

PROJECT COVERED ALL SITE CHECK IN

May 7, 2020; 8am PT

Join Zoom Meeting

<https://us02web.zoom.us/j/81028850085?pwd=V0h2WlhRZlBHK2FWZGIVYmpPbk5dz09>

Meeting ID: 810 2885 0085

Password: 653243

Dial by your location

- +1 669 900 6833 US (San Jose)
- +1 408 638 0968 US (San Jose)
- +1 346 248 7799 US (Houston)
- +1 253 215 8782 US (Tacoma)
- +1 301 715 8592 US (Germantown)
- +1 312 626 6799 US (Chicago)
- +1 646 876 9923 US (New York)

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Agenda

- ◇ Welcome – Nick
- ◇ Specimen Collection and Handling Training – Kavitha
- ◇ Project Updates – Anusha
- ◇ Site Launch Steps - Anusha
- ◇ Questions

Project Update

- ◆ IRB signed off – 20/20
- ◆ Subcontracts – 9/20
- ◆ Site Readiness Calls – 19/20
- ◆ Laboratory Supplies - Expect 4 shipments plus an email with FedEx labels
 1. ARUP lab – Going out Monday 5/11
 2. Labels – Shipped yesterday and today
 3. Therapak Shipping boxes – Shipped today
 4. Absorbent pads – Mailed by Kavitha
 5. FedEx Labels are EMAILED by Kavitha
- ◆ REDCap Access

Checklist - Site Launch

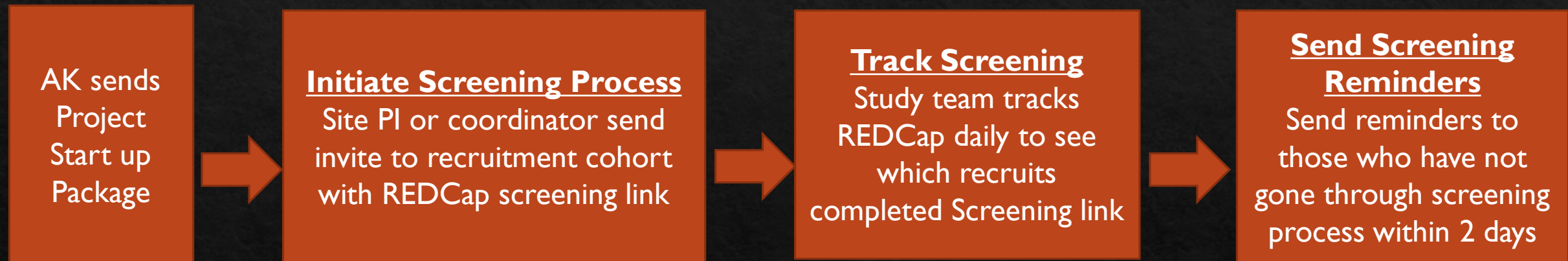
- ☐ Lab and shipping supplies received (or on their way)
- ☐ Names and emails of recruitment cohort
- ☐ Set up for initial blood draws/swabs
- ☐ Set up for blood and swab processing and storage
- ☐ Ready to track intubations and cardiac arrests daily
- ☐ REDCap Access confirmed for all staff – ready for daily tracking
- ☐ REDCap Training completed
- ☐ Subcontract fully executed



