**PRO-TBD\_ManualReview**

**Test Name Verification Protocol**

**Change History**

|  |  |  |  |
| --- | --- | --- | --- |
| **REV** | **DATE** | **CO#** | **CHANGES** |
| A | XX/XX/XXXX | DCO-XX-XXX | Initial release. |

**Contents**

[1. Purpose 2](#_Toc75787383)

[2. Scope 2](#_Toc75787384)

[2.1. Requirement(s) 2](#_Toc75787385)

[3. Reference Documents 5](#_Toc75787386)

[4. Definitions 6](#_Toc75787387)

[5. Responsibilities 6](#_Toc75787388)

[5.1. Quality Assurance 6](#_Toc75787389)

[5.2. Testers 6](#_Toc75787390)

[5.3. Reviewers 6](#_Toc75787391)

[6. General Requirements 7](#_Toc75787392)

[7. Environment and Safety 7](#_Toc75787393)

[8. Deviations/Exceptions 7](#_Toc75787394)

[8.1. Unexpected test results 7](#_Toc75787395)

[8.2. Test instruction changes for clarity 7](#_Toc75787396)

[9. Document Management 7](#_Toc75787397)

[10. Test Results SUMMARY 9](#_Toc75787398)

[11. APPENDIX A – TESTING DEVIATIONS REPORT LOG 10](#_Toc75787409)

[12. APPENDIX B: Design verification by Non-Testing Methods Worksheet : COMPANY DOCUMENT NUMBER-786, COMPANY DOCUMENT NUMBER-787, COMPANY DOCUMENT NUMBER-788, COMPANY DOCUMENT NUMBER-115, COMPANY DOCUMENT NUMBER-360, COMPANY DOCUMENT NUMBER-148, COMPANY DOCUMENT NUMBER-147, COMPANY DOCUMENT NUMBER-038 10](#_Toc75787410)

# Purpose

This document specifies the Inspection verification protocol for System verification. The purpose of this protocol is to provide objective evidence that the final design outputs are tested and meet listed input requirements.

# Scope

The requirements and verification tests described in this document are associated with the overall system. This test is solely testing via inspection for System level requirements.

## Requirement(s)

The following requirements are verified in this procedure.

|  |  |  |
| --- | --- | --- |
| **REQ #** | **NAME** | **DESCRIPTION** |
| COMPANY DOCUMENT NUMBER-067 |  | The COMPANY SYSTEM shall not require wall or table mounting hardware. |
| COMPANY DOCUMENT NUMBER-070 |  | The COMPANY SYSTEM shall require 4 or fewer electrical plugs / power cords. |
| COMPANY DOCUMENT NUMBER-075 |  | The COMPANY SYSTEM shall not require a user to interact with needles or other skin piercing sharps. |
| COMPANY DOCUMENT NUMBER-085 |  | The COMPANY SYSTEM user interface and documentation shall be available in the following languages:-English |
| COMPANY DOCUMENT NUMBER-086 |  | The COMPANY SYSTEM shall provide labeling in the language(s) of the countries of distribution:- English |
| COMPANY DOCUMENT NUMBER-100 |  | The COMPANY SYSTEM labeling shall comply with:ISO 18113-1:2009 In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling)21 CFR 809.10 Labeling for in vitro diagnostic products |
| COMPANY DOCUMENT NUMBER-101 |  | The COMPANY SYSTEM shall be compliant with the unique device identification (UDI) requirements defined in 21 CFR801.45 "Devices that must be directly marked with a unique device identifier" |
| COMPANY DOCUMENT NUMBER-103 |  | The REAGENTS, CARTRIDGE and QUALITY CONTROLS Instructions for Use (IFU) shall be labeled to reflect Global Harmonized System (GHS) hazard warnings and labels.Note: the GHS and the regulations contained in 16 CFR part 1500 are harmonized. |
| COMPANY DOCUMENT NUMBER-104 |  | Bulk REAGENTS, CARTRIDGE and QUALITY CONTROLS shall be labeled to reflect Global Harmonized System (GHS) hazard warnings and labels for the substance in the container.Note: the GHS and the regulations contained in 16 CFR part 1500 are harmonized. |
| COMPANY DOCUMENT NUMBER-115 |  | Only the following COMPANY SYSTEM operational steps shall be manually performed by an operator during normal function:- Input Device and Sample Tracking Data into UI- Pipette 100uL +/-5uL of blood EDTA anticoagulated whole blood into SAMPLE PREP DISPOSABLE- Start Sample Prep Module- Pipette 1000uL +/-100uL of prepared sample from SAMPLE PREP DISPOSABLE into CARTRIDGE- Start Cytometry Module- Read and Report Results |
| COMPANY DOCUMENT NUMBER-147 |  | The COMPANY SYSTEM shall provide instructions for use that describe the proper use of the system. |
| COMPANY DOCUMENT NUMBER-148 |  | The COMPANY SYSTEM shall provide instructions for use that describe how to properly install and service the system. |
| COMPANY DOCUMENT NUMBER-344 |  | The COMPANY SYSTEM shall have Safety Data Sheets (SDS) for the REAGENTS. |
| COMPANY DOCUMENT NUMBER-360 |  | SAMPLE PREP MODULE reagents and waste container shall be on-board and user accessible. |
| COMPANY DOCUMENT NUMBER-785 |  | The COMPANY SYSTEM shall have considerations for preventing unintentional mix-up of reagent & waste connections:- labels on each reagent and waste connection, - bottle rack with specific positions for each reagent and waste,- waste bottle cap unique size,- Reagent A and Reagent B unique cap sizes,- all reagent and waste bottle sizes unique. |
| COMPANY DOCUMENT NUMBER-786 |  | The COMPANY SYSTEM shall specify use of a fixed-volume 100 uL pipette and extended length pipette tips for transfer of blood sample into sample prep tube. |
| COMPANY DOCUMENT NUMBER-787 |  | The COMPANY SYSTEM shall specify use of a lint free swab to ensure the sides of the prep tube are free of blood smears. |
| COMPANY DOCUMENT NUMBER-788 |  | The COMPANY SYSTEM shall specify use of a pipette capable of pipetting 1000uL and mating pipette tips for transfer of sample from sample prep tube to the cartridge. |

