

WOMEN'S INTERAGENCY HIV STUDY - SCHEDULE OF LABORATORY EVALUATIONS

TEST	FORM #	BASELINE Oct 1994 - Nov 1995	VISIT 2 Apr 1995 - Sept 1995	VISIT 3 Oct 1995 - Mar 1996	VISIT 4 Apr 1996 - Sept 1996	VISIT 5 Oct 1996 - Mar 1997	VISIT 6 Apr 1997 - Sept 1997	VISIT 7 Oct 1997 - Mar 1998	VISIT 8 Apr 1998 - Sept 1998	VISIT 9 Oct 1998 - Mar 1999
Blood										
HIV ELISA	L01	X	X HIV- only	X HIV- or indeterminate only	X HIV- or indeterminate only	X HIV- or indeterminate only	X HIV- or indeterminate only	X HIV- or indeterminate only	X HIV- or indeterminate only	X HIV- or indeterminate only
Western Blot	L01	X + ELISA only	X + ELISA only	X + ELISA only	X + ELISA only	X + ELISA only	X + ELISA only	X + ELISA only	X + ELISA only	X + ELISA only
Automated CBC / Differential	L03	X	X	X	X	X	X	X	X	X
Manual Differential	L03A	X if automated diff is flagged	X if automated diff is flagged	X if automated diff is flagged	X if automated diff is flagged	X if automated diff is flagged	X if automated diff is flagged	X if automated diff is flagged	X if automated diff is flagged	X if automated diff is flagged
T-Cell count & subsets	L04	X	X	X	X	X	X	X	X	X
Liver/Renal Function Partial Chemistries	L05	X		X		X		X		X
RPR Syphilis Screening	L06	X			X		X		X	
Hepatitis Serology	L02	X								
Toxoplasma Serology	C30	X								
HTLV 1&2	C31	X								
Herpes Serologies (HSV)	C66	X Save & batch								
HIV RNA Quantification	C54	X HIV+ only	X HIV+ only	X HIV+ only	X HIV+ only	X HIV+ only	X HIV+ only	X HIV+ only	X HIV+ only	X HIV+ only
Serum, Plasma & Cells for central & local repository	F10, L20	X	X	X	X	X	X	X	X	X
Lipid panel										
Insulin and glucose										
HgA1c										
CVD serum for novel assays and EDTA plasma for NMR lipoprotein	CV29									

WOMEN'S INTERAGENCY HIV STUDY - SCHEDULE OF LABORATORY EVALUATIONS

TEST	FORM #	VISIT 10 Apr 1999 - Sept 1999	VISIT 11 Oct 1999 - Mar 2000	VISIT 12 Apr 2000 - Sept 2000	VISIT 13 Oct 2000 - Mar 2001	VISIT 14 Apr 2001 - Sept 2001	VISIT 15 (94/95 Cohort) Oct 2001 - Mar 2002	BASELINE 01/02 Cohort (Visit 15 or 16) Oct 2001 - Sept 2002	VISIT 16 Apr 2002 - Sept 2002	VISIT 17 Oct 2002 - Mar 2003
Blood										
HIV ELISA	L01	X HIV- or indeterminate only	X HIV- or indeterminate only	X HIV- or indeterminate only	X HIV- or indeterminate only	X HIV- or indeterminate only	X HIV- or indeterminate only	X HIV- or indeterminate, or HIV+ with no documentation	X HIV- or indeterminate only	X HIV- or indeterminate only
Western Blot	L01	X + ELISA only	X + ELISA only	X + ELISA only	X + ELISA only	X + ELISA only	X + ELISA only	X + ELISA only	X + ELISA only	X + ELISA only
Automated CBC / Differential	L03	X	X HIV+ only	X	X HIV+ only	X	X HIV+ only	X	X	X HIV+ only
Manual Differential	L03A	X if automated diff is flagged	X if automated diff is flagged	X if automated diff is flagged	X if automated diff is flagged	X if automated diff is flagged	X if automated diff is flagged	X if automated diff is flagged	X if automated diff is flagged	X if automated diff is flagged
T-Cell count & subsets	L04	X	X HIV+ only	X	X HIV+ only	X	X HIV+ only	X	X	X HIV+ only
Liver/Renal Function Partial Chemistries	L05		X		X	X	X	X	X	X
RPR Syphilis Screening	L06							X		
Hepatitis Serology	L02							X		
Toxoplasma Serology	C30									
HTLV 1&2	C31									
Herpes Serologies (HSV)	C66									
HIV RNA Quantification	C54	X HIV+ only	X HIV+ only	X HIV+ only	X HIV+ only	X HIV+ only	X HIV+ only	X HIV+ only	X HIV+ only	X HIV+ only
Serum, Plasma & Cells for central & local repository	F10, L20	X	X	X	X	X	X	X	X	X
Lipid panel					X Save & batch, if fasting	X Save & batch, if fasting	X Save & batch, if fasting	X Save & batch, if fasting	X Save & batch, if fasting	X Save & batch, if fasting
Insulin and glucose					X Save & batch, if fasting	X Save & batch, if fasting	X Save & batch, if fasting	X Save & batch, if fasting	X Save & batch, if fasting	X Save & batch, if fasting
HgA1c					X Save & batch, if fasting	X Save & batch, if fasting	X Save & batch, if fasting	X Save & batch, if fasting	X Save & batch, if fasting	X Save & batch, if fasting
CVD serum for novel assays and EDTA plasma for NMR lipoprotein	CV29									

