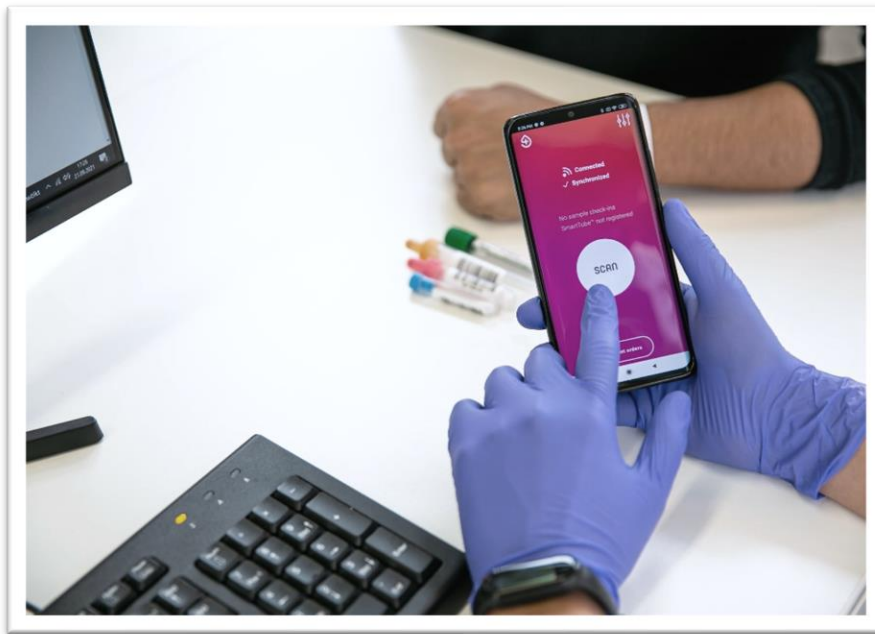




Smart.Safe.Samples™

The new quality standard in preanalytics



Operating Manual

Samples App and Browser Scan

Version 5.0

Revised on 10.12.2024

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We only support problems that are attributable to the application introduced in this operation manual.

This software is subject to version upgrades without prior notice due to the technical advancement of the application. The customer can receive, and use upgraded versions of this application through a method determined by us. Note that version upgrades will be limited to customers who consent to the aforementioned conditions of use.

1 PRODUCT DESCRIPTION AND SPECIFICATION

1.1 Name and address of the manufacturer

S4DX GmbH

Rupert-Mayer-Str. 44

D-81379 München

Germany

1.2 Intended purpose and user






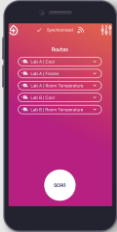
The Samples App and Browser Scan are intended for registration of biological specimens at collection sites such as doctors' offices, clinics, and hospitals. Samples can be linked to SmartTubes for transport monitoring.

The Samples app is highly configurable and offers various features: (i) identification and verification of patients, (ii) annotation of orders with information about the health status of the patients, (iii) instructions for drawing and the required sample containers, (iv) display of pre-analytical guidance, (v) cross-checking of samples belonging to orders (retrieved from LIS), (vi) annotation of samples with information on filling volume, difficulty during blood collection, etc., (vii) registration of collection time, and (viii) feedback for the completeness of orders or for missing samples. The Samples app is also capable of pre-fetching order information for use in offline mode in areas with poor internet coverage.

The data collected and processed by S4DX is not intended for use in any clinical, therapeutic, analytical, or diagnostic purposes and only serve to manage preanalytical sample workflow processes. Therefore, the requirements regarding clinical and analytical performance are not applicable here.

1.3 Overview of the S4DX GmbH product family

This section describes the S4DX product family with an overview of its application and classification in the overall system with a focus on hardware components. Within the product family, this document focuses on the functionality of "Samples App" and the "Browser Scan".

 <p><u>SmartTube</u></p> <p>Used to monitor the storage and transport of biological samples and record environmental factors (temperature, vibration).</p>	 <p><u>S4DX Browser Scan</u></p> <p>Used for web browser-based registration of biological samples.</p> <p>Functional with barcode handscanner.</p>
 <p><u>Gateway</u></p> <p>Offers automatic and contactless data transmission from the SmartTube® Datalogger in the entrance of the laboratory.</p>	 <p><u>Samples App</u></p> <p>Used for the mobile-app-based registration of biological samples.</p> <p>Available for Android and iOS.</p>
 <p><u>S4DX Webservice</u></p> <p>The central platform for digital preanalytics, used for data exchange with the LIS and convenient data analytics and visualization.</p>	 <p><u>Courier App</u></p> <p>Used for digital transport tracking compatible with all common transport containers and methods.</p> <p>Available for Android and iOS.</p>

1.4 Workflow - from blood drawing to sample check-in in the laboratory

Sample Workflow with S4DX



Figure 1. S4DX Workflow

Description of the workflow using the S4DX product family for digital preanalytics. The process starts with patient preparation before sample collection (1), including preanalytical guidance, and post-collection sample processing (2) using the S4DX Samples App or Browser Scan. It could furthermore also cover sample storage at the collection sites and all possible routes of sample transportation in boxes or bags (3) using the SmartTube Datalogger and Lab Gateway (4, 5).

2 SAMPLES APP

This section explains the operation of Samples App for sample registration at collection sites such as clinics and hospitals. The intended users of this application are health care personnel collecting biological samples in specimen tubes.

Notes:

- Users can lose their data if they work offline or clear the cache of the mobile application.
- The smartphone used for the mobile application should be synced with the current time.

2.1 APP Download and Sign in

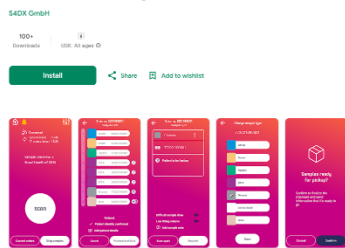
2.1.1 Installation

Install the S4DX Samples App on your smartphone or tablet by scanning one of the following QR codes.



or by searching "S4DX Samples" in the respective stores.

S4DX Samples



App support
More by S4DX GmbH →
S4DX Counter
S4DX GmbH



Note: For mobile device requirements, refer to Annex I technical specification.

2.1.3 Password set-up

You will receive an email with the defined user account to set up the password. Set up the password according to the instructions in the email.

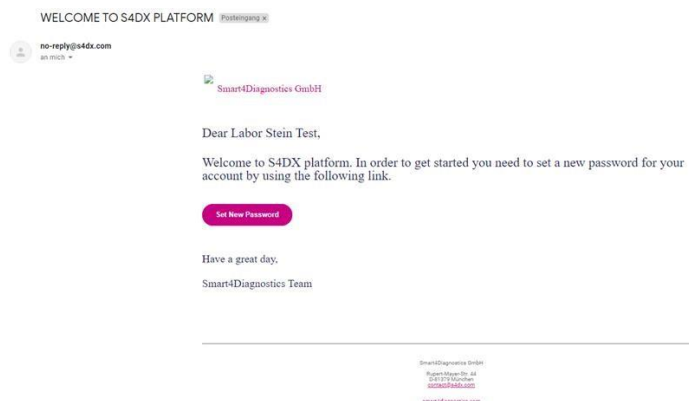




Figure 2. Email to set up password

The email address of the user accounts is defined by the respective organization. The password set-up email will be

- sent by no-reply@s4dx.com
- with the subject line: Welcome to S4DX Platform.

2.1.4 Sign in

Enter the user account in the “E-mail” field and the password in the “Password” field (see Figure 3) and tap the  button to login. Contact your internet provider or institutional help desk if you require additional help connecting to the internet.

- Use the  icon to verify the entered password when needed.
- Upon successful login, the Samples App home screen will load.

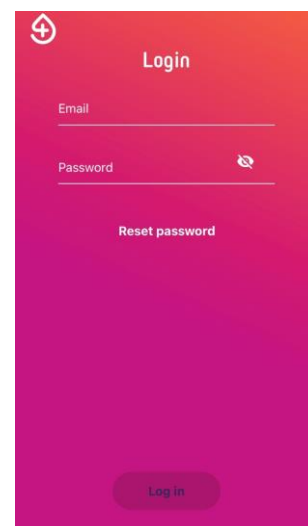


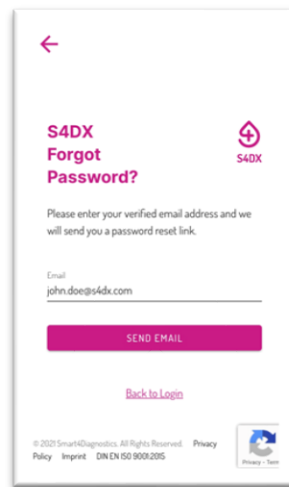
Figure 3. User sign in

Note:

If you enter incorrect log-in credentials (wrong password and/or wrong email address), an error notification will appear at the bottom of the screen. In this case, you can re-enter or reset the password.

To reset the password:

- a) Tap on the **Reset password** button (see Figure 3).
- b) Enter the connected email address and tap "SEND EMAIL" (see the figure below).



- c) Follow the instructions received in the email to reset the password. The password reset email will be sent
 - from no-reply@s4dx.com
 - with the subject: Welcome to S4DX Platform.

