



THE DIAGNOSTIC KIT & REAGENT MANUFACTURING GUIDE

Every component traced. Every kit lot reviewed.

21 CFR 809 and the QMSR in practice, from reagent lot to recall

A practical evaluation guide for teams that manufacture diagnostic kits and reagents: how labeling, quality system and traceability rules shape each kit lot, and what a connected record should show the person who decides release. Written for manufacturers, not for clinical laboratories.



21 CFR 809

21 CFR 820 QMSR

PEOPLE DECIDE RELEASE

U.S. edition with EU scope notes / October 2026

v5ultimate.com

Scope: practical orientation, not legal advice. Photos are staged; lots, kits and results are worked examples.

INSIDE THE GUIDE

One kit lot, start to finish.

A diagnostic kit is a small system: several reagents, a plate or cartridge, controls, instructions and a label, each with its own lot and expiry. This guide follows one kit lot and shows what each rule expects the record to hold.

01 / FRAME

pp. 03–04

What is in scope, which rules

IVD, research use only and general laboratory reagents; Part 809, the QMSR and the EU IVDR.

02 / CONTROL

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Components and formulation

Critical materials, lot status, expiry blocks and weighing to the approved formulation.

03 / MAKE

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Fill, assemble, expiry

Kit reconciliation, lot identity across units, and setting a kit expiry its components can support.

04 / DECIDE

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Test, release, substitute

Lot release testing, documented disposition, and a worked component substitution.

05 / RESPOND

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Label, report, recall

Label checks, complaints and reports, recall trace and the software you rely on.

06 / APPLY

pp. 16–21

V5 fit, worksheets, sources

Where V5 fits and does not, two worksheets, a four-week evaluation and eleven sources.

Who it is for. Quality and regulatory leads, reagent formulation and production managers, QC laboratory leads, supply chain, and anyone choosing a production and quality system for a kit or reagent operation.

How to read it. Operational pages end with a teal Where V5 fits panel. Everything above it is regulation and practice; practice is labelled as such. Statements cite numbered sources; always check the current text.

THREE TAKEAWAYS

01 Classify IVD, research-use and lab reagents before you build the record.

02 Tie every reagent, control and calibrator lot and expiry to the kit lot.

03 Release, reporting and recall decisions stay with qualified people.

WHERE V5 FITS

V5 records the receiving, formulation, filling, kitting, testing, labeling and quality work your procedures define. It does not establish diagnostic performance, classify products, decide release, submit to FDA databases or decide recalls. Those decisions stay with your qualified people.

FRAME / 01

Which products are in scope?

The same plant can make an IVD kit, a research-use reagent and a general laboratory buffer. The rules differ by intended use and labeling, so classify every product before you design its record.

THE U.S. DEFINITION [1]

In vitro diagnostic products are reagents, instruments and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat or prevent disease or its sequelae (21 CFR 809.3(a), paraphrased).

PRODUCT	WHAT APPLIES
IVD kit or reagent	Part 809 labeling; made under Part 820 (809.20(b)) [1][2]
Research Use Only (RUO)	Labeled 'For Research Use Only'; conditions in 809.10(c) [1][5]
Investigational Use Only (IUO)	Labeled for product testing; conditions in 809.10(c) [1][5]
Analyte specific reagent (ASR)	Restricted sale and labeling under 809.30 [1]
General laboratory reagent	Not an IVD unless intended for diagnostic use; check claims

Intended use decides

FDA's RUO/IUO guidance warns that labeling a product RUO does not settle its status if it is marketed for clinical diagnostic use. Record why each product is classified as it is [5].

Not the clinical lab

This guide is about making kits and reagents. Testing patient specimens in a clinical laboratory is regulated separately and is not covered here.

EU: same idea, own law

The IVDR does not apply to general laboratory or research-use-only products unless the manufacturer specifically intends them for IVD examination (Art. 1(3)(a)) [11].

WHERE V5 FITS

Product master data in V5 can carry a product category, intended-use statement and your regulatory notes, so records, labels and reports follow the right template. V5 does not classify products or decide which rules apply.

Sources: [1], [5], [11] (linked on pages 20–21)

FRAME / 02

Three layers, one kit lot record.

Part 809 says what an IVD label must carry. Part 820, the Quality Management System Regulation, says how the device is made and controlled. Other parts cover identification, reporting and corrections.

