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**Description and Use of the Laboratory Compliance Survey Form**

*Form description and intent:*

The Laboratory Compliance Survey form offered by the Society for Assisted Reproductive Technology (SART) to its members is designed to help programs remain in compliance with FDA requirements regarding donor eligibility determination. Specifically, this form is meant to address the regulation that requires all clinics using referral laboratories for relevant disease testing of donors ensure that those laboratories are operating within federal guidelines.

*How to use this form:*

This form is not required, it is offered by SART as a resource to those clinics that may not yet have a system to determine if the laboratory they are using is following federal guidelines on the testing of donors for relevant diseases. You can send this form to the testing lab with a cover letter asking a representative of the lab to complete the questions, sign the form and return it to the clinic for review and to keep as a permanent record to be presented to the FDA in the event of an inspection. It is also recommended that the form be sent to the testing lab at least annually to ensure lab status and/or testing methodology have not changed and remain in compliance with federal guidelines.

We at SART are working hard to assist our member clinics to not only comply with federal guidelines, but provide quality care that benefits our patients. We hope that this form helps achieve that goal. As always, we appreciate your feedback. If you have any concerns you feel need to be addressed by our Society, let us hear from you by e-mail or phone.

Sincerely,



R. Stan Williams, M.D.

President, SART

***LABORATORY COMPLIANCE SURVEY***

***PART 1 – REPRODUCTIVE TISSUE DONOR TESTING***

Laboratory Name:

Street Address:

City, State, Zip Code:

Phone:       Fax:      

***Please circle the appropriate response to the following questions:***

1. Is the laboratory registered with the FDA to perform reproductive

tissue donor testing? YES  NO

**(If yes, please attach copy of registration)**

2. Is the laboratory CLIA certified, or equivalent? YES  NO

**(If yes, please attach copy of certificate)**

3. Is the laboratory located in a state that requires laboratory licensure? YES  NO

**(If yes, please attach copy of license)**

4. Are test kits used FDA licensed, approved or cleared for donor screening? YES  NO

**(Please complete the test kit information on page 3)**

5. Does the anti-HIV test method used detect HIV Group O? YES  NO

6. Is testing performed in strict accordance with the manufacturer’s

package insert? YES  NO

7. Are the manufacturer’s recommendations for specimen type (serum/plasma)

and handling followed? YES  NO

8. Are specimens ever tested beyond the recommended storage time in the

package insert? (If yes, please explain in the comment section on page 2) YES  NO

9. Are the manufacturer’s instructions for evaluating and retesting when an

invalid run or result is obtained carefully applied? YES  NO

10. Are the manufacturer’s instructions for retesting and reporting an

initially reactive result strictly enforced? YES  NO

12. Is the initial testing ever performed in duplicate or triplicate? YES  NO

(This may be done at the request of an OPO when time is critical)

13. Are donor specimens ever pooled for NAT testing? YES  NO

14. Are the manufacturer’s instructions for diluting NAT specimens carefully

applied? YES  NO

15. Are donor testing records maintained for at least ten (10) years? YES  NO

16. How long does the laboratory archive donor specimens? \_\_\_\_\_ \_

If not archived, are excess specimens returned to the tissue bank after testing? YES  NO

17. Do you notify clients/referring physicians when testing methodology changes? YES  NO

(If yes, please describe)

Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Completed by: \_      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_     \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name (please print) Title

\_\_     \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_     \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature Date

***LABORATORY COMPLIANCE SURVEY***

***PART 2 - TEST KITS***

**Laboratory Name:**      

***Please provide the following information, or attach package inserts for each test:***

|  |  |  |
| --- | --- | --- |
| **TEST** | **MANUFACTURER** | **TEST KIT NAME** |
| **Anti-HIV-1/HIV-2** |  |  |
| **HIV-1 NAT** |  |  |
| **HBsAg** |  |  |
| **Anti-HBc (Total)** |  |  |
| **HBV NAT**  **(if performed)** |  |  |
| **Anti-HCV** |  |  |
| **HCV NAT** |  |  |
| **Anti-HTLV I/II** |  |  |
| **Syphilis Screening** |  |  |
| **Syphilis Confirmatory**  **(if performed)** |  |  |
| **WNV NAT**  **(if performed)** |  |  |