LIM INGESTOR PLATFORM 3.0

IRENA machine extraction and evidence-capture manual

NATIVE EVIDENCE FIRST. EVERY DERIVATIVE EXPLAINABLE.

Controlled production implementation baseline. This manual does not authorize patient activation. Each connector remains fail-closed until physical identity, installed software, licensed interface, fixtures, cybersecurity controls, and QA release are approved.

Registry	PREPAIRE-IRENA-ASSET-REGISTRY@3.0.0
Profiles	PREPAIRE-INSTRUMENT-PROFILE-REGISTRY@3.0.0
Source workbook	lab-assets-2026-08-15.xlsx
Source SHA-256	210b65046f7bccb1ec26379e824e825033f076df8f2d70aea31dfb6449296e06
Scope	76 assets / 49 profiles

Universal extraction procedure

1. Match the physical serial, asset label, model, module composition, facility, host, firmware, and software to the governed registry.

2. Create a LIM run identity and bind samples, aliquots, plates or flow-cells, reagents, operator, method, and instrument.

3. Collect the highest-fidelity native evidence supported by the vendor; never overwrite it or substitute a report when native evidence exists.

4. Seal the source bundle in immutable quarantine storage; stream and independently verify SHA-256.

5. Reconcile files, bytes, identifiers, timestamps, controls, flags, and missing intervals against the LIM event.

6. Create open derivatives only with approved digest-pinned builds and recorded references and parameters.

7. Normalize without destroying source value, unit, range, method, or flags.

8. Quarantine any failed acceptance gate. Independent QA releases the verified evidence bundle to the KG.

Analytical instruments

1. BMG LABTECH FLUOstar Omega

Profile key	bmg-labtech-fluostar-omega
Role	analytical
Evidence status	NEEDS_INSTALLED_CONFIGURATION
Execution mode	EXTERNAL_VENDOR_RUNTIME
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- DRE-OF-000001 | Omega Fluostar | model Fluostar Omega | serial 415-3422 | DNA/RNA Extraction | active

Native evidence to preserve

- MARS/Absolute Database measurement project
- plate layout
- protocol
- kinetic/spectral reads
- instrument log

Open derivatives

- ASCII/CSV exports
- spectral and kinetic tables

Capture method

Use the supported export or SiLA/ActiveX/DDE interface and preserve the original measurement database before analysis templates are applied.

Operator procedure

1. Record reader serial, software versions, plate/barcode, protocol, filters, gain, temperature, and timing.
2. Save and transfer the complete native measurement project and plate definition.
3. Hash and seal native files before MARS calculations.
4. Export unrounded well-level values and spectra/kinetics in an open table format.
5. Reconcile well coordinates and controls against the LIM plate map.

Acceptance tests

- CHECK - Native project, open export, plate map, and protocol use the same plate identifier.
- CHECK - Exported unrounded values reproduce the approved control statistics.
- CHECK - Blank, positive, edge-effect, and calibration checks pass.

Activation blockers

Record installed Reader Control/MARS versions and confirm the licensed automation interface.

Primary references

- BMG LABTECH reader software: https://www.bmglabtech.com/en/microplate-reader-software/

- FLUOstar Omega: https://www.bmglabtech.com/en/fluostar-omega/

2. Element AVITI24 710-00975

Profile key	element-biosciences-inc-710-00975
Role	analytical
Evidence status	READY_FOR_LOCAL_VALIDATION
Execution mode	EXTERNAL_VENDOR_RUNTIME
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- SR-ASRS-000001 | AVITI24(Benchtop Short-Read Sequencer) | model 710-00975 | serial AV253803 | Sequencing Room | active

Native evidence to preserve

- Bases files
- AvitiRunStats.json
- run parameters
- instrument logs

Open derivatives

- FASTQ
- run QC JSON

Capture method

Read-only storage connection from the completed AVITI run folder; preserve the complete folder before conversion.

Operator procedure

1. Confirm run completion and the AVITI OS version in the run record.
2. Transfer the complete run folder to the quarantine landing zone using a read-only storage connection.
3. Calculate SHA-256 for every Bases file, AvitiRunStats.json, metadata file, and log before conversion.
4. Seal the native folder manifest in immutable object storage.
5. Run a validated Bases2Fastq image by digest to produce FASTQ and compare read counts against AVITI run statistics.

Acceptance tests

- CHECK - All expected lanes and samples are represented in the sealed manifest.
- CHECK - FASTQ read counts reconcile with AvitiRunStats.json within the approved tolerance.
- CHECK - A repeated conversion from the same Bases inputs produces identical declared outputs.

Activation blockers

Record the installed AVITI OS and Bases2Fastq versions before clinical release.

Primary references

- AVITI24 System User Guide: https://www.elementbiosciences.com/hubfs/element_biosciences_2025/resources_assets/pdfs/AVITI24_System_User_Guide_MA_00051_E.pdf?hsLang=en

3. Illumina iScan

Profile key	illumina-iscan
Role	analytical
Evidence status	NEEDS_INSTALLED_CONFIGURATION
Execution mode	EXTERNAL_VENDOR_RUNTIME
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- IRENA-UNASSIGNED-AXIOM-008 | Illumina iSCAN | model iSCAN | serial SY-101-1001 | BSL3 | inactive

Native evidence to preserve

- IDAT red/green intensity files
- scan metrics
- sample sheet
- instrument logs

Open derivatives

- GTC genotype calls
- VCF after validated normalization

Capture method

Preserve IDAT intensity files and scan metadata before genotype clustering or report generation.

Operator procedure

1. Record array manifest, cluster file, scanner, software versions, and sample mapping.
2. Copy IDAT pairs, metrics, manifest identifiers, sample sheet, and logs to quarantine.
3. Hash and seal the native scan bundle.
4. Generate GTC using the exact approved manifest and cluster versions.
5. Normalize calls into a versioned VCF representation without discarding no-calls.

Acceptance tests

- CHECK - Every sample has a matched red/green IDAT pair.
- CHECK - Manifest and cluster checksums match the approved assay package.
- CHECK - Reference samples meet call-rate, sex-check, identity, and concordance thresholds.

Activation blockers

Instrument is inactive; obtain manifest, cluster, and installed software inventories before requalification.
IRENA-UNASSIGNED-AXIOM-008 / ASSET_ID_MISSING: Reconcile against controlled physical inventory.

Primary references

- iScan System documentation: https://support.illumina.com/downloads/iscan-system-product-documentation.html

4. Illumina NextSeq 550

Profile key	illumina-nextseq-550
Role	analytical
Evidence status	NEEDS_INSTALLED_CONFIGURATION
Execution mode	EXTERNAL_VENDOR_RUNTIME
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- IRENA-UNASSIGNED-AXIOM-009 | Illumina NextSeq | model NextSeq 550 | serial SY-415-1002 | BSL3 | inactive

Native evidence to preserve

- BCL
- InterOp
- RunInfo.xml
- RunParameters.xml
- RTALogs

Open derivatives

- FASTQ
- QC metrics

Capture method

Preserve the complete run folder before demultiplexing or instrument cleanup.

Operator procedure

1. Record control software, RTA, conversion software, flow-cell, kit, and sample-sheet versions.
2. Copy the complete run folder into quarantine and hash all files.
3. Seal BCL, InterOp, XML metadata, logs, and the exact sample sheet.
4. Convert BCL with the validated, digest-pinned converter and explicit command parameters.
5. Reconcile sample indices, undetermined reads, and lane/read metrics.

Acceptance tests

- CHECK - Run folder validation and InterOp parsing pass.
- CHECK - The approved BCL fixture yields the expected FASTQ checksums.
- CHECK - Demultiplexing collision and index-hopping controls meet protocol limits.

Activation blockers

Instrument is inactive; inventory exact installed software and complete requalification before use.
IRENA-UNASSIGNED-AXIOM-009 / ASSET_ID_MISSING: Reconcile against controlled physical inventory.

Primary references

- NextSeq 550 documentation: https://support.illumina.com/sequencing/sequencing_instruments/nextseq-550/documentation.html

5. MGI DNBSEQ-T20x2RS

Profile key	mgi-tech-co-ltd-dnbseq-t20-2rs
Role	analytical
Evidence status	READY_FOR_LOCAL_VALIDATION
Execution mode	EXTERNAL_VENDOR_RUNTIME
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- SR-GSDTR-000001 | Genetic Sequencer(DNBSEQ-T20x2RS) | model DNBSEQ-T20x2RS | serial R31011100230004 | Sequencing Room | active

Native evidence to preserve

- CAL basecall binaries
- run configuration
- cycle metrics
- instrument logs

Open derivatives

- FASTQ
- QC metrics

Capture method

Copy the complete completed-run directory, including CAL, before ZTRON conversion or cleanup.

Operator procedure

1. Record flow-cell, reagent lot, operator, instrument serial, and exact control/basecaller versions.
2. Copy the complete run directory to quarantine without altering timestamps.
3. Hash and seal CAL files, run configuration, cycle metrics, and logs.
4. Run the validated ZTRON conversion package by digest to create FASTQ.
5. Reconcile sample indices, read counts, and cycle metrics before release.

Acceptance tests

- CHECK - CAL files exist for every expected lane and cycle.
- CHECK - Sample-sheet identity is consistent with LIM accession and tube events.
- CHECK - A fixed CAL fixture produces the approved FASTQ checksum set.

Activation blockers

Obtain the installed T20 software, basecaller, and ZTRON version inventory.

Primary references

- DNBSEQ-T20 product documentation: https://jp.mgi-tech.com/products/instruments_info/22/
- MGI ZTRON: https://test-ztron.mgi-tech.com/ztronEN/

6. Oxford Nanopore PromethION 48

Profile key	oxford-nanopore-technologies-promethion-48-p48
Role	analytical
Evidence status	READY_FOR_LOCAL_VALIDATION
Execution mode	EXTERNAL_VENDOR_RUNTIME
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- SR-P-000001 | PromethION 48 | model PromethION 48 (P48) | serial 25804 | Sequencing Room | active

Native evidence to preserve

- POD5 raw signal
- sequencing summary
- run configuration
- MinKNOW logs

Open derivatives

- BAM
- FASTQ
- alignment summaries

Capture method

Preserve POD5 and the complete MinKNOW run directory before basecalling or file retention policies remove signal data.