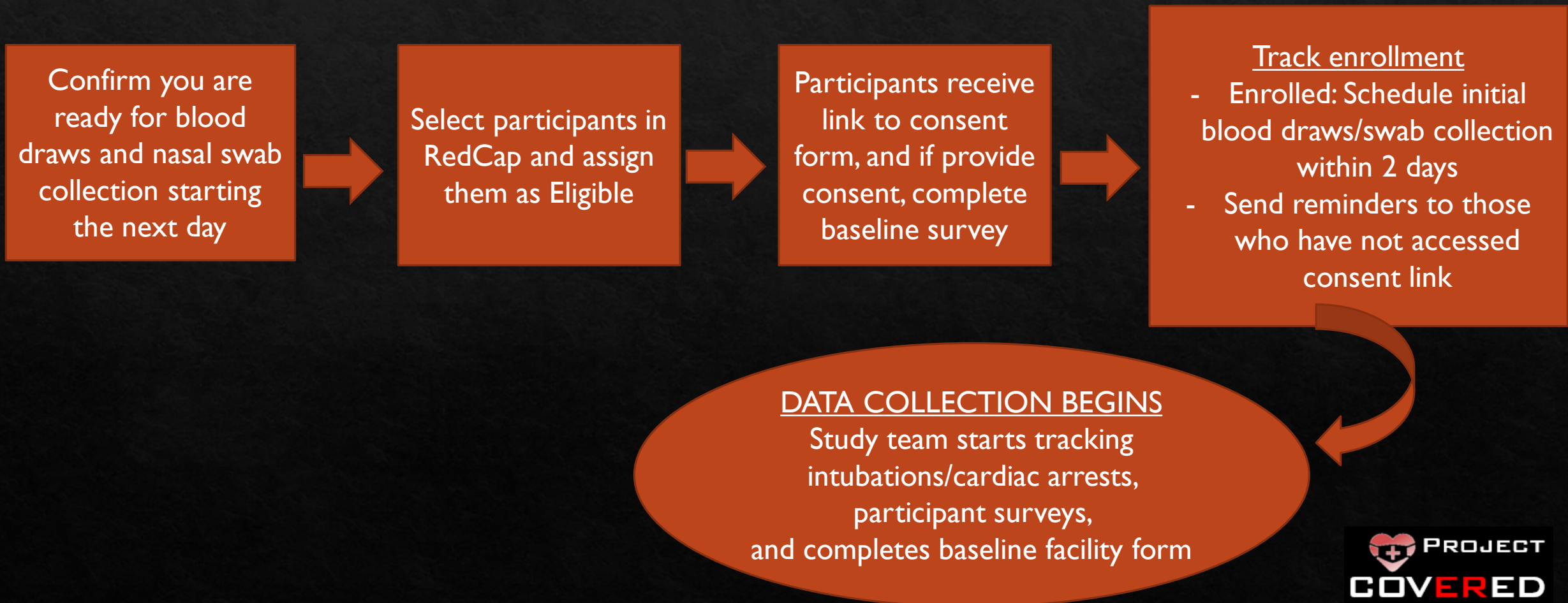
Ready to launch?

- ◆ Project Start up Package – Sent by Anusha to Site PI and study team
 - 1. Email invitation with site-specific screening link
 - 2. Participant fee schedule
 - 3. ARUP requisition order form
 - 4. Participant Letter describing testing and results
 - 5. Generic press release

Screening Process



Enrollment Process



www.covered-study.org

The screenshot shows a web browser window with the URL medicine.uiowa.edu/content/research-tools. The page has a navigation sidebar on the left and a main content area on the right.

Navigation Sidebar:

- COVERED STUDY**
 - Home
 - About the Project
 - Study Overview
 - Participating Sites
 - Study Team
 - Contact Us
 - Research Tools and FAQ
 - FAQ
 - Research Tools

Main Content Area:

Research Tools

Documents to download (pdfs)

- [Site Readiness Checklist](#)
- [Manual of Procedures](#)
- [Laboratory Procedures](#)
- [Study Proposal](#)
- [Human Subjects Research Determination](#)
- [Authorship Policy](#)
- [Data Sharing Policy](#)
- [COVERED Kickoff Call](#)
- [REDCap Data Procedures and Training Slides](#)

Other research links

- [Electronic Case Report Forms Login](#)

Videos

Taskbar: The Windows taskbar at the bottom shows several open files: "COVERED Agmt #....pdf", "TestResultsInterp....docx", "RedCap Training....docx", and "utsw-dhhs-rate-ag....pdf". The system clock indicates 3:15 PM on 5/6/2020.

Questions?

- ◆ Study email: emergencyidnet-covered@uiowa.edu
- ◆ Rescheduling next week's All Site check in to one hour earlier.

