PROVA V1

Temperature verification slides

Digital guide



Proof for every patient.

Verification
Interpretation
Documentation

A clearer view of verification.

Understand the check. Keep the evidence.

03	Why physical verification matters
04–05	The thermal path. The two thresholds.
06–08	Your instrument. Your required interval.
09–11	Prepare, load and run
12–14	Interpret results and respond
15–17	Document the check. Know the kit.
18–20	Answers, references and quick instructions

For trained laboratory personnel and the sales teams who support them.



THE SOFTWARE STARTS IT. THE SLIDE SHOWS IT.

Temperature is part of the process.

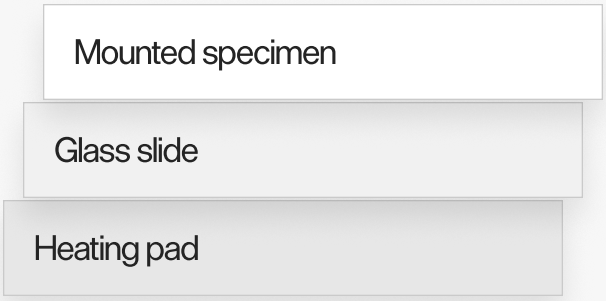
Physical verification provides a visible result at the tested slide position—evidence the laboratory can connect to the instrument and its record.

Illustrative instrument render. Roche ULTRA PLUS guide 1017687EN v1.0, pp. 339–340.

A surrogate for the slide's thermal path.

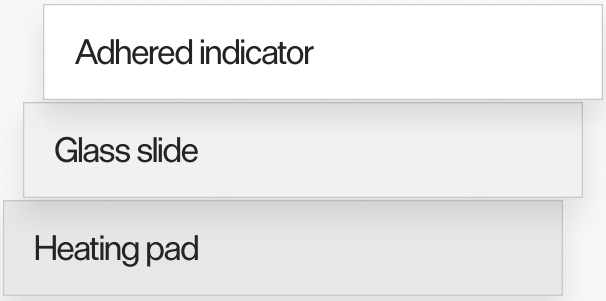
Heat travels through the glass.

Patient slide



↑ Direction of heat transfer

PROVA V1



↑ Direction of heat transfer

THE PHYSICAL ROLE

The verification slide occupies the test position. Its adhered indicator responds where a mounted specimen would otherwise be carried.

WHAT THE ANALOGY DOES NOT CLAIM

A threshold indicator does not reproduce tissue chemistry, provide a continuous temperature trace, or validate every step of a patient staining assay.

Educational physical-path analogy. Equivalence claims require supporting product validation.

One slide.
Two thresholds.

