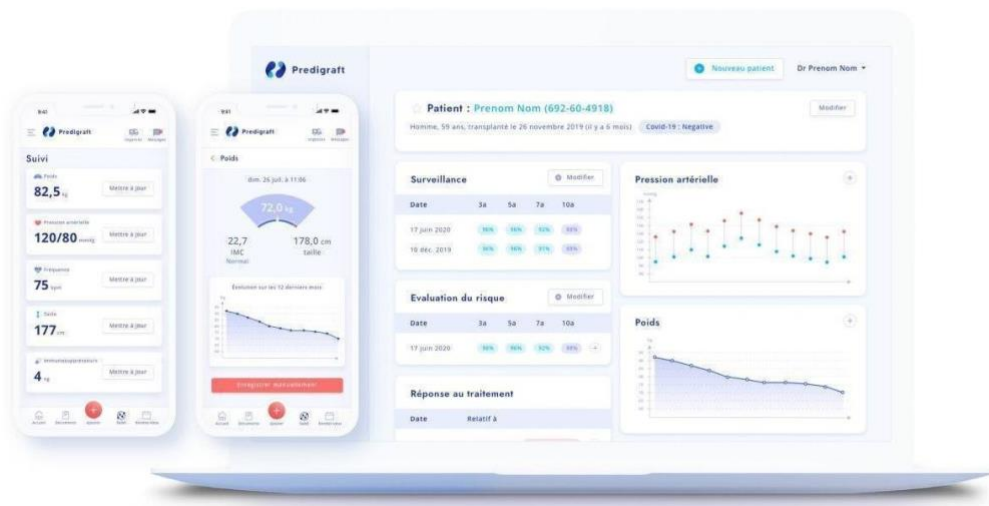


Predigrift v1.17

User manual Healthcare Professional



Please read this entire manual carefully before using Predigrift software, a class IIa medical device.

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This manual complies with **EU Medical Device Regulation 2017/745**.

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1. About this manual

This manual is an integral part of the Predigraft software. It details the presentation of the application, its configuration, and its use.

The electronic version of this manual is available online at www.cibiltech.com. If required, a printed version can be provided upon request at the following address: contact@cibiltech.com.

Note: The screenshots shown in this user manual are examples only, they are not exhaustive and may differ slightly from the views available in the user interface.

Intended Audience: This manual is intended for healthcare professionals.

2. Security Information

Only healthcare personnel who have read these instructions in full are authorized to use Predigraft. For correct and safe use and for all maintenance interventions, it is essential that personnel follow standard safety procedures.

2.1. Primary risks related to the use of Predigraft

The main risks identified are related to the input of data that can result in:

- **An overestimation of the patient's current or expected state of health:**

When an input is erroneous (i.e., falsely reassuring) and an alert is not sent to the healthcare professional, the chances of graft survival are higher than expected.

- **An underestimation of current or expected health status:**

When an input is erroneous (i.e., falsely critical) and an alert is sent to the healthcare professional, the probabilities of graft survival are lower than expected.

Warning: Predigraft is a decision support tool. The clinical assessment of health status by the health professional is not based solely on the prognosis of Predigraft.

2.2. Warnings

- Always ensure that you only open websites via a secure SSL/TLS connection. In this case, the Internet address starts with "https". Simple connections that only start with "http" are a security risk.
- Make sure you are using the latest version of your web browser (compatible with Predigraft *as per the technical specifications chapter*) and regularly update your operating system.
- Keep your passwords up to date. Use a separate password for each application and do not use previous

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password.

- Do not click on links in emails from unknown senders, as this could direct you to a website containing malware.

2.3. Description of product labeling

The following symbols may be visible in the application or in the documentation:

Symbol/Text	Meaning
	Manufacturer's address
Predigraft v1.17	Device name and version identification
	Consult the user manual
CE 2797	CE Marking 2797: identification of the notified body

3. Intended use

Predigraft is a medical device intended to be used as a predictive tool to inform healthcare professionals of the probability of survival of allograft kidney transplants following kidney transplantation. These probabilities, along with available standard clinical data, help describe the condition of the allograft, and provide additional information concerning the patient's care and treatment decisions. Specifically, Predigraft provides probabilities of allograft survival at +3 / +5 / +7 years after evaluation, based on the combination of a set of clinical, biological, and histological parameters.

Predigraft is also intended to be used as a telehealth tool after kidney transplantation to facilitate communication between clinicians and patients by providing a customizable alert system.

Warning: Remote monitoring is not an emergency response system. In the event of a medical problem, patients should contact a healthcare professional or Emergency Medical Services.

3.1. Intended users

The Predigraft solution is intended to be used by:

- Healthcare professionals involved in the treatment and follow-up of kidney transplant patients such as nephrologists, nurses, etc.
- Kidney transplant patients.

3.2. Intended patient population

Patient selection criteria:

- Patient having received a kidney transplant from a living or deceased donor,
- Patient must be at least 18 years old.

3.3. Contraindications

Predigraft cannot be used for the follow-up of patients who have had:

- Previous non-functional kidney transplantation,
- A combined transplant (e.g., kidney - heart transplant, kidney - liver transplant).
- A transplant within the past month.

4. Operating principle and mode of action

4.1. iBox technology

Predigraft was developed using the "integrative BOX" (iBox) technology. The iBox is a predictive algorithm developed by the Paris Transplant Group (INSERM UMR 970; Principal Investigator: Professor Alexandre LOUPY). The algorithm predicts allograft survival at 3, 5, and 7 years after risk assessment with accurate calibration and discrimination (concordance index 0.81; 95% confidence interval - 0.79 to 0.83). It was developed in a cohort of 4000 kidney transplant patients in France and validated in a cohort of 2129 patients in Europe and a second cohort of 1428 patients in three centers in the United State.

4.2. Mode of action

Predigraft is used as a monitoring/risk assessment tool for kidney transplant patients.

During patient follow-up, the healthcare professional uses Predigraft as a tool to monitor his patients. He or she can collect clinical, biological, and histological information and can be informed about the long-term survival probabilities of allografts. The risk of allograft loss is assessed based on biological parameters used in clinical monitoring during standard care, namely: creatinine (to estimate glomerular filtration rate according to dietary modification in renal disease; unit ml/min/1.73 m²) and urine protein to urine creatinine ratio (unit g/g). A report is generated that helps describe the status of the allograft, thus providing additional information in the patient's care and treatment decision.

Predigraft is also used as a remote monitoring tool after kidney transplantation to facilitate communication between the healthcare professional and the patient by providing a customizable alert system. The patient can send clinical information (blood pressure, weight) and biological information (biological and histological reports) to the healthcare professional.



5. Technical data/Prerequisites



The Predigraft tool for healthcare professionals is available in SaaS (Software as a Service) mode via the web. It is compatible with devices supporting the following browsers:

Browser	Compatible version
Chrome	≥ Version 81
Firefox	≥ Version 75
Safari	≥ Version 14
Edge	≥ Version 91

Note: An internet connection is required to use Predigraft. The use of Predigraft does not require any training.

6. Authentication/Account creation

When an account is created, the Cibiltech team configures access to the application for two profiles:

1.  Team owner
2.  Team member

Access rights and functionalities are different for these profiles.

The Cibiltech team creates the "owner" user account and then the team associated with this user. The Cibiltech team creates as many teams as needed. There is one owner per team.

6.1. You are the team owner

When you subscribe, you will receive a link to the "Reset Password" page via email. On this page, enter your email address to receive a reset link. By clicking on the link from your email, you will be redirected to a page where you can enter your password and a confirmation of the password. You are then connected to the application as the "team owner".

6.2. You are the team member

The team owner sends an invitation email to members via the Predigraft interface. If you are in the list of users authorized to create an account on Predigraft, you will receive an invitation link by email.

Click on this link to be redirected to the Account Creation page. You must enter your name, email address (identical to the address to which the invitation was received), password, and password confirmation. You are then connected to the application as a “team member”.

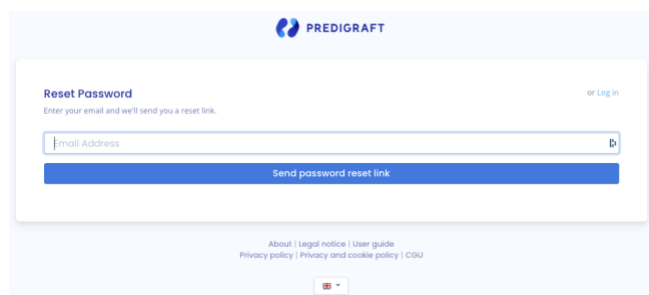
6.3. You are a Predigraft user (owner/member)

To activate your account (owner or member), you must:

- Confirm your email by clicking on a link sent to you by email,
- Read and accept the General Terms and Conditions of Use (GTCU).

Forgot your password?

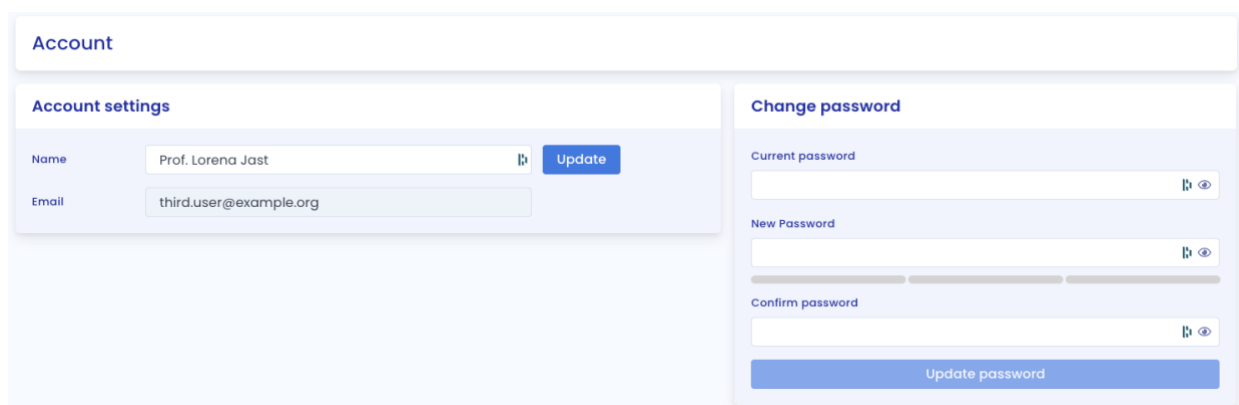
If you have forgotten your password, you can click on "Forgot your password?" on the login page. On the password reset page, enter your email address to receive a reset link. By clicking the link from your email, you will be redirected to a page where you can enter your new password and a confirmation of the password.



Warning: Passwords are personal and confidential. They must not be shared with a third party. They are governed by a confidentiality policy.

Account Setup

Once logged in, you can go to your personal space in the "Account" tab. Here, you have the option to update account details, including your name and password.



7. Team Management

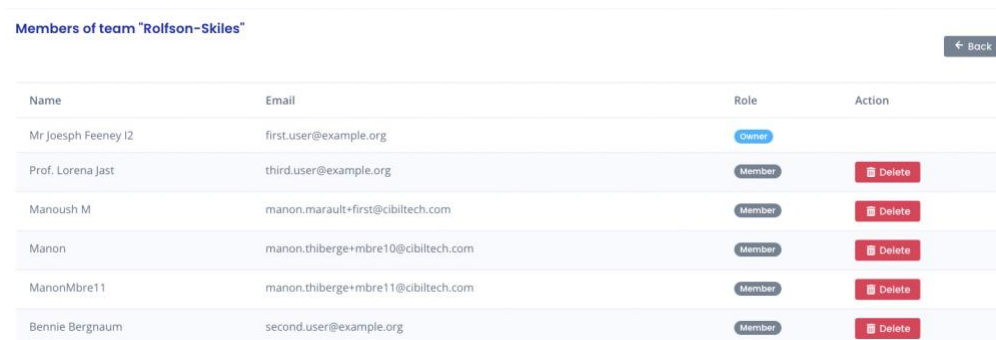
This module allows healthcare professionals to be part of a (hospital) department. The team owner and members have access to the patients of the team or department. The owner and members of the department have access to the Predigraft reports created for each patient in the department. At the time of subscription, the owner will be assigned to a team.

You are a team member

To view the other members of your team, click on your name in the top right corner, click on "My Team" in the drop-down menu, and then click on your team.

On the "Members" page, you can consult the list of team members, including:

- The full name and email address of the member,
- The "owner" badge next to the name of the team owner,
- The "member" badge next to the name of each team member.



Name	Email	Role	Action
Mr Joesph Feeney I2	first.user@example.org	Owner	
Prof. Lorena Jast	third.user@example.org	Member	Delete
Manoush M	manon.marault+first@cibiltech.com	Member	Delete
Manon	manon.thiberge+mbre10@cibiltech.com	Member	Delete
ManonMbre11	manon.thiberge+mbre11@cibiltech.com	Member	Delete
Bennie Bergnaum	second.user@example.org	Member	Delete

You are the team own

To access the members of your team, click on your name in the top right corner, click on "My Team" in the drop-down menu, and then click on your team.

In the "Invite to the team" section you can:

- Enter the email address of a collaborator and click on "send" to send an invitation email to this user. If the user is already part of another team, you cannot invite him/her to an additional team.

In the "Pending Invitations" section, you can:

- View the email addresses of all collaborators invited join the team,
- Delete the invitation: the invited collaborator will no longer be allowed to create an account on Predigraft and will not be able to join your team.