WOMEN'S INTERAGENCY HIV STUDY - SCHEDULE OF LABORATORY EVALUATIONS

TEST	FORM #	VISIT 18 Apr 2003 - Sept 2003	VISIT 19 Oct 2003 - Mar 2004	VISIT 20 Apr 2004 - Sept 2004	VISIT 21 Oct 2004 - Mar 2005	VISIT 22 Apr 2005 - Sept 2005	VISIT 23 Oct 2005 - Mar 2006	VISIT 24 Apr 2006 - Sept 2006	VISIT 25 Oct 2006 - Mar 2007	VISIT 26 Apr 2007 - Sept 2007
Blood										
HIV ELISA	L01	X HIV- or indeterminate only	X HIV- or indeterminate only	X HIV- or indeterminate only	X HIV- or indeterminate only	X HIV- or indeterminate only	X HIV- or indeterminate only	X HIV- or indeterminate only	X HIV- or indeterminate only	X HIV- or indeterminate only
Western Blot	L01	X + ELISA only	X + ELISA only	X + ELISA only	X + ELISA only	X + ELISA only	X + ELISA only	X + ELISA only	X + ELISA only	X + ELISA only
Automated CBC / Differential	L03	X	X HIV+ only	X	X HIV+ only	X	X HIV+ only	X	X HIV+ only	X
Manual Differential	L03A	X if automated diff is flagged	X if automated diff is flagged	X if automated diff is flagged	X if automated diff is flagged	X if automated diff is flagged	X if automated diff is flagged	X if automated diff is flagged	X if automated diff is flagged	X if automated diff is flagged
T-Cell count & subsets	L04	X	X HIV+ only	X	X HIV+ only	X	X HIV+ only	X	X HIV+ only	X
Liver/Renal Function Partial Chemistries	L05	X	X	X	X	X	X	X	X	X
RPR Syphilis Screening	L06									
Hepatitis Serology	L02									
Toxoplasma Serology	C30									
HTLV 1&2	C31									
Herpes Serologies (HSV)	C66									
HIV RNA Quantification	C54	X HIV+ only	X HIV+ only	X HIV+ only	X HIV+ only	X HIV+ only	X HIV+ only	X HIV+ only	X HIV+ only	X HIV+ only
Serum, Plasma & Cells for central & local repository	F10, L20	X	X	X	X	X	X	X	X	X
Lipid panel		X Save & batch, if fasting	X Save & batch, if fasting	X	X	X	X		X	
Insulin and glucose		X Save & batch, if fasting	X Save & batch, if fasting	X if fasting	X if fasting	X if fasting	X if fasting		X if fasting	
HgA1c		X Save & batch, if fasting	X Save & batch, if fasting	X	X	X	X			
CVD serum for novel assays and EDTA plasma for NMR lipoprotein	CV29			X Save & batch	X Save & batch	X Save & batch	X Save & batch			

WOMEN'S INTERAGENCY HIV STUDY - SCHEDULE OF LABORATORY EVALUATIONS

TEST	FORM #	VISIT 27 Oct 2007 - Mar 2008	VISIT 28 Apr 2008 - Sept 2008	VISIT 29 Oct 2008 - Mar 2009	VISIT 30 Apr 2009 - Sept 2009	VISIT 31 Oct 2009 - Mar 2010	VISIT 32 Apr 2010 - Sept 2010	VISIT 33 Oct 2010 - Mar 2011	BASELINE 11/12 Cohort (Visit 33 - 37) Jan 2011 - Dec 2012	VISIT 35 Oct 2011 - Mar 2012
Blood										
HIV ELISA	L01	X HIV- or indeterminate only	X HIV- or indeterminate only	X HIV- or indeterminate only	X HIV- or indeterminate only	X HIV- or indeterminate only	X HIV- or indeterminate only	X HIV- or indeterminate only	X HIV- or indeterminate, or HIV+ with no documentation	X HIV- or indeterminate only
Western Blot	L01	X + ELISA only	X + ELISA only	X + ELISA only	X + ELISA only	X + ELISA only	X + ELISA only	X + ELISA only	X + ELISA only	X + ELISA only
Automated CBC / Differential	L03	X HIV+ only	X	X HIV+ only	X	X HIV+ only	X	X HIV+ only	X	X HIV+ only
Manual Differential	L03A	X if automated diff is flagged	X if automated diff is flagged	X if automated diff is flagged	X if automated diff is flagged	X if automated diff is flagged	X if automated diff is flagged	X if automated diff is flagged	X if automated diff is flagged	X if automated diff is flagged
T-Cell count & subsets	L04	X HIV+ only	X	X HIV+ only	X	X HIV+ only	X	X HIV+ only	X	X HIV+ only
Liver/Renal Function Partial Chemistries	L05	X	X	X	X	X	X	X	X	X
RPR Syphilis Screening	L06								X	
Hepatitis Serology	L02								X	
Toxoplasma Serology	C30									
HTLV 1&2	C31									
Herpes Serologies (HSV)	C66									
HIV RNA Quantification	C54	X HIV+ only	X HIV+ only	X HIV+ only	X HIV+ only	X HIV+ only	X HIV+ only	X HIV+ only	X HIV+ only	X HIV+ only
Serum, Plasma & Cells for central & local repository	F10, L20	X	X	X	X	X	X	X	X	X
Lipid panel		X		X per protocol	X per protocol	X		X	X	X
Insulin and glucose		X if fasting		X per protocol	X per protocol	X if fasting		X if fasting	X if fasting	X if fasting
HgA1c								X	X	X
CVD serum for novel assays and EDTA plasma for NMR lipoprotein	CV29									