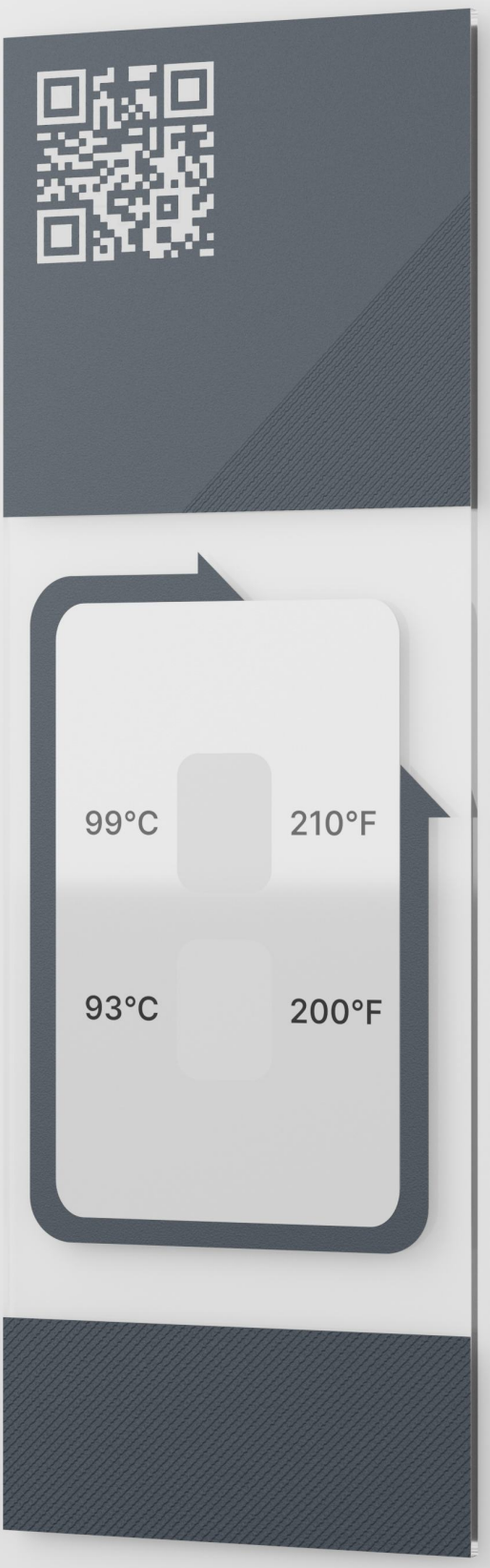
99°C

210°F · Upper indicator

93°C

200°F · Lower indicator

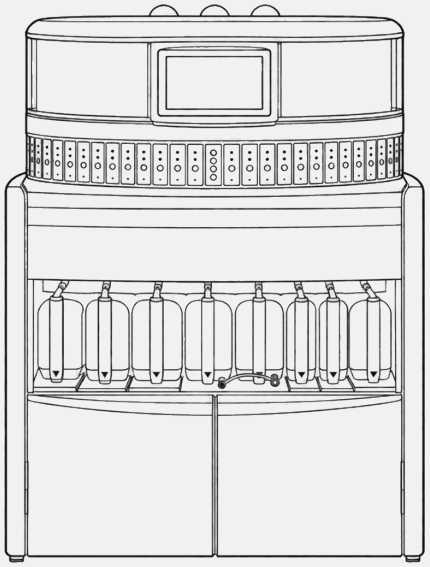
Read both together.
The passing pattern is lower changed, upper unchanged after a valid completed check.



U.S. Patent No. 10,431,126 B2

Know your instrument.

Every 90 days. All slide-pad positions.

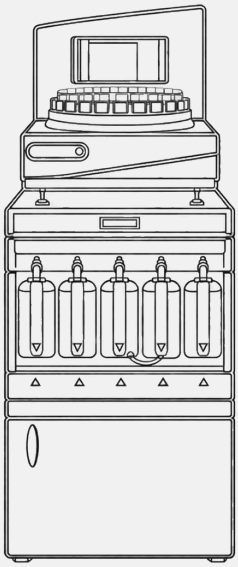


BenchMark ULTRA / ULTRA PLUS

EVERY 90 DAYS · 30 SLIDES

Use one verification slide in every drawer; run the prescribed test.

ULTRA PLUS · 1017687EN v1.0
Software 14.0 · pp. 339–340
ULTRA · 1020058EN v1
Software 12.5.4 · pp. 350–352



BenchMark Special Stains

EVERY 90 DAYS · 20 SLIDES

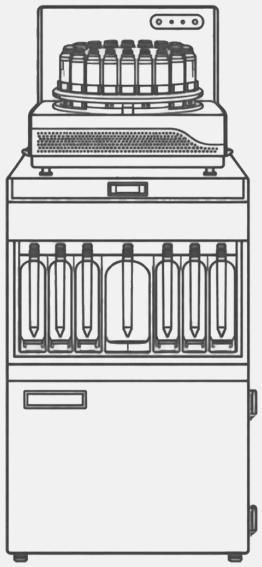
Use one verification slide in every slide position; run the prescribed test.

Special Stains · 1020205EN v1
Software 12.5.5 · pp. 165–166

Roche user guides specify the 90-day interval and the physical-slide procedure.
Match the cited model and software to the guide used by your laboratory.

Follow its procedure.

Every 90 days. All slide-pad positions.