809.10	Label content: intended use, reactive ingredients, warnings, storage, expiry or other assurance, net contents, lot or control number	Part 809
809.20(b)	IVD products are manufactured under the good manufacturing practice requirements of Part 820	Part 809
820.10	Document a QMS that complies with ISO 13485 (incorporated by reference) plus FDA additions	QMSR
820.10(b)	Links ISO clauses to UDI (Part 830), traceability (Part 821), reporting (Part 803) and advisory notices (Part 806)	QMSR
820.35	Extra content for certain records, including complaint records and UDI where used	QMSR
820.45	Labeling and packaging controls: examine identifiers, expiry, storage and handling before release	QMSR
Parts 803, 806	Medical device reporting; reports of corrections and removals	Reporting
Part 7	Recall policy and procedures (Subpart C)	Recall

The QMSR is in effect. FDA's amended Part 820 took effect on 2 February 2026 and replaced the former Quality System Regulation; it incorporates ISO 13485:2016 by reference, with FDA-specific additions [2][3]. Older terms such as the device history record now map to ISO 13485 records. Read the current eCFR text before relying on any requirement.

WHERE V5 FITS

V5 keeps procedures, specifications and records as controlled documents and connected records. Industry configuration adjusts screens and reports; it does not interpret regulations or make a QMS compliant on its own.

CONTROL / 01

Critical materials, held until released.

Antibodies, antigens, enzymes, conjugates, calibrators and controls often decide whether a kit works. Purchasing controls and acceptance activities under ISO 13485 (via 820.10) keep each lot pending until it is accepted [2].



Specify, then accept

Write a specification for each critical material and decide how a lot is accepted: certificate review, identity or functional testing, or both. Record the decision per lot.

Lots and expiry on receipt

Capture supplier lot, internal lot, expiry or retest date and storage class at receipt, because every later label and trace depends on them.

Qualify the supplier

Supplier evaluation and monitoring are part of the QMS. A change of source for a critical antibody is a change to control, not a purchasing detail.

STATUS	MEANING	ISSUE TO PRODUCTION?
Pending	Received, not yet accepted	HOLD
Released	Accepted; may be issued	YES
Rejected	Cannot be used; disposition recorded	DO NOT ISSUE
Past expiry	Expired since release	BLOCK

WHERE V5 FITS

V5 receiving records supplier and internal lots with expiry dates, holds each lot as pending, and issues only released lots. Expired batches are blocked unless your workspace is set to permit them; any permitted use is recorded against the job with the operator's signature. Your team sets acceptance criteria.

Sources: [2] (linked on pages 20–21)

CONTROL / 02

The concentration on the label is real.

For a reagent, the label declares the quantity, proportion or concentration of each reactive ingredient, and for biological material its source and a measure of activity (809.10(a)(3)). The formulation record is where that number comes from [1].

ADDITION (WORKED EXAMPLE)	TARGET	ACTUAL	TOLERANCE	IN LIMIT?
Conjugate concentrate CJ-118	4.80 g	4.82 g	±0.05 g	YES
Stabiliser SB-640	25.0 g	25.1 g	±0.3 g	YES
Preservative PV-22	1.00 g	1.04 g	±0.03 g	HOLD
Buffer base to final volume	2.000 L	2.000 L	QS	YES

WORKED EXAMPLE: ONE OUT OF TOLERANCE

The preservative reads 0.04 g over target, outside ±0.03 g. The entry is flagged, the solution is held and a deviation opens. A qualified person decides whether to adjust, discard or justify use; the batch does not move on until that decision is recorded.

- Right balance, right range**

Small additions of potent reagents need a balance whose range and readability suit the weight, with calibration current on the day.
- Activity, not only mass**

Biological reagents may be added by measured activity or titre. Record the lot's assigned value and the calculation used.
- Version the formulation**

A formulation is a controlled document. The batch record should show which revision was used.

WHERE V5 FITS

V5 formulas carry ingredients and quantities by revision; weigh and dispense steps check the scanned lot, balance and tolerance, flag out-of-limit entries and raise a structured deviation. V5 does not design formulations or set limits.

MAKE / 01

Every kit carries the whole lot story.

For a multiple-unit product, the lot or control number must permit tracing the identity of the individual units, and units used together as a system should share a lot number or other uniform identification (809.10(a)(9)) [1].

