<Date/Time>
IVD v1.2.0.0

Logo

<Username>

Bay 1

Create Run

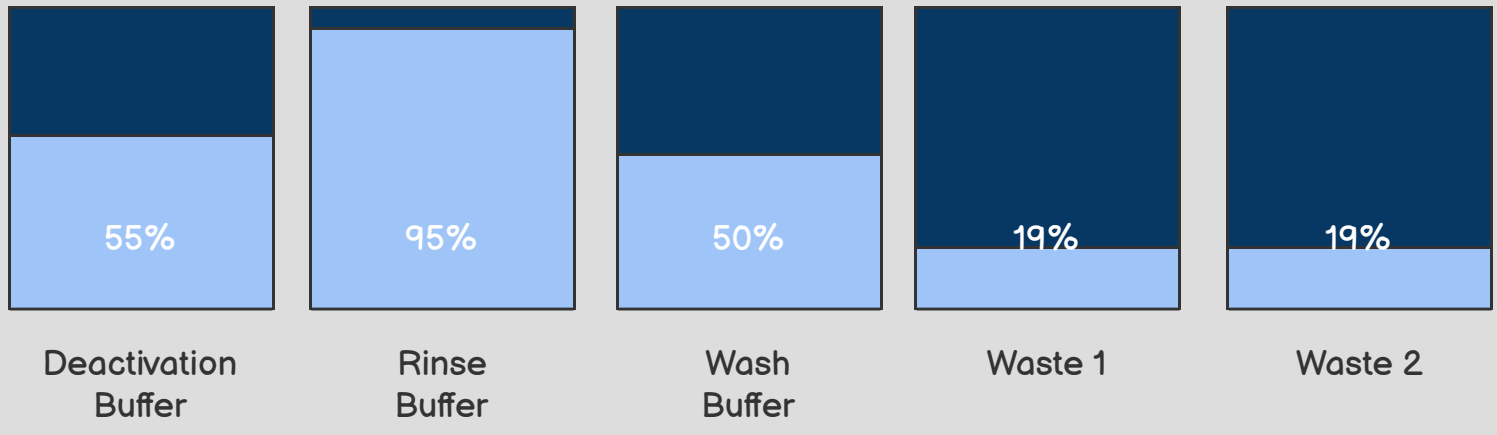
Bay 2

Create Run

Bay 3

Create Run

Bulks



<Date/Time>
IVD v1.2.0.0

Logo

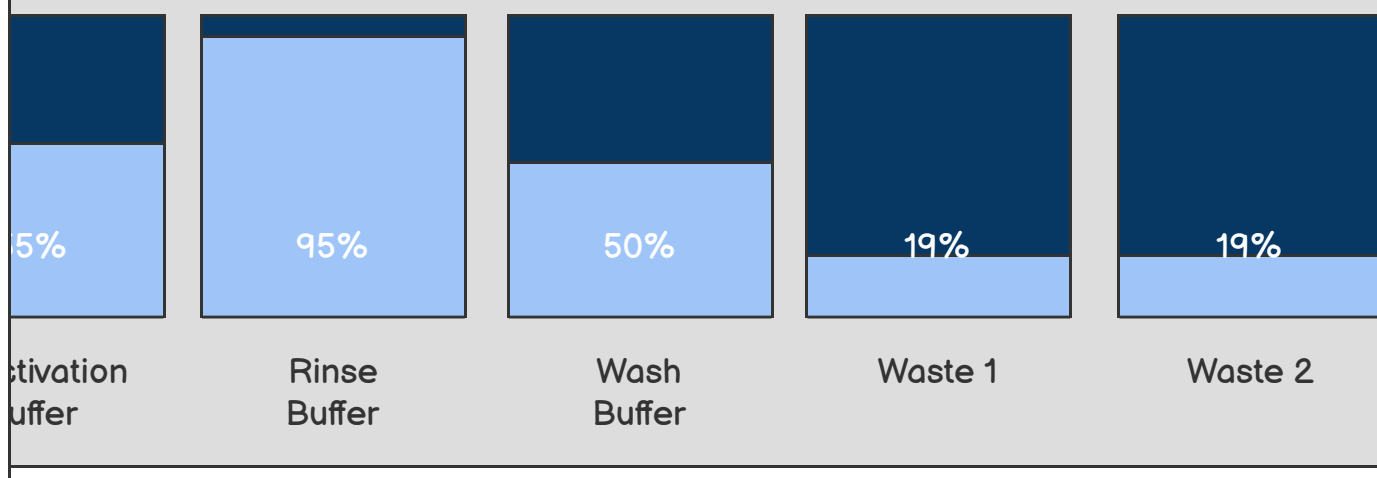
<Username>

- Home
- Results
- Assays
- Quality Controls
- System Events
- Reports
- Maintenance
- Settings
- Support
- Users
- LIS