Specimen Collection & Shipment



Outline

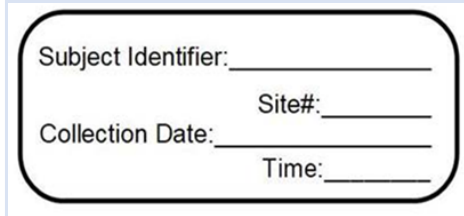
- Supplies Checklist
- Subject Identifier List
- Blood
 - Collection
 - Processing
 - Storage
- Nasal Swab Collection
 - Collection
 - Storage
- Auto Order Requisition Spreadsheet
- Shipping



Supplies Checklist



5mL gold top SST tubes
Not Provided



Specimen Labels
From: Electronic Imaging Materials



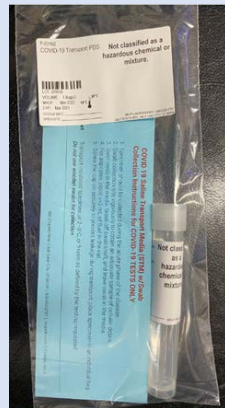
Absorbent Sheets
From: Olive View-UCLA



Frozen shippers w/labels
From: Therapak



4mL Transport Tubes
From: ARUP Lab



Nasal Swabs
From: ARUP Lab



Specimen Racks
From: ARUP Lab



Specimen bags
From: ARUP Lab

Subject Identifier List

Participant Last Name

Participant First Name

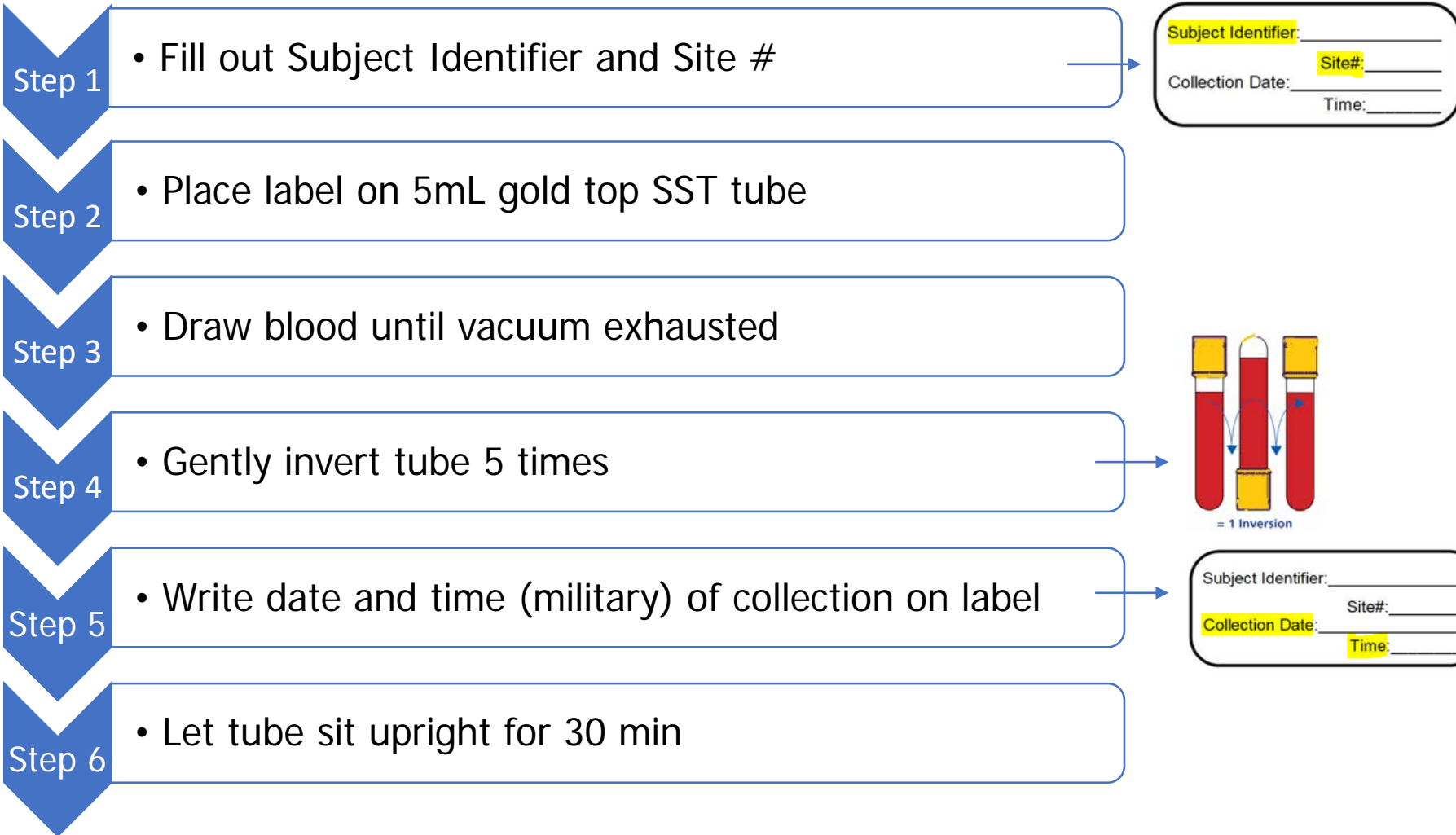
Subject Identifier (4 digits)