COMPONENT (KIT LOT KT-4471)	ISSUED	IN KITS	SAMPLED / REJECTED	MISSING
Coated plate PL-3310	240	240	0	0
Conjugate CJ-118 (filled vials)	246	240	6 QC samples	0
Controls CT-502	240	240	0	0
Wash buffer WB-2231	242	240	2 damaged	0

Reconcile before review. 240 kits × 4 components = 960 components in kits. Anything issued and not in a kit is explained as sampled, rejected or returned. An unexplained difference is a question for QA before release, not after.



WHERE V5 FITS

V5 kit and issue screens issue components by lot against the bill of materials, record fill and assembly steps, and reconcile issued, used, rejected and returned quantities per kit lot. Your procedure sets acceptable variance and who investigates it.

Sources: [1] (linked on pages 20–21)

MAKE / 02

Check every component against the kit date.

For a reagent, the label gives storage instructions adequate to protect stability, and a means of assurance at the time of use such as an expiration date based on those storage instructions (809.10(a)(5)–(6)). The basis must come from reliable test methods [1].

COMPONENT LOT	EXPIRY	AGAINST KIT 2027-05	OK TO ISSUE?
Coated plate PL-3310	2027-09	Later than kit	YES
Conjugate CJ-118	2027-06	Later than kit	YES
Controls CT-502	2027-08	Later than kit	YES
Wash buffer WB-2207	2026-12	Earlier than kit	FLAG
Wash buffer WB-2231 (issued)	2027-11	Later than kit	YES

COMMON PRACTICE, NOT A QUOTED RULE

Many manufacturers set the kit expiry no later than the earliest component expiry, unless stability data support otherwise. The regulation asks that the stated expiry be based on stability under the stated storage conditions; how you derive it belongs in your procedure.

Storage on the label

Temperature, light, humidity and other factors where applicable, and storage after reconstitution or mixing (809.10(a)(5)) [1].

Stability is evidence

Real-time and, where justified, accelerated studies support the dating. Keep pulls, results and decisions with the lot.

Check before assembly

Compare each component's expiry with the planned kit expiry before kitting, not at label print.

WHERE V5 FITS

V5 records expiry dates for every lot and lists lots expiring soon. Comparing component expiry against the kit's planned date is a check your procedure defines and your team performs or configures; V5 does not set shelf life or control storage temperatures.

Sources: [1] (linked on pages 20–21)

DECIDE / 01

Test the lot, keep pending visible.

Lot release testing confirms each kit lot meets the specifications your design and risk files set: performance against reference material, controls, fill and appearance. The plant's question is simple: is every required result in, and in specification?



Test against a reference

A functional test often compares the new lot with a qualified reference lot or panel. Record which reference and its own status.

Pending is a status

Results not yet reported stay visibly pending, so no one reads a partial record as complete.

Stability follows the lot

Enrol lots in the stability programme your dating relies on and keep its pulls on the schedule.

LOT TEST (WORKED EXAMPLE, KT-4471)	RESULT	COMPLETE?
Fill volume, sampled vials	In specification	YES
Kit controls in range	In specification	YES
Functional test against reference lot	Awaiting lab	HOLD
Appearance and packaging	In specification	YES

WHERE V5 FITS

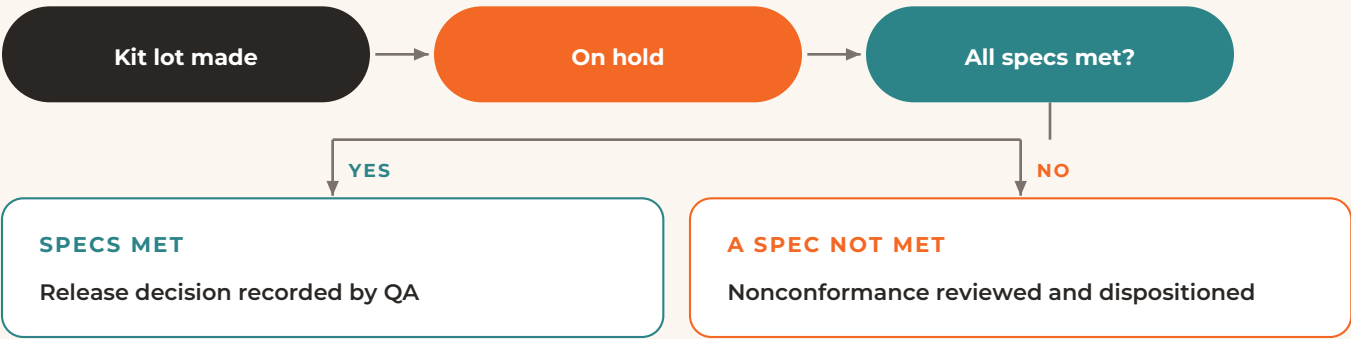
V5 laboratory sample plans carry your lot tests, record results against your specifications, keep pending tests visible and escalate out-of-specification results to a deviation. Methods, acceptance criteria and performance claims stay with your lab and quality team.

