THE TPIDA BIO SPECIMEN COLLECTION AND RESEARCH PRODECURES

TPaIDA

TPAIDA-IPTEI IEC
SCIENCE & MEDICINE

SPECIALIZING IN PROSPECTIVE BIO SPECIMEN COLLECTION AND RESEARCH

F 19 Lucre Pata, Cusco, Peru
Country Code 51, Phone: 995503088, Phone: 984534737

THE TPIDA ORGANIZATION

This document outlines the bio specimens that the TPIDA Organization has the capabilities to collect and the collection procedure implemented by the Organization for each project. This is not an exhaustive list and there are other bio specimens that may not be listed that the Organization has the capabilities of collecting. Please feel free to send an inquiry if you do not see a bio specimen on the list that fits your company's research and or product development needs.

The Organization can provide the bio specimens in a serum and/or a plasma form for both acute and chronic patients, as sputum and as FFPE as it relates to oncology. The bio specimen serum and/or plasma samples provided would be sero-positive by Elisa, PCR and via acute and chronic clinical symptoms.

The TPIDA Organization has the structure and network in place to collect bio specimens from patients who reside in the following Caribbean and South America geographical areas:

- Antigua / Barbuda
- Iquitos, Peru
- Lima, Peru
- Cusco, Peru
- Other Areas of Peru

The TPIDA Organization has approximately 65 doctors that are specialist in all areas of medicine. Inclusive within this group are medical technologists and doctors who are the heads of the following organizations throughout Peru and other areas of the Caribbean and South America:

- National Institute of Organ Transplantation
- National Institute of Cardiology
- National Institute of Cancer
- Chief of Blood Bank / Hematology of Cusco Peru
- Chief of Staff / Vice-President of Medical College of Peru
- Oncology
- Pulmonology Oncology
- Gastroenterology Oncology
- Obstetric & Gynecology Oncology
- Anatomy Oncology
- Clinical Pathology
- Hematology Oncology
- Rheumatologist
- Endocrinologist
- Tropical and Infectious Diseases
- Medical Technologists

Please feel free to visit www.tpida.org for additional information related to the TPIDA Organization's scope of medical expertise in infectious diseases, etc. The Appendix section at the end of this document has an example of the TPIDA Organization Clinical Pathology and Laboratory Report and Case Report Forms. The TPIDA Organization looks forward to providing bio specimens that are important for your company's research and product development needs.