Arm 1: Participant		Arm 2: Facility
Record ID	Screening	Eligibility
	Participant Interest Screening Form	Eligibility
103 Jones	✓	●
104 Jackson	✓	●
105 Kid	✓	●
106 James	✓	●



Subject ID	Last Name	First Name	Survey Completed	Initial Blood Draw Date
0103	Jones	Tommy Lee	5-May-2020	7-May-2020
0104	Jackson	Michael	5-May-2020	7-May-2020
0105	Kid	Rock	6-Mar-2020	8-May-2020
0106	James	Lebron	6-May-2020	9-May-2020

Blood Collection



Blood Processing

Step 1

- Centrifuge within 90 min of collection
- ~ 10 min

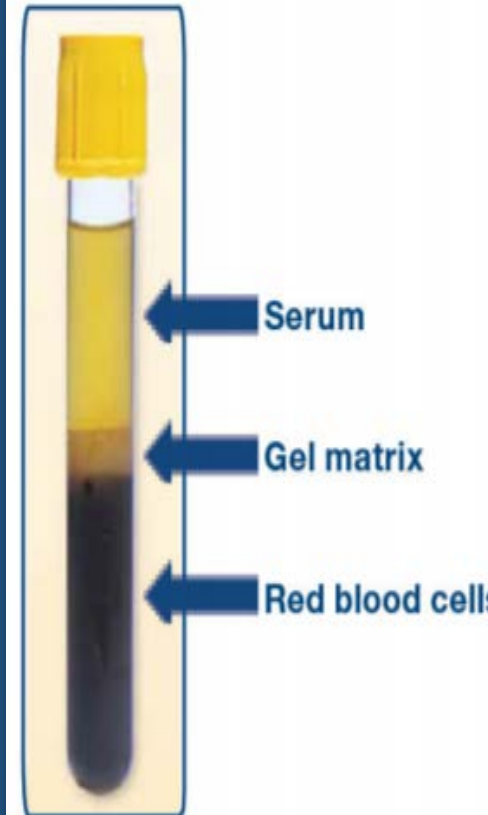
Step 2

- Fill out label and place on 4mL transfer tube
- Military Time

Subject Identifier: _____
Site#: _____
Collection Date: _____
Time: _____

Step 3

- Use pipette to transfer serum to tube



Serum Storage

Best option: store in -20°C or -70°C freezer no more than 1 month

2nd option: store in $2-6^{\circ}\text{C}$ fridge no more than 2 weeks

Note: serum may be left ambient for 24 hrs max from transfer time



Serum
Tubes



Nasal
Swabs



Nasal Swab Collection

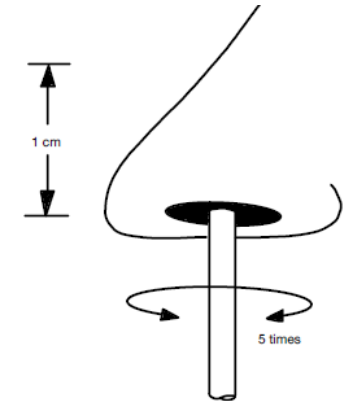
- Step 1
 - Fill out label with all information
 - Military Time
- Step 2
 - Open nasal swab kit and remove transport media tube
- Step 3
 - Place completed label on transport media tube
- Step 4
 - Hand the swab over to participant
- Step 5
 - Ask participant to insert swab $\frac{1}{2}$ -1" straight up into R nare. Resistance will be met at the turbinates
- Step 6
 - Ask participant to rotate swab several times against nasal wall
- Step 7
 - Ask participant to repeat Step 5 and 6 with same swab in L nare.
- Step 8
 - Ask participant to remove swab from nare and place in transport tube and swirl in media a few times
- Step 9
 - Ask participant to break off swab shaft at designated marking and screw the cap on securely

Subject Identifier: _____

Site#: _____

Collection Date: _____

Time: _____



Nasal Swab Storage

Immediately after collection place specimen in ice or wrapped in cold pack. Cannot be left Ambient!

Best option: store in -20°C or -70°C freezer no more than 1 month

2nd option: store in $2-6^{\circ}\text{C}$ fridge no more than 2 DAYS



Serum
Tubes



Nasal
Swabs



Order Requisition Form

- Needs to be completed prior to shipping
- You will receive 2 excel spreadsheets
 - 1) List nasal swabs being shipped
 - 2) List serum transport tubes being shipped
- Excel spreadsheet made up of 3 parts
 - 1) Client Tab – **Do Not Change Anything**
 - 2) Patient Tab
 - 3) Hardcopy Creator – **Do Not Change Anything**



