Delegation of Responsibility and Staff Signature Log

Protocol Title:	
Protocol Number:	**Sponsor:** **UAMS**
Facility:	**Investigator:**

Use One Vertical Column for Each Designee

Designee (Full Name)					
Title and Position					
Delegated Activity (See Codes Below)					
Designee Signature And Date					
Designee Initials (As Signed Above)					

Activity Codes:

01: Obtain Informed Consent
02: Perform Physical Exam
03: Conduct Subject Interviews
04: CRF Entries
05: Drug Dispensing
06: Drug Reconciliation
07: Serious Adverse Event Assessment
08: Serious Adverse Event Documentation and reporting
09: Maintain Regulatory Documents
10: Regulatory Submissions to sponsor and IRB
11: Collect specimens from subject
12: Process and ship specimens

Investigator's Authorization: I hereby delegate the above significant research-related duties to the following persons and understand that the overall Responsibility for conduct of the research remains with me.

**Investigator's Signature: Date:

Investigator must re-sign this log with any change in **KEY RESEARCH PERSONNEL

Adverse Events

Subject ID: I N D # # **U A** * ☐☐

☐ **Mark here if no adverse events occurred**

Subject Initials: ☐☐☐

	Description of Adverse Event	Grade	Relationship: IND Drug	Relationship: Protocol	Action taken	Outcome	Serious?
1	_____	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5	☐	☐ Not related ☐ Unlikely ☐ Possible ☐ Probable ☐ Definite	☐ None ☐ Drug stopped temporarily ☐ Drug stopped permanently	☐ Persisted ☐ Resolved ☐ Unknown ☐ Death	☐ Yes ☐ No
Start Date	☐☐ (Day) ☐☐☐ (Month) ☐☐☐☐ (Year)						
Stop Date	☐☐ (Day) ☐☐☐ (Month) ☐☐☐☐ (Year) ☐ Ongoing?						
2	_____	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5	☐	☐ Not related ☐ Unlikely ☐ Possible ☐ Definite	☐ None ☐ Drug stopped temporarily ☐ Drug stopped permanently	☐ Persisted ☐ Resolved ☐ Unknown ☐ Death	☐ Yes ☐ No
Start Date	☐☐ (Day) ☐☐☐ (Month) ☐☐☐☐ (Year)						
Stop Date	☐☐ (Day) ☐☐☐ (Month) ☐☐☐☐ (Year) ☐ Ongoing?						
3	_____	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5	☐	☐ Not related ☐ Unlikely ☐ Possible ☐ Definite	☐ None ☐ Drug stopped temporarily ☐ Drug stopped permanently	☐ Persisted ☐ Resolved ☐ Unknown ☐ Death	☐ Yes ☐ No
Start Date	☐☐ (Day) ☐☐☐ (Month) ☐☐☐☐ (Year)						
Stop Date	☐☐ (Day) ☐☐☐ (Month) ☐☐☐☐ (Year) ☐ Ongoing?						

Completed by: _____ **On:** ☐☐ (Day) ☐☐☐ (Month) ☐☐☐☐ (Year)

IND Study #_____

Concomitant Medications

Pg ____ of ____

Subject ID: I N D # # U A * ____ ____ **Subject Initials:** ____ ____ ____

	Medication Name	Indication	Dose/Unit/Route
1)			
2)			
3)			
4)			
5)			
6)			
7)			

Start Date: ____ ____ (Day) ____ ____ ____ (Month) ____ ____ ____ ____ (Year)

Stop Date: ____ ____ (Day) ____ ____ ____ (Month) ____ ____ ____ ____ (Year) ____ Ongoing √

Completed by: _____ **On:** ____ ____ (Day) ____ ____ ____ (Month) ____ ____ ____ ____ (Year)

IND Study #_____

Physical Exam

Visit 1 . 0

Subject ID: I N D # # U A * [ ][ ] **Visit Date:** [ ][ ] Day [ ][ ][ ] Month [ ][ ][ ][ ] Year

Subject Initials: [ ][ ][ ]

