

Section Number	Section Title	Version Number	Version Date	Updates and Comments
1	Introduction	1.0	11/25/15	First final version.
		1.1	2/17/16	Clarification Memo #1 added to section 1.1
2	Documentation	1.0	11/25/15	First final version.
3	Accrual and Retention	1.0	11/25/15	First final version.
4	Informed Consent	1.0	11/25/15	First final version.
5	Study Procedures	1.0	11/25/15	First final version.
6	Study Product	1.0	11/25/15	First final version.
7	Clinical Considerations	1.0	11/25/15	First final version.
8	AE Reporting	1.0	11/25/15	First final version.
9	Lab Considerations	1.0	11/25/15	First final version.
		1.1	1/22/16	9.7.2 updated to indicate GC/CT swab collected from cervix
		1.2		Table 9-1 and 9-2 as well as section 9.7.2 updated to reflect changes to quantitative vaginal culture swabs
10	Counseling	1.0	11/25/15	First final version.
		1.1	2/17/16	10.2.2 updated per CM #1 with additional instructions on frequency of at home breastmilk collection.
11	Data Collection	1.0	11/25/15	First final version.
12	Data Communiques	1.0	11/25/15	First final version.
13	Reporting Plans	1.0	11/25/15	First final version.