LOTWARDEN
CUSTODY. COMPLIANCE. CONFIDENTIALITY.

ISO 15189:2022

NATA assessment pack

Chemistry: reagents and consumables, 27/09/2025 to 26/09/2026

8	4	4	5	2
in order	check	partly covered	bring separately	for information

Laboratory	Demonstration	**Department**	Chemistry
Reference	`NATA_Pack_Chemistry_20250927-20260926`	**Period**	27/09/2025 to 26/09/2026
Made	26/09/2026 17:37 by Alex Bennett (demonstration), Senior scientist (AB)	**Program**	LotWarden Release 2026.59 · ca5ac71 · 29/10/2026
Regime	NATA assessment (ISO 15189): ISO 15189:2022	**Visit**	A NATA assessment (ISO 15189)

DEMONSTRATION: made-up data LotWarden Release 2026.59 · ca5ac71 · 29/10/2026. Made 26/09/2026 17:37 by Alex Bennett (demonstration), Senior scientist (AB).

LotWarden and EQAWarden are not affiliated with, endorsed by or certified by NATA or ISO.

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1 At a glance

Chemistry, 27/09/2025 to 26/09/2026. The figures the workbook's Start here and the slides open with.

354 deliveries received

126 lots received

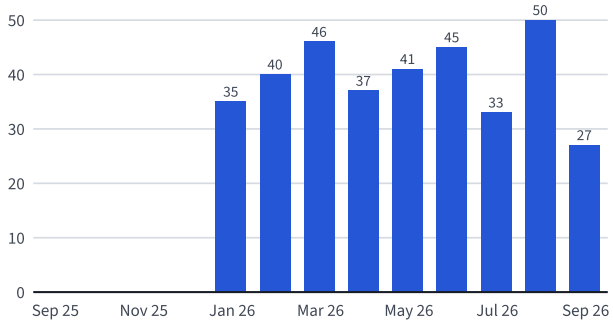
296 lots put into use

6 units taken off the shelf

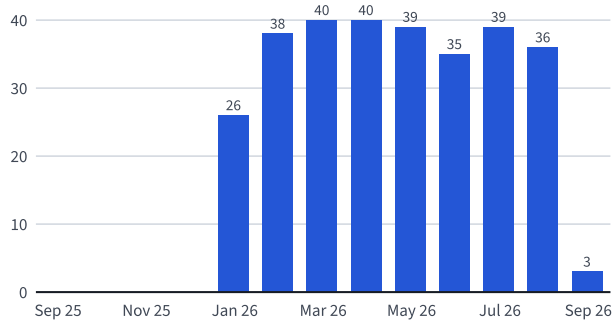
7 CAPA items

13 things to check

Deliveries received each month



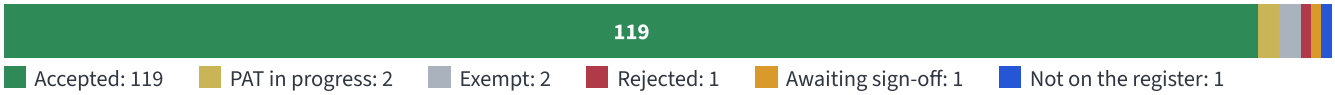
Lots put into use each month



How the deliveries arrived



PAT on the lots received



Things to check before the assessment

SHEET	DATE	PRODUCT	LOT	WHY
Dates in Use	24/08/2026	Mg	MG1133	put into use before PAT acceptance (pat in progress)

SHEET	DATE	PRODUCT	LOT	WHY
Lot acceptance	10/08/2026	Ferritin	FE4102	rejected at PAT
CAPA register	28/07/2026	Procedure (QIS 00042 V1). The receipt log's condition column left blank on two days	lotwarden-20260728-1	lotwarden-20260728-1
Dates in Use	13/07/2026	Mg	MG1133	put into use before PAT acceptance (pat in progress)
CAPA register	23/06/2026	Rejected on the register: CRP lot CP7488	lotwarden-20260623-1	lotwarden-20260623-1
Dates in Use	01/06/2026	Mg	MG1133	put into use before PAT acceptance (pat in progress)
Lot acceptance	18/05/2026	Mg	MG1133	put into use before PAT acceptance (pat in progress)
CAPA register	09/05/2026	Rejected on the register: CRP lot CP7215	lotwarden-20260509-1	lotwarden-20260509-1
Lot acceptance	24/09/2026	CRP	CP7730	not yet accepted (not on register): not to be used until signed off
Receipts	21/09/2026	ALT	AL3301	arrived short-dated (70 days to expiry)
CAPA register	21/09/2026	Equipment (RiskMan 20261017). Reagent fridge alarm after hours, temperature held	lotwarden-20260921-1	lotwarden-20260921-1
Lot acceptance	14/09/2026	CREA_2	CR2603	not yet accepted (awaiting sign-off): not to be used until signed off
Lot acceptance	14/09/2026	Ferritin	FE4215	not yet accepted (pat in progress): not to be used until signed off

2 Deliveries

3 items

What arrived, in what condition, and what each receipt records.

