1. Purpose

Define how the laboratory configures instruments in STACS Casework, schedules and documents maintenance, uploads performance-check records, barcodes equipment, and places offline/online instruments.

Refer to DNA SOP-09 "Equipment and Performance Checks" for the details on each instrument. Schedules will be tracked in STACS. Other minor tasks may have other ways to document, but will be retained (e.g., hood cleaning check list).

2. Scope

This SOP applies to all instruments and equipment used in the DNA Unit that can influence the validity of results (e.g., Genetic Analyzers, qPCR instruments, thermal cyclers, extraction robots, etc.) and selected non-critical equipment tracked per DNA SOP-9.

3. Definitions

Maintenance task: A defined activity configured in STACS for a specific instrument (e.g., cleaning/decontamination, annual service).

Instrument Management

Performance check: Laboratory-defined activity to demonstrate an instrument is functioning within acceptable limits prior to/after use, repair, service, or at prescribed intervals.

In progress: STACS maintenance task status used to prevent use of an instrument during a prolonged maintenance activity.

Files: Electronic attachments (e.g., vendor certificates, diagnostic reports, control runs) uploaded to the maintenance record in STACS.

Critical equipment: Equipment whose functionality directly affects the validity of DNA typing results (see DNA SOP-9 §9.3.1).

Cushion window: Scheduling grace period permitted by DNA SOP-9 (§9.3): Annual ±30 days; Semi-annual within 6 months ±1 month; Quarterly ±2 weeks; Monthly ±7 days; Weekly ±3 days. See 5.6 below.

4. Roles & Permissions

Instrument Coordinator: Maintains instrument records, schedules events, generates reports, files vendor service documents. Designated by TL to authorize instruments back online once Performance Checks are successful and completed.

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5. General

5.1   Users have access to STACS CW Production environment and Maintenance module.

5.2   Each instrument has a unique barcode label physically affixed and registered in STACS.

5.3   Maintenance tasks and frequencies are configured by the STACS Administrator for each instrument model.

5.4   Acceptance criteria for performance checks are defined in laboratory technical procedures and align with QAS/validation.

5.6   The cushions (in case of delays with service) in place for various timeframe +/- are:

Annual +/- 30 days

Semi-annual +/- no less than 4 months no longer than 8 months in between

Quarterly +/- 2 weeks

Monthly +/- 7 days

Weekly +/- 3 days

5.7   Instruments will remain available until the due date + the cushion elapses. At that time the instrument status will change to Out of Service until performance check is passed.

6. Setting up an Instrument in STACS (One time per unit)

6.1   Navigation: Utilities → Instrument Configuration → Instrument Management → New

6.2   Populate: Instrument Type → Manufacturer → Instrument Model → Instrument Bar Code → Current Status; complete Instrument Properties grid.

6.3   Print labels: Instrument Management → Select → Label Type → Print Bar Code; affix barcode and ensure human-readable instrument name.

7. Building a Schedule

7.1   Navigation: Utilities → Maintenance → Maintenance Schedules → New.

7.2   For each required check set the following:

a. Description;

b. Maintenance Type;

c. Lead Time = cushion; See above list

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d. Define Performance Fields (mark any as Required);

7.3   Edit the Next Run Date for each instrument to the due date + applicable cushion. That is the hard stop; Lead Time is for reminders only.

8. Attaching Maintenance Records

8.1   Navigation: Utilities → Maintenance → Instrument/Storage Maintenance.

8.2   Select the unit (scan barcode or pick from list) → Run Schedule → complete Required Performance Fields → set Result:

In Process (long-running), Pass, Fail, or Aborted

Attach files (vendor PM, diagnostics, verification results)

Save to roll for the next due date

8.3   If Result = Fail: set the Status = Out of Service in Instrument Management; tag the machine out physically with a note, perform corrective maintenance; Complete a performance check before return to service.

8.4   If maintenance spans time: use 'In Process' to flag it; the instrument is unavailable for selection in workflows while flagged.

8.5   Return to service: record 'Pass'; it will clear 'In Process'; and then update Status back to 'Available' in Instrument Management.

9. Calendar & Reporting

9.1   Reports → Instrument Reports → Upcoming Instrument Maintenance: you are able to filter by date/type, and export and archive.

9.2   Reports → Instrument Reports → Instrument Maintenance: will give you an audit trail of completed events with attachments.

9.3   Utilities → Maintenance → Maintenance Calendar: Day/Week/Month views; use to Edit the 'Run Date' and to reschedule around holidays; select 'refresh' to sync.

10. Tag-Out Instruments

10.1   On/after due date for maintenance with no Pass recorded: can manually change Status to 'Out of Service' in Instrument Management; and post the physical sign/note if applicable.

10.2   After acceptable performance checks; select 'Pass' and attached the results: then restore the Status to Available.

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11. Instrument Barcoding & Scanning in Workflows

11.1   Ensure barcodes on instruments are tightly adhered. Print these barcodes via the Instrument Management or from Utilities → Print Bar Code.

11.2   Instruments should be able to be scanned now in workflow.

12. Records

12.1   STACS records will constitute the official record of maintenance, service, repair, and performance checks, however as there is a transition in progress, files may be kept on paper or in QMS.

12.2   Attachments should include the instrument name and year.

12.3   Documents that contain the approval of the Performance Check, where required, are documented and uploaded to STACS. Acceptable results are listed on the QR for the specific instrument.

13. Deviations/Failures

13.1   If a maintenance or performance check fails, follow the instrument-specific troubleshooting guidance and contact the Instrument Coordinator.

13.2   Document the failure, corrective actions, and re-checks in STACS.

12.3   If the instrument is nonconforming, halt use and discuss with Lead or TL.

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Appendix A

Example Maintenance Record Tasks Performed

1.   Instrument barcode scanned, and correct instrument displayed.

2.   Maintenance task selected; result recorded.

3.   All required linked reagents/instruments scanned (if prompted).

4.   Performance check acceptance criteria reviewed; result acceptable.

5.   Files uploaded.

6.   Next due date populated and verified.

7.   If prolonged, status set to "In progress"; cleared when complete.

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