In the "Members" section, you can consult the list of team members and:

- See the full name and email of the member,
- Click on the "delete" button to remove a member from the list of team members. You cannot remove yourself from the team.

HCP-1231	manon.thiberge+membre123@cibilttech.com	Member	Delete
ManonT HCP 1.14	manon.thiberge+HCP@cibilttech.com	Member	Delete
HCP MT 114	manon.thiberge+hp114@cibilttech.com	Member	Delete

Pending invitations

Email	Invitation	Action
elisa.negra-dalida@cibilttech.com	Resend invite	Delete

Invite to team "Rolfson-Skiles"

Email Address

[Invite to Team](#)

8. Patient Management

8.1. Patient file

8.1.1. Creation of a patient file

By clicking on the top right button "new patient", the user can create a new patient.



The following information must be completed in order to create the patient record:

- First name,
- Middle name (optional),
- Last name,
- Sex,
- Date of birth,
- ID (must be unique within a team/department),
- Date of transplant.

Click on "Register this patient". A window appears to confirm the information that will be entered into the patient record. Click "Confirm" to create the patient. Click "Cancel" to make changes to the patient information.

✕

- Name: Birttany MACLEAN
- Sex: Female
- ID: 045-444-999
- Date of birth: January 11, 1991
- Date of transplant: July 1, 2020

Cancel
Confirm

8.1.2. Modification of a patient file

To edit a patient record, click on the patient from the patient list to access his or her record. Click on "Modify" in the title bar. You can modify the following information in the patient record:

- Administrative data:
 - First name
 - Middle name (optional),
 - Last name,
 - Sex,
 - Date of birth,
 - ID (must be unique within a team/department),
 - Date of transplant.
- Brief patient description:
 - Description (optional).
- Patient ID:
 - PPI (Permanent Patient Identifier),
 - NEFG of the recipient,
 - NATT,
 - INS,
 - Clinical Study Identifier.
- Referring doctor,
- Clinical Study:
 - Study Name,
 - Clinical study identifier,
 - Date of inclusion,
 - Clinical study arm.

Warning:

- The description field has a limit of 300 characters.
- The IPP field always starts with the number 80 and can contain between 8 and 13 characters.
- The NEFG number field accepts only integer values.
- The NATT number field only accepts integer values.
- The INS number accepts only 15 digits: the first digit can only be 1 or 2 and the 4th and 5th digits can only be between 01 and 12,
- The clinical study field appears in the patient file, only if the service has been added to the study by Cibiltech.

Administrative data

First name :

Middle name :

Last name :

Sex : Female Male

Date of birth :

ID :

Date of transplant :

[Save changes](#)

Referring HCP

[Add a referring hcp](#)

Prof. Lorena Jast [Remove](#)

Patient description Limit of 300 characters

Description

[Save changes](#)

Patient identifiers

IPP

INS

NEFG

NATT 1

NATT 2

Clinical study identifier

[Save changes](#)

Click on "Save Changes". A window will appear reminding you of the information that will be included in the patient record. Click "Confirm" to apply the changes. Click "Cancel" to continue editing the record. Click on "Save Changes".

8.1.3. Deleting a patient file

To delete a patient record, click on the patient from the patient list to access his or her record. Click on "Modify" in the title bar.

At the bottom of the Edit Patient Record page, click on "Delete". You must confirm the deletion by pressing the "Delete patient" button.

You are about to delete Birttany MACLEAN.



8.1.4. Sharing a patient file

To share a patient record, click on the patient from the list of your patients, you are then redirected to his patient record. Click on the "Share patient record" button located in the header.




You can then choose the different partner services with which you wish to share your patient's record.

Note: The "Share a patient record" feature must be activated by Cibiltech beforehand. If you want this feature, please contact Cibiltech.

You can also deactivate the sharing of a patient record by clicking on the "Stop sharing" button located on the record sharing page.

Team name	Shared by	Shared at	
Rolfson-Skiles	-	-	Original team
Prohaska, Russel and Frami	Mr Joesph Feeny I2	2021-10-25 07:02:55	Stop sharing

If you receive a shared patient record, you have the option to add the patient to your patient list by clicking on .

You can also add or remove referring physicians from your department to the patient that has been shared with you. These doctors will then be able to find this patient directly in their patient list.

Note: If you receive a shared patient record:

- You do not have the possibility to share it again,
- You can search for this patient using the search bar in your patient list,
- You can access all the features of your patient's record, but you cannot communicate with this patient through the messaging system,
- You can modify the alert settings of your department or those specific to a shared patient without them being modified in the department that shared the patient with you,

- If the department that shared the patient with you changes their department's alerts or patient-specific alerts after they have shared the patient with you, they will not change in your department.

8.2. Managing a patient

Each department has its own patients. The information below is available in the patient file:

- Patient information,
- Messaging,
- Patient alerts,
- Monitoring / Risk Assessment: link to the patient's iBox evaluations,
- Estimated glomerular filtration rate (GFR-e) according to MDRD: graphical display of GFR-e values (by default),
- Blood pressure: graphical visualization of blood pressure,
- Weight: graphical visualization of weight,
- Biological chart,
- HCP's medical notes,
- Prescriptions,
- Reports,
- Biological analyses,
- Biopsy (histological analysis report),
- DSA,
- Other documents.

★ **Patient : Birtany MACLEAN (045-444-999) ...**
A confirmation email has been sent Edit
Female, 30 years old born on Jan 11, 1991, transplanted on July 1, 2020 (1 year ago)
Send a new confirmation email
Messaging Upload a document

Surveillance / Risk assessment + New iBox Evaluation

Date	Input data	3y	5y	7y
June 28, 2021		96%	94%	91%

Biology table Show more

Day after transplant	2021-06-28	2021-09-14
Time after transplant	11 months	1 year, 2 months
Potassium (mmol/L)		
Creatinine (µmol/L)		104.31
Hemoglobin (g/dL)	15.30	
Polynuclear neutrophils (10 ⁹ /L)	4.97	
Leukocytes (10 ⁹ /L)	7.70	
Platelets (10 ⁹ /L)	182.00	
Protein creatinine ratio (g/g)	10.40	

Medical notes | Prescriptions | Medical reports

[Empty text area]

Save

Biology Analyses | Biopsy | DSA

Title	Confirmed by	
Bio9-2.pdf 2021-09-14	Prof. Lorena Jast	...
Bio4.pdf 2021-07-28	Mr Joesph Feeney IZ	...


Other documents

No other documents uploaded yet.

Immunosuppressive drugs 🔍


No immunosuppressive drugs record yet.


Estimated GFR
Blood Pressure
Weight




Date	Estimated GFR (mL/min/1.73m²)
Jun 28	96
Jul 04	94
Jul 10	92
Jul 16	90
Jul 22	88
Jul 28	86
Aug 03	84
Aug 09	82
Aug 15	80
Aug 21	78
Aug 27	76
Sep 02	74
Sep 08	72
Sep 14	66

8.2.1. Marking a patient as a starred

In the patient file, this button  located on the top left allows you to add the patient in the "My patients" list or to remove him from this list.

A full star  : the patient is in the list "My patients".

An empty star  : the patient is not in the "My patients" list.

Note: Each user has his own "My patients" list. This list belongs to the user and not to the service. It can also be consulted from the "My patients" button in the main menu on the left (see chapter 12 Managing the "My patients" list).

8.2.2. Granting patient access

From each patient record, you can invite a patient to use the Predigraft patient application. Click on the "Create a patient account" button in the title bar.



☆ Patient : **Meta V. FAY (669-75-5379)** ...
 Male, 42 years old born on Nov 12, 1978, transplanted on December 25, 2019 (1 year ago)

Buttons: Create patient account, Edit, Messaging, Upload a document

Then fill in the patient's email address.

New patient account

Please enter the patient's email.

createPatientAccount.referringHcp

Mr Joesph Feeney I2

Buttons: Cancel, Create patient account

The button "Create a patient account" is then replaced by the text "A confirmation email has been sent".



★ Patient : **Birttany MACLEAN (045-444-999)** ...
 Female, 30 years old born on Jan 11, 1991, transplanted on July 1, 2020 (1 year ago)

Buttons: A confirmation email has been sent, Send a new confirmation email, Edit, Messaging, Upload a document

The patient receives an email with the steps to finalize the account creation and confirm the email address. Once

confirmed, the text "A confirmation email has been sent" is replaced with "The patient has an account" and the corresponding patient email address.

Notes: An error message is displayed when the doctor enters an existing patient email.

To understand the data exchange between the physician interface and the patient interface, see Chapter 14 "Patient Application".

You can send a confirmation email to the patient again if the patient has not received an email. If the patient confirms the email, you cannot change the email address.

8.2.3. Messaging system

You can send messages to your patient through a specialized messaging system. You can access your messaging system from a patient record or from the "Messaging" menu (see the chapter Managing messaging).

From a patient file, click on "Messaging" in the banner of your patient file.

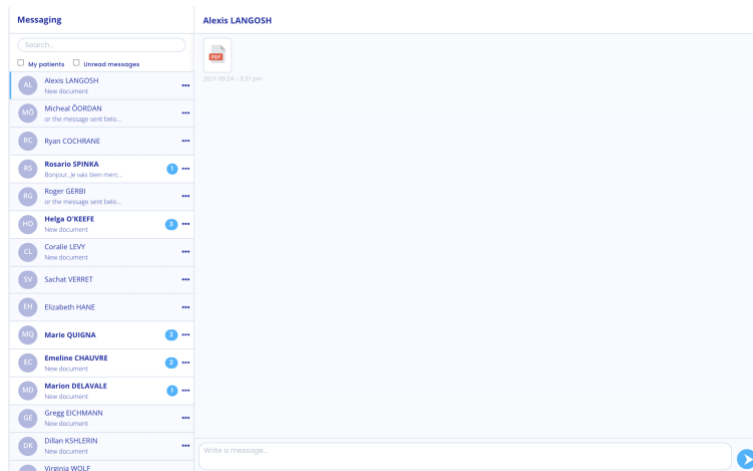


The conversation with your patient is displayed. You can access all the conversations of your patients who have an activated Predigraft account, even those you have never exchanged with before.

You can view only the conversations of your patients in the "My Patients" list by checking the "My Patients" box.

You can display only the unread conversations of your patients by checking the "Unread messages" box.

Note: The "My Patients" filter is enabled by default. The "Unread Messages" filter is disabled by default.



To change the conversation, click on the name of the desired patient. A blue bar will appear on the side, indicating that you are in the conversation.

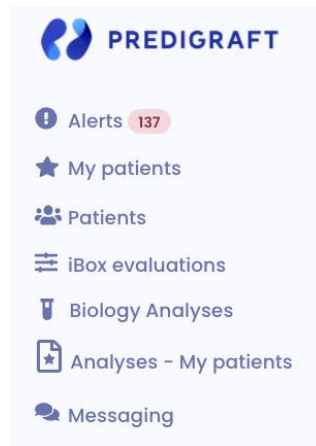
You can also search for a patient by clicking on the search bar at the top left of your message box.

When the patient's name appears in bold, it means that you have an unread message. When you click on it, the patient's name no longer appears in bold.

Note: Conversations are sorted from the most recent message to the oldest.

You can click on the patient's name at the top of the message board to access their patient record.

When one of your patients sends you a message, a red dot in the "Messaging" menu appears. This counter lists the number of unread conversations.



Thus, when you read an initially unread message, the red dot goes down one point.

Warning: If a patient sends you 5 messages, the red dot only considers the unread conversation and not the number of unread messages.

When a patient sends you his blood pressure or a weight, this is not considered as a message. The red dot only considers the sending of messages and documents.

8.2.4. Alerts

Details of the alerts are available in chapter 16 "Alerts" of this document.

8.2.5. Monitoring/Risk Assessment






Surveillance / Risk assessment		+ New iBox Evaluation		
Date	Input data	3y	5y	7y
September 16, 2021	 	83 %	74 %	64 %
September 15, 2021		98 %	97 %	95 %
September 14, 2021		71 %	58 %	44 %
August 16, 2021		81 %	72 %	61 %

By clicking on "New iBox Assessment", you can create an iBox assessment.

The Monitoring/Risk Assessment item lists the patient's iBox assessments. You can click on one of the rows in the list to go to the corresponding iBox assessment.

The date corresponds to the date entered in the first "eGFR" step when the assessment was created.

The data corresponds to:

-  Biological data. This icon is always present. It corresponds to the report creation steps: 1 and 2 eGFR and proteinuria.
-  Graft-specific anti-HLA antibody (DSA) data. This icon is present if you entered data in step 3 - DSA when creating the report.
-  Histology data. This icon is present if you filled in data in step 4 Histology when creating the report.

8.2.6. Clinical data

The "Clinical Data" section consists of:

- Your patient's weight,
- Your patient's blood pressure,
- Your patient's heart rate,
- Maximum Expiratory Volume in one second (FEV1),
- Blood glucose,
- Temperature,

Données cliniques

 Poids 46.00 kg >	 VEMS 4.000 L >
 Pression artérielle 130 / 70 mmHg >	 Glycémie 7.000 g/L >
 Fréquence cardiaque 150 BPM >	 Temperature 37.30 °C >

By going to this section, you can view the history of these clinical data, add or delete them.

8.2.6.1 Blood pressure


You can view the patient's systolic and diastolic pressures over time.

You can read the precise data by moving your mouse cursor over the points on the graph.



Note: You also have the option of viewing these values on a graph for a week, a month, 6 months, a year or you can choose to view all your data.

Click on the “+” button at the top right of your graph to add a blood pressure value at a given date.



