

PROVA V1

Temperature verification slides



Digital guide

PROVA V1
Temperature verification slides

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.

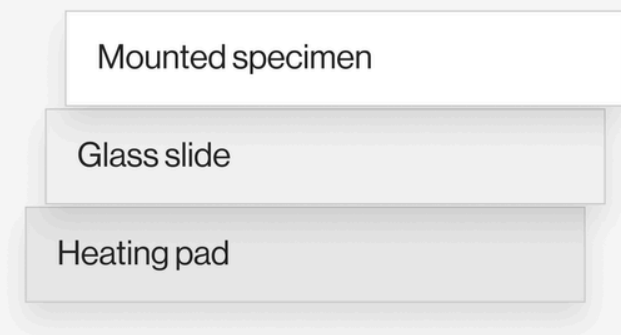
Physical verification provides a visible result at the tested slide position—evidence the laboratory can connect to the instrument and its record.

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

A surrogate for the slide's thermal path.

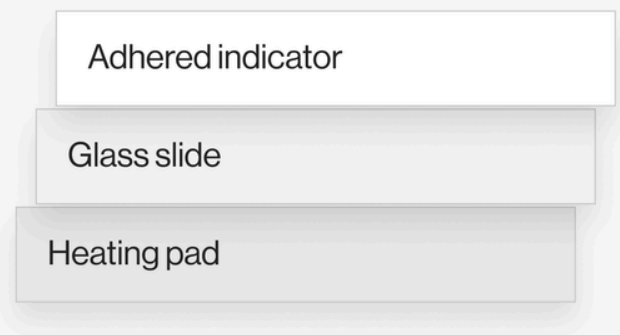
Heat travels through the glass.

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.

