

Notification of Testing of HPTN Stored Specimens for the HPTN Prevention Management Group	
1. Notification Date:	
2a. Name and contact information for proposing HPTN Investigator:	
2b. Name and contact information for non-HPTN collaborating Investigator:	<input type="checkbox"/> Not applicable <i>Note: All non-HPTN investigators must complete an HPTN Materials Transfer Agreement. If applicable, please attach a copy of the signed agreement.</i>
3. HPTN study in which specimens proposed for testing were collected:	
4. Study sites from which specimens are requested:	
5. Rationale and purpose of proposed testing:	
6. Has the Chair (or Co-Chairs) of the main study listed in item 3 approved this proposal?	<input type="checkbox"/> Yes → Please retain documentation on site. <input type="checkbox"/> No → Please defer this notification and the proposed testing until approval has been obtained.
7. Have the following been completed? (a) All primary study endpoints ascertained (b) All protocol-specified testing involving the stored specimens at issue performed (including QC/QA testing) (c) All protocol-specified data analyses finalized	<input type="checkbox"/> Yes → Please retain documentation on site. <input type="checkbox"/> No → Please defer submission of this notification and the proposed testing until all primary endpoints have been ascertained, all protocol-specified testing involving the stored specimens at issue has been completed, and all protocol-specified data analyses have been completed and considered final. Or, if the Protocol Chair (or CoChairs), Statistician, and Central Lab Representative has approved an exemption to these requirements, please mark the box below. <input type="checkbox"/> Exemption received from Protocol Chair(s), Statistician, and Central Lab Representative ~ Please retain documentation on site.
8. Have specimens from participants who did not consent to long term storage for possible future research testing been discarded?	<input type="checkbox"/> Yes → Please retain documentation on site. <input type="checkbox"/> No → Please defer submission of this notification and the proposed testing until the specimens of non-consenting participants have been discarded.
9. Name of laboratory(s) at which the proposed testing will be performed:	
10. Test(s) proposed to be performed:	
11. What specific type and quantity of specimens will be tested?	
12. Will the results of the proposed testing be linked to data collected in the main study (e.g., demographics, HIV risk behaviors, clinical and lab outcomes) for purposes of analysis and publication?	<input type="checkbox"/> Yes <input type="checkbox"/> No

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13. Is the proposed testing considered research subject to IRB/IEC review?	<input type="checkbox"/> Yes → Has approval been obtained from all responsible IRBs/IECs? <input type="checkbox"/> Yes → Please retain documentation on site. <input type="checkbox"/> No → Please defer submission of this notification and the proposed testing until approval has been obtained. <input type="checkbox"/> No → Please retain documentation on site.
14. Will results of the proposed testing be provided to the participants who provided the specimens?	<input type="checkbox"/> Yes <input type="checkbox"/> No Please retain documentation on site of IRB/IEC approval of whether or not results will be provided to participants.
15. Are supplemental HPTN funds required to complete the proposed testing?	<input type="checkbox"/> Yes → Please specify amount and purpose of funds requested: \$ _____ <input type="checkbox"/> No