6.6.2 Goods arrived in good condition

In order

All 354 receipts recorded as received in satisfactory condition

Where: Receipts

6.6.7 a, b Each delivery records the product, lot and supplier

Partly covered

All 354 receipts identify the product and lot; 26 record a type (Calibrator or Control) or nothing in the Supplier column instead of the supplier

Where: Receipts

6.6.7 c Each delivery records when it arrived, its expiry and who received it

In order

All 354 receipts have the date received, condition, expiry and receiver

Where: Receipts

RECEIVED	SUPPLIER / TYPE	PRODUCT	LOT	EXPIRY	CONDITION	RECEIVED BY	TO REVIEW
21/09/2026	Northbridge Diagnostics	ALT	AL3301	30/11/2026	Yes	AB	arrived short-dated (70 days to expiry)

3 New lots, PAT and QC

5 items, 4 to check

Each lot received in the period, how it was accepted, and what was held back.

6.6.3 New lots needing PAT are accepted on the PAT register

Check

119 of 124 lot(s) needing PAT are accepted; 1 awaiting sign-off, 1 not on register, 2 pat in progress, 1 rejected; 2 lot(s) of products ticked exempt from PAT are left out (PAT scope)

Where: Lot acceptance, PAT scope, Acceptance checks

The lots received in the period

PRODUCT	LOT	EXPIRY	FIRST RECEIVED	NEW LOT	PAT VERDICT	DATE IN USE	TO REVIEW
Ferritin	FE4102	30/06/2027	10/08/2026	Yes	REJECTED		rejected at PAT
Mg	MG1133	31/03/2027	18/05/2026	Yes	PAT IN PROGRESS	01/06/2026	put into use before PAT acceptance (pat in progress)
CREA_2	CR2603	31/07/2027	14/09/2026	Yes	AWAITING SIGN-OFF		not yet accepted (awaiting sign-off): not to be used until signed off
CRP	CP7730	31/08/2027	24/09/2026	Yes	NOT ON REGISTER		not yet accepted (not on register): not to be used until signed off
Ferritin	FE4215	30/09/2027	14/09/2026	Yes	PAT IN PROGRESS		not yet accepted (pat in progress): not to be used until signed off
Albumin	AB3122	31/12/2026	05/01/2026	Yes	ACCEPTED	17/01/2026	
Albumin	AB3133	31/05/2027	02/03/2026	Yes	ACCEPTED	14/03/2026	
Albumin	AB3144	31/08/2027	20/07/2026	Yes	ACCEPTED	01/08/2026	
ALP	AP3159	31/01/2027	12/01/2026	Yes	ACCEPTED	22/01/2026	
ALP	AP3170	31/05/2027	09/03/2026	Yes	ACCEPTED	19/03/2026	
ALP	AP3181	31/08/2027	27/07/2026	Yes	ACCEPTED	06/08/2026	
ALT	AL3301	30/11/2026	12/01/2026	Yes	ACCEPTED	26/01/2026	
Ammonia	NH3825	31/03/2027	23/02/2026	Yes	ACCEPTED	09/03/2026	
Ammonia	NH3836	31/07/2027	15/06/2026	Yes	ACCEPTED	29/06/2026	
Amylase	AM2105	31/08/2026	19/01/2026	Yes	ACCEPTED	02/02/2026	
Amylase	AM2290	15/10/2026	11/05/2026	Yes	ACCEPTED	25/05/2026	
AST	AS3196	31/01/2027	19/01/2026	Yes	ACCEPTED	02/02/2026	
AST	AS3207	30/06/2027	16/03/2026	Yes	ACCEPTED	30/03/2026	
AST	AS3218	31/07/2027	03/08/2026	Yes	ACCEPTED	17/08/2026	
Bicarbonate	BC3788	31/01/2027	19/01/2026	Yes	ACCEPTED	25/01/2026	
Bicarbonate	BC3799	30/06/2027	16/03/2026	Yes	ACCEPTED	22/03/2026	
Bicarbonate	BC3810	31/07/2027	03/08/2026	Yes	ACCEPTED	09/08/2026	
Cardiac Control	CD4454	31/01/2027	02/03/2026	Yes	ACCEPTED	09/03/2026	
Cardiac Control	CD4465	31/07/2027	25/05/2026	Yes	ACCEPTED	01/06/2026	
CA_2	CA2231	31/12/2026	26/01/2026	Yes	ACCEPTED	09/02/2026	
CHEM CAL	CC2611	30/09/2026	12/01/2026	Yes	ACCEPTED	26/01/2026	
CHEM CAL	CC2618	31/03/2027	29/06/2026	Yes	ACCEPTED	13/07/2026	
Cholesterol	CH3492	31/01/2027	19/01/2026	Yes	ACCEPTED	29/01/2026	
Cholesterol	CH3503	30/06/2027	16/03/2026	Yes	ACCEPTED	26/03/2026	
Cholesterol	CH3514	31/07/2027	03/08/2026	Yes	ACCEPTED	13/08/2026	
CK	CK3751	31/01/2027	05/01/2026	Yes	ACCEPTED	14/01/2026	
CK	CK3762	31/05/2027	16/03/2026	Yes	ACCEPTED	25/03/2026	
CK	CK3773	31/08/2027	03/08/2026	Yes	ACCEPTED	12/08/2026	