	WNL	ABN	√ if ND	Comment if Abnormal
General	☐	☐	☐	_____
HEENT	☐	☐	☐	_____
Chest Wall	☐	☐	☐	_____
Pulmonary	☐	☐	☐	_____
Abdomen	☐	☐	☐	_____
Musculoskeletal	☐	☐	☐	_____
Extremities	☐	☐	☐	_____
Neurological	☐	☐	☐	_____
Skin	☐	☐	☐	_____
Lymphatic	☐	☐	☐	_____
Psych	☐	☐	☐	_____

Completed by: _____ **Date:** [ ][ ] Day [ ][ ][ ] Month [ ][ ][ ][ ] Year

Tumor Assessment (COR)

Visit 1 . 0

Subject ID: I N D # # U A * [ ][ ] **Visit Date:** [ ][ ] Day [ ][ ][ ] Month [ ][ ][ ][ ] Year

Subject Initials: [ ][ ][ ]

Target Lesion Measurement

Tumor laterality (check one) [ ] Left [ ] Right

Site	Horizontal		Vertical		Product (cm)
[ ][ ][ ]	[ ][ ] . [ ]	x	[ ][ ] . [ ]		[ ][ ] . [ ]
[ ][ ][ ]	[ ][ ] . [ ]	x	[ ][ ] . [ ]		[ ][ ] . [ ]

[ ] √ if Not Applicable

Product of all target lesions [ ][ ][ ] . [ ]

Site codes: UOQ=Upper Outer Quadrant, **LOQ**=Lower Outer Quadrant, **UIQ**=Upper Inner Quadrant, **LIQ**=Lower Inner Quadrant, **CEN**=Centrally Located

Regional Nodes/Axilla

Does the subject have involvement of the regional nodes/axilla? [ ] Yes – complete below [ ] No

Site	Palpable?	Non-palpable?	Measurable?	Horizontal		Vertical		Product (cm)
[ ][ ][ ]	[ ]	[ ]	[ ] →	[ ][ ] . [ ]	x	[ ][ ] . [ ]		[ ][ ] . [ ]

Product of all target lesions [ ][ ] . [ ]

Site codes: RAX=Right Axilla, **LAX**=Left Axilla, **RSC**=Right Supraclavicular, **LSC**=Left Supraclavicular

Completed by: _____ **On:** [ ][ ] Day [ ][ ][ ] Month [ ][ ][ ][ ] Year

Vital Signs

Visit 1 . 0

Subject ID: I N D # # U A * ____ **Visit Date:** ____ (Day) ____ (Month) ____ (Year)

Subject Initials: ____

Date of this exam: ____ (Day) ____ (Month) ____ (Year)

Height: ____ . ____ ____ cm ____ In

Weight: ____ . ____ ____ kg ____ lbs

Blood Pressure: ____ / ____

Pulse: ____ / minute

Temperature: ____ . ____ ____ ºC ____ ºF

Respirations: ____ / minute

Performance Status: ____ 0 ____ 1 ____ 2

____ √ **if Not Applicable** ____ √ **if Not Done**

Post Treatment Time: ____ : ____ (H H : M M)

Blood Pressure: ____ / ____

Pulse: ____ / minute

Temperature: ____ . ____ ____ ºC ____ ºF

Respirations: ____ / minute

Completed by: _____ **On:** ____ (Day) ____ (Month) ____ (Year)

Laboratory

Visit 1 . 0

Subject ID: I N D # # **U** **A** * [ ][ ] **Visit Date:** [ ][ ] Day [ ][ ][ ] Month [ ][ ][ ][ ] Year

Subject Initials: [ ][ ][ ]

