



Technical Specification

ISO/TS 9320

Health informatics — Standardized data set for transfer of hemodialysis patients

*Informatique de santé — Ensemble de données normalisées pour
le transfert des patients en hémodialyse*

**First edition
2024-08**

STANDARDSISO.COM : Click to view the full PDF of ISO/TS 9320:2024

STANDARDSISO.COM : Click to view the full PDF of ISO/TS 9320:2024



COPYRIGHT PROTECTED DOCUMENT

© ISO 2024

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

	Page
Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms, definitions and abbreviations	1
3.1 Terms and definitions.....	1
3.2 Abbreviated terms.....	5
4 Significance of haemodialysis data set	5
4.1 General.....	5
4.2 Unique elements in the haemodialysis data set.....	6
4.3 Purpose of a standardized data set.....	6
5 Use case	7
5.1 General.....	7
5.2 Haemodialytic patient with no special problems.....	7
5.3 HIV positive haemodialytic patient.....	7
5.4 Haemodialytic patient with refractory heart failure.....	7
6 Data sets for transfer of haemodialysis	8
6.1 General.....	8
6.2 Fields of required data.....	10
6.2.1 General.....	10
6.2.2 Last dialysis date.....	10
6.2.3 Haemodialysis interval.....	11
6.2.4 Dry weight.....	11
6.2.5 Haemodialysis machine model.....	12
6.2.6 Haemodialysis blood flow rate.....	12
6.2.7 Haemodialysis access type.....	12
6.2.8 Haemodialysis access site.....	13
6.2.9 Haemodialysis access status.....	13
6.2.10 Hepatitis type B antigen / antibody.....	14
6.2.11 Hepatitis C virus infection.....	14
6.2.12 Human immunodeficiency virus infection.....	15
6.2.13 Dialysis duration.....	15
6.2.14 Dialysate.....	16
6.3 Fields of conditionally-required data.....	16
6.3.1 General.....	16
6.3.2 Initial dialysis date.....	16
6.3.3 Last laboratory test date.....	17
6.3.4 Blood type.....	17
6.3.5 Diagnosis.....	18
6.3.6 Blood haemoglobin concentration.....	18
6.3.7 Blood sodium concentration.....	19
6.3.8 Blood potassium concentration.....	19
6.3.9 Blood calcium concentration.....	20
6.3.10 Blood phosphate concentration.....	20
6.3.11 Venereal disease research laboratory.....	21
6.3.12 Pre-dialysis vital sign.....	22
6.3.13 Post-dialysis vital sign.....	22
6.3.14 Interdialytic weight gain.....	23
6.3.15 Prescription.....	23
6.3.16 Remark note.....	24
6.4 Fields of optional data.....	24
6.4.1 General.....	24
6.4.2 Heparin concentration.....	24

ISO/TS 9320:2024(en)

6.4.3	Remnant kidney function.....	25
6.4.4	Other laboratory results.....	25
6.4.5	Radiology report.....	26
6.4.6	Allergy.....	26
6.4.7	Presence of heart failure.....	27
6.4.8	Heart ejection fraction.....	27
6.4.9	Haemodialysis access construction date.....	28
Annex A	(informative) Example of a haemodialysis referral paper.....	29
Annex B	(informative) Example of an FHIR resource.....	30
Bibliography	53

STANDARDSISO.COM : Click to view the full PDF of ISO/TS 9320:2024

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 215, *Health informatics*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Globally, the population with end-stage renal disease (ESRD) has steadily increased. Haemodialysis, which provides rapid clearance of solutes, is the most popular renal replacement therapy for ESRD patients. However, haemodialysis has a high risk of serious complications for receivers of the treatment. Well-known complications of haemodialysis include hypotension, electrolyte imbalance, infection, fluid overload, and dialysis disequilibrium. Due to these side-effects, patients who receive haemodialysis have lower life expectancy than the general population.

Moreover, haemodialysis requires a patient to frequently visit a hospital and to go through complex and time-consuming dialysis procedures. This is because patients need to know how to care for the haemodialysis access or fistula, exercise, regulate diet and monitor their blood pressure and weight. In addition, haemodialysis patients are more likely to be depressed because they are limited in many areas of their daily activities.

Referral of haemodialysis cases occurs often due to complications of chronic kidney disease, such as myocardial infarction, heart failure, atrial fibrillation and cerebrovascular accidents. Recently, a notable change in these referral cases is the increase of referrals from abroad. One of the reasons behind this increase is that haemodialysis which is done outside of a person's residential area is covered by many payers in the United States. As a result, international travel for haemodialysis is growing fast in east Asian countries.

Since haemodialysis includes a complex procedure and requires attentive monitoring, it is imperative to share important and accurate information about a patient, dialysis setup and haemodialysis access to ensure safe and timely haemodialysis. This would also allow patients who are travelling abroad for a haemodialysis to experience smooth referral.

The purpose of this document is to define the data set for referral of haemodialysis patients. This data set will ensure continuity of haemodialysis-related care. The data set provides optimal dialysate parameters and individualized dialysis settings. Providing this information can reduce the occurrence of dialysis-related complications. The data set can be used for referring haemodialysis patients, for surgery or intensive care, and it can also support safe and timely haemodialysis procedures for ESRD patients from abroad.

STANDARDSISO.COM : Click to view the full PDF of ISO/TS 9320:2024

Health informatics — Standardized data set for transfer of hemodialysis patients

1 Scope

The document defines a data set for the safe and timely transfer of haemodialysis procedure for end-stage renal disease (ESRD) patients. The necessary information for dialysis is provided through required, conditionally-required and optional data fields of the data set. Complicated use cases are also described in this document.

This document does not cover general quality requirements or system requirements for haemodialysis.

2 Normative references

There are no normative references in this document.

3 Terms, definitions and abbreviations

3.1 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1.1

haemodialysis

dialysis

therapy where waste solutes from the blood are removed by diffusion across an artificial extracorporeal semipermeable membrane

3.1.2

haemodialysis interval

currently prescribed interval between *haemodialysis* (3.1.1) sessions

Note 1 to entry: The interval determines how effectively waste products and fluids are cleared from the body.

Note 2 to entry: A longer interval can lead to accumulation of harmful body products and water, resulting in complications such as oedema, electrolyte imbalance and increased blood pressure.

3.1.3

dry weight

optimal or target weight that a patient should achieve during or after a treatment

Note 1 to entry: Dry weight is measured without the excess fluid that builds up between dialysis treatments.

Note 2 to entry: Dry weight is an important concept because it helps clinicians determine how much excess fluid needs to be removed during each *haemodialysis* (3.1.1) session.

3.1.4

haemodialysis machine model

information about haemodialysis machine manufacturer and model used in recent *haemodialysis* (3.1.1) sessions

Note 1 to entry: The product name of *dialysate* (3.1.9) varies depending on the machine model (the manufacturer's product).

Note 2 to entry: The information helps clinicians prescribe dialysate in the receiving unit.

3.1.5

haemodialysis blood flow rate

rate at which a patient's blood is pumped through the dialysis machine during *haemodialysis* (3.1.1) treatment

Note 1 to entry: Haemodialysis blood flow rate is typically measured in millilitres per minute (ml/min) or litres per hour (l/h).

Note 2 to entry: Clinicians need to determine the appropriate blood flow rate for each individual undergoing haemodialysis to balance the benefits and potential risks.

3.1.6

haemodialysis access type

method or route by which blood is withdrawn from the patient's body, filtered through the dialysis machine, and then returned to the patient

Note 1 to entry: Common types of haemodialysis access are arteriovenous fistula, arteriovenous graft and central venous catheter.

3.1.7

haemodialysis access site

anatomical location of *haemodialysis* (3.1.1) access

Note 1 to entry: The preferred access site for an arteriovenous fistula is usually in the forearm.

3.1.8

haemodialysis access status

condition and functionality of the access site through which *haemodialysis* (3.1.1) treatments are performed

Note 1 to entry: Monitoring and assessing access status is necessary to ensure that the access site remains functional, safe and free from complications.

Note 2 to entry: Haemodialysis access status usually refers to patency, infection, maturation and functionality.

3.1.9

dialysate

fluid used in dialysis to exchange solutes with the blood

Note 1 to entry: Dialysate is used to draw fluids and toxins out of the bloodstream and supply electrolytes and other chemicals to the bloodstream

3.1.10

initial dialysis date

date on which a patient with end-stage renal disease (ESRD) begins *haemodialysis* (3.1.1) treatment for the first time.

Note 1 to entry: Initial dialysis date is a significant event for patients, as it marks the beginning of a lifelong or long-term commitment to regular dialysis treatments.

3.1.11

blood haemoglobin concentration

concentration of haemoglobin in whole blood

Note 1 to entry: Anaemia is a common complication in patients with chronic kidney disease.

Note 2 to entry: Haemoglobin is an important determinant for iron supplementation, blood transfusion or nutritional assessment.

3.1.12

blood sodium concentration

concentration of sodium in serum or plasma

Note 1 to entry: Sodium is key for electrolytes in the body.

Note 2 to entry: *Haemodialysis* (3.1.1) patients are at risk of fluid and electrolyte imbalance due to impaired kidney function and haemodialysis process.

3.1.13

blood potassium concentration

concentration of potassium in serum or plasma

Note 1 to entry: Potassium is key for electrolytes in the body.

3.1.14

blood calcium concentration

concentration of calcium in serum or plasma

Note 1 to entry: Calcium is key for electrolytes in the body.

3.1.15

blood phosphate concentration

concentration of phosphate in serum or plasma

Note 1 to entry: Phosphate is key for electrolytes in the body.

3.1.16

venereal disease research laboratory

nontreponemal test result for screening of syphilis

3.1.17

pre-dialysis vital sign

vital sign measured before *haemodialysis* (3.1.1) session

Note 1 to entry: Vital signs can be subcategorized in “blood pressure”, “heart rate”, “body temperature” and “respiration rate.”