WOMEN'S INTERAGENCY HIV STUDY - SCHEDULE OF LABORATORY EVALUATIONS

TEST	FORM #	VISIT 36 Apr 2012 - Sept 2012	VISIT 37 Oct 2012 - Mar 2013	VISIT 38 Apr 2013 - Sept 2013	BASELINE WIHS V Cohort	VISIT 39 Oct 2013 - Mar 2014	VISIT 40 Apr 2014 - Sept 2014	VISIT 41 Oct 2014 - Mar 2015	VISIT 42 Apr 2015 - Sept 2015	VISIT 43 Oct 2015 - Mar 2016
Blood										
HIV ELISA	L01	X HIV- or indeterminate only	X HIV- or indeterminate only	X HIV- or indeterminate only	X HIV- or indeterminate, or HIV+ with no documentation	X HIV- or indeterminate only	X HIV- or indeterminate only	X HIV- or indeterminate only	X HIV- or indeterminate only	X HIV- or indeterminate only
Western Blot	L01	X + ELISA only	X + ELISA only	X + ELISA only	X + ELISA only	X + ELISA only	X + ELISA only	X + ELISA only	X + ELISA only	X + ELISA only
Automated CBC / Differential	L03	X	X HIV+ only	X	X	X HIV+ only	X	X HIV+ only	X	X HIV+ only
Manual Differential	L03A	X if automated diff is flagged	X if automated diff is flagged	X if automated diff is flagged	X if automated diff is flagged	X if automated diff is flagged	X if automated diff is flagged	X if automated diff is flagged	X if automated diff is flagged	X if automated diff is flagged
T-Cell count & subsets	L04	X HIV+ only	X HIV+ only	X HIV+ only	X	X HIV+ only	X HIV+ only	X HIV+ only	X HIV+ only	X HIV+ only
Liver/Renal Function Partial Chemistries	L05	X	X	X	X	X	X	X	X	X
RPR Syphilis Screening	L06				X					
Hepatitis Serology	L02				X					
Toxoplasma Serology	C30									
HTLV 1&2	C31									
Herpes Serologies (HSV)	C66									
HIV RNA Quantification	C54	X HIV+ only	X HIV+ only	X HIV+ only	X HIV+ only	X HIV+ only	X HIV+ only	X HIV+ only	X HIV+ only	X HIV+ only
Serum, Plasma & Cells for central & local repository	F10, L20	X	X	X	X	X	X	X	X	X
Lipid panel		X		X	X		X		X	
Insulin and glucose		X if fasting		X if fasting	X if fasting		X if fasting		X if fasting	
HgA1c		X		X	X		X		X	
CVD serum for novel assays and EDTA plasma for NMR lipoprotein	CV29									

WOMEN'S INTERAGENCY HIV STUDY - SCHEDULE OF LABORATORY EVALUATIONS

TEST	FORM #	VISIT 44 Apr 2016 - Sept 2016	VISIT 45 Oct 2016 - Mar 2017
Blood			
HIV ELISA	L01	X HIV- or indeterminate only	X HIV- or indeterminate only
Western Blot	L01	X + ELISA only	X + ELISA only
Automated CBC / Differential	L03	X	X HIV+ only
Manual Differential	L03A	X if automated diff is flagged	X if automated diff is flagged
T-Cell count & subsets	L04	X HIV+ only	X HIV+ only
Liver/Renal Function Partial Chemistries	L05	X	X
RPR Syphilis Screening	L06		
Hepatitis Serology	L02		
Toxoplasma Serology	C30		
HTLV 1&2	C31		
Herpes Serologies (HSV)	C66		
HIV RNA Quantification	C54	X HIV+ only	X HIV+ only
Serum, Plasma & Cells for central & local repository	F10, L20	X	X
Lipid panel		X	
Insulin and glucose		X if fasting	
HgA1c		X	
CVD serum for novel assays and EDTA plasma for NMR lipoprotein	CV29		

WOMEN'S INTERAGENCY HIV STUDY - SCHEDULE OF LABORATORY EVALUATIONS

TEST	FORM #	BASELINE Oct 1994 - Nov 1995	VISIT 2 Apr 1995 - Sept 1995	VISIT 3 Oct 1995 - Mar 1996	VISIT 4 Apr 1996 - Sept 1996	VISIT 5 Oct 1996 - Mar 1997	VISIT 6 Apr 1997 - Sept 1997	VISIT 7 Oct 1997 - Mar 1998	VISIT 8 Apr 1998 - Sept 1998	VISIT 9 Oct 1998 - Mar 1999
ACSR ACD cells (only if pelvic biopsy obtained)										
Special event additional collection	L20									
HPV sub study										
MSK sub study	L20									
Urine										
Urinalysis	L10	X	X	X	X	X	X	X		
Urine Culture & Sensitivity	L11	X on + U/A	X on + U/A	X on + U/A	X on + U/A	X on + U/A	X on + U/A	X on + U/A		
Urine Pregnancy	L12	X	X	X	X	X	X	X	X	X
Urine for Chlamydia (LCR) for central repository	C50	X		X		X		X		X Save & batch
Urine for GC/Chlamydia (LCR) / Local		X		X		X		X		
Urine for renal testing for repository	L20									
Urine Pellet for repository	L20									
Urine Supernatant for repository	L20	X	X	X	X	X	X	X		
Vaginal Swabs & Samples										
pH, T.vaginalis (wet mount), KOH, Amine Odor test	F08	X	X	X	X	X	X	X	X	X
Trichomonas Culture	L18	optional	optional	optional	optional	optional	optional	optional	optional	optional
Bacterial Vaginosis	C45	X	X	X	X	X	X	X	X Save & batch	X Save & batch
Cervical Swabs										
Chlamydia: Gen-Probe (94/95), LCR (01/02), NAAT (11/12)	L09	X local immediate								
Gonorrhea: Gen-Probe (94/95), LCR (01/02), NAAT (11/12)	L13	X local immediate								
LCR Chlamydia Confirmatory	C51	X collect swab & freeze	X collect swab & freeze	X collect swab & freeze	X collect swab & freeze					
Pap Smear	C60	X	X	X	X	X	X	X	X	X