Ajouter une valeur de pression artérielle

Systolique / Diastolique / mmHg

Date

Annuler Enregistrer

When you move your mouse over the values in the history, a small cross at the top right appears and allows you to delete your data.

8.2.6.2 Weight

You can view the patient's weight over time.

You can read the precise data by passing your mouse cursor over the points on the graph.



Note: You also have the option of viewing these values on a graph at the scale of one week, one month, 6 months, one year or decide to view all your data.

Click on the "+" button at the top right of your graph to add a blood pressure value at a given date.



The screenshot shows a form titled "Ajouter un poids". It has two input fields: "Poids" with a unit selector set to "kg", and "Date". At the bottom, there are two buttons: "Annuler" (Cancel) and "Enregistrer" (Register).

When you move your mouse over the values in the history, a small cross at the top right appears and allows you to delete your data.

Historique des données

78.3 kg	18/08/2021 ✕
Voulez-vous supprimer cette donnée ? ANNULER SUPPRIMER	
78.3 kg	18/08/2021
78.3 kg	18/08/2021

8.2.6.3 Heart rate

In the "Clinical Data" section you can view your patient's heart rates over time. You can read the data more precisely by passing your mouse cursor over the points on the graph.



Note: You also have the possibility to visualize these values on a graph at the scale of one week, one month, 6 months, one year or decide to visualize all your data.

Click on the " + " button at the top right of your graph to add a heart rate value at a given date.

When you move your mouse over the values in the history, a small cross at the top right appears and allows you to delete your data.

8.2.6.4 Forced expiratory volume in one second (FEV1)

In the "Clinical Data" section you can view your patient's heart rates over time.
 You can read the data more precisely by passing your mouse cursor over the points on the graph.



Note: You also have the possibility to visualize these values on a graph at the scale of one week, one month, 6 months, one year or decide to visualize all your data.

Click on the "+" button at the top right of your graph to add a heart rate value at a given date.

When you move your mouse over the values in the history, a small cross at the top right appears and allows you to delete your data.

8.2.6.5 Blood glucose

In the "Clinical Data" section you can view your patient's heart rates over time.
 You can read the data more precisely by passing your mouse cursor over the points on the graph.



Note: You also have the possibility to visualize these values on a graph at the scale of one week, one month, 6 months, one year or decide to visualize all your data.

Click on the "+" button at the top right of your graph to add a heart rate value at a given date.

When you move your mouse over the values in the history, a small cross at the top right appears and allows you to delete your data.

8.2.6.6 Temperature

In the "Clinical Data" section you can view your patient's heart rates over time.

You can read the data more precisely by passing your mouse cursor over the points on the graph.



Note: You also have the possibility to visualize these values on a graph at the scale of one week, one month, 6 months, one year or decide to visualize all your data.

Click on the "+" button at the top right of your graph to add a heart rate value at a given date.

When you move your mouse over the values in the history, a small cross at the top right appears and allows you to delete your data.

8.2.7. Mini biological table

From the patient record you can view a mini biological table with seven important data collected from biological analysis reports you have imported:

- Potassium (mmol/L),
- Creatinine (mol/L),
- Hemoglobin (g/dL),
- Polynuclear neutrophils ($10^9/L$),
- Creatinine protein ratio (g/g),
- Leukocytes (/mm³),
- Platelets (/mm³),
- Total bilirubin ($\mu\text{mol/L}$),
- Conjugated bilirubin ($\mu\text{mol/L}$),
- ALT (IU/L),
- AST (IU/L),
- Alkaline phosphatase (IU/L),
- Gamma GT (IU/L),
- TP (%).

8.2.8. Biological table

By clicking on "More" in the mini biological table, you can view all the data collected from biological analysis reports. The entire biological table is composed of different data:

- The date,
- The value filled in with the preview of the biological analysis report next to it,
- The unit of the biological data.

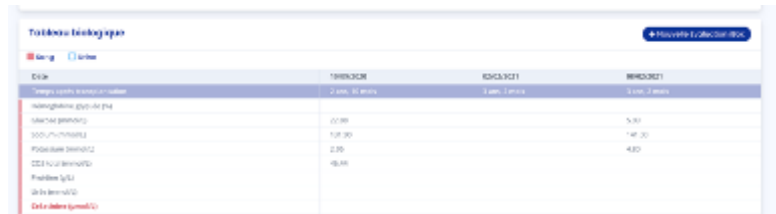
Coralie LEVY (3847) Female, 26 years old born on Jul 24, 1995, transplanted on June 2, 2016 (5 years ago) ← Back								
Biology + New iBox Evaluation								
<input checked="" type="checkbox"/> Blood <input checked="" type="checkbox"/> Urine								
Day after transplant	2018-02-03	2018-02-03	2020-03-20	2020-03-20	2020-04-08	2020-05-02	2020-05-20	2020-08-02
Time after transplant	1 year, 8 months	1 year, 8 months	3 years, 9 months	3 years, 9 months	3 years, 10 months	3 years, 11 months	3 years, 11 months	4 years, 2 months
Associated analysis	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Glycated hemoglobin (%)								
Glucose (mmol/L)					4.92	6.32	4.55	5.09
Sodium (mmol/L)					136.00	141.00	139.00	141.00
Potassium (mmol/L)					4.28	3.90	4.30	4.80
Total CO ₂ (mmol/L)					21.40	20.00	25.00	
Protein (g/L)					77.10	71.00	61.00	
Urea (mmol/L)								
Creatinine (µmol/L)						161.80		
eGFR (mL/min/1.73m ²)			80.00		105.00	37.00	110.00	86.00
Calcium (mmol/L)					2.23	2.50	2.30	
Phosphorus (mmol/L)					0.83	0.71	1.22	
Magnesium (mmol/L)								
Uric acid (µmol/L)								
Total bilirubin (µmol/L)						9.06	9.57	
Conjugated bilirubin (µmol/L)							1.71	
ALAT (U/L)					10.00	15.00	13.00	18.00
ASAT (U/L)					16.00	15.00	17.00	32.00
Alkaline phosphatase (U/L)					124.00	86.00	31.00	
Gamma GT (U/L)					16.30	18.00	17.00	15.00
LDH (U/L)								

Warning: The data "Creatinine" and "Hemoglobin" are important, so they are shown in red on the screen.

In addition, not all the data (blood and urine) from a biological analysis report are present in this biological table. Here are the data that do not appear in the biological table:

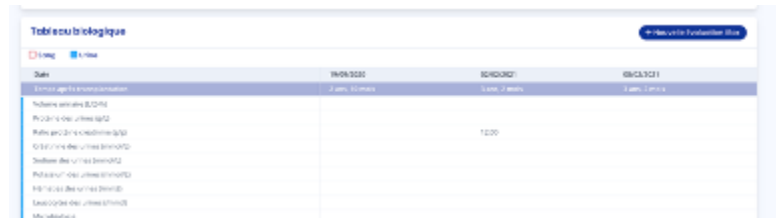
- Chloride,
- Amylase,
- Total cholesterol,
- HDL-cholesterol,
- Dihydroxyvitamin D,
- Prothrombin time,
- Ab antibodies,
- HIV,
- HBV,
- HCV,
- PSA (Prostate Specific Antigen),

If you wish to consult only the hematological data, uncheck the box "Urine".



Date	THERMO	SODIUM	BILAN
10/01/2017	37.0	135	135
10/01/2017	37.0	135	135
10/01/2017	37.0	135	135
10/01/2017	37.0	135	135
10/01/2017	37.0	135	135
10/01/2017	37.0	135	135
10/01/2017	37.0	135	135
10/01/2017	37.0	135	135
10/01/2017	37.0	135	135
10/01/2017	37.0	135	135

If you want to see only urine-related data, uncheck the "Blood" box.




Date	THERMO	SODIUM	BILAN
10/01/2017	37.0	135	135
10/01/2017	37.0	135	135
10/01/2017	37.0	135	135
10/01/2017	37.0	135	135
10/01/2017	37.0	135	135
10/01/2017	37.0	135	135
10/01/2017	37.0	135	135
10/01/2017	37.0	135	135
10/01/2017	37.0	135	135
10/01/2017	37.0	135	135

If you want to display the evolution of a specific data in a graphical form, click on the line corresponding to the data. The graph is then displayed at the top of the biological table.



To remove the graph display, you can click on the cross to the right of the graph.

Note: The documents sent by your patient appear in the biological table on the line "associated analysis". If a document is modified, the document in the biological table is also modified. If a document is deleted, the document in the biological table is also deleted.

Simply press the  icon to access the associated analysis.

Coralie LEVY (3847)
Female, 26 years old born on Jul 24, 1995, transplanted on June 2, 2016 (5 years ago) ← Back

Biology + New iBox Evaluation

■ Blood
 ■ Urine

Day after transplant	2018-02-03	2018-02-03	2020-03-20	2020-03-20	2020-04-08	2020-05-02	2020-05-20	2020-08-02
Time after transplant	1 year, 8 months	1 year, 8 months	3 years, 9 months	3 years, 9 months	3 years, 10 months	3 years, 11 months	3 years, 11 months	4 years, 2 months
Associated analysis								
Glycated hemoglobin (%)								
Glucose (mmol/L)					4.92	6.32	4.55	5.09
Sodium (mmol/L)					136.00	141.00	139.00	141.00
Potassium (mmol/L)					4.28	3.90	4.30	4.80
Total CO2 (mmol/L)					21.40	20.00	25.00	
Protein (g/L)					77.10	71.00	61.00	
Urea (mmol/L)								
Creatinine (µmol/L)						161.80		
eGFR (mL/min/1.73m2)			80.00		105.00	37.00	110.00	86.00
Calcium (mmol/L)					2.23	2.50	2.30	
Phosphorus (mmol/L)					0.83	0.71	1.22	
Magnesium (mmol/L)								
Uric acid (µmol/L)								
Total bilirubin (µmol/L)						9.06	9.57	
Conjugated bilirubin (µmol/L)							1.71	
ALAT (U/L)					10.00	15.00	13.00	18.00
ASAT (U/L)					16.00	15.00	17.00	32.00
Alkaline phosphatase (U/L)					124.00	86.00	31.00	
Gamma GT (U/L)					16.30	18.00	17.00	15.00
LDH (U/L)								

8.2.9. Medical notes

You can add medical notes in the patient record with a maximum of 1500 characters.

When you add a medical note, it is saved and displayed in the medical note history below. Each saved note appears with the date it was saved and the name of the person who wrote the note. Each healthcare professional can access the note history for each patient on the same team.

Medical notes
Prescriptions
Medical reports

Save

Note from Sep 14, 2021 - Written by Dr. Prof. Lorena Jast
Je confirme

Note from Sep 14, 2021 - Written by Dr. Mr Joesph Feeney I2
Le patient est régulier dans son suivi


Please note: Medical notes cannot be shared and remain confidential. Health professionals can only view them on the patient's file.

8.2.10. Prescriptions

You can add prescriptions in the patient record by clicking on "Import a document" in the banner of the patient record, you are then redirected to a new page where you can choose your prescription to import. Select the type of document by checking "Prescription".

You have the possibility to share this file with your patient, to do so check the box "Send to patient". Then click on "Import".

Upload a new document – Roger R GERBI (045)
← Back



Choose a file in my library

Document type

Prescription

Medical report

Biology analysis

DSA

Biopsy

Other document

Send to patient

Note: You can import documents in PDF, jpeg, jpg and png format.

Warning: PDF documents protected by passwords cannot be imported. An error message will be displayed "Cannot read PDF, check that it is not protected by a password".

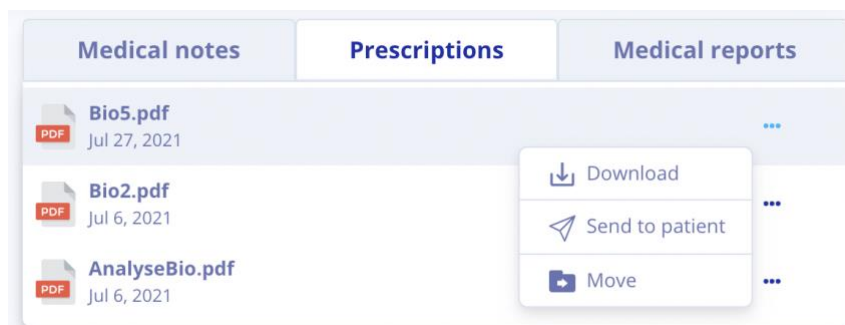
PDF documents must not exceed 20 MB.

The selected document is displayed on the right.

Upon import, you are redirected to the patient record.

In the list of imported prescriptions, the most recently imported report is at the top of the list. The list contains the following information:

- Date the document was imported,
- Name of the document.



You can download a prescription or send it to your patient by clicking on the three little dots and selecting "Download" or "Send to patient".

Warning: The "Send to patient" option does not appear if the patient does not have an account, or if the document was imported by your patient. You have the possibility to send only the documents you have imported.