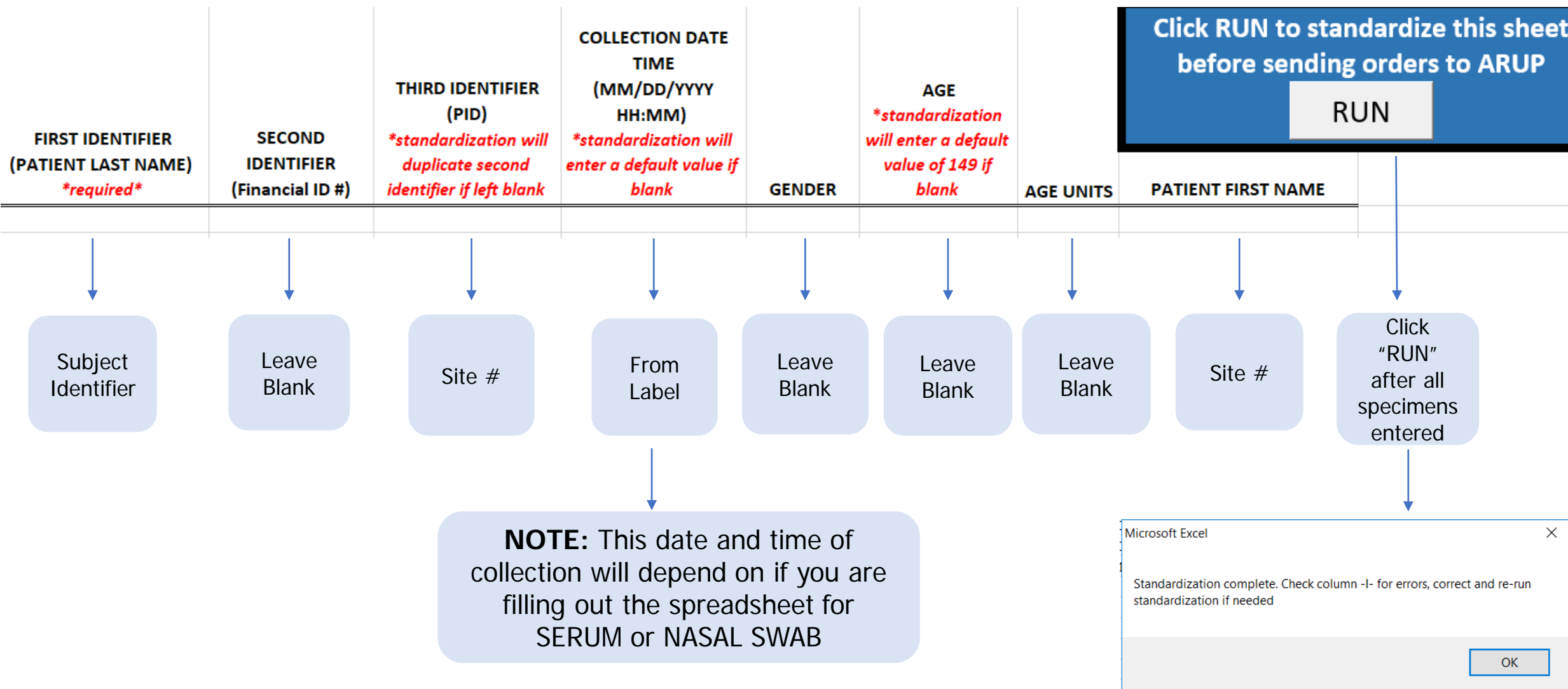
Order Requisition – Client Tab

Will be pre-populated by ARUP Lab

Do Not Change Any Information

CLIENT NAME:		<div>Click RUN to standardize this sheet before sending orders to ARUP</div> <div>RUN</div>
ARUP CLIENT NUMBER:		
SPECIMEN TYPE:	SERUM	
ARUP SPECIMEN TYPE:	SER	
SPECIMEN TEMPERATURE:		ARUP Special Instructions (ALT+ENTER for line return)
IS ARUP STANDARD TUBE:		
WRAP LABEL:		
DISCLAIMER REQUIRED?:		
ARUP TEST NUMBER	ARUP TEST NAME	
	Note:	
	ARUP will pre-populate this entire tab with project specific information.	
	The only tab you will need to supply information on is the "Patients" tab	

Order Requisition – Patient Tab



Example – Serum Patient Tab



Serum Tubes from Freezer

Subject Identifier: 0103
 Site#: 7346
 Collection Date: 05/07/2020
 Time: 07:30

Subject Identifier: 0104
 Site#: 7346
 Collection Date: 05/07/2020
 Time: 08:00

Subject Identifier: 0105
 Site#: 7346
 Collection Date: 05/08/2020
 Time: 14:15

Click RUN to standardize this sheet before sending orders to ARUP							