WOMEN'S INTERAGENCY HIV STUDY - SCHEDULE OF LABORATORY EVALUATIONS

TEST	FORM #	VISIT 10 Apr 1999 - Sept 1999	VISIT 11 Oct 1999 - Mar 2000	VISIT 12 Apr 2000 - Sept 2000	VISIT 13 Oct 2000 - Mar 2001	VISIT 14 Apr 2001 - Sept 2001	VISIT 15 (94/95 Cohort) Oct 2001 - Mar 2002	BASELINE 01/02 Cohort (Visit 15 or 16) Oct 2001 - Sept 2002	VISIT 16 Apr 2002 - Sept 2002	VISIT 17 Oct 2002 - Mar 2003
ACSR ACD cells (only if pelvic biopsy obtained)		X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol
Special event additional collection	L20									
HPV sub study										
MSK sub study	L20									
Urine										
Urinalysis	L10									
Urine Culture & Sensitivity	L11									
Urine Pregnancy	L12	X	X	X	X	X	X	X	X	X
Urine for Chlamydia (LCR) for central repository	C50		X Save & batch		X Save & batch		X Save & batch	X		X Save & batch
Urine for GC/Chlamydia (LCR) / Local										
Urine for renal testing for repository	L20									
Urine Pellet for repository	L20									
Urine Supernatant for repository	L20									
Vaginal Swabs & Samples										
pH, T.vaginalis (wet mount), KOH, Amine Odor test	F08	X	X	X	X	X	X	X	X	X
Trichomonas Culture	L18	optional	optional	optional	optional	optional	optional	optional	optional	optional
Bacterial Vaginosis	C45	X Save & batch	X Save & batch	X Save & batch	X Save & batch	X Save & batch	X Save & batch	X Save & batch	X Save & batch	X Save & batch
Cervical Swabs										
Chlamydia: Gen-Probe (94/95), LCR (01/02), NAAT (11/12)	L09							X local immediate		
Gonorrhea: Gen-Probe (94/95), LCR (01/02), NAAT (11/12)	L13							X local immediate		
LCR Chlamydia Confirmatory	C51									
Pap Smear	C60	X	X	X	X	X	X	X	X	X

WOMEN'S INTERAGENCY HIV STUDY - SCHEDULE OF LABORATORY EVALUATIONS

TEST	FORM #	VISIT 18 Apr 2003 - Sept 2003	VISIT 19 Oct 2003 - Mar 2004	VISIT 20 Apr 2004 - Sept 2004	VISIT 21 Oct 2004 - Mar 2005	VISIT 22 Apr 2005 - Sept 2005	VISIT 23 Oct 2005 - Mar 2006	VISIT 24 Apr 2006 - Sept 2006	VISIT 25 Oct 2006 - Mar 2007	VISIT 26 Apr 2007 - Sept 2007
ACSR ACD cells (only if pelvic biopsy obtained)		X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol
Special event additional collection	L20									
HPV sub study										
MSK sub study	L20									
Urine										
Urinalysis	L10									
Urine Culture & Sensitivity	L11									
Urine Pregnancy	L12	X	X	X	X	X	X	X	X	X
Urine for Chlamydia (LCR) for central repository	C50		X Save & batch							
Urine for GC/Chlamydia (LCR) / Local										
Urine for renal testing for repository	L20									
Urine Pellet for repository	L20									
Urine Supernatant for repository	L20									
Vaginal Swabs & Samples										
pH, T.vaginalis (wet mount), KOH, Amine Odor test	F08	X	X	X	X	X	X	X	X	X
Trichomonas Culture	L18	optional	optional	optional	optional	optional	optional	optional	optional	optional
Bacterial Vaginosis	C45	X Save & batch	X Save & batch	X Save & batch	X Save & batch	X Save & batch	X Save & batch	X Save & batch	X Save & batch	X Save & batch
Cervical Swabs										
Chlamydia: Gen-Probe (94/95), LCR (01/02), NAAT (11/12)	L09									
Gonorrhea: Gen-Probe (94/95), LCR (01/02), NAAT (11/12)	L13									
LCR Chlamydia Confirmatory	C51									
Pap Smear	C60	X	X	X	X	X	X	X	X	X

WOMEN'S INTERAGENCY HIV STUDY - SCHEDULE OF LABORATORY EVALUATIONS

TEST	FORM #	VISIT 27 Oct 2007 - Mar 2008	VISIT 28 Apr 2008 - Sept 2008	VISIT 29 Oct 2008 - Mar 2009	VISIT 30 Apr 2009 - Sept 2009	VISIT 31 Oct 2009 - Mar 2010	VISIT 32 Apr 2010 - Sept 2010	VISIT 33 Oct 2010 - Mar 2011	BASELINE 11/12 Cohort (Visit 33 - 37) Jan 2011 - Dec 2012	VISIT 35 Oct 2011 - Mar 2012
ACSR ACD cells (only if pelvic biopsy obtained)		X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol
Special event additional collection	L20									X as per protocol
HPV sub study										X as per protocol
MSK sub study	L20									X as per protocol
Urine										
Urinalysis	L10								X local immediate	
Urine Culture & Sensitivity	L11									
Urine Pregnancy	L12	X	X	X	X	X	X	X	X	X
Urine for Chlamydia (LCR) for central repository	C50									
Urine for GC/Chlamydia (LCR) / Local										
Urine for renal testing for repository	L20								X	
Urine Pellet for repository	L20					X		X	X	X
Urine Supernatant for repository	L20					X		X	X	X
Vaginal Swabs & Samples										
pH, T.vaginalis (wet mount), KOH, Amine Odor test	F08	X	X	X	X	X	X	X	X	X
Trichomonas Culture	L18	optional	optional	optional	optional	optional	optional	optional	optional	optional
Bacterial Vaginosis	C45	X Save & batch	X Save & batch	X Save & batch	X Save & batch	X Save & batch	X Save & batch	X Save & batch	X Save & batch	X Save & batch
Cervical Swabs										
Chlamydia: Gen-Probe (94/95), LCR (01/02), NAAT (11/12)	L09								X local immediate	
Gonorrhea: Gen-Probe (94/95), LCR (01/02), NAAT (11/12)	L13								X local immediate	
LCR Chlamydia Confirmatory	C51									
Pap Smear	C60	X	X	X	X	X	X	X	X	X