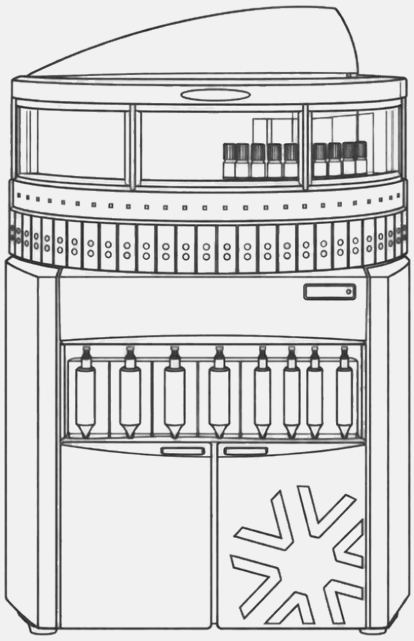


BenchMark GX

EVERY 90 DAYS · 20 SLIDES

Use one verification slide in every slide position; run the prescribed test.

BenchMark GX · 1021468EN v1
Software 12.5.5 · pp. 334–336



DISCOVERY ULTRA

EVERY 90 DAYS · 30 SLIDES

Use one verification slide in every drawer; run the prescribed test.

DISCOVERY ULTRA · D135664 v1
Software 12.5 · pp. 314–315
Research Use Only

Both Roche user guides specify the 90-day interval and physical verification slides. DISCOVERY ULTRA is a research-use instrument; follow its applicable use and maintenance instructions.

Every heating pad.

90 days

Between annual service visits.

Baseline · Day 90 · Day 180 · Day 270 · Day 360

MANUFACTURER → CMS / CLIA → CAP

Manufacturer instructions define the method and interval.
For clinical laboratories, CMS §493.1254(a) and CAP COM.30600 address documented checks at least as frequently as specified.

SCHEDULE FROM THE RECORD

The Roche guides cited on pages 6–7 specify every 90 days. Annual service does not cover checks due between visits; calendar quarters can exceed 90 days.

Sources: model-specific Roche guides, pp. 6–7 of this booklet; 42 CFR §493.1254(a); CAP COM.30600.

Start with a readable baseline.

INSPECT

Check each slide, its lot and applicable expiry. Use only slides with both indicators unchanged.

MAP

Record the instrument, operator and date. Prepare a position map and enough eligible slides for all required positions.

PROTECT

Keep slides in their original packaging until use. Follow product instructions for handling and storage.



UNUSED EXAMPLE
Both indicators unchanged.

Prova V1 IFU; applicable Roche instrument instructions.



02 / LOAD

Every required position. One traceable result.

Load according to the instrument procedure. Maintain the connection between every slide and its tested drawer or heating-pad position.

ULTRA PLUS: 30 slides, one per drawer. Post-run results are illustrated; load unused slides.

Roche 1017687EN v1.0, pp. 339–340.

Run the prescribed verification cycle.

01

Select

Choose the specified temperature-verification test for the instrument and installed software.

02

Execute

Run the cycle with the physical verification slides loaded.

03

Cool

Allow the cycle and cooling to complete before handling or reading the slides.