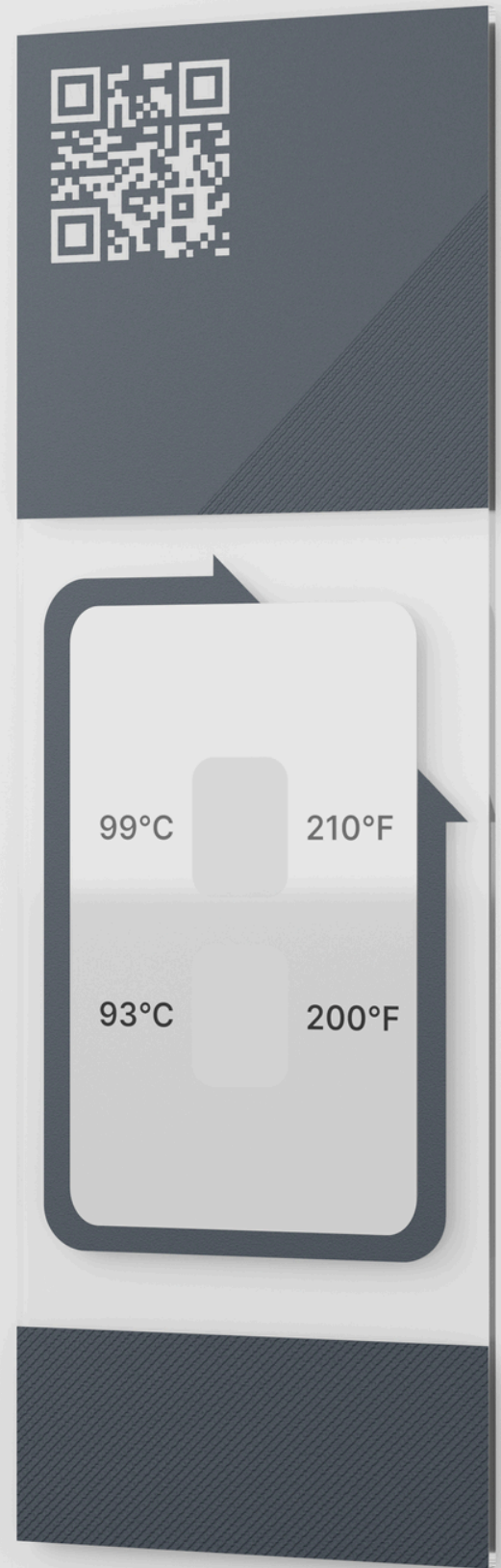
99°C

210°F · Upper indicator

93°C

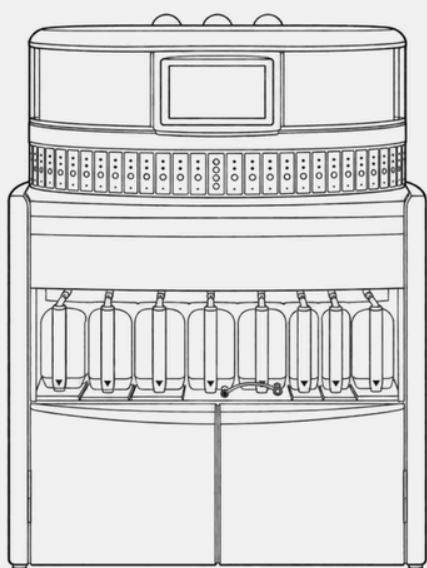
200°F · Lower indicator

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



Know your instrument.

Every 90 days. All slide-pad positions.



BenchMark ULTRA / ULTRA PLUS

EVERY 90 DAYS • 30 SLIDES

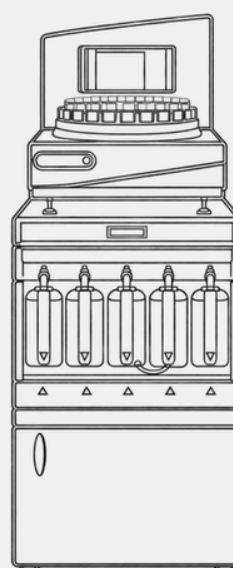
Use one verification slide in every drawer; run the prescribed test.

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.

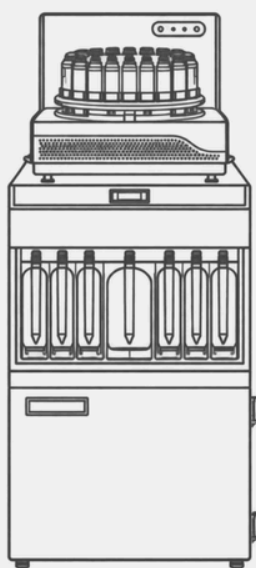
Special Stains • 1020205EN v1

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.

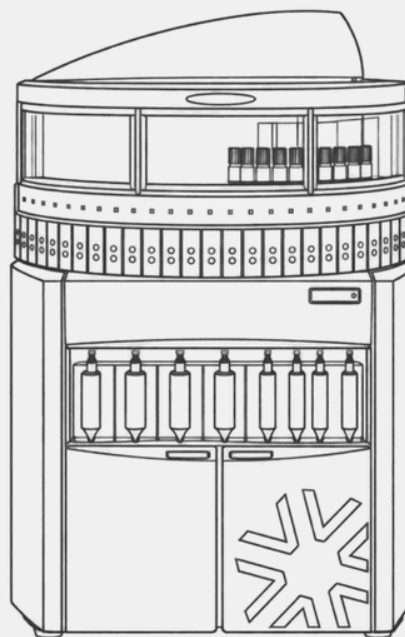


BenchMark GX

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.



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.