Operator procedure

1. Confirm MinKNOW is configured to retain POD5 for the assay protocol.
2. Record flow-cell ID, kit, barcode kit, model, MinKNOW version, and run identifiers.
3. Copy and hash POD5, run metadata, sequencing summary, and logs into quarantine.
4. Basecall from sealed POD5 using a digest-pinned Dorado image and model checksum.
5. Reconcile channel, read, barcode, and sample counts before release.

Acceptance tests

- CHECK - POD5 validation passes and all referenced run IDs are present.
- CHECK - Dorado model checksum and command line match the approved build.
- CHECK - Truth-set basecalling and variant metrics meet the assay-specific contract.

Activation blockers

Record the installed MinKNOW version, flow-cell types, and approved Dorado models.

Primary references

- MinKNOW output structure: https://software-docs.nanoporetech.com/output-specifications/latest/minknow/output_structure/
- POD5 specification: https://software-docs.nanoporetech.com/pod5/0.3.34/specification/

- Dorado basecalling overview: https://software-docs.nanoporetech.com/dorado/latest/basecaller/basecall_overview/

7. PacBio Revio

Profile key	pacbio-revio
Role	analytical
Evidence status	READY_FOR_LOCAL_VALIDATION
Execution mode	EXTERNAL_VENDOR_RUNTIME
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- SR-PR-000002 | PacBio Revio | model Revio | serial 84409 | Sequencing Room | active

Native evidence to preserve

- HiFi reads BAM
- PBI index
- run metadata
- primary analysis metrics
- instrument logs

Open derivatives

- FASTQ
- CRAM
- QC JSON

Capture method

Use the supported Revio/SMRT Link transfer target and preserve the complete primary output bundle before secondary analysis.

Operator procedure

1. Record SMRT Cell, reagent lot, sample accession, run design, and exact software versions.
2. Transfer every primary BAM, index, metadata, metric, and log file to quarantine.
3. Create and seal the native bundle manifest before any alignment or variant calling.
4. Generate open derivatives with a digest-pinned validated toolchain.
5. Reconcile movie/run identifiers and read statistics against the primary report.

Acceptance tests

- CHECK - BAM quick-check, read-group, and PBI integrity checks pass.
- CHECK - Run identifiers agree across BAM headers, metrics, and LIM accession.
- CHECK - Known truth-set material meets the approved HiFi precision and recall contract.

Activation blockers

Pin the installed Revio and SMRT Link versions and validate the local transfer target.

Primary references

- PacBio Revio: https://www.pacb.com/revio/

- SMRT Link downloads: https://www.pacb.com/support/software-downloads/

8. Quantum-Si Platinum

Profile key	quantumsi-platinum
Role	analytical
Evidence status	NEEDS_VENDOR_INTERFACE_PACKAGE
Execution mode	MANAGED_VENDOR_SERVICE
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- IRENA-UNASSIGNED-AXIOM-010 | Quantum Si | model Platinum | serial NI2247014BM | BSL3 | inactive

Native evidence to preserve

- raw fluorescence intensity and lifetime exports
- pulse calls
- recognition segments
- run metadata

Open derivatives

- peptide calls
- protein identification tables
- QC exports

Capture method

Use the vendor-supported cloud export and record service, algorithm, and model versions in the evidence manifest.

Operator procedure

1. Confirm consent and data-processing terms for the managed service.
2. Export all available raw and analysis files plus run metadata from the vendor account.
3. Hash the files immediately on receipt and preserve the original export package.
4. Record algorithm/model versions and every parameter exposed by the service.
5. Normalize only after reference-protein and negative-control validation.

Acceptance tests

- CHECK - Vendor export completeness is verified against the run inventory.
- CHECK - Raw-to-pulse and pulse-to-peptide fixture outputs meet the approved concordance contract.
- CHECK - Managed-service version changes trigger automatic revalidation.

Activation blockers

Instrument is inactive. Obtain the current vendor data export specification, API terms, and algorithm version contract. IRENA-UNASSIGNED-AXIOM-010 / ASSET_ID_MISSING: Reconcile against controlled physical inventory.

Primary references

- Quantum-Si Cloud informatics platform: https://www.quantum-si.com/wp-content/uploads/2023/04/Quantum-Si-Cloud-A-Scalable-Informatics-Platform-for-Protein-Sequence-Data-Analysis.pdf

- Quantum-Si data analysis: https://www.quantum-si.com/wp-content/uploads/Data-Analysis-Technical-Note_KDN3_Digital.pdf

9. Roche cobas i 601

Profile key	roche-cobas-i601
Role	analytical
Evidence status	NEEDS_VENDOR_INTERFACE_PACKAGE
Execution mode	EXTERNAL_VENDOR_RUNTIME
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- CP-CPMS-000001 | Cobas Pro Mass Spec | model cobas i601 | serial (21)2512-03 | Clinical Pathology | active

Native evidence to preserve

- native LC-MS acquisition or chromatogram evidence when Roche exposes a supported export
- original assay result records and flags
- calibration and QC records
- Ionify reagent, calibrator, internal-standard, method and lot identities
- instrument logs and audit events

Open derivatives

- original host result stream
- FHIR DiagnosticReport/Observation projection
- mzML only if a Roche-supported and locally validated conversion path exists

Capture method

Use the supported Roche host or middleware interface and seal every original result, flag, calibration and QC event. Capture native chromatographic or spectral evidence only through a documented Roche export; do not infer that an open raw-data path exists.

Operator procedure

1. Record the analyzer serial, installed system software, middleware, firmware, Ionify assay menu, method versions and host-interface profile.

2. Obtain Roche's current host-interface and any supported raw or chromatogram export specifications, including licensing and retention constraints.

3. Capture and hash original result messages, flags, calibration, QC, reagent-lot, internal-standard, maintenance and audit records before normalization.

4. If native LC-MS evidence is exportable, seal it unchanged and qualify any open conversion separately against the vendor record.

5. Normalize analyte identity, method, units, precision, flags and reference intervals without replacing the source result.

6. Run assay-specific analytical and interface validation before accepting patient evidence.

Acceptance tests

- CHECK - Golden host-message fixtures preserve analyte, value, units, precision, flags, method, lot and amendment semantics.
- CHECK - Calibrator, internal-standard and QC failures prevent patient-evidence release.
- CHECK - Any native-data conversion is byte-traceable to its source and meets the approved concordance contract.

- CHECK - The validated reportable assay menu, measuring ranges and reference-interval sources are explicit.

Activation blockers

Obtain the exact installed software, host-interface and supported native-data export package from Roche. Confirm the installed Ionify assay menu and complete assay-specific analytical validation.

Primary references

- Roche cobas i 601 analyzer: https://diagnostics.roche.com/global/en/products/instruments/cobas-i-601-ms-ins-6728.html

10. Roche cobas pure c 303 / e 402

Profile key	roche-cobas-e-402-cobas-c-303
Role	analytical
Evidence status	NEEDS_VENDOR_INTERFACE_PACKAGE
Execution mode	EXTERNAL_VENDOR_RUNTIME
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- CP-CP-000001 | Cobas Pure | model COBAS E 402 | COBAS c 303 | serial (21)U5K2-09 | (21)25E6-06 | Clinical Pathology | active

Native evidence to preserve

- result messages
- reaction flags
- calibration and QC events
- reagent lots
- maintenance and audit events

Open derivatives

- HL7 v2 ORU messages
- FHIR DiagnosticReport/Observation projection

Capture method

Receive vendor-supported host messages through a mutually authenticated interface and retain the original byte stream plus acknowledgements.

Operator procedure

1. Obtain Roche's interface specification for the exact installed software release and freeze the message profile.
2. Capture original inbound and outbound messages with timestamps, message-control IDs, acknowledgements, and connection identity.
3. Hash and seal each message envelope before terminology mapping.
4. Map local test codes, units, flags, methods, and reference intervals under version control.
5. Compare every normalized result to the source message and block duplicates, unit ambiguity, and missing specimen identity.

Acceptance tests

- CHECK - Golden HL7 fixtures round-trip without numeric, unit, flag, or precision loss.
- CHECK - Duplicate and amended-result scenarios produce the approved state transitions.
- CHECK - Calibration/QC lockouts prevent patient-evidence release.

Activation blockers

Obtain the exact host interface guide, installed versions, and supported fields from Roche. Raw detector signals are not assumed to be available through the host interface.

Primary references

- Roche cobas pure integrated solutions:
https://diagnostics.roche.com/global/en/products/systems/cobas-pure-integrated-solutions-sys-2528.html

11. SCIEX ZenoTOF 8600

Profile key	sciex-zenotof-8600
Role	analytical
Evidence status	NEEDS_INSTALLED_CONFIGURATION
Execution mode	EXTERNAL_VENDOR_RUNTIME
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- IRENA-UNASSIGNED-AXIOM-011 | SCIEX ZenoTOF 8600 | model ZenoTOF 8600 | serial MISSING | facility unrecorded | planned

Native evidence to preserve

- WIFF/WIFF2 acquisition files

- batch file

- method file

- calibration records

- audit trail

Open derivatives

- mzML 1.1

- QC tables

Capture method

Watch the validated acquisition export directory and preserve WIFF/WIFF2 plus acquisition methods and audit records before conversion.

Operator procedure

1. Record the serial, SCIEX OS version, acquisition method checksum, column, source, and calibration status.

2. Copy the complete acquisition bundle to quarantine after acquisition closes.

3. Hash and seal WIFF/WIFF2, batch, method, calibration, and audit files.

4. Convert with the validated SCIEX MS Data Converter package to mzML 1.1.

5. Run blank, pooled-QC, retention-time, mass-accuracy, carryover, and intensity-drift gates.

Acceptance tests

- CHECK - Vendor software reopens the sealed native file without error.

- CHECK - mzML spectra/counts reconcile with the native acquisition.

- CHECK - Reference-material mass accuracy, precision, and carryover meet the assay contract.

Activation blockers

Instrument is planned and has no serial number. Obtain the licensed SCIEX OS and converter versions plus supported headless automation terms. IRENA-UNASSIGNED-AXIOM-011 / SERIAL_MISSING: Reconcile against controlled physical inventory. IRENA-UNASSIGNED-AXIOM-011 / ASSET_ID_MISSING: Reconcile against controlled physical inventory.