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NORMAL BLOOD			
PLASMA/SERUM			
"Normal" Peruvian Blood Bank Donors-8ml-P		"Normal" Peruvian Blood Bank Donors-15ml-P	
TROPICAL DISEASES			
PLASMA/SERUM	**VERIFICATION TEST**	**PLASMA/SERUM**	**VERIFICATION TEST**
Zika Virus	**KIT TARIKI-ELISA**	**Toxoplasma**	**BIOKIT-BIOELISA**
Zika-8ml-P	*Kit Tariki-Elisa*	Toxoplasma IgM-8ml-P	*BIOKIT-BIOELISA*
Zika-15ml-P	*Kit Tariki-Elisa*	Toxoplasma IgM-15ml-P	*BIOKIT-BIOELISA*
Brucellosis	**FEBRILE ANTIGEN TEST**	**Typhoid**	**FEBRILE ANTIGEN TEST**
Brucellosis-BC-8ml-LP	*Febrile Antigen Test*	Typhoid Fever-8ml-P	*Febrile Antigen Test*
Brucellosis-BC-15ml-LP	*Febrile Antigen Test*	Typhoid Fever-15ml-P	*Febrile Antigen Test*
Dengue	**BIOKIT-BIO RAD DENGUE PLATELIA NS1 AG ASSAY-FRANCE**	**Leishmaniasis**	**SMEAR OF INJURY IN SHEET-WIGT-GIENSA**
Dengue-DG-8ml-LP	*Biokit-Bio Rad Dengue Platelia Ns1 AG Assay-France*	Leishmaniasis-8ml-P	*Smear of Injury in Sheet-WIGT-GIENSA*
Dengue-DG-15ml-LP	*Biokit-Bio Rad Dengue Platelia Ns1 AG Assay-France*	Leishmaniasis-15ml-P	*Smear of Injury in Sheet-WIGT-GIENSA*
Malaria	**BLOOD SMEAR**	**Leptospirosis**	**MAT/ELISA**
Malaria(By Species)-ML-8ml-IP	*Blood Smear*	Leptospirosis-8ml-P	*MAT/Elisa*
Malaria(By Species)-ML-15ml-IP	*Blood Smear*	Leptospirosis-15ml-P	*MAT/Elisa*
HIV	**BIOKIT-BIOELISA HIV 1-2 AG/AB - SPAIN**	**Schistosomiasis**	**Microscopic Identification Of Eggs In Stool Or Urine / Elisa**
HIV-8ml-LP	*Biokit-Bioelisa HIV 1-2 Ag/AB - Spain*	Schistosomiasis-8ml-P	*Elisa*
HIV-15ml-LP	*Biokit-Bioelisa HIV 1-2 Ag/AB - Spain*	Schistosomiasis-15ml-P	*Elisa*
Chagas	**BIOKIT-BIOELISA CHAGAS - SPAIN**	**Strongyloides**	**DIRECT FECAL SMEAR**
Chagas (T.Cruzi)-8ml-P	*Biokit-Bioelisa Chagas - Spain*	Strongyloides-8ml-P	*Direct Fecal Smear*
Chagas (T.Cruzi)-15ml-P	*Biokit-Bioelisa Chagas - Spain*	Strongyloides-15ml-P	*Direct Fecal Smear*
HCV	**BIOKIT-BIOELISA HCV 4.0 - SPAIN**	**Leprosy**	**SKIN SMEAR**
HCV-8ml-P	*Biokit-Bioelisa HCV 4.0 - Spain*	Hansen's Diseases (Leprosy)-8ml-P	*Skin Smear*
HCV-15ml-P	*Biokit-Bioelisa HCV 4.0 - Spain*	Hansen's Diseases (Leprosy)-15ml-P	*Skin Smear*
Hepatitis	**BIOKIT-BIOELISA HBsAG 3.0 - SPAIN**	**Chikungunya**	**KIT TARIKI-ELISA**
(Acute) 1 Hepatitis A IgM-8ml-LP	*Biokit-Bioelisa*	Chikungunya-8ml-AG	*Kit Tariki-Elisa*
(Acute) 2 Hepatitis A IgM-15ml-LP	*Biokit-Bioelisa*	Chikungunya-15ml-AG	*Kit Tariki-Elisa*

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TROPICAL DISEASES			
PLASMA/SERUM	**VERIFICATION TEST**		
(Acute) 1 Hepatitis B Anti-HBc IgM-8ml-LP	*Biokit-Bioelisa HBsAG 3.0 - Spain*		
(Acute) 2 Hepatitis B Anti-HBc IgM-15ml-LP	*Biokit-Bioelisa HBsAG 3.0 - Spain*		
(Acute) 1 Hepatitis C Anti-HBc IgM-8ml-LP	*Biokit-Bioelisa HCV 4.0 - Spain*		
(Acute) 2 Hepatitis C Anti-HBc IgM-15ml-LP	*Biokit-Bioelisa HCV 4.0 - Spain*		
Anti Hb Core-8ml-LP	*Biokit-Bioelisa Anti:HBC Core - Spain*		
Anti Hb Core-15ml-LP	*Biokit-Bioelisa Anti:HBC Core - Spain*		
OTHER DISEASES			
PLASMA/SERUM	**VERIFICATION TEST**		
HTLV 1/2	Biokit-Bioelisa 5.0 - Spain		
Syphilis	Biokit-Bioelisa 3.0 - Spain		
Yellow Fever	*KIT-TARIKI-ELISA*		
Plasmodium Falviparum	*THICK DROP-WIGHT-GIENSA*		
***Dengue (Other Verification Test)**	*KIT-TARIKI-ELISA*		
***Chagas (Other Verification Test)**	*BIOKIT-ELISA*		
***Toxoplasmosis (Other Verification Test)**	*Sabin-Feldman dye test / ELISA*		
TUBERCULOSIS			
SPUTUM/CEREBRAL SPINAL FLUID/PLEURAL	**VERIFICATION TEST**		
Tuberculosis	*Acid Fast Stain, ADA*		
Tuberculosis MDX	*Acid Fast Stain, ADA*		
*** Represents Diseases with multiple Verification Tests.			