Sources: [2] (linked on pages 20–21)

DECIDE / 02

Hold the lot until a person decides.

ISO 13485, incorporated by the QMSR, requires that product is not released until planned arrangements are complete, and that nonconforming product is identified, segregated and dispositioned with records [2].



A DOCUMENTED DISPOSITION OF NONCONFORMING PRODUCT IS ONE OF (ISO 13485 CLAUSE 8.3)

Correct it

Action to eliminate the nonconformity, for example rework to a documented procedure, then re-verify.

Prevent its use

Action to preclude the original intended use, such as scrapping or relabeling for another use where allowed.

Accept by concession

Only with justification, approval by an authorized person and where regulatory requirements are met.

Name the decision-maker. The release record shows who reviewed the lot, which results and deviations they saw and what they decided. ISO 13485 itself is a purchased standard; this page paraphrases its clause titles and should be read against your copy [2].

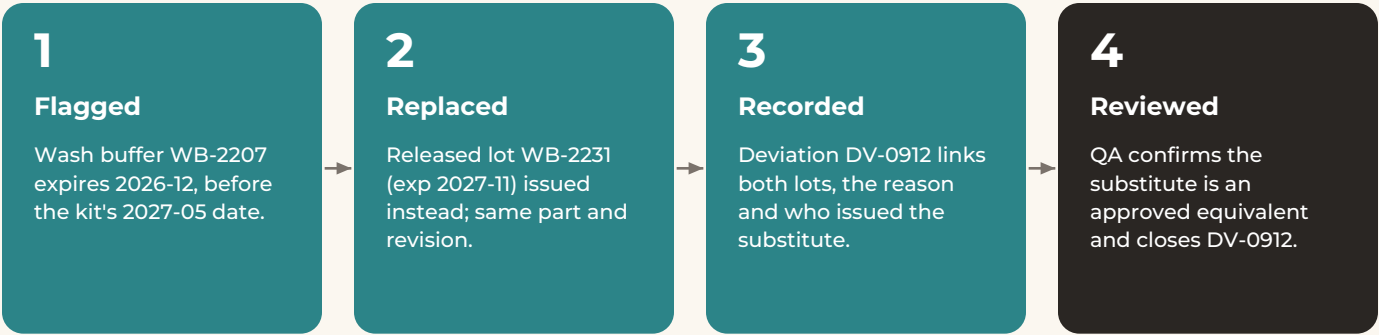
WHERE V5 FITS

V5's QC release queue shows each kit lot's results, open deviations, reconciliation and label checks in one view. A named reviewer records the decision with an electronic signature. V5 never releases product automatically and never makes the disposition decision.

DECIDE / 03

A substitution the reviewer can see.

A worked example from kit lot KT-4471. A component was replaced before assembly. The question is not whether substitutions happen; it is whether the reviewer can see one without asking.



RECORD FIELD	WORKED EXAMPLE
Kit lot	KT-4471, 240 kits, BOM rev C
Component replaced	Wash buffer WB-2207 to WB-2231
Reason	Earlier expiry than planned kit date
Equivalence	Same part number and approved revision
Deviation	DV-0912, closed by QA before release
Change control needed?	No: same approved part; a new part or supplier would be

WHERE V5 FITS

V5 records which component lots were issued to each kit lot, flags issues your configuration defines, and links deviations to the lot so they appear in the release review. Whether a substitute is equivalent, and whether change control is needed, is your quality team's decision.

RESPOND / 01

Right label, right lot, right expiry.