Note 2 to entry: Pre-dialysis vital signs help ensure patient’s safety and provide information about their readiness for haemodialysis.

3.1.18

post-dialysis vital sign

vital signs measured after *haemodialysis* (3.1.1) session

Note 1 to entry: Vital sign can be subcategorized in “blood pressure”, “heart rate”, “body temperature” and “respiration rate.”

Note 2 to entry: Post-dialysis vital signs are needed to assess haemodialysis response and to ensure patient’s safety.

3.1.19

interdialytic weight gain

amount of weight gain between two *haemodialysis* (3.1.1) sessions

Note 1 to entry: Interdialytic weight gain is the result of salt and water intake.

Note 2 to entry: Interdialytic weight gain helps clinicians assess how effectively the patient is managing fluid intake and output between dialysis sessions.

Note 3 to entry: Interdialytic weight gain is used to determine the target fluid removal for each dialysis session.

3.1.20

remark note

note containing information or precautions regarding *haemodialysis* (3.1.1), disease management and general patient-care

Note 1 to entry: A remark note is usually provided in plain text.

3.1.21

heparin concentration

concentration of an anticoagulant in *haemodialysis* (3.1.1) fluid required to prevent thrombosis in catheter, filter and circuit

Note 1 to entry: Heparin concentration usually refers to heparin bolus dose as initial and maintenance dose.

3.1.22

remnant kidney function

renal working capacity remaining after *haemodialysis* (3.1.1)

Note 1 to entry: Remnant kidney function is usually measured as daily urine output or *glomerular filtration rate* (3.1.29).

3.1.23

other laboratory results

laboratory examination of a blood sample other than those mentioned among required and conditionally-required data set

3.1.24

radiology report

text that represents the interpretation of a radiological study

3.1.25

allergy

altered bodily reactivity (such as hypersensitivity) to an antigen in response to a first exposure

3.1.26

presence of heart failure

presence of a condition in which the heart cannot pump enough blood to meet the body's needs

Note 1 to entry: *Haemodialysis* (3.1.1) patients are at an elevated risk of cardiovascular complications.

Note 2 to entry: Managing heart failure is important for fluid management, blood pressure control and dialysis procedure.

3.1.27

heart ejection fraction

measure of cardiac function reflecting the average fraction of emptying of the left ventricle with each contraction

Note 1 to entry: Heart ejection fraction is a crucial indicator of heart function and is commonly assessed using echocardiography.

3.1.28

haemodialysis access construction date

procedure date of current *haemodialysis* (3.1.1) access

Note 1 to entry: Haemodialysis access construction date helps clinicians check the duration of access use and complications that can arise over time.

3.1.29

glomerular filtration rate

calculated measure of renal function which is expressed by the total volume of fluid filtered through all renal glomeruli in a minute

Note 1 to entry: The glomerular filtration rate is usually corrected for estimated body surface area, and reported in ml/min/1,73 m².

3.2 Abbreviated terms

ESRD	end-stage renal disease
HD	haemodialysis
HBsAg	surface antigen of the hepatitis B virus
HBV	hepatitis B virus
HCV	hepatitis C virus
HIV	human immunodeficiency virus
LOINC	Logical Observation Identifiers Names and Codes
FHIR	Fast Healthcare Interoperability Resources
VDRL	venereal disease research laboratory
GFR	glomerular filtration rate
NYHA	New York Heart Association

4 Significance of haemodialysis data set

4.1 General

Haemodialysis is one method of renal replacement therapy for ESRD patients. Since ESRD patients do not have functioning kidneys, patients experience symptoms such as water retention and accumulation of waste metabolites. Typically, ESRD patients require extracorporeal blood circulation that connects to the patient's vascular structures (vascular access), which are artificially constructed in the body.

The basic principle of haemodialysis is to remove unnecessary body water and toxic wastes, such as urea and creatinine, by extracorporeal filtration of patients' blood. Haemodialysis is conventionally performed and managed by highly trained staff. Furthermore, many clinics have specialized haemodialysis facilities such as high-quality water purification system and electricity system. The facility should apply additional measures to prevent microbial contamination.

Although the number of haemodialysis medical institutions and haemodialysis machines is steadily increasing, it is difficult to manage the quality of haemodialysis treatment for various reasons. Patients' lack of awareness of their dialysis data and their non-compliance to medical staff's instructions are obstacles to the improvement of patient's life quality and the reduction of mortality in ESRD patients. Additionally, ESRD patients usually suffer from severe anaemia, malnutrition, hyperparathyroidism, hyperphosphatemia, hypocalcaemia, metabolic acidaemia, hypertension and congestive heart failure at the start of dialysis. Hypoalbuminemia, anaemia and left ventricular hypertrophy are common side effects of dialysis treatment. Sometimes dialysis results in premature death. Details of these cases should be communicated through standardized data set so that this ultimately leads to improvement in dialysis treatment and better prognosis for ESRD patients.^{[8],[9]}

4.2 Unique elements in the haemodialysis data set

There are unique data elements that exist only for haemodialysis and these elements are sometimes misleading. Procedural data is often misunderstood as observational data. Caution is required as the meaning of a specific data element can be conveyed inaccurately. Some data sets do not use standard medical terminology. [Table 1](#) provides unique data elements which exist only in the haemodialysis domain and often lack standard terminology.

Table 1 — Unique data elements in haemodialysis

Elements	Element description and its significance
Dry weight	<ul style="list-style-type: none"> — Target weight of haemodialysis without fluid overload or hypovolemia. — It should not be misinterpreted as common body weight.
Haemodialysis blood flow rate	<ul style="list-style-type: none"> — Blood flow in haemodialysis machine. — It should not be misinterpreted as the blood flow in the patient's body. — It represents setting value in the haemodialysis machine.
Haemodialysis access	<ul style="list-style-type: none"> — Body site to reach the blood for haemodialysis.
Dialysate	<ul style="list-style-type: none"> — Kind of chemical bath used in dialysis to draw fluids and toxins out of the blood stream. — It is not considered as medication data.
Interdialytic weight gain	<ul style="list-style-type: none"> — Amount of weight gain as a result of salt and water intake between two haemodialysis sessions. — It is used as value to calculate target weight during haemodialysis. — It should not be misinterpreted as common weight gain.
Haemodialysis machine model	<ul style="list-style-type: none"> — Information of haemodialysis machine manufacturer and model. — Importance of model is often neglected. — Standard terminology not given.

4.3 Purpose of a standardized data set

Safe and timely haemodialysis requires a complex set of data and it is practically unfeasible for a patient to remember each element. Therefore, it has been a common practice to carry paper-based data when they are transferred (see [Annex A](#)). A standard haemodialysis data set benefits both patients and medical staff by electronically transferring relevant and accurate dialysis data.

Moreover, a standard haemodialysis data set can provide safe dialysis to patients by reducing the possibility of haemodialysis-related complications. Haemodialysis is a care-intensive process that requires the utmost attention to prevent various complications. For example, if haemodialysis parameters are set inappropriately, too much water can be removed from patients which can lead to hypovolemia, hypotension and fatigue. Therefore, it is critical to have data from previous dialysis about end-dialysis weight and dialysis speed. Such information can be accurately and electronically transferred from one medical institution to another using the standardized data set proposed in this document.

Timely haemodialysis is important, because delays in haemodialysis schedule can lead to worsening uraemia, increased infection susceptibility and other preventable complications. Sometimes, medical staff need to additionally contact the medical institution that issued the referral because patients did not know all the necessary information for their haemodialysis. Since the standardized data set proposed in this document provides basic parameters to start and monitor haemodialysis procedure, it can reduce the time for medical staff to prepare a haemodialysis session.

5 Use case

5.1 General

Haemodialysis transfer is a multidisciplinary process because it involves wide range of agenda, including educating a patient on diet and exercise and explaining inadvertent complications of haemodialysis to the patient's family members.

A transfer can be done for various reasons, for example if the patient needs a procedure unrelated to kidney issues or if they move to another state. It can also occur if the patient's family planned a family trip to a near-by country.

Reviewing the data elements in the proposed data set provides helpful information to medical staff, especially in the case of a haemodialysis patient who is planned to be transferred. For instance, the time between receiving the data and the patient's visit would help medical staff to evaluate risk factors for the upcoming transfer and to decide on appropriate transfer time. Sending the proposed data set to a recipient hospital is more than a simple data transfer because it helps a recipient hospital prepare for unexpected events that can occur at any step of the transfer process. Detailed information on the transfer process should be shared with the patient, and discussions can be necessary with patient's custodians.

Patients can have very different complication risks depending on their age, race and comorbidities. Some patients can develop repetitive complications by haemodialysis and can develop similar complications in the recipient hospital. Repetitive adverse events can be notified and can be prevented. Sometimes it is necessary to contact the recipient hospital to query whether all necessary medical equipment is ready for expected emergency.

[5.2](#), [5.3](#) and [5.4](#) are intended to provide several use cases with different risks of complication.

5.2 Haemodialytic patient with no special problems

In this use case, the haemodialysis patient has had stable haemodialysis repeatedly. The patient is young. Vital signs are stable. No adverse event has been notable in repeated haemodialysis session. The patient can be transferred with only the required data set. Other fields are either conditionally-required or optional. The required, conditionally-required and optional field are further explained in [Clause 6](#).

5.3 HIV positive haemodialytic patient

When a haemodialytic patient is HIV positive, additional measures should take place to minimize the risk of spreading HIV to other patients and clinic staff. HIV test result shall be included in the data set. Clinic staff are also required to share the information because careless contacts with the patient must be avoided. Also, a recipient haemodialysis clinic must provide a haemodialysis machine which is dedicated to HIV patients. Before referral, a physician can contact the recipient hospital for the availability of HIV haemodialysis. Since an HIV dedicated machine is equipped in limited numbers, it is imperative to check that schedules are not overlapping and that those machines are ready for the next scheduled haemodialysis.

