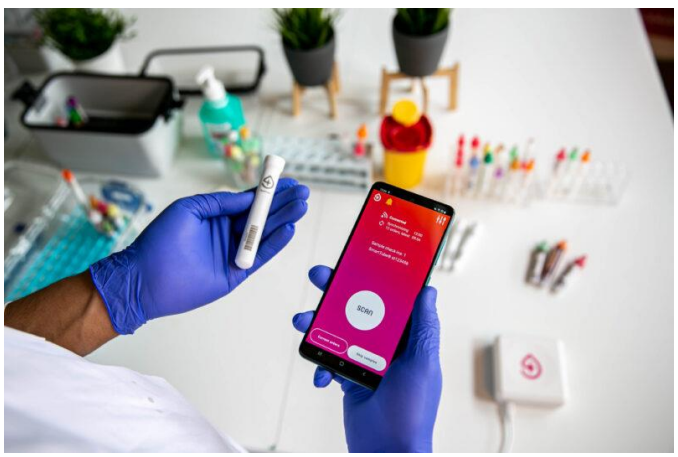
S4DX

ISO 15189:2022 Requirements for preanalytics

How does S4DX help you be compliant with ease ?

Get a more detailed overview on ISO preanalytical relevant requirements and how exactly S4DX helps you fulfil them.



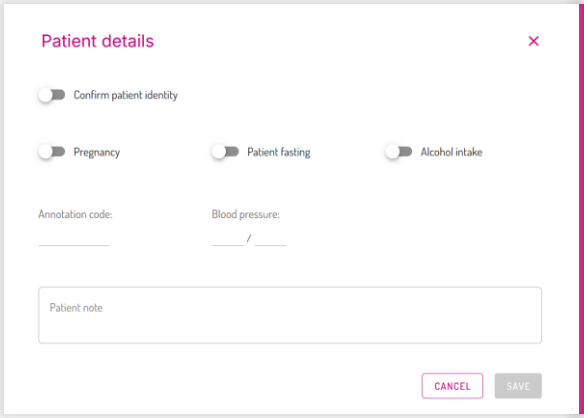
The latest version of ISO 15189, the **ISO 15189:2022**, will be enforced **on Dec 5, 2025.** Laboratories that want to stay compliant with the highest industry standards need to get certified to the newest version of ISO by this December.

Have a look at all the preanalytical-relevant ISO criteria and how S4DX can help you fulfill them!

7.2.4.2 Sample pre-collection activities

Laboratories are required to provide information and instructions for pre-collection activities with sufficient detail to ensure that the integrity of the sample is not compromised, including:

REQUIREMENT	S4DX SOLUTION
Preparation of the patient (e.g. instructions to caregivers, sample collectors and patients)	• In S4DX Webservices (web application) or in S4DX Samples App (mobile app), users can simply scan an order barcode or a patient ID to identify the patient and see the orders associated to him • Orders for specific patient will be displayed and instructions for collection/pre-collection will be showed
Type and amount of the primary sample to be collected with descriptions of the containers and any necessary additives, and when relevant the order of collecting samples (order overview and preanalytical guidance)	• S4DX Webservices takes order data and analytes and displays them to the phlebotomist • Tube type and color, preanalytical guidance and order of draw is displayed in a visual way so that users see at one glance everything that is needed
Special timing of collection	• Upon collection, samples are scanned using a barcode scanner or mobile app, and the S4DX system records automatically the time as the time of collection
Provision of clinical information relevant to, or affecting sample collection, examination performance or result interpretation (e.g. history of administration of drugs)	• In S4DX Webservices (web application) or in S4DX Samples App (mobile app), users can add free text comments, click toggles and respond with alphanumeric data to predefined laboratory questions about the collection (e.g. history of administration of drugs, fasting, pregnancy, etc).
Link patient/sample for unequivocal identification of the patient, when several samples from the same patient are to be collected	• Upon scanning the patient or order ID, the phlebotomists work is tied to one same patient • Samples scanned not belonging to the patients' order are automatically detected and sorted out, so that only the right samples are linked to the patient