# Reference Documents

|  |  |
| --- | --- |
| **DOC NUMBER** | **TITLE/DESCRIPTION** |
| 598-003-018 | Company System Requirements |
| FRM-0046 | Deviations Form |
| LAB-0001 | Exposure Control Plan |
| LAB-0002 | Chemical Hygiene Plan |
| SOP-0001 | Document Control Procedure |
| SOP-0006 | Risk Management Procedure |
| SOP-0040 | Design Verification Procedure |
| SOP-0046 | Deviations Procedure |
|  | *Add and remove as necessary, IN ALPHABETICAL ORER; ensure that all references either directly pertain to the document or are referenced within the document* |

# Definitions

|  |  |
| --- | --- |
| **TERM** | **DEFINITION** |
| CIM/CYM | Cell Imaging Module; the Cytometry Module /CYM was the early project name/acronym for the Cytovale Cell Imaging Module (CIM); Cytometer, CYM or CIM can be used interchangeably throughout this document. |
| IAM | Imaging Analysis Module. The part of the Cytovale System that analyzes the video and determines the IntelliSep index. |
| IntelliSep | The commercial name of the Cytovale Test, previously known as Company test or assay |
| IntelliSep Index | A synonym for the score provided by the IntelliSep Test |
| REA | Reagent(s) specified for use with the Cytovale System. Diluent, Cleanse, and Reagent Kit (Lyse and Quench). |
| Company | The initial development name of the Cytovale System. Company System and Cytovale System may be used interchangeably throughout the document. |
| SPM | Sample Prep Module. The part of the Cytovale System that prepares the samples for analysis. |
|  | *Remove/Add applicable terms, in ALPHABETICAL ORDER; ensure that all terms are present in the document* |

# Responsibilities

## Quality Assurance

QA shall be responsible for document control activities , the review of any testing deviations, and for performing final review of the executed protocol (including additional objective evidence) to ensure that it is conformance with good documentation practices per Cytovale SOPs. This review of testing deviations and final review of the executed protocol is documented via the QA signature(s) on the FRM-0046 deviation forms (where applicable) and the QA signature(s) on the change order form releasing the final report. The final QA approver on the change order is responsible for the conformance of the report and its attachments against Cytovale SOPs.

## Testers

The testers are responsible for completing training on the protocol and supporting procedures and equipment and providing those records to QA to insert into the training files.

Testers are responsible for printing out the entirety of this protocol, filling it out as applicable, and submitting these records to QA for retention upon the completion of the test.

## Reviewers

The reviewers shall be persons other than the testers. The reviewers are responsible for reviewing the executed setup and/or test to ensure the following: all blanks are filled in, all attachments e.g., pictures are attached and properly identified per protocol, checking the actual vs expected results to ensure the correct “PASS”, “FAIL”, or “Completed” selection was marked.

Reviewers are not required to be trained to this protocol because their role is to confirm good documentation practices rather than collect or analyze data. Reviewers are required to have documented training completed on SOP-0014, Good Documentation Practices.

# General Requirements

* All equipment used is qualified and within calibration. Per SOP-0040, all custom-developed test equipment, test methods, and/or software used in verification test data collection or analysis shall be validated for intended use before use in a verification study.
* Training of all personnel executing this protocol is documented for this protocol and all related WIs, SOPs, etc.
* All deviations are to be processed according to the instructions described in SOP-0046 and in Section 8, Deviations/Exceptions. All deviations, regardless of type, will be submitted along with the executed protocol to QA.
* All test materials are released and acceptable for use.

# Environment and Safety

Follow the facility's safety procedures, LAB-0001 and LAB-0002, including but not limited to, the use of personal protective equipment, lab safety, and appropriate labeling of materials.

# Deviations/Exceptions

Any deviation with the execution of a released protocol shall be documented according to the process below. Deviations are tabulated in the Deviations section of the test report using Appendix A and in accordance with SOP-0046, Deviations Procedure. Test deviations fall into two categories: unexpected test results, and test instruction changes for clarity.

## Unexpected test results

These types of testing deviations, including step failures, and occasions where the test procedure was not or could not be followed as written, shall be documented using FRM-0046, Deviations Form (see SOP-0046, Deviations Procedure for details). Completed FRM-0046s are attached and summarized in the Deviations table in the test report.

## Test instruction changes for clarity

These types of testing deviations include minor errors in instructions such as grammar and typos and do not require FRM-0046. They shall be documented/summarized in the Deviations table in the test report.

# Document Management

All verification documentation will be submitted, approved, and released per document control procedures as outlined in SOP-0001, Document Control Procedure. The executed verification test protocol and all supporting documentation will be attached to the respective final verification test report for inclusion with the respective final report.

#   Test Results SUMMARY

|  |  |
| --- | --- |
| **Final Comments** |  |
| **OVERALL TEST RESULTS** | **PASS ☐ FAIL ☐** |
|  | **Printed Name** | **Signature** | **Date** |
| **Results Certified By:** |  |  |  |
| **Results Reviewed By:** |  |  |  |

1.
2.
3.
4.
5.
6.
7.
8.
9.
10.