You can also move a prescription by clicking on the three dots and selecting "Move". By choosing this option, you

can then choose a new category:

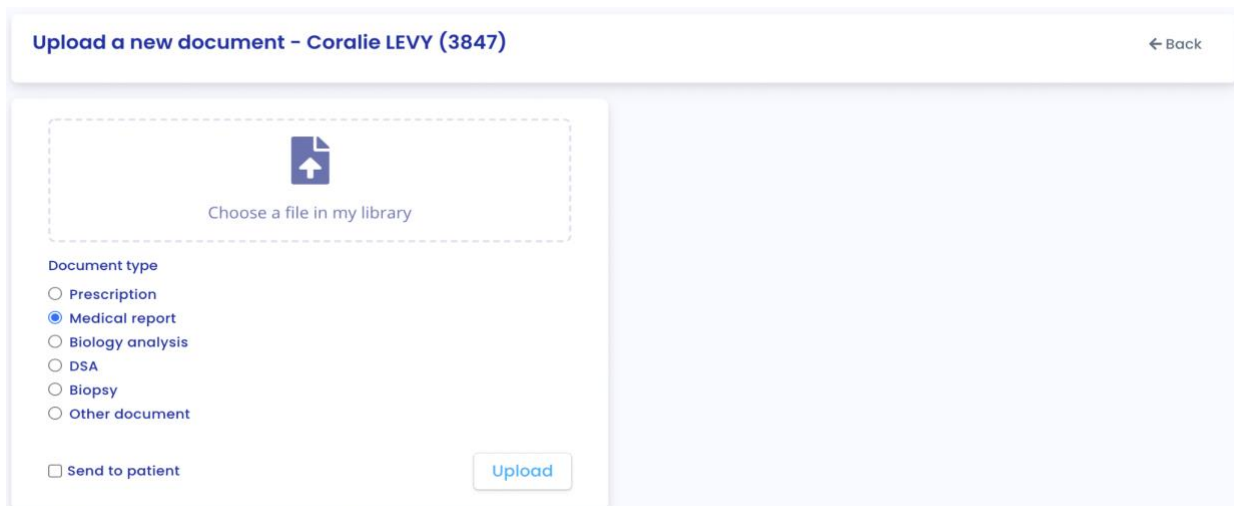
- Medical report,
- Biological analysis,
- DSA,
- Biopsy,
- Other documents.

Note: You can view the prescription by clicking on the line of the document you wish to view. The document will then open in another tab.

8.2.11. Medical reports

You can add medical reports in the patient record by clicking on "Import a document" in the banner of the patient record, you are then redirected to a new page where you can choose your report to import. Select the type of document by checking "Medical Report".

You have the possibility to share this file with your patient, to do so check the box "Send to patient". Then click on "Import".



Upload a new document - Coralie LEVY (3847) ← Back

Choose a file in my library

Document type

- Prescription
- Medical report
- Biology analysis
- DSA
- Biopsy
- Other document

Send to patient Upload

Note: You can import documents in PDF, jpeg, jpg and png format.

Warning: PDF documents protected by passwords cannot be imported. An error message will be displayed "Cannot read PDF, check that it is not protected by a password".

PDF documents must not exceed 20 MB.

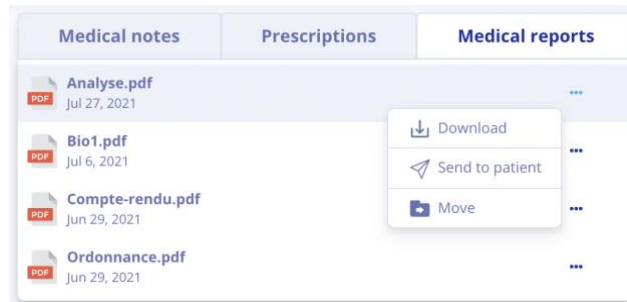
The selected document is displayed on the right.

Upon import, you are redirected to the patient record.

In the list of imported prescriptions, the most recently imported report is at the top of the list.

The list contains the following information:

- Date the document was imported,
- Name of the document.



You can download a report or send it to your patient by clicking on the three small dots and selecting "Download" or "Send to patient".

Please note: The "Send to Patient" option does not appear if the patient does not have an account, or if the document was imported by your patient. You have the option to send only the documents you have imported.




You can also move an order by clicking on the three small dots and selecting "Move". By choosing this option, you can then choose a new category:

- Prescription,
- Biological analysis,
- DSA,
- Biopsy,
- Other documents.

Note: You can view the medical report by clicking on the line of the document you wish to view. The document will then open in another tab.

8.2.12. Biological analysis

You can view the list of biological analysis reports saved in the patient record.

Biology Analyses		Biopsy	DSA
Title		Confirmed by	
 Bio4.pdf 2021-09-17		To confirm	...
 Bio6_page-0002.pdf 2021-09-17		Prof. Lorena Jast	...
 Bio6_page-0006.pdf 2021-09-17		To confirm	...

The date is the date the report was saved in the patient record. The title is the title of the report when it was saved. You can see if the document has been confirmed or not:

- In case of non-confirmation, a "To be confirmed" message appears in the "Confirmed by" column,

- In case of confirmation, the name of the person who confirmed the report appears.

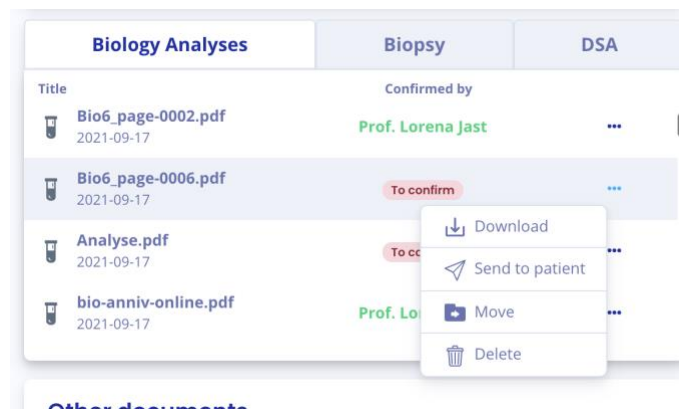
You can delete a biological analysis, provided it has not yet been validated. To do so, click on the three small dots and select "Delete".

You can also download or move the biological analysis by clicking on the three dots and selecting "Download" or "Move". By choosing the option to move a document, you can choose a new category among:

- Prescription,
- Medical report,
- DSA,
- Biopsy,
- Other documents.

You can send a biological analysis to your patient by clicking on the three small dots and selecting "Send to patient".


Please note: The "Send to patient" option does not appear if the patient does not have an account, or if the document was imported by your patient. You can only send documents that you have imported.



You can add biological analysis reports by clicking on "Import a document" in the banner of the patient record, you are then redirected to a new page where you can choose your biological analysis document to import. Select the type of document by checking "Biological analysis".

You have the possibility to share this file with your patient, to do so check the box "Send to patient". Then click on "Import".

Upload a new document - Coralie LEVY (3847)



Choose a file in my library

Document type

Prescription
 Medical report
 Biology analysis
 DSA
 Biopsy
 Other document

Send to patient


[Upload](#)

Note: You can import documents in PDF, jpeg, jpg and png format.

Warning: PDF documents protected by passwords cannot be imported. An error message will be displayed "Cannot read PDF, check that it is not password protected".

PDF documents must not exceed 20 MB.

The selected document is displayed on the right.



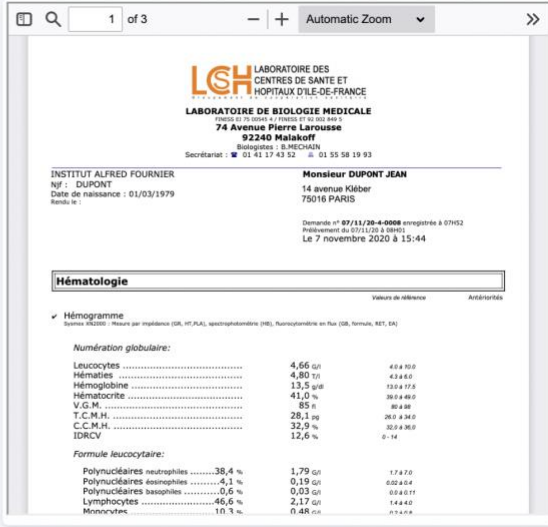
Or import another document

Document type

Prescription
 Medical report
 Biology analysis
 DSA
 Biopsy
 Other document

Send to patient

[Upload](#)



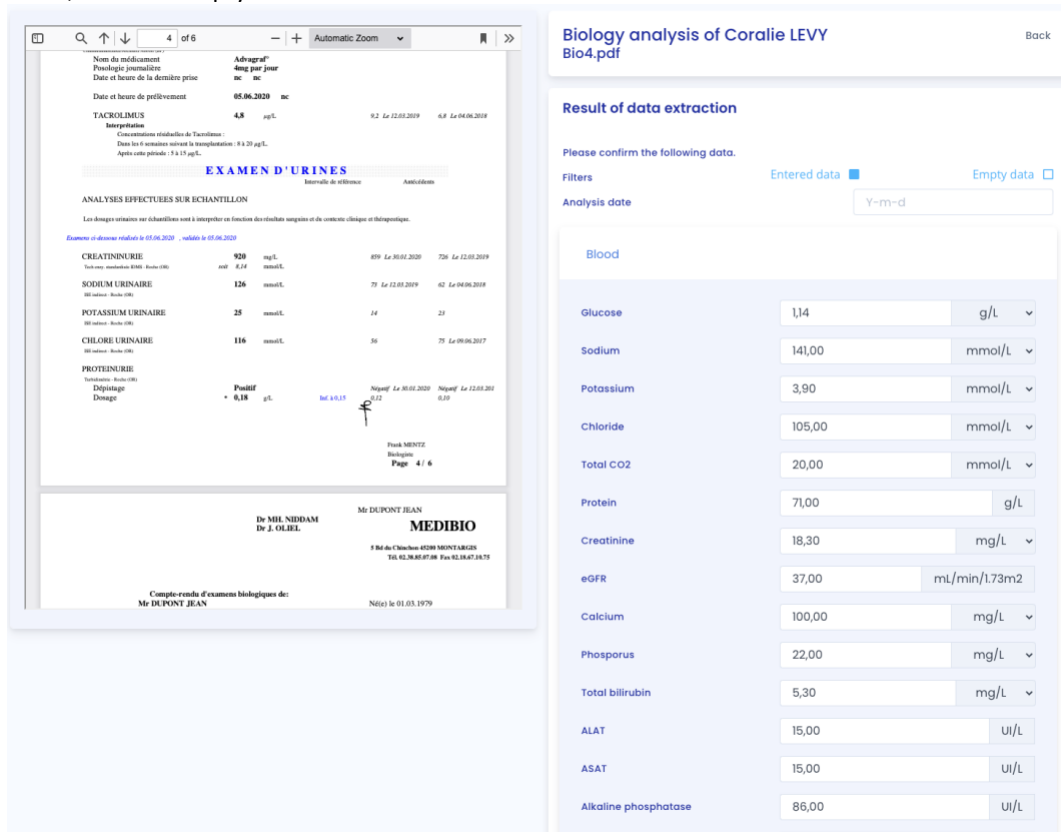
Hématologie		
	Valeurs de référence	Anormales
✓ Hémogramme		
Numération globulaire:		
Leucocytes	4,56 G/L	4,0 à 10,0
Hématies	4,80 T/L	4,0 à 6,0
Hémoglobine	13,3 g/dl	12,0 à 17,0
Hématocrite	41,0 %	38,0 à 48,0
V.C.M.	85 fL	80 à 100
T.C.M.H.	28,1 pg	26,0 à 34,0
C.C.M.H.	32,9 %	29,0 à 36,0
IDNCV	12,6 %	6 à 14
Formule leucocytaire:		
Polynucléaires neutrophiles	39,4 %	1,79 G/L
Polynucléaires éosinophiles	4,1 %	0,19 G/L
Polynucléaires basophiles	0,6 %	0,03 G/L
Lymphocytes	46,6 %	2,17 G/L
Monocytes	10,3 %	0,48 G/L

Then click on "Upload" and you will be redirected to a new data validation page.

The data from the biological analysis are analyzed by Predigraft, extracted and grouped into several parts:

- The analysis date,
- A "Blood" part,
- A "Urine" part.

By default, only the data that have been extracted from the biological report are displayed. To add data in the empty fields, click on "Empty data".



The screenshot displays two main components of the software interface:

- Left Panel (Biological Report):** A PDF document titled "EXAMEN D'URINES" (Urine Examination) for patient Coralie LEVY. It lists various test results such as Creatinine (920 mg/L), Sodium (126 mmol/L), Potassium (25 mmol/L), Chloride (116 mmol/L), and Protein (0.18 g/L). The report is signed by Dr. M.H. NIDJAM and Dr. J. OLHEL.
- Right Panel (Data Extraction Form):** A form titled "Biology analysis of Coralie LEVY Bio4.pdf". It includes a "Result of data extraction" section with a list of tests and their corresponding values and units. The tests listed are:

Test	Value	Unit
Glucose	1,14	g/L
Sodium	141,00	mmol/L
Potassium	3,90	mmol/L
Chloride	105,00	mmol/L
Total CO2	20,00	mmol/L
Protein	71,00	g/L
Creatinine	18,30	mg/L
eGFR	37,00	mL/min/1.73m2
Calcium	100,00	mg/L
Phosphorus	22,00	mg/L
Total bilirubin	5,30	mg/L
ALAT	15,00	UI/L
ASAT	15,00	UI/L
Alkaline phosphatase	86,00	UI/L

You can view all the data of the biological analysis that has been extracted on the right side of the biological analysis report. In case of errors, you can modify the fields (value and unit if available) of the test date, blood data and urine data.

If a data can be recorded in several units, the Predigrapt reference unit is the first unit in the list.

You can click on "Save" to save all the data of the biological analysis. In case of inconsistent values during saving, an error message appears. For example:



The screenshot shows the "Urine" section of the data entry form. The "Urine sodium" field has a value of 12849 mmol/L. A red error message box is displayed over the field, stating: "Cette valeur doit être inférieure ou égale à 1000." (This value must be less than or equal to 1000).