WOMEN'S INTERAGENCY HIV STUDY - SCHEDULE OF LABORATORY EVALUATIONS

TEST	FORM #	VISIT 36 Apr 2012 - Sept 2012	VISIT 37 Oct 2012 - Mar 2013	VISIT 38 Apr 2013 - Sept 2013	BASELINE WIHS V Cohort	VISIT 39 Oct 2013 - Mar 2014	VISIT 40 Apr 2014 - Sept 2014	VISIT 41 Oct 2014 - Mar 2015	VISIT 42 Apr 2015 - Sept 2015	VISIT 43 Oct 2015 - Mar 2016
ACSR ACD cells (only if pelvic biopsy obtained)		X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol
Special event additional collection	L20	X as per protocol	X as per protocol	X as per protocol		X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol
HPV sub study		X as per protocol								
MSK sub study	L20	X as per protocol	X as per protocol	X as per protocol		X as per protocol	X as per protocol	X as per protocol	X as per protocol	
Urine										
Urinalysis	L10				X local immediate					
Urine Culture & Sensitivity	L11									
Urine Pregnancy	L12	X	X	X	X	X	X	X	X	X
Urine for Chlamydia (LCR) for central repository	C50									
Urine for GC/Chlamydia (LCR) / Local										
Urine for renal testing for repository	L20				X					
Urine Pellet for repository	L20			X	X				X	
Urine Supernatant for repository	L20	X		X	X		X		X	
Vaginal Swabs & Samples										
pH, T.vaginalis (wet mount), KOH, Amine Odor test	F08	X	X	X	X	X	X	X	X	X
Trichomonas Culture	L18	optional	optional	optional	optional	optional	optional	optional	optional	optional
Bacterial Vaginosis	C45	X Save & batch	X Save & batch	X Save & batch	X Save & batch	X Save & batch	X Save & batch	X Save & batch	X Save & batch	X Save & batch
Cervical Swabs										
Chlamydia: Gen-Probe (94/95), LCR (01/02), NAAT (11/12)	L09				X local immediate					
Gonorrhea: Gen-Probe (94/95), LCR (01/02), NAAT (11/12)	L13				X local immediate					
LCR Chlamydia Confirmatory	C51									
Pap Smear	C60	X	X	X	X	X	X	X	X	X

WOMEN'S INTERAGENCY HIV STUDY - SCHEDULE OF LABORATORY EVALUATIONS

TEST	FORM #	VISIT 44 Apr 2016 - Sept 2016	VISIT 45 Oct 2016 - Mar 2017
ACSR ACD cells (only if pelvic biopsy obtained)		X as per protocol	X as per protocol
Special event additional collection	L20	X as per protocol	X as per protocol
HPV sub study			
MSK sub study	L20		
Urine			
Urinalysis	L10		
Urine Culture & Sensitivity	L11		
Urine Pregnancy	L12	X	X
Urine for Chlamydia (LCR) for central repository	C50		
Urine for GC/Chlamydia (LCR) / Local			
Urine for renal testing for repository	L20		
Urine Pellet for repository	L20		
Urine Supernatant for repository	L20	X	
Vaginal Swabs & Samples			
pH, T.vaginalis (wet mount), KOH, Amine Odor test	F08	X	X
Trichomonas Culture	L18	optional	optional
Bacterial Vaginosis	C45	X Save & batch	X Save & batch
Cervical Swabs			
Chlamydia: Gen-Probe (94/95), LCR (01/02), NAAT (11/12)	L09		
Gonorrhea: Gen-Probe (94/95), LCR (01/02), NAAT (11/12)	L13		
LCR Chlamydia Confirmatory	C51		
Pap Smear	C60	X	X

WOMEN'S INTERAGENCY HIV STUDY - SCHEDULE OF LABORATORY EVALUATIONS

TEST	FORM #	BASELINE Oct 1994 - Nov 1995	VISIT 2 Apr 1995 - Sept 1995	VISIT 3 Oct 1995 - Mar 1996	VISIT 4 Apr 1996 - Sept 1996	VISIT 5 Oct 1996 - Mar 1997	VISIT 6 Apr 1997 - Sept 1997	VISIT 7 Oct 1997 - Mar 1998	VISIT 8 Apr 1998 - Sept 1998	VISIT 9 Oct 1998 - Mar 1999
Syphilis DFA	C65	X ulcers & fissures only	X ulcers & fissures only	X ulcers & fissures only	X ulcers & fissures only	X ulcers & fissures only	X ulcers & fissures only	X ulcers & fissures only	X ulcers & fissures only	X ulcers & fissures only
HPV DNA swab supernatant										
HIV RNA Quantitation										
Cervico-Vaginal Lavage										
HPV by PCR	C52	X	X	X	X	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save
HPV by Hybrid Capture	C53	X PCR+ & sample of PCR-	X PCR+ & sample of PCR-	X PCR+ & sample of PCR-	X PCR+ & sample of PCR-	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save
CVL for central & local repository	F10, F31, L20	X	X	X	X	X	X	X	X	X
NIDA Immun/Virol CVL subset	C54	X		X		X		X		X
Other clinical exams										
Colposcopy	L14	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol
Pelvic Exam Biopsy and Histopathology	L15	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol
ACSR Pelvic Exam Biopsy										
Anergy Panel	L07	X		X		X		X		X
Liver Biopsy (upon self-report and MRA, retrospective collection through visit 23)	QCLB	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol
Tuberculin PPD	L08	X		X negative reactors only		X negative reactors only		X negative reactors only		X negative reactors only
Hair collection	F31									
Intensive Pharmacokinetics Study	PK forms									
Prospective Metabolic	MS01									