# APPENDIX A – TESTING DEVIATIONS REPORT LOG

Total number of Testing Deviation logs (copies of this page): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

All deviations must be listed in this table, including those captured on a separate FRM-0046. Testing deviations that are not covered under a separate FRM-0046 shall have the following nomenclature:

TD-[Protocol Number]-[number increasing from 01], e.g. “TD-PRO-00XX-01”

|  |  |  |  |
| --- | --- | --- | --- |
| **TD #** | **Test #** | **Description** | **Status** |
|   |  |  |  |
|   |  |  |  |
|   |  |  |  |
|   |  |  |  |
|   |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

# APPENDIX B: Design verification by Non-Testing Methods Worksheet: COMPANY DOCUMENT NUMBER-786, COMPANY DOCUMENT NUMBER-787, COMPANY DOCUMENT NUMBER-788, COMPANY DOCUMENT NUMBER-115, COMPANY DOCUMENT NUMBER-360, COMPANY DOCUMENT NUMBER-148, COMPANY DOCUMENT NUMBER-147, COMPANY DOCUMENT NUMBER-038, COMPANY DOCUMENT NUMBER-070

Description of Appropriate Use of the Worksheet:

* The worksheet below should not be used on its own and should be included in the protocol driving specific requirements verification. It should be added to the protocol as an appendix.
* Requirements may only be grouped on a single worksheet if the verification method, document(s) or material(s) evaluated, and material(s) or equipment used for testing are the same across requirements.
* This worksheet may only be used if the requirement description includes all details, including acceptance criteria, relevant to ensure unambiguous testing.
* This worksheet may only be used where no special training is required, where no additional description of responsibilities is needed, and where no sample size justification is required.
* The worksheet may be filled in electronically and then signed.
* Ensure that appropriate notes and evidence are included such that the reviewer can confirm pass/fail results. When a requirement to be verified includes several items, it is recommended to itemize or number them so they can be easily found on corresponding reference documents.
* Once a tester begins the execution section during a formal execution, the record shall be archived and a corresponding report released, regardless of the results of the testing.

|  |
| --- |
| **Planning** |
| **Rqmnt ID(s):** | **Requirement Description:** |
| COMPANY DOCUMENT NUMBER-038 | The COMPANY SYSTEM shall process samples serially, one sample at a time. |
| COMPANY DOCUMENT NUMBER-070 | The SEPTICAN SYSTEM require 4 or fewer electrical plugs / power cords. |
| COMPANY DOCUMENT NUMBER-786 | The COMPANY SYSTEM shall specify use of a fixed-volume 100 uL pipette and extended length pipette tips for transfer of blood sample into sample prep tube. |
| COMPANY DOCUMENT NUMBER-787 | The COMPANY SYSTEM shall specify use of a lint free swab to ensure the sides of the prep tube are free of blood smears. |
| COMPANY DOCUMENT NUMBER-788 | The COMPANY SYSTEM shall specify use of a pipette capable of pipetting 1000uL and mating pipette tips for transfer of sample from sample prep tube to the cartridge. |
| COMPANY DOCUMENT NUMBER-115 | Only the following COMPANY SYSTEM operational steps shall be manually performed by an operator during normal function:- Input Device and Sample Tracking Data into UI- Pipette 100uL +/-5uL of blood EDTA anticoagulated whole blood into SAMPLE PREP DISPOSABLE- Start Sample Prep Module- Pipette 1000uL +/-100uL of prepared sample from SAMPLE PREP DISPOSABLE into CARTRIDGE- Start Cytometry Module- Read and Report Results |
| COMPANY DOCUMENT NUMBER-360 | SAMPLE PREP MODULE reagents and waste container shall be on-board and user accessible. |
| COMPANY DOCUMENT NUMBER-148 | The COMPANY SYSTEM shall provide instructions for use that describe how to properly install and service the system. |
| COMPANY DOCUMENT NUMBER-147 | The COMPANY SYSTEM shall provide instructions for use that describe the proper use of the system. |
| Verification Method: Inspection [x]  Analysis [ ]  Demonstration [ ]   |
| Description of evaluation process:[x]  Evaluate attributes of subject document(s) or material(s) compared to the requirement description[ ]  Compare requirement description attributes of the subject to a reference document (such as a regulatory guidance or analytical report). [ ]  Demonstrate by manipulation of the on-test subject as it is intended to be used to verify that the results are as planned or expected[ ]  Other (describe, such as measure dimensions): |
| **Execution** |
| Performed by (Tester): | Performed-on Date(s): |
| Document(s) or material(s) evaluated:User Manual |
| Material(s) or equipment used for the evaluation, including calibration information, if applicable: N/A |
| Evaluation Results:Evaluate the User Manual for verification of the following requirements:**Yes** [ ]  **No** [ ]  The COMPANY SYSTEM shall specify use of a fixed-volume 100 uL pipette and extended length pipette tips for transfer of blood sample into sample prep tube.**Yes** ☐ **No** ☐ Only the following COMPANY SYSTEM operational steps shall be manually performed by an operator during normal function:- Input Device and Sample Tracking Data into UI- Pipette 100uL +/-5uL of blood EDTA anticoagulated whole blood into SAMPLE PREP DISPOSABLE- Start Sample Prep Module- Pipette 1000uL +/-100uL of prepared sample from SAMPLE PREP DISPOSABLE into CARTRIDGE- Start Cytometry Module - Read and Report Results**Yes** [ ]  **No** [ ]  SAMPLE PREP MODULE reagents and waste container shall be on-board and user accessible.**Yes** ☐ **No** ☐ The COMPANY SYSTEM shall provide instructions for use that describe how to properly install and service the system.**Yes** [ ]  **No** [ ]  The COMPANY SYSTEM shall provide instructions for use that describe the proper use of the system.**Yes** ☐ **No** ☐ The COMPANY SYSTEM shall process samples serially, one sample at a time. | **Verification Disposition:**COMPANY DOCUMENT NUMBER-786 **Pass □ Fail □**COMPANY DOCUMENT NUMBER-787 **Pass □ Fail □**COMPANY DOCUMENT NUMBER-788 **Pass □ Fail □**COMPANY DOCUMENT NUMBER-115 **Pass □ Fail □**COMPANY DOCUMENT NUMBER-360 **Pass □ Fail □**COMPANY DOCUMENT NUMBER-148 **Pass □ Fail □**COMPANY DOCUMENT NUMBER-147 **Pass □ Fail □**COMPANY DOCUMENT NUMBER-038 **Pass □ Fail □** |
| Attachments (e.g. highlighted document, raw data, etc.):Attached and highlighted: User Manual Doc#xxx |
| Deviation record number(s) for each failure/unexpected result (FRM-0046): |
| Tester Signature:  | Date: |
| Reviewer Name: |
| Reviewer Signature: | Date: |