Create Run

Create Run

Create Run



<Date/Time>
IVD v1.2.0.0

Logo

<Username>

Home | Results | Assays | Settings | Tools

Bay 1

Create Run

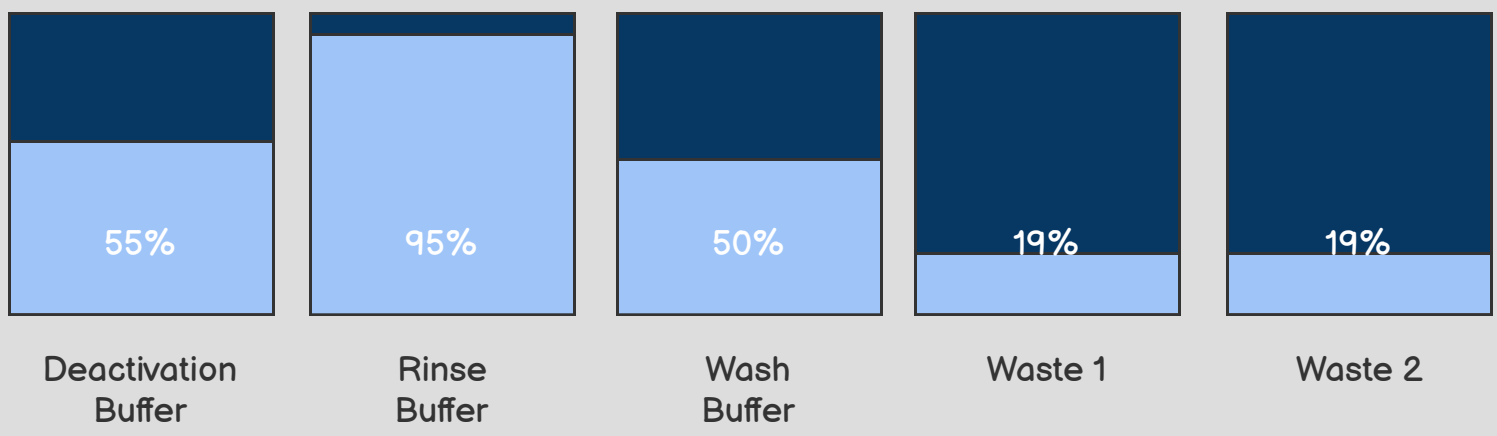
Bay 2

Create Run

Bay 3

Create Run

Bulks



<Date/Time>
IVD v1.2.0.0

Logo

<Username>

Bay 1

Create Run

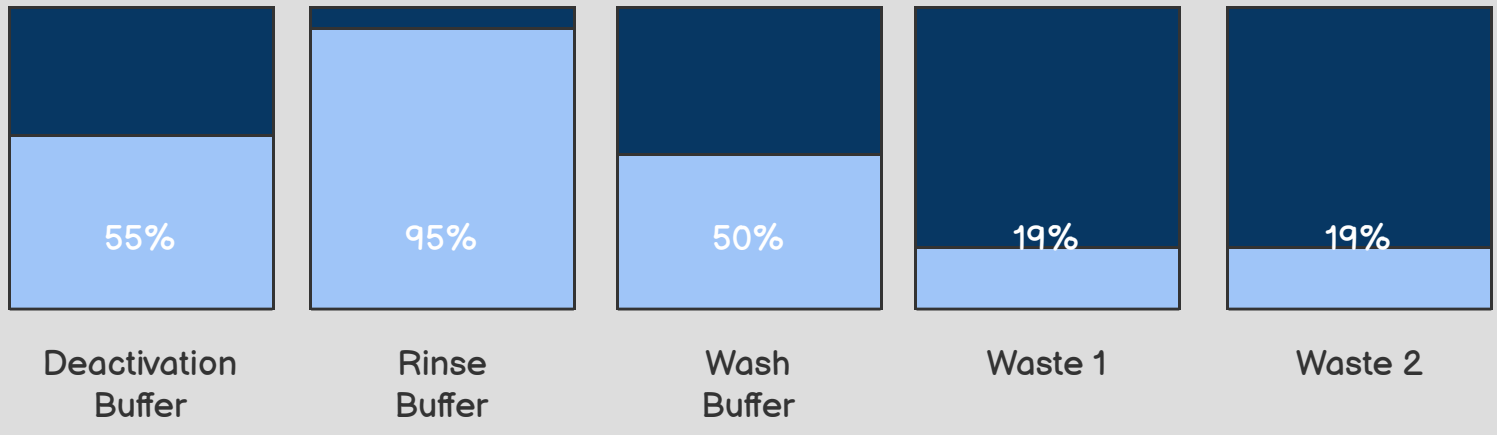
Bay 2

Create Run

Bay 3

Create Run

Bulks



Home | Results | Assays | Settings | Tools

<Date/Time>

IVD v1.2.0.0

Logo

<Username>

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Bay 1

Create Run

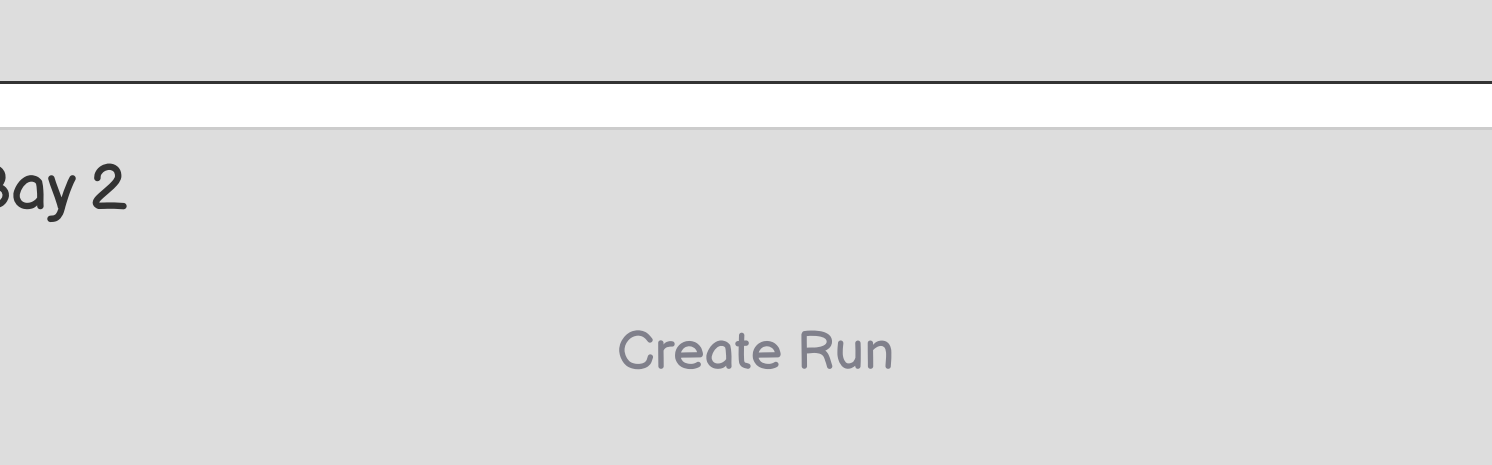
Bay 2

Create Run

Bay 3

Create Run

Bulks



<Date/Time>
IVD v1.2.0.0

Logo

<Username>

Home | Results | Assays | Settings | Tools

Create Run

Assay: *Assay 1*

Run Name: 20250825-1515_Bay2_Assay1

Edit Sample Sheet

Total Sample Volume (uL): 71

	1	2	3	4	5	6	7	8	9	10	11	12
A	○	○	○	○	○	○	○	○	○	○	○	○
B	○	○	○	○	○	○	○	○	○	○	○	○
C	○	○	○	○	○					○	○	○
D	○	○	○	○	○					○	○	○
E	○	○	○	○	○					○	○	○
F	○	○	○	○	○	○	○	○	○	○	○	○
G	○	○	○	○	○	○	○	○	○	○	○	○
H	○	○	○	○	○	○	○	○	○	○	○	○

Plate control here will have the same functionality as the existing RUO version.