WOMEN'S INTERAGENCY HIV STUDY - SCHEDULE OF LABORATORY EVALUATIONS

TEST	FORM #	VISIT 10 Apr 1999 - Sept 1999	VISIT 11 Oct 1999 - Mar 2000	VISIT 12 Apr 2000 - Sept 2000	VISIT 13 Oct 2000 - Mar 2001	VISIT 14 Apr 2001 - Sept 2001	VISIT 15 (94/95 Cohort) Oct 2001 - Mar 2002	BASELINE 01/02 Cohort (Visit 15 or 16) Oct 2001 - Sept 2002	VISIT 16 Apr 2002 - Sept 2002	VISIT 17 Oct 2002 - Mar 2003
Syphilis DFA	C65	X ulcers & fissures only	X ulcers & fissures only	X ulcers & fissures only	X ulcers & fissures only	X ulcers & fissures only	X ulcers & fissures only	X ulcers & fissures only	X ulcers & fissures only	X ulcers & fissures only
HPV DNA swab supernatant										
HIV RNA Quantitation				X Save & batch	X Save & batch	X Save & batch	X Save & batch	X Save & batch	X Save & batch	X Save & batch
Cervico-Vaginal Lavage										
HPV by PCR	C52	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save
HPV by Hybrid Capture	C53	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save
CVL for central & local repository	F10, F31, L20	X	X	X	X	X	X	X	X	X
NIDA Immun/Virol CVL subset	C54		X		X					
Other clinical exams										
Colposcopy	L14	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol
Pelvic Exam Biopsy and Histopathology	L15	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol
ACSR Pelvic Exam Biopsy		X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol
Anergy Panel	L07		X							
Liver Biopsy (upon self-report and MRA, retrospective collection through visit 23)	QCLB	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol
Tuberculin PPD	L08		X negative reactors only		X negative reactors only		X negative reactors only	X		X negative reactors only
Hair collection	F31									X batch & ship at end of visit, HIV+ on ART
Intensive Pharmacokinetics Study	PK forms									
Prospective Metabolic	MS01									

WOMEN'S INTERAGENCY HIV STUDY - SCHEDULE OF LABORATORY EVALUATIONS

TEST	FORM #	VISIT 18 Apr 2003 - Sept 2003	VISIT 19 Oct 2003 - Mar 2004	VISIT 20 Apr 2004 - Sept 2004	VISIT 21 Oct 2004 - Mar 2005	VISIT 22 Apr 2005 - Sept 2005	VISIT 23 Oct 2005 - Mar 2006	VISIT 24 Apr 2006 - Sept 2006	VISIT 25 Oct 2006 - Mar 2007	VISIT 26 Apr 2007 - Sept 2007
Syphilis DFA	C65	X ulcers & fissures only	X ulcers & fissures only	X ulcers & fissures only	X ulcers & fissures only	X ulcers & fissures only	X ulcers & fissures only	X ulcers & fissures only	X ulcers & fissures only	X ulcers & fissures only
HPV DNA swab supernatant										
HIV RNA Quantitation		X Save & batch	X Save & batch	X Save & batch	X Save & batch	X Save & batch	X Save & batch	X Save & batch	X Save & batch	X Save & batch
Cervico-Vaginal Lavage										
HPV by PCR	C52	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save
HPV by Hybrid Capture	C53	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save
CVL for central & local repository	F10, F31, L20	X	X	X	X	X	X	X	X	X
NIDA Immun/Virol CVL subset	C54									
Other clinical exams										
Colposcopy	L14	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol
Pelvic Exam Biopsy and Histopathology	L15	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol
ACSR Pelvic Exam Biopsy		X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol
Anergy Panel	L07									
Liver Biopsy (upon self-report and MRA, retrospective collection through visit 23)	QCLB	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol
Tuberculin PPD	L08									
Hair collection	F31	X batch & ship at end of visit, HIV+ on ART	X batch & ship at end of visit, HIV+ on ART	X batch & ship at end of visit, HIV+ on ART	X batch & ship at end of visit, HIV+ on ART	X batch & ship at end of visit, HIV+ on ART	X batch & ship at end of visit, HIV+ on ART	X batch & ship at end of visit, HIV+ on ART	X batch & ship at end of visit, HIV+ on ART	X batch & ship at end of visit, HIV+ on ART
Intensive Pharmacokinetics Study	PK forms	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol
Prospective Metabolic	MS01	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol

WOMEN'S INTERAGENCY HIV STUDY - SCHEDULE OF LABORATORY EVALUATIONS

TEST	FORM #	VISIT 27 Oct 2007 - Mar 2008	VISIT 28 Apr 2008 - Sept 2008	VISIT 29 Oct 2008 - Mar 2009	VISIT 30 Apr 2009 - Sept 2009	VISIT 31 Oct 2009 - Mar 2010	VISIT 32 Apr 2010 - Sept 2010	VISIT 33 Oct 2010 - Mar 2011	BASELINE 11/12 Cohort (Visit 33 - 37) Jan 2011 - Dec 2012	VISIT 35 Oct 2011 - Mar 2012
Syphilis DFA	C65	X ulcers & fissures only	X ulcers & fissures only	X ulcers & fissures only	X					
HPV DNA swab supernatant						X Save & batch	X Save & batch	X Save & batch	X Save & batch	X Save & batch
HIV RNA Quantitation		X Save & batch	X Save & batch							
Cervico-Vaginal Lavage										
HPV by PCR	C52	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save
HPV by Hybrid Capture	C53	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save
CVL for central & local repository	F10, F31, L20	X	X	X	X	X	X	X	X	X
NIDA Immun/Virol CVL subset	C54									
Other clinical exams										
Colposcopy	L14	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol
Pelvic Exam Biopsy and Histopathology	L15	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol
ACSR Pelvic Exam Biopsy		X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol
Anergy Panel	L07									
Liver Biopsy (upon self-report and MRA, retrospective collection through visit 23)	QCLB	X as per protocol	X as per protocol							
Tuberculin PPD	L08									
Hair collection	F31	X batch & ship at end of visit, HIV+ on ART	X batch & ship at end of visit, HIV+ on ART	X batch & ship at end of visit, HIV+ on ART	X batch & ship at end of visit, HIV+ on ART	X batch & ship at end of visit, HIV+ on ART	X batch & ship at end of visit, HIV+ on ART	X batch & ship at end of visit, HIV+ on ART	X batch & ship at end of visit, HIV+	X batch & ship at end of visit, HIV+
Intensive Pharmacokinetics Study	PK forms	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol
Prospective Metabolic	MS01	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol		

WOMEN'S INTERAGENCY HIV STUDY - SCHEDULE OF LABORATORY EVALUATIONS

TEST	FORM #	VISIT 36 Apr 2012 - Sept 2012	VISIT 37 Oct 2012 - Mar 2013	VISIT 38 Apr 2013 - Sept 2013	BASELINE WIHS V Cohort	VISIT 39 Oct 2013 - Mar 2014	VISIT 40 Apr 2014 - Sept 2014	VISIT 41 Oct 2014 - Mar 2015	VISIT 42 Apr 2015 - Sept 2015	VISIT 43 Oct 2015 - Mar 2016
Syphilis DFA	C65									
HPV DNA swab supernatant		X Save & batch	X Save & batch	X Save & batch	X Save & batch	X Save & batch	X Save & batch	X Save & batch	X Save & batch	X Save & batch
HIV RNA Quantitation										
Cervico-Vaginal Lavage										
HPV by PCR	C52	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save
HPV by Hybrid Capture	C53	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save	X collect & save
CVL for central & local repository	F10, F31, L20	X	X	X	X	X	X	X	X	X
NIDA Immun/Virol CVL subset	C54									
Other clinical exams										
Colposcopy	L14	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol
Pelvic Exam Biopsy and Histopathology	L15	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol
ACSR Pelvic Exam Biopsy		X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol
Anergy Panel	L07									
Liver Biopsy (upon self-report and MRA, retrospective collection through visit 23)	QCLB									
Tuberculin PPD	L08									
Hair collection	F31	X batch & ship at end of visit, HIV+	X batch & ship at end of visit, HIV+	X batch & ship at end of visit, HIV+	X batch & ship at end of visit, HIV+	X batch & ship at end of visit, HIV+	X batch & ship at end of visit, HIV+	X batch & ship at end of visit, HIV+	X batch & ship at end of visit, HIV+	X batch & ship at end of visit, HIV+
Intensive Pharmacokinetics Study	PK forms	X as per protocol			X as per protocol					
Prospective Metabolic	MS01									

WOMEN'S INTERAGENCY HIV STUDY - SCHEDULE OF LABORATORY EVALUATIONS

TEST	FORM #	VISIT 44 Apr 2016 - Sept 2016	VISIT 45 Oct 2016 - Mar 2017
Syphilis DFA	C65		
HPV DNA swab supernatant		X Save & batch	X Save & batch
HIV RNA Quantitation			
Cervico-Vaginal Lavage			
HPV by PCR	C52	X collect & save	X collect & save
HPV by Hybrid Capture	C53	X collect & save	X collect & save
CVL for central & local repository	F10, F31, L20	X	X
NIDA Immun/Virol CVL subset	C54		
Other clinical exams			
Colposcopy	L14	X as per protocol	X as per protocol
Pelvic Exam Biopsy and Histopathology	L15	X as per protocol	X as per protocol
ACSR Pelvic Exam Biopsy		X as per protocol	X as per protocol
Anergy Panel	L07		
Liver Biopsy (upon self-report and MRA, retrospective collection through visit 23)	QCLB		
Tuberculin PPD	L08		
Hair collection	F31	X batch & ship at end of visit, HIV+	X batch & ship at end of visit, HIV+
Intensive Pharmacokinetics Study	PK forms		
Prospective Metabolic	MS01		

WOMEN'S INTERAGENCY HIV STUDY - SCHEDULE OF LABORATORY EVALUATIONS

TEST	FORM #	BASELINE Oct 1994 - Nov 1995	VISIT 2 Apr 1995 - Sept 1995	VISIT 3 Oct 1995 - Mar 1996	VISIT 4 Apr 1996 - Sept 1996	VISIT 5 Oct 1996 - Mar 1997	VISIT 6 Apr 1997 - Sept 1997	VISIT 7 Oct 1997 - Mar 1998	VISIT 8 Apr 1998 - Sept 1998	VISIT 9 Oct 1998 - Mar 1999
Oral/Vaginal Cultures										
Oral & Vaginal Cultures for Candida		X								
Oral & Vaginal Cultures for HSV	L17	X ulcers & fissures only								
Oral Protocol specimens										
HIV RNA Quantitation	C54									
Stimulated Saliva Evaluation	C70	X	X	X	X	X	X	X	X	X
Subgingival plaque	C71	X when indicated	X when indicated	X when indicated	X when indicated	X when indicated	X when indicated	X when indicated	X when indicated	X when indicated
Erythematous candidiasis	C72									
ACSR Scope or saline oral rinse (only if pelvic biopsy obtained)										