If the values are recorded successfully, you are redirected to a biological table (see Chapter 8.2.12. "Biological Table").

When you choose a unit different from the reference unit when extracting the biological data, Predigrapt records the data in two ways:

- The value as well as the unit you chose,
- The value converted into the reference unit: this value will be displayed in the biological table (for more information on the reference units of the biological table see Appendix 3 of this

document).

Warning: The data entered in the biological table may differ from the values entered during the extraction due to the choice of the unit.

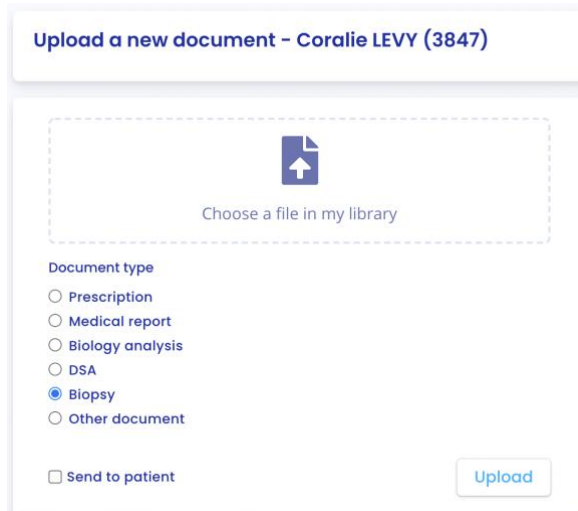
To modify the values of the extraction of the biological analysis report after recording, from the patient file, click on the corresponding biological analysis report in the list "Biological Analyses". The analysis report opens and you can modify the values.

8.2.13. Biopsy

You can view the list of biopsy reports imported by members of your department.

You can add biopsy reports by clicking on "Import a document" in the patient record banner, you are then redirected to a new page where you can choose your biopsy to import. Select the type of document by checking "Biopsy".

You have the possibility to share this file with your patient, to do so check the box "Send to patient". Then click on "Import".



Upload a new document - Coralie LEVY (3847)

Choose a file in my library

Document type

- Prescription
- Medical report
- Biology analysis
- DSA
- Biopsy
- Other document

Send to patient

Upload

Note: You can import documents in PDF, jpeg, jpg and png format.

Warning: PDF documents protected by passwords cannot be imported. An error message will be displayed "Cannot read PDF, check that it is not password protected".

PDF documents must not exceed 20 MB.

The selected document is displayed on the right.

Upon import, you are redirected to the patient record.

In the list of imported biopsy reports, the most recently imported report is at the top of the list.

The list contains the following information:

- Date of the document import,
- Type: histological analysis,
- Name of the document.

You can download a biopsy by clicking on the three small dots and selecting "Download".

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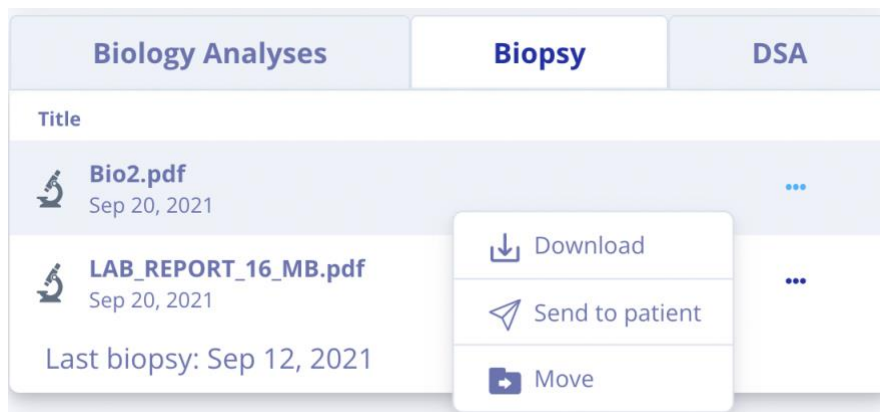
You can also move a biopsy by clicking on the three small dots and selecting "Move". By choosing this option, you can then choose a new category from:

- Prescription,
- Medical report,
- Biological analysis,
- DSA,
- Other documents.

You can send a biopsy to your patient by clicking on the three small dots and selecting "Send to patient".

Please note: The "Send to Patient" option does not appear if the patient does not have an account, or if the document was imported by your patient. You can only send documents that you have imported.

Note: You can view the biopsy by clicking on the line of the document you wish to view. The document will then open in another tab.



8.2.14. DSA

You can view the list of DSA reports saved in the patient record.

Biology Analyses	Biopsy	DSA
Title		
 AnalyseBio.pdf Jul 27, 2021		...
 Bio3.pdf Jul 27, 2021		...


The date is the date the DSA report was saved in the patient record.

The title is the title of the DSA report when it is saved.

You can add DSA reports by clicking on "Import a document" in the patient record banner, you are then redirected to a new page where you can choose your document to import. Select the type of document by checking "DSA".

You have the possibility to share this file with your patient, to do so check the box "Send to patient".

Upload a new document - Coralie LEVY (3847)



Choose a file in my library

Document type

Prescription
 Medical report
 Biology analysis
 DSA
 Biopsy
 Other document

Send to patient

[Upload](#)

Note: You can import documents in PDF, jpeg, jpg and png format.

Warning: PDF documents protected by passwords cannot be imported. An error message will be displayed "Cannot read PDF, check that it is not password protected".

PDF documents must not exceed 20 MB.

The selected document is displayed on the right.

Upload a new document - Coralie LEVY (3847) ← Back

Bio4.pdf ×
 Or import another document

Document type

Prescription
 Medical report
 Biology analysis
 DSA
 Biopsy
 Other document

Send to patient

[Upload](#)

4 of 6 Automatic Zoom

Nom du médicament: **Adragraf®**
 Posologie journalière: **1mg par jour**
 Date et heure de la dernière prise: **06/06/2020 06:00**

Date et heure de prélèvement: **05/06/2020 06:00**

TACKOLMIS **4,8** µg/L 9,2 Le 12/01/2019 6,8 Le 04/06/2019
 Interprétation: **Circulation rétinolécine de Tacrolimus**
 Dans les 6 semaines après la transplantation: 0 à 20 µg/L
 Après cette période: 0 à 15 µg/L

EXAMEN D'URINES

Biométrie de référence Antidépresseurs

ANALYSES EFFECTUEES SUR ECHANTILLON

Les dosages réalisés sur échantillons sont à interpréter en fonction des résultats sanguins et de contexte clinique et thérapeutique.

Examens et dates réalisés le 05/06/2020 - validés le 05/06/2020

CREATININURIE	920	µg/L	859	Le 05/01/2020	726	Le 12/01/2019
Tous ces résultats (RNI) - Règle (RNI)						
SODIUM URINAIRE	126	mmol/L	75	Le 12/01/2019	62	Le 04/06/2019
00 Analyse - Règle (RNI)						
POTASSIUM URINAIRE	25	mmol/L	14		21	
00 Analyse - Règle (RNI)						
CHLORE URINAIRE	116	mmol/L	56		75	Le 04/06/2017
00 Analyse - Règle (RNI)						
PROTEINURIE						
Interprétation - Règle (RNI)						
Dépistage		Positif				
Dosage	0,18	g/L	Inf 0,10		0,12	
Niquel/ Le 09/01/2020 Niquel/ Le 12/01/2019						
0,10 0,10						

Frank MENZ
Biologiste
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Then click on "Import", you are redirected to the patient record, you can then view the DSA report.

You can download a DSA report by clicking on the three small dots and selecting "Download".

You can also move a DSA report by clicking on the three dots and selecting "Move". By choosing this option, you can then choose a new category from:

- Prescriptions,
- Medical report,
- Biological analysis,
- Biopsy,

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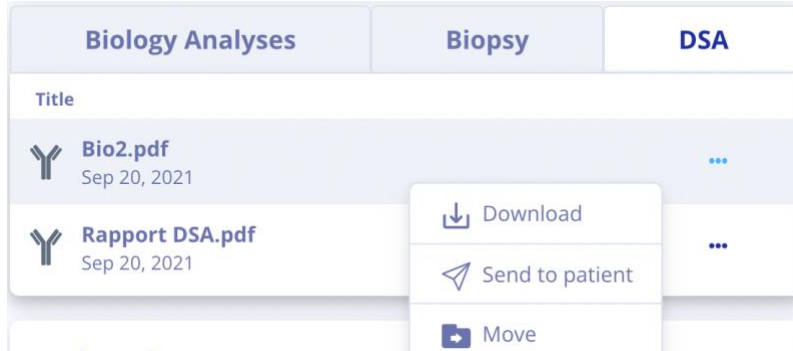
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- Other documents.

You can send a DSA report to your patient by clicking on the three small dots and selecting "Send to Patient".

Please note: The "Send to Patient" option does not appear if the patient does not have an account, or if the document was imported by your patient. You can only send documents that you have imported.



Note: You can view the DSA report by clicking on the row of the document you wish to view. The document will then open in another tab.

8.2.15. Other documents

You can add other documents by clicking on "Import a document" in the banner of the patient record, you are then redirected to a new page where you can choose your document to import. Select the type of document by checking "Other document".

You have the possibility to share this file with your patient, to do so check the box "Send to patient".

Upload a new document - Coralie LEVY (3847) ← Back

Bio4.pdf ✕

Or import another document

Document type

- Prescription
- Medical report
- Biology analysis
- DSA
- Biopsy
- Other document

Send to patient

Upload

4 of 6 Automatic Zoom

Chromosomes (carré) 200x (20^x)

Nom du médicament: Advagraf[®]

Posologie journalière: 4mg par jour

Date et heure de la dernière prise: nc

Date et heure de prélèvement: 05.06.2020 nc

TACROLIMUS: 4,8 µg/L. 9,2 Le 12.03.2019 4,8 Le 04.06.2018

Interprétation: Concentrations résiduelles de Tacrolimus: Dans les 6 semaines suivant la transplantation: 0,3-20 µg/L. Après cette période: 1,5 à 17 µg/L.

EXAMEN D'URINES

Intervalle de référence: Antibiotés

ANALYSES EFFECTUEES SUR ECHANTILLON

Les dosages réalisés sur échantillon sont à interpréter en fonction des résultats sanguins et du contexte clinique et thérapeutique.

Examen et dosage réalisés le 05.06.2020 - validé le 05.06.2020

CREATININURIE	920 mg/L	859 Le 30.01.2020	706 Le 12.03.2019
Tactérolimus (MMS) - Roche (®)	µmol 8,14 mmol/L		
SODIUM URINAIRE	126 mmol/L	79 Le 12.03.2019	62 Le 04.06.2018
POTASSIUM URINAIRE	25 mmol/L	14	23
CHLORE URINAIRE	116 mmol/L	36	79 Le 09.06.2017
PROTEINURIE			
Tactérolimus - Roche (®)			
Dépistage	Positif	Négatif Le 30.01.2020	Négatif Le 12.03.2019
Dosage	0,18 µL	Inf à 0,15	0,12

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Note: You can import documents in PDF, jpeg, jpg and png format.

Warning: PDF documents protected by passwords cannot be imported. An error message will be displayed "Cannot read PDF, check that it is not protected by a password".

PDF documents must not exceed 20 MB.

The selected document is displayed on the right.

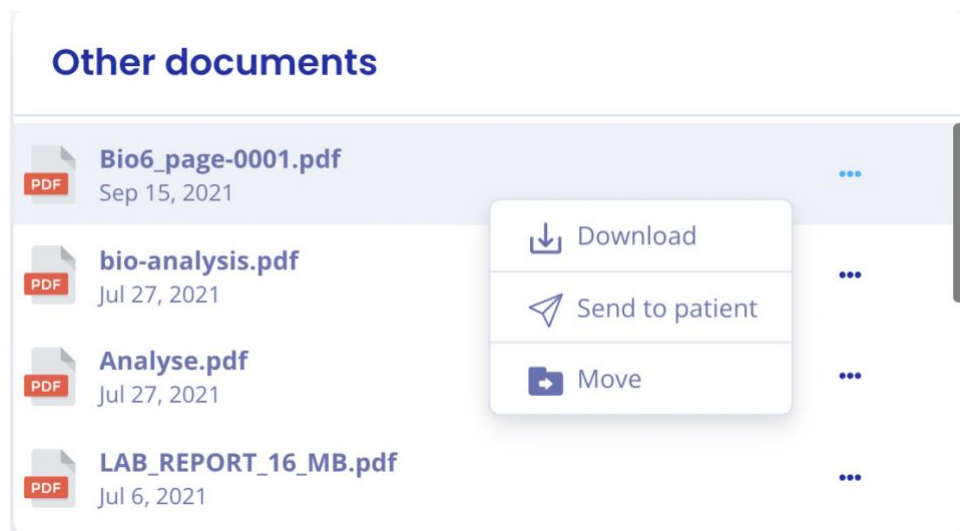
You can upload a document in the "Other Documents" category by clicking on the three small dots and selecting "Download".

You can also move a document by clicking on the three dots and selecting "Move". By choosing this option, you can then choose a new category from:

- Prescription,
- Medical report,
- Biological analysis,
- DSA,
- Biopsy.

You can send a document to your patient by clicking on the three small dots and selecting "Send to patient".




Please note: The "Send to Patient" option does not appear if the patient does not have an account, or if the document was imported by your patient. You can only send documents that you have imported.



Note: You can view the document by clicking on the line of the document you wish to view. The document will then open in another tab.

9. Biological analysis management

Click on "Biological analysis" in the main menu on the left to view a list of the biological analysis reports you have imported, as well as the biological analysis reports sent by patients in the team via the Patient Application.