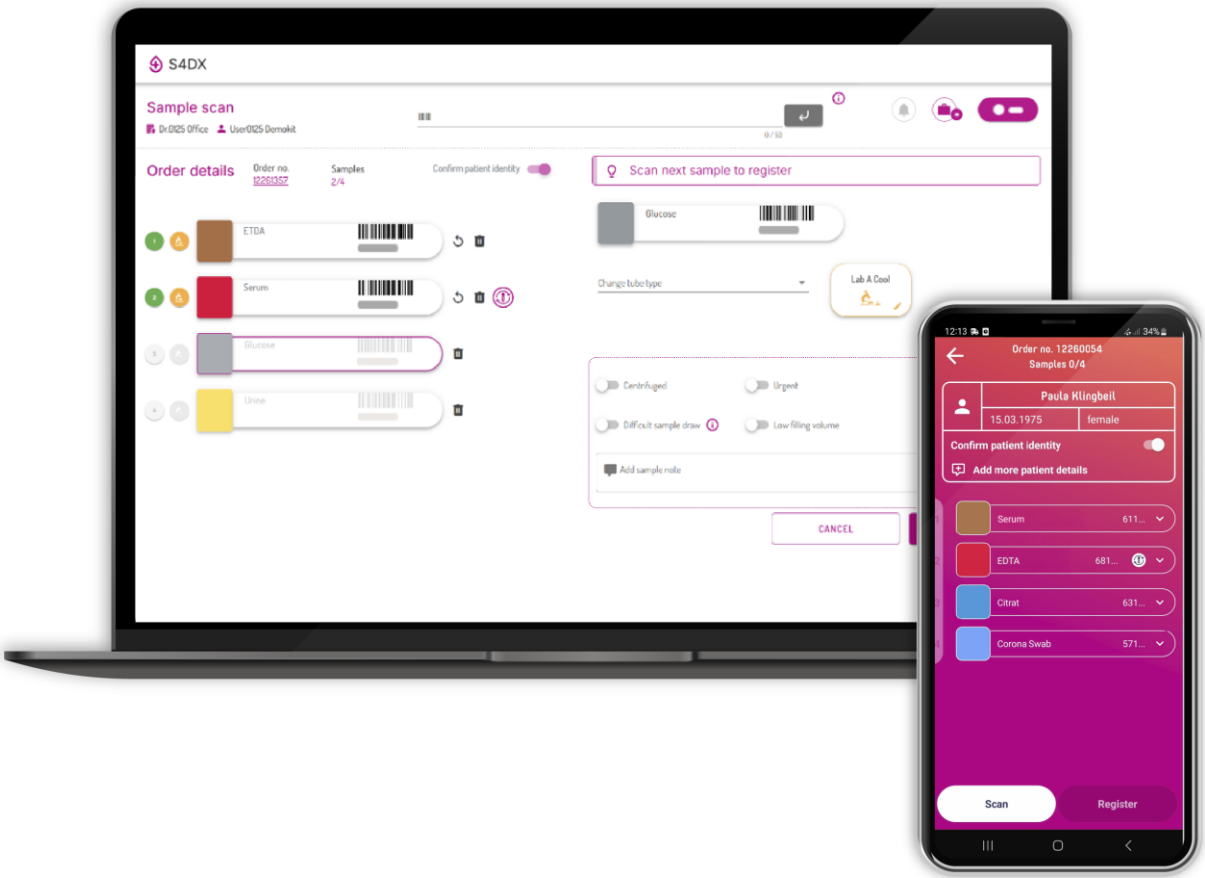
Pop-up to confirm patient's identity and add sample collection-relevant information (e.g. data about patient status)

7.2.4.4. Sample collection

To ensure safe, accurate and clinically appropriate sample collection and pre-examination storage, labs have to provide:

REQUIREMENT	S4DX SOLUTION
 **Verification of the identity of the patient from whom a primary sample is collected**	• Upon scanning the patient or order ID, a pop up with patient personal data appears (name, birthdate, gender) • Users have to click on “confirm identity” in order to be able to register any samples for this patient and this order, ensuring a verified patient identification
 **Verification recording that the patient meets pre-examination requirements (e.g. fasting status, medication status)**	• In the patient confirmation pop-up, users can as well add comments, click on confirmation toggles, and introduce alphanumeric information to add information about the patient´s status (e.g. fasting, medication, blood pressure, etc). This pop-up can be completely personalized according to your labs needs
 **Collection of primary samples with descriptions of the primary sample containers, as well as the order of sample collection**	• S4DX Webservices takes order data and analytes and displays them to the phlebotomist • Tube type and color, preanalytical guidance and order of draw is displayed in a visual way so that users see at one glance everything that is needed
 **Unequivocal link sample/patient with the patients from whom samples are collected**	• Upon scanning the patient or order ID, the phlebotomists work is tied to one same patient • Samples scanned not belonging to the patients’ order are automatically detected and sorted out, so that only the right samples are linked to the patient
 **Recording of the identity of the person collecting the primary sample and the collection date and time**	• To use the S4DX system, the user has to identify him/herself, and his/her identity is then recorded and showed in any S4DX data related to the orders and patients he/she worked with while using the system • Collection date and time are automatically recorded upon scanning samples and confirming the order registration
 **Requirements for separating or dividing the primary sample *(if secondary sample has same barcode).***	• With previous knowledge about the laboratory logic, kinds of tubes and samples used and barcode system, S4DX can indicate when an aliquote is needed, and/or work with aliquotes within the system
 **Tracking of storage conditions before collected samples are delivered to the laboratory *(temperature, shock)***	• Upon collection and registration, samples are put in to their racks and/or sample boxes or bags. An S4DX SmartTube Datalogger is scanned and put into the sample box, and it will start tracking temperature and schock events from the samples from the activation moment until samples arrive to the laboratory

Order overview in S4DX sample tracking system with



Sample container information, order of draw, preanalytical guidance, tube color.

Link patient/ order/tube

Toggle for patient confirmation (linked to adding patient data)

Add collection-relevant information

Register timing of collection

7.2.5. Sample transportation

To ensure the timely and safe transportation of samples, the laboratory shall provide instructions for:

REQUIREMENT	S4DX SOLUTION
Ensuring the time between collection and receipt in the laboratory is appropriate for the requested examinations	• S4DX generates various timestamp and data points across the sample journey, amongst which the time of collection and receipt in laboratory is counted • Laboratories can easily view the data in S4DX Webservices and act on their processes to ensure the time between collection and sample receipt is the appropriate, or just to document this data point for quality purposes.
Maintaining* the temperature interval specified for sample collection and handling *(S4DX "Monitors" temperature)	• S4DX monitors sample temperature from the moment the S4DX SmartTube is registered until samples arrive to the laboratory • S4DX Flag tracks and signals when temperature is out of the range the laboratory has established
Any specific requirements to ensure integrity of samples	• S4DX system ensures a solid set of information related to samples and their handling from pre-collection up to lab . The aim is to help the lab in preserving the integrity of the sample
If the integrity of a sample has been compromised and there is a health risk, the organization responsible for the transport of the sample shall be notified immediately and action taken to reduce the risk and to prevent recurrence	• S4DX Webservices tracks sample transport incidences and courier drivers • If the integrity of a sample has been compromised, S4DX enables the laboratory to identify company and person doing transportation for easy localization

7.2.6.Sample receipt

7.2.6.1 Sample receipt procedure

The laboratory shall have a procedure for sample receipt that includes:

REQUIREMENT	S4DX SOLUTION
The unequivocal traceability of samples by request to a uniquely identified patient and when applicable, the anatomical site	• S4DX digital match patient/order/tube ensures samples are associated to the right patient and are traced along the complete journey until reaching the lab • The match is done in the S4DX Samples App or S4DX Webservices, by simply scanning patient ID or order ID, confirming his/her identity, and scanning the samples associated to the order or patient. The system rejects automatically samples that are not associated to the patient that is in process, and notifies when samples from orders /patients are missing.
Criteria for acceptance and rejection of samples* (through S4DX sample flags)	• S4DX Flag is an alerting/flagging system, in which laboratories can setup their quality parameters needed for the acceptance of samples (e.g. accepted temperature ranges or schock events). Samples outside of the personalized predefined ranges will be marked with a “Non ok” flag, so laboratories can identify them upfront.
Recording the date and time of receipt of the sample	• Upon laboratory arrival, data from the S4DX SmartTube is automatically downloaded and a time stamp with the arrival time of the samples is created • As a second security step, courier drivers have to confirm the delivery of the samples in the Courier App, so the lab has a second sample arrival time stamp. This happens completely automated
Evaluation of received samples, by authorized personnel, to ensure compliance with acceptability criteria relevant for the requested examinations	• Evaluation of samples can happen already while samples are traveling to the lab • Lab staff can check what is on their way and what incidences are samples having to ensure compliance with the acceptability criteria of the requested examinations • Upon lab arrival, all data will be final and lab staff can finalize checking. Staff will know upfront in which container are samples that need immediate handling because of not being compliant
Instructions for samples specifically marked as urgent	• Laboratories can provide with S4DX with their set of samples that are typically urgent, so the software displays special instructions for them every time such a sample appears in an order • On top of that, collection users can mark a sample as “urgent” as they collect it so the lab is aware
Ensuring that all portions of the sample shall be unequivocally traceable to the original sample	• If laboratories are using aliquotes, these can be tracked using S4DX Sample tracking system. Our software can reproduce the laboratory´s barcode logic and track samples through their whole journey until lab arrival

7.2.6.2 Sample acceptance exceptions

The laboratory shall have a process that considers the best interests of the patient in receiving care, when a sample has been compromised due to

REQUIREMENT	S4DX SOLUTION
Incorrect patient or sample identification	• S4DX Webservices offers a data dashboard and downloadable data tables containing all information collected from samples, all incidences and errors listed in 7.2.6.2 that can support the laboratory create a safety process as per 7.2.6.2 • Users involved in sample collection and scanning samples after phlebotomy with S4DX can indicate as well in S4DX that a sample comes with low filling volume
Sample instability due to, for example, delay in transport	
Incorrect storage or handling temperature	
Inappropriate container(s) and	
Insufficient sample volume	
When a compromised clinically critical or irreplaceable sample is accepted, after consideration of the risk to patient safety, the final report shall indicate the nature of the problem.	

7.6.3 Information systems management (requirements to software providers)

The systems used for the collection, processing, recording, reporting, storage or retrieval of examination data and information shall be:

Validated by the supplier and verified for functionality by the laboratory before introduction. Any changes to the system, including laboratory software configuration or modifications to commercial off-the-shelf software, shall be authorized, documented and validated before implementation

Documented, and the documentation readily available to authorized users, including that for day-to-day functioning of the system

Implemented taking cybersecurity into account, to protect the system from unauthorized access and safeguard data against tampering or loss

Operated in an environment that complies with supplier specifications

Maintained in a manner that ensures the integrity of the data and information and includes the recording of system failures and the appropriate immediate and corrective actions

Calculations and data transfers shall be checked in an appropriate and systematic manner

7.6.4 Downtime plans

The laboratory shall have planned processes to maintain operations in the event of failure or during downtime in information systems that affects the laboratory's activities. This includes automated selection and reporting of results.* with respect to S4DX part (preanalytics)

S4DX helps you to be fully compliant with ISO 15189:2022.

If you have questions on how to implement our solution or want to know more details about the product, contact us!

S4DX

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