Cancel | Finish

Import Sample Layout

<Date/Time>
IVD v1.2.0.0

Logo

<Username>

Home | Results | Assays | Settings | Tools

Sample Sheet

Import Sample Sheet

Well^	Sample Type	Sample Name	Matrix Type
A1	Sample 1	Patient	Serum
A2	Sample 2	Patient	Serum
A3	Sample 3	Patient	Serum
A4	Sample 4	Patient	Serum
A5	Sample 5	Patient	Serum
A6	Sample 6	Patient	Serum
A7	Sample 7	Patient	Serum
A8	Sample 8	Patient	Serum
A9	Sample 9	Patient	Serum
A10	Sample 10	Patient	Serum
A11	Sample 11	Patient	Serum
A12	Sample 12	Patient	Serum
B1	Control Pos	Control	Serum
B2	Control Net	Control	Serum
B3	Calibrator Hi	Calibrator	Serum
B4	Calibrator Mid	Calibrator	Serum
B5	Calibrator Low	Calibrator	Serum
B6	UDC-1	Control	Serum
B7	UDC-2	Control	Serum
B8	Sample 13	Patient	Serum
B9	Sample 14	Patient	Serum
B10	Sample 15	Patient	Serum

Cancel Apply

<Date/Time>
IVD v1.2.0.0

Logo

<Username>

Home | Results | Assays | Settings | Tools

Bay 1

Run ID
20250822-1305_Bay1_Assay1

Assay
Assay1

Load Run

Should the user be able to view / review the configured run?

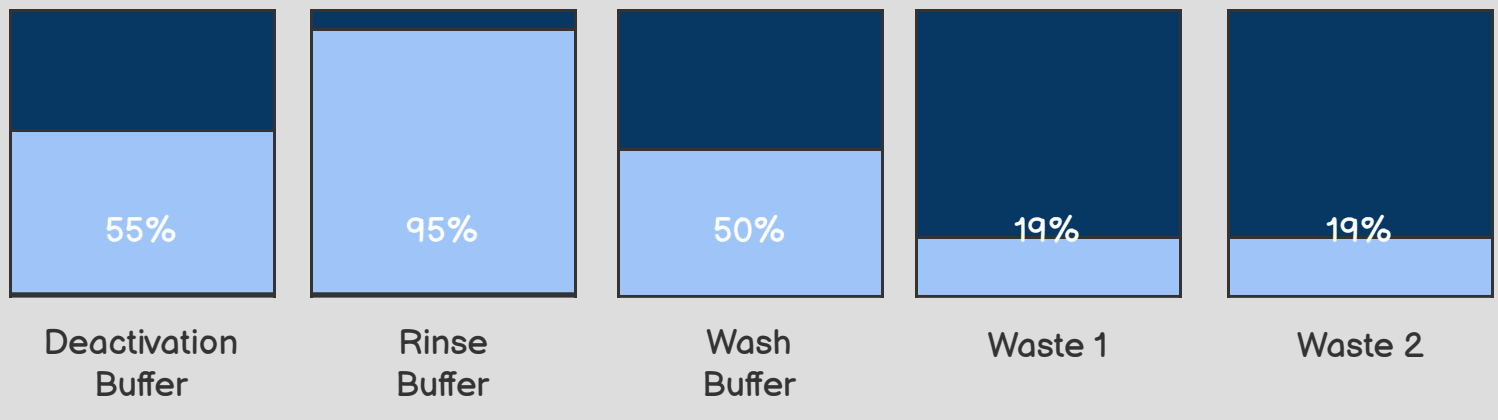
Bay 2

Create Run

Bay 3

Create Run

Bulks



Cancel Run Group

Start Run Group

<Date/Time>
IVD v1.2.0.0

Logo

<Username>

Home | Results | Assays | Settings | Tools

<-- Back

Bay 2

Run ID
20250822-1305_Bay1_Assay1

Assay
Assay1

Edit Sample Sheet

Is there any chain of custody from the sample plate to the run definition?