5.4 Haemodialytic patient with refractory heart failure

Heart failure and renal dysfunction can coexist. The number of comorbidities increases over time. A critical issue with this combination is that each disease can exacerbate another. ESRD can lead to retention of water which can cause cardiac dysfunction. ESRD can also exacerbate heart failure progressively and finally make it refractory to treatment. A possible treatment approach can be to address the treatable cause of valvular heart disease. Physicians should deal with the volume of excess fluid. Patients are requested to reduce the dietary intake of salt during the transfer process. The data set which is related to heart failure shall be transmitted before transfer process. The recipient clinic shall make a decision on whether they accept the transfer. Medication should be also monitored and approximated because renal dysfunction commonly limits the use of medication on cardiac problems.

6 Data sets for transfer of haemodialysis

6.1 General

In this document, data set types are categorized as required, conditionally-required and optional. Data sets are also categorized according to when they are needed, so they are defined as needed before, during or after the haemodialysis procedure. Data sets are also categorized according to the importance of the dialysis procedure, as the focus is on the dialysis procedure rather than general health. Therefore, they may differ from general healthcare data sets. [Table 2](#) shows the overall data tabulated and accompanied by the necessary metadata, including a glossary of terms and brief examples with code and value property. Also, more detailed exemplary data are provided in Annex B.

Table 2 — data elements for haemodialysis

Attribute name/Data element name	Coding system	Code value	Data value type	Qualifier ^a
Last dialysis date	Applicable terminology		DateTime	R
Haemodialysis interval	LOINC	LOINC 50951-9 Interdialytic time (ESRD)	DateTime	R
Dry weight	LOINC	LOINC 8341-0 Dry body weight measured	kg, lb	R
Haemodialysis machine model			Text	R
Haemodialysis blood flow rate	LOINC	LOINC 99711-4 Blood flow rate Renal replacement therapy circuit	ml/min	R
Haemodialysis access type	LOINC	LOINC 72050-8 Dialysis access	LOINC Answer List LL2169-2 ESRD-dialysis access type	R
Haemodialysis access site	LOINC	LOINC 99715-5 Dialysis access site	SNOMED Body Structure	R
Haemodialysis access status	LOINC	LOINC 99716-3 Dialysis access site appearance	LOINC Answer List LL2150-8 Access site appearance	R
Hepatitis type B antigen / antibody	LOINC	LOINC 5195-3 Hepatitis B virus surface Ag (presence) in serum	LOINC Answer List LL3865-4 True -False Unknown	R
Hepatitis C virus infection	LOINC	LOINC 11259-9 Hepatitis C virus RNA (presence) in serum or plasma	LOINC Answer List LL3865-4 True -False Unknown	R
Human immunodeficiency virus infection	LOINC	LOINC 7917-8 HIV 1 Ab (Presence) in serum	LOINC Answer List LL3865-4 True -False Unknown	R
Dialysis duration	LOINC	LOINC 68489-4 Dialysis hours per session	Hours	R
Dialysate	LOINC	LOINC 99732-0 Dialysate fluid renal replacement therapy circuit	Text	R
Initial dialysis date	Applicable terminology		DateTime	C (6.3.2.2)
Last laboratory test date	Applicable terminology		DateTime	C (6.3.3.2)

^a R = required; C = conditionally required; O = optional.

ISO/TS 9320:2024(en)

Table 2 (continued)

Attribute name/Data element name		Coding system	Code value	Data value type	Qualifier ^a
Blood type		LOINC	LOINC 882 ABO and Rh group (type) in blood	LOINC Answer List LL2972-9 ABORh	C (6.3.4.2)
Diagnosis		ICD 10/11, SNOMED Applicable Terminology	ICD10 M47 Spondylosis arthrosis or osteoarthritis of spine	Code, List of Codes	C (6.3.5.2)
Blood haemoglobin concentration		LOINC	LOINC 42810-2 Haemoglobin (mass/volume) in blood	g/dl	C (6.3.6.2)
Blood sodium concentration		LOINC	LOINC 2951-2 Sodium (moles/volume) in serum or plasma	mmol/l	C (6.3.7.2)
Blood potassium concentration		LOINC	LOINC 2823 Potassium (moles/volume) in serum or plasma	mmol/l	C (6.3.8.2)
Blood calcium concentration		LOINC	LOINC 2000-8 Calcium (moles/volume) in serum or plasma	mmol/l	C (6.3.9.2)
Blood phosphate concentration		LOINC	LOINC 2777-1 Phosphate (mass/volume) in serum or plasma	mg/dl	C (6.3.10.2)
Venereal disease search laboratory		LOINC	LOINC 5292-8 Reagin Ab in serum	LOINC Answer List LL3865-4 True - False Unknown	C (6.3.11.2)
Pre/post-dialysis vital sign	Systolic Blood pressure	LOINC	LOINC 8480-6 Systolic blood pressure	mmHg	C (6.3.12.2, 6.3.13.2)
	Diastolic blood pressure	LOINC	LOINC 8462-4 Diastolic blood pressure	mmHg	
	Heart rate	LOINC	LOINC 8867-4 Heart rate	/min	
	Respiration rate	LOINC	LOINC 9279-1 Respiratory rate	/min	
	Body temperature	LOINC	LOINC 8310-5 Body temperature	Degrees Celsius, Fahrenheit °C, °F	
Interdialytic weight gain		LOINC	LOINC-74006-8 Weight difference: pre-dialysis vs. post-dialysis	Numeric (kg, lb)	C (6.3.14.2)
Prescription		RxNorm, SNOMED	RxCUI 385629 Acetaminophen 5 mg/ml	Code/ List of Codes	C (6.3.15.2)
Remark note		Applicable terminology	Not determined	Text	C (6.3.16.2)
Heparin concentration		Applicable terminology	Not determined	Heparin unit/dose	0
Remnant kidney function		LOINC	LOINC 9188-4 urine output 1 hour	ml/h	0

^a R = required; C = conditionally required; 0 = optional.

Table 2 (continued)

Attribute name/Data element name	Coding system	Code value	Data value type	Qualifier ^a
Other laboratory result	LOINC / SNOMED applicable terminology	LOINC 789-8 erythrocytes in blood by automated count	Numeric /nominal /ordinal depending on element	0
Radiology report	LOINC	LOINC 18782-3 Radiology study observation	Text	0
Allergy	LOINC	LOINC 48765-2 Allergies and adverse reactions and document	Text/Code (SNOMED 703925004)	0
Presence of heart failure	LOINC	88020-3 Functional capacity NYHA	LOINC Answer List (LL4734-1, NYHA FA: Class I Class II Class III Class IV)	0
Heart ejection fraction	LOINC	10230-1 left ventricular ejection fraction	Numeric (%)	0
Haemodialysis access construction date	LOINC		Date/Time	0

^a R = required; C = conditionally required; 0 = optional.

6.2 Fields of required data

6.2.1 General

The required data set is composed of information that helps clinicians making critical decisions and making sessions manageable by haemodialysis staff. For example, when medical staff are about to start a dialysis session, the data set helps them choose which machine to use and setting the parameters of a procedure. Infectious markers, such as HIV, HCV and HBV shall be included in the required data set. The information is important when a dialysis is prepared and during the initial stage of the procedure. When a patient is referred, all required data field shall be filled. The data elements are summarized in [Table 2](#). The table covers terminology, data type and meta data.

6.2.2 Last dialysis date

6.2.2.1 Purpose

It is the date of most recent haemodialysis, which is required for deciding next dialysis schedule. Patients will suffer accumulation of toxins, fluid retention and electrolyte imbalance if they don't follow prescribed schedule of haemodialysis. Usually, patients are also instructed on the importance of haemodialysis schedule.

6.2.2.2 Business rules

- a) This is a required element and shall be in the data set.
- b) Unknown and known absence should be stated explicitly.

6.2.2.3 Missing data

This is a required element for conformance and shall not be empty; at least, a statement shall be given explaining the missing data.

6.2.2.4 Example

“url”: “last-dialysis-date”

“performedDateTime”: “2022-08-22”

6.2.3 Haemodialysis interval

6.2.3.1 Purpose

It refers to currently prescribed interval between haemodialysis sessions. It provides information on when to start the next haemodialysis in receiving clinic.

6.2.3.2 Business Rules

- a) This is a required element and shall be in the data set.
- b) Unknown and known absence should be stated explicitly.

6.2.3.3 Missing Data

This is a required element for conformance and shall not be empty; at least, a statement shall be given explaining the missing data.

6.2.3.4 Example

“url”: “dialysis-interval”

“frequency”: 3

“periodUnit”: “wk”

6.2.4 Dry weight

6.2.4.1 Purpose

It helps clinicians determine how much excess fluid needs to be removed during each haemodialysis session, because it refers to optimal or target weight that a patient should achieve during the treatment.

6.2.4.2 Business rules

- a) This is a required element and shall be in the data set.
- b) Unknown and known absence should be stated explicitly.

6.2.4.3 Missing data

This is a required element for conformance and shall not be empty.

6.2.4.4 Example

“url”: “dialysis-dryweight”

“value”: 47.5

“unit”: “kg”

6.2.5 Haemodialysis machine model

6.2.5.1 Purpose

It refers to information on haemodialysis machine manufacturer and model used in recent haemodialysis sessions. The element provides unique features, configuration requirement to receiving unit. It also provides information on specific dialysate products.

6.2.5.2 Business rules

- a) This is a required element and shall be in the data set.
- b) Unknown and known absence should be stated explicitly.

6.2.5.3 Missing data

This is a required element for conformance and shall not be empty.

6.2.5.4 Example

“model-name”: “Theranova 400”

6.2.6 Haemodialysis blood flow rate

6.2.6.1 Purpose

It is required to determine the appropriate blood flow rate for each individual undergoing haemodialysis to balance the benefits and potential risks.