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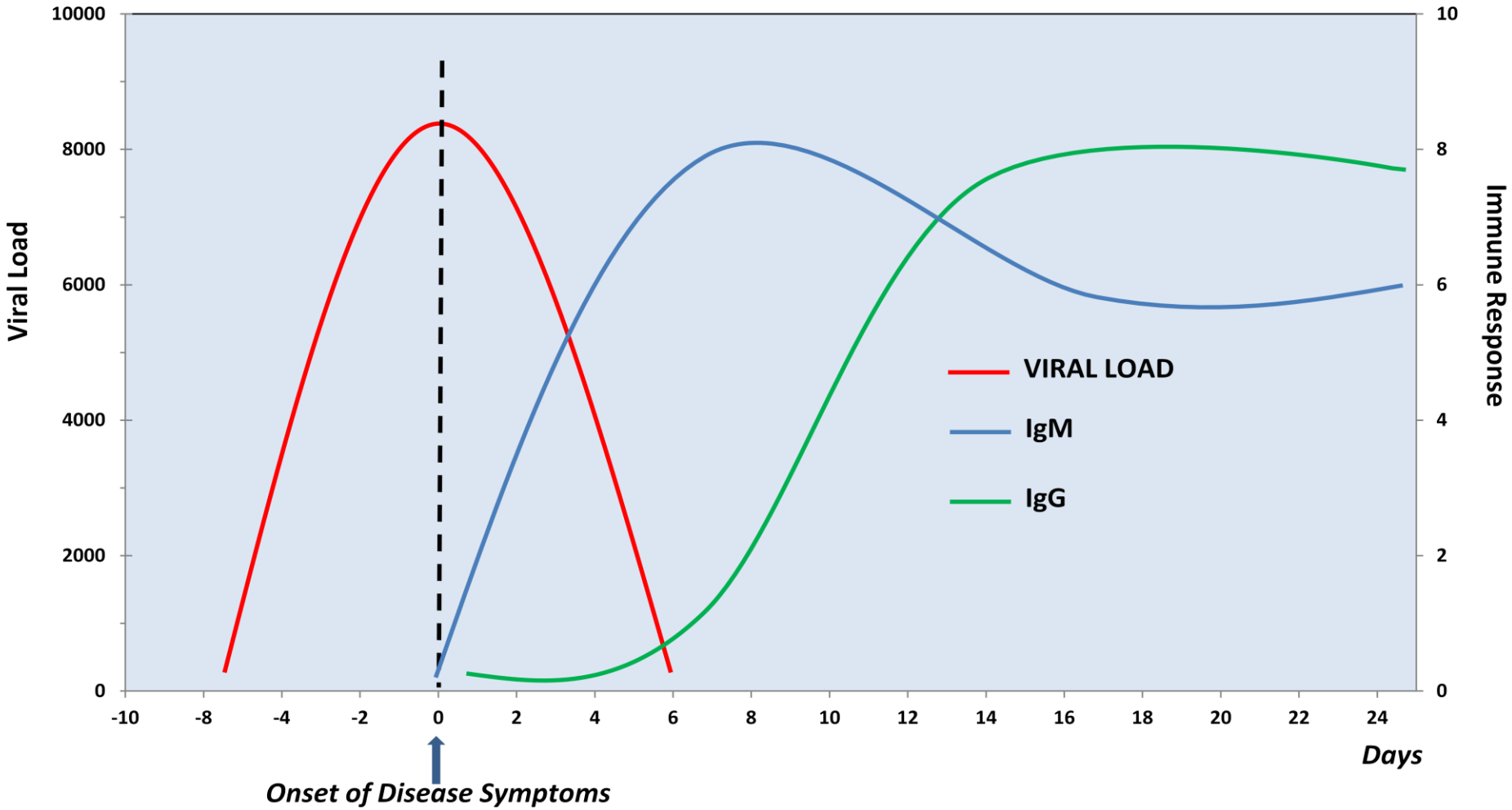
TYPICAL VIRAL INFECTION PROFILE

Chikungunya, Dengue, ZIKA



THE TPDIA ORGANIZATION SCIENCE & MEDCIAL RESEARCH COMMITTEE v1

C.O.A. APPROVAL

TPAIDA-IPTEI IEC SCIENCE & MEDICINE

SPECIALIZING IN PROSPECTIVE BIO SPECIMEN COLLECTION AND RESEARCH

CERTIFICATE OF ANALYSIS	
TROPICAL DISEASES	
Disease	
PLASMA/SERUM/SPUTUM/CEREBRAL SPINAL FLUID/PLEURAL	
Sample Type	
Sample ID#	
Donor Gender	
Collection Date	
Volume	
ANALYSIS	
Analyte	
Analysis Method	
Manufacture (If Applicable)	
ANALYSIS RESULTS	
Analyte	
ROUTINE TESTING	
This material was tested and found negative for the following	
APPROVAL	
Signature (Stamp)	**Date**