04

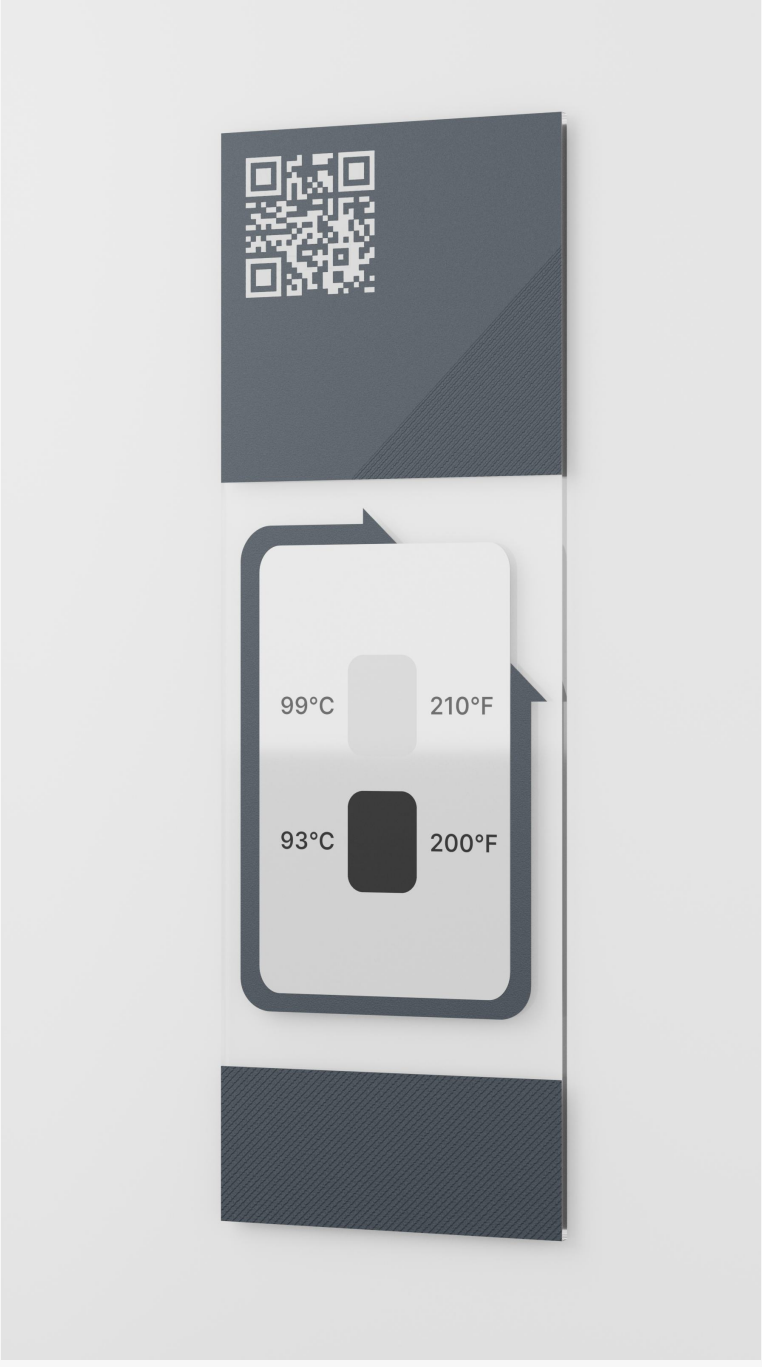
Assess

Read the physical results and complete the required maintenance record.

95°C	10 minutes, followed by cooling ULTRA PLUS software 14.0 example

Follow current model and software instructions. Roche 1017687EN v1.0, pp. 339–340.

Read the pattern. Keep the position.



Illustrative example. Follow the applicable product and instrument IFUs.

✓

Passing pattern

93°C / 200°F

Lower indicator changed to black.

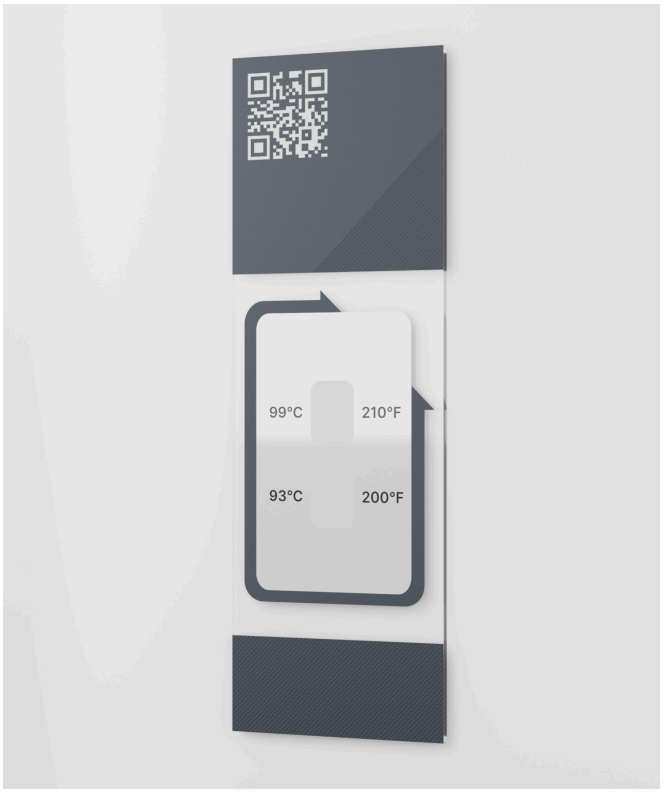
99°C / 210°F

Upper indicator remains unchanged.

Read after a valid completed run. Retain the result with its position identity.

