CENETRON

SPONSOR: MASSACHUSETTS GENERAL HOSPITAL
PETAL CLINICAL COORDINATING CENTER

PROTOCOL: **Acetaminophen in Sepsis: Targeted Therapy to Enhance Recovery**
(ASTER)

Laboratory Manual Version 2.2

11 AUG 2022

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1.0 CENETRON PERSONNEL AND CONTACT INFORMATION

Medical Director:
Matt Anderson, MD
Cenetron Diagnostics
2111 West Braker Lane
Suite 300
Austin, Texas 78758

Primary Study Contact:
JoyHardcaslte@cenetron.com
+1 512-439-2000 ext 264
+1 888-834-6632
+1 512-439-5006 (Fax)

If you have questions pertaining to specimen collection, transport, test results, or ordering supplies, please contact the appropriate department at Cenetron Diagnostics directly:

Clinical Trials	**Kits and Collection Supplies**	**Project Management**
clinicaltrials@cenetron.com	kits@cenetron.com	projectmanagement@cenetron.com
+1 512-439-2000 Option 2	+1 512-439-2000 Option 3	+1 512-439-2000
+1 888-834-6632 Option 2	+1 888-834-6632 Option 3	+1 888-834-6632
+1 512-439-5006 (Fax)	+1 512-439-5000 (Fax)	+1 512-439-5006 (fax)

Please be aware that the hours of service are Monday through Friday, 8:00 am until 5:00 pm Central Time (USA). **If an emergency situation should arise outside of our normal business hours, please call Cenetron Diagnostics at +1 888-520-2045 or +1 512 431 0725 and someone will assist you.**

For protocol-specific questions, please contact the PETAL Clinical Coordinating Center:

Nancy Ringwood, RN	Katie Oldmixon, RN
nringwood@mgh.harvard.edu	coldmixon@mgh.harvard.edu
617.724.9836	617.726.4447

For FedEx please contact:

FedEx: +1 800 GO FEDEX or +1 800.463.3339

2.0 LABORATORY TESTING SCHEDULE

Samples	Day 0 (Baseline)	Day 2	Day 3
Plasma (EDTA)	X	X	X
Whole Blood (RNA)	X		X
Whole Blood (DNA)	X		X
Urine	X	X	X

Sample Types	Day 0 (Baseline)	Day 2	Day 3
Cell Free Hemoglobin	X	X	X
Biomarkers for 2° Outcomes	X	X	X
Acetaminophen Levels		X	
Plasma for Banking	X	X	X
DNA	X		X
RNA	X		X
Urine	X	X	X

3.0 RECEIVING SUPPLIES

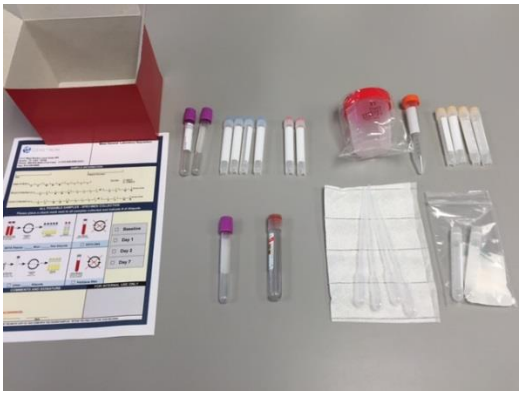
3.1 Collection Kits and Materials to Site

Cenetron will provide you with the necessary sample collection materials, processing and storage instructions, shipping forms and courier information for ASTER samples.

The use of the supplied materials for ASTER sampling is mandatory. For any questions related to sampling, handling, storage or shipping please contact Nancy Ringwood at the PETAL CCC.

The following kits will be supplied:

- Day 0 or Day 3
- Day 2



Please note: Each kit box contains all the sample collection materials needed for the patient for the timepoint.

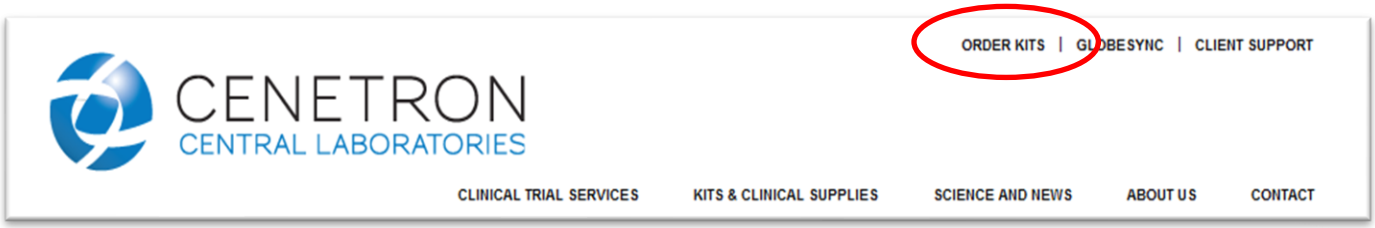
Kits will contain the required prelabeled collection tubes, prelabeled transfer vials, lab requisition, and other required materials. To replace damaged tubes, and to provide substitutes for unexpected events, each site will be provided with bulk supplies of collection tubes and transfer vials. Supplies required for universal precautions during sample collection, must be worn at all times and are the responsibility of the site to provide.

Each individual kit will arrive with labels indicating the expiration date. **Please verify the date before opening the Specimen Collection Kits to maintain the testing integrity of the supplies inside**. If you encounter any expired Specimen Collection Kits, please discard and order more kits as required. Should you have any questions concerning the expiration date of the kits, please do not hesitate to contact us.

All collection tubes provided by Cenetron must be stored at room temperature (15–25°C).

3.2 Additional Kits and Supplies

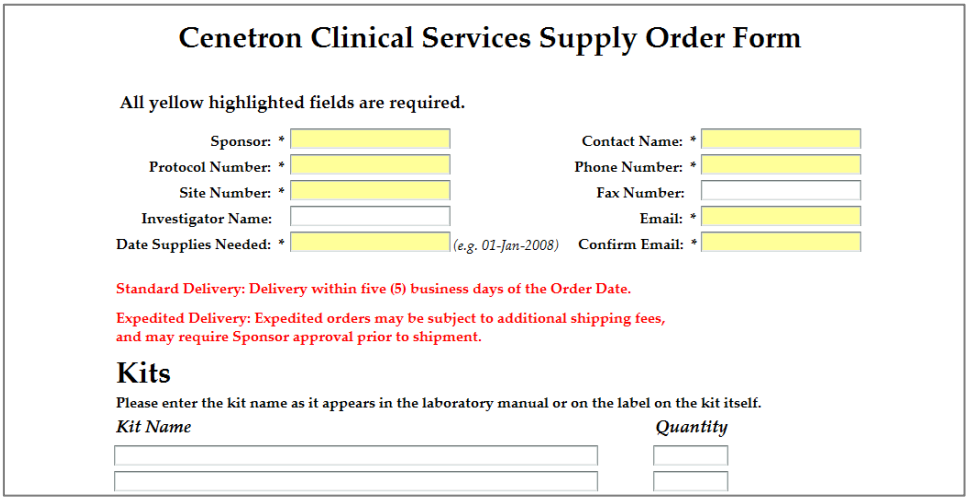
For additional kits or supplies, please notify Cenetron Clinical Supplies by completing a Laboratory Supply Request Form and faxing it to Cenetron Diagnostics at 512-439-5000 or by email at kits@cenetron.com. In addition, you may request supplies by visiting the Cenetron website (www.cenetron.com) and clicking the link at the top of the page for "**Order Kits**".



Please ensure all highlighted fields are completed.

- **A date is required in the "Date Supplies Needed" field. Please do not enter ASAP.**
- Sponsor: Enter "PETAL CCC"
- Protocol Number: Will be the study you are ordering for (i.e., ASTER and/or CLOVERS)
- There are two sizes of shippers provided by Cenetron for this study: Medium and Large
  - Medium shippers can appropriately hold up to 100 samples, or 6 visits worth.
  - Large shippers can hold as many as 190 samples, or 12 visits worth.
- Please consider how many sample shipments you will need to make, as well as how many samples you will be sending at once, when ordering kits and frozen shippers.

Once the order is submitted, an email will be sent to the email entered indicating receipt of the order. Within one business day, you will also receive a confirmation email with the approximate shipping and delivery date.



Cenetron Clinical Services Supply Order Form

All yellow highlighted fields are required.

Sponsor: *		Contact Name: *	
Protocol Number: *		Phone Number: *	
Site Number: *		Fax Number:	
Investigator Name:		Email: *	
Date Supplies Needed: *	(e.g. 01-Jan-2008)	Confirm Email: *	

Standard Delivery: Delivery within five (5) business days of the Order Date.

Expedited Delivery: Expedited orders may be subject to additional shipping fees, and may require Sponsor approval prior to shipment.

Kits

Please enter the kit name as it appears in the laboratory manual or on the label on the kit itself.

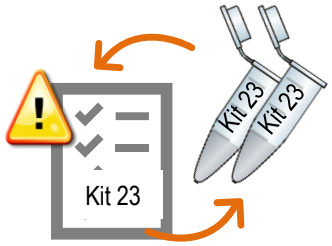
Kit Name	*Quantity*

Supply requests will have a two week turnaround time.

Exceptions will be made for **emergency requests received prior to 12:00 noon** Central Time (USA). All emergency requests received after 12:00 noon will be shipped out the next regular business day.