THE TPIDA ORGANIZATION SCIENCE & MEDICAL RESEARCH COMMITTEE
Chief of Blood Bank, Chief of Staff & Clinical Pathologist
Es Salud,
Cusco, Perú

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ONCOLOGY			
PLASMA/SERUM/FFPE	**VERIFICATION TEST**	**PLASMA/SERUM/FFPE**	**VERIFICATION TEST**
Lung Cancer	*Cytology*	**Hematopioetic Cancers**	*Cytology*
NSCLC (Stage I or II) Adenocarcinoma	*Brushing*	CLL	*Brushing*
NSCLC (Stage I or II) Squamous Cell Carcinoma	*Aspirate Smear*	CML	*Aspirate Smear*
NSCLC (Stage I or II) Large Cell	*Cell Block*	ALL	*Cell Block*
NSCLC (Stage III or IV) Adenocarcinoma	*Histopathology of Biopsy*	AML	*Histopathology of Biopsy*
NSCLC (Stage III or IV) Squamous Cell Carcinoma	*Partial/Full Organectomy*	Non-Hodgkin's Lymphoma (NHL)	*Partial/Full Organectomy*
NSCLC (Stage III or IV) Large Cell	*CT Guided Fine Needle*		*CT Guided Fine Needle*
Small Cell Lung Cancer	*Biopsy*		*Biopsy*
Stage III/IV Solid Tumors			
Breast Cancer	***Other***		***Other***
Prostate Cancer			
Bladder Cancer			
Thyroid Cancer			
Kidney Cancer			
Pancreas Cancer			
Ovarian Cancer			
Esophageal Cancer			
Liver/Bile Duct Cancer			
Endometrial Cancer			
Colorectal Cancer			

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CERTIFICATE OF ANALYSIS	
ONCOLOGY	
Type of Cancer	
PLASMA/SERUM/FFPE	
Sample Type	
Sample ID#	
Donor Gender	
Collection Date	
Volume	
ANALYSIS	
Analyte	
Analysis Method	
Manufacture (If Applicable)	
ANALYSIS RESULTS	
Analyte	
ROUTINE TESTING	
This material was tested and found negative for the following	
APPROVAL	
Signature (Stamp)	**Date**
THE TPIDA ORGANIZATION SCIENCE & MEDICAL RESEARCH COMMITTEE **Chief of Blood Bank, Chief of Staff & Clinical Pathologist** **Es Salud,** **Cusco, Perú**	

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National Institute of Organ Transplantation
National Institute of Cardiology
National Institute of Cancer
Chief of Blood Bank / Hematology of Cusco Peru
Chief of Staff / Vice-President of Medical College of Peru
Oncology
Pulmonology Oncology
Gastroenterology Oncology
Obstetric & Gynecology Oncology
Anatomy Oncology
Clinical Pathology
Hematology Oncology
Rheumatologist
Endocrinologist
Tropical and Infectious Diseases
Medical Technologists

Please feel free to visit www.tpida.org for additional information related to the organization's scope of medical expertise in infectious diseases.

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SPECIALIZING IN PROSPECTIVE BIO SPECIMEN COLLECTION AND RESEARCH

PROSPECTIVE ONCOLOGY BIO SPECIMEN PROJECT INITIATION PROCEDURE

CLIENT COMPANY

Master Service Agreement
Material Transfer Agreement
IRB (Internal Review Board by Project)
Non Disclosure Agreements
Additional Documents and Agreements

SUBJECT

IC (Informed Consent), Other documentation
Collection of ALL demographic information per subject

PROSPECTIVE ONCOLOGY BIO SPECIMEN COLLECTION AND RESEARCH PROCEDURE

ONCOLOGY

The following is an overview of the TPIDA Organization prospective bio specimen collection and research procedure for all Oncology projects:

A.) The following is a broad overview of the medical personnel that is deployed for each ONCOLOGY project:

1. Oncologist Specialist - MD Surgeon
2. Anatomist & Oncologist - MD
3. Clinical Pathologist - MD
4. Medical Technologist
5. Other Support Personnel - Nurses

B.) The following is a broad overview of the resources utilized for each ONCOLOGY project:

1. Hospitals , Operating Rooms
2. Clinical Rooms
3. Centrifuges
4. Other Specialized Medical Equipment and Instruments
5. *Client Company specified and preferred bio specimen collection kits.*

Provided by Client Company

C.) The following is a broad overview of the final verification and shipping procedure for each ONCOLOGY project:

1. Finalize all documents and verify all bio specimens for Client Company.
2. Properly prepare and secure package for shipping via WORLD COURIER or Client Company preferred shipper.
3. **IMPORTANT NOTICE WHEN SENDING MEDICAL EQUPIMENT AND SUPPLIES TO PERU**: Certain medical items need a Peruvian import permit. In order to avoid shipping and project delays the following items should not be included in any of your company's shipments of medical equipment or medical supplies to PERU: ***Biohazard Bag, Gauze Pads, Absorbent Strips, Alcohol Pads, Bandages, Stat-Strips Adhesive, BD367281 Butterfly Needles.***

Please feel free to visit www.tpida.org for additional information related to the organization's scope of medical expertise.

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SPECIALIZING IN PROSPECTIVE BIO SPECIMEN COLLECTION AND RESEARCH

PROSPECTIVE INFECTIOUS DISEASE BIO SPECIMEN PROJECT INITIATION PROCEDURE

CLIENT COMPANY

Master Service Agreement
Material Transfer Agreement
IRB (Internal Review Board by Project)
Non Disclosure Agreements
Additional Documents and Agreements

SUBJECT

IC (Informed Consent), Other documentation
Collection of ALL demographic information per subject

PROSPECTIVE INFECTIOUS DISEASE BIO SPECIMEN COLLECTION AND RESEARCH PROCEDURE

INFECTIOUS DISEAESES

The following is an overview of the TPIDA Organization prospective bio specimen collection and research procedure for all Infectious Disease projects:

A.) The following is a broad overview of the medical personnel that is deployed for each INFECTIOUS DISEASE project:

1. Infection Disease Specialist - MD - Cellular & Molecular Biologist
2. Clinical Pathologist - MD
3. Medical Technologist
4. Other Support Personnel - Nurses

B.) The following is a broad overview of the resources utilized for each INFECTIOUS DISEASE project:

1. Hospitals, On Site Location (Jungles)
2. Clinical Rooms
3. Centrifuges
4. Other Specialized Medical Equipment and Instruments
5. *Client Company specified and preferred bio specimen collection kits.*

   Provided by Client Company

C.) The following is a broad overview of the final verification and shipping procedure for each INFECTIOUS DISEASE project:

1. Finalize all documents and verify all bio specimens are sero-positive by Elisa, PCR and via acute and chronic clinical symptoms.
2. Properly prepare and secure package for shipping via WORLD COURIER or Client Company preferred shipper.
3. **IMPORTANT NOTICE WHEN SENDING MEDICAL EQUPIMENT AND SUPPLIES TO PERU**: Certain medical items need a Peruvian import permit. In order to avoid shipping and project delays the following items should not be included in any of your company's shipments of medical equipment or medical supplies to PERU: ***Biohazard Bag, Gauze Pads, Absorbent Strips, Alcohol Pads, Bandages, Stat-Strips Adhesive, BD367281 Butterfly Needles.***

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APPENDIX

1. EXAMPLE - THE TPIDA ORGANIZATION CLINICAL PATHOLOGY & LABORATORY DATA REPORT FORM

2. EXAMPLE - THE TPIDA ORGANIZATION CASE REPORT FORM – CANCER

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CLINICAL PATHOLOGY & LABORATORY DATA REPORT FORM

ALL INFORMAITON ASSOCIATED WITH THIS REPORT IS CONSIDER CONFIDENTIAL AND THE PROPERTY OF THE TPIDA ORGANIZATON.

STUDY #:	
PROJECT #:	
SITE ID #:	

CLINCIAL PATHOLOGY REPORT

PLEASE WRITE OR ATTACHED A CLINICAL PATHOLOGY REPORT AND DIAGNOSIS FOR THE CANCER OR THE DISEASE.	STAMP
Number of Pages Attached:	**SIGNATURE**

LABORATORY DATA REPORT

PLEASE WRITE OR ATTACHED A LABORATORY DATA REPORT FOR VERIFICATION OF THE CANCER OR THE DISEASE.	STAMP
Number of Pages Attached:	**SIGNATURE**

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CASE REPORT FORM

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STUDY #:

PROJECT#:

SITE ID#:

INCLUSION CRITERIA

1. Has the subject signed an informed consent form? ☐ NO ☐ YES DATE: MONTH | DATE | YEAR

2. Is the subject aged 50 – 79 years (inclusive)? ☐ NO ☐ YES

3. Has the subject been diagnosed with CT Radiologically confirmed pulmonary nodule(s) classified as Lung-RADSTM category 2, 3, 4A, 4B, or 4X requiring additional follow-up? ☐ NO ☐ YES DATE OF DIAGNOSIS: MONTH | DATE | YEAR

**Pathology diagnosis may be derived from bronchoscopic cytology (brushing, aspirate smear or cell block) or histopathology of transbronchial biopsy or CT guided fine needle biopsy.*

4. Is a copy of the subject's de-identified CT Radiological report with diagnosis available to attach to this CRF? ☐ NO ☐ YES

All responses to the above questions must be "YES" to continue.

EXCLUSION CRITERIA

5. Does the subject have a prior history of cancer (other than non-melanoma skin cancer or an in-situ carcinoma)? ☐ NO ☐ YES

6. Has the subject received treatment for or advisement by a physician of evidence of any cancer (other than non-melanoma skin cancer or an in-situ carcinoma) within the past five years? ☐ NO ☐ YES

7. Has the subject had prior removal of any portion of the lung (other than a percutaneous lung biopsy)? ☐ NO ☐ YES

8. Has the subject had additional treatment* or procedures for the radiologically diagnosed pulmonary nodules prior to blood sample collection for this trial? (*Additional treatment or procedures include, but are not limited to, additional radiological imaging, biopsy, spirometry, surgical resection.) ☐ NO ☐ YES

9. Has the subject experienced unexplained weight loss of over 15 lbs or has the subject coughed up blood within the past 12 months (365 days)? ☐ NO ☐ YES

10. Has the subject had any cytotoxic therapy (i.e., chemotherapy or radiation therapy) within the past 6 months? ☐ NO ☐ YES

11. Has the subject self-reported being diagnosed with HIV or Hepatitis A, B, or C? ☐ NO ☐ YES

Response to the above questions must be "NO" to continue.

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CASE REPORT FORM

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STUDY #:

PROJECT#:

SITE ID#:

SUBJECT DEMOGRAPHICS

12. **DATE OF BIRTH** | | | |
MONTH DATE YEAR

13. **GENDER**: ☐ Male ☐ Female

14. **RACE/ETHNICITY:** (Select one or more)
☐ American Indian or Alaska Native
☐ Asian
☐ Black or African American
☐ White, Non-Hispanic or Non-Latino
☐ White, Hispanic or Latino
☐ Native Hawaiian or Other Pacific Islander

MEDICAL HISTORY

15**. MENOPAUSAL STATUS:** ☐ Not Applicable → Reason: ☐ Male ☐ Other: _____

☐ Pre-Menopausal ☐ Peri-Menopausal ☐ Post-Menopausal

16. **HEIGHT:** FT. | IN.

17. **WEIGHT:** LBS.

18. **SMOKING HISTORY:**
Does the subject currently smoke?

☐ NO → Quit? _____ (*Circle*): Day(s) / Week(s) / Month(s) / Year(s) ago

☐ YES → Last Cigarette _____ (*Circle*): Hour(s) / Day(s) / Week(s) / Month(s) ago

Number of packs smoked: _____ per (*Circle*): Day / Week / Month / Year

Duration of time that subject smoked: _____ years

19**. ALCOHOL CONSUMPTION HISTORY:**
Does subject currently consume alcohol beverages? ☐ NO ☐ YES

Length of time since subject had last alcohol beverage: _____ (*Circle*): Day(s) / Week(s) / Month(s) / Year(s) ago

Average number of alcohol beverages subject consumed: _____ per (*Circle*): Day / Week / Month / Year

Duration of time that subject consumed alcohol: _____ years

20**. BENIGN LUNG NODULE (BLN) TYPE:**

☐ Granuloma(s)

☐ Hamartoma(s)

☐ Infection-associated BLN(s) (*e.g.,* tuberculosis, histoplasmosis, coccidioidomycosis, cryptococcosis, aspergillosis, pneumocystis carinii pneumonia (PCP) in an immune deficient patient)

☐ inflammation- /fibrosis- associated BLN(s) (*e.g.,* rheumatoid arthritis, sarcoidosis, Wegener's granulomatosis, rounded atelectasis, bronchogenic cysts, healed pulmonary infarcts, focal hemorrhage, hemangiomas and multiple recurrent bronchopneumonias)