Primary references

- SCIEX OS software: https://sciex.com/products/software/sciex-os-software
- SCIEX MS Data Converter 2.0 guide: https://download.sciex.com/sciex-ms-data-converter-2.0-user-guide.pdf

12. Sysmex CA-660

Profile key	sysmex-ca-660
Role	analytical
Evidence status	NEEDS_VENDOR_INTERFACE_PACKAGE
Execution mode	EXTERNAL_VENDOR_RUNTIME
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- IRENA-UNASSIGNED-AXIOM-014 | Sysmex -CA-660 | model CA-660 | serial MISSING | Clinical Pathology | inactive

Native evidence to preserve

- coagulation results
- reaction curves when supported
- flags
- QC
- calibration
- reagent lots

Open derivatives

- HL7 v2 result stream
- FHIR DiagnosticReport/Observation projection

Capture method

Capture the original supported host messages and reaction-curve exports, preserving the vendor record before normalization.

Operator procedure

1. Record analyzer serial, exact software, interface, method, reagent, calibration, and QC versions.
2. Obtain the supported host and reaction-curve export specification.
3. Capture and seal source messages, curves, flags, calibration, and QC evidence.
4. Normalize results using versioned local-code, LOINC, and UCUM mappings.
5. Block release on clot-detection, interference, QC, or identity exceptions.

Acceptance tests

- CHECK - Golden fixtures preserve result, precision, units, flags, and curve association.
- CHECK - Reference material, precision, carryover, and interference checks meet protocol limits.
- CHECK - Amended and cancelled results propagate correctly.

Activation blockers

Instrument is inactive and lacks a serial number in the current AXIOM list. Obtain the exact interface and curve-export specifications. IRENA-UNASSIGNED-AXIOM-014 / SERIAL_MISSING: Reconcile against controlled physical inventory. IRENA-UNASSIGNED-AXIOM-014 / ASSET_ID_MISSING: Reconcile against controlled physical inventory.

Primary references

- Sysmex CA-600 Series specification: https://www.sysmex.com/-/media/project/sysmex/sysmex/documents/brochures/ca-600-series-specification-sheet_en.pdf?sc_lang=en-us

13. Sysmex UN-Series - module composition unresolved

Profile key	sysmex-un5000
Role	analytical
Evidence status	BLOCKED
Execution mode	REPORT_ONLY_BLOCKED
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- IRENA-UNASSIGNED-AXIOM-012 | Sysmex -UN5000 | model UN5000 | serial MISSING | Clinical Pathology | inactive

Native evidence to preserve

- urine particle counts
- flags
- scattergrams/images when supported
- QC
- reagent lots
- audit events

Open derivatives

- HL7 v2 result stream
- FHIR DiagnosticReport/Observation projection

Capture method

No connector activation until the exact UF/UC/UD modules and serials are recorded; then use the supported UDM/host interface and seal original messages.

Operator procedure

1. Inventory every installed UN-Series module, sampler, middleware component, serial, and software version.
2. Obtain the matching host and image/scattergram export specifications.
3. Configure read-only capture of original messages and supported native measurement files.
4. Validate local code, unit, flag, image, and amendment handling.
5. Obtain laboratory director approval before patient-evidence use.

Acceptance tests

- CHECK - Physical module inventory matches connector configuration.
- CHECK - Golden fixtures preserve all reported values, units, flags, images, and amendments.
- CHECK - QC and carryover failures block release.

Activation blockers

UN-5000 is a system label; installed UF/UC/UD modules and serials are missing. Instrument is inactive.
IRENA-UNASSIGNED-AXIOM-012 / SERIAL_MISSING: Reconcile against controlled physical inventory.
IRENA-UNASSIGNED-AXIOM-012 / ASSET_ID_MISSING: Reconcile against controlled physical inventory.
IRENA-UNASSIGNED-AXIOM-012 / SYSTEM_CONFIGURATION_UNRESOLVED: UN-5000 is a system label. Record the installed UF/UD/UC modules and their serials.

Primary references

- Sysmex UN-Series: https://www.sysmex.com/en-us/lab-solutions/urinalysis/un-series

14. Sysmex XR-1000

Profile key	sysmex-xr1000
Role	analytical
Evidence status	NEEDS_INSTALLED_CONFIGURATION
Execution mode	EXTERNAL_VENDOR_RUNTIME
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- IRENA-UNASSIGNED-AXIOM-013 | Sysmex -XR1000 | model XR1000 | serial MISSING | Clinical Pathology | inactive

Native evidence to preserve

- cell counts
- flags
- scattergram/measurement channel outputs when exportable
- QC
- reagent lots
- audit events

Open derivatives

- HL7 v2 result stream
- FHIR DiagnosticReport/Observation projection

Capture method

Use the supported host/middleware connection and preserve original messages; separately capture scattergram/measurement exports if licensed and supported.

Operator procedure

1. Record exact analyzer, sampler, middleware, and software versions plus reagent and QC lots.
2. Obtain the Sysmex host interface and extended-data export specifications.
3. Capture and seal original messages and available measurement/scattergram files.
4. Normalize local codes and UCUM units while preserving flags and comments verbatim.
5. Apply identity, delta-check, QC, calibration, and amended-result gates.

Acceptance tests

- CHECK - Golden host-message fixtures preserve values, units, precision, flags, comments, and amendments.
- CHECK - CBC reference material and inter-instrument comparison meet the approved method contract.
- CHECK - No result releases while required QC is invalid.

Activation blockers

Instrument is inactive and lacks a serial number in the current AXIOM list. Obtain the exact host interface and extended-data export package. IRENA-UNASSIGNED-AXIOM-013 / SERIAL_MISSING: Reconcile against controlled physical inventory. IRENA-UNASSIGNED-AXIOM-013 / ASSET_ID_MISSING: Reconcile against controlled physical inventory.

Primary references

- Sysmex XR-1000: https://www.sysmex.com/en-us/lab-solutions/hematology/xr-series/xr-1000

Pre-analytical instruments

15. GeOptics Sequencing Equipment Co.,Ltd IMA20T

Profile key	geoptics-sequencing-equipment-co-ltd-ima20t
Role	pre_analytical
Evidence status	NEEDS_VENDOR_INTERFACE_PACKAGE
Execution mode	EXTERNAL_VENDOR_RUNTIME
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- SR-MFIS-000001 | MGI(Fluorescence Imaging System) | model IMA20T | serial IMA20T-2023-12 | Sequencing Room | active

Native evidence to preserve

- method/worklist
- barcode events
- executed steps
- volumes or positions
- errors
- audit log

Open derivatives

- sample lineage JSON
- process-event JSON

Capture method

Use a supported authenticated interface or signed export and retain the complete execution trace before deriving sample lineage.

Operator procedure

1. Record asset, control software, firmware, method checksum, operator, deck/layout, and consumable lots.
2. Capture worklist identity, barcode events, executed actions, errors, interventions, and timestamps.
3. Hash and seal method and execution records before interpretation.
4. Reconcile input sample identity to every output container or plate position.
5. Block downstream evidence when trace, identity, method, or process-control checks fail.

Acceptance tests

- CHECK - Positive, negative, duplicate, and mismatch fixtures produce the approved lineage states.
- CHECK - Manual interventions and errors remain visible and force the configured review.
- CHECK - Method or software changes invalidate the current validation decision.

Activation blockers

Obtain the vendor interface/export specification and exact installed software, firmware, and method versions.

Primary references

No primary interface source is recorded. Obtain a current vendor-controlled interface specification before activation.

16. Hamilton Microlab STAR

Profile key	hamilton-microlab-star
Role	pre_analytical
Evidence status	READY_FOR_LOCAL_VALIDATION
Execution mode	EXTERNAL_VENDOR_RUNTIME
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- LPR-HMS-000001 | Hamilton Microlab STAR | model Microlab Star | serial 385K | Library Preparation Room | active

Native evidence to preserve

- method file
- run trace
- executed commands
- liquid-level and volume events
- errors
- audit trail

Open derivatives

- REST/LIMS events
- run-event JSON
- plate/tube lineage

Capture method

Use the validated VENUS REST/LIMS interface and archive method plus detailed run logs after every execution.

Operator procedure

1. Record instrument, deck layout, method checksum, VENUS version, operator, consumable lots, and carrier identities.
2. Receive barcode and worklist identity from LIM through the authenticated integration.
3. Capture executed commands, liquid handling events, volumes, errors, and timestamps.
4. Hash and seal the method and complete run trace.
5. Publish tube-to-well lineage only after volume, barcode, and error gates pass.

Acceptance tests

- CHECK - Positive and negative identity fixtures produce the approved lineage graph.
- CHECK - Aspirate/dispense errors and manual interventions force review.
- CHECK - Method checksum mismatch blocks execution evidence release.

Activation blockers

Record the installed VENUS release and enable the licensed REST/LIMS interface.

Primary references

- Hamilton VENUS: https://www.hamiltoncompany.com/venus
- Hamilton Microlab STAR: https://www.hamiltoncompany.com/microlab-star?part-number=microlab+starlet+ivd

17. Hamilton STARlet EasyBlood

Profile key	hamilton-microlab-starlet-easyblood
Role	pre_analytical
Evidence status	READY_FOR_LOCAL_VALIDATION
Execution mode	EXTERNAL_VENDOR_RUNTIME
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- SRA-HBF-000001 | Hamilton Blood Fractionation | model Microlab STARlet EasyBlood | serial 364k | Sample Reciving Area | active

Native evidence to preserve

- method file
- tube barcode events
- fractionation run trace
- volumes
- errors
- audit trail

Open derivatives

- fraction lineage JSON
- LIM process events

Capture method

Use the authenticated VENUS/LIM interface and preserve the exact method and run trace for every fractionation.

Operator procedure

1. Record input tube, output container, method checksum, operator, consumable lots, and VENUS version.
2. Capture every barcode read, fraction destination, volume, liquid-level event, and intervention.
3. Hash and seal the method and complete execution trace.
4. Reconcile source tube to every derived aliquot in LIM.
5. Block downstream evidence when identity, volume, or intervention policy fails.