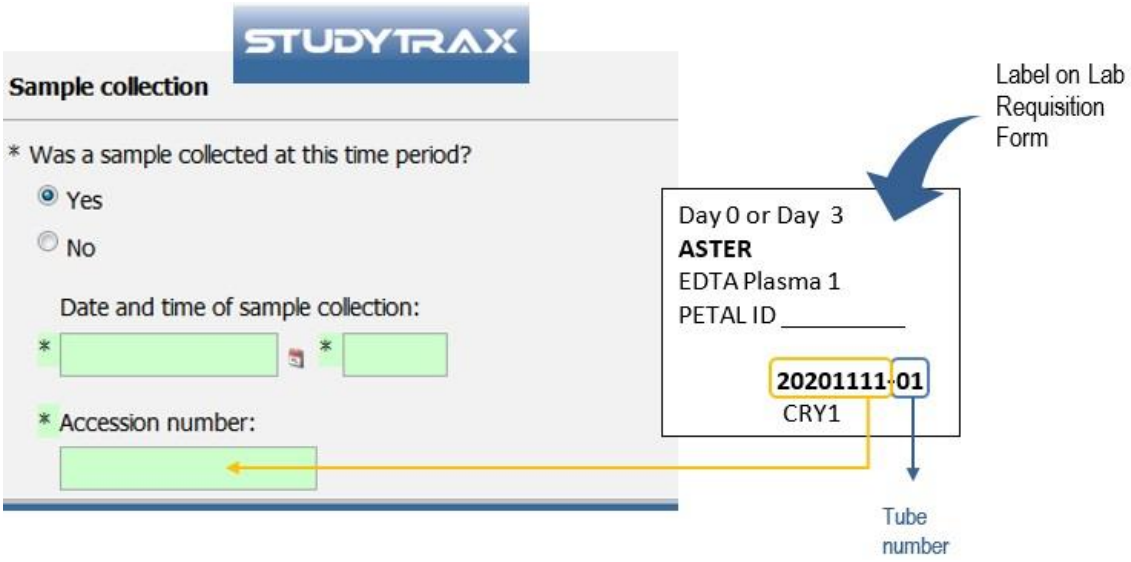
4.0 COMPLETING THE LABELS

Labels will be provided for all tubes and Laboratory Requisition Forms (LRFs).



- **THE TUBES AND REQUISITION IN EACH KIT ARE BAR-CODED AND MUST BE USED TOGETHER.**
- **DO NOT MIX TUBES AND/OR REQUISITIONS FROM DIFFERENT KITS.**

LINKING SAMPLES TO A SUBJECT: In addition to the lab requisition, the 8-digit accession number from the kit used for a sample collection day for a subject will be entered into the eCRF (StudyTRAX). Only include the first 8 digits. **DO NOT INCLUDE THE 2 DIGIT EXTENSION AFTER THE DASH**. Each subject can have up to 3 accession numbers (one for each collection day (Day 0, 2, and 3).



5.0 COMPLETING THE LABORATORY REQUISITION FORM (LRF)

A corresponding Laboratory Requisition Form (LRF) must be completed for each patient's sample collection time point (Day 0, 2, and 3). In order to ensure proper sample processing, the Laboratory Requisition Form must be filled out completely and correctly using a black or blue ballpoint pen. Please print legibly.

Keep the "Investigator Copy" (pink) of the completed Laboratory Requisition Form for your files, and return the white copy to Cenetron along with the specimen shipment.

Please place the white copy in the provided Specimen Transportation Bag and seal before placing it into the box with the corresponding specimens.

Your site is responsible for completing the following information prior to specimen shipment:

- Site: Enter the name of the site (hospital)
- PETAL ID: Enter the Patient's PETAL ID Number (XXX-XXXXX)
- AGE (enter year of birth only): 01/JAN/YYYY (e.g. 01/JAN/1981) Month and day will be prefilled with: "01/JAN"
- Gender: Select Male or Female
- Collection Date: DD/MMM/YYYY (e.g.01/JAN/2009)
- Collection Time: Specimen Collection Time (**indicate in military/24 Hour time – 2:12 pm would be 14:12**)
- Place a check mark next to all samples collected for that visit and note the processing and freezing times in the spaces provided
- **IMPORTANT:** Please confirm that the RNA hours at room temp field is completed prior to shipment. RNA samples **CANNOT** be used without this information.
- Note the number of aliquots (urine and plasma) collected
- Comments: please note any deviations (hemolysis, freezer thaw, etc.) in the comments section
- Study Site Signature: Please sign and date the Laboratory Requisition Form

5.1 Correction of Errors

If an error occurs, please correct in the following way:

- Cross through with a single straight line.
- Write the correct value above or to the side of the error.
- Initial and date the correction.
- **Do not use correction fluid.**

6.0 SPECIMEN COLLECTION AND PROCESSING

6.1 General Guidelines

1. Practice proper universal precautions throughout specimen collection and handling.
2. Obtain the Specimen Collection Kit for the correct visit and time-point.
3. Verify the expiration date on the Specimen Collection Kit. If the expiration date has not expired, open the Specimen Collection Kit.

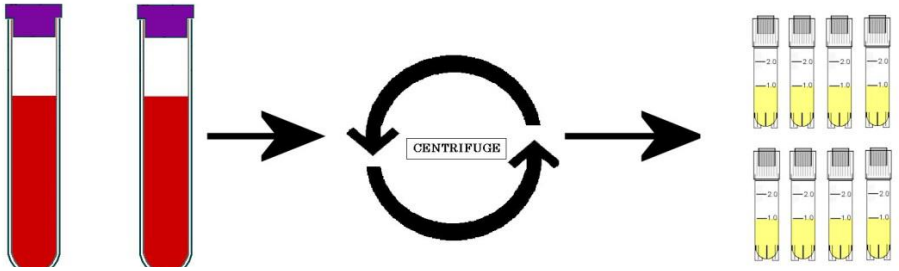
6.2 EDTA Plasma-All Visits

Collection:

1. Fill the two provided 6 mL EDTA blood tubes with blood from patient via arterial line, venous line, or by venipuncture. Use largest needle routinely used in your ICU for phlebotomy (up to 18g) for venipuncture and when instilling blood into the EDTA vacutainer to prevent hemolysis of the specimen. Hemolyzed samples should be redrawn if possible.
2. Gently invert the vacutainer 8-10 times to mix. Do NOT shake.
3. Process samples within **1 hour** of collection. This is to prevent potential hemolysis which can affect the cell free hemoglobin measurement.
4. Place on ice if anticipated time to processing is greater than **30 minutes**.

Processing:

1. Centrifuge for 10 minutes at approximately 1000 G (standard tabletop centrifuge may be used).
2. Aliquoting of plasma:
   - Withdraw plasma (do not remove buffy coat) using a pipette and fill pre-labeled cryovial tubes with plasma.
   - Fill all gray-top aliquots with 1 ml of plasma. NOTE: If you do not have enough plasma to fill all 8 aliquot vials, distribute so that those vials filled have **at least 500 mL** of plasma (may not be able to fill all vials). Please note this in the comments field of the Lab Requisition Form. Place on ice if anticipated time to freezing is greater than **30 minutes**.
3. Store promptly in a -70 or -80˚C freezer.



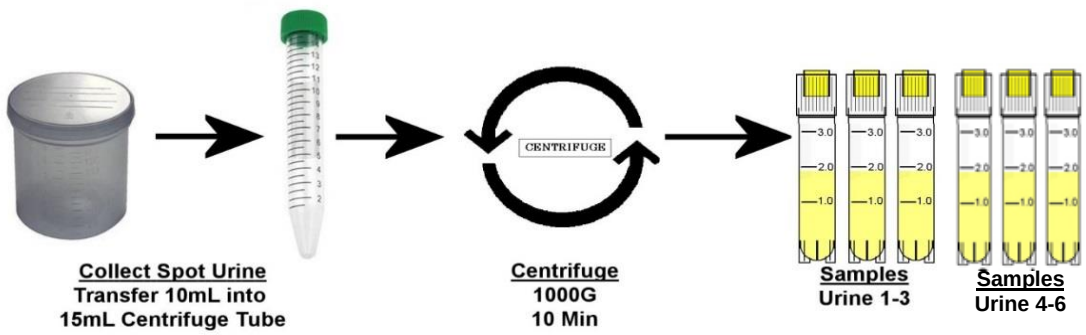
6.3 Urine

Collection:

1. Collect 10 mL of freshly voided urine; obtain from the catheter tubing port for patients with a Foley catheter in place.

Processing:

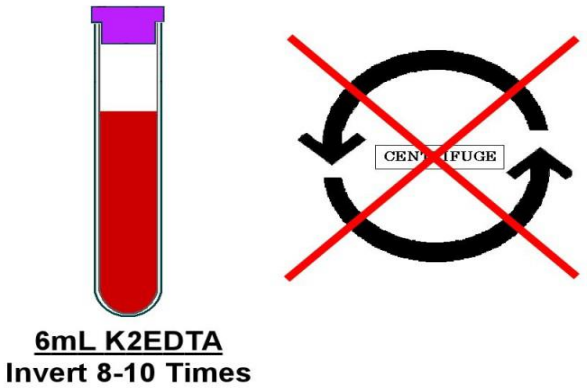
1. Place in 15 ml tube provided and centrifuge for 10 minutes at approximately 1000 G (standard tabletop centrifuge may be used).
2. Use provided labeled cryovials.
3. Place 1.5-2mls of urine supernatant in each of the 6 vials.
4. Store promptly (within 30 minutes) in a -70 or-80˚C freezer.
5. Place on ice if anticipated time to freezing is greater than **30 minutes**.