# APPENDIX C: Design verification by Non-Testing Methods Worksheet: COMPANY DOCUMENT NUMBER-075

Description of Appropriate Use of the Worksheet:

* The worksheet below should not be used on its own and should be included in the protocol driving specific requirements verification. It should be added to the protocol as an appendix.
* Requirements may only be grouped on a single worksheet if the verification method, document(s) or material(s) evaluated, and material(s) or equipment used for testing are the same across requirements.
* This worksheet may only be used if the requirement description includes all details, including acceptance criteria, relevant to ensure unambiguous testing.
* This worksheet may only be used where no special training is required, where no additional description of responsibilities is needed, and where no sample size justification is required.
* The worksheet may be filled in electronically and then signed.
* Ensure that appropriate notes and evidence are included such that the reviewer can confirm pass/fail results. When a requirement to be verified includes several items, it is recommended to itemize or number them so they can be easily found on corresponding reference documents.
* Once a tester begins the execution section during a formal execution, the record shall be archived and a corresponding report released, regardless of the results of the testing.

|  |
| --- |
| **Planning** |
| **Rqmnt ID(s):** | **Requirement Description:** |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
| Verification Method: Inspection [x]  Analysis [ ]  Demonstration [ ]   |
| Description of evaluation process:[x]  Evaluate attributes of subject document(s) or material(s) compared to the requirement description[ ]  Compare requirement description attributes of the subject to a reference document (such as a regulatory guidance or analytical report). [ ]  Demonstrate by manipulation of the on-test subject as it is intended to be used to verify that the results are as planned or expected[ ]  Other (describe, such as measure dimensions): |
| **Execution** |
| Performed by (Tester): | Performed-on Date(s): |
| Document(s) or material(s) evaluated: |
| Material(s) or equipment used for the evaluation, including calibration information, if applicable: N/A |
|  |  |
| Attachments (e.g. highlighted document, raw data, etc.):Attached and highlighted: User Manual Doc#xxx |
| Deviation record number(s) for each failure/unexpected result (FRM-0046): |
| Tester Signature:  | Date: |
| Reviewer Name: |
| Reviewer Signature: | Date: |
| **Execution** |
| Performed by (Tester): | Performed-on Date(s): |
| Document(s) or material(s) evaluated:User Manual |
| Material(s) or equipment used for the evaluation, including calibration information, if applicable: N/A |
| Evaluation Results:Evaluate the User Manual for verification of the following requirements:**Yes** [ ]  **No** [ ]  The COMPANY SYSTEM shall not require a user to interact with needles or other skin piercing sharps.**Yes** [ ]  **No** [ ]  SAMPLE PREP MODULE reagents and waste container shall be on-board and user accessible.**Yes** ☐ **No** ☐ The COMPANY SYSTEM shall provide instructions for use that describe how to properly install and service the system.**Yes** [ ]  **No** [ ]  The COMPANY SYSTEM shall provide instructions for use that describe the proper use of the system.**Yes** ☐ **No** ☐ The COMPANY SYSTEM shall process samples serially, one sample at a time.- Input Device and Sample Tracking Data into UI- Pipette 100uL +/-5uL of blood EDTA anticoagulated whole blood into SAMPLE PREP DISPOSABLE- Start Sample Prep Module- Pipette 1000uL +/-100uL of prepared sample from SAMPLE PREP DISPOSABLE into CARTRIDGE- Start Cytometry Module - Read and Report Results**Yes** [ ]  **No** [ ]  SAMPLE PREP MODULE reagents and waste container shall be on-board and user accessible.**Yes** ☐ **No** ☐ The COMPANY SYSTEM shall provide instructions for use that describe how to properly install and service the system.**Yes** [ ]  **No** [ ]  The COMPANY SYSTEM shall provide instructions for use that describe the proper use of the system.**Yes** ☐ **No** ☐ The COMPANY SYSTEM shall process samples serially, one sample at a time. | **Verification Disposition:**COMPANY DOCUMENT NUMBER- 075**Pass □ Fail □** |

# APPENDIX d: Design verification by Non-Testing Methods Worksheet: COMPANY DOCUMENT NUMBER-086

Description of Appropriate Use of the Worksheet:

* The worksheet below should not be used on its own and should be included in the protocol driving specific requirements verification. It should be added to the protocol as an appendix.
* Requirements may only be grouped on a single worksheet if the verification method, document(s) or material(s) evaluated, and material(s) or equipment used for testing are the same across requirements.
* This worksheet may only be used if the requirement description includes all details, including acceptance criteria, relevant to ensure unambiguous testing.
* This worksheet may only be used where no special training is required, where no additional description of responsibilities is needed, and where no sample size justification is required.
* The worksheet may be filled in electronically and then signed.
* Ensure that appropriate notes and evidence are included such that the reviewer can confirm pass/fail results. When a requirement to be verified includes several items, it is recommended to itemize or number them so they can be easily found on corresponding reference documents.
* Once a tester begins the execution section during a formal execution, the record shall be archived and a corresponding report released, regardless of the results of the testing.