2.1.5 User guide

After successful log-in to the Samples App for the first time after installation, the App will guide you through the general workflow (see the figures below).

After reading the information on each screen, you can swipe right to access the following pages.



2.1.6 Terms and policies

After displaying the user guide, the terms and policies of the Samples App will be displayed.

- Tap on both check boxes to accept the terms and policies and the end-user license agreement.
- Finally, tap on the button "Continue" to start using the Samples App.

If you do not agree with any of the terms and policies or the end-user license agreement, you will not be able to access the Samples App.

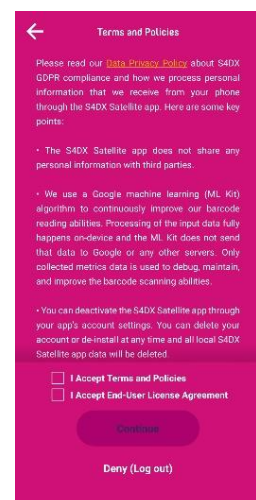


Figure 4. Terms and Policies

2.2 SmartTube registration

Before collecting biological samples, you should register the SmartTube(s). By assigning a SmartTube to a particular route, the SmartTube will be virtually linked to that route and will collect and store its transport parameters such as temperature and shock events.

Notes:

- Registering a SmartTube is only enabled for users with the SmartTube function (one SmartTube per shipment)
- Registering multiple SmartTubes to various routes is only for users with simultaneous SmartTube function enabled.
- If your organization uses the Courier App for transport monitoring, Samples App users do not have to register the SmartTube, and can proceed to chapter 2.3.
- Organizations that do not use the Courier App for transport monitoring should follow the steps below.

2.2.1 Scan SmartTube

- a. To start scanning, tap the "SCAN" button (see Figure 5).
- b. Place the SmartTube in front of the smartphone/tablet so that its camera faces the barcode attached to the SmartTube, and hold still for 1-2 seconds. (See Figure 6).

Note: tap the barcode in the camera view to focus on the barcode.

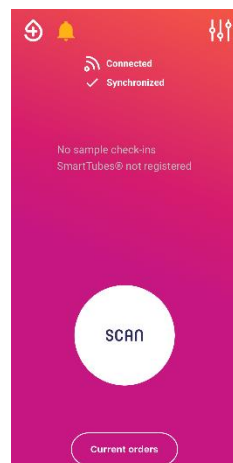



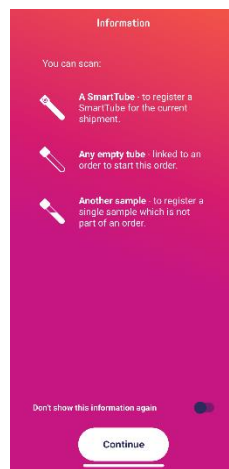
Figure 5. Home screen



Figure 6. Scan SmartTube

Note:

- The first time you are using the Satellite App, the mobile device will ask for an approval to access the camera. Tap "OK" to enable the Satellite App's camera access to use the scan function of Satellite App.
- The first time you are using the Satellite App, an information screen will appear to guide you through the different scanning possibilities of the Satellite App (see the figure below).
 - Tap on the button "Continue" to continue scanning
 - Or tap the button  to disable this information page for the following scans.





2.2.2 Register SmartTubes

To register SmartTubes, there are two ways based on different configurations.

- Users with defined transport routes, proceed to step 2.2.2.1.
- Users without defined transport routes, proceed to step 2.2.2.2.

2.2.2.1 Select route for SmartTube (users with defined transport routes/simultaneous SmartTubes on)

This step is for users whose collection sites have defined the transport routes for the samples.

- a. Tap on the "SCAN" button on the main screen.
- b. Place the relevant SmartTube in front of the camera.
- c. Tap the  button to select the desired route. Only one route may be selected. After a route has been selected, the  button will appear solid, and the "Register" button will be enabled (see Figure 7).

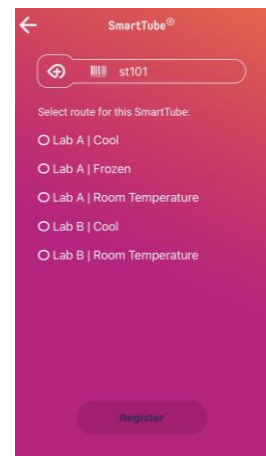


Figure 7. Assign SmartTubes to routes

In this step, a SmartTube is linked to one transport route to facilitate the monitoring of samples with that destination and/or transport conditions.

- d. Tap "Register".

- e. Place the registered SmartTube in the transport container (bag, box) corresponding to the transport route chosen in step c. (See below).



- f. For example, if SmartTube "st101" is registered for the route "Lab A | Cool", then the SmartTube "st101" should be placed in the transport container for Lab A in cooled condition.

Each time the user registers a SmartTube to a transport route, this transport route will be hidden on the SmartTube registration screen the next time it is shown to the user, until all transport routes for sample collection have been registered.

2.2.2.2 Confirm SmartTube registration (users without defined transport routes)

This step is for users whose collection sites have not defined the transport routes for the samples.

Tap the "Register" button to confirm the SmartTube registration (Figure 8).

The number of SmartTubes for each shipment is limited to one.

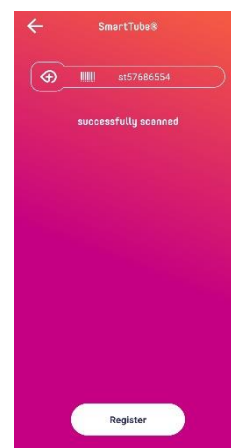


Figure 8. Registered transport routes

2.2.3 Repeat SmartTube registration for additional SmartTubes (if necessary)

- a. Tap the button "SCAN" to start scanning and register a second SmartTube to a second transport route (if any).
- b. Repeat steps 2.2.2 to 2.2.3 to register all remaining SmartTubes.

Each time a SmartTube is successfully registered, the number of SmartTubes will be updated on the home screen.

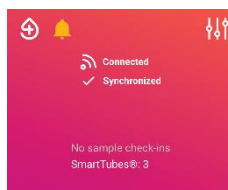


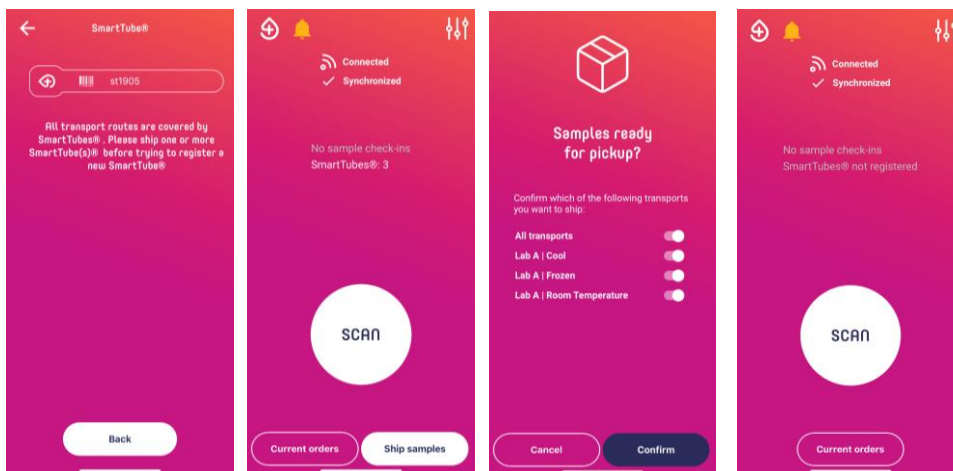
Figure 9. Number of SmartTubes registered

Note:

- Each SmartTube can only be assigned to one transport route. By trying to register an already registered SmartTube again, an error information will appear (see below). Tap "Back" to continue the SmartTube registration with an unregistered SmartTube.



- When all transport routes for sample collection of the current day are covered and user continues scanning further SmartTube, an error information will appear (see below). In this case, if you continue scanning new SmartTubes, you will be asked to first ship the already registered samples and SmartTubes by following the steps:
 - Tap on the button "Back" to return to home screen.
 - Tap on the button "Ship Samples".
 - Tap on the corresponding transport routes of the samples and the button "Confirm" to complete the shipment.
 - The home screen appears and tap on "Scan" to continue scanning SmartTubes.



2.3 Identifying orders and verifying patients

This section explains the process of identifying an order and verifying patient identity to ensure the correct management of the collected samples and to eliminate mismatches between the order(s), sample(s), and the patients. You will have three options to identify an order and can choose freely among them, based on available resources.

Note: The order identifying function is only available to users with the order flow active. Users without this function should refer directly to step 2.4.

The patient verification step is only available to users with patient flow function. User without this function active should skip step 2.3.2 and 2.3.3.

2.3.1 Requesting order information

- a. Tap the button "SCAN" to start scanning.
- b. To request order information (see Figure 10), place one of the following objects in front of the smartphone/tablet such that the camera faces the barcode attached to the object, and hold still for 1-2 seconds.

2.3.1.1 Scan Order ID

After scanning order ID, the order overview will appear.

2.3.1.2 Scan Sample

After scanning a sample that is part of the order you would like to retrieve, the order overview will appear.

The scanned sample tubes could be empty or filled.

2.3.1.3 Scan patient ID

After scanning the patient ID, the order overview will appear.