6.4 DNA Collection

Collection:

1. Fill the provided 6 mL EDTA blood tube with blood from patient via arterial line, venous line, or by venipuncture. Use largest needle routinely used in your ICU for phlebotomy (up to 18g) for venipuncture and when instilling blood into the EDTA vacutainer to prevent hemolysis of the specimen. Hemolyzed samples should be redrawn if possible.
2. Gently invert the vacutainer 8-10 times to mix. Do NOT shake.
3. Store in a -70 or -80˚C freezer



6.5 RNA Collection (PaxGENE)

Collection:

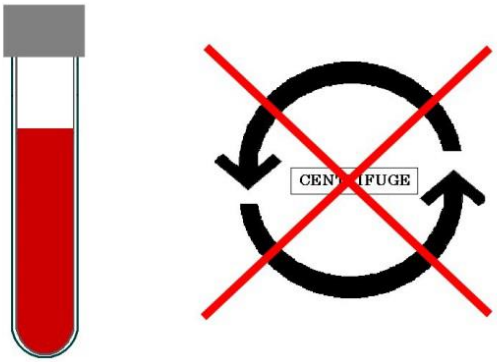
1. The PaxGENE tube contains a special preservative, and every effort should be made to prevent backflow of the preservative. ***The PaxGENE tube should always be the last tube filled, and the tube should be filled upright in a vertical position to avoid contact between the preservative and stopper, if possible.***

2. The provided 2.5 mL blood tube can be filled with blood from patient via arterial line, venous line, or by venipuncture.
   a. For venipuncture, a butterfly needle should be used for venipuncture to prevent tube additive from coming in contact with patient bloodstream (alternatively collection into a syringe for transfer into vials including PaxGENE can be done with any needle)
      i. Place the donor's arm in a downward position
      ii. Hold tube in a vertical position, below the donor's arm during blood collection
      iii. Release tourniquet as soon as blood starts flowing into the tube
      iv. Make sure the tube additives do not touch the stopper or the end of the needle.

3. Gently **invert the vacutainer 8-10 times to mix**. Do NOT shake. The blood will turn much darker, which is expected.

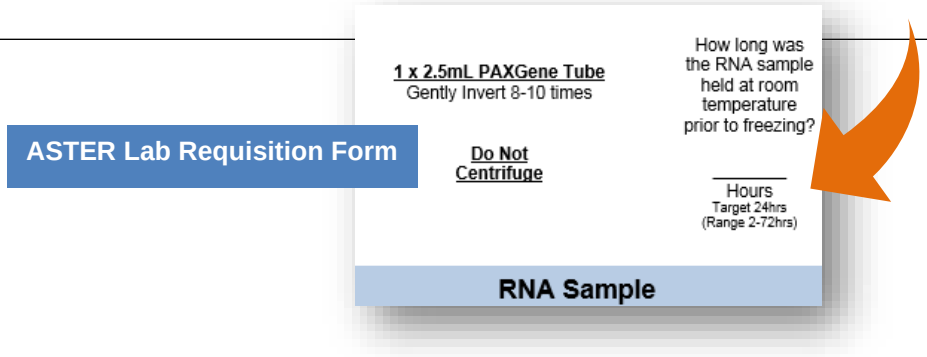
4. Cure the tube (i.e., let it sit at room temperature) for 24 hours (target). *Allowable range: 2 to 72 hours.*

5. **Store tubes upright in a -70 or -80˚C freezer [of note this can take up substantial space in the freezer].**



IMPORTANT:

- *The quality and yield of the sample is dependent upon immediate and proper mixing!*
- *The sample cannot be used unless the **cure time** (hours at room temp) is documented*



7.0 PACKING AND SHIPPING SPECIMENS

<u>Frozen</u> specimens should be shipped Monday through Wednesday only, if possible. DO NOT ship frozen samples on Thursday, Friday, or Saturday. Please hold these samples frozen until Monday for shipment.

<u>If shipping specimens on Friday via FedEx, it is very important that you check the box for Saturday Delivery on the air waybill and place a Saturday Delivery sticker on the box.</u> If this is not filled out, the package will be held over until Monday and the specimens will thaw, compromising the integrity of the results.

Holidays observed by FedEx and Cenetron Diagnostics are as listed:

Holiday/Observance
New Year's Day
Memorial Day
Independence Day
Labor Day
Thanksgiving Day
Christmas Day

Please do not ship specimens on a business day prior to a scheduled holiday, follow the observed holidays listed above.

When dealing with frozen specimens, store them at the required temperature as noted in the lab manual until shipment.

7.1 Sample Flow and Shipping Schedule

Site Samples

- EDTA Plasma
- Whole Blood DNA
- Whole Blood RNA
- Urine

Sample	Shipment frequency	Shipment conditions	Documents to include	Delivery Address
EDTA Plasma	Every 6 months	FROZEN on dry ice	Laboratory Requisition Form (WHITE Copy)	Cenetron Diagnostics 2111 West Braker Lane Suite 300 Austin, TX USA +1 512.439.2000
Whole Blood DNA				
Whole Blood RNA				
Urine				

7.2 Frozen Samples (All Samples)

Please contact FedEx at (800) 463-3339 (800-GO-FEDEX) for US shipments to find out the time you must schedule a same day pickup. Notify the FedEx dispatcher that you require a pick-up and provide him/her with your name, address, and exact location of the box. Also, ask for a pick-up confirmation number to help keep track of when the courier will arrive.

SHIP FROZEN VIA FEDEX TO CENETRON DIAGNOSTICS

Sites will be responsible for supplying dry ice for all frozen shipments to Cenetron.

1. Prior to placing the specimens in the shipping containers (provided by Cenetron), verify that all tubes have been properly identified.

2. Verify that the specimens match those listed on the Laboratory Requisition Form.

3. Be sure to inspect the shipping boxes for accurate labeling information.

4. Remove the vials from the freezer.

5. Place a layer of dry ice at the bottom of the frozen shipper.

6. Ensure that the absorbent sheet is placed in the transport bag with the cryovials. Place the lab requisition into the outer pouch of the bag. It is acceptable to ship specimens from more than one subject together in the box, **provided each subject visit's samples are in their own bag. Please do not put more than one subject visit's samples or requisition form in each transport bag.**

7. Seal the transport bag and place it into the bottom of the shipping box.

8. Fill the remainder of the box with dry ice (minimum of 8 lbs or ~4 kg). Place the Styrofoam cover on the inner Styrofoam container.

9. Close box flaps and seal the exterior box with tape. **DO NOT TAPE THE STYROFOAM BOX.**

10. Complete the necessary sections on the pre-printed FedEx Air Waybill. Date all forms where necessary and retain the "Sender's Copy" for your files. Place completed air waybill into the clear plastic air bill pouch face up.

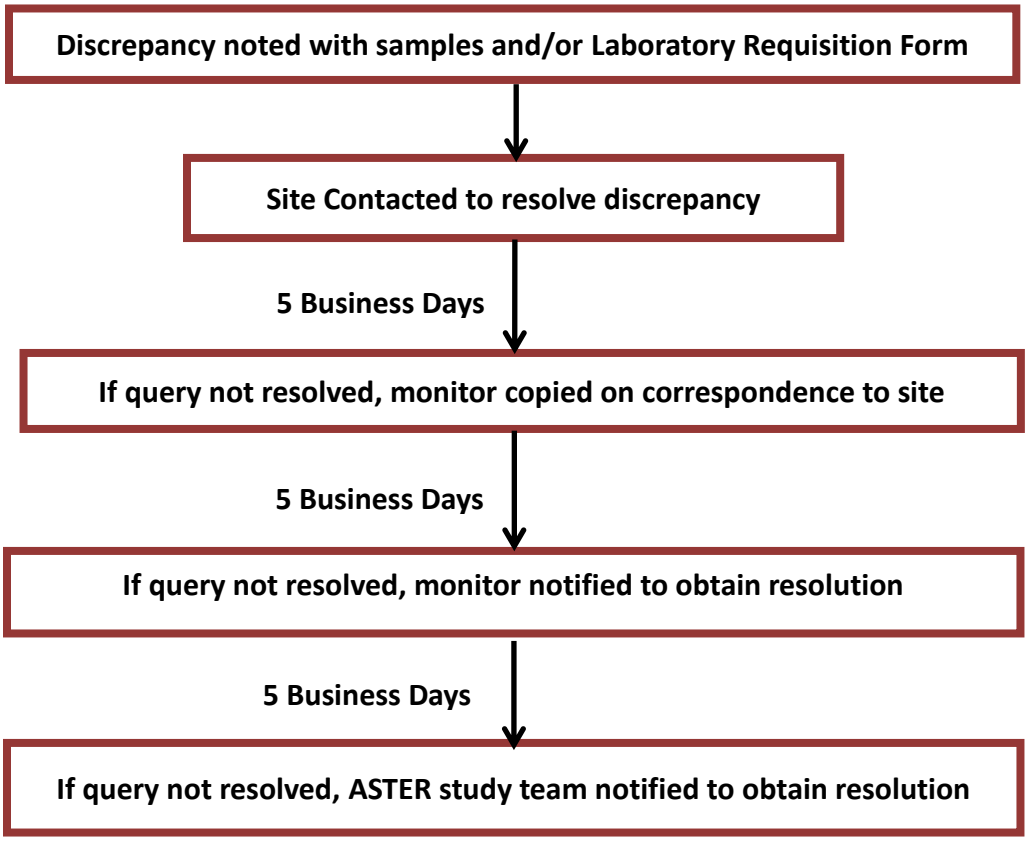
8.0 DATA QUERIES AND RECONCILIATION

8.1 Data Queries

If any discrepancies are noted on the lab requisition and sample labels, Cenetron will contact you directly to resolve the query. Please respond to the query either by phone at +1 512-439-2000 or by email at ClinicalTrials@Cenetron.com.