PRODUCT	LOT	EXPIRY	FIRST RECEIVED	NEW LOT	PAT VERDICT	DATE IN USE	TO REVIEW
Cortisol	CO4121	31/03/2027	09/02/2026	Yes	ACCEPTED	23/02/2026	
Cortisol	CO4132	31/08/2027	15/06/2026	Yes	ACCEPTED	29/06/2026	
CREA_2	CR2410	31/08/2026	05/01/2026	Yes	ACCEPTED	19/01/2026	
CREA_2	CR2507	28/02/2027	28/04/2026	Yes	ACCEPTED	11/05/2026	
CRP	CP7215	31/10/2026	05/01/2026	Yes	ACCEPTED	19/01/2026	
CRP	CP7488	31/05/2027	30/03/2026	Yes	ACCEPTED	13/04/2026	
Direct Bilirubin	DB3307	30/04/2027	12/01/2026	Yes	ACCEPTED	26/01/2026	
Direct Bilirubin	DB3318	31/08/2027	29/06/2026	Yes	ACCEPTED	13/07/2026	
Enzyme Cal	EC4380	30/04/2027	16/02/2026	Yes	ACCEPTED	28/02/2026	
Enzyme Cal	EC4391	30/06/2027	03/08/2026	Yes	ACCEPTED		
Ferritin	FE3990	31/01/2027	16/02/2026	Yes	ACCEPTED	26/02/2026	
Folate	FO4084	31/12/2026	02/02/2026	Yes	ACCEPTED	14/02/2026	
Folate	FO4095	31/05/2027	09/03/2026	Yes	ACCEPTED	21/03/2026	
Folate	FO4106	31/07/2027	27/07/2026	Yes	ACCEPTED	08/08/2026	
FT3	F34010	31/03/2027	19/01/2026	Yes	ACCEPTED	31/01/2026	
FT3	F34021	31/07/2027	25/05/2026	Yes	ACCEPTED	06/06/2026	
FT4	F43973	31/01/2027	26/01/2026	Yes	ACCEPTED	05/02/2026	
FT4	F43984	30/06/2027	23/03/2026	Yes	ACCEPTED	02/04/2026	
FT4	F43995	31/08/2027	10/08/2026	Yes	ACCEPTED	20/08/2026	
GGT	GG3233	31/01/2027	12/01/2026	Yes	ACCEPTED	24/01/2026	
GGT	GG3244	30/06/2027	23/03/2026	Yes	ACCEPTED	04/04/2026	
GGT	GG3255	31/08/2027	10/08/2026	Yes	ACCEPTED	22/08/2026	
Glucose	GL3455	31/01/2027	12/01/2026	Yes	ACCEPTED	19/01/2026	
Glucose	GL3466	31/05/2027	09/03/2026	Yes	ACCEPTED	16/03/2026	
Glucose	GL3477	31/08/2027	27/07/2026	Yes	ACCEPTED	03/08/2026	
HbA1c	HB2981	30/09/2026	19/01/2026	Yes	ACCEPTED	26/01/2026	
HbA1c	HB3055	31/08/2026	16/02/2026	Yes	ACCEPTED		
HbA1c	HB3204	30/04/2027	13/04/2026	Yes	ACCEPTED	20/04/2026	
hCG	HC4195	30/04/2027	12/01/2026	Yes	ACCEPTED	21/01/2026	
hCG	HC4206	31/08/2027	29/06/2026	Yes	ACCEPTED	08/07/2026	
HDL Cholesterol	HD3529	31/12/2026	02/02/2026	Yes	ACCEPTED	14/02/2026	
HDL Cholesterol	HD3540	31/05/2027	09/03/2026	Yes	ACCEPTED	21/03/2026	
HDL Cholesterol	HD3551	31/07/2027	27/07/2026	Yes	ACCEPTED	08/08/2026	
Immunoassay Plus	40110	30/06/2027	09/02/2026	Yes	ACCEPTED	23/02/2026	
IMT	IM6602	30/06/2026	12/01/2026	Yes	ACCEPTED	26/01/2026	
IMT	IM6620	31/08/2026	09/02/2026	Yes	ACCEPTED	23/02/2026	
IMT	IM6711	31/12/2026	25/05/2026	Yes	ACCEPTED	08/06/2026	
Iron	FE3640	31/03/2027	02/02/2026	Yes	ACCEPTED	14/02/2026	
Iron	FE3651	31/07/2027	08/06/2026	Yes	ACCEPTED	20/06/2026	
Lactate	LA0331	31/03/2027	13/04/2026	Yes	ACCEPTED	27/04/2026	
LDH	LD3714	30/04/2027	05/01/2026	Yes	ACCEPTED	15/01/2026	
LDH	LD3725	31/08/2027	22/06/2026	Yes	ACCEPTED	02/07/2026	
Lipase	LP5120	31/12/2026	12/01/2026	Yes	ACCEPTED	24/01/2026	
Lipase	LP5466	30/06/2027	01/06/2026	Yes	ACCEPTED	13/06/2026	
Lipid Cal	LC4343	31/03/2027	09/02/2026	Yes	ACCEPTED	23/02/2026	