Patient identification will be automatically confirmed and enabled upon scanning patient ID.

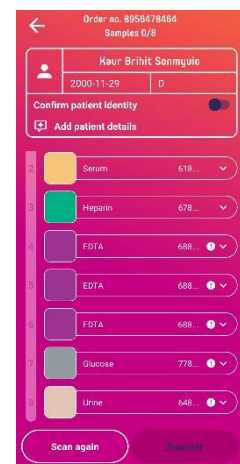


Figure 10. Order information

Note:

- Scanning patient ID to identify order is only available to the users with this function enabled. If scanning patient ID is not available to users, please use other two approaches to identify orders.
- Patient data, such as patient name and birthday, only appears when this function is enabled.

2.3.2 Confirm patient

Users who scan patient ID to confirm the patient identity can skip this step.

- a. Review patient identity to ensure that the order belongs to the correct patient.
- b. Tap on the toggle to confirm patient identity, if the toggle is not yet enabled.



Figure 11. Confirm patient identity

2.3.3 Add patient details (optional)

In certain cases, patient conditions such as pregnancy and drug intake could influence the diagnostic result. In such cases, adding a patient note in the Samples App is recommended to share the information needed for diagnosis with laboratories.

- a. Tap on the field "Add patient details" to start adding patient details.
- b. Tap on the toggle that applies to the patient's conditions and add notes, if necessary. The patient conditions displayed on the screen may vary according to the different configurations of laboratories.
- c. Tap on the button "Save" to save the changes.
After saving the changes, the order overview screen will appear.
For further editing, tap on the field "show patient details".

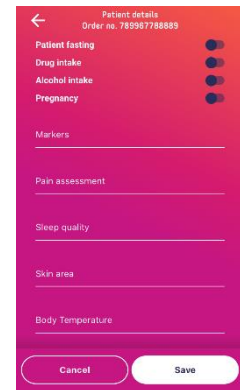


Figure 12. Add patient details

2.4 Sample scanning and registration

This section explains the process of scanning and registering the collected samples. When a sample is registered, the sample information on the home page of the S4DX dashboard will update in real time.

S4DX provides four workflows for sample scanning and registration based on customer requirements:

- basic workflow without order and patient verification
- basic patient flow after order and patient verification
- multiple sample check-in after order and patient verification
- continuous scan after order and patient verification

Refer directly to the relevant workflow, based on the configuration, to complete this step.

2.4.1 Basic workflow for sample registration

This workflow shows the basic steps for sample registration, without order or patient verification.

It applies when:

1. users do not have the patient flow function enabled
2. users scan individual samples without orders

The steps are as follows:

- a.** Tap on the "SCAN" button in the main screen. The camera function of the smartphone/tablet will open automatically.
- b.** Place one sample tube that is part of the order in front of the smartphone/tablet, such that the camera faces the barcode attached to the sample tube, and hold still for 1-2 seconds.
- c.** The sample information page will appear after successful scanning, showing, when available (see Figure 13):
 - i. Pre-analytical handling requirements
 - ii. sample type
 - iii. sample number
 - iv. order identifier
 - v. transport route (availability varies depending on the configuration)
 - vi. additional information regarding sample drawing, filling volume, and notes.
- d.** Edit sample information (optional). (For detailed instructions on adding sample information, refer to the Notes for editing sample information below.)

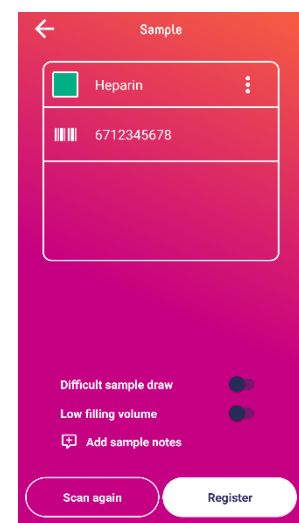



Figure 13. Sample information screen after scanning one sample

For samples without a pre-defined tube code (sample type unknown on the sample information page), choose a sample type. To change sample type, refer to the Notes for editing sample information.

- e.** Tap on the 'Register' button to finish the sample registration.

2.4.2 Basic patient flow after order and patient verification

- a.** To scan the first sample, tap on the  button at the bottom of the Order Overview screen. The camera function of the smartphone/tablet will open automatically.
- b.** Place one sample that is part of the current order in front of the smartphone/tablet such that its camera faces the barcode attached to the sample, and hold still for 1-2 seconds.
- c.** The sample detail page will appear after successful scanning, showing
 - Pre-analytical handling requirements
 - sample type
 - sample number
 - order identifier

- transport route (availability varies depending on the configuration)
 - additional information regarding sample drawing, filling volume, and notes.
- d. Edit sample information (optional). (For detailed operating instructions, refer to the Notes for editing sample information below.)
 - e. Tap on 'Register' to finish the sample registration.
The user can continue scanning the rest of the samples belonging to the same order.

2.4.3 Multiple sample check-in after order and patient verification

A further way of registering samples. This function will be available for users with the workflow "multiple sample check-in" active.

You will see an information screen (see Figure 14) describing the operation instruction of the multiple sample check-in workflow when you navigate to the order overview screen after scanning a patient ID, order ID, or sample ID.

- a. Read the information displayed on the screen.
- b. Tap on the button "Continue" to start sample registration.

Tap on the toggle "Do not show this information again" to prevent this information from further appearing.

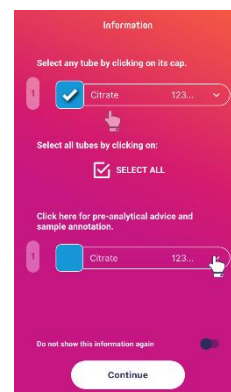



Figure 14. Multiple samples check-in guidance screen

This screen will appear every time you scan an order identifier unless you click the toggle "do not show this information again"

Steps to follow when registering samples with multiple sample check-in functions:

- a.** Tap on the sample(s) that need to be registered on the order overview page after verifying the order and patient ID (see Figure 15).
For users scanning a sample for order and patient verification, this scanned sample will be marked selected. In this case, select the remaining unselected samples.
- b.** Edit sample information (optional). (For detailed instructions on how to add sample details, refer to the Notes for editing sample information below.)
- c.** Tap on "Register" to confirm the sample registration.
You can select all samples in an order by tapping on the  button (see Figure 15).
- d.** By selecting and registering samples, you can confirm that the selected and registered samples of the order have been physically collected and are ready for shipment.

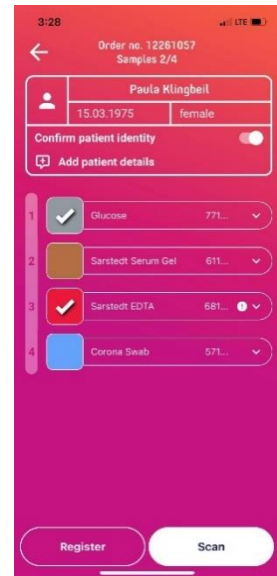


Figure 15. Multiple samples check-in

Notes for editing sample information: For continuous scan, the options for editing sample information including the ones described below are available to the samples that have already been scanned.


- **Add additional information to the sample**

When any of the following situations or other situation that could influence the diagnostic result happens, tap on respective toggles to add additional description to the sample:


- "Difficult sample draw"
- "Low filling volume"

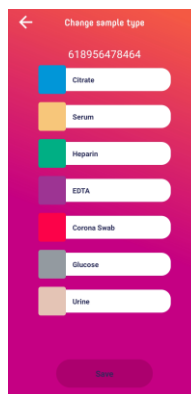
or tap on "Add patient details" to describe the situation that needs to be considered while doing the examination.

For continuous scan and multiple sample check-in,

- Tap on the down-pointing arrow  on the right side of the corresponding sample in Order Overview
- Tap on "Add sample notes" to continue adding additional information to the sample as described above.


- **Change sample type**

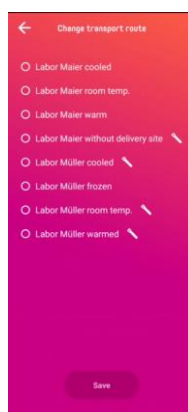
- a) Tap on the down-pointing arrow  on the right side of the corresponding sample in Order Overview.
- b) Tap on "Change sample type" displayed below the sample.
- c) Tap on the desired sample type displayed on the screen
- d) Tap on the button "Save" to save the changes



Change sample type

- **Change transport route**

- a) Tap on the down-pointing arrow  on the right side of the corresponding sample in Order Overview
- b) Tap on "Change transport route" displayed below the particular sample.
- c) Tap on the desired transport route displayed on the screen



Change transport route

2.4.4 Continuous scan after order and patient verifications

A further way of registering samples. This function will be available for users with the workflow "continuous scan" active. When this is selected, the scan and register buttons are disabled until the patient's identity is confirmed. Furthermore, there are also two toggles which can be easily managed on the top of the screen. Below this, there is an option for opening a patient details page.