If an emergency situation should arise outside of our normal business hours, please call Cenetron Diagnostics at +1 888 520 2045 or +1 512 431 0725 and someone will assist you.

Data Query Process



Please note that a failure to respond to data queries in a timely manner could result in delays to samples being shipped for analysis thus resulting in a delay in data being available for study decisions.

9.0 DANGEROUS GOODS TRAINING REQUIREMENTS

Any person who ships dangerous goods (infectious specimens, culture isolates, dry ice) by air must follow certain regulations. The International Air Transport Association (IATA) produces a manual based on the International Civil Aviation Organization (ICAO) Technical Instructions, which outlines the procedures that must be followed to ensure safe transport. Training is an essential part of the process. It is necessary for all individuals involved in the preparation or transport of dangerous goods to be properly trained and tested initially with follow-up training every 24 months. As per the regulations, the investigator site is responsible for ensuring that their staff is properly trained.

Link to IATA endorsed Training Schools
http://www.iata.org/training/pages/endorsed_schools.aspx

10.0 FREQUENTLY ASKED QUESTIONS

Q. I have incorrectly drawn a patient's sample into a tube from another patient's kit, what should I do?
Document what has happened as completely as possible on the Lab Requisition indicating the details currently on the sample label and how the sample should correctly be labelled. Do not correct the details on the label of the incorrectly drawn sample by hand (this sample will be relabelled by Cenetron, as appropriate). Replace the incorrectly used tube from the patient kit using one of the spare tubes provided for that sample type. Spare materials are included in each kit.

Q. I have incorrectly labelled a tube and it has already been sent it to Cenetron, what should I do?
Document what has happened as completely as possible in a file note. Clearly indicate the details currently on the sample and how the sample should correctly be labelled. Send this file note to the PETAL CCC and explain what has happened. Cenetron who will ensure the sample is correctly relabelled. Your site may be contacted by the PETAL CCC to confirm details of the relabelling required.

Q. I have lost a sample label, what should I do?
Use one of the "Extra Labels" provided for that kit, ensuring that you clearly write the sample number and patient number in the spaces provided (using indelible ink). Spare materials are included in each kit.

Q. I have spun my blood sample and have drawn off the plasma/serum, and now have the blood tube left with the red cells in the bottom, should I also send this to Cenetron?
NO, once you have removed the plasma/serum as outlined in the manual instructions, you should discard the blood collection tube following your local site protocol for biohazardous trash.

Q. A sample collection is missed, what shall I do with the pre-labelled tube for this sample collection?
If a sample is missed, please do not send the empty tube to Cenetron.

Q. Can I send more than one patient's samples in a shipment?
Yes, as long as the relevant request form has been completed for all samples. Please separate each patient's samples into a separate specimen bag.

Q. The freezer storing the samples broke down and the samples thawed. What should we do?
Refreeze the samples as soon as possible. The incident should be noted in a note to file for the affected patients and the samples should be sent to Cenetron as normal with a note on the Lab Requisition, indicating the issue. If in doubt, please contact the PETAL Clinical Coordinating Center.

Q. Do we have to use the materials supplied by Cenetron or can we use our own supplies?
Use of the materials supplied by Cenetron is mandatory. The materials have been specifically chosen as they are suitable for processing and sample analysis or because they are compliant with shipping requirements.

Q. How should I dispose of expired Blood Collection Tubes?

Local trash collectors should be consulted to see what the proper method of disposal is for unused, expired blood collection products.

Q. What are the proper numbers of inversions for the various BD Vacutainer® Blood Collection Tubes?

An inversion is one complete turn of the wrist, 180 degrees, and back. Tubes should be inverted according to the following recommendations:

- EDTA plasma tubes – 8-10 inversions
- PaxGENE tubes – 8-10 inversions

Q. What constitutes a tube inversion?

An inversion is one complete turn of the wrist, 180 degrees, and back. The contents of the tube should have time to touch each side of the tube.

Q. How do I obtain quality certificates and MSDS on BD Blood Collection Products?

You can access most quality certificates (certificate of quality, sterility and conformance) and Material Safety Data Sheets (MSDS) on the BD website, at the following address - catalog.bd.com

Q. I have booked a shipment, but I do not have packaging materials for the shipment. Should Cenetron have sent these to me?

Yes, Cenetron will provide EPS shippers for shipments of frozen samples. Sites are responsible for providing dry ice for the shipments.

Q. I made a mistake when booking the courier, and now samples will be shipped to the wrong laboratory. How can I correct this?

You must phone or email your local courier office to make any changes to your courier booking. You can find their contact details in your Courier Starter pack. The driver cannot make any changes to the shipment destination at the time of pick-up; this can only be corrected by the local courier office in their system. You must also make sure that the samples are sent at the correct temperature.

Q. The sample issue I have is not listed here.....Help!

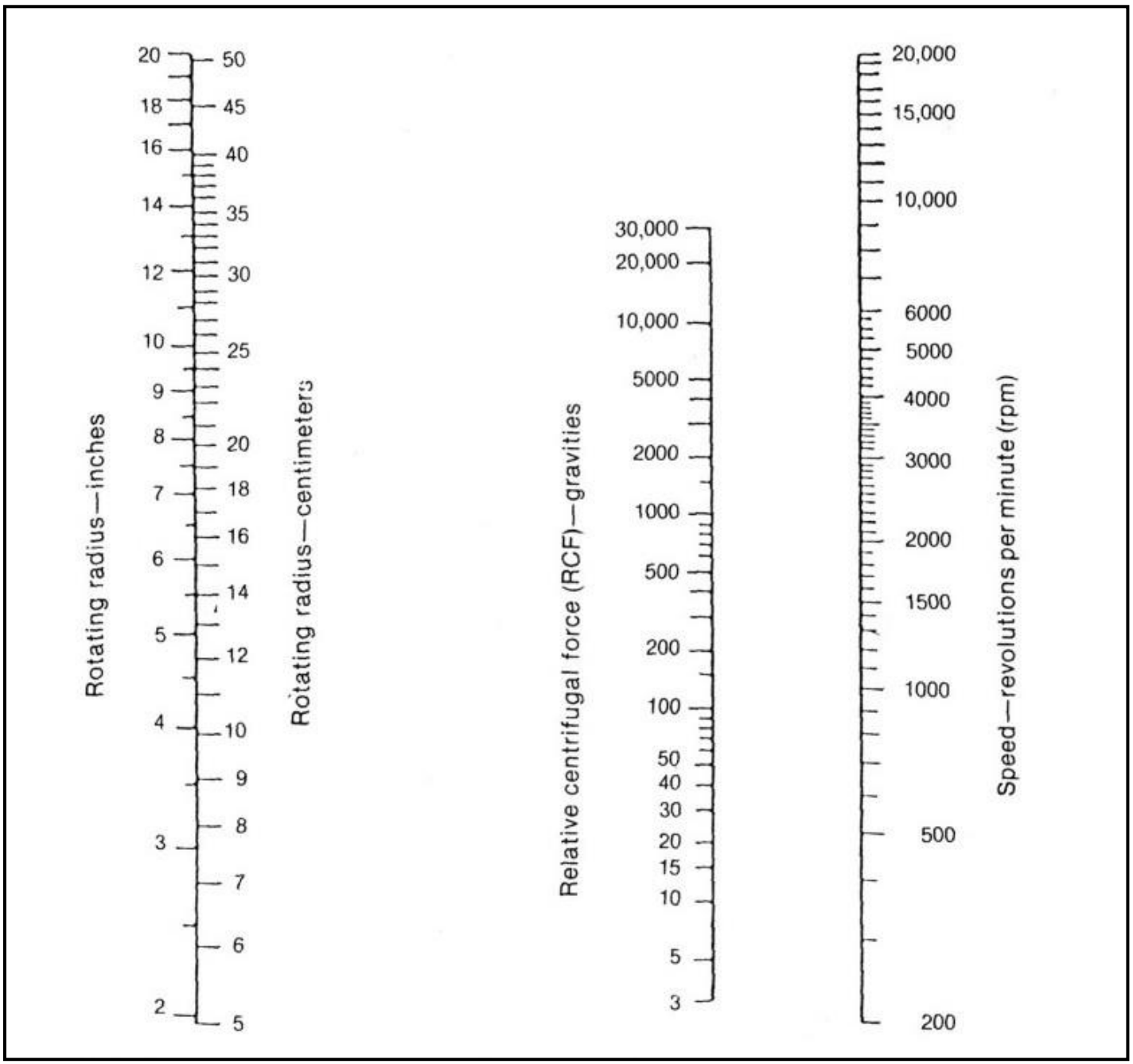
Study Sample related info and tools can be found under the SPECIMEN MANAGEMENT section on the ASTER study page of the PETAL website: http://petalnet.org/studies/aster

You can also contact the PETAL Clinical Coordinating Center for further assistance.