PRODUCT	LOT	EXPIRY	FIRST RECEIVED	NEW LOT	PAT VERDICT	DATE IN USE	TO REVIEW
Lipid Cal	LC4354	30/06/2027	27/07/2026	Yes	ACCEPTED		
Lithium	LI3862	31/03/2027	05/01/2026	Yes	ACCEPTED	17/01/2026	
Lithium	LI3873	31/07/2027	22/06/2026	Yes	ACCEPTED	04/07/2026	
Mg	MG0917	30/09/2026	02/02/2026	Yes	ACCEPTED	16/02/2026	
Microalbumin	MA3936	30/04/2027	05/01/2026	Yes	ACCEPTED	18/01/2026	
Microalbumin	MA3947	31/08/2027	22/06/2026	Yes	ACCEPTED	05/07/2026	
Multiqual	45670	31/12/2027	19/01/2026	Yes	ACCEPTED	02/02/2026	
NT-proBNP	BN4269	31/12/2026	02/02/2026	Yes	ACCEPTED	12/02/2026	
NT-proBNP	BN4280	31/05/2027	09/03/2026	Yes	ACCEPTED	19/03/2026	
NT-proBNP	BN4291	31/07/2027	27/07/2026	Yes	ACCEPTED	06/08/2026	
Phosphate	PH3603	31/03/2027	26/01/2026	Yes	ACCEPTED	09/02/2026	
Phosphate	PH3614	31/07/2027	01/06/2026	Yes	ACCEPTED	15/06/2026	
Protein Cal	PC0644	28/02/2027	23/03/2026	Yes	ACCEPTED	06/04/2026	
PSA	PS4158	31/01/2027	12/01/2026	Yes	ACCEPTED	22/01/2026	
PSA	PS4169	30/06/2027	23/03/2026	Yes	ACCEPTED	02/04/2026	
PSA	PS4180	31/08/2027	10/08/2026	Yes	ACCEPTED	20/08/2026	
Sample Cups	SC2609	30/06/2029	07/09/2026	Yes	PAT exempt		
System Wash Solution	SW0826	31/12/2027	24/08/2026	Yes	PAT exempt		
Thyroid Cal	TC4417	30/04/2027	23/02/2026	Yes	ACCEPTED	05/03/2026	
Thyroid Cal	TC4428	31/07/2027	10/08/2026	Yes	ACCEPTED		
Total Bilirubin	TB3270	31/12/2026	05/01/2026	Yes	ACCEPTED	14/01/2026	
Total Bilirubin	TB3281	31/05/2027	02/03/2026	Yes	ACCEPTED	11/03/2026	
Total Bilirubin	TB3292	31/08/2027	20/07/2026	Yes	ACCEPTED	29/07/2026	
Total Protein	TP3344	31/12/2026	02/02/2026	Yes	ACCEPTED	13/02/2026	
Total Protein	TP3355	31/05/2027	09/03/2026	Yes	ACCEPTED	20/03/2026	
Total Protein	TP3366	31/07/2027	27/07/2026	Yes	ACCEPTED	07/08/2026	
Transferrin	TF3677	30/04/2027	26/01/2026	Yes	ACCEPTED	09/02/2026	
Transferrin	TF3688	31/08/2027	13/07/2026	Yes	ACCEPTED	27/07/2026	
Triglycerides	TG3566	31/12/2026	05/01/2026	Yes	ACCEPTED	16/01/2026	
Triglycerides	TG3577	31/05/2027	02/03/2026	Yes	ACCEPTED	13/03/2026	
Triglycerides	TG3588	31/08/2027	20/07/2026	Yes	ACCEPTED	31/07/2026	
Troponin I	TN4232	31/01/2027	19/01/2026	Yes	ACCEPTED	26/01/2026	
Troponin I	TN4243	30/06/2027	16/03/2026	Yes	ACCEPTED	23/03/2026	
Troponin I	TN4254	31/07/2027	03/08/2026	Yes	ACCEPTED	10/08/2026	
TSH3UL	TS2201	31/12/2026	12/01/2026	Yes	ACCEPTED	26/01/2026	
Urea	UR3381	31/01/2027	26/01/2026	Yes	ACCEPTED	03/02/2026	
Urea	UR3392	30/06/2027	23/03/2026	Yes	ACCEPTED	31/03/2026	
Urea	UR3403	31/08/2027	10/08/2026	Yes	ACCEPTED	18/08/2026	
Uric Acid	UA3418	31/03/2027	02/02/2026	Yes	ACCEPTED	15/02/2026	
Uric Acid	UA3429	31/07/2027	08/06/2026	Yes	ACCEPTED	21/06/2026	
Urine Chemistry Control	UC8355	31/03/2027	12/01/2026	Yes	ACCEPTED	19/01/2026	
Urine Protein	UP3899	31/03/2027	09/02/2026	Yes	ACCEPTED	20/02/2026	
Urine Protein	UP3910	31/08/2027	15/06/2026	Yes	ACCEPTED	26/06/2026	
Vitamin B12	VB4047	31/12/2026	26/01/2026	Yes	ACCEPTED	06/02/2026	