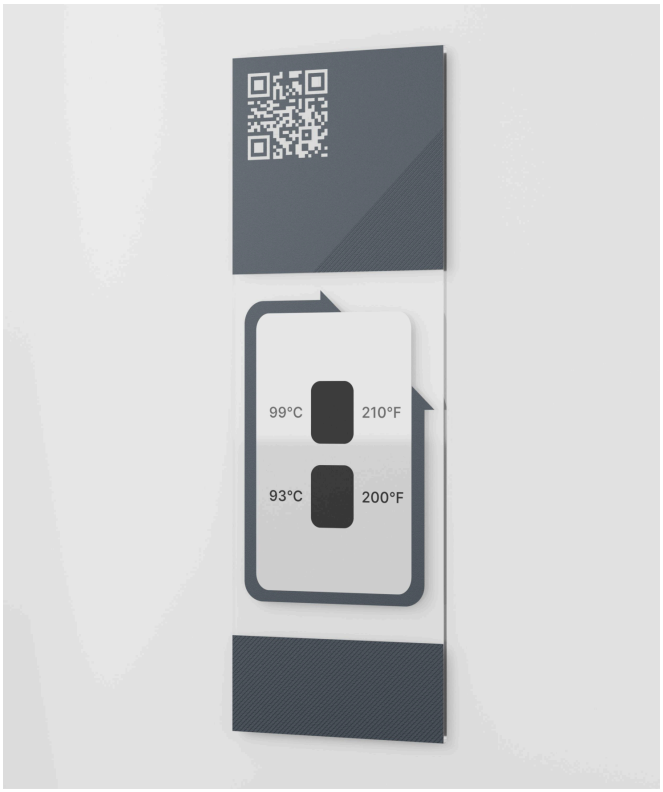
A pattern to investigate.

Observe first. Diagnose with evidence.



✕ Neither changed

After a valid run, lower-threshold activation was not demonstrated.



✕ Both changed

Upper-threshold activation is indicated. Follow the instrument failure procedure.

Damaged, ambiguous or pre-activated indicators cannot establish a reliable new result. Renders illustrate recognition; they do not identify a root cause.

Record. Escalate. Resolve.

01 Record

Preserve the pattern, instrument identity, position and cycle information.

02 Escalate

Notify the laboratory lead. Follow the instrument instructions, including Roche support when required.

03 Control testing

Function checks must meet applicable limits before patient testing. Apply the laboratory's procedure to affected instruments or positions.

04 Close the loop

Document corrective action, repeat verification when required and authorized return to use. Assess whether prior results need review.

42 CFR §493.1254(a)(2); Roche 1017687EN v1.0, p. 340. Do not repeat a failed check solely to obtain a pass.

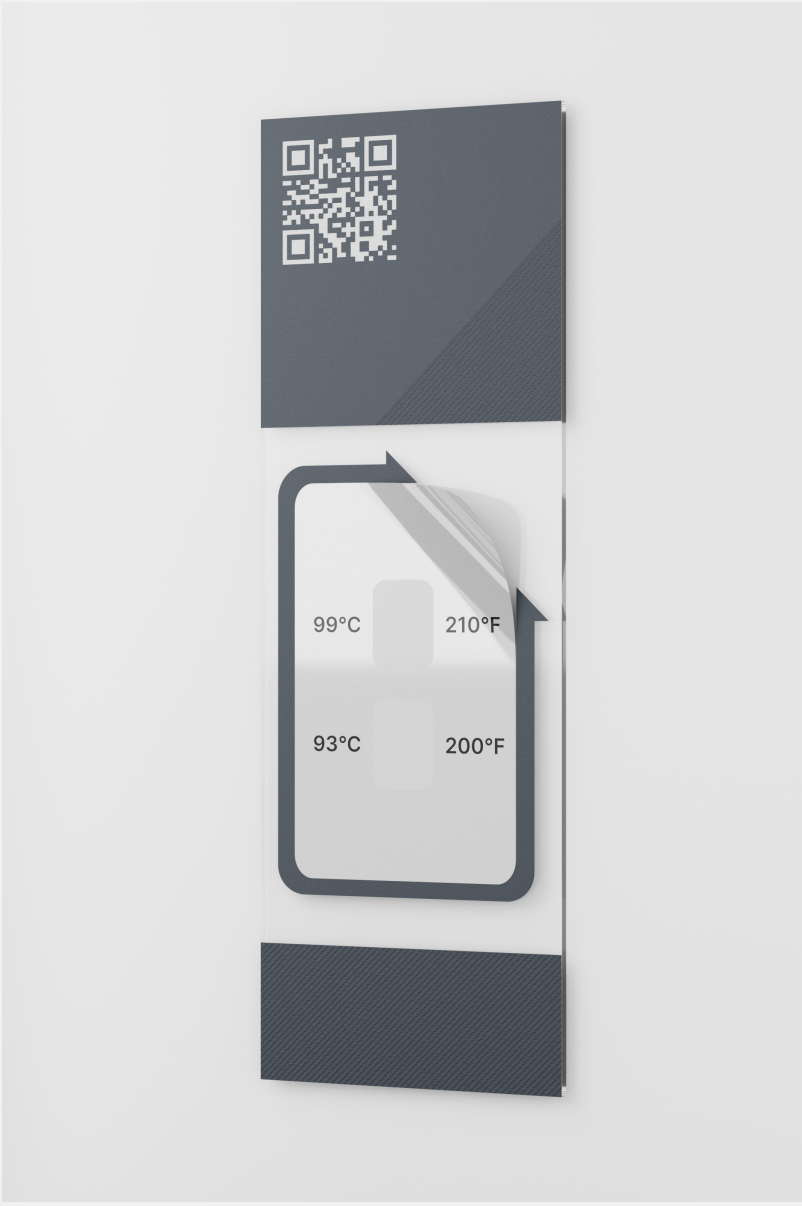
Keep the evidence. Keep the connection.