11.0 FORMS AND ATTACHMENTS

11.1 Force to RPM Conversion Nomograph
11.2 Time Conversion Chart
11.3 Laboratory Supply Request Form
11.4 Report Correction Request
11.5 Sample Laboratory Requisitions
11.6 Processing and Shipping Log
11.7 Accreditation and Permits
11.8 BD Vacutainer™ Evacuated Blood Collection System

G Force to RPM Conversion Nomograph



Time Conversion Chart

TIME IN HOURS		24 HOUR TIME
12:00 AM	----------(MIDNIGHT)----------	00:00
1:00 AM	----------	01:00
2:00 AM	----------	02:00
3:00 AM	----------	03:00
4:00 AM	----------	04:00
5:00 AM	----------	05:00
6:00 AM	----------	06:00
7:00 AM	----------	07:00
8:00 AM	----------	08:00
9:00 AM	----------	09:00
10:00 AM	----------	10:00
11:00 AM	----------	11:00
12:00 PM	----------(NOON)----------	12:00
1:00 PM	----------	13:00
2:00 PM	----------	14:00
3:00 PM	----------	15:00
4:00 PM	----------	16:00
5:00 PM	----------	17:00
6:00 PM	----------	18:00
7:00 PM	----------	19:00
8:00 PM	----------	20:00
9:00 PM	----------	21:00
10:00 PM	----------	22:00
11:00 PM	----------	23:00

PETAL Network
Protocol ASTER – Supply Request Form

Today's Date: _____

Date Supplies Needed: (exact date needed) ____/____/____ (DD / MMM / YYYY)

Site Number: _____

Contact Name: _____

Investigator Name: _____

Phone Number: _____

Email Address: _____

Collection Kits (Indicate Quantity Needed)

Please indicate quantity required	
Day 0 or Day 3	_____
Day 2	_____
EPS Frozen Shippers	_____ Please Indicated Size (ie. "2 Small", "1 Medium", ect.)

Additional Supplies (Please indicate supply and quantity needed)

Other (Serum Tubes, Cryovials, Biohazard bag, etc.): _____

UPON COMPLETION FAX TO +1 512-439-5000

CENETRON

REPORT CORRECTION REQUEST

If any report is incomplete or contains incorrect information, **please complete ALL of the information in Section 1 as shown on the incorrect report**. The item(s) needing a correction or completion should then be supplied in Section 2. **Only record in Section 2 the information to be changed.** Fax this completed Report Correction Request to Cenetron at (512) 439-5006. A corrected report will be faxed to you as soon as completed.

SECTION 1 – Information as shown on **INCORRECT** report

Site: _____

Massachusetts General Hospital (PETAL CCC)
Protocol ASTER

Subject Initials: _____ _____ _____

Visit: _____

Gender: Male Female

Patient Number (PETAL ID Number): _____

Accession Number: _____

Date of Birth: _01_/___Jan__/_____

Date of Collection: _____/_____/_____

Time of Collection: _____:_____

Other:_____

SECTION 2 – Information to be **CORRECTED**

Site: _____

Massachusetts General Hospital (PETAL CCC)
Protocol ASTER

Subject Initials: _____ _____ _____

Visit: _____

Gender: Male Female

Patient Number (PETAL ID Number): _____

Accession Number: _____

Date of Birth: _01_/___Jan__/_____

Date of Collection: _____/_____/_____

Time of Collection: _____:_____

Other:_____

Study Coordinator Signature:_____ Date:_____

Cenetron Employee Signature:_____ Date:_____

CENETRON

2111 West Braker Lane Suite 300
Austin, TX USA 78758
Phone: 888.834.6632 (Toll Free) +1 512.439.2000 (Intl.)
Fax: 512.439.5006

ASTER: Day 0 or Day 3 Laboratory Requisition

SAMPLE INFORMATION

[_____] Hospital Name

[_____|_____|_____] -- [_____|_____|_____|_____|_____] PETAL ID

Date of Birth **0 1 J A N** [_____|_____|_____|_____] **Provide Year Only**

Gender: ☐ **MALE** ☐ **FEMALE**

Timepoint: ☐ **DAY 0** ☐ **DAY 3**

Blood Collected on [__|__] [__|__|__] [__|__|__|__] **at** [__|__] : [__|__] **(24 Hour Clock)**
D D M M M Y Y Y Y H H M M

Urine Collected on [__|__] [__|__|__] [__|__|__|__] **at** [__|__] : [__|__] **(24 Hour Clock)**
D D M M M Y Y Y Y H H M M

Please Complete ALL Requested Sample Information

Plasma Sample

2 x 6mL K2EDTA Tube
Gently Invert 8-10 times
DO NOT Shake

→ **Centrifuge** 1000G 10 Min

→ **Samples** EDTA Plasma 1-8 8 x 2mL Cryovials

# of Aliquots: _____

Processing Time
_____:_____ **(24-Hr Clock)**

Freezing Time
_____:_____ **(24-Hr Clock)**

DNA Sample

1 x 6mL K2EDTA Tube
Gently Invert 8-10 times

Do Not Centrifuge

Freezing Time
_____:_____
(24-Hr Clock)

Urine Sample

Collect Spot Urine
Transfer 10mL into 15mL Centrifuge Tube

→ **Centrifuge** 1000G 10 Min

→ **Samples** Urine 1-6 6 x 2mL Cryovials

# of Aliquots: _____

Processing Time
_____:_____ **(24-Hr Clock)**

Freezing Time
_____:_____ **(24-Hr Clock)**

RNA Sample

1 x 2.5mL PAXGene Tube
Gently Invert 8-10 times

Do Not Centrifuge

How long was the RNA sample held at room temperature prior to freezing?

_____
Hours
Target 24hrs
(Range 2-72hrs)

COMMENTS AND SIGNATURE

Laboratory Requisition Completed By:

_____ _____
Signature ***Date***

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Fax: 512.439.5006

ASTER: Day 2 Laboratory Requisition

SAMPLE INFORMATION

[_____] Hospital Name

[_____|_____|_____] -- [_____|_____|_____|_____|_____] PETAL ID

Date of Birth **0 1 J A N** [_____|_____|_____|_____] **Provide Year Only**

Gender: ☐ **MALE** ☐ **FEMALE**

Timepoint: **DAY 2**

Blood Collected on [__|__] [__|__|__] [__|__|__|__] **D D M M M Y Y Y Y** **at** [__|__] : [__|__] **(24 Hour Clock)** **H H M M**

Urine Collected on [__|__] [__|__|__] [__|__|__|__] **D D M M M Y Y Y Y** **at** [__|__] : [__|__] **(24 Hour Clock)** **H H M M**

Please Complete ALL Requested Sample Information

2 x 6mL K2EDTA Tube
Gently Invert 8-10 times → DO NOT Shake

Centrifuge
1000G
10 Min

→ **Samples**
EDTA Plasma 1-8
8 x 2mL Cryovials

# of Aliquots: _____

Processing Time _____:_____ **(24-Hr Clock)**

Freezing Time _____:_____ **(24-Hr Clock)**

Plasma Sample

Collect Spot Urine
Transfer 10mL into 15mL Centrifuge Tube

→ **Centrifuge**
1000G
10 Min

→ **Samples**
Urine 1-6
6 x 2mL Cryovials

# of Aliquots: _____

Processing Time _____:_____ **(24-Hr Clock)**

Freezing Time _____:_____ **(24-Hr Clock)**

Urine Sample

COMMENTS AND SIGNATURE

FOR INTERNAL USE ONLY

Laboratory Requisition Completed By:

_____ _____
Signature ***Date***

Day 2 LRF Version 1 (R60902)

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Matthew Anderson

Curriculum Vitae

Education

Stanford University School of Medicine; Stanford, CA

Director-in-Training, Histocompatibility Laboratory	July 2010 – June 2011
Fellow, Molecular Genetic Pathology	July 2009 – June 2010
Fellow, Hematopathology	July 2008 – June 2009
Resident, Anatomic Pathology	July 2006 – June 2008

M.D., 2006 (*Medical Scientist Training Program)*
Ph.D., 2004 (*Department of Microbiology and Molecular Genetics, Thesis advisor: Jack Gorski, Ph.D.)*
Medical College of Wisconsin; Milwaukee, WI

Bachelor of Science, Biology, 1995
University of California San Diego; La Jolla, CA

Board Certification and Licensure

Physician, State of Texas	2019 – Present
Diplomate, American Board of Histocompatibility and Immunogenetics	2014 – Present
Laboratory Director, New York Department of Health	2013 – Present
Physician and Surgeon, State of Wisconsin	2013 – Present
Molecular Genetic Pathology, American Board of Pathology	2012 – Present
Anatomic Pathology, American Board of Pathology	2010 – Present
Physician and Surgeon, State of California	2007 – Present

Professional Experience

Cenetron Diagnostics — **Austin, TX**
Medical Director — April 2020 – Present

Responsible for all aspects of the directorship of the clinical laboratory.