- a. Tap on "Scan" to start scanning.
- b. Place one unscanned sample that is part of the current order in front of the smartphone/tablet such that its camera faces the barcode attached to the sample tube and hold still for 1-2 seconds.
 - In step 2.3, if you have scanned a sample from the order to verify the order, this sample will appear selected after scanning in continuous scan. In this case, scan an unscanned sample to complete the sample registration of the order.
- c. The camera view will remain open, and a notice will pop up at the top of the screen showing notices for next steps after scanning each sample. The speed at which this notice appears can be selected. You can proceed further, based on the notice.
 - "Success! Sample added." - this notice will appear when unscanned samples from the correct order has been scanned. The user can continue scanning the rest of the samples in the order.
 - "Sample already scanned." - this notice will appear when the user scans a sample for a second time or more times. The user should scan an unscanned sample.
 - "Sample is not part of the order" - this notice will appear when the scanned sample does not belong to the correct order, and the device will vibrate. Then, the user should click on "Dismiss" button in order to be able to scan an unscanned sample belonging to the correct order.



Figure 16. Scanning samples in continuous scan mode

- d. The progress bar on the left side of the screen will progressively turn green as correct samples are scanned. Ticks on the colored caps appear once the sample has been registered.
- e. After the last sample in the order has been scanned, a screen showing "Order complete" will appear. You will then be navigated to the order overview screen.
- f. Tap on "Register" to confirm the sample registration.

Note: Scan samples sharing the same sample number in an order

Follow the steps to complete registering samples sharing the same sample number in an order.


- a) Scan one of the samples that shares the same sample number.
- b) Users are navigated to the screen showing a list of samples sharing the same sample number in this order.
- c) Select the desired sample in the list.
- d) Return to camera view and repeat step a) to c) to complete scanning the samples in the list.
- e) Continue scanning if there are unscanned sample(s) left in the order, until all the samples in this order are scanned and users are navigated to the Order Overview screen.



Scanning samples with same number in an order

2.5 Ship samples

When the samples are ready to be shipped, follow the steps below:

- a. Tap on "Ship samples"  on the home screen.
- b. A screen appears to require a confirmation of the shipment. Tap on "Confirm" to complete the sample shipment.

For users with the SmartTube and Route function enabled, the relevant transport routes appear on the shipment confirmation screen. Select desired transport route(s) to confirm the order shipment.

If any order is incomplete in the shipment, a notification will pop up. Users can choose whether to ship the incomplete order(s) or continue registering the missing sample(s) to complete the order(s).

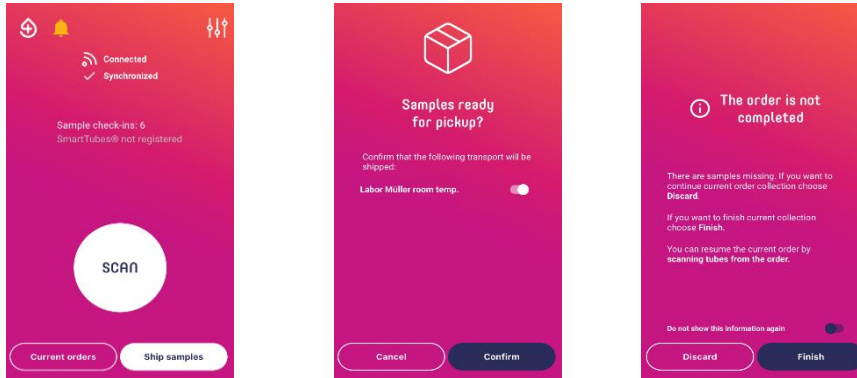


Figure 17. Ship samples

2.6 Scanning and registering pre-barcoded samples

In Samples version 4.4, there is the possibility of scanning and registering pre-barcoded tubes, currently restricted to pre-barcoded Monovettes from Sarstedt. A prefix will appear next to the scanned tube indicating whether the type is pre-barcoded or not, allowing to scan both types in the same order.

When continuous scan cycle is used, the user can scan pre-barcoded tubes, and these are automatically assigned to the sample that requires the scanned tube type.

- a. Scan patient ID in order to retrieve the order data.
- b. A list of all the samples belonging to the order will appear:
 - Samples that require a pre-barcoded tube will appear marked with "pre-xx", being the xx the corresponding prefix in Sarstedt.
 - Samples that do not have pre-barcoded tubes available appear with the suffix of the LIS-generated sample identifier.
- c. After the last sample in the order has been scanned, a screen showing "Order complete" will appear. You will then be navigated to the order overview screen.
- d. Notes can be added to each sample (Optional) and tubes can be unassigned from samples in case of a wrong scan.
- e. Tap on "Register" to confirm the sample registration.



Figure 18. Pre-barcoded and no pre-barcoded list of samples

2.7 Supporting functions

2.7.1 Working without internet:

In case you are using the Samples app without internet, then all the information from sample registration and patient details/comments will be automatically saved and stored, and later updated in the app when it is connected to the internet. SmartTube registration and samples shipment require internet connection.

2.7.2 Prefetch orders:

In cases where the Samples app is used without internet, there is an option for prefetching orders. This allows all order belonging to the collection site and not yet touched to be saved in the local storage of the app in the device. Therefore, the app is fully functional in areas where there is no internet.

3 BROWSER SCAN

This section explains the operation of Browser Scan for sample registration at collection sites such as clinics and hospitals. The intended users of this application are health care practitioners collecting biological samples in specimen tubes.

Browser Scan is part of the S4DX Webservice. Therefore, a general introduction of S4DX Webservice will be provided first.

3.1 General Information about S4DX Webservice

The S4DX Webservice is the central platform of the S4DX digital preanalytical product family. It is a web-based application that aggregates, analyses and visualises the information from the Samples App, Browser scan, Courier App, SmartTube, and LIS/HIS system (if any), and provides sample registration functions.

3.1.1 System overview

The S4DX Webservice has the following functionalities:

- 1) Order management
- 2) Sample management
- 3) SmartTube management
- 4) Browser scan¹
- 5) Transport management
- 6) User management
- 7) Data export
- 8) Search and filter data

3.1.2 User roles and access

Each user of the S4DX Webservice is assigned one or more roles. The following table lists the services or functions of each role and its corresponding explanation and target users.

It is important to note that the roles are not necessarily identical to a person's title and that one person can be assigned several roles.

User role	Access	Target users
Dashboard	S4DX Webservice <ul style="list-style-type: none"> • Only users (usually laboratory users) not assigned to any HCP ² will see the "SmartTubes" function. 	Laboratory users Healthcare practitioners
App (sample registration)	Samples App and Browser scan	Healthcare practitioners
Courier	Courier App	Courier drivers

¹ Refer to Operating Manual Satellite App and Browser Scan.

² Refers to the entity/ clinician requesting the specimen collection and corresponding testing. Associated to the tenant that can have one or several HCP's.

Admin	User management to create, delete, and manage users	Laboratory managers
Patient Data View	The patient information such as name, birthday etc.	Healthcare practitioners

Accesses and user roles are initially set up by S4DX during the onboarding phase and can later be managed by the person assigned the "Admin" role in the laboratory.

Notes:

- Users can lose their data if they clear the cache of the web application.
- The browser used for the web application should be synced with the current time.

3.2 Access to Browser Scan and User Sign In

3.2.1 Set up the password

You will receive an email with the defined user account to set up the password. Set up the password according to the instructions in the email.

The user account to log into S4DX's services is defined by your organisation.

The password set-up email will be

- sent by no-reply@s4dx.com
- with the subject: Welcome to S4DX Platform.

Note: This invitation link to set up the password is only valid within 1 week upon receiving the email. Contact the person with "admin" role of S4DX platform to resend the invitation if the request is overdue.

3.2.2 Enter web address in a browser

Open an internet browser (Google Chrome, Firefox, etc.) and type in the following URL <http://webservices.s4dx.com> in the address bar.

S4DX Webservice is compatible with:

- Operation System: Windows, MacOs, Linux
- Browsers: Google Chrome, Mozilla Firefox, Microsoft Edge

3.2.3 Enter the page

Press the "Enter key" on the keyboard to enter the S4DX Webservice web page.

3.2.4 User sign in

Enter the account credentials in the respective fields and click on the “LOGIN” button to sign in (see Figure 20).

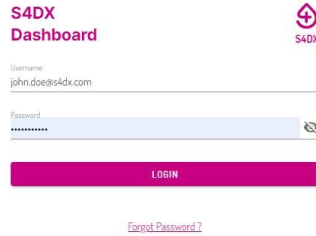




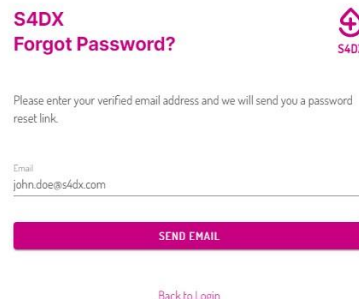
Figure 20. User sign in

- Use the  button to view or hide the entered password.
- With the correct email and password, you can log in to the homepage of S4DX Webservice.

Note: If you enter incorrect log-in credentials (wrong password and/or wrong email address), an error notification will appear at the bottom of the page (see below).



- In this case, you can use  button to check the entered password and try again or
- Reset password by clicking on [Forgot Password?](#) button. Enter the email address and tap “SEND EMAIL” (see below).



Reset password

- Follow the instructions received in the email to reset the password. The password reset email will be sent
 - from: no-reply@s4dx.com
 - with the subject: RESET PASSWORD

3.2.5 Enter Browser Scan

After successful login into S4DX Webservice, you will be navigated to the home page.