Specimen Collection Date: [ ][ ] Day [ ][ ][ ] Month [ ][ ][ ][ ] Year

		√ if ND			√ if ND
WBC (K/µL)	[ ][ ] . [ ][ ]		Neutrophils (%)	[ ][ ] . [ ]	
Absolute Neutrophil Count	[ ][ ][ ][ ][ ]		Total bilirubin (mg/dL)	[ ][ ] . [ ]	
Platelets (K/µL)	[ ][ ][ ]		LDH (IU/L)	[ ][ ][ ][ ]	
RBC (M/µL)	[ ][ ] . [ ][ ]		Alk. phos. (IU/L)	[ ][ ][ ][ ]	
Hemoglobin (g/dL)	[ ][ ][ ] . [ ]		SGOT/AST (IU/L)	[ ][ ][ ]	
BUN (mg/dL)	[ ][ ][ ]		SGPT/ALT (IU/L)	[ ][ ][ ]	
Creatinine (mg/dL)	[ ][ ][ ] . [ ]		GGT (IU/L)	[ ][ ][ ]	
Sodium (mEq/L)	[ ][ ][ ]		PT (sec)	[ ][ ] . [ ]	
Potassium (mEq/L)	[ ] . [ ]		PTT (sec)	[ ][ ] . [ ]	
CO_2 (mEq/L)	[ ][ ][ ]		INR	[ ][ ][ ] . [ ]	
Chloride (mEq/L)	[ ][ ][ ]				

Assay Collection

_____ [ ][ ] Day [ ][ ][ ] Month [ ][ ][ ][ ] Year [ ][ ] H H : [ ][ ] M M [ ]

_____ [ ][ ] Day [ ][ ][ ] Month [ ][ ][ ][ ] Year [ ][ ] H H : [ ][ ] M M [ ]

Completed by: _____ **On:** [ ][ ] Day [ ][ ][ ] Month [ ][ ][ ][ ] Year

Urine Analysis

Visit 1 . 0

Subject ID: I N D # # **U** **A** * ____ **Visit Date:** __ (Day) __ __ __ (Month) __ __ __ __ (Year)

Subject Initials: ___

Specimen Collection Date: __ (Day) __ __ __ (Month) __ __ __ __ (Year)

UPC

		√ if ND
Protein (mg/dL)	__	☐
Creatinine (mg/dL)	__ __ __ . __	☐
Protein / Creatinine ratio	__ . __ __ __	☐

Urine Pregnancy Test

Date of Urine Pregnancy Test: __ (Day) __ __ __ (Month) __ __ __ __ (Year) **or** ☐ √ if NA

Completed by: _____ **On:** __ (Day) __ __ __ (Month) __ __ __ __ (Year)

Drug Information

Visit 1 . 0

Subject ID: I N D # # **U** **A** * ____ **Visit Date:** ____ (Day) ____ (Month) ____ (Year)

Subject Initials: ____

Study Drug Dosing Information

IND Drug (15mg/kg) ____ mg ____ (Day) ____ (Month) ____ (Year)

Lot No. ____ Infusion Time: Start Time ____ : ____

Solution _____ ☐ 90 ± Mins Stop Time ____ : ____

Reaction: ☐ Yes ☐ 60 ± Mins

☐ No ☐ 30 ± Mins

Docetaxel (75mg/m^2) ____ mg ____ (Day) ____ (Month) ____ (Year)

Cyclophosphamide ____ mg

Completed by: _____ **On:** ____ (Day) ____ (Month) ____ (Year)

Eligibility Checklist

Visit 0 . 0

Subject ID: I N D # # U A * [ ] [ ] **Consent Date:** [ ][ ] Day [ ][ ][ ] Month [ ][ ][ ][ ] Year

Subject Initials: [ ][ ][ ]

Instructions: *Check the appropriate box for each Inclusion and Exclusion Criterion below. Each criterion must be marked and all protocol criteria have to be met prior to enrolling the subject.*

Inclusion Criteria

Each criterion must be addressed and documented in the subject's medical record or source.