- Implements and maintains the standards of the College of American Pathologists to ensure CLIA compliance as well as other applicable accreditation/regulatory/permitting requirements.
- Ensures provision of appropriately trained supervisory and technical staff and the identification of their responsibilities.
- Performs periodic on-site assessment of physical and environmental conditions and the adequacy of staffing.
- Approves new technical policies and procedures, as well as substantial changes thereto.
- Monitors and oversees reference laboratory selection/performance, quality management, proficiency testing, assay validation/verification and other key aspects impacting laboratory performance/compliance.
- Provides consultation re: results to the laboratory's clients.

Versiti Wisconsin — **Milwaukee, WI**

Vice President, Diagnostic Laboratories	2017 – Present
Medical Director, Diagnostic Laboratories	2013 – Present
Associate Investigator, Blood Research Institute	2014 – Present

TCR Biotherapeutics — **Wauwatosa, WI**
Co-Founder, Chief Executive Officer — 2020 – Present

Medical College of Wisconsin — **Milwaukee, WI**

Assistant Professor of Pathology and Clinical and Translational Sciences Institute	2014 – Present
Member, Human and Molecular Genetics Center	2015 – 2018

Stanford University School of Medicine **Stanford, CA**
Assistant Professor of Pathology and Assistant Director;
Histocompatibility, Immunogenetics, and Disease Profiling Laboratory 2011 – 2013
Instructor of Pathology 2010 – 2011

Awards and Honors

Stanford Society of Physician Scholars 2010
Wisconsin Society of Pathologists Award for Excellence in Pathology 2006
Alpha Omega Alpha National Medical Honor Society 2005

Professional and Administrative Experience

Science and Technology Initiatives Committee, ASHI 2020 – Present
Scientific Advisory Board, CareDx, Inc. 2018 – Present
Chair, Precision Medicine Resource Center, College of American Pathologists 2016 – Present
Scientific Advisory Board, Omixon, Inc. 2016 – Present
Personalized Healthcare Committee, College of American Pathologists 2014 – Present

MSTP Admissions Committee, Medical College of Wisconsin 2013 – Present
Board of Directors, BioForward Wisconsin 2016 – 2020
Government Affairs Committee, BioForward Wisconsin 2013 – 2020
Next Generation Sequencing Standards Committee, ASHI 2013 – 2015
CP Faculty Representative (elected), Stanford Pathology Leadership Group 2012 – 2013
Stanford Genomics and Personalized Medicine Working Group 2010 – 2013

Professional Memberships

Member, American Society for Histocompatibility and Immunogenetics (ASHI) 2010 – Present
Member, Association for Molecular Pathology 2010 – Present
Fellow, College of American Pathologists 2006 – Present

Teaching Experience

Course Director, Resident and Fellow Rotation, BCW Diagnostic Laboratories 2013 – Present
Course Director, Stanford Resident and Fellow Rotation in Histocompatibility 2012 – 2013
Instructor, Health and Human Disease Course, Stanford School of Medicine 2006 – 2013

Research Support

Clinical and Translational Science Institute of Southeast Wisconsin April 2015 – April 2016
Role: Co-PI
The goal of this project was to create a bioinformatics and bioengineering training core. Projects included the design of algorithms to enhance detection of rare variants and alignment of homologous regions of the genome.

Industry Sponsored Trial, Illumina, Inc. February 2013 – February 2015
Role: PI
The goal of this project was to assist in the development of an assay designed to sequence HLA genes using Illumina next-generation sequencing technology.

Investigator Initiated Grant, Life Technologies Corporation May 2012 – April 2013
Role: PI
The goal of this project was to evaluate the use of the Ion Torrent next-generation sequencing platform to perform shotgun sequencing of the HLA-DQA1 locus.

Center for Genomics and Personalized Medicine Seed Grant, Stanford August 2011 – April 2013
Role: Co-PI (with M. Fernandez-Vina and D. Tyan)
The goal of this project was to develop an amplicon-based next-generation sequencing assay for HLA genotyping using a nanofluidic PCR instrument and next-generation sequencing.

Publications

1. Cushman-Vokoun, A.M., Voelkerding, K.V., Fung, M.K., Nowak, J.A., Thorson, J.A., Duncan, H.L., Kalicanin, T., Anderson, M. W., and Yohe, S.L. A primer on CAR-T therapy: what does it mean for pathologists? A summary guidance from the College of American Pathologists CAR-T workgroup. *Archives of Pathology and Laboratory Medicine*. (2020) https://doi.org/10.5858/arpa.2019-0632-CP.

2. Compton, C.C., Robb, J.A., Anderson, M.W., Berry, A.B., Birdsong, G.G., Bloom, K.J., Branton, P.A., Crothers, J.W., Cushman-Vokoun, A.M., Hicks, D.G., Khoury, J.D., Laser, J., Marshall, C.B., Misialek, M.J., Natale, K.E., Nowak, K.E., Olson, D., Pfeifer, J.D., Schade, A., Vance, G.H., Walk, E.E., and Yohe, S.L. Preanalytics and precision pathology: pathology practices to ensure molecular integrity of cancer patient biospecimens for precision medicine. *Archives of Pathology and Laboratory Medicine.* (2019) PMID: 31329478.

3. Vazirabad, I., Chhabra, S., Nytes, J., Mehra, V., Narra, R.K., Szabo, A., Jerkins, J.H., Dhakal, B., Hari, P., and Anderson, M.W. Direct HLA genetic comparisons identify highly matched unrelated donor/recipient transplant pairs with improved transplant outcome. *Biology of Blood and Marrow Transplantation.* (2019) 25(5):921-931.

4. Yamamoto, F., Höglund, B., Fernandez-Vina, M., Tyan, D., Rastrou, M., Williams, T., Moonsamy, P., Goodridge, D., Anderson, M.W., Erlich, H.A., and Holcomb, C.L. Very high resolution single pass HLA genotyping using amplicon sequencing on the 454 next generation DNA sequencers: comparison with Sanger sequencing. *Human Immunology* (2015) 76(12): 910-196.

5. Sahoo, M.K., Tan, S.K., Chen, S.F, Kapusinszky, B., Concepcion, K.R., Kjelson, L., Mallempati, K., Farina, H.M., Fernández-Viña, M., Tyan, D., Grimm, P.C., Anderson, M.W., Concepcion, W., and Pinsky, B.A. Limited variation in BK virus T-cell epitopes revealed by next-generation sequencing. *Journal of Clinical Microbiology* (2015) 53(10): 3226-3233.

6. Mojtahed, A., Pai, R.K., Anderson, M.W., Arber, D.A., and Longacre, T.A. Reactive lymphoid hyperplasia of the terminal ileum: a benign (lymphoma-like) condition that may harbor aberrant immunohistochemical patterns or clonal immunoglobulin heavy chain gene rearrangements. *Applied Immunohistochemistry and Molecular Morphology.* (2014) 22(8): 585-592.

7. Yabu, J.M.*, Anderson, M.W.*, Kim, D.*, Bradbury, B.D., Lou, C.D., Petersen, J., Rossert, J., Chertow, G.M., and Tyan, D.B. Sensitization from transfusion in patients awaiting primary kidney transplant. *Nephrology Dialysis Transplantation.* (2013) 28(11): 2908-2918. (**co-first authors*)

8. Sahoo, M.K., Lefterova, M.I., Yamamoto, F., Waggoner, J.J., Chou, S., Holmes, S.P., Anderson, M.W., and Pinsky, B.A. Detection of cytomegalovirus drug resistance mutations by next-generation sequencing. *Journal of Clinical Microbiology.* (2013) 51(11): 3700-3710.

9. Anderson, M.W., Zhao, S., Freud, A.G., Czerwinski, D.K., Kohrt, H., Alizadeh, A.A., Houot, R., Azambuja, D., Morais, J.C., Spector, N., Molina-Kirsch, H.F., Warnke, R.A., Levy, R., and Natkunam, Y. CD137 is expressed in follicular dendritic cell tumors and in classical Hodgkin and T cell lymphomas: diagnostic and therapeutic implications. *American Journal of Pathology* (2012) 181(3): 795-803.

10. Azambuja, D., Natkunam, Y., Biasoli, I., Lossos, I.S., Anderson, M.W., Morais, J.C., and Spector, N. Lack of association of tumor-associated macrophages with clinical outcome in Hodgkin lymphoma. *Annals of Oncology* (2012) 23(3): 736-742.

11. Holcomb, C.L., Höglund, B., Anderson, M.W., Blake, L.A., Böhme, I., Egholm, M., Ferriola, D., Gabriel, C., Gelber, S.E., Goodridge, D., Hawbecker, S., Klein, R., Ladner, M., Lind, C., Monos, D., Pando, M.J., Pröll, J., Sayer, D.C., Schmitz-Agheguian, G., Simen, B.B., Thiele, B., Trachtenberg, E.A., Tyan, D.B., Wassmuth, R., White, S., and Erlich, H.A. A multi-site study employing high resolution HLA genotyping by next generation sequencing. *Tissue Antigens* (2011) 77(3): 206-217.

12. Tseng, D., Jones, C.D., Anderson, M., Warnke, R., Zehnder, J.L., and Miklos, D.B. Clonally identical Hodgkin's disease develops after allogeneic hematopoietic cell transplant for chronic lymphocytic leukemia. *Bone Marrow Transplantation* (2011) 46(12): 1576-1578.

13. Anderson, M.W. and Schrijver, I. Next generation sequencing and the future of genomic medicine. *Genes* (2010) 1(1): 38-69.

