

#	Required	If available	Optional
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MIATA Sub-Modules

Module 1 - Sample

Module 1A - Donor

1.1 Essential donor info

Module 1B Source

1.2 Source of cell material

1.3 Collection methodology

1.4 anti-coagulant, if available

1.5 Transportation/storage conditions for unprocessed samples, if available

1.6 Cell processing methodology

1.7 Median time and ranges from sample collection until end of cell processing, if available

1.8 Cut-offs, if used

Module 1C - Cryopreservation and Storage

1.9 Fresh or cryopreserved

1.10 If cryopreserved

1.11 devices used

1.12 freezing process

1.13 medium used for freezing

1.14 Median time and temperature for each transportation and storage step, if available

1.15 Cut-offs, if used

Module 1D - Cell Counting

1.16 Median cell yield and viability (where available)

1.17 before freezing

1.18 after thawing

1.19 after overnight resting

1.20 Cut-offs, if used

1.21 Cell counting methodology

1.22 *Optional: Additional assessments*

Module 2 - Assay

Module 2A - Medium/serum

2.1 Medium/(serum) details

2.2 Pretesting info

Module 2B - Assay

2.3 Treatment procedures of cells prior to assay, if applicable

2.4 Sufficient assay details

Module 2C - Controls

2.5 Internal assay controls

2.6 Acceptance criteria, if available

2.7 External reference samples, if used

2.8 Assay acceptance criteria, if available

Module 3 - Data Acquisition

Module 3A - Equipment and software

3.1 Equipment and software version

3.2 Basic equipment settings, if available

Module 3B - Acquisition Strategy and Gating

3.3 Detailed gating strategy or strategy for establishing spot detection parameters

3.4 Representative data set

3.5 Mean, median, ranges of event counts for relevant populations, if available

3.6 *Optional: Unusual strategies explained*

3.7 *Optional: Review of raw data*

Module 4 - Results

Module 4A - Raw data

4.1 Background and ag-specific reactivity levels, if available

4.2 Cut-off specifications and # of tests OOS, if available

4.3 Accessibility of raw data addressed?

Module 4B - Response determination

4.4 Definition of positive reactivity (above background) including tests applied

4.5 Parameters, software and version used for response determination, if applicable

4.6 Response definition predefined or post-hoc?

4.7 Definition of response induced by treatment, if applicable

4.8 Any data excluded and why, if applicable?

4.9 *Optional: Why test was used*

Module 5

Module 5A - General Lab Operation

5.1 Guidance of lab operations

5.2 Laboratory accreditations and certifications, if available

5.3 *Optional: Details on audits*

Module 5B - Standardization

5.4 Status of protocols

Module 5C - Qualification/Validation

5.5 Status of assays

5.6 *Optional: Specific performance criteria*