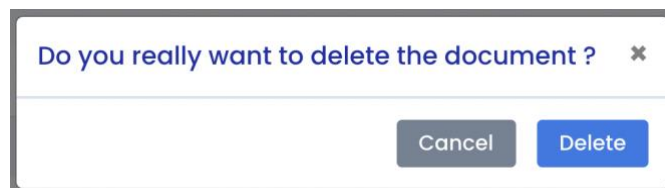
Biology Analyses						
Document name	Document uploaded	Confirmed by	Patient name	ID	Patient date of transplant	
Bio6_page-0004.pdf	September 24, 2021	To confirm	Alexis G. LANGOSH	009-06-2742	Apr 8, 2014	✕
 Bio6_page-0003.pdf	September 23, 2021	Prof. Lorena Jast	Micheal ÓORDAN	9876	May 4, 2018	
 Bio6_page-0001.pdf	September 23, 2021	Prof. Lorena Jast	Micheal ÓORDAN	9876	May 4, 2018	
 Bio6_page-0006.pdf	September 23, 2021	Prof. Lorena Jast	Roger R GERBI	045	Apr 8, 2020	
to_improve2.pdf	September 22, 2021	To confirm	Mary Z.ROWN	495-129-111	Apr 4, 2020	✕
AB6.pdf	September 22, 2021	To confirm	Mary Z.ROWN	495-129-111	Apr 4, 2020	✕
AB6.pdf	September 22, 2021	To confirm	Mary Z.ROWN	495-129-111	Apr 4, 2020	✕
AB6.pdf	September 22, 2021	To confirm	Mary Z.ROWN	495-129-111	Apr 4, 2020	✕
AB6.pdf	September 22, 2021	To confirm	Mary Z.ROWN	495-129-111	Apr 4, 2020	✕
Bio2.pdf	September 21, 2021	To confirm	Micheal ÓORDAN	9876	May 4, 2018	✕

Biological analysis reports are sorted in antechronological order: the most recently imported report appears first.

The list of documents contains the following information:

- A logo indicating whether the biological analysis data has been validated,
- The name of the biological analysis report,
- The date the biological analysis report was received,
- The person who validated the biology report data,
- The patient to whom the Biology Report belongs,
- The patient's ID,
- The patient's transplant date.

You have the possibility to delete a biological analysis from this list by clicking on the cross on the right. A confirmation window appears.



10. Management of biological analyses in "My Patients" list

Click on "Analysis - My Patients" in the main menu on the left to display the list of bioanalysis reports from your "My Patients" list that you have imported, as well as the bioanalysis reports sent by patients from your "My

Patients" list via the patient application.

Biology analyses sent by My patients						
Document name	Document uploaded	Confirmed by	Patient name	ID	Patient date of transplant	
asemn-gwc4d.pdf	September 20, 2021	To confirm	Roger R GERBI	045	Apr 8, 2020	X
Bio9-2.pdf	September 20, 2021	To confirm	Roger R GERBI	045	Apr 8, 2020	X
Analyses-bio-1p-97ko.pdf	September 20, 2021	To confirm	Roger R GERBI	045	Apr 8, 2020	X
AnalyseBio.pdf	September 20, 2021	To confirm	Roger R GERBI	045	Apr 8, 2020	X
Résultats d'analyses biologiques - Cibiltech.pdf	September 20, 2021	To confirm	Roger R GERBI	045	Apr 8, 2020	X
LAB_REPORT_23_MB.pdf	September 17, 2021	To confirm	Roger R GERBI	045	Apr 8, 2020	X
Bio6_page-0001.pdf	September 17, 2021	To confirm	Roger R GERBI	045	Apr 8, 2020	X
Bio6_page-0005.pdf	September 17, 2021	To confirm	Roger R GERBI	045	Apr 8, 2020	X
Bio6_page-0003.pdf	September 17, 2021	To confirm	Roger R GERBI	045	Apr 8, 2020	X
asemn-gwc4d.pdf	September 17, 2021	To confirm	Roger R GERBI	045	Apr 8, 2020	X

The biological analyses reports are sorted in antechronological order: the most recently imported report appears first.

The document list contains the following information:

- The name of the biological analysis report,
- The date of receipt of the biological analysis report,
- The person who validated the data in the Biology Report,
- The patient to whom the Biology Report belongs,
- The patient's ID,
- The patient's transplant date.

You have the possibility to delete a biological analysis from this list by clicking on the cross on the right. A confirmation window appears.

11. Patient list management

Click on "Patients" in the main menu on the left to view a list of patients in the team/department.

The list contains the following information:

- A clickable star to add the patient to the list of favorites,
- Patient's full name and a badge indicating whether the patient has an alert,
- Patient's date of birth,
- Patient ID,
- Last evaluation date (indicated in Step 2, eGFR when creating a Predigraft report),
- Date of transplant,
- Patient account (if the account is activated, pending or not invited),
- Date of creation of the patient file.

When the page loads, the list is ordered by the last evaluation date column.

Patients							
<input type="text" value="Rechercher..."/>							Patients favoris ☆ <input type="text" value="10"/>
☆	Nom	Date de naissance	ID	Dernière évaluation	Date de transplantation	Temps après Tx	Créé le
★	Theodora T. Schimmel	10 août 1971	847-73-3688	5 oct. 2020	29 juil. 2014	6 ans	9 oct. 2020
☆	Rhiannon J. Hilpert	11 avr. 1964	591-27-8951	25 sept. 2020	19 juin 2020	3 mois	9 oct. 2020
☆	Okey Q. DuBuque	1 août 1967	882-78-3476	21 sept. 2020	3 déc. 2018	1 an	9 oct. 2020
☆	Glen Z. Hills	10 août 1969	168-29-6537	13 sept. 2020	28 janv. 2020	8 mois	9 oct. 2020
☆	Stacy X. Stokes	13 juil. 1956	879-12-3362	31 août 2020	17 juin 2013	7 ans	9 oct. 2020
☆	Althea Q. Muller	2 juin 1973	450-98-7831	26 août 2020	5 juil. 2020	3 mois	9 oct. 2020
☆	Candace E. Kihn	14 oct. 1964	373-23-3998	8 août 2020	3 avr. 2020	6 mois	9 oct. 2020
☆	Eleazar J. Kuphal	24 mars 1977	849-18-8748	15 juil. 2020	14 juil. 2019	1 an	9 oct. 2020
☆	Jameson D. Osinski	22 janv. 1970	826-29-9882	16 juin 2020	7 nov. 2018	1 an	9 oct. 2020
☆	Trenton A. Lindgren	28 août 1966	536-16-8870	12 juin 2020	29 déc. 2019	9 mois	9 oct. 2020

1 à 10 enregistrements sur 100

Précédent Suivant

11.1. Search options:



In the search field, you can enter:


- All or part of the patient's name,
- All or part of an ID,
- A date (corresponding to the columns "Last evaluation", "Transplant date", "Created on") in the format dd/mm/yyyy or /mm or /yyyy.

The list of patients corresponding to the entry is displayed by pressing the "Enter" key on your keyboard.


Note: The search function does not apply to the "Time after Tx" column.

11.2. List of favorites:












From the patient list, click on  to add the patient to your favorites. Click on  to remove the patient from the favorites.

Click on  **My patients** to display the list of patients saved in the favorites list.

11.3. Display filter:

Click the scroll box on the top right  to change the number of patients displayed on a page.

You can display 10, 25, 50, or 100 patients.

Patients							
<input type="text" value="Rechercher..."/>							Patients favoris  <input type="text" value="10"/>
☆	Nom	Date de naissance	ID	Dernière évaluation	Date de transplantation	Temps après Tx	Créé le
	Theodora T. Schimmel	10 août 1971	847-73-3688	5 oct. 2020	29 juil. 2014	6 ans	9 oct. 2020
	Carleton A. Gislason	4 sept. 1973	801-62-7750	24 déc. 2019	6 nov. 2014	5 ans	9 oct. 2020
	Alessandro G. McCullough	26 juil. 1980	161-11-6771	23 oct. 2019	6 mai 2012	8 ans	9 oct. 2020
	Isaiah V. Rath	4 janv. 1978	857-05-2042	15 sept. 2018	8 juin 2017	3 ans	9 oct. 2020
	Woodrow H. Leannon	20 oct. 1952	428-60-5016	26 août 2018	14 déc. 2016	3 ans	9 oct. 2020
	Ozella F. Cummerata	12 janv. 1969	598-15-1010	25 avr. 2018	16 oct. 2010	9 ans	9 oct. 2020
	Edwina G. Batz	3 mai 1953	608-80-0622	16 juin 2017	1 sept. 2011	9 ans	9 oct. 2020
	Lexie G. Lynch	11 mai 1980	467-67-5323	30 avr. 2017	8 août 2016	4 ans	9 oct. 2020
	Sandra V. Douglas	6 juil. 1957	743-40-3428	18 janv. 2017	2 oct. 2014	6 ans	9 oct. 2020
	Agustina O. Macejkovic	27 janv. 1956	017-99-9228	29 déc. 2015	25 août 2015	5 ans	9 oct. 2020

1 à 10 enregistrements sur 10 (filtré parmi 100) Précédent **1** Suivant

11.4. Order the list:

Click on the column header to change whether the list is displayed in ascending or descending order. Click a second time to order in the opposite way.

Example: Order names in ascending alphabetical order.

Patients								
Rechercher...							Patients favoris ☆	10
☆	Nom ▲	Date de naissance	ID	Dernière évaluation	Date de transplantation	Temps après Tx	Créé le	
★	Edwina G. Batz	3 mai 1953	608-80-0622	16 juin 2017	1 sept. 2011	9 ans	9 oct. 2020	
☆	Talon V. Beahan	1 août 1970	196-08-9346	1 juil. 2016	3 mars 2012	8 ans	9 oct. 2020	
☆	Reinhold E. Beatty	3 mai 1980	241-55-4720		19 juin 2015	5 ans	9 oct. 2020	
☆	Kiana G. Beer	24 juil. 1968	448-73-3918	1 juil. 2015	31 déc. 2014	5 ans	9 oct. 2020	
☆	Andres S. Block	21 mai 1979	204-36-3503	10 sept. 2019	30 juin 2017	3 ans	9 oct. 2020	
☆	Jayne L. Breitenberg	27 juil. 1959	880-69-7722	22 août 2015	23 janv. 2011	9 ans	9 oct. 2020	
☆	Kaia Z. Carroll	28 juin 1966	385-51-2830	7 janv. 2019	12 août 2011	9 ans	9 oct. 2020	
☆	Kevon M. Champlin	2 févr. 1966	838-40-0339	17 déc. 2016	18 oct. 2013	6 ans	9 oct. 2020	
☆	Alexandrea Q. Cole	12 févr. 1972	679-30-4964	14 août 2016	7 avr. 2016	4 ans	9 oct. 2020	
☆	Elliot D. Cruickshank	24 juin 1975	720-81-5659	15 févr. 2017	29 déc. 2015	4 ans	9 oct. 2020	

1 à 10 enregistrements sur 100

Précédent 1 2 3 4 5 6 ... 10 Suivant


A second click on the Name column allows you to order the list in descending order.

11.5. Browse the list:

To browse the list, click on one of the numbers, "Previous" or "Next" from the list.

Previous 1 2 3 4 5 6 ... 21 Next












12. Managing the "My Patients" list

Click on "My Patients" in the main menu on the left to display the list of patients with . The list contains the following information:

- Clickable star to remove the patient from the "My Patients" list,
- Patient's full name,
- Patient's date of birth,
- Patient's ID number,
- Last date of assessment (most recent date of step 2, eGFR when creating an iBox assessment),
- Date of transplantation,
- Patient account (if the account is activated, pending or not invited),
- Date of creation of the patient record.

My patients

Search... 10

Name	Date of Birth	ID	Latest evaluation	Date of transplant	Patient account	Created
  Roger R GERBI	Jun 28, 1950	045	Sep 20, 2021	Apr 8, 2020	Activated	Apr 28, 2021
  Floriane DÛMÀNÈÉÍÖËÑ	Oct 10, 1996	8493	Sep 3, 2021	Sep 4, 2014	Pending	Sep 14, 2021
 Birtany MACLEAN	Jan 11, 1991	045-444-999	Jun 28, 2021	Jul 1, 2020	Pending	Jul 28, 2021
  Sunny O. ABERNATHY	Oct 24, 1969	895-44-0241	Nov 6, 2020	Nov 14, 2015	Activated	Dec 18, 2020
  Oma F. REINGER	Mar 31, 1967	271-25-4043	May 13, 2020	May 28, 2016	Activated	Dec 18, 2020
  Lucas Luc LEF	May 8, 1990	12345678	Apr 8, 2020	May 6, 2018	Pending	May 11, 2021

Showing 1 to 6 of 6 entries (filtered from 204 total entries) Previous **1** Next

Note: As soon as some of your patients are added to this list, you will be automatically redirected to this list when you connect to Predigraft.

12.1. Display filter

Click on 10 to change the number of patients displayed on a page. You can display 10, 25, 50 or 100 patients.

12.2. Ordering the list

Click on the column header to change the display order, ascending or descending, of the list.

Example:

Order the names in ascending order.

