



## MATRIX-001 Operational Guidance # 2

### Operational Guidance Category:

- Clinical Procedures   
  Pharmacy   
  Laboratory   
  Sociobehavioral Data  
 Other, specify:

**Brief Description:** Reduction in minimum storage volume required for HSV-2 testing.

The purpose of this Operational Guidance document is to reduce the minimum volume of serum required to be stored for HSV-2 testing.

The MATRIX-001 Study Specific Procedures (SSP) Manual section 9, Laboratory Considerations Version 1.0 (18Oct2023) and Version 2.0 (19Dec2023), section 9.7.7 states "*Store minimum 3 mL of serum in 1 mL aliquots at  $\leq -70^{\circ}\text{C}$  until shipment or testing is requested*". Per Operational Guidance #2, the following has been updated: "*Store minimum 2 mL of serum in 1 mL aliquots at  $\leq -70^{\circ}\text{C}$  until shipment or testing is requested*".

Operational Guidance memos, once signed, must be distributed to MATRIX sites via email. Sites are responsible for ensuring that appropriate staff review and understand the content of each memo and file the memo with their essential documents. Operational Guidance memos must also be posted to the appropriate MATRIX webpage. As per SSP section 13, the memos are official study documentation and will be considered an official part of the MATRIX SSP Manual. The Operational Memo becomes effective the date it is signed.

DocuSigned by:

Signer Name: Edward Livant  
 Signing Reason: I approve this document  
 Signing Time: 1/26/2024 | 3:59:20 PM EST  
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1/26/2024

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