PRODUCT	LOT	EXPIRY	FIRST RECEIVED	NEW LOT	PAT VERDICT	DATE IN USE	TO REVIEW
Vitamin B12	VB4058	31/05/2027	02/03/2026	Yes	ACCEPTED	13/03/2026	
Vitamin B12	VB4069	31/07/2027	20/07/2026	Yes	ACCEPTED	31/07/2026	
Vitamin D	VD4306	31/03/2027	02/02/2026	Yes	ACCEPTED	15/02/2026	
Vitamin D	VD4317	31/07/2027	08/06/2026	Yes	ACCEPTED	21/06/2026	

6.6.3 No lot went into use before PAT acceptance

Check

1 lot(s) put into use before PAT acceptance or sign-off; 0 with QC recorded as not acceptable

Where: Lot acceptance, Dates in Use; bring Unity Real Time QC records

PRODUCT	LOT	EXPIRY	FIRST RECEIVED	NEW LOT	PAT VERDICT	DATE IN USE	TO REVIEW
Ferritin	FE4102	30/06/2027	10/08/2026	Yes	REJECTED		rejected at PAT
Mg	MG1133	31/03/2027	18/05/2026	Yes	PAT IN PROGRESS	01/06/2026	put into use before PAT acceptance (pat in progress)

6.6.4 Stock not yet accepted is kept apart

Check

5 lot(s) not yet accepted, or rejected, are listed: show they are kept apart from accepted stock

Where: Lot acceptance; show the quarantine area or labels

PRODUCT	LOT	EXPIRY	FIRST RECEIVED	NEW LOT	PAT VERDICT	TO REVIEW
Ferritin	FE4102	30/06/2027	10/08/2026	Yes	REJECTED	rejected at PAT
CREA_2	CR2603	31/07/2027	14/09/2026	Yes	AWAITING SIGN-OFF	not yet accepted (awaiting sign-off): not to be used until signed off
CRP	CP7730	31/08/2027	24/09/2026	Yes	NOT ON REGISTER	not yet accepted (not on register): not to be used until signed off
Ferritin	FE4215	30/09/2027	14/09/2026	Yes	PAT IN PROGRESS	not yet accepted (pat in progress): not to be used until signed off

6.6.7 d Records show each lot was accepted, at first and ongoing

Partly covered

Initial acceptance: PAT register verdicts for products in PAT scope. QC at first use and ongoing QC are recorded in Unity Real Time, and EQA in its own records, not in LotWarden.