Acceptance tests

- CHECK - Tube-to-aliquot lineage is complete and one-to-one with physical labels.
- CHECK - Volume exceptions and manual overrides force review.
- CHECK - The approved method fixture reproduces the expected event sequence.

Activation blockers

Record the installed VENUS and EasyBlood method versions.

Primary references

- Hamilton VENUS: https://www.hamiltoncompany.com/venus

18. Hettich ROTANTA 460 Robotic

Profile key	hettich-rotanta-460-robotic
Role	pre_analytical
Evidence status	NEEDS_VENDOR_INTERFACE_PACKAGE
Execution mode	EXTERNAL_VENDOR_RUNTIME
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- SRA-ATC-000001 | Automated Tube Centrifuge | model ROTANTA 460 Robotic | serial 0000162-08 | Sample Reciving Area | active

Native evidence to preserve

- method/worklist
- barcode events
- executed steps
- volumes or positions
- errors
- audit log

Open derivatives

- sample lineage JSON
- process-event JSON

Capture method

Use a supported authenticated interface or signed export and retain the complete execution trace before deriving sample lineage.

Operator procedure

1. Record asset, control software, firmware, method checksum, operator, deck/layout, and consumable lots.
2. Capture worklist identity, barcode events, executed actions, errors, interventions, and timestamps.
3. Hash and seal method and execution records before interpretation.
4. Reconcile input sample identity to every output container or plate position.
5. Block downstream evidence when trace, identity, method, or process-control checks fail.

Acceptance tests

- CHECK - Positive, negative, duplicate, and mismatch fixtures produce the approved lineage states.
- CHECK - Manual interventions and errors remain visible and force the configured review.
- CHECK - Method or software changes invalidate the current validation decision.

Activation blockers

Obtain the vendor interface/export specification and exact installed software, firmware, and method versions.

Primary references

No primary interface source is recorded. Obtain a current vendor-controlled interface specification before activation.

19. MGI Tech Co., Ltd. IMA20T

Profile key	mgi-tech-co-ltd-ima20t
Role	pre_analytical
Evidence status	NEEDS_VENDOR_INTERFACE_PACKAGE
Execution mode	EXTERNAL_VENDOR_RUNTIME
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- SR-MITBI-000001 | MGI(IMA20T-Bio-Imager) | model IMA20T | serial IMA20T-2023-09 | Sequencing Room | active

Native evidence to preserve

- method/worklist
- barcode events
- executed steps
- volumes or positions
- errors
- audit log

Open derivatives

- sample lineage JSON
- process-event JSON

Capture method

Use a supported authenticated interface or signed export and retain the complete execution trace before deriving sample lineage.

Operator procedure

1. Record asset, control software, firmware, method checksum, operator, deck/layout, and consumable lots.
2. Capture worklist identity, barcode events, executed actions, errors, interventions, and timestamps.
3. Hash and seal method and execution records before interpretation.
4. Reconcile input sample identity to every output container or plate position.
5. Block downstream evidence when trace, identity, method, or process-control checks fail.

Acceptance tests

- CHECK - Positive, negative, duplicate, and mismatch fixtures produce the approved lineage states.
- CHECK - Manual interventions and errors remain visible and force the configured review.
- CHECK - Method or software changes invalidate the current validation decision.

Activation blockers

Obtain the vendor interface/export specification and exact installed software, firmware, and method versions.

Primary references

No primary interface source is recorded. Obtain a current vendor-controlled interface specification before activation.

20. MGI Tech MGIDL-T20ARS

Profile key	mgi-tech-mgidl-t20ars
Role	pre_analytical
Evidence status	NEEDS_VENDOR_INTERFACE_PACKAGE
Execution mode	EXTERNAL_VENDOR_RUNTIME
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- LAE_00000032 | MGIDL- T20ARS | model MGIDL-T20ARS | serial R32006100230011 | Sequencing Room | active
- SR-MT-000001 | MGIDL-T20 | model MGIDL-T20ARS | serial R32006100230010 | Sequencing Room | active

Native evidence to preserve

- method/worklist
- barcode events
- executed steps
- volumes or positions
- errors
- audit log

Open derivatives

- sample lineage JSON
- process-event JSON

Capture method

Use a supported authenticated interface or signed export and retain the complete execution trace before deriving sample lineage.

Operator procedure

1. Record asset, control software, firmware, method checksum, operator, deck/layout, and consumable lots.
2. Capture worklist identity, barcode events, executed actions, errors, interventions, and timestamps.
3. Hash and seal method and execution records before interpretation.
4. Reconcile input sample identity to every output container or plate position.
5. Block downstream evidence when trace, identity, method, or process-control checks fail.

Acceptance tests

- CHECK - Positive, negative, duplicate, and mismatch fixtures produce the approved lineage states.
- CHECK - Manual interventions and errors remain visible and force the configured review.
- CHECK - Method or software changes invalidate the current validation decision.

Activation blockers

Obtain the vendor interface/export specification and exact installed software, firmware, and method versions.

Primary references

No primary interface source is recorded. Obtain a current vendor-controlled interface specification before activation.

21. MGI Tech MGISP - Smart 8RS

Profile key	mgi-tech-mgisp-smart-8rs
Role	pre_analytical
Evidence status	NEEDS_VENDOR_INTERFACE_PACKAGE
Execution mode	EXTERNAL_VENDOR_RUNTIME
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- LPR-MS-000001 | MGISP- Smart 8 | model MGISP - Smart 8RS | serial R2301510230065 | Library Preparation Room | active

Native evidence to preserve

- method/worklist
- barcode events
- executed steps
- volumes or positions
- errors
- audit log

Open derivatives

- sample lineage JSON
- process-event JSON

Capture method

Use a supported authenticated interface or signed export and retain the complete execution trace before deriving sample lineage.

Operator procedure

1. Record asset, control software, firmware, method checksum, operator, deck/layout, and consumable lots.
2. Capture worklist identity, barcode events, executed actions, errors, interventions, and timestamps.
3. Hash and seal method and execution records before interpretation.
4. Reconcile input sample identity to every output container or plate position.
5. Block downstream evidence when trace, identity, method, or process-control checks fail.

Acceptance tests

- CHECK - Positive, negative, duplicate, and mismatch fixtures produce the approved lineage states.
- CHECK - Manual interventions and errors remain visible and force the configured review.
- CHECK - Method or software changes invalidate the current validation decision.

Activation blockers

Obtain the vendor interface/export specification and exact installed software, firmware, and method versions.

Primary references

No primary interface source is recorded. Obtain a current vendor-controlled interface specification before activation.

22. MGI Tech MGISP-960RS(Version 5)

Profile key	mgi-tech-mgisp-960rs-version-5
Role	pre_analytical
Evidence status	NEEDS_VENDOR_INTERFACE_PACKAGE
Execution mode	EXTERNAL_VENDOR_RUNTIME
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- DRE-M-000001 | MGISP-960 | model MGISP-960RS(Version 5) | serial R33003700230209 | DNA/RNA Extraction | active
- LPR-M-000001 | MGISP-960 | model MGISP -960RS(Version 5) | serial R33003700230205 | Library Preparation Room | active
- LPR-M-000002 | MGISP-960 | model MGISP-960RS (Version 5) | serial R33003700230206 | Library Preparation Room | active
- LPR-M-000003 | MGISP-960 | model MGISP-960RS(Version 5) | serial R402710022228 | Library Preparation Room | active

Native evidence to preserve

- method/worklist
- barcode events
- executed steps
- volumes or positions
- errors
- audit log

Open derivatives

- sample lineage JSON
- process-event JSON

Capture method

Use a supported authenticated interface or signed export and retain the complete execution trace before deriving sample lineage.

Operator procedure

1. Record asset, control software, firmware, method checksum, operator, deck/layout, and consumable lots.
2. Capture worklist identity, barcode events, executed actions, errors, interventions, and timestamps.
3. Hash and seal method and execution records before interpretation.
4. Reconcile input sample identity to every output container or plate position.
5. Block downstream evidence when trace, identity, method, or process-control checks fail.

Acceptance tests

- CHECK - Positive, negative, duplicate, and mismatch fixtures produce the approved lineage states.
- CHECK - Manual interventions and errors remain visible and force the configured review.
- CHECK - Method or software changes invalidate the current validation decision.

Activation blockers

Obtain the vendor interface/export specification and exact installed software, firmware, and method versions.

Primary references

No primary interface source is recorded. Obtain a current vendor-controlled interface specification before activation.

23. MGI Tech MGISP-NE384RS

Profile key	mgi-tech-mgisp-ne384rs
Role	pre_analytical
Evidence status	NEEDS_VENDOR_INTERFACE_PACKAGE
Execution mode	EXTERNAL_VENDOR_RUNTIME
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- DRE-MN-000001 | MGISP-NE384 | model MGISP-NE384RS | serial R2300910230005 | DNA/RNA Extraction | active

Native evidence to preserve

- method/worklist
- barcode events
- executed steps
- volumes or positions
- errors
- audit log

Open derivatives

- sample lineage JSON
- process-event JSON

Capture method

Use a supported authenticated interface or signed export and retain the complete execution trace before deriving sample lineage.

Operator procedure

1. Record asset, control software, firmware, method checksum, operator, deck/layout, and consumable lots.
2. Capture worklist identity, barcode events, executed actions, errors, interventions, and timestamps.
3. Hash and seal method and execution records before interpretation.
4. Reconcile input sample identity to every output container or plate position.
5. Block downstream evidence when trace, identity, method, or process-control checks fail.

Acceptance tests

- CHECK - Positive, negative, duplicate, and mismatch fixtures produce the approved lineage states.
- CHECK - Manual interventions and errors remain visible and force the configured review.
- CHECK - Method or software changes invalidate the current validation decision.

Activation blockers

Obtain the vendor interface/export specification and exact installed software, firmware, and method versions.

Primary references

No primary interface source is recorded. Obtain a current vendor-controlled interface specification before activation.