|  |
| --- |
| **Planning** |
| **Rqmnt ID(s):** | **Requirement Description:** |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
| Verification Method: Inspection [x]  Analysis [ ]  Demonstration [ ]   |
| Description of evaluation process:[x]  Evaluate attributes of subject document(s) or material(s) compared to the requirement description[ ]  Compare requirement description attributes of the subject to a reference document (such as a regulatory guidance or analytical report). [ ]  Demonstrate by manipulation of the on-test subject as it is intended to be used to verify that the results are as planned or expected[ ]  Other (describe, such as measure dimensions): |
| **Execution** |
| Performed by (Tester): | Performed-on Date(s): |
| Document(s) or material(s) evaluated: |
| Material(s) or equipment used for the evaluation, including calibration information, if applicable: N/A |
|  |  |
| Attachments (e.g. highlighted document, raw data, etc.):Attached and highlighted: User Manual Doc#xxx |
| Deviation record number(s) for each failure/unexpected result (FRM-0046): |
| Tester Signature:  | Date: |
| Reviewer Name: |
| Reviewer Signature: | Date: |
| **Execution** |
| Performed by (Tester): | Performed-on Date(s): |
| Document(s) or material(s) evaluated:User Manual |
| Material(s) or equipment used for the evaluation, including calibration information, if applicable: N/A |
| Evaluation Results:Evaluate the User Manual for verification of the following requirements:**Yes** [ ]  **No** [ ]  The COMPANY SYSTEM shall provide labeling in the language(s) of the countries of distribution: English.**Yes** ☐ **No** ☐ Only the following COMPANY SYSTEM operational steps shall be manually performed by an operator during normal function:- Input Device and Sample Tracking Data into UI- Pipette 100uL +/-5uL of blood EDTA anticoagulated whole blood into SAMPLE PREP DISPOSABLE- Start Sample Prep Module- Pipette 1000uL +/-100uL of prepared sample from SAMPLE PREP DISPOSABLE into CARTRIDGE- Start Cytometry Module - Read and Report Results**Yes** [ ]  **No** [ ]  SAMPLE PREP MODULE reagents and waste container shall be on-board and user accessible.**Yes** ☐ **No** ☐ The COMPANY SYSTEM shall provide instructions for use that describe how to properly install and service the system.**Yes** [ ]  **No** [ ]  The COMPANY SYSTEM shall provide instructions for use that describe the proper use of the system.**Yes** ☐ **No** ☐ The COMPANY SYSTEM shall process samples serially, one sample at a time. | **Verification Disposition:**COMPANY DOCUMENT NUMBER-086 **Pass □ Fail □**  |

# APPENDIX E: Design verification by Non-Testing Methods Worksheet: COMPANY DOCUMENT NUMBER-785

Description of Appropriate Use of the Worksheet:

* The worksheet below should not be used on its own and should be included in the protocol driving specific requirements verification. It should be added to the protocol as an appendix.
* Requirements may only be grouped on a single worksheet if the verification method, document(s) or material(s) evaluated, and material(s) or equipment used for testing are the same across requirements.
* This worksheet may only be used if the requirement description includes all details, including acceptance criteria, relevant to ensure unambiguous testing.
* This worksheet may only be used where no special training is required, where no additional description of responsibilities is needed, and where no sample size justification is required.
* The worksheet may be filled in electronically and then signed.
* Ensure that appropriate notes and evidence are included such that the reviewer can confirm pass/fail results. When a requirement to be verified includes several items, it is recommended to itemize or number them so they can be easily found on corresponding reference documents.
* Once a tester begins the execution section during a formal execution, the record shall be archived and a corresponding report released, regardless of the results of the testing.

|  |
| --- |
| **Planning** |
| **Rqmnt ID(s):** | **Requirement Description:** |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
| Verification Method: Inspection [x]  Analysis [ ]  Demonstration [ ]   |
| Description of evaluation process:[x]  Evaluate attributes of subject document(s) or material(s) compared to the requirement description[ ]  Compare requirement description attributes of the subject to a reference document (such as a regulatory guidance or analytical report). [ ]  Demonstrate by manipulation of the on-test subject as it is intended to be used to verify that the results are as planned or expected[ ]  Other (describe, such as measure dimensions): |
| **Execution** |
| Performed by (Tester): | Performed-on Date(s): |
| Document(s) or material(s) evaluated: |
| Material(s) or equipment used for the evaluation, including calibration information, if applicable: N/A |
|  |  |
| Attachments (e.g. highlighted document, raw data, etc.):Attached and highlighted: User Manual Doc#xxx |
| Deviation record number(s) for each failure/unexpected result (FRM-0046): |
| Tester Signature:  | Date: |
| Reviewer Name: |
| Reviewer Signature: | Date: |
| Performed by (Tester): | Performed-on Date(s): |
| Document(s) or material(s) evaluated:User Manual |
| Material(s) or equipment used for the evaluation, including calibration information, if applicable: N/A |
| Evaluation Results:Evaluate the User Manual for verification of the following requirements:**Yes** [ ]  **No** [ ]  The COMPANY SYSTEM shall have considerations of preventing unintentional mix-up of reagent & waste connections – labels on each reagent and waste connection, – bottle rack with specific positions for each reagent and waste,– waste bottle cap unique cap sizes, – Reagent A and Reagent B unique cap sizes– all reagent and waste bottle sizes unique**Yes** ☐ **No** ☐ Only the following COMPANY SYSTEM operational steps shall be manually performed by an operator during normal function:- Input Device and Sample Tracking Data into UI- Pipette 100uL +/-5uL of blood EDTA anticoagulated whole blood into SAMPLE PREP DISPOSABLE- Start Sample Prep Module- Pipette 1000uL +/-100uL of prepared sample from SAMPLE PREP DISPOSABLE into CARTRIDGE- Start Cytometry Module - Read and Report Results**Yes** [ ]  **No** [ ]  SAMPLE PREP MODULE reagents and waste container shall be on-board and user accessible.**Yes** ☐ **No** ☐ The COMPANY SYSTEM shall provide instructions for use that describe how to properly install and service the system.**Yes** [ ]  **No** [ ]  The COMPANY SYSTEM shall provide instructions for use that describe the proper use of the system.**Yes** ☐ **No** ☐ The COMPANY SYSTEM shall process samples serially, one sample at a time. | **Verification Disposition:**COMPANY DOCUMENT NUMBER-785**Pass □ Fail □** |

# APPENDIX F: Design verification by Non-Testing Methods Worksheet: COMPANY DOCUMENT NUMBER-085

Description of Appropriate Use of the Worksheet:

