working. Note: you may need to change the top offset and left off set settings to see an image on the label.

At this point, if you have followed all of the instructions above and the label is still not printing, contact support@ruro.com

7.4 Customizing FreezerPro for PERCH

7.4.1. Customize Sample Types: When adding a sample to a box in FreezerPro, you must select a sample type. It is recommended to disable the default sample types that do not apply to PERCH, and to create new sample type that correspond to the samples you will be storing for PERCH.

- To disable sample types, you must first create a freezer and a box. This can be a dummy freezer/box that you delete later. Open the box and click on a well. To the right, you will see the default sample type icons. If you right-click on the sample type icon, you can click “disable sample type” and it will disappear (These are not gone forever – they can be “re-enabled” using the settings and preferences menu).
- To create new sample types, click the “define new sample type” option. Enter the name of the sample type and select an icon to correspond to it. See example below, customized for PERCH sample types. The name of the sample type appears when you hover the mouse over the icon:



- Suggested sample types to create include the following (from SOP 3.0 Appendix A):
 - Serum
 - ETT w Sputasol (*Thailand and S. Africa only*)
 - Blood Clot
 - Urine
 - EDTA aliquot
 - Bacterial isolate
 - STGG
 - Mycobacterial isolate
 - STGG-THY
 - Extracted NA
 - VTM
 - Pleural Fluid
 - Induced Sputum
 - Lung Aspirate (*Bangaldesh, South Africa, only*)
 - Induced Sputum w Sputasol
 - ETT (*Thailand and S. Africa only*)

Note: It is up to each site to decide how to handle this. If you create customized sample types for PERCH as shown in the example above, you are essentially creating a standardized drop down menu of sample types for the user to choose from. As an alternative, you could create one new sample type, e.g. “PERCH sample” to be used every time a new sample is entered, and users can enter text into the “description” field when they enter the rest of the data for that sample. This may or may not be an easier approach.

7.4.2 Create a Date Field

- In the settings and preferences menu, create a new user-defined field for the “date”. This will be the date of collection for stored specimen aliquots, the date of extraction for extracted NA, and the date of storage for an isolate. ***Note: When you create the field, create it as a text field rather than a date field. A date field will provide a convenient calendar for you to select the date from, but will appear as 9/7/11 rather than 7Sep11, which is the notation required for the study.** When setting up the variable, you can use enter DDMMYY as help text to remind users of the date format.
- Link the date field to the sample type (Go to sample type → Properties, click the user-defined field, tab, search for your date field, check the box, click the “add” button, and select “Yes” under required field. Finally, save). Do this for each available sample type that will be used for PERCH.

7.4.3 Create Isolate Code Field

- In the settings and preferences menu, create a new user-defined field for the “isolate code”. This will be organism code for all stored isolates, per the PERCH organism dictionary.
- Link the isolate code field to the sample type (Go to sample type → Properties, click the user-defined field, tab, search for your isolate code field, check the box, and click the “add” button. Do not make this field “required”. Finally, save). Do this for each available sample type that will be used for PERCH.

7.5 Entering new samples into FreezerPro:

Enter data into the following fields for all PERCH samples entered into FreezerPro. In addition, enter any other information that is deemed useful by your site.

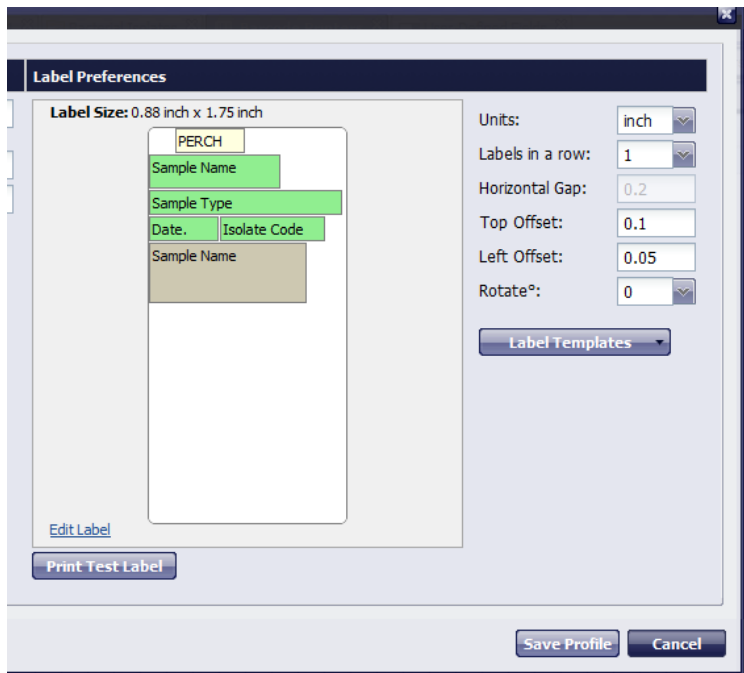
1. **Sample Name** – This is a required field for all new samples. **Enter the PERCH sample ID here**, e.g. Z00001-11. To enter, scan a barcode with the participant ID into the data entry field, and then modify the last two digits to correspond with the sample ID code for the same you are storing (Reference SOP 3.0).
2. **Description** – Enter the sample type only if you have not already pre-defined the sample types for PERCH as described in section 7.4.1 above.
3. **Isolate code**- For isolates, enter the 4 letter organism code here
4. **Date** - Enter the date in the user defined date field (as created in 7.4.2 above).
5. May sites may want to enter sample volume – however, this is optional.

7.6 Creating a barcode template for PERCH

- 7.6.1. Select barcode printers from the settings and preferences menu.
- 7.6.2. Select 'edit settings' for the Zebra printer
- 7.6.3. After you've confirmed that your printer can print a test label, you are ready to create a PERCH specific label template. (Make sure the label dimensions are set at 0.88in x 1.75 in / 22.35mm x 44.45mm.)
- 7.6.4. Click "edit label". Delete any existing fields on the label.
- 7.6.5. Click "add field" and select "static text". Type 'PERCH' in the text field and align it with the top of the label (you may want to center it a bit rather than having it flush with the left side of the label since the label is slightly curved on the upper left corner).
- 7.6.5. Click "add field" and select "text field". From the drop down menu, select "sample name". Place the text box under the PERCH text box (flush with the left side of the label).
- 7.6.6. Click "add field" and select "text field". From the drop down menu, select "sample type". Place the text box under the PERCH text box.
- 7.6.7. Click "add field" and select "text field". From the drop down menu, select "isolate code". Place the text box under the PERCH text box.
- 7.6.7. Click "add field" and select "text field". From the drop down menu, select "date". Place the text box under or next to the date text box.
- 7.6.8. Click "add field" and select "linear barcode". From the drop down menu, select "Sample name". Select "code 128" as the type and "1" as the module. A grey text box will appear – position under the date field.

7.6.9 Print a test label – *you'll likely have to adjust the top offset and left offset settings and the text box sizes to get everything to fit nicely on the label.*

Example:



7.7 Printing a barcode label for a stored sample

7.7.1 Select the sample that you wish to print a label for. Click the barcode icon on the right hand side of the screen. A dialog box will pop up asking if you want to “Print 1 barcode?”. Click yes and the barcode label will print.

Note: FreezerPro will print from the printer that is assigned to you in the user preferences settings. If you want to change the printer that FreezerPro prints from, use the drop down menu in your user preference settings to do so.

You should end up with a barcode label that looks like this:



Appendices:

A. Zebra GX430t manual

B. FreezerPro 2011 User Guide