24. MGI Tech MGISTP-7000RS

Profile key	mgi-tech-mgistp-7000rs
Role	pre_analytical
Evidence status	NEEDS_VENDOR_INTERFACE_PACKAGE
Execution mode	EXTERNAL_VENDOR_RUNTIME
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- DRE-M-000002 | MGISTP-7000 | model MGISTP-7000RS | serial R2300710230007 | DNA/RNA Extraction | active

Native evidence to preserve

- method/worklist
- barcode events
- executed steps
- volumes or positions
- errors
- audit log

Open derivatives

- sample lineage JSON
- process-event JSON

Capture method

Use a supported authenticated interface or signed export and retain the complete execution trace before deriving sample lineage.

Operator procedure

1. Record asset, control software, firmware, method checksum, operator, deck/layout, and consumable lots.
2. Capture worklist identity, barcode events, executed actions, errors, interventions, and timestamps.
3. Hash and seal method and execution records before interpretation.
4. Reconcile input sample identity to every output container or plate position.
5. Block downstream evidence when trace, identity, method, or process-control checks fail.

Acceptance tests

- CHECK - Positive, negative, duplicate, and mismatch fixtures produce the approved lineage states.
- CHECK - Manual interventions and errors remain visible and force the configured review.
- CHECK - Method or software changes invalidate the current validation decision.

Activation blockers

Obtain the vendor interface/export specification and exact installed software, firmware, and method versions.

Primary references

No primary interface source is recorded. Obtain a current vendor-controlled interface specification before activation.

25. Telesis Bio BioXp 9600

Profile key	telesis-bio-bioxp-9600
Role	pre_analytical
Evidence status	NEEDS_VENDOR_INTERFACE_PACKAGE
Execution mode	EXTERNAL_VENDOR_RUNTIME
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- LPR-B-000001 | BioXp 9600 | model BioXp 9600 | serial BioXP001000217 | Library Preparation Room | active

Native evidence to preserve

- design/work-order package
- deck and reagent identity
- run logs
- output plate map
- errors

Open derivatives

- run manifest
- construct-to-well lineage

Capture method

Export the complete supported run package and preserve design inputs, consumables, execution logs, and output plate identity.

Operator procedure

1. Record instrument serial, software version, project/design checksum, reagents, deck, and operator.
2. Capture the complete supported run export after execution.
3. Hash and seal design inputs, run logs, output map, and errors.
4. Reconcile every construct and output well with LIM lineage.
5. Release process evidence only after controls and identity checks pass.

Acceptance tests

- CHECK - Design checksum and output plate map match the approved work order.
- CHECK - Control constructs and process checkpoints meet protocol limits.
- CHECK - Manual interventions and partial runs are represented without suppression.

Activation blockers

Obtain the installed software version and supported machine-readable export/interface specification.

Primary references

- BioXp 9600 user guide: https://files.telesisbio.com/docs/43056_BioXp_9600_system%E2%80%94User_guide.pdf

26. Thermo Scientific NanoDrop Eight

Profile key	thermo-fisher-scientific-nanodrop-eight
Role	pre_analytical
Evidence status	READY_FOR_LOCAL_VALIDATION
Execution mode	EXTERNAL_VENDOR_RUNTIME
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- LPR-NE-000001 | NanoDrop Eight | model NanoDrop Eight | serial NDE2601650 | Library Preparation Room | active

Native evidence to preserve

- N8DB database with spectra and measurements

- method

- instrument audit/log data

Open derivatives

- CSV/TSV measurements

- spectrum exports

Capture method

Preserve the N8DB database and export full spectra plus unrounded measurements for each plate/sample map.

Operator procedure

1. Record instrument serial, software version, method, blank, pathlength, and plate/sample map.

2. Copy the N8DB file after the run is closed and hash it in quarantine.

3. Export measurements and all available spectrum data without spreadsheet reformatting.

4. Reconcile well/sample identifiers with the LIM plate map.

5. Apply concentration and purity QC gates without overwriting original values.

Acceptance tests

- CHECK - N8DB opens in the recorded software version and contains every expected well.

- CHECK - Open exports reproduce the native displayed values at full available precision.

- CHECK - Reference material and blank checks meet the approved method limits.

Activation blockers

Record the installed software version and validate N8DB backup/restore.

Primary references

- NanoDrop Eight user guide:
https://documents.thermofisher.com/TFS-Assets/MSD/Product-Guides/M020-nanodrop-eight-spectrophotometer-user-guide.pdf

Automation assets

27. Epson C8-A1401S

Profile key	epson-c8-a1401s
Role	automation
Evidence status	NEEDS_VENDOR_INTERFACE_PACKAGE
Execution mode	EXTERNAL_VENDOR_RUNTIME
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- SR-CE-000001 | Cobot(Epson) | model C8-A1401S | serial P301030863 | Sequencing Room | active

Native evidence to preserve

- method/worklist
- barcode events
- executed steps
- volumes or positions
- errors
- audit log

Open derivatives

- sample lineage JSON
- process-event JSON

Capture method

Use a supported authenticated interface or signed export and retain the complete execution trace before deriving sample lineage.

Operator procedure

1. Record asset, control software, firmware, method checksum, operator, deck/layout, and consumable lots.
2. Capture worklist identity, barcode events, executed actions, errors, interventions, and timestamps.
3. Hash and seal method and execution records before interpretation.
4. Reconcile input sample identity to every output container or plate position.
5. Block downstream evidence when trace, identity, method, or process-control checks fail.

Acceptance tests

- CHECK - Positive, negative, duplicate, and mismatch fixtures produce the approved lineage states.
- CHECK - Manual interventions and errors remain visible and force the configured review.
- CHECK - Method or software changes invalidate the current validation decision.

Activation blockers

Obtain the vendor interface/export specification and exact installed software, firmware, and method versions.

Primary references

No primary interface source is recorded. Obtain a current vendor-controlled interface specification before activation.

28. Fairino Fairino FR10

Profile key	fairino-fairino-fr10
Role	automation
Evidence status	NEEDS_VENDOR_INTERFACE_PACKAGE
Execution mode	EXTERNAL_VENDOR_RUNTIME
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- SRA-CK-000001 | Cobot 10Kg | model Fairino FR10 | serial SN.126023-0025568-01 | Sample Reciving Area | active

Native evidence to preserve

- method/worklist
- barcode events
- executed steps
- volumes or positions
- errors
- audit log

Open derivatives

- sample lineage JSON
- process-event JSON

Capture method

Use a supported authenticated interface or signed export and retain the complete execution trace before deriving sample lineage.

Operator procedure

1. Record asset, control software, firmware, method checksum, operator, deck/layout, and consumable lots.
2. Capture worklist identity, barcode events, executed actions, errors, interventions, and timestamps.
3. Hash and seal method and execution records before interpretation.
4. Reconcile input sample identity to every output container or plate position.
5. Block downstream evidence when trace, identity, method, or process-control checks fail.

Acceptance tests

- CHECK - Positive, negative, duplicate, and mismatch fixtures produce the approved lineage states.
- CHECK - Manual interventions and errors remain visible and force the configured review.
- CHECK - Method or software changes invalidate the current validation decision.

Activation blockers

Obtain the vendor interface/export specification and exact installed software, firmware, and method versions.

Primary references

No primary interface source is recorded. Obtain a current vendor-controlled interface specification before activation.

29. Fairino Fairino FR5

Profile key	fairino-fairino-fr5
Role	automation
Evidence status	NEEDS_VENDOR_INTERFACE_PACKAGE
Execution mode	EXTERNAL_VENDOR_RUNTIME
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- SRA-CK-000002 | Cobot 5Kg | model Fairino FR5 | serial SN.124022-0010941-09 | Sample Reciving Area | active

Native evidence to preserve

- method/worklist
- barcode events
- executed steps
- volumes or positions
- errors
- audit log

Open derivatives

- sample lineage JSON
- process-event JSON

Capture method

Use a supported authenticated interface or signed export and retain the complete execution trace before deriving sample lineage.

Operator procedure

1. Record asset, control software, firmware, method checksum, operator, deck/layout, and consumable lots.
2. Capture worklist identity, barcode events, executed actions, errors, interventions, and timestamps.
3. Hash and seal method and execution records before interpretation.
4. Reconcile input sample identity to every output container or plate position.
5. Block downstream evidence when trace, identity, method, or process-control checks fail.

Acceptance tests

- CHECK - Positive, negative, duplicate, and mismatch fixtures produce the approved lineage states.
- CHECK - Manual interventions and errors remain visible and force the configured review.
- CHECK - Method or software changes invalidate the current validation decision.

Activation blockers

Obtain the vendor interface/export specification and exact installed software, firmware, and method versions.

Primary references

No primary interface source is recorded. Obtain a current vendor-controlled interface specification before activation.

Environmental evidence assets

30. Alphavita Bioscientific MDF-339

Profile key	alphavita-bioscientific-mdf-339
Role	environmental
Evidence status	NEEDS_VENDOR_INTERFACE_PACKAGE
Execution mode	EXTERNAL_VENDOR_RUNTIME
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- BSCR-AF-000001 | Alphavita Freezer -20 | model MDF-339 | serial BPFMUD001AAN2401YYTQ | BSL-3 Stem Cell Room | active

Native evidence to preserve

- timestamped sensor readings
- alarms
- set-point changes
- calibration records

Open derivatives

- signed environmental event JSON
- CSV time series

Capture method

Use a supported read-only API or export. Preserve source timezone, sensor identity, calibration, alarms, and missing-data intervals.

Operator procedure

1. Record controller, probe, serial, location, software/firmware, timezone, and calibration identity.
2. Export readings, alarms, set-point changes, and missing-data intervals at the highest supported resolution.
3. Hash and seal each source export before time normalization.
4. Convert timestamps to UTC while preserving source timestamps and offsets.
5. Associate excursions with affected sample and reagent custody windows only through explicit time/location joins.

Acceptance tests

- CHECK - Clock drift, timezone, calibration, and missing-data checks pass.
- CHECK - Alarm events and source readings reconcile for a controlled excursion fixture.
- CHECK - Environmental data cannot silently change an analytical value; it creates a release gate or qualifier.

Activation blockers

Obtain the exact controller/logger interface and installed firmware/software inventory.

Primary references

No primary interface source is recorded. Obtain a current vendor-controlled interface specification before activation.