* The worksheet below should not be used on its own and should be included in the protocol driving specific requirements verification. It should be added to the protocol as an appendix.
* Requirements may only be grouped on a single worksheet if the verification method, document(s) or material(s) evaluated, and material(s) or equipment used for testing are the same across requirements.
* This worksheet may only be used if the requirement description includes all details, including acceptance criteria, relevant to ensure unambiguous testing.
* This worksheet may only be used where no special training is required, where no additional description of responsibilities is needed, and where no sample size justification is required.
* The worksheet may be filled in electronically and then signed.
* Ensure that appropriate notes and evidence are included such that the reviewer can confirm pass/fail results. When a requirement to be verified includes several items, it is recommended to itemize or number them so they can be easily found on corresponding reference documents.
* Once a tester begins the execution section during a formal execution, the record shall be archived and a corresponding report released, regardless of the results of the testing.

|  |
| --- |
| **Planning** |
| **Rqmnt ID(s):** | **Requirement Description:** |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
| Verification Method: Inspection [x]  Analysis [ ]  Demonstration [ ]   |
| Description of evaluation process:[x]  Evaluate attributes of subject document(s) or material(s) compared to the requirement description[ ]  Compare requirement description attributes of the subject to a reference document (such as a regulatory guidance or analytical report). [ ]  Demonstrate by manipulation of the on-test subject as it is intended to be used to verify that the results are as planned or expected[ ]  Other (describe, such as measure dimensions): |
| **Execution** |
| Performed by (Tester): | Performed-on Date(s): |
| Document(s) or material(s) evaluated: |
| Material(s) or equipment used for the evaluation, including calibration information, if applicable: N/A |
| Attachments (e.g. highlighted document, raw data, etc.):Attached and highlighted: User Manual Doc#xxx |
| Deviation record number(s) for each failure/unexpected result (FRM-0046): |
| Tester Signature:  | Date: |
| Reviewer Name: |
| Reviewer Signature: | Date: |
| **Execution** |
| Performed by (Tester): | Performed-on Date(s): |
| Document(s) or material(s) evaluated:User Manual |
| Material(s) or equipment used for the evaluation, including calibration information, if applicable: N/A |
| Evaluation Results:Evaluate the User Manual for verification of the following requirements:**Yes** [ ]  **No** [ ]  The COMPANY SYSTEM user interface and documentation shall be available in the following languages: – English**Yes** ☐ **No** ☐ Only the following COMPANY SYSTEM operational steps shall be manually performed by an operator during normal function:- Input Device and Sample Tracking Data into UI- Pipette 100uL +/-5uL of blood EDTA anticoagulated whole blood into SAMPLE PREP DISPOSABLE- Start Sample Prep Module- Pipette 1000uL +/-100uL of prepared sample from SAMPLE PREP DISPOSABLE into CARTRIDGE- Start Cytometry Module - Read and Report Results**Yes** [ ]  **No** [ ]  SAMPLE PREP MODULE reagents and waste container shall be on-board and user accessible.**Yes** ☐ **No** ☐ The COMPANY SYSTEM shall provide instructions for use that describe how to properly install and service the system.**Yes** [ ]  **No** [ ]  The COMPANY SYSTEM shall provide instructions for use that describe the proper use of the system.**Yes** ☐ **No** ☐ The COMPANY SYSTEM shall process samples serially, one sample at a time. | **Verification Disposition:**COMPANY DOCUMENT NUMBER-085**Pass □ Fail □** |

# APPENDIX G: Design verification by Non-Testing Methods Worksheet: COMPANY DOCUMENT NUMBER-103

Description of Appropriate Use of the Worksheet:

* The worksheet below should not be used on its own and should be included in the protocol driving specific requirements verification. It should be added to the protocol as an appendix.
* Requirements may only be grouped on a single worksheet if the verification method, document(s) or material(s) evaluated, and material(s) or equipment used for testing are the same across requirements.
* This worksheet may only be used if the requirement description includes all details, including acceptance criteria, relevant to ensure unambiguous testing.
* This worksheet may only be used where no special training is required, where no additional description of responsibilities is needed, and where no sample size justification is required.
* The worksheet may be filled in electronically and then signed.
* Ensure that appropriate notes and evidence are included such that the reviewer can confirm pass/fail results. When a requirement to be verified includes several items, it is recommended to itemize or number them so they can be easily found on corresponding reference documents.
* Once a tester begins the execution section during a formal execution, the record shall be archived and a corresponding report released, regardless of the results of the testing.

|  |
| --- |
| **Planning** |
| **Rqmnt ID(s):** | **Requirement Description:** |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
| Verification Method: Inspection [x]  Analysis [ ]  Demonstration [ ]   |
| Description of evaluation process:[x]  Evaluate attributes of subject document(s) or material(s) compared to the requirement description[ ]  Compare requirement description attributes of the subject to a reference document (such as a regulatory guidance or analytical report). [ ]  Demonstrate by manipulation of the on-test subject as it is intended to be used to verify that the results are as planned or expected[ ]  Other (describe, such as measure dimensions): |
| **Execution** |
| Performed by (Tester): | Performed-on Date(s): |
| Document(s) or material(s) evaluated: |
| Material(s) or equipment used for the evaluation, including calibration information, if applicable: N/A |
|  |  |
| Attachments (e.g. highlighted document, raw data, etc.):Attached and highlighted: User Manual Doc#xxx |
| Deviation record number(s) for each failure/unexpected result (FRM-0046): |
| Tester Signature:  | Date: |
| Reviewer Name: |
| Reviewer Signature: | Date: |
| **Execution** |
| Performed by (Tester): | Performed-on Date(s): |
| Document(s) or material(s) evaluated:User Manual |
| Material(s) or equipment used for the evaluation, including calibration information, if applicable: N/A |
| Evaluation Results:Evaluate the User Manual for verification of the following requirements:**Yes** [ ]  **No** [ ]  The REAGENTS, CARTRIDGE and QUALITY CONTROLS Instructions for Use (IFU) shall be labeled to reflect Global Harmonized System (GHS) hazard warnings and labels.Note: the GHS and the regulations contained in 16 CFR part 1500 are harmonized.**Yes** ☐ **No** ☐ Only the following COMPANY SYSTEM operational steps shall be manually performed by an operator during normal function:- Input Device and Sample Tracking Data into UI- Pipette 100uL +/-5uL of blood EDTA anticoagulated whole blood into SAMPLE PREP DISPOSABLE- Start Sample Prep Module- Pipette 1000uL +/-100uL of prepared sample from SAMPLE PREP DISPOSABLE into CARTRIDGE- Start Cytometry Module - Read and Report Results**Yes** [ ]  **No** [ ]  SAMPLE PREP MODULE reagents and waste container shall be on-board and user accessible.**Yes** ☐ **No** ☐ The COMPANY SYSTEM shall provide instructions for use that describe how to properly install and service the system.**Yes** [ ]  **No** [ ]  The COMPANY SYSTEM shall provide instructions for use that describe the proper use of the system.**Yes** ☐ **No** ☐ The COMPANY SYSTEM shall process samples serially, one sample at a time. | **Verification Disposition:**COMPANY DOCUMENT NUMBER-103**Pass □ Fail □** |

