

MTN-042 Study-Specific Procedures Manual Overview and Control Document – Version History and Notice of Changes

Section Number	Section Title	Version Number(s)*	Version Date(s)*	Notice of Changes*
1	Introduction	1.0 1.1 1.2	19DEC2019 9APR2020 30JUN2020	
2	Documentation Requirements	1.0	19DEC2019	
3	Accrual and Retention	1.0 1.1 1.2	19DEC2019 9APR2020 30JUN2020	
4	Informed Consent	1.0	19DEC2019	
5	Study Procedures	1.0 1.1 1.2	19DEC2019 9APR2020 30JUN2020	
6	Study Product Considerations for Non-Pharmacy Staff	1.0 1.1	19DEC2019 9APR2020	
7	Clinical Considerations	1.0 1.1	19DEC2019 9APR2020	
8	Adverse Event Reporting and Safety Monitoring	1.0 1.1 1.2	19DEC2019 9APR2020 30JUN2020	
9	Counseling Considerations	1.0 1.1	19DEC2019 9APR2020	
10	Laboratory Considerations	1.0 1.1 1.2 1.3	19DEC2019 9APR2020 30JUN2020 01FEB2021	<ul style="list-style-type: none"> • Incorporates Changes from Operational Guidance #1 <ul style="list-style-type: none"> ○ Change Vaginal Microbiota collection from 1 flocced swab to 2 dacron swabs ○ Changes DBS storage temp to $\leq -70^{\circ}\text{C}$. • 10.6.2: allows for alternate urine hCG kit • 10.7.2:

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
				<ul style="list-style-type: none"> ○ allows for use of Abbott Determine with letter of equivalence to Alere HIV Combo ○ Allows for use of WHO PQ versions of kits with letter of equivalence ● 10.7.7 : adds new LDMS “other SPEC ID” code “SER” to be used when collecting plasma resulting from positive HIV rapid ● Incorporates Clarification memo #2, allowing for alternate methodology for NAAT CT/NG/TV ● Appendix 10-5: updated LDMS tracking sheet
11	Data Collection	1.0 1.1 1.2	19DEC2019 9APR2020 30JUN2020	
12	Data Communiques	1.0	19DEC2019	
13	Reporting Plan	1.0	19DEC2019	
14	DELIVER Qualitative Component	1.0 1.1	19DEC2019 9APR2020	

***Highest version number/date listed is current and supersedes all previous listed version(s). Notice of Changes summarizes any significant changes that have been made during the current review period.**

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SSP Approval Sheet

Review Period: 14JAN2021- 01FEB2021

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MTN LC Research Manager	Section 10	Edward Livant, MTN LC	<p>DocuSigned by:  Signer Name: Ted Livant Signing Reason: I approve this document Signing Time: 01-Feb-2021 14:32 EST 9E61B06A181441D3A698FBE00AECF2FC</p>

**Applicable section version numbers and dates as listed in Overview and Control Document table, Version 1.3, dated 01FEB2021*

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