31. Govee H5075

Profile key	govee-h5075
Role	environmental
Evidence status	NEEDS_VENDOR_INTERFACE_PACKAGE
Execution mode	EXTERNAL_VENDOR_RUNTIME
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- DRE-STH-000001 | Smart Thermo-Hygrometer | model H5075 | serial ZSZ04G243000376 | DNA/RNA Extraction | active
- LPR-STH-000001 | Smart Thermo-Hygrometer | model H5075 | serial ZSZ04G162001154 | Library Preparation Room | active
- RS-STH-000001 | Smart Thermo-Hygrometer | model H5075 | serial ZS42F473000958 | Reagent Storage | active
- RS-STH-000002 | Smart Thermo-Hygrometer | model H5075 | serial ZSZ04G2440003692 | Reagent Storage | active
- RS-STH-000003 | Smart Thermo-Hygrometer | model H5075 | serial ZSZ04G243000376 | Reagent Storage | active

Native evidence to preserve

- timestamped sensor readings
- alarms
- set-point changes
- calibration records

Open derivatives

- signed environmental event JSON
- CSV time series

Capture method

Use a supported read-only API or export. Preserve source timezone, sensor identity, calibration, alarms, and missing-data intervals.

Operator procedure

1. Record controller, probe, serial, location, software/firmware, timezone, and calibration identity.
2. Export readings, alarms, set-point changes, and missing-data intervals at the highest supported resolution.
3. Hash and seal each source export before time normalization.
4. Convert timestamps to UTC while preserving source timestamps and offsets.
5. Associate excursions with affected sample and reagent custody windows only through explicit time/location joins.

Acceptance tests

- CHECK - Clock drift, timezone, calibration, and missing-data checks pass.
- CHECK - Alarm events and source readings reconcile for a controlled excursion fixture.
- CHECK - Environmental data cannot silently change an analytical value; it creates a release gate or qualifier.

Activation blockers

Obtain the exact controller/logger interface and installed firmware/software inventory. DRE-STH-000001 / SERIAL_DUPLICATED: Reconcile against controlled physical inventory. RS-STH-000003 / SERIAL_DUPLICATED: Reconcile against controlled physical inventory.

Primary references

No primary interface source is recorded. Obtain a current vendor-controlled interface specification before activation.

32. Haier DW-25L262

Profile key	haier-dw-25l262
Role	environmental
Evidence status	NEEDS_VENDOR_INTERFACE_PACKAGE
Execution mode	EXTERNAL_VENDOR_RUNTIME
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- BSCR-HF-000001 | Haier Freezer -20 | model DW-25L262 | serial BE02Q-5E000-0QENA-Q0012 | BSL-3 Stem Cell Room | active

Native evidence to preserve

- timestamped sensor readings
- alarms
- set-point changes
- calibration records

Open derivatives

- signed environmental event JSON
- CSV time series

Capture method

Use a supported read-only API or export. Preserve source timezone, sensor identity, calibration, alarms, and missing-data intervals.

Operator procedure

1. Record controller, probe, serial, location, software/firmware, timezone, and calibration identity.
2. Export readings, alarms, set-point changes, and missing-data intervals at the highest supported resolution.
3. Hash and seal each source export before time normalization.
4. Convert timestamps to UTC while preserving source timestamps and offsets.
5. Associate excursions with affected sample and reagent custody windows only through explicit time/location joins.

Acceptance tests

- CHECK - Clock drift, timezone, calibration, and missing-data checks pass.
- CHECK - Alarm events and source readings reconcile for a controlled excursion fixture.
- CHECK - Environmental data cannot silently change an analytical value; it creates a release gate or qualifier.

Activation blockers

Obtain the exact controller/logger interface and installed firmware/software inventory.

Primary references

No primary interface source is recorded. Obtain a current vendor-controlled interface specification before activation.

33. Haier HYC-610

Profile key	haier-hyc-610
Role	environmental
Evidence status	NEEDS_VENDOR_INTERFACE_PACKAGE
Execution mode	EXTERNAL_VENDOR_RUNTIME
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- DRE-HR-000001 | Haier Refrigerator 2-8 | model HYC-610 | serial BE07C 2EAQ0 0QJM2 K0009 | DNA/RNA Extraction | active

- RS-HR-000002 | Haier Refrigerator 2-8 | model HYC-610 | serial BE06P 6E0U0 0QJL3 P0008 | Reagent Storage | active

- RS-HR-000003 | Haier Refrigerator 2-8 | model HYC-610 | serial BE06P 1EQUO 0QJL6 B0005 | Reagent Storage | active

Native evidence to preserve

- timestamped sensor readings

- alarms

- set-point changes

- calibration records

Open derivatives

- signed environmental event JSON

- CSV time series

Capture method

Use a supported read-only API or export. Preserve source timezone, sensor identity, calibration, alarms, and missing-data intervals.

Operator procedure

1. Record controller, probe, serial, location, software/firmware, timezone, and calibration identity.

2. Export readings, alarms, set-point changes, and missing-data intervals at the highest supported resolution.

3. Hash and seal each source export before time normalization.

4. Convert timestamps to UTC while preserving source timestamps and offsets.

5. Associate excursions with affected sample and reagent custody windows only through explicit time/location joins.

Acceptance tests

- CHECK - Clock drift, timezone, calibration, and missing-data checks pass.

- CHECK - Alarm events and source readings reconcile for a controlled excursion fixture.

- CHECK - Environmental data cannot silently change an analytical value; it creates a release gate or qualifier.

Activation blockers

Obtain the exact controller/logger interface and installed firmware/software inventory.

Primary references

No primary interface source is recorded. Obtain a current vendor-controlled interface specification before activation.

34. Manufacturer unrecorded MPR-722-PC

Profile key	unknown-mpr-722-pc
Role	environmental
Evidence status	NEEDS_VENDOR_INTERFACE_PACKAGE
Execution mode	EXTERNAL_VENDOR_RUNTIME
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- SR-PR-000001 | PHCBI Refrigerator 2-8 | model MPR-722-PC | serial 21080860 | Sequencing Room | active

Native evidence to preserve

- timestamped sensor readings
- alarms
- set-point changes
- calibration records

Open derivatives

- signed environmental event JSON
- CSV time series

Capture method

Use a supported read-only API or export. Preserve source timezone, sensor identity, calibration, alarms, and missing-data intervals.

Operator procedure

1. Record controller, probe, serial, location, software/firmware, timezone, and calibration identity.
2. Export readings, alarms, set-point changes, and missing-data intervals at the highest supported resolution.
3. Hash and seal each source export before time normalization.
4. Convert timestamps to UTC while preserving source timestamps and offsets.
5. Associate excursions with affected sample and reagent custody windows only through explicit time/location joins.

Acceptance tests

- CHECK - Clock drift, timezone, calibration, and missing-data checks pass.
- CHECK - Alarm events and source readings reconcile for a controlled excursion fixture.
- CHECK - Environmental data cannot silently change an analytical value; it creates a release gate or qualifier.

Activation blockers

Obtain the exact controller/logger interface and installed firmware/software inventory. SR-PR-000001 / MANUFACTURER_MISSING: Reconcile against controlled physical inventory.

Primary references

No primary interface source is recorded. Obtain a current vendor-controlled interface specification before activation.

35. MGIMA Co., Ltd MGICLab-LN55K

Profile key	mgima-co-ltd-mgiclab-ln55k
Role	environmental
Evidence status	NEEDS_VENDOR_INTERFACE_PACKAGE
Execution mode	EXTERNAL_VENDOR_RUNTIME
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- CS-B-000001 | BioBank | model MGICLab-LN55K | serial R3800610260005 | Cold Storage | out_of_service

Native evidence to preserve

- timestamped sensor readings
- alarms
- set-point changes
- calibration records

Open derivatives

- signed environmental event JSON
- CSV time series

Capture method

Use a supported read-only API or export. Preserve source timezone, sensor identity, calibration, alarms, and missing-data intervals.

Operator procedure

1. Record controller, probe, serial, location, software/firmware, timezone, and calibration identity.
2. Export readings, alarms, set-point changes, and missing-data intervals at the highest supported resolution.
3. Hash and seal each source export before time normalization.
4. Convert timestamps to UTC while preserving source timestamps and offsets.
5. Associate excursions with affected sample and reagent custody windows only through explicit time/location joins.

Acceptance tests

- CHECK - Clock drift, timezone, calibration, and missing-data checks pass.
- CHECK - Alarm events and source readings reconcile for a controlled excursion fixture.
- CHECK - Environmental data cannot silently change an analytical value; it creates a release gate or qualifier.

Activation blockers

Obtain the exact controller/logger interface and installed firmware/software inventory.

Primary references

No primary interface source is recorded. Obtain a current vendor-controlled interface specification before activation.

36. Milli-Q CLX-7040

Profile key	milli-q-clx-7040
Role	environmental
Evidence status	NEEDS_VENDOR_INTERFACE_PACKAGE
Execution mode	EXTERNAL_VENDOR_RUNTIME
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- CP-MQWPS-000001 | Milli-Q Water Purification System | model CLX-7040 | serial F5MB16481A | Clinical Pathology | active

- CP-MQWPS-000002 | Milli-Q Water Purification System | model CLX-7040 | serial F5MB16481B | Clinical Pathology | active

Native evidence to preserve

- timestamped sensor readings

- alarms

- set-point changes

- calibration records

Open derivatives

- signed environmental event JSON

- CSV time series

Capture method

Use a supported read-only API or export. Preserve source timezone, sensor identity, calibration, alarms, and missing-data intervals.

Operator procedure

1. Record controller, probe, serial, location, software/firmware, timezone, and calibration identity.

2. Export readings, alarms, set-point changes, and missing-data intervals at the highest supported resolution.

3. Hash and seal each source export before time normalization.

4. Convert timestamps to UTC while preserving source timestamps and offsets.

5. Associate excursions with affected sample and reagent custody windows only through explicit time/location joins.

Acceptance tests

- CHECK - Clock drift, timezone, calibration, and missing-data checks pass.

- CHECK - Alarm events and source readings reconcile for a controlled excursion fixture.

- CHECK - Environmental data cannot silently change an analytical value; it creates a release gate or qualifier.

Activation blockers

Obtain the exact controller/logger interface and installed firmware/software inventory.

Primary references

No primary interface source is recorded. Obtain a current vendor-controlled interface specification before activation.