You should click on the **SCAN** button on top of the screen to enter Browser Scan. You will then be guided to the start page of Browser Scan (see Figure 21).

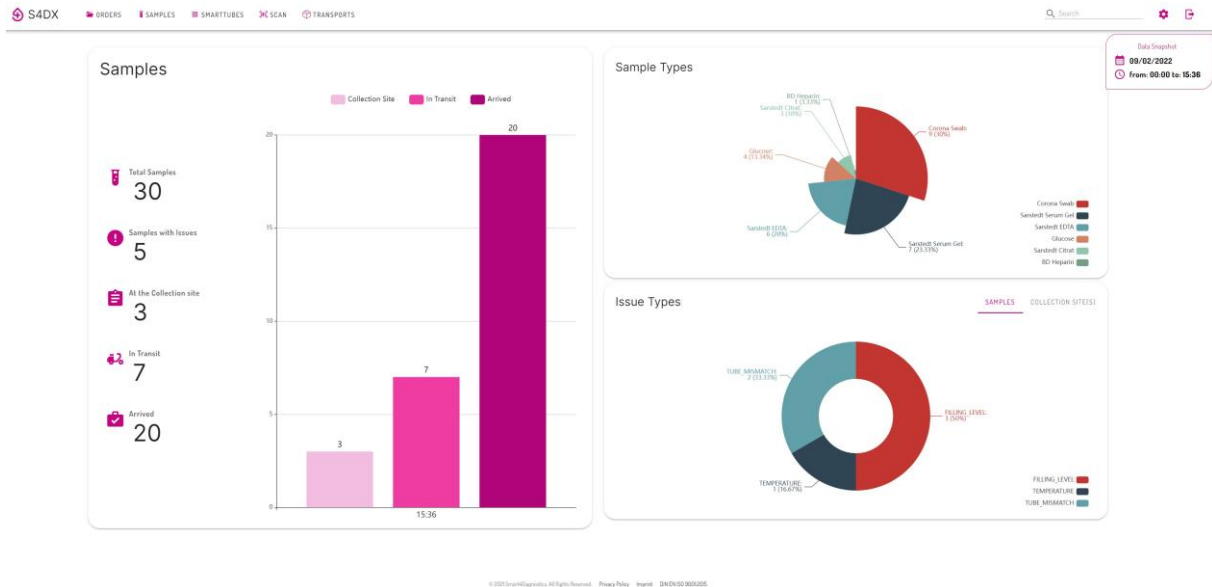


Figure 21. S4DX Webservice starting page

3.3 Connect data input device(s)

To use the Browser Scan function, a data input device should be connected to the computer. This is primarily a barcode scanner, with a keyboard as supplement in certain conditions.

For detailed instructions on installing and using barcode scanners and/or keyboards, refer to the instructions provided by the respective manufacturers.

3.4 SmartTube registration

Before collecting biological samples, you should register the SmartTube(s). By assigning a SmartTube to a particular route, the SmartTube will be virtually linked to this route and will collect and store its transport parameters such as temperature and shock events.

- Registering the SmartTube is only for users with the SmartTube function enabled.
- Registering the SmartTube to a particular route is only for users with simultaneous SmartTube function enabled.
- If your organization uses the Courier App for transport monitoring, Browser Scan users do not have to register the SmartTube, and can proceed to chapter 3.5.
- User laboratories that do not engage the Courier App for transport monitoring should follow the steps below.

3.4.1 Scan SmartTube

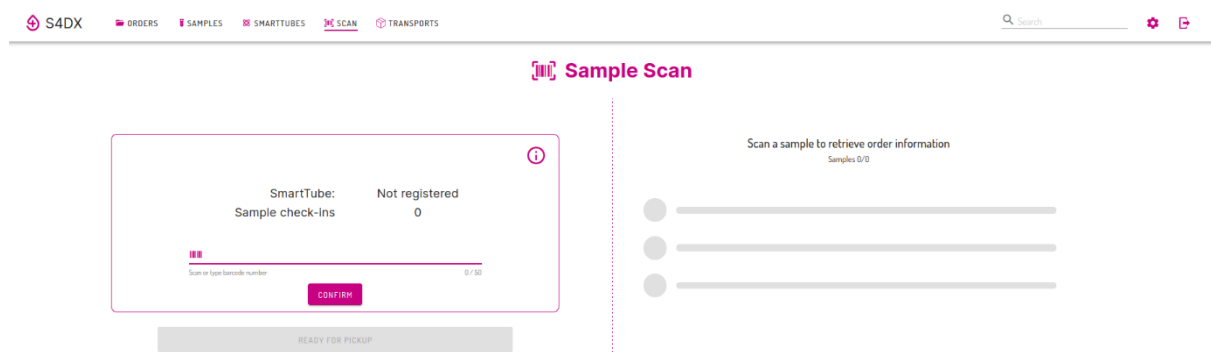

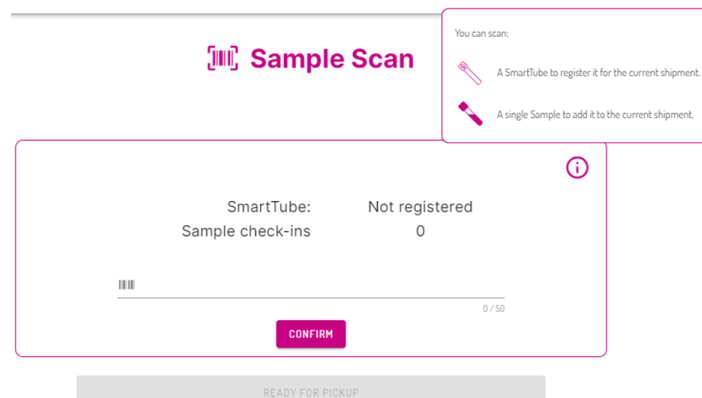


Figure 22. Browser scan

- Move the cursor to the data input field and click on it to start scanning.
- Place the SmartTube in front of the barcode scanner such that the barcode attached to the SmartTube faces the scan window, and then press the key on barcode scanner to confirm the scan and read the barcode.

Note: According to different functions that laboratory acquired from S4DX, the scannable objects on Browser Scan differs for users.

You can click on the information icon  in the scan page to view the scannable objects.



Browser scan information icon

3.4.2 Register SmartTubes

To register SmartTubes, there are two ways according to different configurations.

- For users with defined transport routes, refer to step 3.4.2.1.
- For users without defined transport routes, refer to step 3.4.2.2.

3.4.2.1 Select route for SmartTube (users with defined transport routes)

This step is for users whose collection sites have defined the transport routes for the samples.

Users without defined transport routes can skip the following steps and proceed to step 3.4.2.2.

- a. After a successful scan of a SmartTube at the collection site, a SmartTube picture with the corresponding number will appear on the screen, with available transport routes to select.
- b. Click on the desired route (see Figure 23). Only one route may be selected.

SmartTube

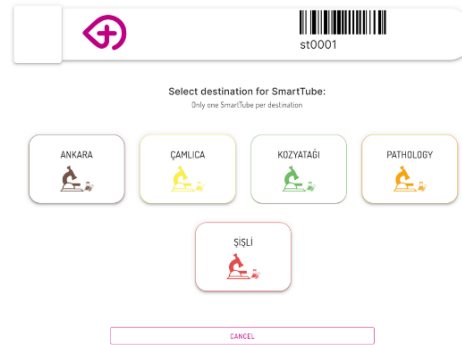


Figure 23. Select route for SmartTube

In this step, a SmartTube is linked to one transport route to facilitate the monitoring of samples with that destination and/or transport condition.

- c.** You will then be navigated back to the home screen of Browser Scan.
- d.** The registered SmartTube should then be placed in the transport container (bag, box) corresponding to the chosen transport route in step **b.** (see below).



For example, if SmartTube "st101" is registered for the route "Lab A | Cool", then the SmartTube "st101" should be placed in the transport container for Lab A in cooled condition.

The steps a and b can be repeated to register the remaining SmartTubes.

Each time a SmartTube is successfully registered, the list of SmartTubes will be updated on the home screen.

Each time you register a SmartTube to a transport route, that route will be marked as registered on the SmartTube registration screen the next time it is shown to the user, until all transport routes for sample collection are registered (see below).



3.4.2.2 Confirm SmartTube registration (users without defined transport routes)

SmartTube



Figure 24. Confirm SmartTube

The following steps are for users whose collection sites have not defined the transport routes for the samples.

- a. After successful scan of a SmartTube, a virtual SmartTube with corresponding number appears on the screen.
- b. Tap "Register" to confirm the SmartTube registration.

The number of SmartTubes for each shipment is limited to one.

Note:

- Each SmartTube can only be assigned to one transport route. By trying to register an already registered SmartTube again, an error information occurs (see below). Click on "CANCEL" to continue the SmartTube registration with an unregistered SmartTube.

SmartTube already scanned



Lab A | Cool

CANCEL

One SmartTube to one transport route

- When transport routes for sample collection of the current day are all covered and user continues scanning further SmartTube, the transport routes are all disabled thus not selectable (see below).

SmartTube



Select destination for SmartTube:
Only one SmartTube per destination



CANCEL

Once all transports for the day are done

In this case, if the user continues scanning new SmartTubes, the user will be asked to first ship the already registered samples and SmartTubes by following the steps:

- a) Click on the button "CANCEL" to return to home screen.
- b) Click on the button "READY FOR PICKUP".
- c) Click on the corresponding transport routes of the samples and the button "Confirm" to complete the shipment.