Y	N	NA	
☐	☐		1. The diagnosis of _____ should be established by _____. In case of participation of other sub-sites in the study, pathology slides and blocks should be submitted for central review at the UAMS Pathology Laboratory. However, enrollment may proceed based on the results of the local review of this material.
☐	☐		2. Subjects should have normal serum BUN and Creatinine levels based on institutional norms at screening.
☐	☐		3. Subjects should have normal LVEF evaluated by MUGA scan ≥ 45% at screening.
☐	☐		4. Female age > 18
☐	☐		5. Good performance status defined by ECOG scale of 0 or 1 (Appendix F).
☐	☐		6. Written consent.
☐	☐	☐	7. Women of childbearing potential must have a negative pregnancy test.
☐	☐	☐	8. Use of effective means of contraception in subjects of child-bearing potential while on treatment and for at least 3 months thereafter.
☐	☐		9. Peripheral neuropathy: must be ≤ grade 1
☐	☐		10. Hematologic (minimal values) Absolute neutrophil count ≥ 1,500/mm^3 Hemoglobin ≥ 8.0 g/dl Platelet count ≥ 100,000/mm^3

Subject ID: | I | N | D | # | # | **U** | **A** | * | | | **Consent Date:** | | Day | | | | Month | | | | | Year

Subject Initials: | | | |

Y **N** **NA**

☐ ☐

11. Hepatic

Total Bilirubin ≤ ULN

AST **and** ALT **and** Alkaline Phosphatase must be within the range allowing for eligibility. In determining eligibility, the more abnormal of the two values (AST or ALT) should be used.

	AST or ALT:			
ALK PHOS:	≤ ULN	> 1X BUT ≤1.5X	>1.5X BUT ≤5X	>5X ULN
≤ ULN	Eligible	Eligible	Eligible	Ineligible
>1x but ≤2.5x	Eligible	Eligible	Ineligible	Ineligible
>2.5x but ≤5x	Eligible	Ineligible	Ineligible	Ineligible
>5x ULN	Ineligible	Ineligible	Ineligible	Ineligible

Eligibility Checklist

Subject ID: I N D # # U A * [ ][ ] **Consent Date:** [ ][ ] Day [ ][ ][ ] Month [ ][ ][ ][ ] Year

Subject Initials: [ ][ ][ ]

Exclusion Criteria

Each criterion must be addressed and documented in the subject's medical record.

Y	N	NA	
			a. Disease-Specific Concerns
☐	☐		1. Subjects who have _____ will be excluded from this study due to the risk of worsening ulcers and healing difficulties
☐	☐		2. Stage _____ cancer
☐	☐		3. Inflammatory cancer
			b. General Medical Concerns
☐	☐		1. Subjects with ECOG performance status 2, 3, and 4 are not eligible for this study
☐	☐		2. Allergy to any component of the treatment regimen
☐	☐	☐	3. Refusal to use effective contraception while participating in this study
☐	☐		4. Inability to comply with study and/or follow-up procedures
☐	☐		5. Subjects with secondary malignancy other than superficial skin cancer (squamous cell carcinoma and basal cell carcinoma of the skin) should be excluded
			c. Study Drug - Specific Concerns
☐	☐		1. Current, recent (within 4 weeks of the first infusion of this study), or planned participation in an experimental drug study
☐	☐		2. Blood pressure of > 150/100 mmHg. Essential hypertension well controlled with antihypertensive is not an exclusion criterion.
☐	☐		3. Unstable angina
☐	☐		4. New York Heart Association (NYHA) Grade II or greater congestive heart failure (see Appendix D)
☐	☐		5. History of myocardial infarction within 6 months
☐	☐		6. History of stroke within 6 months

Eligibility Checklist

Subject ID: I N D # # **U** **A** * ____ **Consent Date:** ____ (Day) ____ (Month) ____ (Year)

Subject Initials: ____

Y	N	NA	
☐	☐		7. Clinically significant peripheral vascular disease
☐	☐		8. Evidence of bleeding diathesis or coagulopathy
☐	☐		9. Presence of central nervous system or brain metastases
☐	☐		10. Major surgical procedure, open biopsy, or significant traumatic injury within 28 days prior to Day 0, anticipation of need for major surgical procedure during the course of the study
☐	☐		11. Minor surgical procedures such as fine needle aspirations or core biopsies within 7 days prior to Day 0
☐	☐	☐	12. Pregnant (positive pregnancy test) or breast feeding
☐	☐		13. Urine protein: creatinine ratio ≥1.0 at screening
☐	☐		14. History of abdominal fistula, gastrointestinal perforation, or intra-abdominal abscess within 6 months prior to Day 0
☐	☐		15. Serious, non-healing wound, ulcer, or bone fracture
☐	☐		***Subject meets all eligibility criteria***
☐	☐	☐	***If the subject did not meet all eligibility criteria, was a waiver granted by the medical monitor***