☐ Unknowns

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STUDY #:

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MEDICAL HISTORY CONTINUED

21. BLN Lung-RADSTM CATEGORY:

☐ 2 - (benign appearance, <1% chance of malignancy)
- solid nodule(s)
  - <6 mm
  - new nodule <4 mm
- subsolid nodule(s)
  - <6 mm on baseline screening
- ground glass nodule(s)
  - <20 mm
  - ≥20 mm and unchanged or slowly growing
- category 3 or 4 nodules that are unchanged for ≥3 months

☐ 3 - (probably benign, 1-2% chance of malignancy)
- solid nodule(s)
  - ≥6 mm to <8 mm at baseline
  - new nodule 4 mm to <6 mm
- subsolid nodule(s)
  - ≥6 mm total diameter with solid component <6 mm
  - new <6 mm total diameter
- ground glass nodule(s)
  - ≥20 mm on baseline CT or new

☐ 4A - (suspicious, 5-15% chance of malignancy)
- solid nodule(s)
  - ≥8 mm to <15 mm at baseline
  - growing nodule(s) <8 mm
  - new nodule 6 mm to <8 mm
- subsolid nodule(s)
  - ≥6 mm total diameter with solid component >=6 mm to <8 mm
  - new or growing <4 mm solid component
- endobronchial nodule

☐ 4B - (suspicious, >15% chance of malignancy)
- solid nodule(s)
  - ≥15 mm
  - new or growing, and ≥8 mm
- subsolid nodule(s)
  - solid component ≥8 mm
  - new or growing ≥4 mm solid component

☐ 4X - (suspicious, >15% chance of malignancy)
- category 3 or 4 nodules with additional features or imaging findings that increases the suspicion of malignancy includes:
  - spiculation
  - ground glass nodule(s) that double in size in 1 year
  - enlarged regional lymph nodes

CASE REPORT FORM

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MEDICAL HISTORY CONTINUED

22. FAMILIAL HISTORY:

Does the subject have a family history of Lung Cancer? ☐ YES ☐ NO ☐ UNKNOWN

Does the subject have a family history of other Lung Disease? ☐ YES ☐ NO ☐ UNKNOWN

CONCURRENT MEDICAL CONDITIONS

☐ **NO CONCURRENT MEDICAL CONDITIONS**

CARDIOLOGY

- ☐ Congestive Heart Failure
- ☐ Angina (Stable Exertional)
- ☐ Angina (Unstable)
- ☐ Atrial Fibrillation
- ☐ Chest Pain
- ☐ Cor Pulmonale
- ☐ Coronary Artery Disease(CAD)
- ☐ Deep Vein Thrombosis (DVT)
- ☐ Edema
- ☐ Hypercholesterolemia
- ☐ Hyperlipidemia / Dyslipidemia
- ☐ Hypertension
- ☐ Ischemic Cardiomyopathy
- ☐ Mitral Regurgitation
- ☐ Myocardial Ischemia
- ☐ Myocarditis
- ☐ Pericarditis
- ☐ Thrombosis / Embolism

CONSTITUTIONAL

- ☐ Fatigue
- ☐ Obesity
- ☐ Weight Loss
- ☐ Weight Gain

NEPHROLOGY

- ☐ Hematuria
- ☐ Proteinuria
- ☐ Renal Failure
- ☐ Urinary Tract Infection (UTI)

MUSCULOSKELETAL

- ☐ Arthritis
- ☐ Rheumatoid Arthritis
- ☐ General Pain / Inflammation
- ☐ Gout
- ☐ Osteoporosis
- ☐ Osteopenia

DIGESTIVE

- ☐ Anorexia
- ☐ Constipation
- ☐ Dehydration
- ☐ Diarrhea
- ☐ Diverticular Disease
- ☐ Dysphagia / Odynophagia
- ☐ Esophagitis
- ☐ GERD
- ☐ Irritable Bowel Syndrome (IBS)
- ☐ Mucositis
- ☐ Nausea
- ☐ Ulcerative Colitis
- ☐ Vomiting

ENDOCRINE

- ☐ Diabetes:
  - ☐ Type I
  - ☐ Type II
  - ☐ Unknown
- ☐ Hot Flashes / Flushes
- ☐ Hyperthyroidism
- ☐ Hypothyroidism