COOL. IDENTIFY.

After cooling, annotate the corresponding slide-pad number. Record the result before removing the label from its designated lift corner.

TRANSFER TO LOG ASSIST

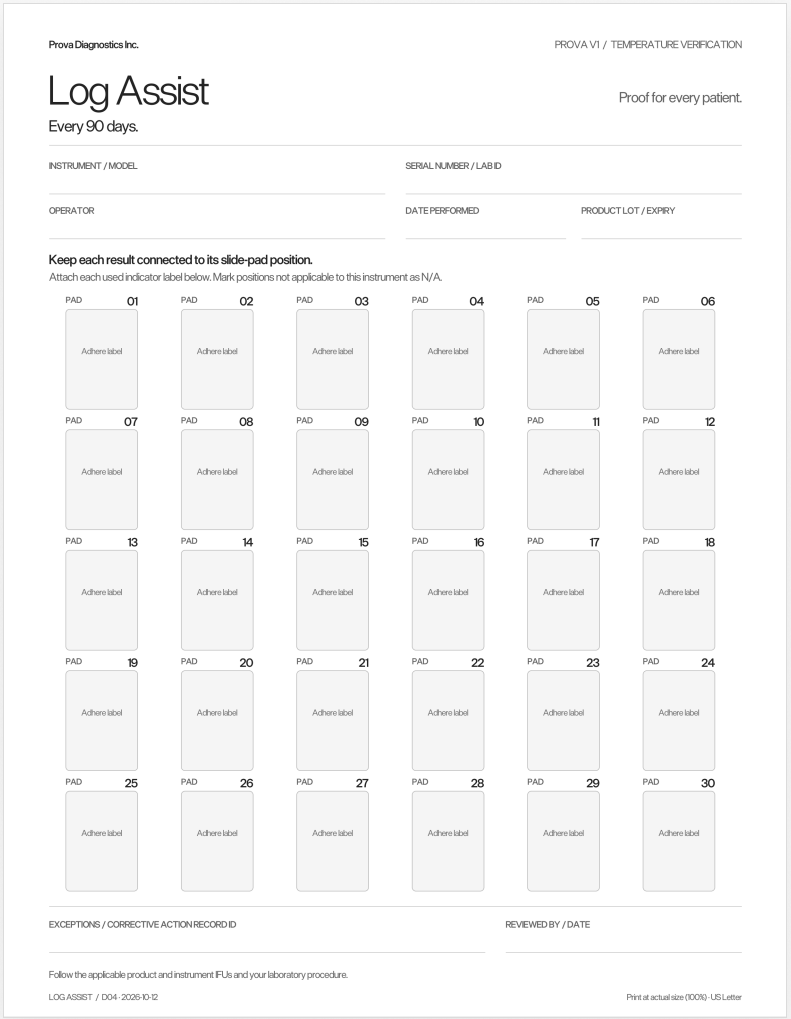
Re-adhere the label in the matching position field. Confirm legibility and identity. Retain the record according to laboratory policy.