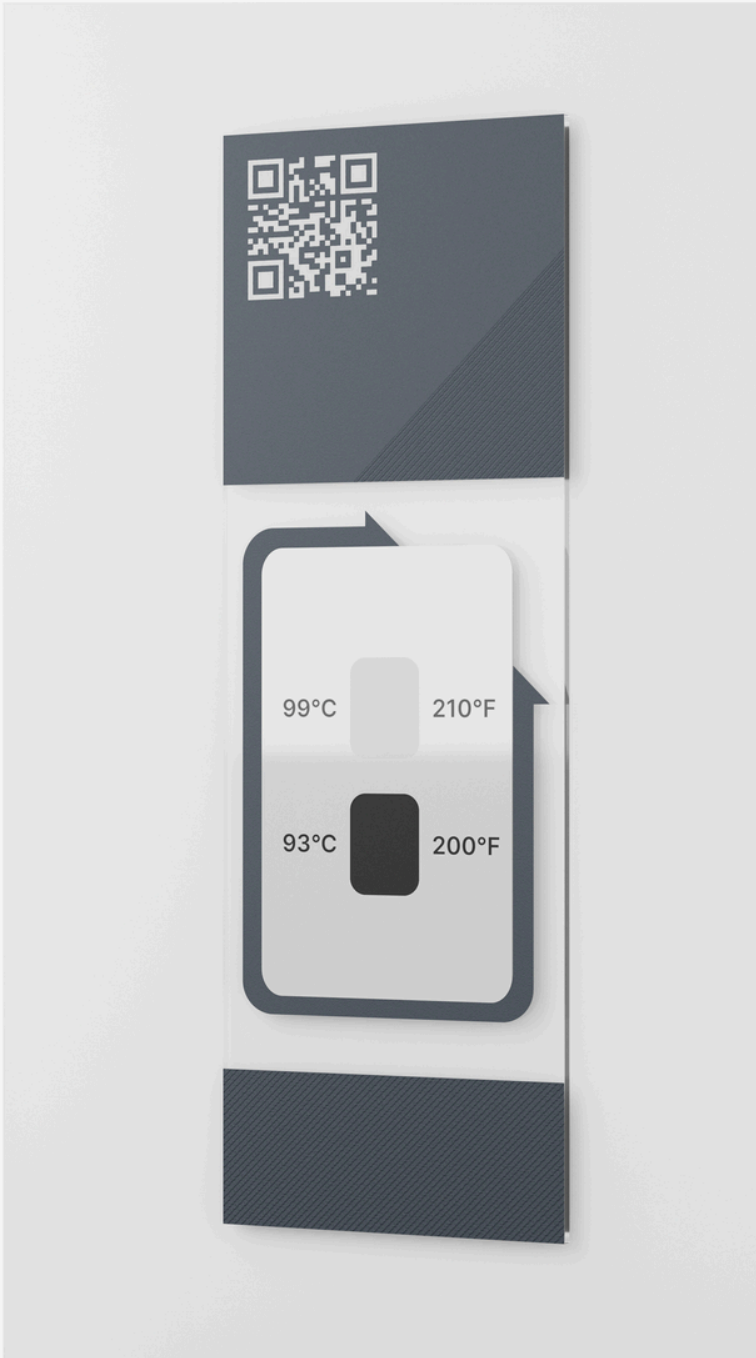
- 01 **Select**
Choose the specified temperature-verification test for the instrument and installed software.
- 02 **Execute**
Run the cycle with the physical verification slides loaded.
- 03 **Cool**
Allow the cycle and cooling to complete before handling or reading the slides.
- 04 **Assess**
Read 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.

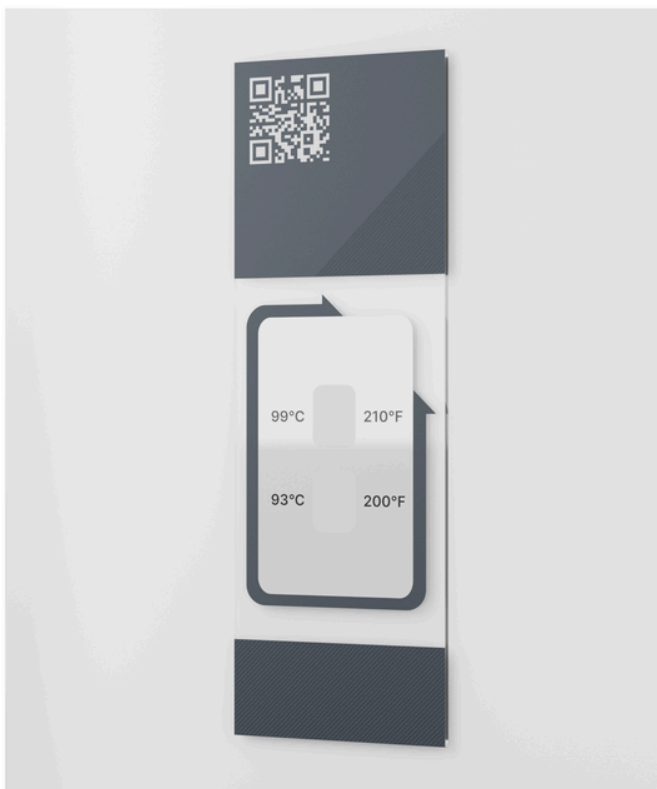
99°C / 210°F

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.