# APPENDIX H: Design verification by Non-Testing Methods Worksheet: COMPANY DOCUMENT NUMBER-104

Description of Appropriate Use of the Worksheet:

* The worksheet below should not be used on its own and should be included in the protocol driving specific requirements verification. It should be added to the protocol as an appendix.
* Requirements may only be grouped on a single worksheet if the verification method, document(s) or material(s) evaluated, and material(s) or equipment used for testing are the same across requirements.
* This worksheet may only be used if the requirement description includes all details, including acceptance criteria, relevant to ensure unambiguous testing.
* This worksheet may only be used where no special training is required, where no additional description of responsibilities is needed, and where no sample size justification is required.
* The worksheet may be filled in electronically and then signed.
* Ensure that appropriate notes and evidence are included such that the reviewer can confirm pass/fail results. When a requirement to be verified includes several items, it is recommended to itemize or number them so they can be easily found on corresponding reference documents.
* Once a tester begins the execution section during a formal execution, the record shall be archived and a corresponding report released, regardless of the results of the testing.

|  |
| --- |
| **Planning** |
| **Rqmnt ID(s):** | **Requirement Description:** |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
| Verification Method: Inspection [x]  Analysis [ ]  Demonstration [ ]   |
| Description of evaluation process:[x]  Evaluate attributes of subject document(s) or material(s) compared to the requirement description[ ]  Compare requirement description attributes of the subject to a reference document (such as a regulatory guidance or analytical report). [ ]  Demonstrate by manipulation of the on-test subject as it is intended to be used to verify that the results are as planned or expected[ ]  Other (describe, such as measure dimensions): |
| **Execution** |
| Performed by (Tester): | Performed-on Date(s): |
| Document(s) or material(s) evaluated: |
| Material(s) or equipment used for the evaluation, including calibration information, if applicable: N/A |
|  |  |
| Attachments (e.g. highlighted document, raw data, etc.):Attached and highlighted: User Manual Doc#xxx |
| Deviation record number(s) for each failure/unexpected result (FRM-0046): |
| Tester Signature:  | Date: |
| Reviewer Name: |
| Reviewer Signature: | Date: |
| **Execution** |
| Performed by (Tester): | Performed-on Date(s): |
| Document(s) or material(s) evaluated:User Manual |
| Material(s) or equipment used for the evaluation, including calibration information, if applicable: N/A |
| Evaluation Results:Evaluate the User Manual for verification of the following requirements:**Yes** [ ]  **No** [ ]  Bulk REAGENTS, CARTRIDGE and QUALITY CONTROLS shall be labeled to reflect Global Harmonized System (GHS) hazard warnings and labels for the substance in the container.**Yes** ☐ **No** ☐ Only the following COMPANY SYSTEM operational steps shall be manually performed by an operator during normal function:- Input Device and Sample Tracking Data into UI- Pipette 100uL +/-5uL of blood EDTA anticoagulated whole blood into SAMPLE PREP DISPOSABLE- Start Sample Prep Module- Pipette 1000uL +/-100uL of prepared sample from SAMPLE PREP DISPOSABLE into CARTRIDGE- Start Cytometry Module - Read and Report Results**Yes** [ ]  **No** [ ]  SAMPLE PREP MODULE reagents and waste container shall be on-board and user accessible.**Yes** ☐ **No** ☐ The COMPANY SYSTEM shall provide instructions for use that describe how to properly install and service the system.**Yes** [ ]  **No** [ ]  The COMPANY SYSTEM shall provide instructions for use that describe the proper use of the system.**Yes** ☐ **No** ☐ The COMPANY SYSTEM shall process samples serially, one sample at a time. | **Verification Disposition:**COMPANY DOCUMENT NUMBER-104 **Pass □ Fail □**  |

# APPENDIX I: Design verification by Non-Testing Methods Worksheet: COMPANY DOCUMENT NUMBER-344

Description of Appropriate Use of the Worksheet:

* The worksheet below should not be used on its own and should be included in the protocol driving specific requirements verification. It should be added to the protocol as an appendix.
* Requirements may only be grouped on a single worksheet if the verification method, document(s) or material(s) evaluated, and material(s) or equipment used for testing are the same across requirements.
* This worksheet may only be used if the requirement description includes all details, including acceptance criteria, relevant to ensure unambiguous testing.
* This worksheet may only be used where no special training is required, where no additional description of responsibilities is needed, and where no sample size justification is required.
* The worksheet may be filled in electronically and then signed.
* Ensure that appropriate notes and evidence are included such that the reviewer can confirm pass/fail results. When a requirement to be verified includes several items, it is recommended to itemize or number them so they can be easily found on corresponding reference documents.
* Once a tester begins the execution section during a formal execution, the record shall be archived and a corresponding report released, regardless of the results of the testing.