_____ Date: ____ (Day) ____ (Month) ____ (Year)

Signature of Principal Investigator

_____ Date: ____ (Day) ____ (Month) ____ (Year)

Completed by

Demographics

Visit 0 . 0

Subject ID: I N D # # **U A** * ____ **Consent Date:** ____ (Day) ____ (Month) ____ (Year)

Subject Initials: ____

Date of Birth: ____ (**Day**) ____ (**Month**) ____ (**Year**)

Race:
(Mark all which apply)

- ☐ White
- ☐ Black or African American
- ☐ Native Hawaiian or other Pacific Islander
- ☐ Asian
- ☐ American Indian or Alaska Native
- ☐ Unknown

Ethnicity:
(Mark only 1)

- ☐ Hispanic or Latino
- ☐ Non-Hispanic
- ☐ Unknown

Completed by: _____ **On:** ____ (Day) ____ (Month) ____ (Year)

Disease History

Visit 0 . 0

Subject ID: I N D # # **U A** * ____ **Consent Date:** ____ (Day) ____ (Month) ____ (Year)

Subject Initials: ____

Date of initial diagnosis of _____ ____ (Day) ____ (Month) ____ (Year)

				√ if ND
Receptor Analyses:	Estrogen	☐ Positive	☐ Negative	☐
	Progesterone	☐ Positive	☐ Negative	☐
HER2 Analyses:	IHC	☐ Positive	☐ Negative	☐
	FISH	☐ Positive	☐ Negative	☐

Staging

Primary tumor ☐ T1 ☐ T2 ☐ T3 ☐ T4

Lymph Node ☐ NX ☐ N0 ☐ N1 ☐ N2 ☐ N3

Metastasis ☐ MX ☐ M0 ☐ M1

Menopausal Status (√ one):

☐ Pre (< 6 mo since LMP and no prior bilateral ovariectomy and not on estrogen replacement)
***If √, a urine pregnancy test is required**

☐ Post (prior bilateral ovariectomy OR > 12 mo since LMP and no prior hysterectomy)

☐ Above not applicable AND age < 50 (pre) ☐ Above not applicable AND age > 50 (post)

Name of Biopsy

Was _____ node sampling performed? ☐ Yes ☐ No

_____ Biopsy Date: ____ (Day) ____ (Month) ____ (Year)

_____ Biopsy Results: ☐ Positive ☐ Negative

Number of _____ Examined: ____ Number of _____ Positive: ____

Completed by: _____ **On:** ____ (Day) ____ (Month) ____ (Year)

Medical History

Visit 0 . 0

Subject ID: I N D # # U A * [ ][ ] **Consent Date:** [ ][ ] Day [ ][ ][ ] Month [ ][ ][ ][ ] Year

Subject Initials: [ ][ ][ ]

Record pertinent medical and/or surgerical history in the space provided below

System	Normal	Abnormal	List Diagnosis and Date
Head/Ears/Eyes/Nose/Throat	☐	☐	
Respiratory	☐	☐	
Cardiovascular	☐	☐	
Gastrointestinal	☐	☐	
Hepatic/GallBladder	☐	☐	
Renal	☐	☐	
Genitourinary	☐	☐	
Musculoskeletal	☐	☐	
Dermatological	☐	☐	
Nervous System	☐	☐	
Hematological	☐	☐	
Lymphatic	☐	☐	
Endocrine	☐	☐	
Psychological/Psychiatric	☐	☐	
Other _____	☐	☐	

Completed by: _____ **On:** [ ][ ] Day [ ][ ][ ] Month [ ][ ][ ][ ] Year

Radiology

Subject ID: I N D # # **U** **A** * ____ **Consent Date:** ____ (Day) ____ (Month) ____ (Year)