Mes patients

Rechercher... 10 ▾

Nom ▲	Date de naissance ▾	ID ▾	Dernière évaluation ▾	Date de transplantation ▾	Compte patient ▾	Créé ▾
★ Sunny O. ABERNATHY	24 oct. 1969	895-44-0241	6 nov. 2020	14 nov. 2015	Activé	18 déc. 2020
★ Ryan COCHRANE	28 juil. 1980	045-222-056	25 oct. 2021	2 juil. 2019	Activé	28 juil. 2021
★ Floriane DÛMÀNÈÈÏÒËN	10 oct. 1996	8493	3 sept. 2021	4 sept. 2014	En attente	14 sept. 2021
★ Franklin LATORTURE	9 oct. 1996	djfqkjmfsqjdfmlsqj	13 oct. 2021	1 oct. 2020	Activé	27 oct. 2021
★ Lucas Luc LEF	8 mai 1990	12345678	8 avr. 2020	6 mai 2018	En attente	11 mai 2021
★ Coralie LEVY	24 juil. 1995	3847	16 sept. 2021	2 juin 2016	Activé	10 juin 2021
★ Birttany MACLEAN	11 janv. 1991	045-444-999	28 juin 2021	1 juil. 2020	En attente	28 juil. 2021
★ Micheal ÓORDAN	4 mai 1974	9876	25 oct. 2021	4 mai 2019	Activé	12 mai 2021
★ Oma F. REINGER	31 mars 1967	271-25-4043	13 mai 2020	28 mai 2016	Activé	18 déc. 2020

1 à 9 enregistrements sur 9 (filtré parmi 220) Précédent 1 Suivant

A second click on the Name column allows you to order the list in descending order.

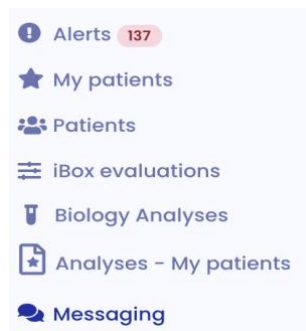
12.3. Browse the list

To browse the list, click on one of the numbers, "Previous" or "Next".



13. Messaging system management

You can also access the messaging system from the "Messaging" menu. Click on "Messaging" in the menu on the left.

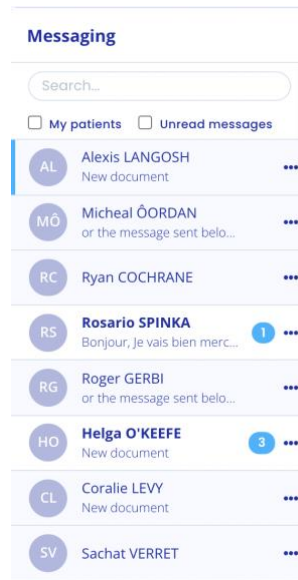


When one of your patients sends you a message, a red dot in the "Messaging" menu appears. This counter lists the number of unread conversations of your patients in the "My Patients" list. A second blue counter appears in each of your unread conversations and allows you to know the number of unread messages per conversation.

So, when you read an initially unread conversation, the red dot goes down one point.

Warning: If a patient sends you 5 messages, the red dot only takes into account the number of unread conversations of your patients (part of the "My Patients" list) and not the number of unread messages per conversation. Unread messages per conversation will be indicated by a blue dot next to the conversation.

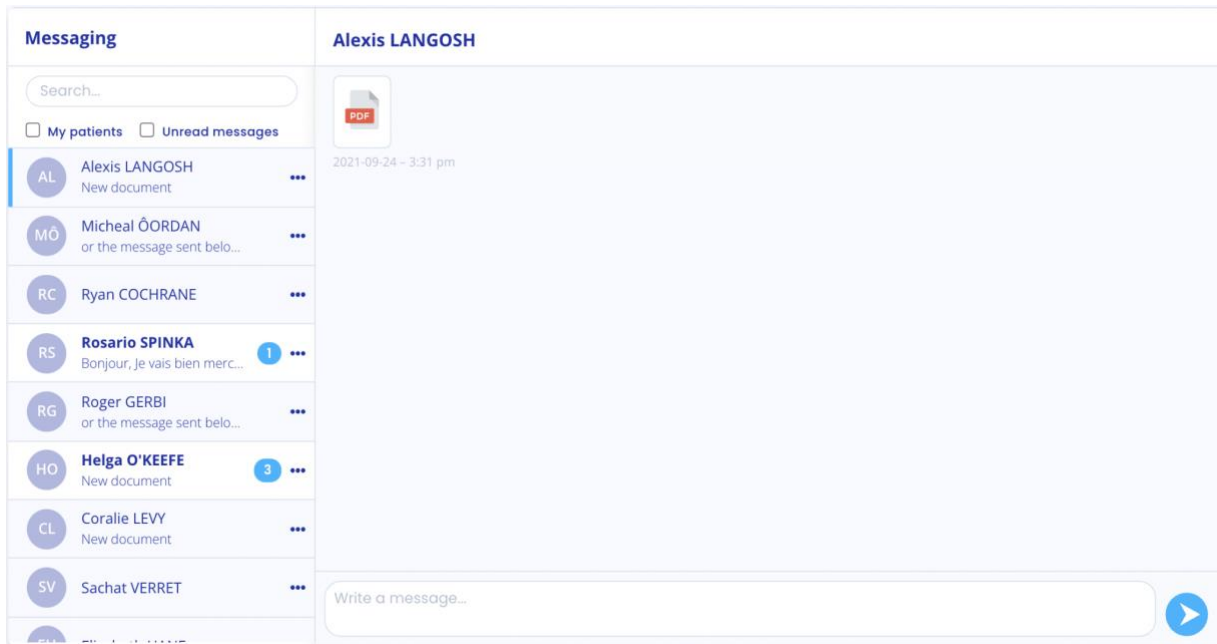
Adding a weight or blood pressure by your patient is not considered a notification. The red dot is therefore only triggered by a new message or document sent by your patient.



The most recent conversation is displayed. You can access all the conversations of your patients with an activated Predigraft account, even those with whom you have never exchanged before.

You can view only the conversations of your patients in the "My Patients" list by checking the "My Patients" box.

Note: The "My Patients" filter is enabled by default.



To change the conversation, click on the name of the desired patient. A blue bar will appear on the side indicating that you are on the conversation.

You can also search for a patient by clicking on the search bar at the top left of your mailbox.

When the patient's name appears in bold, it means that you have an unread message. When you click on it, the patient's name no longer appears in bold.

Note: Conversations are sorted from the most recent message to the oldest.

Note: You can view a document by clicking on the icon of the document you wish to view. The document will open in a new tab.

14. Report generation

To create a Predigraft report select a patient from the list to open his or her record.

If your patient has an account on the Predigraft patient application and has sent biology documents or if you have imported biology documents, you can view one of these documents from the patient record, in the "Analysis reports" item, click on the document you want to view.

To generate a new iBox assessment, click on the "New iBox Assessment" button in the Monitoring/Risk Assessment item. This will take you to the "New iBox Assessment" page.

Surveillance / Risk assessment		+ New iBox Evaluation		
Date	Input data	3y	5y	7y
February 1, 2015	  	20 %	8 %	2 %
January 1, 2015	 	99 %	99 %	98 %
December 1, 2014	  	81 %	71 %	60 %
November 1, 2014	 	85 %	77 %	68 %

You can also generate a new iBox evaluation from the biological table. To do so, click on "Biological Table" and then on the "New iBox Evaluation" button located at the top right of the table.

Alexis G. LANGOSH (009-06-2742)		← Back				
Female, 58 years old born on Aug 24, 1963, transplanted on April 8, 2014 (7 years ago)						
Biology		+ New iBox Evaluation				
<input checked="" type="checkbox"/> Blood <input type="checkbox"/> Urine						
Day after transplant	2020-09-27	2020-10-18	2020-11-27	2020-12-02	2020-12-03	2020-12-07
Time after transplant	6 years, 5 months	6 years, 6 months	6 years, 7 months	6 years, 7 months	6 years, 7 months	6 years, 7 months
Associated analysis						
Glycated hemoglobin (%)		11.66	14.63			7.04

14.1. Creating a report

Fill out all required fields in the form in order to proceed to the next step.

1. Estimated glomerular filtration flow rate value (eGFR)
2. Proteinuria value
3. DSA value if available, if not check "Not available".
4. Histology information if available, if not check "Not available".

If you have chosen to create an iBox assessment for a patient who does not have imported biology reports, click "Not Available" in the drop-down list :

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For steps 1 and 2, you can fill in the following patient information:

- GFR-e,
- Proteinuria.

For step 3, you fill in the patient's DSA information. If you do not have this information, you can check the "Not available" box.

For step 4, you can click in the empty field on the left side of the report creation if you want to import a histology report from your computer and view it next to the form. You can save the histology report to the patient record. Then you can fill in the patient's histology information. If you do not have this information, you can check the "Not available" box.

If you chose to create an iBox evaluation for a patient who has imported biology reports:

For steps 1 and 2, the biological analysis document displays on the left side of the report creation.

You can fill in the following patient information:

- GFR-e,
- Proteinuria.

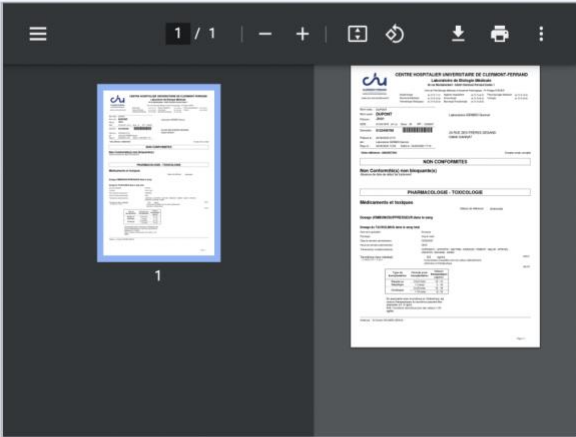
Warning: The biological analysis report with the most recent date is displayed by default. To choose another report, please click on the arrow, a drop-down menu appears with all the biological analysis reports related to the patient.

Note: The biological analysis reports that you can display are the reports for which the data extracted at the import have been validated. If you have validated the following data, it will already be pre-populated automatically during steps 1 and 2 of the iBox assessment creation:

- GFR date,
- The estimated GFR,
- The creatinine level in the blood,
- Proteinuria date,
- Protein to creatinine ratio in urine,
- The creatinine level in urine,
- Protein level in urine.

New iBox Evaluation Roger R. Gerbi (045)
Male, 71 years old born on June 28, 1950, transplanted on April 8, 2020
[← Back to patient file](#)

1
Estimated GFR
2
Proteinuria
3
DSA
4
Histology



Choose a document

Bio6_page-0006.pdf - September 23, 2021

Is eGFR available? (estimated according to the MDRD equation) Yes No

Creatinine

5.00 μmol/L mg/dL

Date of creatinine analysis

September 23, 2021

The estimated GFR is greater than 500 mL/min/1.73m².

[Previous](#) [Next](#)

For step 3, you fill in the DSA information you have about the patient. If you do not have this information, you can check the "Not available" box.

For step 4, you can click in the empty field on the left side of the report creation if you want to import a histology report from your computer and view it next to the form. You can save the histology report to the patient record. Then you can fill in the patient's histology information. If you do not have this information, you can check the "Not available" box.

- Dates

The dates of steps 1, 2, 3 and 4 are mandatory. They cannot be earlier than the date of transplantation. In order to help you enter this information, you have access to a calendar where you can click on the corresponding date:

During the 1st step, you can click on:

- A date on the calendar,
- The "Today" button.

Date of creatinine analysis

23/09/2021

September 2021

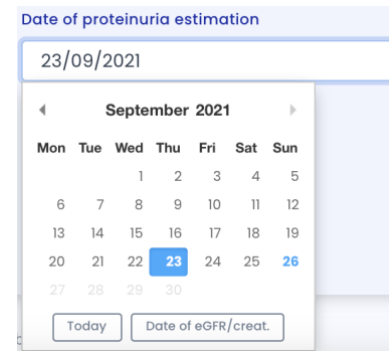
Mon	Tue	Wed	Thu	Fri	Sat	Sun
			1	2	3	4
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30			

Today

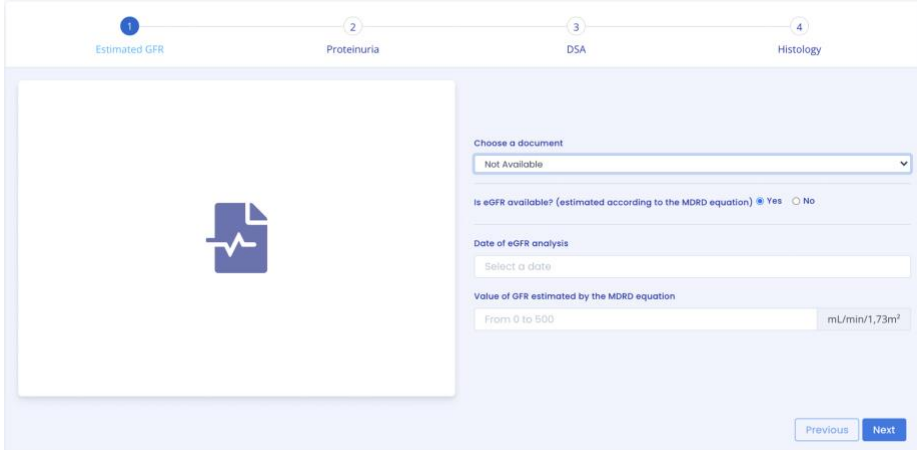
0 mL/min/1.73m².