37. Qingdao Haier Biomedical Co., Ltd HYC-610

Profile key	qingdao-haier-biomedical-co-ltd-hyc-610
Role	environmental
Evidence status	NEEDS_VENDOR_INTERFACE_PACKAGE
Execution mode	EXTERNAL_VENDOR_RUNTIME
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- LPR-HR-000002 | Haier Refrigerator 2-8 | model HYC-610 | serial BEDSP SEUD0 OCJL1 F0012 | Library Preparation Room | active

- RS-HR-000001 | Haier Refrigerator 2-8 | model HYC-610 | serial BE06P 6E0U0 0QJL1 F0012 | Reagent Storage | active

- SR-HR-000001 | Haier Refrigerator 2-8 | model HYC-610 | serial BE06P 1EQU0 00JK9 30014 | Sequencing Room | out_of_service

Native evidence to preserve

- timestamped sensor readings

- alarms

- set-point changes

- calibration records

Open derivatives

- signed environmental event JSON

- CSV time series

Capture method

Use a supported read-only API or export. Preserve source timezone, sensor identity, calibration, alarms, and missing-data intervals.

Operator procedure

1. Record controller, probe, serial, location, software/firmware, timezone, and calibration identity.

2. Export readings, alarms, set-point changes, and missing-data intervals at the highest supported resolution.

3. Hash and seal each source export before time normalization.

4. Convert timestamps to UTC while preserving source timestamps and offsets.

5. Associate excursions with affected sample and reagent custody windows only through explicit time/location joins.

Acceptance tests

- CHECK - Clock drift, timezone, calibration, and missing-data checks pass.

- CHECK - Alarm events and source readings reconcile for a controlled excursion fixture.

- CHECK - Environmental data cannot silently change an analytical value; it creates a release gate or qualifier.

Activation blockers

Obtain the exact controller/logger interface and installed firmware/software inventory.

Primary references

No primary interface source is recorded. Obtain a current vendor-controlled interface specification before activation.

Support and maintenance-only assets

38. Agibot A2 Ultra

Profile key	agibot-a2-ultra
Role	support
Evidence status	NO_PATIENT_ANALYTICAL_OUTPUT
Execution mode	REPORT_ONLY_BLOCKED
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- DRE-H-000001 | Heile | model A2 Ultra | serial A210041B800314 | DNA/RNA Extraction | in_calibration

- LPR-H-000001 | Heilo | model A2 Ultra | serial A210041BB00798 | Library Preparation Room | in_calibration

Native evidence to preserve

- maintenance record

- calibration/service record when applicable

Open derivatives

- asset availability event

Capture method

This asset does not generate patient analytical evidence. Record maintenance and availability only.

Operator procedure

1. Confirm the asset identity and current service/calibration state.

2. Attach approved maintenance or service records to the asset, not to a patient result.

3. Record only availability events required by an assay execution record.

4. Do not infer patient measurements from this asset.

Acceptance tests

- CHECK - Asset identity and service state are current.

- CHECK - No maintenance-only record is published as patient analytical evidence.

Primary references

No primary interface source is recorded. Obtain a current vendor-controlled interface specification before activation.

39. Benchmark Benchmixer

Profile key	benchmark-benchmixer
Role	support
Evidence status	NO_PATIENT_ANALYTICAL_OUTPUT
Execution mode	REPORT_ONLY_BLOCKED
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- LPR-LVM-000001 | Laboratory vortex mixers | model Benchmixer | serial 23010095 | Library Preparation Room | active

Native evidence to preserve

- maintenance record

- calibration/service record when applicable

Open derivatives

- asset availability event

Capture method

This asset does not generate patient analytical evidence. Record maintenance and availability only.

Operator procedure

1. Confirm the asset identity and current service/calibration state.

2. Attach approved maintenance or service records to the asset, not to a patient result.

3. Record only availability events required by an assay execution record.

4. Do not infer patient measurements from this asset.

Acceptance tests

- CHECK - Asset identity and service state are current.

- CHECK - No maintenance-only record is published as patient analytical evidence.

Activation blockers

LPR-LVM-000001 / SERIAL_DUPLICATED: Reconcile against controlled physical inventory.

Primary references

No primary interface source is recorded. Obtain a current vendor-controlled interface specification before activation.

40. Benchmark MC-24 Touch

Profile key	benchmark-mc-24-touch
Role	support
Evidence status	NO_PATIENT_ANALYTICAL_OUTPUT
Execution mode	REPORT_ONLY_BLOCKED
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- LPR-MT-000001 | MC-24 Touch | model MC-24 Touch | serial 23010095 | Library Preparation Room | active

Native evidence to preserve

- maintenance record

- calibration/service record when applicable

Open derivatives

- asset availability event

Capture method

This asset does not generate patient analytical evidence. Record maintenance and availability only.

Operator procedure

1. Confirm the asset identity and current service/calibration state.

2. Attach approved maintenance or service records to the asset, not to a patient result.

3. Record only availability events required by an assay execution record.

4. Do not infer patient measurements from this asset.

Acceptance tests

- CHECK - Asset identity and service state are current.

- CHECK - No maintenance-only record is published as patient analytical evidence.

Activation blockers

LPR-MT-000001 / SERIAL_DUPLICATED: Reconcile against controlled physical inventory.

Primary references

No primary interface source is recorded. Obtain a current vendor-controlled interface specification before activation.

41. Cangzhou Labotery Instrument Co., Ltd. GFL-70

Profile key	cangzhou-labotery-instrument-co-ltd-gfl-70
Role	support
Evidence status	NO_PATIENT_ANALYTICAL_OUTPUT
Execution mode	REPORT_ONLY_BLOCKED
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- SR-LG-000001 | Labotery GFL-70 | model GFL-70 | serial G200310L 10-1503(6) | Sequencing Room | active

Native evidence to preserve

- maintenance record
- calibration/service record when applicable

Open derivatives

- asset availability event

Capture method

This asset does not generate patient analytical evidence. Record maintenance and availability only.

Operator procedure

1. Confirm the asset identity and current service/calibration state.
2. Attach approved maintenance or service records to the asset, not to a patient result.
3. Record only availability events required by an assay execution record.
4. Do not infer patient measurements from this asset.

Acceptance tests

- CHECK - Asset identity and service state are current.
- CHECK - No maintenance-only record is published as patient analytical evidence.

Primary references

No primary interface source is recorded. Obtain a current vendor-controlled interface specification before activation.

42. DLAB DLAB HB120-S LED

Profile key	dlab-dlab-hb120-s-led
Role	support
Evidence status	NO_PATIENT_ANALYTICAL_OUTPUT
Execution mode	REPORT_ONLY_BLOCKED
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- LPR-D-000001 | DLAB | model DLAB HB120-S LED | serial BA233AQ0001353 | Library Preparation Room | active

Native evidence to preserve

- maintenance record

- calibration/service record when applicable

Open derivatives

- asset availability event

Capture method

This asset does not generate patient analytical evidence. Record maintenance and availability only.

Operator procedure

1. Confirm the asset identity and current service/calibration state.

2. Attach approved maintenance or service records to the asset, not to a patient result.

3. Record only availability events required by an assay execution record.

4. Do not infer patient measurements from this asset.

Acceptance tests

- CHECK - Asset identity and service state are current.

- CHECK - No maintenance-only record is published as patient analytical evidence.

Primary references

No primary interface source is recorded. Obtain a current vendor-controlled interface specification before activation.

43. HP Laser Jet Pro 4003dn

Profile key	hp-laser-jet-pro-4003dn
Role	support
Evidence status	NO_PATIENT_ANALYTICAL_OUTPUT
Execution mode	REPORT_ONLY_BLOCKED
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- CP-LJP-000001 | Laser Jet Printer | model Laser Jet Pro 4003dn | serial VNM0942833 | Clinical Pathology | active

Native evidence to preserve

- maintenance record

- calibration/service record when applicable

Open derivatives

- asset availability event

Capture method

This asset does not generate patient analytical evidence. Record maintenance and availability only.

Operator procedure

1. Confirm the asset identity and current service/calibration state.

2. Attach approved maintenance or service records to the asset, not to a patient result.

3. Record only availability events required by an assay execution record.

4. Do not infer patient measurements from this asset.

Acceptance tests

- CHECK - Asset identity and service state are current.

- CHECK - No maintenance-only record is published as patient analytical evidence.

Primary references

No primary interface source is recorded. Obtain a current vendor-controlled interface specification before activation.

44. PEAK GENIUS XE70

Profile key	peak-genius-xe70
Role	support
Evidence status	NO_PATIENT_ANALYTICAL_OUTPUT
Execution mode	REPORT_ONLY_BLOCKED
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- CP-NG-000001 | Nitrogen Generator | model GENIUS XE70 | serial 726020168 | Clinical Pathology | active

Native evidence to preserve

- maintenance record
- calibration/service record when applicable

Open derivatives

- asset availability event

Capture method

This asset does not generate patient analytical evidence. Record maintenance and availability only.

Operator procedure

1. Confirm the asset identity and current service/calibration state.
2. Attach approved maintenance or service records to the asset, not to a patient result.
3. Record only availability events required by an assay execution record.
4. Do not infer patient measurements from this asset.

Acceptance tests

- CHECK - Asset identity and service state are current.
- CHECK - No maintenance-only record is published as patient analytical evidence.

Primary references

No primary interface source is recorded. Obtain a current vendor-controlled interface specification before activation.

45. Siemens Home Appliances (BSH Group) SN216I00AM (iQ100 Series)

Profile key	siemens-home-appliances-bsh-group-sn216i00am-iq100-series
Role	support
Evidence status	NO_PATIENT_ANALYTICAL_OUTPUT
Execution mode	REPORT_ONLY_BLOCKED
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- SR-SSIAD-000001 | Siemens SN216I00AM(Dishwasher) | model SN216I00AM (iQ100 Series) | serial 27665652 | Sequencing Room | active

Native evidence to preserve

- maintenance record

- calibration/service record when applicable

Open derivatives

- asset availability event

Capture method

This asset does not generate patient analytical evidence. Record maintenance and availability only.