6.2.6.2 Business rules

- a) This is a required element and shall be in the data set.
- b) If the element is not in usual range, the reason should be provided in remark note.
- c) Unknown and known absence should be stated explicitly.

6.2.6.3 Missing data

This is a required element for conformance and shall not be empty.

6.2.6.4 Example

“url”: “dialysis-blood-flow-rate”

“value”: 250

“unit”: “m/min”

6.2.7 Haemodialysis access type

6.2.7.1 Purpose

The purpose is to inform clinicians on how a patient’s blood stream is connected to haemodialysis machine.

6.2.7.2 Business rules

- a) This is a required element and shall be in the data set.

- b) If there are multiple access types, all lists shall be provided.
- c) Unknown and known absence should be stated explicitly.

6.2.7.3 Missing data

This is a required element for conformance and shall not be empty.

6.2.7.4 Example

“system”: “<http://snomed.info/sct>”

“code”: “445085009”

“display”: “Tunneled central venous catheter”

6.2.8 Haemodialysis access site

6.2.8.1 Purpose

It is to inform clinicians of where a patient’s blood stream is connected to haemodialysis machine.

6.2.8.2 Business rules

- a) This is a required element and shall be in the data set.
- b) If there are multiple access sites, a list of all sites should be provided.
- c) If there are multiple access sites, the most suitable one shall be provided.

6.2.8.3 Missing data

This is a required element for conformance and shall not be empty.

6.2.8.4 Example

“system”: “<http://snomed.info/sct>”

“code”: “368503001”

“display”: “Structure of right radial artery (body structure)”

6.2.9 Haemodialysis access status

6.2.9.1 Purpose

It is required for clinicians to check the condition and functionality of the access site through which haemodialysis treatments are performed. The element covers information of patency, infectious sign or any issues that can affect the blood flow during dialysis.

6.2.9.2 Business rules

- a) This is a required element and shall be in the data set.
- b) When patency is not normal, necessary interventions should be provided in the remark note.
- c) When access shows infectious finding, relevant medications should be provided in the medication element.

- d) When access shows infectious finding, relevant laboratory results should be provided in the “other laboratory result” element.
- e) When patency is not normal, access construction date may be provided.
- f) Unknown and known absence should be stated explicitly.

6.2.9.3 Missing data

This is a required element for conformance and shall not be empty.

6.2.9.4 Example

“system”: “<http://loinc.org>”

“code”: “LA16666-2”

“display”: “Active”

6.2.10 Hepatitis type B antigen / antibody

6.2.10.1 Purpose

It is important to prevent the spread of hepatitis B within haemodialysis unit. For positive patients, healthcare providers implement infection control measures to prevent of spread of the disease.

6.2.10.2 Business rules

- a) This is a required element and shall be in the data set.
- b) Unknown and known absence should be stated explicitly.

6.2.10.3 Missing data

This is a required element for conformance and shall not be empty.

6.2.10.4 Example

“system”: “<http://loinc.org>”

“code”: “39535-0”

“display”: “Hepatitis B virus surface Ab [Presence] in Serum by Radioimmunoassay (RIA)”

6.2.11 Hepatitis C virus infection

6.2.11.1 Purpose

The purpose is to prevent the spread of hepatitis C within haemodialysis unit. For positive patients, healthcare providers implement increased infection control measures to prevent of spread of the disease. In haemodialysis unit, there can be shared equipment such as haemodialysis machines and blood tubing kits. If equipment is not adequately cleaned, sterilized and maintained between patients uses, it can pose a risk of cross-contamination.

6.2.11.2 Business rules

- a) This is a required element and shall be in the data set.
- b) Unknown and known absence should be stated explicitly.

6.2.11.3 Missing data

This is a required element for conformance and shall not be empty.

6.2.11.4 Example

“system”: “<http://loinc.org>”

“code”: “16128-1”

“display”: “Hepatitis C virus Ab [Presence] in Serum”

“value”: “Negative”

6.2.12 Human immunodeficiency virus infection

6.2.12.1 Purpose

The purpose is to prevent the spread of human immunodeficiency virus within haemodialysis unit. For positive patients, healthcare providers implement infection control measures to prevent of spread of the disease. Some haemodialysis patients can have weakened immune systems due to chronic kidney disease, which can potentially make them more susceptible to HIV infections.

6.2.12.2 Business rules

- a) This is a required element and shall be in the data set.
- b) Unknown and known absence should be stated explicitly.

6.2.12.3 Missing data

This is a required element for conformance and shall not be empty.

6.2.12.4 Example

“system”: “<http://loinc.org>”

“code”: “41145-4”

“display”: “HIV 1 Ab [Presence] in Capillary blood”

“value”: “Negative”

6.2.13 Dialysis duration

6.2.13.1 Purpose

It refers to the duration of a haemodialysis session. It is required to design a haemodialysis session for a specific patient. Usual haemodialysis ranges from 3 hours to 4 hours. Longer duration means removal of more water and uremic toxins for a given blood flow rate. It is also related to patient tolerance and haemodynamic stability.

6.2.13.2 Business rules

- a) This is a required element and shall be in the data set.
- b) Unknown and known absence should be stated explicitly.
- c) Can be provided as last or average duration.

6.2.13.3 Missing data

This is a required element for conformance and shall not be empty.

6.2.13.4 Example

“url”: “dialysis-duration”

“value”: 4

“unit”: “h”

6.2.14 Dialysate

6.2.14.1 Purpose

This information is important for consistency in haemodialysis session. Depending on the dialysate products used in haemodialysis, parameters and components vary to tailor the treatment to the specific needs of each patient. Those variations include electrolyte concentration, conductivity and pH. Sometimes dialysates can be customized to accommodate comorbid conditions.

6.2.14.2 Business rules

- a) This is a required element and shall be in the data set.
- b) Preferred brand and product name shall be provided.

6.2.14.3 Missing data

This is a required element for conformance and shall not be empty.

6.2.14.4 Example

“url”: “dialysate”

“value”: “HD sol - BCGA”

6.3 Fields of conditionally-required data

6.3.1 General

Conditionally-required data should be provided under certain circumstances at the time of transfer. There are elements to be monitored to prevent complications during haemodialysis, such as sodium, potassium or other electrolyte concentrations. Some elements are also required to manage situations when a complication develops. For example, patient’s blood type is required if urgent blood transfusion is necessary. However, elements in the conditionally-required field are less critical than required elements because they are usually necessary during or after dialysis session.

6.3.2 Initial dialysis date

6.3.2.1 Purpose

It refers to the date of the first haemodialysis session, which serves as a foundational reference point for planning and managing the life-long care of haemodialysis patients. It affects haemodialysis interval and duration. It is also required to plan nutritional and medication management.

6.3.2.2 Business rules

- a) When haemodialysis session is not effective in removing water and toxic material, the element shall be provided.
- b) When haemodialysis interval and duration is not optimal, or treatment planning is changed, initial dialysate shall be provided.

6.3.2.3 Missing data

Missing data implies that stable and effective haemodialysis result was achievable.

6.3.2.4 Example

“url”: “dialysis-initial-date”

“valueDateTime”: “2018-05-15”

6.3.3 Last laboratory test date

6.3.3.1 Purpose

It is important for timely monitoring of the overall dialysis effect and various medical conditions. Regular laboratory test is required to monitor dialysis adequacy, electrolyte imbalance, anaemia management. It provides clinicians with information on when to perform the next laboratory tests.

6.3.3.2 Business rules

- a) This is a conditionally-required element.
- b) If patient has issues regarding infection, access functionality or dialysis effectiveness, lab test date shall be provided.
- c) When laboratory result is abnormal, the element shall be provided.

6.3.3.3 Missing data

Missing data implies that there was no significant finding in laboratory result.

6.3.3.4 Example

“url”: “dialysis-last-lab-test-date”

“valueDateTime”: “2022-08-28”

6.3.4 Blood type

6.3.4.1 Purpose

It is important for possible blood transfusions and kidney transplant. Haemodialysis patients can occasionally require blood transfusion due to anaemia or bleeding.

6.3.4.2 Business rules

- a) This is a conditionally-required element.
- b) The element shall be provided if the patient is in anaemic condition or in case of previous history of transfusion.

6.3.4.3 Missing data

Missing data implies transfusion is not considered at the time of referral.

6.3.4.4 Example

“system”: “<http://loinc.org>”

“code”: “LA21321-7”

“display”: “O Pos”

6.3.5 Diagnosis

6.3.5.1 Purpose

It is the classification of a particular illness or disease. It is required to inform recipient clinicians of additional medical conditions or diseases that coexist with ESRD.

6.3.5.2 Business rules

- a) Active disease shall be in the list.
- b) Severity, chronicity may be provided if data is present.
- c) Start date and end date should be provided if data is present.

6.3.5.3 Missing data

Missing data implies that no significant disease is observed other than kidney disease.

6.3.5.4 Example

“system”: “<http://hl7.org/fhir/sid/icd-10-cm>”

“code”: “E08.22”

“display”: “Diabetes mellitus due to underlying condition with diabetic chronic kidney disease”

6.3.6 Blood haemoglobin concentration

6.3.6.1 Purpose

It is important for monitoring anaemic conditions in ESRD, to assess severity and management of symptoms. Anaemia is common in ESRD due to reduced erythropoietin production by kidneys, which leads to decreased red blood cell production.

6.3.6.2 Business rules

- a) This element shall be provided if result is abnormal.
- b) If data is provided, lab test date should be provided.
- c) If result is abnormal, relevant lab test results should be optionally provided such as complete blood count, iron studies, blood folate level.
- d) If result is abnormal, relevant medication should be provided.

6.3.6.3 Missing data

Missing data implies that haemoglobin is within the normal range.

6.3.6.4 Example

“system”: “<http://loinc.org>”

“code”: “718-7”

“display”: “Haemoglobin [Mass/volume] in Blood”

“value”: 7.2

“unit”: “g/dl”

“system”: “<http://unitsofmeasure.org>”

6.3.7 Blood sodium concentration

6.3.7.1 Purpose

It is important to monitor and maintain the concentration of sodium in serum or plasma. Hypernatremia or hyponatremia can occur in ESRD patient due to dietary sodium intake, fluid imbalance and effectiveness of haemodialysis treatment.