3.5 Identify order and verify patient

In this step, users will identify an order and verify patient identity to ensure the correct management of the collected samples and to eliminate mismatches between the order(s), sample(s), and the patients. Users have three options to identify an order and can choose freely among them, based on available resources.

This step is only available to users with patient flow function. Users without this function should refer directly to step 3.6.

3.5.1 Scan one of the following objects to request order information

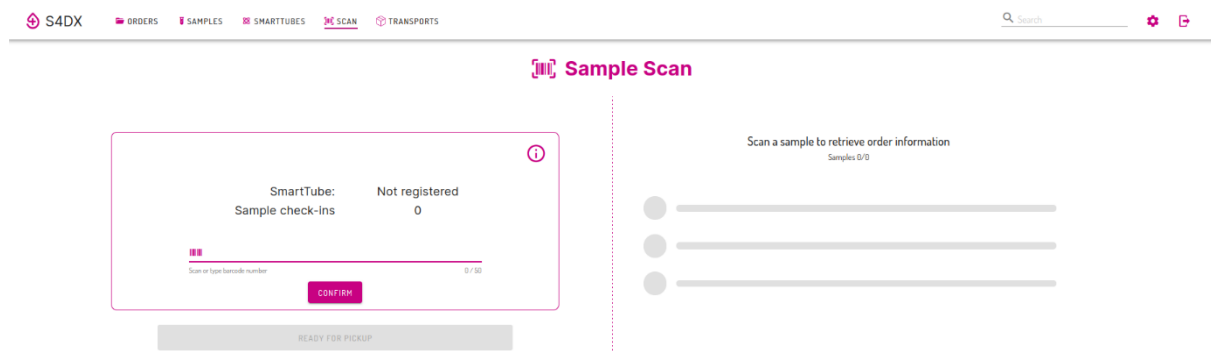


Figure 25. Start scanning

- Move the mouse to the data input field and click on it (see Figure 25).
- Place one of the following objects in front of the barcode scanner scanning area (tube barcode or Order ID). Face the barcode attached on the object towards the scanning area. Press on the key on barcode scanner to confirm the scan and read the barcode.



Figure 26. First scan of an order

3.5.1.1 Scan Order ID

After scanning order ID, the order overview will appear.

Click on one sample displayed on the screen. Users are then navigated to this sample confirmation page.

3.5.1.2 Scan Sample

After scanning a sample from the order that belongs to the patient, users are navigated to this sample confirmation page.

The scanned samples could be empty or filled.

3.5.1.3 Scan patient ID

After scanning the patient ID, the order overview will appear.


Click on one sample displayed on the screen, and then will be navigated to this sample confirmation page.

Patient identification will be automatically confirmed and enabled upon scanning patient ID.

Note:

- Scanning patient ID to identify order is only available to the users with this function enabled. If scanning patient ID is not available to users, please use other two approaches to identify orders.
- Patient data, such as patient name and birthday, only appears when this function is enabled.


3.5.2 Confirm patient

- a. You should review patient identity to ensure that the order belongs to the correct patient.
- b. Tap on the toggle  to confirm patient identity if toggle is not yet enabled.

Users scanning patient ID to confirm patient identity can skip this step.

3.5.3 Add patient details (optional)

Patient Details

Paula Klingbeil 
Date of Birth: 1985-03-05
 Gender: male

Confirm Patient Identity

Patient fasting Pregnancy

Pain assessment _____

Patient Note

BACK
UPDATE

Figure 27. Patient details

In certain cases, the patient conditions such as pregnancy and drug intake could influence the diagnostic result. In such cases, adding a patient note in the Browser Scan is recommended to share the information needed for diagnosis with laboratories.

- a.** Click on the field that applies to the patient's conditions and add notes, if necessary.
 The patient conditions displayed on the screen may vary according to the different configurations of laboratories.
- b.** Within Browser Scan, patient identity appears together with the first selected sample. After adding patient's details, move to the right side of the screen to proceed with sample registration as described in section **3.6**.

3.6 Sample scanning and registration

This section explains the steps to scan and register the collected samples. When a sample is registered, the sample information on the home page of the S4DX dashboard will update in real time.

S4DX provides four workflows of sample scanning and registration, based on different customer requirements, including:

- basic workflow without order and patient verification
- basic patient flow after order and patient verification
- continuous scan after order and patient verification
- Scanning samples with aliquots
- Manual selection of tube types after scanning samples

You should refer directly to the relevant workflow, based on their configuration, to complete this step.

3.6.1 Basic workflow for sample registration




Figure 28. Sample Scan

This workflow shows the basic steps for sample registration, without order or patient verification.

It applies when

1. users do not have the patient flow function enabled
2. users scan individual samples without order

The steps are as follows:

- a. Move the cursor to the data input field  and click on it.
- b. Now place one sample tube in front of the barcode scanner such that the barcode attached to the sample faces the scan window. Then press the key on the barcode scanner to confirm the scan and read the barcode.
- c. The sample information page will appear after successful scanning, showing, when available:
 - i. Pre-analytical handling requirements
 - ii. sample type
 - iii. sample number
 - iv. order identifier
 - v. transport route (availability varies depending on the configuration)
 - vi. additional information regarding sample drawing, filling volume, and notes.
- d. Edit the sample information (optional). (For detailed instructions on adding sample information, refer to the **Editing sample information** under the section **Supporting functions**).
- e. For samples without a pre-defined tube code (sample type unknown on the sample information page, choose a sample type. To Change sample type, refer to the **Editing sample information** under the section **Supporting functions**).
- f. Tap on 'Confirm' to finish this sample registration.

3.6.2 Basic patient flow after order and patient verification

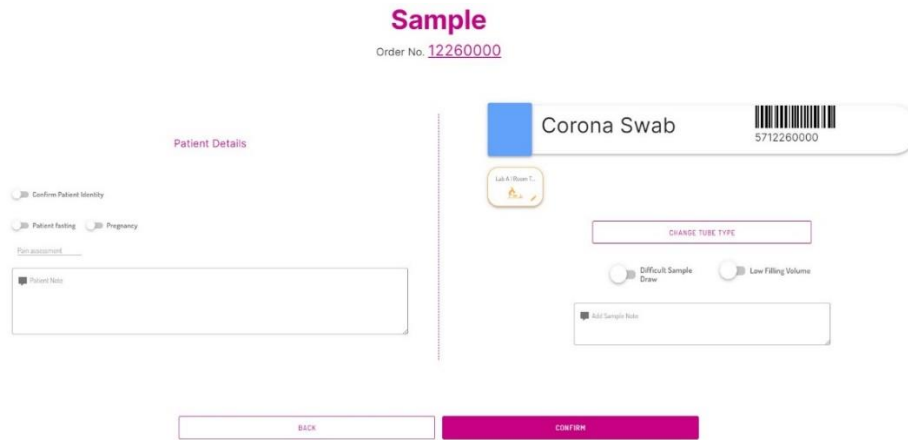


Figure 29. Basic patient flow

After confirming the patient identity on the sample confirmation page, you should proceed with sample confirmation on the right side of the screen.

- a. The sample information page on the right side of the screen shows
 - Pre-analytical handling requirements
 - sample type
 - sample number
 - order identifier
 - transport route (availability varies depending on the configuration)
 - additional information regarding sample drawing, filling volume, and notes.
- b. Edit the sample information (optional). (For detailed operating instructions, you should refer to the **Editing sample information** under the section **Supporting functions**).
- c. Click on "CONFIRM" to finish the sample confirmation.
- d. By confirming the sample, you have confirmed that the sample has been physically collected and ready for shipment.
- e. You will then be navigated to the Order Overview Screen.

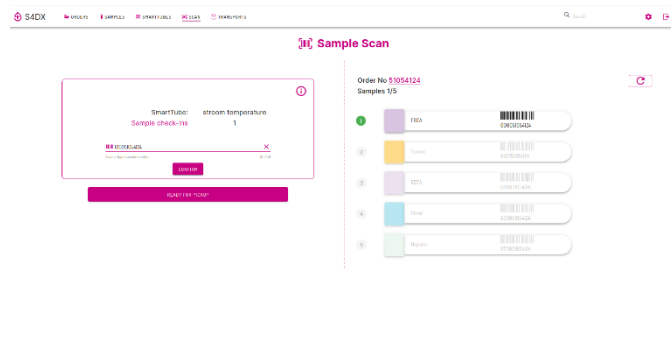



Figure 30. Order overview screen

- f. To register the rest of the samples, move the cursor to the data input field  on the left side of the screen and click on it.
- g. Place a sample in front of the barcode scanner such that the barcode attached to the SmartTube faces the scan window, and press the key on barcode scanner to confirm the scan and read the barcode.