|  |
| --- |
| **Planning** |
| **Rqmnt ID(s):** | **Requirement Description:** |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
| Verification Method: Inspection [x]  Analysis [ ]  Demonstration [ ]   |
| Description of evaluation process:[x]  Evaluate attributes of subject document(s) or material(s) compared to the requirement description[ ]  Compare requirement description attributes of the subject to a reference document (such as a regulatory guidance or analytical report). [ ]  Demonstrate by manipulation of the on-test subject as it is intended to be used to verify that the results are as planned or expected[ ]  Other (describe, such as measure dimensions): |
| **Execution** |
| Performed by (Tester): | Performed-on Date(s): |
| Document(s) or material(s) evaluated: |
| Material(s) or equipment used for the evaluation, including calibration information, if applicable: N/A |
|  |  |
| Attachments (e.g. highlighted document, raw data, etc.):Attached and highlighted: User Manual Doc#xxx |
| Deviation record number(s) for each failure/unexpected result (FRM-0046): |
| Tester Signature:  | Date: |
| Reviewer Name: |
| Reviewer Signature: | Date: |
| **Execution** |
| Performed by (Tester): | Performed-on Date(s): |
| Document(s) or material(s) evaluated:User Manual |
| Material(s) or equipment used for the evaluation, including calibration information, if applicable: N/A |
| Evaluation Results:Evaluate the User Manual for verification of the following requirements:**Yes** [ ]  **No** [ ]  The COMPANY SYSTEM shall have Safety Data Sheets (SDS) for the REAGENTS.**Yes** ☐ **No** ☐ Only the following COMPANY SYSTEM operational steps shall be manually performed by an operator during normal function:- Input Device and Sample Tracking Data into UI- Pipette 100uL +/-5uL of blood EDTA anticoagulated whole blood into SAMPLE PREP DISPOSABLE- Start Sample Prep Module- Pipette 1000uL +/-100uL of prepared sample from SAMPLE PREP DISPOSABLE into CARTRIDGE- Start Cytometry Module - Read and Report Results**Yes** [ ]  **No** [ ]  SAMPLE PREP MODULE reagents and waste container shall be on-board and user accessible.**Yes** ☐ **No** ☐ The COMPANY SYSTEM shall provide instructions for use that describe how to properly install and service the system.**Yes** [ ]  **No** [ ]  The COMPANY SYSTEM shall provide instructions for use that describe the proper use of the system.**Yes** ☐ **No** ☐ The COMPANY SYSTEM shall process samples serially, one sample at a time. | **Verification Disposition:**COMPANY DOCUMENT NUMBER-344 **Pass □ Fail □** |

# APPENDIX J: Design verification by Non-Testing Methods Worksheet: COMPANY DOCUMENT NUMBER-067

Description of Appropriate Use of the Worksheet:

* The worksheet below should not be used on its own and should be included in the protocol driving specific requirements verification. It should be added to the protocol as an appendix.
* Requirements may only be grouped on a single worksheet if the verification method, document(s) or material(s) evaluated, and material(s) or equipment used for testing are the same across requirements.
* This worksheet may only be used if the requirement description includes all details, including acceptance criteria, relevant to ensure unambiguous testing.
* This worksheet may only be used where no special training is required, where no additional description of responsibilities is needed, and where no sample size justification is required.
* The worksheet may be filled in electronically and then signed.
* Ensure that appropriate notes and evidence are included such that the reviewer can confirm pass/fail results. When a requirement to be verified includes several items, it is recommended to itemize or number them so they can be easily found on corresponding reference documents.
* Once a tester begins the execution section during a formal execution, the record shall be archived and a corresponding report released, regardless of the results of the testing.

|  |
| --- |
| **Planning** |
| **Rqmnt ID(s):** | **Requirement Description:** |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
| Verification Method: Inspection [x]  Analysis [ ]  Demonstration [ ]   |
| Description of evaluation process:[x]  Evaluate attributes of subject document(s) or material(s) compared to the requirement description[ ]  Compare requirement description attributes of the subject to a reference document (such as a regulatory guidance or analytical report). [ ]  Demonstrate by manipulation of the on-test subject as it is intended to be used to verify that the results are as planned or expected[ ]  Other (describe, such as measure dimensions): |
| **Execution** |
| Performed by (Tester): | Performed-on Date(s): |
| Document(s) or material(s) evaluated: |
| Material(s) or equipment used for the evaluation, including calibration information, if applicable: N/A |
|  |  |
| Attachments (e.g. highlighted document, raw data, etc.):Attached and highlighted: User Manual Doc#xxx |
| Deviation record number(s) for each failure/unexpected result (FRM-0046): |
| Tester Signature:  | Date: |
| Reviewer Name: |
| Reviewer Signature: | Date: |
| **Execution** |
| Performed by (Tester): | Performed-on Date(s): |
| Document(s) or material(s) evaluated:User Manual |
| Material(s) or equipment used for the evaluation, including calibration information, if applicable: N/A |
| Evaluation Results:Evaluate the User Manual for verification of the following requirements:**Yes** [ ]  **No** [ ]  The COMPANY SYSTEM shall not require wall or table mounting hardware.**Yes** ☐ **No** ☐ Only the following COMPANY SYSTEM operational steps shall be manually performed by an operator during normal function:- Input Device and Sample Tracking Data into UI- Pipette 100uL +/-5uL of blood EDTA anticoagulated whole blood into SAMPLE PREP DISPOSABLE- Start Sample Prep Module- Pipette 1000uL +/-100uL of prepared sample from SAMPLE PREP DISPOSABLE into CARTRIDGE- Start Cytometry Module - Read and Report Results**Yes** [ ]  **No** [ ]  SAMPLE PREP MODULE reagents and waste container shall be on-board and user accessible.**Yes** ☐ **No** ☐ The COMPANY SYSTEM shall provide instructions for use that describe how to properly install and service the system.**Yes** [ ]  **No** [ ]  The COMPANY SYSTEM shall provide instructions for use that describe the proper use of the system.**Yes** ☐ **No** ☐ The COMPANY SYSTEM shall process samples serially, one sample at a time. | **Verification Disposition:**COMPANY DOCUMENT NUMBER-067 **Pass □ Fail □** |