Where: Lot acceptance, PAT scope; bring Unity Real Time QC and EQA records

8.7, 8.5, 7.3.7.2 Nonconformities are recorded, their causes found, actions taken and effectiveness checked

Check

3 item(s) overdue in the CAPA register

Where: CAPA register sheet

The CAPA register: items opened in the period and items still open

ITEM	OPENED	SOURCE	STATE	WHAT HAPPENED	CAUSE	CORRECTIVE ACTION	OWNER	DUE	CLOSED BY	CLOSED
lotwarden-20251031-1	31/10/2025	Lot held at the door	Closed	Rejected on the register: Ferritin lot FE3650	Materials and suppliers: Lot failed PAT	Return or discard, Supplier told, Supplier evaluation noted	KM	01/12/2025	KM	30/11/20

ITEM	OPENED	SOURCE	STATE	WHAT HAPPENED	CAUSE	CORRECTIVE ACTION	OWNER	DUE	CLOSED BY	CLOSED
lotwarden-20260129-1	29/01/2026	Lot held at the door	Closed	Expired on arrival: Lipase lot LP0877	Materials and suppliers: Supplier error	Return or discard, Supplier told	RT	02/03/2026	RT	10/04/20
lotwarden-20260509-1	09/05/2026	Lot held at the door	Open	Rejected on the register: CRP lot CP7215		return_or_discard, supplier_told	KM	10/06/2026		
lotwarden-20260623-1	23/06/2026	Lot held at the door	Open	Rejected on the register: CRP lot CP7488				23/07/2026		
lotwarden-20260728-1	28/07/2026	By hand	Actions due	Procedure (QIS 00042 V1). The receipt log's condition column left blank on two days	People and procedures: Procedure not followed	Training recorded	JW	28/08/2026		
lotwarden-20260817-1	17/08/2026	Lot held at the door	Effectiveness pending	Refused a Date in Use because unreleased: Mg lot MG1133	People and procedures: Procedure not followed	Training recorded	KM	17/09/2026		
lotwarden-20260921-1	21/09/2026	By hand	Open	Equipment (RiskMan 20261017). Reagent fridge alarm after hours, temperature held				21/10/2026		

4 Using and removing stock

3 items

When lots went into use, what came off the shelf, and the shelf counts.

6.6.4 Stock levels and shelf counts are kept

For information

Kept in LotWarden's stock outlook: stock levels, lots to use first and expired lots; 12 shelf count(s) in the period

Where: Shelf counts; the Stock outlook tab

COUNTED	BY	LOTS COUNTED	DIFFERENCES FROM THE LOGS
03/10/2025 13:15	AB	48	0
03/11/2025 13:15	RT	49	0
03/12/2025 13:15	JW	50	0
05/01/2026 13:15	KM	39	0
03/02/2026 13:15	RT	40	1
03/03/2026 13:15	RT	41	0
03/04/2026 13:15	KM	42	0
04/05/2026 13:15	JW	43	0
03/06/2026 13:15	RT	44	0
03/07/2026 13:15	JW	45	1
03/08/2026 13:15	AB	46	0
03/09/2026 13:15	RT	47	0

6.6.7 c Each lot's first use is dated, and nothing was used after expiry

In order

296 lot(s) put into use in the period, each with its Date in Use; none after expiry

Where: Dates in Use

DATE IN USE	AS WRITTEN	PRODUCT	LOT	EXPIRY	RECORDED THROUGH THE APP	TO REVIEW
01/06/2026	01/06/2026 JW	Mg	MG1133	31/03/2027	Yes, 13/07/2026 07:51 by RT	put into use before PAT acceptance (pat in progress)
13/07/2026	13/07/2026 RT	Mg	MG1133	31/03/2027	Yes, 13/07/2026 07:51 by RT	put into use before PAT acceptance (pat in progress)
24/08/2026	24/08/2026 JW	Mg	MG1133	31/03/2027	Yes, 13/07/2026 07:51 by RT	put into use before PAT acceptance (pat in progress)

6.6.7 c The date a lot was finished or withdrawn is recorded

Partly covered

6 removal row(s) recorded in Number Discarded. The logs hold no date a lot was finished or withdrawn: record it (for example in Comments) or show it from other records.

Where: Removals

PRODUCT	LOT	EXPIRY	NUMBER DISCARDED	REMOVAL NOTE	RECORDED THROUGH THE APP
Bicarbonate	BC3810	31/07/2027	1	Removed 18.08.2026 KM	Yes, 18/08/2026 14:20 by KM
Cardiac Control	CD4454	31/01/2027	1	Removed 18.03.2026 JW	Yes, 18/03/2026 14:20 by JW
Glucose	GL3466	31/05/2027	1	Removed 15.07.2026 JW	Yes, 15/07/2026 14:20 by JW
IMT	IM6602	30/06/2026	1	Removed 26.02.2026 KM	Yes, 26/02/2026 14:20 by KM
Triglycerides	TG3577	31/05/2027	1	Removed 14.06.2026 AB	Yes, 14/06/2026 14:20 by AB
Vitamin B12	VB4047	31/12/2026	1	Removed 15.02.2026 AB	Yes, 15/02/2026 14:20 by AB

5 Suppliers

1 item

Deliveries by supplier in the period, and the deliveries with a problem.