6.3.7.2 Business rules

- a) This element shall be provided if result is abnormal.
- b) If data is provided, lab test date should be provided.

6.3.7.3 Missing data

Missing data implies serum sodium concentration is within normal range.

6.3.7.4 Example

“system”: “<http://loinc.org>”

“code”: “2951-2”

“display”: “Sodium [Moles/volume] in Serum or Plasma”

“value”: 132.6

“unit”: “mmol/L”

6.3.8 Blood potassium concentration

6.3.8.1 Purpose

It is important to maintain proper concentration of potassium in serum or plasma of patient. Patients with ESRD are at high risk of developing hyperkalaemia, because potassium can be ineffectively excreted by the kidneys. Regular monitoring of serum potassium levels is crucial in ESRD patients. Healthcare providers should adjust dietary recommendations and medications based on this element.

6.3.8.2 Business rules

- a) This element shall be provided if result is abnormal.

- b) If data is provided, lab test date should be provided.
- c) If patient is highly hyperkalaemic, reason of transfer shall be provided.

6.3.8.3 Missing data

Missing data implies that potassium is within normal range.

6.3.8.4 Example

“system”: “<http://loinc.org>”

“code”: “2823-3”

“display”: “Potassium [Moles/volume] in Serum or Plasma”

“value”: 4.93

“unit”: “mmol/L”

6.3.9 Blood calcium concentration

6.3.9.1 Purpose

It is important to maintain proper concentration of calcium in serum or plasma. Calcium concentration in blood is very important because calcium plays fundamental roles in regulating cardiac function, muscle contraction and nerve conduction system. Hypocalcaemia can occur in ESRD because of the decreased activation of vitamin D.

6.3.9.2 Business rules

- a) This element shall be provided if result is abnormal.
- b) If data is provided, lab test date should be provided.

6.3.9.3 Missing data

Missing data implies serum calcium concentration is within normal range.

6.3.9.4 Example

“system”: “<http://loinc.org>”

“code”: “2000-8”

“display”: “Calcium [Moles/volume] in Serum or PlasmaActive”

“value”: 2.3

“unit”: “mmol/L”

6.3.10 Blood phosphate concentration

6.3.10.1 Purpose

It is important to monitor and maintain proper concentration of phosphate in serum or plasma. In ESRD, the phosphate concentration often becomes elevated, because impaired kidney function results in decreased phosphate excretion in urine.

6.3.10.2 Business rules

- a) This element shall be provided if result is positive.
- b) If data is provided, lab test date should be provided.

6.3.10.3 Missing data

Missing data implies serum concentration is within normal range.

6.3.10.4 Example

“system”: “<http://loinc.org>”

“code”: “2777-1”

“display”: “Phosphate [Mass/volume] in Serum or Plasma”

“value”: 2.3

“unit”: “mg/dL”

6.3.11 Venereal disease research laboratory

6.3.11.1 Purpose

It is important to prevent potential cross transmission of syphilis. Syphilis can be transmitted through blood contact, including contaminated dialysis equipment or through open wounds such as those used for haemodialysis access. The element helps identify any cases of syphilis among haemodialysis patients, allowing for appropriate infection control measures to prevent further transmission.

6.3.11.2 Business rules

- a) This element shall be provided if result is positive.
- b) If data is provided, lab test date should be provided.
- c) If result is positive, it should be indicated whether the syphilis status is active or not.
- d) If result is positive, specific syphilis test results, such as fluorescent treponemal antibody absorption, should be provided if available.
- e) If result is positive, treatment history of syphilis should be provided in remark note.

6.3.11.3 Missing data

Missing data implies VDRL result is negative or VDRL test result is not available.

6.3.11.4 Example

“system”: “<http://loinc.org>”

“code”: “5292-8”

“display”: “Reagin Ab [Presence] in Serum by VDRL”

“value”: “Non-Reactive”

6.3.12 Pre-dialysis vital sign

6.3.12.1 Purpose

It is important to prevent haemodialytic complication and assess the effect of haemodialysis. Some patients can experience hypotension, cramps or chest pain during a dialysis session. Monitoring vital signs throughout the procedure helps clinicians detect and respond to events promptly. Blood pressure measurements help determine the appropriate level of ultrafiltration during haemodialysis. Many haemodialysis patients have hypertension before the start of their dialysis session. Pre-dialysis blood pressure readings can be higher than the target range for normal blood pressure. Vital signs in referral data set serve as a foundation for planning a specific haemodialysis session.

6.3.12.2 Business rules

- a) The data shall be provided if any pre-dialysis vital sign is abnormal.
- b) If vital signs are variable, a list of vital signs should be provided.

6.3.12.3 Missing data

Missing data implies that vital signs are not remarkable.

6.3.12.4 Example

“system”: “<http://loinc.org>”

“code”: “8867-4”

“display”: “Heart rate”

“value”: 67

“unit”: “/min”

6.3.13 Post-dialysis vital sign

6.3.13.1 Purpose

It is important to prevent haemodialytic complication and assess the effect of haemodialysis. The information is foundation for evaluating the effectiveness of a haemodialysis session. After completing a haemodialytic session, blood pressure usually stabilizes or decreases further, depending on how effectively excessive water was removed during dialysis.

6.3.13.2 Business rules

- a) The data shall be provided if any post-dialysis vital sign is abnormal.
- b) If vital signs are variable, a list of vital signs should be provided.

6.3.13.3 Missing data

Missing data implies vital signs are not remarkable.

6.3.13.4 Example

“text”: “Systolic Blood Pressure”

“system”: “<http://loinc.org>”

“code”: “8480-6”

“display”: “Systolic blood pressure”

“value”: 150

“unit”: “mmHg”

6.3.14 Interdialytic weight gain

6.3.14.1 Purpose

It is important to provide information for proper fluid balance, preventing complications and optimizing dialysis prescription. This information helps receiving clinicians understand patients’ dialysis and fluid management needs.

6.3.14.2 Business rules

a) If dry weight is unavailable, this shall be provided.

6.3.14.3 Missing data

Missing data implies weight gain is stable or readily inferable when dry weight is provided.

6.3.14.4 Example

“system”: “<http://loinc.org>”

“code”: “74006-8”

“display”: “Weight difference [Mass difference] --pre dialysis - post dialysis”

“unit”: “kg”

6.3.15 Prescription

6.3.15.1 Purpose

It is important to provide direction for the preparation, compounding, and administration of medication. It usually covers current medication status. Since dialysis is performed 2-3 times a week and medications are prescribed on a monthly basis, it is often not necessary to have a prescription at the time of transferring a dialysis patient.

6.3.15.2 Business rules

a) Prescription list shall be provided if prescription is necessary at the time of haemodialysis session.

b) Prescription list shall be provided if referral is not temporarily transferred.

c) If case of anaemia, infection or access malfunction, relevant medication shall be provided.

d) Dosage and frequency shall be provided.

6.3.15.3 Missing data

Missing data implies that the prescription is not due.

6.3.15.4 Example

“system”: “<https://www.nlm.nih.gov/research/umls/rxnorm>”

“code”: “317655”

“display”: “Nifedipine”

“frequency”: 3

“period”: 1

“periodUnit”: “d”

“doseQuantity”: {“value”: 30, “unit”: “mg”}

6.3.16 Remark note

6.3.16.1 Purpose

It is important to cover important information which is not standardized or structured in data set. Remark note may include clinical history of a patient including reason for referral, any relevant medical conditions, past treatment, surgeries and medications.

6.3.16.2 Business rules

- a) Any issues during haemodialysis session which can endanger patient/staff safety shall be provided.
- b) Any special consideration that receiving healthcare provider should be aware of should be provided.

6.3.16.3 Missing data

Missing data implies that there is no specific remark to be made.

6.3.16.4 Example

“The patient becomes distressed when systolic blood pressure drops below 160 mm Hg”

6.4 Fields of optional data

6.4.1 General

Optional fields may be included if available and appropriate. Usually, the elements are necessary after a dialysis session is finished. These provide information to make a prescription, for additional clinical exams and to manage patients' long-term prognosis. They are necessary for consultation and follow up plan.

6.4.2 Heparin concentration

6.4.2.1 Purpose

It provides the concentration of heparin in haemodialysis fluid, which is necessary to prevent catheter thrombosis.

6.4.2.2 Business rules

- a) If heparin dosage is either higher or lower than typical amount, heparin concentration should be provided.

6.4.2.3 Missing data

Missing data implies heparin concentration can be administered as usual protocol of receiving unit.

6.4.2.4 Example

“url”: “initial-dose-heparin”

“value”: 2000

“units”: “[IU]”

6.4.3 Remnant kidney function

6.4.3.1 Purpose

It is important to tailor treatment plans and optimize long-term treatment. Not all individuals retain significant kidney function. However, when present, small amount of remnant kidney function can have substantial impact on patient health status and management of ESRD, because native kidneys help regulate fluid balance in the body. Patients with some remnant kidney function can have better control over fluid retention between dialysis sessions, reducing the risk of fluid overload. If remnant kidney function data is not available, it can be inferred by evaluating dry weight and haemodialysis interval.

6.4.3.2 Business rules

a) This is an optional element.

6.4.3.3 Missing data

Missing data implies that remnant kidney function is not available.

6.4.3.4 Example

“system”: “<http://loinc.org>”

“code”: “9192-6”

“display”: “Urine output 24 hour”

“value”: 150

“unit”: “ml/(24 h)”

6.4.4 Other laboratory results

6.4.4.1 Purpose

The objective is to provide potentially significant details regarding data sets beyond those specified as required or conditionally-required. There can be crucial information omitted, which is not encompassed within the designated data set elements.