Section 820.45 adds FDA-specific labeling and packaging controls: examine labeling for accuracy before release or storage, document the release of labeling for use, and prevent mix-ups [2].

CHECK BEFORE RELEASE	WHAT IS EXAMINED	SECTION
Device identifier	Correct UDI, UPC or other identification	820.45(a)(1)
Expiration date	Matches the kit lot record	820.45(a)(2)
Storage instructions	As approved for the product	820.45(a)(3)
Handling instructions	As approved for the product	820.45(a)(4)
Other processing instructions	Any additional instructions	820.45(a)(5)

Label content (809.10)

Names, intended use, reactive ingredients, warnings and 'For In Vitro Diagnostic Use', storage, expiry, net contents, manufacturer, lot or control number [1][4].

Unique device identification

820.10(b)(1) links ISO identification to Part 830. Database submissions and labeler duties are your regulatory team's [6].

Instructions for use

Package insert content is set out in 809.10(b). Version it with the product, not the batch.

PRACTICE: CHECK THE PRINTED LOT, NOT THE PLAN

Verify a printed sample from the line against the kit lot record: lot number, expiry and identifier. Record who checked, when and how many labels were issued, used and destroyed.

WHERE V5 FITS

V5 label design prints lot, expiry and identifiers you provide from the kit lot record, and pack-out checks record what was verified, with counts. V5 does not submit to FDA's GUDID database; label content and claims are approved by your regulatory team.

RESPOND / 02

Complaints, reports and corrections.

Section 820.35 adds content to complaint records, including any UDI or UPC. Reportable events follow Part 803, and certain corrections and removals follow Part 806. Each has its own criteria and clocks; read them in the current text [2][7][8].

Complaint received	Record device, date, identifiers, complainant and the nature of the complaint (820.35(a))
Is it reportable?	Evaluate against Part 803 medical device reporting criteria (820.10(b)(3))
Correction or removal?	Evaluate whether Part 806 reporting applies (820.10(b)(4))
Investigate and link	Link to the kit lot, component lots, tests and any CAPA
Close with a record	Who decided, what was found, and why no further action if none

Deadlines are deliberately not summarised here. Parts 803 and 806 set different reporting clocks for different events. Confirm them in the current eCFR text and in your procedures, and name who decides [7][8].

WHERE V5 FITS

V5 records complaints, links them to kit lots and component lots, and routes investigations and CAPA. V5 does not decide whether an event is reportable and does not submit reports to FDA. Those decisions stay with your people.

RESPOND / 03

From one antibody lot to every customer.

If a critical reagent lot is in question, the first hours are about finding every kit lot that used it and every customer who received them. Part 7 Subpart C sets out FDA's recall policy and procedures [9].



Trace forward

From conjugate lot CJ-118: kit lots, quantities, shipments and customers, with dates. Then from one kit lot back to every component lot.

Mock recall

Time it. Record what was found, what was missing and who did what, and repeat after changes.



WORKED EXAMPLE: ONE REAGENT LOT, TWO KIT LOTS, TWO SHIPMENTS

KIT LOT	MADE	SHIPMENT	CONSIGNEES
KT-4471	240 kits	SHP-3390	Customer A, 240 kits
KT-4480	180 kits	SHP-3402	Customer C, 180 kits
Unshipped	0 kits	None	No stock on hand from CJ-118

WHERE V5 FITS

V5 traces from a component lot to kit lots and shipments and back, records mock recalls with timings and keeps distribution records. Recall strategy, customer notices and any FDA reports stay with your people.

Sources: [9] (linked on pages 20–21)

RESPOND / 04

Your software is part of the QMS.

ISO 13485, incorporated by the QMSR, requires documented validation of computer software used in the QMS and in production and service, before first use and after changes, proportionate to risk [2]. Part 11 applies to electronic records and signatures where relevant [10].

01

Define intended use

What the software does in your process, which records it holds and which decisions it supports.

02

Assess risk

Scale validation effort to the risk of the software's use, as your procedure describes.

03

Validate before use

Plan, test and approve before relying on it; keep the evidence.

04

Revalidate after change

Assess each change, including supplier releases, and revalidate as needed.

WHO DOES WHAT

You, the manufacturer, decide the intended use, assess risk, plan and approve validation, including performance qualification, and decide when a change needs revalidation. **A supplier** can provide documentation and, where agreed, installation and operational qualification support. In V5's case, IQ/OQ and validation support are part of the Enterprise plan, scoped in the accepted quote or statement of work.