LOAD

- [ ] 1 Detection Plate
- [ ] 2 Target Plate
- [ ] 3 Sample Plate
- [ ] 4 Consumables Cartridge
- [ ] 5 Two Tip Boxes

- [ ] ALL ITEMS LOADED

Close Bay Door

<Date/Time>
IVD v1.2.0.0

Logo

<Username>

Home | Results | Assays | Settings | Tools

Bay 1

Run ID
20250822-1305_Bay1_Assay1

Assay
Assay1

Ready to Run

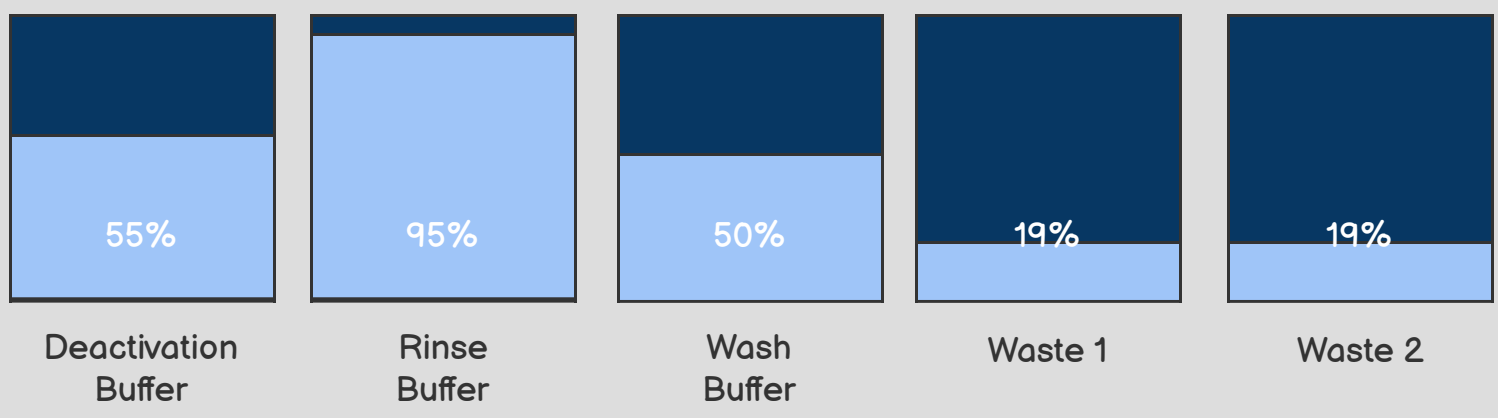
Bay 2

Create Run

Bay 3

Create Run

Bulks



Cancel Run Group

Start Run Group

<Date/Time>

IVD v1.2.0.0

Logo

<Username>

Home | Results | Assays | Settings | Tools

Bay 1

Run ID
20250822-1305_Bay1_Assay1

Assay
Assay1

Running...