14. Anderson, M.W., Zhao, S., Ai, W.Z., Tibshirani, R., Levy, R., Lossos, I.S., and Natkunam, Y. C-C chemokine receptor 1 expression in human hematolymphoid neoplasia. *American Journal of Clinical Pathology* (2010) 133(3): 473-483.

15. Metcalf, R.A., Zhao, S., Anderson, M.W., Lu, Z.S., Galperin, I., Marinelli, R.J., Cherry, A.M., Lossos, I.S., and Natkunam, Y. Characterization of D-cyclin proteins in hematolymphoid neoplasms: lack of specificity of cyclin-D2 and D3 expression in lymphoma subtypes. *Modern Pathology* (2010) 23(3): 420-433.

16. Ferrante, A., Anderson, M.W., Klug, C.S., and Gorski, J. HLA-DM mediates epitope selection by a "compare-exchange" mechanism when a potential peptide pool is available. *PLoS ONE* (2008) 3(11): e3722.

17. Anderson, M.W. and Gorski, J. Cooperativity during the formation of peptide/MHC class II complexes. *Biochemistry* (2005) 44(15): 5617-5624.

18. Zavala-Ruiz, Z., Strug, I., Anderson, M.W., Gorski, J. and Stern, L.J. A polymorphic pocket at the P10 position contributes to peptide binding specificity in class II MHC proteins. *Chemistry and Biology* (2004) 11(10): 1395-1402.

19. Anderson, M.W. and Gorski, J. Cutting edge: TCR contacts as anchors: effects on affinity and HLA-DM stability. *Journal of Immunology* (2003) 171(11): 5683-5687.

Books and Book Chapters

1. Anderson, M.W. Emerging next-generation sequencing technologies. *Genomic Applications in Pathology (*2nd edition). Netto, G. and Kaul, K.L.. (Eds). Springer-Verlag (2019) DOI: 10.1007/978-3-319-96830-8.

2. Perez Botero J., Dugan S.N., and Anderson M.W. *ANKRD26*-Related Thrombocytopenia. 2018 Jun 21. In: Adam MP, Ardinger HH, Pagon RA, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2018. Available from: https://www.ncbi.nlm.nih.gov/books/NBK507664/.

3. Misalek, M. Anderson, M.W., Chandra, P., Crothers, J., Vance, G., and Zutter, M. (Eds.). *Short Presentations on Emerging Concepts: Emerging tests for molecular pathology*. College of American Pathologists (2016) (3rd ed.).

4. Cushman-Vokoun, A.M., Anderson M.W., Chandra, P., Laser, J., Bismar, T., Coleman, J., Gandour-Edwards, R., Gruver, A., Kiechle, F., Moore, F., Moyer, A., and Olsen, R. (Eds.). *CAP Pathology Resource Guide: Precision Medicine.* College of American Pathologists (2016) (v. 2.0, 1).

5. Cushman-Vokoun, A.M., Abel, G., Anderson M.W., Arnaout, R., Chandra, P.K., Coleman, J.F., Kaufman, J.H., Kiechle, F.L., Laser, J.S., Moyer, A.M., and Olsen, R.J. (Eds.). *CAP Pathology Resource Guide: Precision Medicine.* College of American Pathologists (2015) (v. 1.0, 1).

6. Anderson M.W., Bagg A., and Witte D.L. Molecular testing in the workup of polycythemia and thrombocythemia. *CAP Short Presentations on Emerging Concepts (SPECS)*. Caughron S.K., Chandra P.K., Foo W.C., Misialek M.J., Nowak J.A., and Wood J., (Eds). College of American Pathologists (2015) (v. 2.0e rev 7/7/15).

7. Anderson, M.W. Emerging next-generation sequencing technologies. *Genomic Applications in Pathology.* Netto, G. and Schrijver, I. (Eds). Springer-Verlag (2014) DOI: 10.1007/978-1-4939-0727-4.

8. Anderson, M.W. Acute myeloid leukemia: *CEBPA*. *Diagnostic Molecular Pathology in Practice.* Schrijver, I. (Ed). Springer-Verlag (2011) DOI: 10.1007/978-3-642-19677-5.

9. Anderson, M.W. and Natkunam, Y. Immunohistochemical profiling of lymphoma. *Neoplastic Hematopathology*. Jones, D. (Ed). Humana Press (2010) DOI: 10.1007/978-1-60761-384-8.

Abstracts

1. Chhabra, S., Narra, R.K., Szabo, A., Dhakal, B., Jerkins, J., Vazirabad, I., Mehra, V., Nytes, J., Anderson, M.W.*, and Hari, P.N.* Sequence-level comparison of unrelated donor allogeneic transplant donor-recipient pairs: clinical outcomes of alloHCT pairs with no exonic sequence differences in the HLA loci. ASBMT/CIBMTR Tandem Meeting. Salt Lake City, Utah, 2018. (**co-senior authors*)

2. Sullivan, M.J., Friedman, K.D., McCreery, J., Springer, M.G., Trapp-Stamborski, V., Curtis, B.R., Anderson, M.W., Wang, L., Perez Botero, J., and Dugan, S.N. Clinical correlation with a multidisciplinary approach facilitates the diagnosis of patients with a suspected inherited platelet disorder using next generation sequencing; Haemophilia (2018) May;24 Suppl 5:97. Oral Presentation, Dugan SN, World Federation of Hemophilia World Congress, Glasgow, Scotland, 2018.

3. Vazirabad, I., Mehra, V, Nytes, J., and Anderson, M.W., The recipient is the reference: sequence-level comparison of HLA loci in unrelated hematopoietic cell transplant pairs. ASHI Annual Meeting. San Francisco, California, 2017.

4. Dugan, S.N., McCreery, J., Friedman, K.D., Anderson, M.W., and Udani, R. Subspecialty genetic test utilization guidance supports diagnostic certainty: a case series in hemophilia A. National Society of Genetic Counselors Annual Conference, Columbus, Ohio, 2017.

5. Harb, J., Lakshmanan, K., Chandrakasan, S., Anderson, M.W., and Dash, D.P. Use of a next generation sequencing (NGS) panel to determine related donor eligibility in a case of pediatric myelodysplastic syndrome (MDS). Cancer Genomics Consortium Annual Meeting, Denver, Colorado, 2016 (http://dx.doi.org/10.1016/j.cancergen.2016.04.017).

6. Alabek, M.L., Ghate, S.M., Udani, R., Friedman, K.D., Anderson, M.W., Malec, L.M., Palmer, L.C., Ragni, M.V., and Dugan, S.N. Complexities and resolution of gene variant interpretation in two hemophilia cases. World Federation of Hemophilia World Congress, Orlando, Florida, 2016.

7. Narayan, S. Udani, R.A., Dugan, S., Anderson, M.W., Ben-Ezer, D., and Friedman, K.D. Atypical hemolytic uremic syndrome (aHUS) due to a novel sequence variation of diacylglycerol kinase epsilon (DGKE). American Society of Nephrology Annual Meeting (Kidney Week), San Diego, California, 2015.

8. Trapp-Stamborski, V., Dugan, S.N., Friedman, K.D., Anderson, M.W., and Udani, R. Genetic evaluation in aHUS: characterization of a variant of unknown significance in *CFHR3*. American Society of Hematology Annual Meeting, Orlando, Florida, 2015.

9. Yamamoto, F., Lindell, A., Bass, B., Crawford, A., Won, M., Baird, N., Anderson, M.W., Nytes, J., Schiller, J.J., Goodridge, D., and Tyan, D.B. Validation of 2070 common, rare, and novel HLA alleles using Illumina TruSight® HLA ultra-high resolution sequencing. ASHI Annual Meeting. Savannah, Georgia, 2015.

10. Harb, J.G., Essenmacher, A.N., Carlson, K.B., Anderson, M.W., and Dash, D.P. Identification of additional therapeutic options for *de novo* acute myeloid leukemia (AML) patient enabled by next generation sequencing. J Clin Oncol 33, 2015 (suppl; abstr e18027).

11. Yamamoto, F., Holcomb, C.L., Goodridge, D., Anderson, M.W., Erlich, H.A., Tyan, D.B., and Fernandez-Vina, M.A. HLA high resolution genotyping using 454 NGS and GS type assay. ASHI Annual Meeting. Denver, Colorado, 2014.

12. Chen, S.F., Sahoo, M.K., Yamamoto, F., Mallempati, K., Kjelson, K., Anderson, M.W., Gallo, A., Grimm, P., Concepcion, W., Pinsky, B.A., Kapusinszky, B., and Concepcion, K. BK virus genetic changes in pediatric kidney transplant patients with prolonged BK viral load. Infectious Diseases Society of America Annual Meeting, Philadelphia, Pennsylvania, 2014.

13. Yamamoto, F., Mallempati, K., Bialozynski, C., Shi, J., Major, E., Hague, T., Dinauer, D., Tyan, D.B., Fernandez-Vina, M., and Anderson, M.W. High-throughput shotgun sequencing of the HLA-DQA1 gene using next generation sequencing. ASHI Annual Meeting. Chicago, Illinois, 2013.

14. Chen, S.F., Kapusinszky, B., Sahoo, M.K., Yamamoto, F., Mallempati, K., Kjelson, K., Anderson, M.W., Gallo, A., Grimm, P., Concepcion, W. and Pinsky, B.A. Novel BK virus variants in pediatric immunocompromised patients. Infectious Diseases Society of America Annual Meeting, San Francisco, California, 2013.