WHERE V5 FITS

V5 records configuration changes in an audit trail and releases software in versions, so you can see what changed. V5 is not validated for your use until you validate it, and it does not make your QMS compliant on its own.

Sources: [2], [10] (linked on pages 20–21)

APPLY / 01

Where V5 fits, and where it does not.

A plain map from the rule to the V5 capability that keeps its record, and the decision that stays with you. Capabilities are from the V5 product reference reviewed 1 October 2026 and depend on plan and configuration.

RULE OR AREA	V5 KEEPS THE RECORD	YOUR PEOPLE DECIDE
Critical materials	Receiving, lot status, expiry, issue blocks	Acceptance criteria
Formulation (809.10(a)(3))	Formulas by revision, weigh and dispense	Formulation and limits
Kit assembly	Kit and issue by lot, reconciliation	Variance limits
Expiry (809.10(a)(6))	Lot expiry dates, expiring-soon lists	Shelf life and dating
Lot testing	LIMS sample plans and results	Methods, specs, claims
Stability	Stability schedules and results	Study design, decisions
Release	QC release queue, e-signature	The release decision
Labels (820.45)	Label print, pack-out checks	Label content, UDI data
Complaints (820.35)	Complaint records, CAPA links	Reportability, reports
Recall (Part 7)	Lot trace, mock recall, shipments	Recall decision, notices
Software (ISO 13485)	Versioned releases, change audit trail	Validation, incl. PQ

Coming soon, not available today: AI demand and yield forecasting and process anomaly detection.
Plan-dependent: IQ/OQ and validation support are Enterprise only, scoped in the accepted quote or statement of work. **Not offered:** GUDID submission, regulatory submissions, or control of storage temperatures.

WHERE V5 FITS

Nothing in V5 releases a kit lot, decides a disposition, classifies a product, reports to FDA or starts a recall. It keeps the evidence connected so the qualified people who make those decisions can see it.

WORKSHEET 01

Release readiness for one kit lot.

Use with a real (or test) kit lot record. Tick what the record shows today without asking anyone.

	SHOWN	PARTLY	NOT SHOWN
Components released Every component lot was released before issue	☐	☐	☐
Expiry against kit date No component expiry conflicts with the kit date under the approved dating procedure	☐	☐	☐
Formulation weights Each addition in tolerance, lot and balance recorded	☐	☐	☐
Reconciliation Issued, in kits, sampled and rejected all accounted	☐	☐	☐
Substitutions Any replaced component recorded and reviewed	☐	☐	☐
Lot tests complete No required result still pending	☐	☐	☐
Deviations closed Each reviewed, with a recorded decision	☐	☐	☐
Label check Lot, expiry, storage and identifier verified	☐	☐	☐
Named reviewer Who released, when, with what evidence	☐	☐	☐
Distribution Shipments linked to the kit lot	☐	☐	☐

NOTES AND OWNERS

WORKSHEET 02

Questions for any software demo.

Ask the vendor to show, not tell, using test data. Record what you saw.

	SHOWN	PARTLY	NOT SHOWN
Pending lot Try to issue a pending antibody lot; show the block.	☐	☐	☐
Expired lot Try to issue an expired buffer; show what happens.	☐	☐	☐
Expiry vs kit Show how a component expiring before the kit is caught.	☐	☐	☐
Tolerance Enter an out-of-tolerance weight; show the hold.	☐	☐	☐
Substitution Replace a component lot; show it in the release view.	☐	☐	☐
Reconciliation Show issued vs used for every component of a lot.	☐	☐	☐
Missing result Try to release with a lot test pending.	☐	☐	☐
Trace From one reagent lot, list kit lots and customers, timed.	☐	☐	☐
Calibration look-back Fail a balance calibration; list affected lots.	☐	☐	☐
Audit trail Show who changed a value, when and why.	☐	☐	☐

NOTES AND OWNERS

APPLY / 02

A fair evaluation in four weeks.

A practical way to test any system with your own people and one real kit, without touching live records.

WEEK 1

Agree one kit and the five questions that matter most. Load the bill of materials, formulation, specs and lot tests.

WEEK 2

Run a kit lot end to end with test data: receipt, formulation, fill, kitting, tests, labels, release review.