Operator procedure

1. Confirm the asset identity and current service/calibration state.

2. Attach approved maintenance or service records to the asset, not to a patient result.

3. Record only availability events required by an assay execution record.

4. Do not infer patient measurements from this asset.

Acceptance tests

- CHECK - Asset identity and service state are current.

- CHECK - No maintenance-only record is published as patient analytical evidence.

Primary references

No primary interface source is recorded. Obtain a current vendor-controlled interface specification before activation.

46. SINDIN Dongguan shengding precision instrument co.,LTD SPV100

Profile key	sindin-dongguan-shengding-precision-instrument-co-ltd-spv100
Role	support
Evidence status	NO_PATIENT_ANALYTICAL_OUTPUT
Execution mode	REPORT_ONLY_BLOCKED
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- SR-DVPC-000001 | Dynetech Vacuum plasma cleaner | model SPV100 | serial DYTV210608 | Sequencing Room | active

Native evidence to preserve

- maintenance record
- calibration/service record when applicable

Open derivatives

- asset availability event

Capture method

This asset does not generate patient analytical evidence. Record maintenance and availability only.

Operator procedure

1. Confirm the asset identity and current service/calibration state.
2. Attach approved maintenance or service records to the asset, not to a patient result.
3. Record only availability events required by an assay execution record.
4. Do not infer patient measurements from this asset.

Acceptance tests

- CHECK - Asset identity and service state are current.
- CHECK - No maintenance-only record is published as patient analytical evidence.

Primary references

No primary interface source is recorded. Obtain a current vendor-controlled interface specification before activation.

47. Thermo Fisher Scientific Finnpipette F1 GLP Kit 2

Profile key	thermo-fisher-scientific-finnpipette-f1-glp-kit-2
Role	support
Evidence status	NO_PATIENT_ANALYTICAL_OUTPUT
Execution mode	REPORT_ONLY_BLOCKED
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- LPR-FFU-000001 | Finnpipette F1 20-200ul | model Finnpipette F1 GLP Kit 2 | serial UH43354 | Library Preparation Room | active

Native evidence to preserve

- maintenance record

- calibration/service record when applicable

Open derivatives

- asset availability event

Capture method

This asset does not generate patient analytical evidence. Record maintenance and availability only.

Operator procedure

1. Confirm the asset identity and current service/calibration state.

2. Attach approved maintenance or service records to the asset, not to a patient result.

3. Record only availability events required by an assay execution record.

4. Do not infer patient measurements from this asset.

Acceptance tests

- CHECK - Asset identity and service state are current.

- CHECK - No maintenance-only record is published as patient analytical evidence.

Primary references

No primary interface source is recorded. Obtain a current vendor-controlled interface specification before activation.

48. Thermo Fisher Scientific Finnpipette F1 GLP Kit 2 4700860N

Profile key	thermo-fisher-scientific-finnpipette-f1-glp-kit-2-4700860n
Role	support
Evidence status	NO_PATIENT_ANALYTICAL_OUTPUT
Execution mode	REPORT_ONLY_BLOCKED
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- CP-FFU-000002 | Finnpipette F1 100-1000ul | model Finnpipette F1 GLP Kit 2 4700860N | serial UH43504 | Clinical Pathology | active

- CP-FFU-000003 | Finnpipette F1 100-1000ul | model Finnpipette F1 GLP Kit 2 4700860N | serial UH43502 | Clinical Pathology | active

- CP-FFU-000004 | Finnpipette F1 100-1000ul | model Finnpipette F1 GLP Kit 2 4700860N | serial UH43505 | Clinical Pathology | active

- CP-FFU-000005 | Finnpipette F1 100-1000ul | model Finnpipette F1 GLP Kit 2 4700860N | serial UH43506 | Clinical Pathology | active

- CP-FFU-000006 | Finnpipette F1 20-200ul | model Finnpipette F1 GLP Kit 2 4700860N | serial UH43358 | Clinical Pathology | active

- CP-FFU-000007 | Finnpipette F1 2-20ul | model Finnpipette F1 GLP Kit 2 4700860N | serial UH43311 | Clinical Pathology | active

- CP-FFUM-000001 | Finnpipette F1 0.2-2ul micro | model Finnpipette F1 GLP Kit 2 4700860N | serial UH43236 | Clinical Pathology | active

- CP-FFUM-000002 | Finnpipette F1 0.2-2ul micro | model Finnpipette F1 GLP Kit 2 4700860N | serial UH43238 | Clinical Pathology | active

- CP-FFUM-000004 | Finnpipette F1 0.2-2ul micro | model Finnpipette F1 GLP Kit 2 4700860N | serial UH43239 | Clinical Pathology | active

- DRE-FFU-000001 | Finnpipette F1 20-200ul | model Finnpipette F1 GLP Kit 2 4700860N | serial UH43357 | DNA/RNA Extraction | active

- DRE-FFU-000002 | Finnpipette F1 2-20ul | model Finnpipette F1 GLP Kit 2 4700860N | serial UH43308 | DNA/RNA Extraction | active

- LPR-FFU-000002 | Finnpipette F1 2-20ul | model Finnpipette F1 GLP Kit 2 4700860N | serial UH43312 | Library Preparation Room | active

- SR-FFU-000001 | Finnpipette F1 20-200ul | model Finnpipette F1 GLP Kit 2 4700860N | serial UH43356 | Sequencing Room | active

- SR-FFU-000002 | Finnpipette F1 2-20ul | model Finnpipette F1 GLP Kit 2 4700860N | serial UH43310 | Sequencing Room | active

Native evidence to preserve

- maintenance record

- calibration/service record when applicable

Open derivatives

- asset availability event

Capture method

This asset does not generate patient analytical evidence. Record maintenance and availability only.

Operator procedure

1. Confirm the asset identity and current service/calibration state.
2. Attach approved maintenance or service records to the asset, not to a patient result.
3. Record only availability events required by an assay execution record.
4. Do not infer patient measurements from this asset.

Acceptance tests

- CHECK - Asset identity and service state are current.
- CHECK - No maintenance-only record is published as patient analytical evidence.

Primary references

No primary interface source is recorded. Obtain a current vendor-controlled interface specification before activation.

49. Thermo Fisher Scientific Thermo Scientific Finnpipette F1 GLP Kit 2 (Catalog Number: 4700860N)

Profile key	thermo-fisher-scientific-thermo-scientific-finnpipette-f1-glp-kit-2-catalog-number-4700860n
Role	support
Evidence status	NO_PATIENT_ANALYTICAL_OUTPUT
Execution mode	REPORT_ONLY_BLOCKED
Patient graph eligible	NO - LOCAL VALIDATION REQUIRED

Installed assets

- CP-FFU-000001 | Finnpipette F1 0.2-2ul micro | model Thermo Scientific Finnpipette F1 GLP Kit 2 (Catalog Number: 4700860N) | serial UH43240 | Clinical Pathology | active

Native evidence to preserve

- maintenance record

- calibration/service record when applicable

Open derivatives

- asset availability event

Capture method

This asset does not generate patient analytical evidence. Record maintenance and availability only.

Operator procedure

1. Confirm the asset identity and current service/calibration state.

2. Attach approved maintenance or service records to the asset, not to a patient result.

3. Record only availability events required by an assay execution record.

4. Do not infer patient measurements from this asset.

Acceptance tests

- CHECK - Asset identity and service state are current.

- CHECK - No maintenance-only record is published as patient analytical evidence.

Primary references

No primary interface source is recorded. Obtain a current vendor-controlled interface specification before activation.

Registry reconciliation queue

Severity	Asset / code	Required disposition
BLOCKER	IRENA-UNASSIGNED-AXIOM-008 / ASSET_ID_MISSING	Reconcile with physical asset, inventory owner, and controlled evidence.
BLOCKER	IRENA-UNASSIGNED-AXIOM-009 / ASSET_ID_MISSING	Reconcile with physical asset, inventory owner, and controlled evidence.
BLOCKER	IRENA-UNASSIGNED-AXIOM-010 / ASSET_ID_MISSING	Reconcile with physical asset, inventory owner, and controlled evidence.
BLOCKER	IRENA-UNASSIGNED-AXIOM-011 / ASSET_ID_MISSING	Reconcile with physical asset, inventory owner, and controlled evidence.
BLOCKER	IRENA-UNASSIGNED-AXIOM-011 / SERIAL_MISSING	Reconcile with physical asset, inventory owner, and controlled evidence.
BLOCKER	IRENA-UNASSIGNED-AXIOM-012 / ASSET_ID_MISSING	Reconcile with physical asset, inventory owner, and controlled evidence.
BLOCKER	IRENA-UNASSIGNED-AXIOM-012 / SERIAL_MISSING	Reconcile with physical asset, inventory owner, and controlled evidence.
BLOCKER	IRENA-UNASSIGNED-AXIOM-012 / SYSTEM_CONFIGURATION_UNRESOLVED	UN-5000 is a system label. Record the installed UF/UD/UC modules and their serials.
BLOCKER	IRENA-UNASSIGNED-AXIOM-013 / ASSET_ID_MISSING	Reconcile with physical asset, inventory owner, and controlled evidence.
BLOCKER	IRENA-UNASSIGNED-AXIOM-013 / SERIAL_MISSING	Reconcile with physical asset, inventory owner, and controlled evidence.
BLOCKER	IRENA-UNASSIGNED-AXIOM-014 / ASSET_ID_MISSING	Reconcile with physical asset, inventory owner, and controlled evidence.
BLOCKER	IRENA-UNASSIGNED-AXIOM-014 / SERIAL_MISSING	Reconcile with physical asset, inventory owner, and controlled evidence.
REVIEW	DRE-STH-000001 / SERIAL_DUPLICATED	Reconcile with physical asset, inventory owner, and controlled evidence.
REVIEW	LPR-LVM-000001 / SERIAL_DUPLICATED	Reconcile with physical asset, inventory owner, and controlled evidence.
REVIEW	LPR-MT-000001 / SERIAL_DUPLICATED	Reconcile with physical asset, inventory owner, and controlled evidence.
REVIEW	RS-STH-000003 / SERIAL_DUPLICATED	Reconcile with physical asset, inventory owner, and controlled evidence.
REVIEW	SR-PR-000001 / MANUFACTURER_MISSING	Reconcile with physical asset, inventory owner, and controlled evidence.