NEUROLOGY

- ☐ Anxiety Disorder
- ☐ Depression
- ☐ Insomnia
- ☐ Neuropathy
- ☐ Sleep Apnea
- ☐ Sleep Disorder
- ☐ Headaches
- ☐ Syncope

PULMONARY

- ☐ Allergies
- ☐ Asthma
- ☐ Chronic Bronchitis
- ☐ Chronic Obstructive Pulmonary Disease (COPD)
- ☐ Cold/Congestion
- ☐ Cough
- ☐ Dyspnea
- ☐ Emphysema
- ☐ Hiccups
- ☐ Hypoxia
- ☐ Pleural Effusion (non-malignant)
- ☐ Pleural Effusion (malignant)

OTHER

- ☐ Specify:_____

_____

_____

_____

_____

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CASE REPORT FORM

TPAIDA-IPTEI IEC
SCIENCE & MEDICINE

SPECIALIZING IN PROSPECTIVE BIO SPECIMEN COLLECTION AND RESEARCH

TOS&MRC APPROVAL FOR RESEARCH USE ONLY

STUDY #:

PROJECT#:

SITE ID#:

CONCURRENT MEDICATIONS

RECORD ALL MEDICATIONS THE SUBJECT IS CURRENTLY TAKING: ☐ NONE

_____

_____

_____

DIAGNOSTIC IMAGING

(RECORD ALL IMAGING RESULTS OBTAINED WITHIN THE LAST 120 DAYS)

Imaging Results: Attach copies of all supporting Imaging Reports to Case Report Form.

TEST	DATE OF RESULTS	TEST	DATE OF RESULTS
☐ CHEST X RAY		☐ PET SCAN	
☐ ULTRASOUND		☐ MRI	
☐ CT SCAN		☐ OTHER(Indicate))	

☐ **NO DIAGNOSTIC INAGING RESULTS AVAILABE**

DIAGNOSTIC TESTING

(RECORD ALL IMAGING RESULTS OBTAINED WITHIN THE LAST 120 DAYS)

Most Recent Tumor Marker Test Results: Attach Copies Of All Supporting Lad Reports To Case Report Form.

TEST	RESULTS	DATE OF RESULTS	TEST	RESULTS	DATE OF RESULTS
☐ CA 15-3			☐ PAP		
☐ CA 125			☐ CYFRA 21-1		
☐ CA 27.9			☐ EGFR MUTATION		
☐ CEA			☐ KRAS MUTATION		
☐ CHROMOGRANIN A			☐ OTHER:		
☐ NSE			☐ OTHER:		

☐ **NO TUMOR MARKER TEST RESULTS AVAILABLE**

FOOD CONSUMPTION

22. WHEN DID THE SUBJECT EAT LAST? DATE:

MONTH	DATE	YEAR

_____ : _____
(Military Time)

23. **HAS IT BEEN AT LEAST 2 HOUTS SINCE THE SUBJECT ATE LAST?**

☐ YES ☐ NO → DO NOT PROCEED WITH COLLECTION UNTIL AT LEAST 2

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STUDY #:

PROJECT#:

SITE ID#:

SPECIMEN COLLECTION & PROCESSING

TUBE TYPE: **LOT #:** **EXPIRATION DATE:**

CENTRIFUGE: MODEL ST8, ROTOR TX150 WITH TX150 ROUND BUCKETS
ADAPTERS: 4X10 ML ROUND BUCKET FOR ROTOR TX150 / 4X15 ML CONICAL ROUND BUCKET FOR ROTOR TX150

SPECIEMEN MATRIIX: ☐ EDTA PLASMA

DATE DRAWN: MONTH | DAY | YEAR

TIME DRAWN: _____:_____ Military Time

STUDY STAFF INITIALS (COLLECTION):

TIME OF CENRIFUGATION #1 (K2 EDTA TUBES)

START: _____:_____ Military Time

FINISH: _____:_____ Military Time

DO SAMPLES APPEAR HEMOLYZED*? ☐ YES ☐ NO

***Evidenced by the PLASMA sample color ranging from pale red to cherry red in color.**

LONG TERM STORAGE:

Date & Time Placed at -80°C	FREEZER ID #:	FREEZER TEMP.
_____/_____/_____ _____:_____ Military Time		-80°C

STUDY STAFF INITIALS (Processing):

I have reviewed the data on all pages of the Case Report Form and certify that the information recorded is complete, accurate, and compatible with the corresponding source documents.

Investigator's Signature:_____

Date:_____/_____/_____

☐

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