15. Sahoo M.K., Lefterova, M.I., Yamamoto, F., Waggoner, J.J., Chou, S., Holmes, S.P., Anderson, M.W., and Pinsky, B.A. Improved detection of cytomegalovirus drug resistance mutations by a next-generation sequencing assay. Infectious Diseases Society of America Annual Meeting, San Francisco, California, 2013.

16. Lefterova, M., Sahoo, M., Yamamoto, F., Farina, H., Anderson, M.W., and Pinsky, B.A. Development of an amplicon enrichment and barcoding strategy for cytomegalovirus (CMV) genotypic drug resistance testing by next-generation sequencing. Association for Molecular Pathology Annual Meeting on Genomic Medicine. Long Beach, California, 2012.

17. Yabu, J.*, Anderson, M.W.*, Kim, D.*, Bradbury, B., Lou, C., Petersen, J., Rossert, J., Chertow, G., and Tyan, D. RBC transfusions are associated with human leukocyte antigen (HLA) allosensitization in patients awaiting kidney transplantation. American Society of Nephrology Annual Meeting (Kidney Week), San Diego, California, 2012 (**co-first authors*).

18. Hollander, S.A.*, Anderson M.W.*, Tyan, D., Bernstein, D., and Chin, C. A reduced immunosuppressive protocol in highly sensitized pediatric heart transplant patients with a C1q negative virtual crossmatch. International Society of Heart and Lung Transplantation. Prague, Czech Republic, 2012 (**co-first authors*).

19. Anderson, M.W., Freud, A., Zhao, S., Alizadeh, A., Kohrt, H., Warnke, R., Levy, R., and Natkunam, Y. Expression of CD137 protein in select hematopoietic tumors: implications for anti-CD137

immunomodulatory therapy. USCAP. San Antonio, Texas, 2011 (*nominated for Stowell-Orbison award*).

20. Alizadeh, A.A., Anderson, M.W., Shyam, R.M., Kohrt, H.E., Bangs, C.D., Cherry, A.M., Advani, R.H., Natkunam, Y., and Levy, R. Clinical and pathological features of non-Hodgkin lymphomas harboring concurrent t(14;18) and 8q24 abnormalities. American Society of Hematology. Orlando, Florida, 2010.

21. Holcomb, C.L., Hoglund, B., Simen, B., Egholm, M., Blake, L., Tyan, D.B., Pando, M.J., Anderson, M.W., Trachtenberg, E., Ladner, M., White, S., Wassmuth, R., Bohme, I., Gabriel, C., Proll, J., Klein, R., Thiele, B., Monos, D., Ferriola, D., Lind, C., Goodridge, D., Sayer, D., Schmitz-Aghegulan, G., and Erlich, H.A. A multi-site study employing high resolution HLA genotyping by next generation sequencing. 24th European Immunogenetics and Histocompatibility Conference. Florence, Italy, 2010.

22. Anderson, M.W., Zhao, S., Lossos, I.S., and Natkunam, Y. C-C chemokine receptor 1 (CCR1) is expressed in specific subsets of B cell lymphomas. USCAP. Denver, Colorado, 2008.

23. Anderson, M.W. and Gorski, J. TCR contact / minor anchor residues act cooperatively to control peptide binding to HLA-DR1 but dominantly influence stability in the presence of HLA-DM. 9th National Symposium: Basic Aspects of Vaccines. Bethesda, Maryland, 2003.

24. Anderson, M.W. and Gorski, J. Epitope selection: natural sequences flanking an influenza viral epitope impact binding to HLA-DR1 and stability in the presence of HLA-DM. National M.D./Ph.D. Student Conference. Aspen, Colorado, 2002.

Invited Presentations

1. HLA “matching” in the NGS era: from alleles to direct genetic comparisons. Frontiers in Academic Pathology, Mt. Sinai School of Medicine, New York Academy of Medicine, January 31st, 2020.

2. HLA in the genomics era: from antigens to alleles and beyond. ASHI Regional Meeting, Indianapolis, Indiana, October 31st, 2019.

3. HLA in the genomics era: from antigens to alleles and beyond. Wisconsin Association of Blood Banks Annual Meeting, Pewaukee, Wisconsin, September 11th, 2019.

4. The complexity of HLA: when is HLA testing appropriate… and when is it not? PLUGS Midwest Regional Summit, Milwaukee, Wisconsin, October 26th, 2018.

5. Precision medicine: how genomics is changing healthcare. American Society of Clinical Laboratory Scientists Regional Conference, Milwaukee, Wisconsin, April 26th, 2018.

6. The precision medicine paradigm: what is the impact on healthcare and industry? BioFoward Biohealth Summit, Madison, Wisconsin, October 10th, 2017.

7. HLA in the genomics era. World Stem Cell Summit, West Palm Beach, Florida, December 9th, 2016.

8. Precision medicine: will genomic information improve healthcare? American Society of Clinical Laboratory Scientists (Racine/Kenosha Branch), Racine, Wisconsin, September 8th, 2015.

9. Genomics for leukemia patients: from discovery to diagnosis and treatment. Fourth Annual Controversies in Hematologic Malignancies Symposium. Milwaukee, Wisconsin, March 7th, 2015.

10. High resolution HLA genotyping with TruSight HLA. EFI European Immunogenetics and Histocompatibility Conference. Stockholm, Sweden, June 26th, 2014.

11. First impressions: high resolution genotyping with TruSight HLA. ASHI Annual Meeting. Chicago, Illinois, November 18th, 2013.

12. High-throughput sequencing of the DQA1 gene with Ion Torrent PGM. EFI European Immunogenetics and Histocompatibility Conference. Maastricht, Netherlands, May 12th, 2013.

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19. Next-generation sequencing for clinical HLA genotyping. NIST Advances in Biomedical Measurement Science Workshop. Stanford, California, September 7th, 2011.

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COLLEGE of AMERICAN PATHOLOGISTS

CERTIFICATE OF ACCREDITATION

Cenetron Diagnostics, LLC
Laboratory
Austin, Texas
Matthew W. Anderson, MD, PhD, D(ABHI)

CAP Number: 6704501
AU-ID: 1191130
CLIA Number: 45D0907734

The organization named above meets all applicable standards for accreditation and is hereby accredited by the College of American Pathologists' Laboratory Accreditation Program. Reinspection should occur prior to November 21, 2022 to maintain accreditation.

Accreditation does not automatically survive a change in director, ownership, or location and assumes that all interim requirements are met.

Chair, Accreditation Committee

President, College of American Pathologists

CENTERS FOR MEDICARE & MEDICAID SERVICES

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF ACCREDITATION

LABORATORY NAME AND ADDRESS

CENETRON DIAGNOSTICS, LLC
2111 WEST BRAKER LANE, BLD 5, SUITE 300
AUSTIN, TX 78758

CLIA ID NUMBER

45D0907734

EFFECTIVE DATE

08/08/2020

LABORATORY DIRECTOR

MATTHEW W ANDERSON M.D.

EXPIRATION DATE

08/07/2022

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.

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Karen W. Dyer, Director
Division of Laboratory Services
Survey and Certification Group
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179 certs2_071420

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LAB CERTIFICATION (CODE)	EFFECTIVE DATE	LAB CERTIFICATION (CODE)	EFFECTIVE DATE
GENERAL IMMUNOLOGY (220)	06/24/2018		

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PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE

Centers for Disease Control and Prevention
Office of Health and Safety, MS A-46
Atlanta, Georgia 30333
TEL: 404-718-2077; FAX: 404-718-2093; Email: importpermit@cdc.gov

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Permit to Import Infectious Biological Agents, Infectious Substances, and Vectors

In accordance with 42 CFR Section 71.54 of the Public Health Service Foreign Quarantine Regulators, cited on the bottom of this permit, permission is granted the permittee to import into any port under control of the United States, or to receive by transfer within the United States, the material described in Item 1 below.

PHS PERMIT NO. : 20200721-2418A	ISSUED DATE: 08/03/2020 EXPIRATION DATE: 08/03/2021
1. DESCRIPTION OF MATERIAL	HUMAN BLOOD/BLOOD PRODUCTS THAT MAY CONTAIN HUMAN IMMUNODEFICIENCY VIRUS, HEPATITIS C VIRUS, OR HEPATITIS B VIRUS.
2. PERMITTEE (NAME, ORGANIZATION, ADDRESS AND CONTACT INFORMATION)	**BRANDON HARPER (512) 717-9231** **CENETRON DIAGNOSTICS, LLC** **2111 W. BRAKER LANE, SUITE 300** **AUSTIN TX 78758**
3. SOURCE OF MATERIAL (NAME, ORGANIZATION, ADDRESS, COUNTRY)	WORLDWIDE
4. TYPE OF PERMIT AND INSTRUCTIONS FOR USE	MULTIPLE IMPORTATIONS WITHIN THE U.S. A. RECORD OF EACH IMPORTATION SHALL BE MAINTAINED ON PERMANENT FILE BY PERMITTEE. B. USDA/APHIS MAY REQUIRE ADDITIONAL PERMITS FOR MATERIALS FROM ANIMALS, MATERIALS EXPOSED TO ANIMAL PRODUCTS/BYPRODUCTS, AND AGENTS THAT ARE INFECTIOUS TO ANIMALS OR PLANTS.U.S.FISH AND WILDLIFE SERVICE MAY REQUIRE ADDITIONAL PERMITS FOR MATERIALS FROM ENDANGERED ANIMALS.
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