6.4.4.2 Business rules

a) If other laboratory result is abnormal, the time should be provided.

6.4.4.3 Missing data

Missing data implies other laboratory results are not remarkable or not available.

6.4.4.4 Example

“system”: “<http://loinc.org>”

“code”: “789-8”

“display”: “Erythrocytes [number/volume] in Blood by Automated count”

“value”: 3.05

“unit”: “10⁶/μL”

6.4.5 Radiology report

6.4.5.1 Purpose

The objective is to provide information about any imaging studies that have been conducted, such as X-rays, CT scans, MRIs, or ultrasound. The radiologic report contains details on patient’s kidneys, urinary tract, or any other relevant organs. It can reveal the presence or progression of underlying kidney-related conditions or complications such as kidney stones, cysts, tumours or calcifications.

6.4.5.2 Business rules

a) This is an optional element.

6.4.5.3 Missing data

Missing data implies radiologic report is not available.

6.4.5.4 Example

“system”: “<http://loinc.org>”

“code”: “8341-0”

“display”: “Radiology Study observation (narrative)”

“valueString”: “Chest PA: DLC insertion, right \n Cardiomegaly \n Blunting of both CP angles \n Left pleural effusion \n Subsegmental atelectasis at RLL.”

6.4.6 Allergy

6.4.6.1 Purpose

It informs receiving clinicians on altered bodily reactivity (such as hypersensitivity) to a diet, medication and contrast agent. Haemodialysis patients often require a complex medication regimen. Allergies to specific medication or their components can lead to adverse reactions, including rashes, hives, itching, swelling, difficulty breathing, or even anaphylaxis.

6.4.6.2 Business rules

a) This is an optional data element.

b) If allergies are present, they should be listed.

6.4.6.3 Missing data

Missing data implies that no allergy is ever observed.

6.4.6.4 Example

“system”: “<http://loinc.org>”

“code”: “52472-8”

“display”: “Allergies and Adverse Drug Reactions”

“code”: “nilknown”

“display”: “Nil Known”

6.4.7 Presence of heart failure

6.4.7.1 Purpose

It is important to assess risk, tailor treatment plans and optimize fluid management in ESRD patient. It provides information whether the heart cannot pump enough blood to meet the body's needs. Patients with heart failure can require different management approaches, including medications, dietary restrictions and fluid management strategies.

6.4.7.2 Business rules

- a) If heart failure is positive, diagnosis should provide relevant conditions.
- b) If heart failure is positive, NYHA functional classification class should be provided.
- c) If heart failure is positive, heart ejection fraction should be provided.

6.4.7.3 Missing data

Missing data implies data is not available or presence is negative.

6.4.7.4 Example

“code”: “45641-8”

“display”: “Congestive heart failure”

“system”: “<http://loinc.org>”

“code”: “LA32-8”

“display”: “No”

6.4.8 Heart ejection fraction

6.4.8.1 Purpose

It is important to help risk assessment, to guide treatment decisions and to allow clinicians to understand and manage complex interplay between kidney and heart problems. It provides a measure of cardiac function reflecting the average fraction of emptying of the left ventricle with each contraction.

6.4.8.2 Business rules

- a) If ejection fraction is not within the normal range, it should be provided in the data set.

6.4.8.3 Missing data

Missing data implies data is not available or the element is within normal range.

6.4.8.4 Example

“system”: “<http://loinc.org>”

“code”: “10230-1”

“display”: “Left ventricular ejection fracture”

“value”: 78

“unit”: “%”

“system”: “<http://unitsofmeasure.org>”

6.4.9 Haemodialysis access construction date

6.4.9.1 Purpose

It provides patient’s access history, assessing its suitability and function. Knowing when the access was constructed helps clinicians evaluate whether it is suitable for haemodialysis and if any issues with its maturity or function can be present.

6.4.9.2 Business rules

- a) If access status has issues, it should be provided in the data set.
- b) If a patient has multiple access sites created over time, all relevant list of sites should be provided with construction dates.

6.4.9.3 Missing data

Missing data implies data is not available, or that there is no issue regarding access status.

6.4.9.4 Example

“system”: “<http://snomed.info/sct>”

“code”: “46196009”

“display”: “Surgical construction of arteriovenous shunt (procedure)”

“performedDateTime”: “2022-05-20”

Annex A
(informative)

Example of a haemodialysis referral paper

Figure A.1 presents an example of a haemodialysis referral paper.

DIALYSIS PATIENT HOSPITAL TRANSFER FORM

PATIENT INFORMATION

Name	XX An	Resident Registration Number	250909-2005813	Sex/Age	F/75	Payer	<input checked="" type="checkbox"/> KP	<input checked="" type="checkbox"/> Premius
Address	3rd Hyundai APT in Gaepodong, Gangnam-gu, Seoul		Phone	02) 574-XXXX			<input type="checkbox"/> Econo	
Transfer reason	Transfer hospitals due to housing issues							

DIALYSIS INFORMATION

Cause Disease	DM							
Dialysis start date	30/03/99 [dd/mm/yy]			Last dialysis date	13/01/00 [dd/mm/yy]			
Dialysis machines	AK POS	Dialyzer	GFr +12	Dialysate	bicarbonate			
Number of dialysis	3 times/week		Dialysis time	4 hr	Blood flow rate (ml/min)	200		
Arteriovenous access	<input type="checkbox"/> AVF() <input type="checkbox"/> AVG() <input checked="" type="checkbox"/> Perm C(99,6,30) <input type="checkbox"/> JVC() <input type="checkbox"/> SVC() <input type="checkbox"/> FVC()							
Heparin	Initial dose	1500 unit		Blood pressure	Before dialysis	180/80 mmhg		
	Maintenance dose	500 unit/hr			After dialysis	180/90 mmhg		
Dry Weight	50,5 Kg			Average weight gain between dialysis	1,0 – 1,5 Kg			
Infection	HBsAg/Ab	(negative/positive 99/6/30)		AntiHIV	(negative 99/6/30)			
	AntiHCV	(negative 99/6/30)		VDRL	(negative 99/6/30)			
Blood type	<input checked="" type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> AB <input type="checkbox"/> O		<input checked="" type="checkbox"/> Rh+ <input type="checkbox"/> Rh- <input type="checkbox"/> unidentified		Test date : 00/1/5			

TEST RESULT

RBC	3,11 million	WBC	7700	Hb	10,4	Hct	29,7	Platelet	127		
Na	138	K	5,7	C	104	Co2	21	Ca	9,4	P	3,9
AST	16	ALT	15	ALP	77	PTH	15,8	Cholest erol	128	Uric acid	4,0
FBS	302			PP2hr	180			HbA1 C	7,8%		
BUN/Cr	99,9/10,1		Fe/TIBC	67/290		Ferritin	320		T.Protein /Alb	6,6/3,9	
ETC.	2-0 Echo GF:70 % severe MR+ mild tomoderate TR										

MEDICATION

- Pyridoxine 50 mg
- Nifedipine 30 mg t.i.d
- Folic acid 1 mg
- Alaxyl (P)

SIGNIFICANT

Catheter function is good
Patient struggles when SBP goes below 150 mg

Date : 13 01 00 [dd mm yy] Origin : Pusan Hospital Tel : 02) 3010-2070 Signature :

Figure A.1 — Example of haemodialysis referral paper which covers the data in this document

Annex B (informative)

Example of an FHIR resource

```

{
  "resourceType": "Bundle",
  "id": "dialysis-data-example-001",
  "meta": {
    "versionId": "1",
    "lastUpdated": "2022-06-30T00:52:51Z"
  },
  "type": "collection",
  "entry": [
    {
      "fullUrl": "http://example.fhir.org/fhir/dialysis/Procedure/procedure-001",
      "resource": {
        "resourceType": "Procedure",
        "id": "procedure-001",
        "meta": {
          "profile": [
            "https://example.org/fhir/StructureDefinition/HaemodialysisProcedure"
          ]
        },
        "text": {
          "status": "generated",
          "div": "<div xmlns=\\"https://www.w3.org/1999/xhtml\\">Haemodialysis</div>"
        },
        "extension": [
          {
            "extension": [
              {
                "url": "dialysis-interval",
                "valueTiming": {
                  "repeat": {
                    "frequency": 4,
                    "period": 1,
                    "periodUnit": "wk"
                  }
                }
              },
              {
                "url": "dialysis-blood-flow-rate",
                "valueQuantity": {
                  "value": 250,
                  "unit": "m/min",
                  "system": "http://unitsofmeasure.org",
                  "code": "m/min"
                }
              },
              {
                "url": "dialysis-duration",
                "valueQuantity": {
                  "value": 4,
                  "unit": "h",
                  "system": "http://unitsofmeasure.org",
                  "code": "h"
                }
              }
            ],
            "extension": [
              {
                "url": "inital",
                "valueQuantity": {
                  "value": 2000,
                  "unit": "units",