B+B DIAGNOSTICS

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

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

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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.

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.

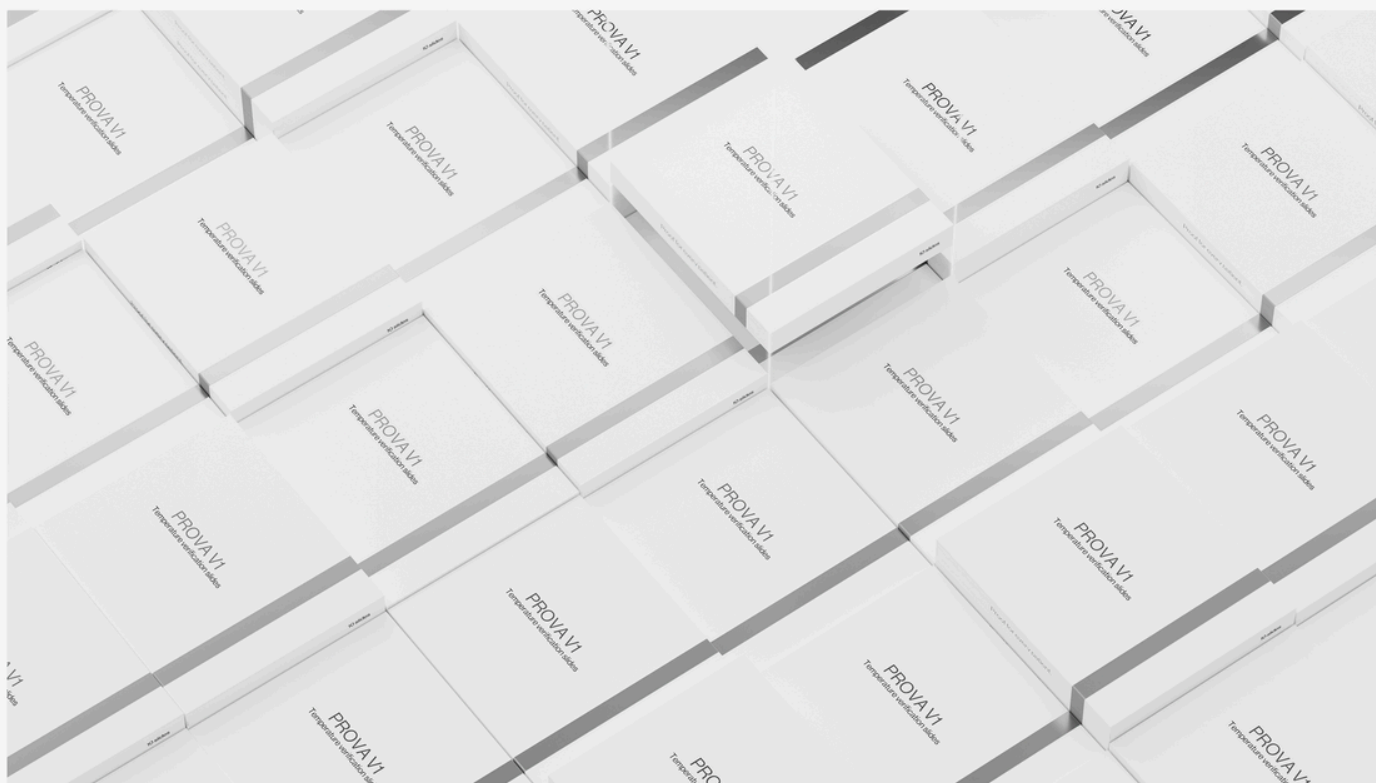
04 / PRODUCT

B+B Diagnostics, 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.

info@bbdiagnostics.com

Digital product manual / prova-v1-manual.netlify.app



Digital guide