PROVA V1 IFU, Additional Features.

A record worth retrieving.

Connect every observation to its position.



Prova Diagnostics Inc.

PROVA V1 / TEMPERATURE VERIFICATION

Log Assist

Every 90 days.

Proof for every patient.

INSTRUMENT / MODEL

SERIAL NUMBER / LAB ID

OPERATOR

DATE PERFORMED

PRODUCT LOT / EXPIRY

Keep each result connected to its slide-pad position.

Attach each used indicator label below. Mark positions not applicable to this instrument as N/A.

PAD 01	PAD 02	PAD 03	PAD 04	PAD 05	PAD 06
PAD 07	PAD 08	PAD 09	PAD 10	PAD 11	PAD 12
PAD 13	PAD 14	PAD 15	PAD 16	PAD 17	PAD 18
PAD 19	PAD 20	PAD 21	PAD 22	PAD 23	PAD 24
PAD 25	PAD 26	PAD 27	PAD 28	PAD 29	PAD 30

Adhere label

EXCEPTIONS / CORRECTIVE ACTION RECORD ID

REVIEWED BY / DATE

Follow the applicable product and instrument IFUs and your laboratory procedure.

LOG ASSIST / D04 · 2026-10-12

Print at actual size (100%) · US Letter

IDENTIFY THE CHECK

Record the instrument, operator, date and product lot before transferring labels.

MATCH THE POSITION

Attach each label in its numbered field. Mark positions not applicable to the instrument as N/A.

KEEP THE CONNECTION

Reference exceptions and corrective action. Retain the completed record under laboratory policy.

Keep the original observations with corrective-action records. Use laboratory-approved methods for electronic images and retention.

Download Log Assist from provadx.com/V1guide. Print at actual size (100%).



PROVA V1 / TEMPERATURE VERIFICATION SLIDES

Clear from the first opening.

10 slides

Two thresholds. Removable labels for a position-linked record.

Product manual

The underside QR opens the digital guide.

Find product identification, lot and applicable storage/expiry information on the underside.

order@provadx.com

The questions worth asking.

IS SOFTWARE ENOUGH?

The software runs the cycle. Where the manufacturer specifies physical slides, the indicator response is part of the check.

DOES ANNUAL SERVICE COVER IT?

Only checks performed and documented at the required intervals meet that schedule. Follow the instrument instructions.

WHAT DOES A PASS TELL ME?

The indicators show the expected pattern after a valid check. It does not validate every step of a patient assay.

HOW MANY SLIDES DO WE NEED?

Count required positions across instruments and scheduled checks. Each PROVA V1 box contains 10 slides. Confirm the applicable configuration.

For ordering and technical questions, have the instrument model, software version and next due date available.

Clear sources. Clear scope.

01 / REGULATION

42 CFR §493.1254(a)(1)–(2); CMS interpretive guidance for maintenance and function checks.

02 / INSTRUMENT

Roche user guides, cited editions:
ULTRA PLUS · 1017687EN v1.0 · pp. 339–340
ULTRA · 1020058EN v1 · pp. 350–352
Special Stains · 1020205EN v1 · pp. 165–166
GX · 1021468EN v1 · pp. 334–336
DISCOVERY ULTRA · D135664 v1 · pp. 314–315

03 / ACCREDITATION

CAP All Common Checklist COM.30600, supplied December 26, 2024 edition. Verify against the laboratory's current edition.

04 / PRODUCT

Prova Diagnostics Inc., Prova V1 Instructions for Use and Log Assist.

Manufacturer instructions define the required check. CMS and CAP do not endorse the PROVA brand. Third-party names identify instruments and ordering channels, not sponsorship.

PROVA V1

Prepare. Verify. Document.



BEFORE

Confirm the instructions, due date, product condition and position map.

DURING

Load all required positions and run the specified physical-slide procedure.

AFTER

Read both indicators, record each result, resolve failures and log completion.

Order direct or contact your Cardinal Health or Thermo Fisher sales representative.

order@provadx.com

Digital product manual / provadx.com/V1guide

Digital guide