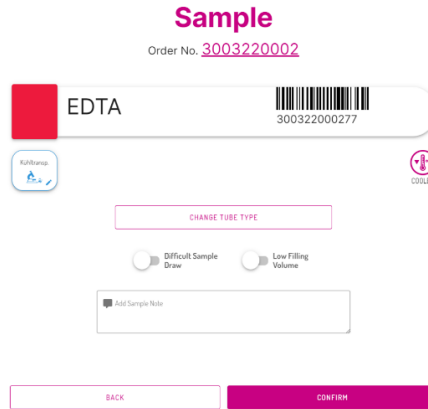


Figure 31. Sample information

Steps a. and b. can be repeated to edit sample information, if necessary. Finally, click on "CONFIRM" for sample confirmation. The remaining samples belonging to the order should be scanned until all samples of the order are registered.

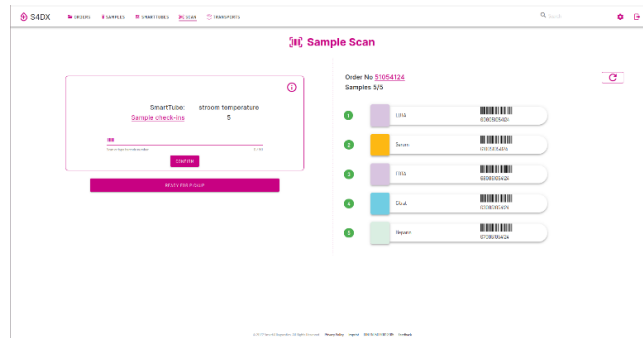


Figure 32. Scanned order list

3.6.3 Continuous scan after order and patient verifications

- a. Place a sample container in front of barcode scanner such that the barcode attached to the SmartTube faces the scan window, and press the key on the barcode scanner to confirm the scan and read the barcode.
"Sample already scanned." - This notice will appear if you scan the same sample for a second time or more times. The user should scan an unscanned sample to avoid this error.
- b. After a successful scan, the sample information will appear on the screen.

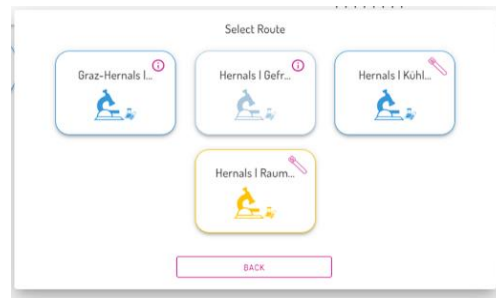


Figure 33. Route selection

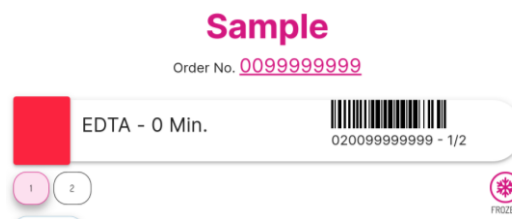
- c. The sample registration will be automatically confirmed, and you scan the next sample.
- d. Continue scanning until all samples in the order have been registered.

Note:

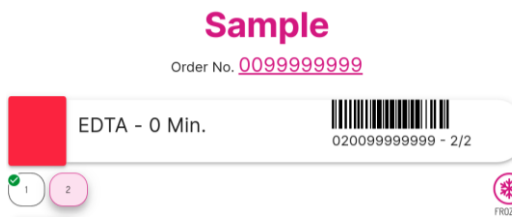
Scan samples sharing the same sample number in an order

Follow the steps to complete registering samples sharing the same sample number in an order.

- a) Scan one of the samples that shares the same sample number.
- b) Users are navigated to the sample screen with tile below the tube showing the sequences of samples sharing the same sample number in this order. By default, the tile below the tube with sequence 1 appears highlighted.

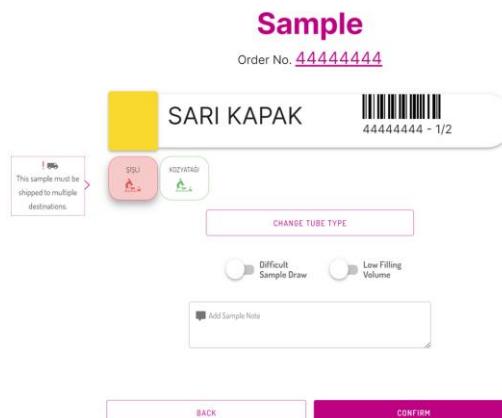


- c) Scan a second sample with the same barcode as the previous. The tile below the tube with sequence 1 appears now with a check mark and the sequence 2 is highlighted.



- d) Return to camera view and repeat step a) to c) to complete scanning the samples in the sequence.
- e) Continue scanning if there are unscanned sample(s) left in the order, until all the samples in the order have been scanned and users are navigated to the Order Overview screen.

In some situations, the samples sharing the same sample number are assigned to different transport routes (aliquots). In this case, instead of sequence number, the corresponding transport routes and a notification will be shown below the tube (see below). In such case, users can still complete the sample confirmation by following the steps described above. This time, the transport route will be highlighted or marked as selected.




3.6.4 Scan samples with aliquots

This workflow shows the steps for sample registration for orders when aliquoting is needed to perform tests/ analyses in different destinations. Whether or not a sample must be aliquoted is based on the observations (tests) sent in the order request by the Laboratory Information System (LIS)

It applies when

1. users scan individual samples with order
2. users have the *simultaneous SmartTubes* function enabled
3. users have the *samples transport route* function enabled

Note: The following steps apply after the SmartTubes are already scanned:

- a. Move the cursor to the data input field  and click on it.
- b. Now place one sample tube in front of the barcode scanner such that the barcode attached to the sample faces the scan window, and then press the key on the barcode scanner to confirm the scan and read the barcode.
- c. The sample information page will appear after successful scanning, showing, when available:
 - i. Pre-analytical handling requirements
 - ii. sample type
 - iii. sample number
 - iv. order identifier
 - v. transport route based on the destination of each aliquot
 - vi. additional information regarding sample drawing, filling volume, and notes.

Example of two aliquots: The sample information page will show two tiles below the tube with the two possible routes, and the first route will be highlighted. You can select any of the routes to register the current sample. Moreover, the barcode will appear with a sequence at the end (1/2) or (2/2) if the user clicks on the second route.

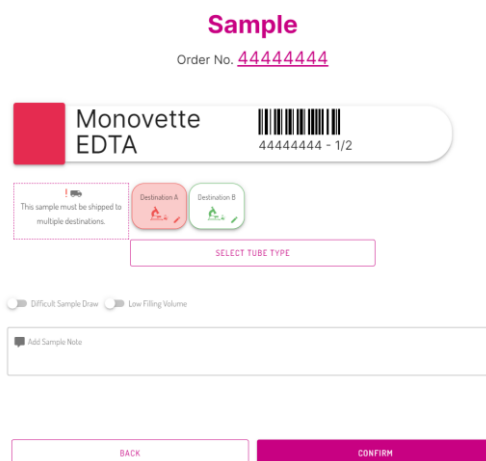


Figure 34. Register samples with aliquots

- d. Edit the sample information (optional). (For detailed instructions on adding sample information, refer to **Editing sample information** under the section **Supporting functions**)
Click on 'Confirm' to finish this sample registration.
- e. Repeat steps from **a** to **d** as many times as there are aliquots

Following the example, scan the sample with sequence (2/2) of the same order. In the sample scan page, the first route will appear now with a green check mark and the second sample will be highlighted. In addition, the barcode will now show the sequence 2/2.

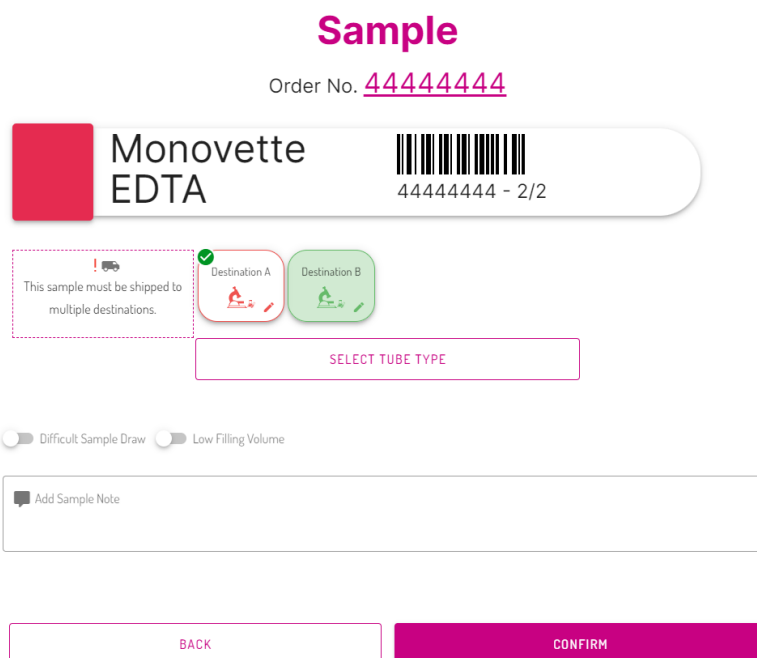


Figure 35. Sample details with aliquots

3.6.5 Manual selection of tube type after scanning samples

This workflow applies for users who do not have the sample barcode identifying the type of samples in the S4DX systems, or who use the same barcode for multiple sample types.

To be able to use this, your organization will have to activate the workflow “manual selection”.

There are two ways for manual sample selection (check with your organization which kind of manual sample selection you have activated).