```

ISO/TS 9320:2024(en)

```
        "system": "http://unitsofmeasure.org",
        "code": "[IU]"
      }
    },
    {
      "url": "main",
      "valueQuantity": {
        "value": 500,
        "unit": "unit/hr",
        "system": "http://unitsofmeasure.org",
        "code": "[IU]/h"
      }
    }
  ],
  "url": "heparin-concentration"
},
{
  "url": "dialysis-dryweight",
  "valueQuantity": {
    "value": 47.5,
    "unit": "kg",
    "system": "http://unitsofmeasure.org",
    "code": "kg"
  }
},
{
  "url": "dialysis-initial-date",
  "valueDateTime": "2018-05-15"
},
{
  "url": "dialysis-last-lab-test-date",
  "valueDateTime": "2022-08-28"
},
{
  "url": "dialysis-pre-vital-sign",
  "valueReference": [
    {
      "reference": "Observation/observation-vital-001",
      "text": "Blood Pressure: (Systolic: 137, Diastolic: 54)"
    },
    {
      "reference": "Observation/observation-vital-001",
      "text": "Heart Rate: 68"
    }
  ]
},
{
  "url": "dialysis-post-vital-sign",
  "valueReference": [
    {
      "reference": "Observation/observation-vital-002",
      "text": "Blood Presure: { Systolic: 131, Diastolic: 43 }"
    },
    {
      "reference": "Observation/observation-vital-002",
      "text": "Heart Rate: 61"
    }
  ]
}
]
},
  "url": "https://example.org/fhir/StructureDefinition/dialysis-property"
}
],
"status": "completed",
"code": {
  "coding": [
    {
      "system": "http://snomed.info/sct",
      "code": "302497006",
      "display": "Haemodialysis "
    }
  ]
}
```

```

    ],
    "subject": {
      "reference": "Patient/patient-001"
    },
    "performedDateTime": "2022-06-01",
    "bodySite": [
      {
        "coding": {
          "system": "http://snomed.info/sct",
          "code": "771195007",
          "display": "Structure of right internal jugular vein"
        }
      }
    ],
    "note": [
      {
        "text": ""
      }
    ],
    "usedReference": [
      {
        "reference": "Device/device-001",
        "display": "Theranova 400"
      },
      {
        "reference": "Substance/substance-001",
        "display": "H-D Sol"
      }
    ],
    "usedCode": [
      {
        "coding": {
          "system": "http://snomed.info/sct",
          "code": "445085009",
          "display": "Tunneled central venous catheter"
        }
      }
    ]
  },
  {
    "fullUrl": "http://example.fhir.org/fhir/dialysis/Patient/patient-001",
    "resource": {
      "resourceType": "Patient",
      "id": "patient-001",
      "text": {
        "status": "generated",
        "div": "<div xmlns=\"https://www.w3.org/1999/xhtml\">\n      <p>Patient
Example</p>\n    </div>"
      },
      "identifier": [
        {
          "type": {
            "coding": [
              {
                "system": "https://terminology.hl7.org/CodeSystem/v2-0203",
                "code": "MR"
              }
            ]
          },
          "system": "urn:oid:1.2.3.4.5.6",
          "value": "MR12345"
        }
      ],
      "name": [
        {
          "text": "□□□"
        }
      ],
      "telecom": [

```

ISO/TS 9320:2024(en)

```
        "system" : "phone",
        "value" : "010-1234-5678"
    },
    "gender" : "male",
    "birthDate" : "2001-01-01"
}
},
{
    "fullUrl": "http://example.fhir.org//fhir/dialysis/Observation/observation-lab-001",
    "resource" : {
        "resourceType": "Observation",
        "id": "observation-lab-001",
        "text": {
            "status": "generated",
            "div": "<div xmlns=\\"https://www.w3.org/1999/xhtml\\">Laboratory Test 001</div>"
        },
        "status": "final",
        "category": [
            {
                "coding": [
                    {
                        "system": "https://terminology.hl7.org/CodeSystem/observation-
category",
                        "code": "laboratory",
                        "display": "Laboratory "
                    }
                ]
            }
        ],
        "code": {
            "coding": [
                {
                    "system": "http://loinc.org",
                    "code": "881-3",
                    "display": "ABO and Rh group [Type] in Blood from Blood product unit"
                }
            ]
        },
        "subject": {
            "reference": "Patient/patient-001"
        },
        "effectiveDateTime": "2022-06-08T00:00:00+09:00",
        "valueCodeableConcept": {
            "coding": [
                {
                    "system": "http://loinc.org",
                    "code": "LA21321-7",
                    "display": "O Pos"
                }
            ]
        }
    }
},
{
    "fullUrl": "http://example.fhir.org//fhir/dialysis/Observation/observation-lab-002",
    "resource" : {
        "resourceType": "Observation",
        "id": "observation-lab-002",
        "text": {
            "status": "generated",
            "div": "<div xmlns=\\"https://www.w3.org/1999/xhtml\\">Laboratory Test 002</div>"
        },
        "status": "final",
        "category": [
            {
                "coding": [
                    {
                        "system": "https://terminology.hl7.org/CodeSystem/observation-
category",
```

ISO/TS 9320:2024(en)

```

        "code": "laboratory",
        "display": "Laboratory "
    }
  ]
},
"code": {
  "coding": [
    {
      "system": "http://loinc.org",
      "code": "718-7",
      "display": "Haemoglobin [Mass/volume] in Blood"
    }
  ]
},
"subject": {
  "reference": "Patient/patient-001"
},
"effectiveDateTime": "2022-06-08T00:00:00+09:00",
"valueQuantity": {
  "value": 7.2,
  "unit": "g/dl",
  "system": "http://unitsofmeasure.org",
  "code": "g/dL"
}
},
{
  "fullUrl": "http://example.fhir.org//fhir/dialysis/Observation/observation-lab-003",
  "resource": {
    "resourceType": "Observation",
    "id": "observation-lab-003",
    "text": {
      "status": "generated",
      "div": "<div xmlns=\\"https://www.w3.org/1999/xhtml\">Laboratory Test 003</div>"
    },
    "status": "final",
    "category": [
      {
        "coding": [
          {
            "system": "https://terminology.hl7.org/CodeSystem/observation-
category",
            "code": "laboratory",
            "display": "Laboratory "
          }
        ]
      }
    ],
    "code": {
      "coding": [
        {
          "system": "http://loinc.org",
          "code": "2951-2",
          "display": "Sodium [Moles/volume] in Serum or Plasma"
        }
      ]
    },
    "subject": {
      "reference": "Patient/patient-001"
    },
    "effectiveDateTime": "2022-06-08T00:00:00+09:00",
    "valueQuantity": {
      "value": 132.6,
      "unit": "mmol/L",
      "system": "http://unitsofmeasure.org",
      "code": "mmol/L"
    }
  }
},
{

```

ISO/TS 9320:2024(en)

```
"fullUrl": "http://example.fhir.org//fhir/dialysis/Observation/observation-lab-004",
  "resource" : {
    "resourceType": "Observation",
    "id": "observation-lab-004",
    "text": {
      "status": "generated",
      "div": "<div xmlns=\\"https://www.w3.org/1999/xhtml\\">Laboratory Test 004</
div>"
    },
    "status": "final",
    "category": [
      {
        "coding": [
          {
            "system": "https://terminology.hl7.org/CodeSystem/observation-
category",
            "code": "laboratory",
            "display": "Laboratory "
          }
        ]
      }
    ],
    "code": {
      "coding": [
        {
          "system": "http://loinc.org",
          "code": "2823-3",
          "display": "Potassium [Moles/volume] in Serum or Plasma"
        }
      ]
    },
    "subject": {
      "reference": "Patient/patient-001"
    },
    "effectiveDateTime": "2022-06-08T00:00:00+09:00",
    "valueQuantity": {
      "value": 4.93,
      "unit": "mmol/L",
      "system": "http://unitsofmeasure.org",
      "code": "mmol/L"
    }
  }
},
{
  "fullUrl": "http://example.fhir.org//fhir/dialysis/Observation/observation-lab-005",
  "resource" : {
    "resourceType": "Observation",
    "id": "observation-lab-005",
    "text": {
      "status": "generated",
      "div": "<div xmlns=\\"https://www.w3.org/1999/xhtml\\">Laboratory Test 005</
div>"
    },
    "status": "final",
    "category": [
      {
        "coding": [
          {
            "system": "https://terminology.hl7.org/CodeSystem/observation-
category",
            "code": "laboratory",
            "display": "Laboratory "
          }
        ]
      }
    ],
    "code": {
      "coding": [
        {
          "system": "http://loinc.org",
          "code": "2000-8",
          "display": "Calcium [Moles/volume] in Serum or PlasmaActive"
        }
      ]
    }
  }
}
```

```

    }
  ]
},
"subject": {
  "reference": "Patient/patient-001"
},
"effectiveDateTime": "2022-06-08T00:00:00+09:00",
"valueQuantity": {
  "value": 8.08,
  "unit": "mmol/L",
  "system": "http://unitsofmeasure.org",
  "code": "mmol/L"
}
}
},
{
  "fullUrl": "http://example.fhir.org//fhir/dialysis/Observation/observation-lab-006",
  "resource": {
    "resourceType": "Observation",
    "id": "observation-lab-006",
    "text": {
      "status": "generated",
      "div": "<div xmlns=\\"https://www.w3.org/1999/xhtml\\">Laboratory Test 006</div>"
    },
    "status": "final",
    "category": [
      {
        "coding": [
          {
            "system": "https://terminology.hl7.org/CodeSystem/observation-
category",
            "code": "laboratory",
            "display": "Laboratory"
          }
        ]
      }
    ],
    "code": {
      "coding": [
        {
          "system": "http://loinc.org",
          "code": "2777-1",
          "display": "Phosphate [Mass/volume] in Serum or Plasma"
        }
      ]
    },
    "subject": {
      "reference": "Patient/patient-001"
    },
    "effectiveDateTime": "2022-06-08T00:00:00+09:00",
    "valueQuantity": {
      "value": 3.50,
      "unit": "mg/dL",
      "system": "http://unitsofmeasure.org",
      "code": "mg/dL"
    }
  }
},
{
  "fullUrl": "http://example.fhir.org//fhir/dialysis/Observation/observation-lab-007",
  "resource": {
    "resourceType": "Observation",
    "id": "observation-lab-007",
    "text": {
      "status": "generated",
      "div": "<div xmlns=\\"https://www.w3.org/1999/xhtml\\">Laboratory Test 007</div>"
    },
    "status": "final",
    "category": [
      {