6.8.3 Suppliers are evaluated

Partly covered

Evidence for the evaluation: 5 supplier(s) and 1 delivery problem(s) in the period

Where: Suppliers, Delivery problems; bring the evaluation criteria and approvals

Deliveries by supplier

SUPPLIER	DELIVERIES	PRODUCTS	SHORT-DATED ON ARRIVAL	ARRIVED EXPIRED	CONDITION NOT SATISFACTORY	QC NOT ACCEPTABLE
Kestrel Bay Diagnostics	249	35	0	0	0	0
Northbridge Diagnostics	50	7	1	0	0	0
(no supplier recorded)	26	9	0	0	0	0
Harbourline Scientific	16	2	0	0	0	0
Meridian Lab Supply	13	3	0	0	0	0

Deliveries with a problem

SUPPLIER	PRODUCT	LOT	RECEIVED	EXPIRY	ISSUE
Northbridge Diagnostics	ALT	AL3301	21/09/2026	30/11/2026	Short-dated: 70 days to expiry on arrival

6 Records and software

6 items

Who is named in the records, how the records are kept, and the software keeping them.

7.6.3 The software keeping these records is a validated release

In order

Release 2026.59 · ca5ac71 · 29/10/2026

Where: Change control; bring LotWarden's validation dossier for this release

RELEASE	DATE	NOTE
2026.59	29/10/2026	The assessment pack cites ISO 15189:2022 clause 7.6.3 (information systems) for the software keeping the records, in place of 7.11, which is the ISO/IEC 17025 number; the security brief and the dossier builder cite 7.6 likewise
2026.58	28/10/2026	Every output as a designed page beside its workbook, the one signature block, the CAPA register's signing points, the demonstration guide as bullets
2026.57	27/10/2026	Demonstration guide section 27: the investigation report filled, signatures and all
2026.56	26/10/2026	Demonstration guide sections for the features since 2026.50: Products and PAT, rejected lots, expiry thresholds, the LotWarden log across the years, records kept, the CAPA register closed with a signature, Dates in Use from the QC record, signed in by name
2026.55	26/10/2026	The Login follows the person's name as it is typed
2026.54	25/10/2026	Named logins in every copy; expiry thresholds per department and per supplier; the CAPA register (nonconformities and corrective actions, ISO 15189 8.7)

53 earlier releases, in the workbook's Change control sheet.

8.4.1 Staff are named at each step

In order

Receipts and Dates in Use name the person; QC is signed in Unity Real Time

Where: Receipts, Dates in Use; Unity Real Time for QC

The reviews signed off in the period

REVIEW	SIGNED OFF BY	WHEN	NOTE
Weekly review, week of 21/09/2026	AB	30/10/2026 17:37	Queue reviewed

Their electronic signatures

Weekly review, week of 21/09/2026

✓ **Electronically signed by Alex Bennett (demonstration), Senior scientist**
26/09/2026 17:37 on the licensed PC (+10:00)
Meaning: Signed off: Weekly review
Signature S-a4d30560b74565d3, account ab.demo, key generation 1: Valid, checked 26/09/2026

8.4.1 Records are protected from change and loss

In order

Originals kept untouched, a backup before every write, and 54 audit records verified

Where: Audit trail

RECORD	ITS STATE
Audit trail	54 records, hash chain verified
Network audit log	verified; 0 blocked outbound attempt(s) in the period

8.4.3 **Records are kept for at least 4 years (NPAAC)** For information

Keep this pack, the controlled logs and archived_logs for at least 4 years, and longer where legislation or contracts require.

Where: NPAAC Requirements for the Retention of Laboratory Records and Diagnostic Material

---

LotWarden **LotWarden sent nothing off the licensed PC** In order

None

Where: Network audit log

LotWarden **LotWarden is authorised on the licensed PC** In order

licensed, DEMO Pathology Laboratory, term ends 07/12/2026

Where: Authorisation

7 Bring separately

5 items

Evidence held outside LotWarden that the assessor will ask for.

6.6.1 A written procedure for buying, receiving, storing and checking reagents

Bring separately

Not held in LotWarden.

Where: The laboratory's reagents and consumables procedure

6.6.2 Storage temperatures are monitored

Bring separately

Not held in LotWarden.