5.7.5.1 Manual sample selection 1:


- a. Move the cursor to the data input field  and click on it.
- b. Now place one sample tube or order ID in front of the barcode scanner such that the barcode attached to the sample faces the scan window, and then press the key on the barcode scanner to confirm the scan and read the barcode.
- c. A pop up will appear, showing all possible tube types for this barcode.



Figure 36. Manual Sample selection 1

- d. Now select the tube type you are scanning.
- e. Click on "register", and the sample will be registered. Before doing so, you can look at the preanalytical handling requirements, change the transport route, or add any other information regarding the sample drawing.

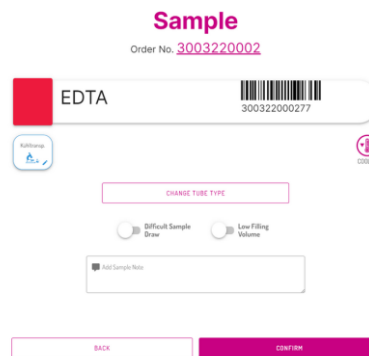
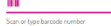


Figure 37. Add sample details after manual sample selection

5.7.5.2 **Manual sample selection 2:**

- a. Move the cursor to the data input field  and click on it.
- b. Now place one sample tube that belongs to an order in front of the barcode scanner such that the barcode attached to the sample faces the scan window, and then press the key on the barcode scanner to confirm the scan and read the barcode.
- c. If patient flow is active, add patient details and confirm patient identity to continue.
- d. Scan the second sample with quantity >1 (several samples with the same barcode) and sequence 1. The patient information will disappear from the sample registration page. The tiles below the tube represent the sequence and, by default, the sequence 1 will appear highlighted.

- e. Scan the third sample with the same barcode as the previous one but with different sequence. The tile below the tube with sequence 1 will appear now with a check mark and the sequence 2 will be highlighted.

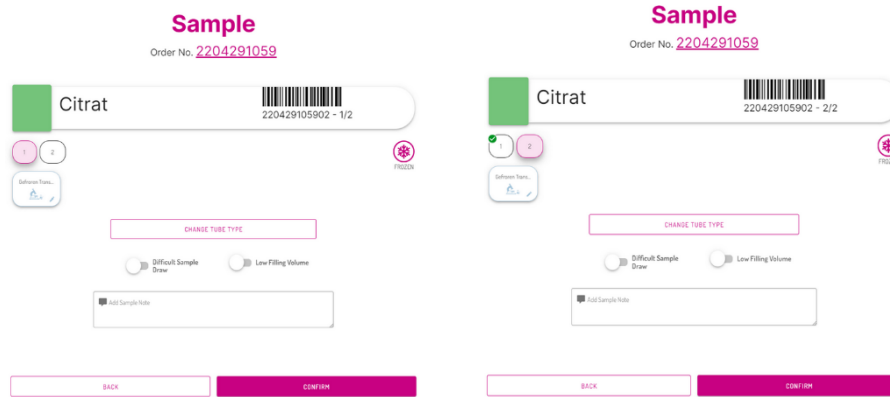


Figure 38. Manual Sample selection 2

- f. Scan a fourth sample with unique barcode.

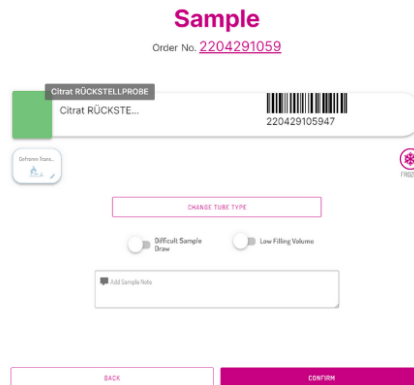


Figure 39. Sample scan with unique barcode in manual sample selection

3.7 Ship samples

When the samples are ready to be shipped, you can:

- a. Tap on "READY FOR PICKUP" shown on the home screen.

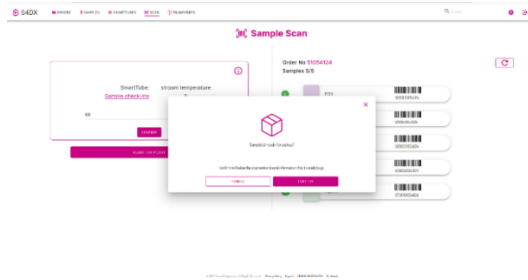


Figure 40. Ready for pickup

- b. A screen appears to require a confirmation of the shipment. Tap on "Confirm" to complete the sample shipment.
- c. For users with the SmartTube and Route function enabled, the relevant transport routes appear on the shipment confirmation screen. In such case, you should select desired transport route(s) to confirm the order shipment.

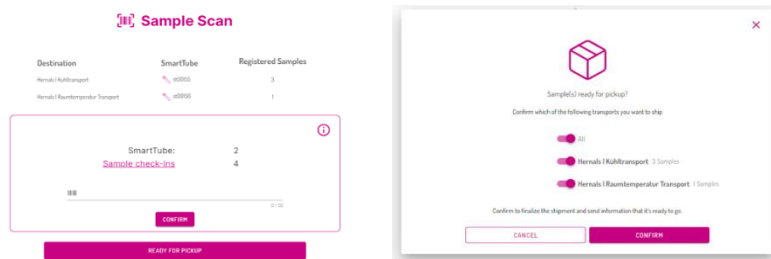


Figure 41. Confirm sample pickup

- d. If any order is incomplete in the shipment, a notification will pop up. Users can choose whether to ship the incomplete order(s) by clicking on the button "SHIP ANYWAY" or continue registering the missing sample(s) to complete the order(s).

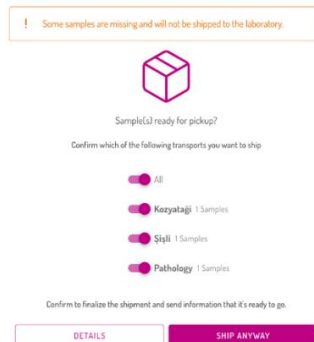


Figure 42. Incomplete order

- e. The notification of the successful shipment is shown in the bottom of the screen and the list of SmartTubes is cleaned up.

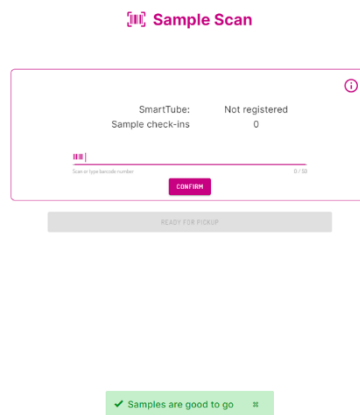


Figure 43. Confirmation of sample shipment

3.8 Supporting functions

Editing sample information

The options for editing sample information including those described below are available to the samples that have already been scanned.

a. Add additional information to the sample

When any of the following situations or other situation that could influence the diagnostic result happens, click on respective toggles to add additional description to the sample:

- "Difficult sample draw"
- "Low filling volume"

or type in the field "Add sample notes" to describe the situation that needs to be considered while doing the examination.

For continuous scan and multiple sample check-in,

- tap on the down-pointing arrow on the right side of the corresponding sample in Order Overview
- tap on "Add sample notes" to continue adding additional information to the sample as described above.

b. Change sample type

- i. Click on CHANGE TUBE TYPE the sample confirmation page, a list of configured sample types is displayed on the screen. For continuous sample check-in, tap on "Change sample type" displayed below the particular sample.
- ii. Click on the desired sample type. Users are then navigated back to the sample confirmation page.

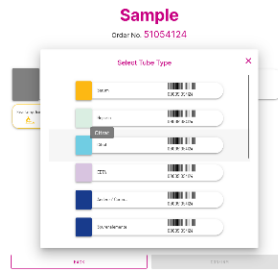


Figure 44. Select sample type

c. Change transport route

- i. Click on the transport route below the sample.



Figure 45. Select transport route

- ii. A list of available transport routes are displayed on the screen.

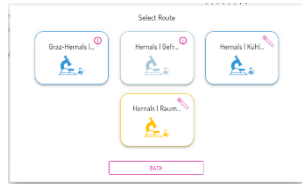


Figure 46. Available transport routes

- iii. Click on the desired transport route.
- iv. Click on the button "Save" to save the changes

VERSION OVERVIEW

Version	Change	Author
1.0	Create Review	Anda Ardean Yannick Boege
2.0	Add instruction for browser scan and trouble shooting Review	João Carlos Pinho da Silva Yannick Boege
3.0	Add app and browser scan updates. Explanation of different workflows Review	Tanaya Dhar, Veronica García Caro, Monica Tuta Yannick Boege
4.0	Additional features	
5.0	Add notes in 2.1 and 3.1 for cache removal and sync of time. Change Smart4Diagnostics for S4DX Change Satellite app for Samples app	Mónica Tuta Fajardo

We are glad to be there for you!

We look forward to working with you and appreciate your opinion!

We can only achieve high-quality and efficient development of our product with your help. Please let us know your experience, difficulties, or suggestions for improvement of the Samples App through:

- Webpage: [s4dx.com - Contact](https://s4dx.com)
- E-Mail: contact@s4dx.com
- Telephone: +49 (0) 89 724 018 40
- Samples-App: "Contact us" – Write us a message

Thank you!

Together for the precision of clinical decisions!

Your S4DX team