Time Remaining:
1:45

Estimated Completion:
5:30 PM

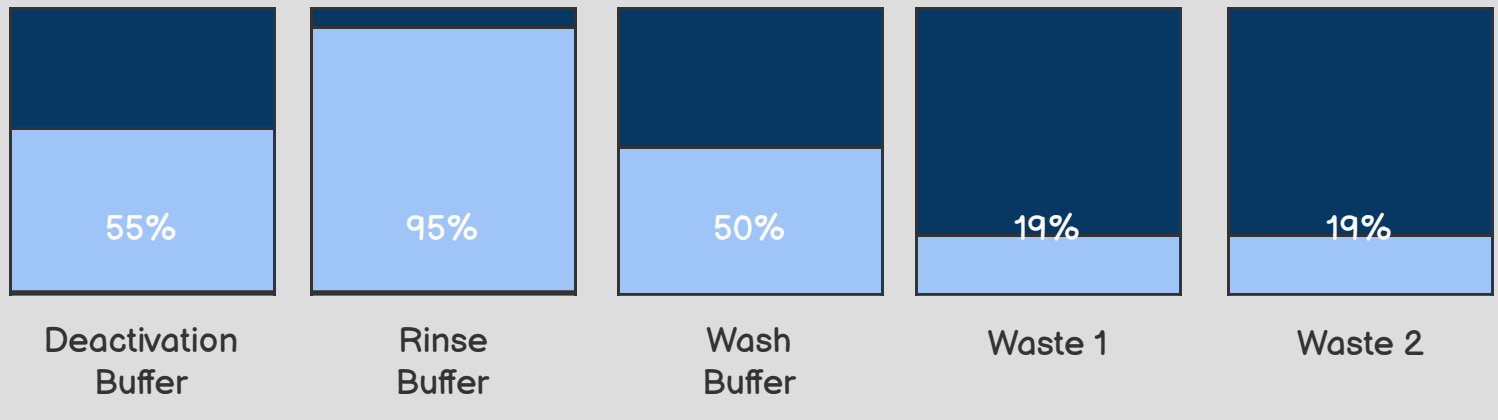
Bay 2

Create Run

Bay 3

Create Run

Bulks



Cancel Run Group

Start Run Group

<Date/Time>
IVD v1.2.0.0

Logo

<Username>

Home | Results | Assays | Settings | Tools

Bay 1

Run Complete - Unload

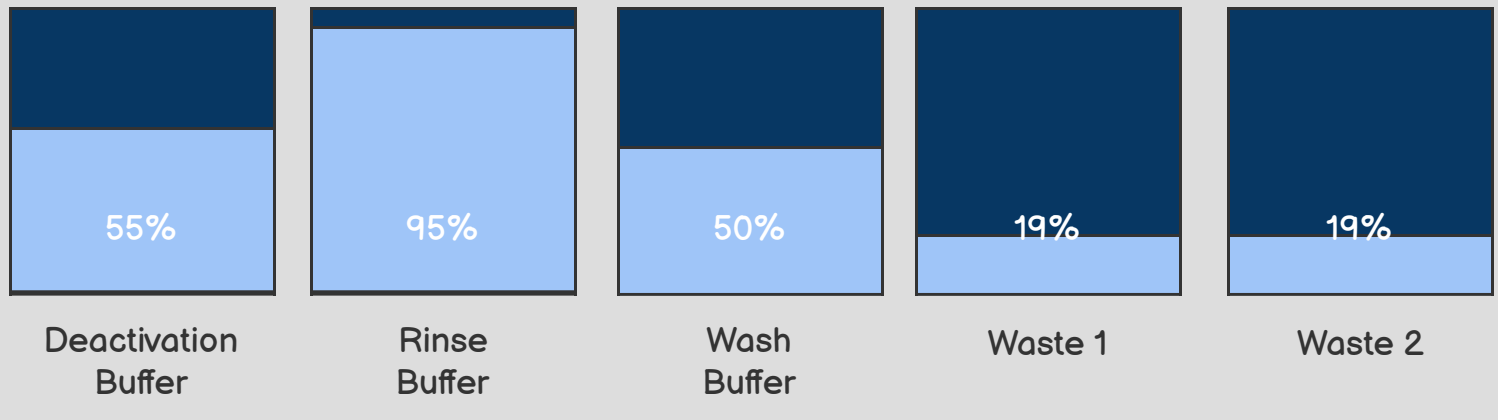
Bay 2

Create Run

Bay 3

Create Run

Bulks



Cancel Run Group

Start Run Group

<Date/Time>
IVD v1.2.0.0

Logo

<Username>

Home | Results | Assays | Settings | Tools

Bay 1

Run Complete - View Results

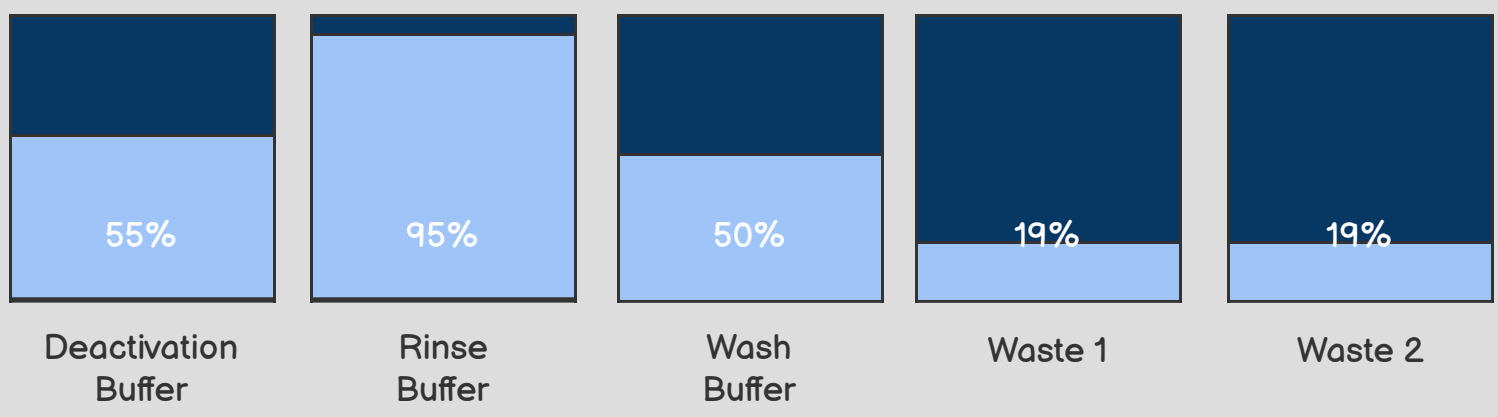
Bay 2

Create Run

Bay 3

Create Run

Bulks



Cancel Run Group

Start Run Group

<Date/Time>
IVD v1.2.0.0

Logo

<Username>

Home | Results | Assays | Settings | Tools

Today | Filter | View Curves | Export | Report

	Run Name	Assay(s	Bay	Run Completion	Status	Operator	Approval Status
☐	AAA08/12/2025Run001	Assay 1	Bay 1	08/12/2025 11:15 AM	Complete	Admin1	Approved
☐	AAA08/12/2025Run00	Assay 1	Bay 1	08/12/2025 12:12 P	Complete	Internal	Operator Approval Require
☐	T808/12/2025Run003	Assay 2	Bay 2	08/12/2025 3:15 PM	Aborted	Operator	Rejected
☐	T908/12/2025Run004	Assay 3	Bay 3	08/12/2025 4:15 PM	Complete	Admin1	Approved

<Date/Time>
IVD v1.2.0.0

Logo

<Username>

Home | Results | Assays | Settings | Tools

<- Back | View Curves | Export | Report

	Position	Sample ID	Result	Detected Targets	Release Status
☐	1	Negative Control	Valid		Not Released
☐	2	Positive Control	Valid		Not Released
☑	3	Sample 1234	Negative		Not Released
☑	4	Sample XXYYYZZZ	Positive	Target 1	Not Released
☐	5	Sample WWWWWWWW	Invalid		Not Released

<Date/Time>
IVD v1.2.0.0

Logo

<Username>

Home | Results | Assays | Settings | Tools

Show Active Assays Only

Deactivate Assay | Import Assay

Assay Name^	Version	Description	Status	Release Date	LIS Identifier	