Where: Refrigerator, freezer and room temperature records, and any corrective actions

6.6.5 Instructions for use are available, and changed kit inserts reviewed

Bring separately

No changed kit inserts recorded; show where current instructions are kept

Where: Receipts; the instructions for use

6.6.6 Faulty reagents and recalls are reported and acted on

Bring separately

Not held in LotWarden. 6 removal row(s) in the period are listed.

Where: Incident register, reports to the TGA and manufacturer, recall notices and actions

6.6.7 e Records for reagents made up in-house

Bring separately

Not recorded in the receipt logs.

Where: Preparation records, if the laboratory prepares reagents

8 How this pack was made

The details the workbook's Start here carries, word for word.

Prepared	26/09/2026 by AB
Regime	NATA assessment, ISO 15189:2022 (nata15189)
Signatures	Initials are the record's signature, in the logs LotWarden writes and in the records it keeps; they are not an electronic signature in the sense of PIC/S Annex 11 clause 14. The laboratory validates LotWarden for its own use.
Software	Release 2026.59 · ca5ac71 · 29/10/2026
Section versions	Reader 9.1 · Routing 5.1 · Log writer 11.1 · Pre-acceptance 5.0 · Security 9.3 · Interface 22.4 · Stock outlook 15.2 · Regime 2.0 · Acceptance record 1.3 · Accounts 3.0 · Cellular therapy 1.1 · CAPA register 2.0
Authorisation	licensed, DEMO Pathology Laboratory, term ends 07/12/2026 (machine TEST-0000)
Audit trail	54 records, hash chain verified
Network audit log	verified; 0 blocked outbound attempt(s) in the period
Logs read	Cal/QC log: 7d479d4085ece0bc_DEMO Cal - QC Log 2026.xlsx; Reagent log: b2e831405ed45708_DEMO Reagent Log 2026.xlsx
PAT register	20260926_DEMO Stock Report.xlsx, loaded 26/09/2026 17:37
PAT scope	54 product(s) need PAT; 2 ticked exempt on the product list

Notes

Red rows: act on or explain before the assessment. Amber rows: check them. The reason is in the To review column, and a red sheet tab has rows to review.

Every heading row has filters, and dates sort as dates.

Read from the working copies of the logs loaded in LotWarden when the pack was prepared; working copies must be transferred to the controlled logs.

Only audit records vouched for by the hash chain are included, and records for other departments are left out.

PAT is done only for products the PAT register lists; the others are exempt and not counted against PAT.

PAT verdicts come from the acceptance register loaded when the pack was prepared, not as it stood on the day each lot arrived.

QC is run when each lot is put into use and recorded in Unity Real Time, so a blank QC column in a log is not flagged; QC recorded as not acceptable is.

Nothing in the logs or the app was changed to prepare this pack.

9 Checklist status and signatures

Every question in this pack and where it stands, then who prepared the pack and the signatures it holds.



In order: 8 Check: 4 Partly covered: 4 Bring separately: 5 For information: 2

AREA	IN ORDER	CHECK	PARTLY COVERED	BRING SEPARATELY	FOR INFORMATION
Deliveries	2		1		
New lots, PAT and QC		4	1		
Using and removing stock	1		1		1
Suppliers			1		
Records and software	5				1
Bring separately				5	
Every question	**8**	**4**	**4**	**5**	**2**

Still to check, or partly covered

CLAUSE	QUESTION	STATUS
6.6.7 a, b	Each delivery records the product, lot and supplier	Partly covered
6.6.3	New lots needing PAT are accepted on the PAT register	Check
6.6.3	No lot went into use before PAT acceptance	Check
6.6.4	Stock not yet accepted is kept apart	Check
6.6.7 d	Records show each lot was accepted, at first and ongoing	Partly covered
8.7, 8.5, 7.3.7.2	Nonconformities are recorded, their causes found, actions taken and effectiveness checked	Check
6.6.7 c	The date a lot was finished or withdrawn is recorded	Partly covered
6.8.3	Suppliers are evaluated	Partly covered

The signatures that made this pack

1 electronic signature in the records of this pack, each checked when the page was made: 1 valid. Each is shown in full beside its record above.

RECORD	SIGNED BY	WHEN	MEANING	CHECK
Weekly review, week of 21/09/2026	Alex Bennett (demonstration), Senior scientist	26/09/2026 17:37	Signed off: Weekly review	Valid

Prepared on 26/09/2026 at 17:37 by Alex Bennett (demonstration), Senior scientist (AB), from the records LotWarden held then. Preparing a pack is not an electronic signature: the person who prepared it and the person who checks it sign here.

Prepared by Alex Bennett (demonstration), Senior scientist (AB)

_____

_____

Signature, then date. Name, printed:

_____

Checked by the quality manager before the assessment

_____

_____

Signature, then date. Name, printed:

_____