Subject Initials: ____

	Day	Month	Year	Normal	Local/ Regional	Metastatic	√ if ND
Chest X-ray							
CT Brain and/or MRI Brain							
CT Chest and/or MRI Chest							
CT Abdomen and/or MRI Abdomen							
Bone Scan							
PET CT							

Completed by: _____ **On:** ____ (Day) ____ (Month) ____ (Year)

EKG

Subject ID: | I | N | D | # | # | **U** | **A** | * | | | **Consent Date:** | | | Day | | | Month | | | | Year

Subject Initials: | | | |

Date of ECG: | | | Day | | | | Month | | | | Year

Overall interpretation:

☐ Normal

☐ Clinically insignificant abnormality

☐ Clinically significant abnormality *(specify)*

1 _____

2 _____

3 _____

4 _____

5 _____

6 _____

Completed by: _____ **On:** | | Day | | | | Month | | | | Year

Ancillary Exams

Visit 0 . 0

Subject ID: I N D # # **U** **A** * _____ **Consent Date:** _____ (Day) _____ (Month) _____ (Year)

Subject Initials: _____

Date of Mammogram: _____ (Day) _____ (Month) _____ (Year)

☐ Normal

☐ Abnormal

Birad: ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

Date of MUGA: _____ (Day) _____ (Month) _____ (Year)

LVEF _____ %

Completed by: _____ **On:** _____ (Day) _____ (Month) _____ (Year)

Physical Exam

Visit 0 . 0

Subject ID: | I | N | D | # | # | U | A | * | | | **Consent Date:** Day | | Month | | | Year

Subject Initials: | | | |

	WNL	ABN	√ if ND	Comment if Abnormal
General	☐	☐	☐	_____
HEENT	☐	☐	☐	_____
Chest Wall	☐	☐	☐	_____
Pulmonary	☐	☐	☐	_____
Abdomen	☐	☐	☐	_____
Musculoskeletal	☐	☐	☐	_____
Extremities	☐	☐	☐	_____
Neurological	☐	☐	☐	_____
Skin	☐	☐	☐	_____
Lymphatic	☐	☐	☐	_____
Psych	☐	☐	☐	_____

Completed by: _____ **On:** Day | | Month | | | Year

Tumor Assessment (COR)

Visit 0 . 0

Subject ID: I N D # # U A * [ ][ ] **Consent Date:** [ ][ ] Day [ ][ ][ ] Month [ ][ ][ ][ ] Year

Subject Initials: [ ][ ][ ]

Target Lesion Measurement

Tumor laterality (√ one) [ ] Left [ ] Right

Site		Horizontal		Vertical		Product (cm)
[ ][ ][ ]		[ ][ ] . [ ]	x	[ ][ ] . [ ]		[ ][ ] . [ ]
[ ][ ][ ]	[ ] √ if Not Applicable	[ ][ ] . [ ]	x	[ ][ ] . [ ]		[ ][ ] . [ ]
[ ][ ][ ]	[ ] √ if Not Applicable	[ ][ ] . [ ]	x	[ ][ ] . [ ]		[ ][ ] . [ ]

Product of all target lesions [ ][ ][ ] . [ ]

Site codes: UOQ=Upper Outer Quadrant, **LOQ**=Lower Outer Quadrant, **UIQ**=Upper Inner Quadrant, **LIQ**=Lower Inner Quadrant, **CEN**=Centrally Located

Regional Nodes

Does the subject have involvement of the regional nodes/axilla? [ ] Yes – complete below [ ] No

Site	Palpable?	Non-palpable?	Measurable?	Horizontal		Vertical		Product (cm)
[ ][ ][ ]	[ ]	[ ]	[ ] →	[ ][ ] . [ ]	x	[ ][ ] . [ ]		[ ][ ] . [ ]

Product of all target lesions [ ][ ] . [ ]

Site codes: RAX=Right Axilla, **LAX**=Left Axilla, **RSC**=Right Supraclavicular, **LSC**=Left Supraclavicular