Assay 1	1.0.1	First Assay	Active	08/26/2015	TST	
Assay 2	3.0.1	Second Assay	Active	08/26/2015	EBG	

<Date/Time>

IVD v1.2.0.0

Logo

<Username>

Home | Results | Assays | Settings | Tools

General ->

Run Settings ->

User Management ->

Network Shares ->

Database ->

Quality Controls ->

LIS ->

<Date/Time>

IVD v1.2.0.0

Logo

<Username>

Home | Results | Assays | Settings | Tools

Language

English (United States)

Date/Time Settings

System Date

08/11/2025

System Time

11 : 15 PM

Time Zone

(UTC-05:00) Eastern Time (US & Canada)

Adjust for daylight saving time

Cancel Apply

Date Format

MM/dd/yyyy

Time Format

h:mm tt

Lab Information

Lab Name

RND Labs Inc.

Lab Address 1

1234 Main St

Lab Address 2

Fishers, IN 46038

<Date/Time>

IVD v1.2.0.0

Logo

<Username>

Home | Results | Assays | Settings | Tools

Run Workflow

Run Approval Required

Administrator Approval Required

Require Sample ID Double Entry

Allow Expired Reagents and Test Strips

Allow Used Reagents and Test Strips

Allow deselection of Assay Targets

Sample Result Settings

Show Sample Ct Results

Show Sample Melt Temp Results

Show Sample Curve Results

Auto Generated Run Name

Run Name Options

Operator Initials

Add Run Name Option

Selected Run Name Options

Selected Assays

Current Date

*Assay(s) Run Sequence Number

* Required

Example Run Name

AS1-AS2-05-Aug-2025-Run001

Cancel

Apply

<Date/Time>

IVD v1.2.0.0

Logo

<Username>

Home | Results | Assays | Settings | Tools

Users

Show Active Users Only

Add User | Edit User

First Name^	Last Name	Role	User Name	Active
Mouse	Mickey	Administrator	mickey	☑
Mouse	Minnie	Operator	minnie	☑

<Date/Time>

IVD v1.2.0.0

Logo

<Username>

Home | Results | Assays | Settings | Tools

Network Drives

Server Name^	Server Path	Local Path
\FileShare	Exports	Z:\
\FileShare	Imports	X:\