WEEK 3

Break it on purpose: pending lot, expired component, out-of-tolerance weight, substitution, failed calibration.

WEEK 4

Run a timed mock recall from one reagent lot. Review with QA, QC, production and IT; plan validation.

Rules for the evaluation. Use test data only. Keep your current records and release process live until a validated change is approved. Record what was shown, not what was promised.

ASK V5

“We make [IVD kits / reagents / research-use reagents] at [number] sites. Our hardest moment is [e.g. component expiry at kitting]. Which workflows should we evaluate first?”

Start a 7-day free trial, no card required, or ask V5 on v5ultimate.com.

WHERE V5 FITS

Try V5 with your own kit in a trial workspace using test data. The assistant answers questions about features and plans; it does not give regulatory advice.

SOURCES

Keep the evidence close.

Primary sources behind this guide, checked 2 October 2026. Click a title to open the publisher's page.

- | | | |
|---|--|---------------------------|
| [1] | U.S. eCFR, 21 CFR Part 809: in vitro diagnostic products for human use | BINDING U.S. REGULATION |
| https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-809 | | |
| [2] | U.S. eCFR, 21 CFR Part 820: Quality Management System Regulation (QMSR) | BINDING U.S. REGULATION |
| https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820 | | |
| [3] | U.S. FDA, Quality Management System Regulation (QMSR) information page | FDA INFORMATION PAGE |
| https://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-man... | | |
| [4] | U.S. FDA, In vitro diagnostic device labeling requirements | FDA INFORMATION PAGE |
| https://www.fda.gov/medical-devices/device-labeling/in-vitro-diagnostic-device-... | | |
| [5] | U.S. FDA, Distribution of IVD products labeled for Research Use Only or Investigational Use Only (guidance) | FDA GUIDANCE (NONBINDING) |
| https://www.fda.gov/regulatory-information/search-fda-guidance-documents/distri... | | |
| [6] | U.S. eCFR, 21 CFR Part 830: unique device identification | BINDING U.S. REGULATION |
| https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-830 | | |
| [7] | U.S. eCFR, 21 CFR Part 803: medical device reporting | BINDING U.S. REGULATION |
| https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-803 | | |
| [8] | U.S. eCFR, 21 CFR Part 806: reports of corrections and removals | BINDING U.S. REGULATION |
| https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-806 | | |

SOURCES

Sources, continued.

[9] [U.S. eCFR, 21 CFR Part 7: enforcement policy \(recalls, Subpart C\)](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-7)

U.S. REGULATION / POLICY

<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-7>

[10] [U.S. eCFR, 21 CFR Part 11: electronic records and electronic signatures](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-11)

BINDING U.S. REGULATION

<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-11>

[11] [Regulation \(EU\) 2017/746 on in vitro diagnostic medical devices \(IVDR\)](https://eur-lex.europa.eu/eli/reg/2017/746/oj)

BINDING EU REGULATION

<https://eur-lex.europa.eu/eli/reg/2017/746/oj>

How to read the status labels. Binding regulations are law in their jurisdiction. FDA guidance documents describe FDA's current thinking and are not binding. FDA information pages explain and announce. ISO 13485:2016 is incorporated by reference in Part 820 and is available from ISO; it is paraphrased here, not quoted.

SCOPE AND LIMITS

This guide is practical orientation for evaluating diagnostic kit and reagent manufacturing operations and software. It is not legal or regulatory advice and does not list every requirement that applies to you. It covers U.S. rules for in vitro diagnostic products, with an EU scope note; it does not cover clinical laboratory testing, and it does not guarantee conformity with the EU IVDR. Regulatory text was checked on eCFR on 2 October 2026; confirm the current text before relying on it. V5 capability statements reflect the V5 product reference reviewed on 1 October 2026 and depend on plan, configuration, devices and permissions. AI forecasting and anomaly detection are coming soon. V5 does not establish diagnostic performance, classify products, release kit lots, decide dispositions, submit to FDA databases, control storage temperatures, report to FDA or decide recalls; it is not validated for your use until you validate it and does not by itself make you compliant. Photography is illustrative; lots, kits and results are worked examples, not customer data.



Every component traced. Every kit lot reviewed.

See diagnostic kit workflows at v5ultimate.com · U.S. edition · October 2026