FIRST IDENTIFIER (PATIENT LAST NAME) <i>*required*</i>	SECOND IDENTIFIER (Financial ID #)	THIRD IDENTIFIER (PID) <i>*standardization will duplicate second identifier if left blank*</i>	COLLECTION DATE TIME (MM/DD/YYYY HH:MM) <i>*standardization will enter a default value if blank*</i>	GENDER	AGE <i>*standardization will enter a default value of 149 if blank*</i>	AGE UNITS	PATIENT FIRST NAME
0103		7346	05/07/2020 07:30				7346
0104		7346	05/07/2020 08:00				7346
0105		7346	05/08/2020 14:15				7346

RUN

Example – Serum Hardcopy Creator Tab

Print this page and provide with shipment

Do Not Change Any Information

Client Name	/		ARUP AUTO ORDERING - DO NOT ORDER MANUALLY			
Client Number						
Test Name(s)	/Note:	/ARUP will pre-populate this entire tab		/with project specific information.		
Test Number(s)	/The only tab you will need to supply	/information on is the "Patients" tab		/		
-						
ARUP Special Instructions (ALT+ENTER for line return)						
FOR ARUP SP ONLY	Last Name, First Name	FIN #	PID #	DDT	GENDER	AGE
	0103, 7346		7346	5/7/20 7:30		149-Y
	0104, 7346		7346	5/7/20 8:00		149-Y
	0105, 7346		7346	5/8/20 14:15		149-Y

Age will default to "149-Y"

Email Order Requisition

Save the Order Requisition Excel Spreadsheets.