Add Remove

<Date/Time>
IVD v1.2.0.0

Logo

<Username>

Home | Results | Assays | Settings | Tools

Network Drives

Add Network Drive

Server Name: \FileShare

Server Path: Images

User Name: labuser

Server Password: **********

Local Path: F:\

Connect | Cancel

<Date/Time>

IVD v1.2.0.0

Logo

<Username>

Home | Results | Assays | Settings | Tools

Automatic Backup Configuration

Recurrence: Monthly

Time of Day: 12:00 AM

Day of Week: Sunday

Backup File Location: D:\Backups\

Browse

Database Actions

Backup Database

Restore Database

Purge

<Date/Time>
IVD v1.2.0.0

Logo

<Username>

Home | Results | Assays | Settings | Tools

<- Back

User-Defined Quality Controls

Settings | Filter | Add Control | Edit Control

Assay	Control Name	Sample IDs	Last Run	Run Expiration	Lot #	Active
Assay 1	My Control1	C11111111 D2222222222	5/15/2024 2:15 PM	6/15/2024 2:15 PM	123456	☑
Assay 1	My Control1	B444444444	4/30/2024 12:34 PM	5/30/2024 12:34 PM	123456	☑
Assay 2	My Control2	H55555444	5/28/2024 9:17 AM	6/28/2024 9:17 AM	123457	☑
Assay 3	My Control3	ABC123456	Expired	6/28/2024 8:45 AM	123458	☑
Assay 3	My Control3	ABC123457	Never Run		123458	☑
Assay 4	My Control4	ABC123458	Last Run Failed		123410	x
Assay 4	My Control4	ABC123459	Expired	5/29/2024 8:05 AM	123411	☑
Assay 4	My Control5	ABC1234510	5/30/2024 10:59 AM	6/30/2024 10:59 AM	123412	☑
Assay 4	My Control5	ABC1234510	5/27/2024 8:45 AM	6/27/2024 8:45 AM	098765	☑

<Date/Time>
IVD v1.2.0.0

Logo

<Username>

Home | Results | Assays | Settings | Tools

<- Back

User-Defined Quality Controls

Settings | Filter | Add Control | Edit Control

Assay	Control Name	Sample IDs	Last Run	Run Expiration	Lot #	Active
Assay 1	My Control1	C11111111 D2222222222	5/15/2024 2:15 PM	6/15/2024 2:15 PM	123456	☑
Assay 1						☑
Assay 2						☑
Assay 3						☑
Assay 3						☑
Assay 4						x
Assay 4						☑
Assay 4						☑
Assay 4						☑

User-Defined Quality Controls Settings

Run Frequency — Days: 30 — Lot Frequency

Allow run to proceed without valid user-defined control(s)

Cancel | Apply

<Date/Time>
IVD v1.2.0.0

Logo

<Username>

Home | Results | Assays | Settings | Tools

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User-Defined Quality Controls

Settings | Filter | Add Control | Edit Control

Assay	Control Name	Sample IDs	Last Run	Run Expiration	Lot #	Active
Assay 1		C11111111	5/15/2024	6/15/2024		☑
Assay 1						☑
Assay 2						☑
Assay 3						☑
Assay 3						☑
Assay 4						x
Assay 4						☑
Assay 4						☑
Assay 4			8:45 AM	8:45 AM		☑

Filters

Assay
Select Assay

Active Only

Quality Control Name
Enter Quality Control Name

Quality Control Status
Select Quality Control Status

Lot Number
Enter Lot Number

Clear | Apply

<Date/Time>
IVD v1.2.0.0

Logo

<Username>

Home | Results | Assays | Settings | Tools

<- Back

User-Defined Quality Controls

Settings | Filter | Add Control | Edit Control

Assay	Control Name	Sample IDs	Last Run	Run Expiration	Lot #	Active

Add User-Defined Quality Control

Assay: First Assay

Name:

Add Sample ID Mapping:

Add Mapping

Remove Mapping

Sample ID Mappings

Target Results

Assay Target	Expected Result
Target 1	(•) Positive ( ) Negative
Target 2	(•) Positive ( ) Negative
Target 3	(•) Positive ( ) Negative
Target 4	( ) Positive ( ) Negative

You must set all expected results to Positive or Negative

Cancel | Add Control