Completed by: _____ **On:** [ ][ ] Day [ ][ ][ ] Month [ ][ ][ ][ ] Year

Vital Signs

Visit 0 . 0

Subject ID: I N D # # **U A** * [ ][ ] **Consent Date:** [ ][ ] Day [ ][ ][ ] Month [ ][ ][ ][ ] Year

Subject Initials: [ ][ ][ ]

Exam Date: [ ][ ] Day [ ][ ][ ] Month [ ][ ][ ][ ] Year

Height: [ ][ ][ ] . [ ] [ ] cm [ ] In

Weight: [ ][ ][ ] . [ ] [ ] kg [ ] lbs

Blood Pressure: [ ][ ][ ] / [ ][ ][ ]

Pulse: [ ][ ][ ] / minute

Temperature: [ ][ ][ ] . [ ] [ ] ºC [ ] ºF

Respirations: [ ][ ] / minute

Performance Status:

[ ] **0** [ ] **1** [ ] **2**

Completed by: _____ **On:** [ ][ ] Day [ ][ ][ ] Month [ ][ ][ ][ ] Year

Laboratory

Visit 0 . 0

Subject ID: I N D # # U A * [ ][ ] **Consent Date:** [ ][ ] Day [ ][ ][ ] Month [ ][ ][ ][ ] Year

Subject Initials: [ ][ ][ ]

Specimen Collection Date: [ ][ ] Day [ ][ ][ ] Month [ ][ ][ ][ ] Year

		√ if ND			√ if ND
WBC (K/µL)	[ ][ ] . [ ][ ]		Neutrophils (%)	[ ][ ] . [ ]	
Absolute Neutrophil Count	[ ][ ][ ][ ][ ]		Total bilirubin (mg/dL)	[ ][ ] . [ ]	
Platelets (K/µL)	[ ][ ][ ]		LDH (IU/L)	[ ][ ][ ][ ]	
RBC (M/µL)	[ ][ ] . [ ][ ]		Alk. phos. (IU/L)	[ ][ ][ ][ ]	
Hemoglobin (g/dL)	[ ][ ][ ] . [ ]		SGOT/AST (IU/L)	[ ][ ][ ]	
BUN (mg/dL)	[ ][ ][ ]		SGPT/ALT (IU/L)	[ ][ ][ ]	
Creatinine (mg/dL)	[ ][ ][ ] . [ ]		GGT (IU/L)	[ ][ ][ ]	
Sodium (mEq/L)	[ ][ ][ ]		PT (sec)	[ ][ ] . [ ]	
Potassium (mEq/L)	[ ] . [ ]		PTT (sec)	[ ][ ] . [ ]	
CO_2 (mEq/L)	[ ][ ][ ]		INR	[ ][ ][ ] . [ ]	
Chloride (mEq/L)	[ ][ ][ ]				

Assay Collection

√ if ND

_____ [ ][ ] Day [ ][ ][ ] Month [ ][ ][ ][ ] Year [ ][ ] H H : [ ][ ] M M [ ]

_____ [ ][ ] Day [ ][ ][ ] Month [ ][ ][ ][ ] Year [ ][ ] H H : [ ][ ] M M [ ]

Completed by: _____ **On:** [ ][ ] Day [ ][ ][ ] Month [ ][ ][ ][ ] Year

Urine Analysis

Visit 0 . 0

Subject ID: I N D # # **U A** * ____ **Consent Date:** ____ (Day) ____ (Month) ____ (Year)

Subject Initials: ____

Specimen Collection Date: ____ (Day) ____ (Month) ____ (Year)

UPC

		√ if ND
Protein (mg/dL)	____	____
Creatinine (mg/dL)	____ . ____	____
Protein / Creatinine ratio	____ . ____	____

Urine Pregnancy Test

Date of Urine Pregnancy Test: ____ (Day) ____ (Month) ____ (Year) **or** ____ √ if NA

Completed by: _____ **On:** ____ (Day) ____ (Month) ____ (Year)