One file for Serum Tubes and separate file for Nasal Swabs.

Email these files to ARUP Laboratories and DCC on day of shipment.

Email Subject: COVERED Project Shipment Site <insert site #>

Include FedEx Tracking Number in email

ARUP Laboratories Emails:

Marcie.Traballoni@aruplab.com

Kelsey.Lynch@aruplab.com

DCC Email:

Emergencyidnet-covered@uiowa.edu



Shipping



Each rack should have all Nasal Swabs or Serum Tubes.

The specimens should be placed to match the chronological order shown on Requisition Form.

NOTE: Specimens should have been frozen for 5 hrs before shipping



Place one rack in specimen bag
On the bag fill out the following:

Date of shipment
Client # = 389700
Specimen Count

Tear off top portion for your records.



Place 1 absorbent sheet in the bag



Client Name		ARUP AUTO ORDERING - DO NOT ORDER MANUALLY				
/						
Test Name(s)	Photo		ARUP will not process this entire tab		ARUP cannot provide information	
Test Number(s)	If the only tab you will need to supply		ARUP cannot provide information on this "Patient's" tab			
ARUP Special Instructions (ALPHA CENTER for line return)						
FOR ARUP ID ONLY						
Last Name, First Name		File #	File #	DOB	GENDER	AGE
0000, 7346			7346	5/1/00 7:50	1495 N	
0000, 7346			7346	5/1/00 8:00	1495 N	
0000, 7346			7346	5/1/00 14:15	1495 N	

Print out list of specimens, and highlight the specific specimens in that bag.

Place print out of Requisition Form with highlighted list in the outside pouch of bag.

Do Not Place Inside with Specimens

Shipping



Place bags with specimen racks inside insulated shipper box.

Styrofoam insert:
12" x 10" x 9"

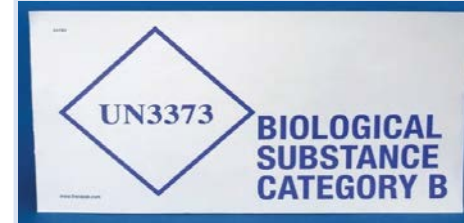
Can fit 8 bags along bottom of box



Add minimum 15 lbs and maximum 20 lbs of dry ice pellets.

Make sure all specimens are covered with dry ice.

Close box and seal securely with packing tape.



On outside of box, any side, place the "UN3373 Biological Substance Category B" sticker



On same side, place the "DRY ICE UN1845" Sticker

Shipping – Dry Ice UN1845 Sticker

Amount of Dry Ice in kilograms

2 lbs = 1kg

Update FedEx Label with Amount of Dry Ice

Shipper's Name and Address

Shipper's Declaration not Required. Part B is required. Dry Ice amount must be in kilograms. Note: 2 lbs. = 1 kg.

Airwaybills/Airbills must have the following:

1. "Dangerous Goods - Shipper's Declaration not required".
2. Dry Ice: 9; UN1845;
3. _____ x _____ kg
(Number pkgs) (wt)

DRY ICE
_____ kg.

Shipper's Name and Address

9

UN1845

Consignee Name and Address

_____ x _____ kg
(# of pkgs) x (wt in kg)

Consignee Name and Address:

ARUP Laboratories
Attn: Specimen/CTSM
500 Chipeta Way
Salt Lake City, UT 84108

Shipping - FedEx

A set of 10 FedEx Priority Overnight labels each month will be emailed to the address provided. Labels will indicate shipping with Dry Ice.

Must print all 10 labels within 24 hours of receipt otherwise will not be able to use

Once labels are printed they are valid for 30 days

Shipments to ARUP Laboratories should go out 2x/wk on any day between Sunday-Thursday



Questions?