```

ISO/TS 9320:2024(en)

```
category",
    "coding": [
      {
        "system": "https://terminology.hl7.org/CodeSystem/observation-
category",
        "code": "laboratory",
        "display": "Laboratory "
      }
    ]
  },
  "code": {
    "coding": [
      {
        "system": "http://loinc.org",
        "code": "5292-8",
        "display": "Reagin Ab [Presence] in Serum by VDRL"
      }
    ]
  },
  "subject": {
    "reference": "Patient/patient-001"
  },
  "effectiveDateTime": "2022-05-31T00:00:00+09:00",
  "valueCodeableConcept": {
    "coding": [
      {
        "system": "http://snomed.info/sct",
        "code": "131194007",
        "display": "Non-Reactive"
      }
    ]
  }
},
{
  "fullUrl": "http://example.fhir.org/fhir/dialysis/Observation/observation-lab-008",
  "resource": {
    "resourceType": "Observation",
    "id": "observation-lab-008",
    "text": {
      "status": "generated",
      "div": "<div xmlns='https://www.w3.org/1999/xhtml'>Laboratory Test 008</
div>"
    },
    "status": "final",
    "category": [
      {
        "coding": [
          {
            "system": "https://terminology.hl7.org/CodeSystem/observation-
category",
            "code": "laboratory",
            "display": "Laboratory "
          }
        ]
      }
    ],
    "code": {
      "coding": [
        {
          "system": "http://loinc.org",
          "code": "5195-3",
          "display": "Hepatitis B virus surface Ag [Presence] in Serum"
        }
      ]
    },
    "subject": {
      "reference": "Patient/patient-001"
    },
    "effectiveDateTime": "2022-05-31T00:00:00+09:00",
    "valueCodeableConcept": {
      "coding": [
```

ISO/TS 9320:2024(en)

```
        {
          "system": "http://snomed.info/sct",
          "code": "260385009",
          "display": "Negative"
        }
      ]
    }
  },
  {
    "fullUrl": "http://example.fhir.org/fhir/dialysis/Observation/observation-lab-009",
    "resource": {
      "resourceType": "Observation",
      "id": "observation-lab-009",
      "text": {
        "status": "generated",
        "div": "<div xmlns=\"https://www.w3.org/1999/xhtml\">Laboratory Test 009</div>"
      },
      "status": "final",
      "category": [
        {
          "coding": [
            {
              "system": "https://terminology.hl7.org/CodeSystem/observation-
category",
              "code": "laboratory",
              "display": "Laboratory "
            }
          ]
        },
        {
          "code": {
            "coding": [
              {
                "system": "http://loinc.org",
                "code": "39535-0",
                "display": "Hepatitis B virus surface Ab [Presence] in Serum by
Radioimmunoassay (RIA)"
              }
            ]
          },
          "subject": {
            "reference": "Patient/patient-001"
          },
          "effectiveDateTime": "2022-05-31T00:00:00+09:00",
          "valueCodeableConcept": {
            "coding": [
              {
                "system": "http://snomed.info/sct",
                "code": "10828004",
                "display": "Positive"
              }
            ]
          }
        }
      ]
    }
  },
  {
    "fullUrl": "http://example.fhir.org/fhir/dialysis/Observation/observation-lab-010",
    "resource": {
      "resourceType": "Observation",
      "id": "observation-lab-010",
      "text": {
        "status": "generated",
        "div": "<div xmlns=\"https://www.w3.org/1999/xhtml\">Laboratory Test 010</div>"
      },
      "status": "final",
      "category": [
        {
          "coding": [
            {

```

ISO/TS 9320:2024(en)

```
category",
    "system": "https://terminology.hl7.org/CodeSystem/observation-
category",
    "code": "laboratory",
    "display": "Laboratory "
  }
]
},
"code": {
  "coding": [
    {
      "system": "http://loinc.org",
      "code": "16128-1",
      "display": "Hepatitis C virus Ab [Presence] in Serum"
    }
  ]
},
"subject": {
  "reference": "Patient/patient-001"
},
"effectiveDateTime": "2022-05-31T00:00:00+09:00",
"valueCodeableConcept": {
  "coding": [
    {
      "system": "http://snomed.info/sct",
      "code": "260385009",
      "display": "Negative"
    }
  ],
  "text": "Negative(0.13)"
}
},
{
  "fullUrl": "http://example.fhir.org//fhir/dialysis/Observation/observation-lab-011",
  "resource": {
    "resourceType": "Observation",
    "id": "observation-lab-011",
    "text": {
      "status": "generated",
      "div": "<div xmlns=\\"https://www.w3.org/1999/xhtml\\">Laboratory Test 011</
div>"
    },
    "status": "final",
    "category": [
      {
        "coding": [
          {
            "system": "https://terminology.hl7.org/CodeSystem/observation-
category",
            "code": "laboratory",
            "display": "Laboratory "
          }
        ]
      }
    ],
    "code": {
      "coding": [
        {
          "system": "http://loinc.org",
          "code": "41145-4",
          "display": "HIV 1 Ab [Presence] in Capillary blood"
        }
      ]
    },
    "subject": {
      "reference": "Patient/patient-001"
    },
    "effectiveDateTime": "2022-05-31T00:00:00+09:00",
    "valueCodeableConcept": {
      "coding": [
        {

```

ISO/TS 9320:2024(en)

```

        "system": "http://snomed.info/sct",
        "code": "260385009",
        "display": "Negative"
      }
    ],
    "text": "Negative(0.09)"
  }
}
},
{
  "fullUrl": "http://example.fhir.org//fhir/dialysis/Observation/observation-lab-012",
  "resource": {
    "resourceType": "Observation",
    "id": "observation-lab-012",
    "text": {
      "status": "generated",
      "div": "<div xmlns=\\"https://www.w3.org/1999/xhtml\\">Laboratory Test 012</div>"
    }
  },
  "status": "final",
  "category": [
    {
      "coding": [
        {
          "system": "https://terminology.hl7.org/CodeSystem/observation-
category",
          "code": "laboratory",
          "display": "Laboratory "
        }
      ]
    }
  ],
  "code": {
    "coding": [
      {
        "system": "http://loinc.org",
        "code": "41145-4",
        "display": "HIV 1 Ab [Presence] in Capillary blood"
      }
    ]
  },
  "subject": {
    "reference": "Patient/patient-001"
  },
  "effectiveDateTime": "2022-05-31T00:00:00+09:00",
  "valueCodeableConcept": {
    "coding": [
      {
        "system": "http://snomed.info/sct",
        "code": "260385009",
        "display": "Negative"
      }
    ]
  },
  "text": "Negative(0.09)"
}
},
{
  "fullUrl": "http://example.fhir.org//fhir/dialysis/Observation/observation-
vital-001",
  "resource": {
    "resourceType": "Observation",
    "id": "observation-vital-001",
    "text": {
      "status": "generated",
      "div": "<div xmlns=\\"https://www.w3.org/1999/xhtml\\">Vital Sign 001</div>"
    }
  },
  "status": "final",
  "category": [
    {
      "coding": [
        {

```

ISO/TS 9320:2024(en)

```
category",
    "system": "https://terminology.hl7.org/CodeSystem/observation-
    "code": "vital-signs",
    "display": "Vital Signs "
  }
]
},
"code": {
  "coding": [
    {
      "system": "http://loinc.org",
      "code": "85354-9",
      "display": "Blood pressure systolic & diastolic"
    }
  ]
},
"subject": {
  "reference": "Patient/patient-001"
},
"effectiveDateTime": "2022-06-01T09:00:00+09:00",
"component": [
  {
    "code": {
      "coding": [
        {
          "system": "http://loinc.org",
          "code": "8480-6",
          "display": "Systolic blood pressure"
        }
      ]
    },
    "valueQuantity": {
      "value": 137,
      "unit": "mmHg",
      "system": "http://unitsofmeasure.org",
      "code": "mm[Hg]"
    }
  },
  {
    "code": {
      "coding": [
        {
          "system": "http://loinc.org",
          "code": "8462-4",
          "display": "Diastolic blood pressure"
        }
      ]
    },
    "valueQuantity": {
      "value": 54,
      "unit": "mmHg",
      "system": "http://unitsofmeasure.org",
      "code": "mm[Hg]"
    }
  }
]
},
{
  "fullUrl": "http://example.fhir.org/fhir/dialysis/Observation/observation-
  vital-002",
  "resource" : {
    "resourceType": "Observation",
    "id": "observation-vital-002",
    "text": {
      "status": "generated",
      "div": "<div xmlns=\\"https://www.w3.org/1999/xhtml\">Vital Sign 002</div>"
    },
    "status": "final",
    "category": [
      {
```

ISO/TS 9320:2024(en)

```
category",
    "coding": [
      {
        "system": "https://terminology.hl7.org/CodeSystem/observation-
        "code": "vital-signs",
        "display": "Vital Signs "
      }
    ]
  },
  "code": {
    "coding": [
      {
        "system": "http://loinc.org",
        "code": "85354-9",
        "display": "Blood pressure systolic & diastolic"
      }
    ]
  },
  "subject": {
    "reference": "Patient/patient-001"
  },
  "effectiveDateTime": "2022-06-01T09:00:00+09:00",
  "component": [
    {
      "code": {
        "coding": [
          {
            "system": "http://loinc.org",
            "code": "8480-6",
            "display": "Systolic blood pressure"
          }
        ]
      },
      "valueQuantity": {
        "value": 131,
        "unit": "mmHg",
        "system": "http://unitsofmeasure.org",
        "code": "mm[Hg]"
      }
    },
    {
      "code": {
        "coding": [
          {
            "system": "http://loinc.org",
            "code": "8462-4",
            "display": "Diastolic blood pressure"
          }
        ]
      },
      "valueQuantity": {
        "value": 43,
        "unit": "mmHg",
        "system": "http://unitsofmeasure.org",
        "code": "mm[Hg]"
      }
    }
  ]
},
{
  "fullUrl": "http://example.fhir.org//fhir/dialysis/Observation/observation-
  vital-003",
  "resource" : {
    "resourceType": "Observation",
    "id": "observation-vital-003",
    "text": {
      "status": "generated",
      "div": "<div xmlns=\\"https://www.w3.org/1999/xhtml\\">Vital Sign 003</div>"
    },
    "status": "final",

```