WOMEN'S INTERAGENCY HIV STUDY - SCHEDULE OF LABORATORY EVALUATIONS

TEST	FORM #	VISIT 10 Apr 1999 - Sept 1999	VISIT 11 Oct 1999 - Mar 2000	VISIT 12 Apr 2000 - Sept 2000	VISIT 13 Oct 2000 - Mar 2001	VISIT 14 Apr 2001 - Sept 2001	VISIT 15 (94/95 Cohort) Oct 2001 - Mar 2002	BASELINE 01/02 Cohort (Visit 15 or 16) Oct 2001 - Sept 2002	VISIT 16 Apr 2002 - Sept 2002	VISIT 17 Oct 2002 - Mar 2003
Oral/Vaginal Cultures										
Oral & Vaginal Cultures for Candida								X Save & batch		
Oral & Vaginal Cultures for HSV	L17							X ulcers & fissures only		
Oral Protocol specimens										
HIV RNA Quantitation	C54									
Stimulated Saliva Evaluation	C70	X	X	X	X	X	X	X	X	X
Subgingival plaque	C71	X when indicated	X when indicated	X when indicated	X when indicated	X when indicated	X when indicated	X when indicated	X when indicated	X when indicated
Erythematous candidiasis	C72	X when indicated	X when indicated	X when indicated	X when indicated	X when indicated	X when indicated	X when indicated	X when indicated	X when indicated
ACSR Scope or saline oral rinse (only if pelvic biopsy obtained)										

WOMEN'S INTERAGENCY HIV STUDY - SCHEDULE OF LABORATORY EVALUATIONS

TEST	FORM #	VISIT 18 Apr 2003 - Sept 2003	VISIT 19 Oct 2003 - Mar 2004	VISIT 20 Apr 2004 - Sept 2004	VISIT 21 Oct 2004 - Mar 2005	VISIT 22 Apr 2005 - Sept 2005	VISIT 23 Oct 2005 - Mar 2006	VISIT 24 Apr 2006 - Sept 2006	VISIT 25 Oct 2006 - Mar 2007	VISIT 26 Apr 2007 - Sept 2007
Oral/Vaginal Cultures										
Oral & Vaginal Cultures for Candida										
Oral & Vaginal Cultures for HSV	L17									
Oral Protocol specimens										
HIV RNA Quantitation	C54									
Stimulated Saliva Evaluation	C70	X	X	X						
Subgingival plaque	C71	X when indicated	X when indicated	X when indicated						
Erythematous candidiasis	C72	X when indicated	X when indicated	X when indicated						
ACSR Scope or saline oral rinse (only if pelvic biopsy obtained)						X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol

WOMEN'S INTERAGENCY HIV STUDY - SCHEDULE OF LABORATORY EVALUATIONS

TEST	FORM #	VISIT 27 Oct 2007 - Mar 2008	VISIT 28 Apr 2008 - Sept 2008	VISIT 29 Oct 2008 - Mar 2009	VISIT 30 Apr 2009 - Sept 2009	VISIT 31 Oct 2009 - Mar 2010	VISIT 32 Apr 2010 - Sept 2010	VISIT 33 Oct 2010 - Mar 2011	BASELINE 11/12 Cohort (Visit 33 - 37) Jan 2011 - Dec 2012	VISIT 35 Oct 2011 - Mar 2012
Oral/Vaginal Cultures										
Oral & Vaginal Cultures for Candida										
Oral & Vaginal Cultures for HSV	L17									
Oral Protocol specimens										
HIV RNA Quantitation	C54									
Stimulated Saliva Evaluation	C70									
Subgingival plaque	C71									
Erythematous candidiasis	C72									
ACSR Scope or saline oral rinse (only if pelvic biopsy obtained)		X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol

WOMEN'S INTERAGENCY HIV STUDY - SCHEDULE OF LABORATORY EVALUATIONS

TEST	FORM #	VISIT 36 Apr 2012 - Sept 2012	VISIT 37 Oct 2012 - Mar 2013	VISIT 38 Apr 2013 - Sept 2013	BASELINE WIHS V Cohort	VISIT 39 Oct 2013 - Mar 2014	VISIT 40 Apr 2014 - Sept 2014	VISIT 41 Oct 2014 - Mar 2015	VISIT 42 Apr 2015 - Sept 2015	VISIT 43 Oct 2015 - Mar 2016
Oral/Vaginal Cultures										
Oral & Vaginal Cultures for Candida										
Oral & Vaginal Cultures for HSV	L17									
Oral Protocol specimens										
HIV RNA Quantitation	C54									
Stimulated Saliva Evaluation	C70									
Subgingival plaque	C71									
Erythematous candidiasis	C72									
ACSR Scope or saline oral rinse (only if pelvic biopsy obtained)		X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol	X as per protocol

WOMEN'S INTERAGENCY HIV STUDY - SCHEDULE OF LABORATORY EVALUATIONS

TEST	FORM #	VISIT 44 Apr 2016 - Sept 2016	VISIT 45 Oct 2016 - Mar 2017
Oral/Vaginal Cultures			
Oral & Vaginal Cultures for Candida			
Oral & Vaginal Cultures for HSV	L17		
Oral Protocol specimens			
HIV RNA Quantitation	C54		
Stimulated Saliva Evaluation	C70		
Subgingival plaque	C71		
Erythematous candidiasis	C72		
ACSR Scope or saline oral rinse (only if pelvic biopsy obtained)		X as per protocol	X as per protocol