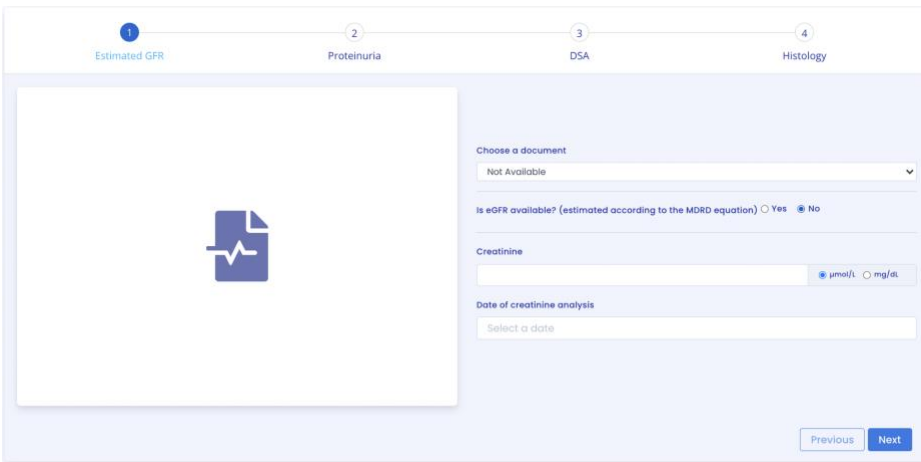
In steps 2, 3 and 4, you can click on:

- A date on the calendar,
- The "Today" button,
- The "Date of GFR/creatinine" button (date of the 1st step).




The following screenshots show the necessary steps to create a report without viewing biological analysis reports.

<p>Title banner</p>	<p>The title banner is available on all report creation pages.</p> <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 10px;"> <p>New iBox Evaluation Laurence Bronzini (2605)</p> <p style="text-align: right; font-size: small;">Female, 54 years old born on August 25, 1967, transplanted on September 1, 2019</p> <p style="text-align: right; font-size: x-small;">← Back to patient file</p> </div> <p>You will see the following patient information:</p> <ul style="list-style-type: none"> - Name, - ID, - Sex, - Age and date of birth, - Date of transplant.
<p>1) Estimated glomerular filtration rate value (eGFR)</p>	<p>Option 1:</p> <p>The estimated GFR value must be between 0 and 500. Above 120, a message informs you that the iBox calculation will be done with a GFR equal to 120.</p> <p>Warning message: "Are you sure that the estimated GFR is above 120mL/min/1.73m²? The iBox calculation will use a GFR equal to 120 mL/min/1.73m²."</p> <p>Error message: "The estimated GFR must be between 0 and 500."</p> <div style="border: 1px solid #ccc; padding: 10px; margin: 10px 0;">  <p>The screenshot shows a multi-step form with four steps: 1. Estimated GFR, 2. Proteinuria, 3. DSA, and 4. Histology. Step 1 is active. The form contains a 'Choose a document' dropdown menu (set to 'Not Available'), a radio button for 'Is eGFR available? (estimated according to the MDRD equation)' (set to 'Yes'), a 'Date of eGFR analysis' field (set to 'Select a date'), and a 'Value of GFR estimated by the MDRD equation' field (set to 'From 0 to 500' with units 'mL/min/1.73m²'). A 'Next' button is visible at the bottom right.</p> </div> <p>Option 2:</p>

	 <p>Predigraft applies the MDRD formula from creatinine. Creatinine value is limited: Error message: "Creatinine value must be between 1 and 1300 μmol/L." Error message: "Creatinine value must be between 0.02 and 33.92 mg/dL."</p> <p>GFR is calculated: Success message: "Estimated GFR is <value> mL/min/1.73m² from MDRD equation" or if GFR is between 120 and 500: "Estimated GFR is <value> mL/min/1.73m² from MDRD equation. The iBox calculation will use an estimated GFR equal to 120 mL/min/1.73m²." Error message: "The estimated GFR is greater than 500 mL/min/1.73m²." Error message: "The estimated GFR is less than 0 mL/min/1.73m²."</p> <p>Notes:</p> <ul style="list-style-type: none"> - The upper limit of 500 mL/min/1.73m² exists to account for extreme cases. - The limit of 120 mL/min/1.73m² for calculating the iBox score was established because the calculation of iBox probabilities and the expected survival benefit at 3, 5, 7 years are unchanged above 120 mL/min/1.73m².
<p>2) Proteinuria value</p>	<p>Option 1:</p>

1 Estimated GFR 2 Proteinuria 3 DSA 4 Histology



Are either the urine protein/creatinine ratio in g/g or a 24 hour collection available?
 Yes No

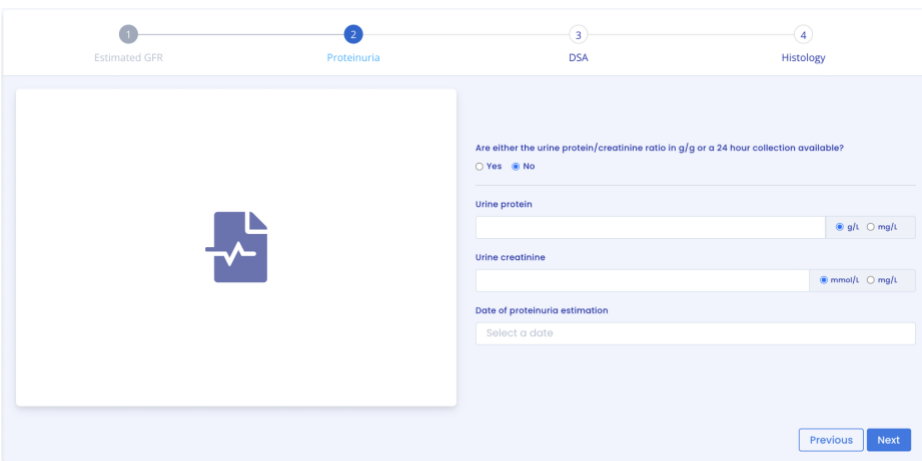
Date of proteinuria
Select a date

Proteinuria value
From 0 to 12 g/g

Previous Next

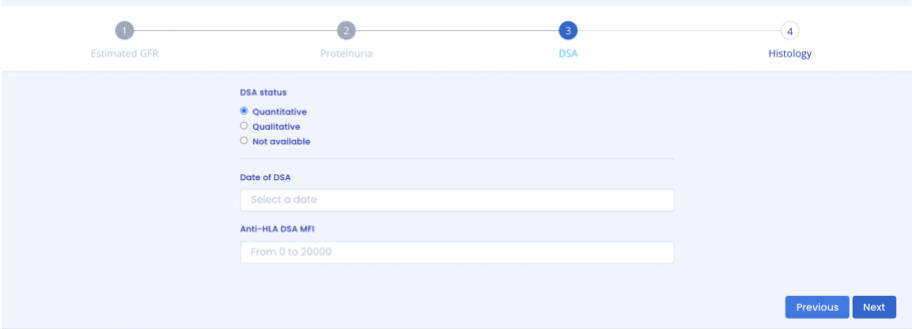
The proteinuria value should be between 0 and 12.
Error message: Proteinuria must be between 0 and 12 g/g.

Option 2:

	 <p>Predigraft calculates proteinuria by the ratio of urine protein to urine creatinine.</p> <p>Urine protein is limited: Error message: "Proteinuria value must be between 0 and 30 g/L." or "Proteinuria value must be between 0 and 30000 mg/L."</p> <p>Urine creatinine is limited: Error message: "Creatinine value must be between 0 and 35 mmol/L." or "Creatinine value must be between 0 and 3959.27 mg/L."</p> <p>Ratio is calculated: Success message: "The urine protein/creatinine ratio is <value> g/g." Error message: "Protein/creatinine ratio in urine must not exceed 12 g/g." Error message: "Protein/creatinine ratio in urine cannot be negative."</p> <p>Note on proteinuria date: Predigraft recommends measuring GFR and proteinuria 15 days apart. Warning message: "The time between the estimated GFR and proteinuria is longer than the recommended 15 days." Error message: "The time between estimated GFR and proteinuria is greater than 30 days".</p>
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3) DSA value

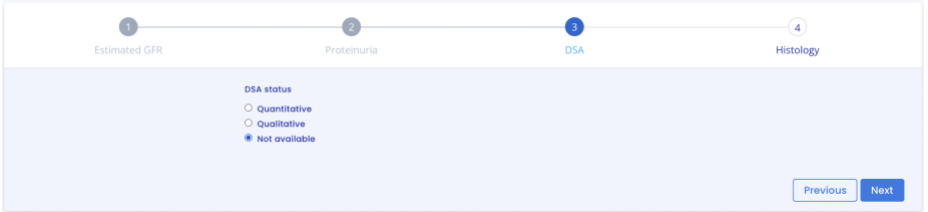
Option 1:



The screenshot shows a multi-step form with four steps: 1. Estimated GFR, 2. Proteinuria, 3. DSA, and 4. Histology. Step 3 is currently active. The form includes the following fields:

- DSA status:** Radio buttons for Quantitative (selected), Qualitative, and Not available.
- Date of DSA:** A date selection field with the placeholder text "Select a date".
- Anti-HLA DSA MFI:** A numerical input field with the placeholder text "From 0 to 20000".
- Navigation:** "Previous" and "Next" buttons.

The anti-HLA antibody value should be between 0 and 20000.

	<p>Error message: “The MFI must be between 0 and 20000.”</p> <p><u>Option 2:</u></p>  <p>"Presence" or "Absence" must be selected.</p> <p><u>Option 3:</u></p>  <p><u>Note on DSA date:</u> Predigraft recommends measuring GFR and DSA at 2-month intervals.</p> <p>Warning Message: The time between the estimated GFR and DSA is more than the recommended 2-month interval.</p> <p>Error Message: The time between the estimated GFR and DSA is more than 4 months.</p>
<p>4) Histology informati on</p>	<p>You can import a histology report to view it. Once the histology report is visible, you can decide to save it in the patient record.</p> <p><u>Option 1:</u></p>

1 Estimated GFR
2 Proteinuria
3 DSA
4 Histology

Upload histology report

Histology Status

Banff Scores Available

Diagnosis Available

Not available

Date of biopsy

Glomerulitis (g score) 0 0 1 2 3

Peritubular capillaritis (ptc score) 0 0 1 2 3

Interstitial inflammation (i score) 0 0 1 2 3

Tubulitis (t score) 0 0 1 2 3

Transplant Glomerulopathy (cg score) 0 0 1 2 3

Interstitial fibrosis tubular atrophy (IFTA score) 0 0 1 2 3

A value of "0", "1", "2" or "3" must be selected for each Banff score.

Option 2:

1 Estimated GFR
2 Proteinuria
3 DSA
4 Histology

Upload histology report

Histology Status

Banff Scores Available

Diagnosis Available

Not available

Date of biopsy

Diagnosis

Antibody-mediated rejection

T cell-mediated rejection

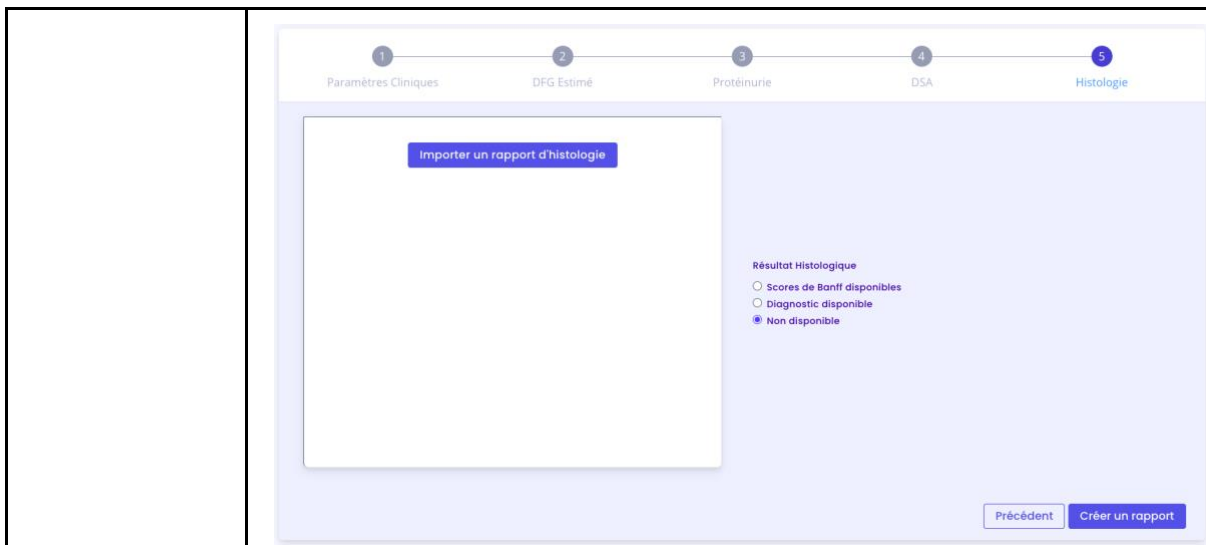
Recurrence of nephropathy (glomerulopathy...)

BK virus nephropathy

Calcineurin-inhibitor toxicity

Acute kidney injury

Other



Note on histology date:
 Predigraft recommends measuring GFR and histology at 2-month intervals. Error Message:
 The time between estimated GFR and biopsy must be less than 2 months.

Predigraft selects the iBox algorithmic model corresponding to the input data. The "Create Report" button checks the input data for errors. The generated iBox evaluation contains the results of the iBox algorithm calculation: survival probability at 3, 5 and 7 years post evaluation date (date of step 1).

14.2. Visualization of results

The title banner recalls the patient's name, the date of evaluation (date of step 1) GFR-e), the patient's date of transplantation.

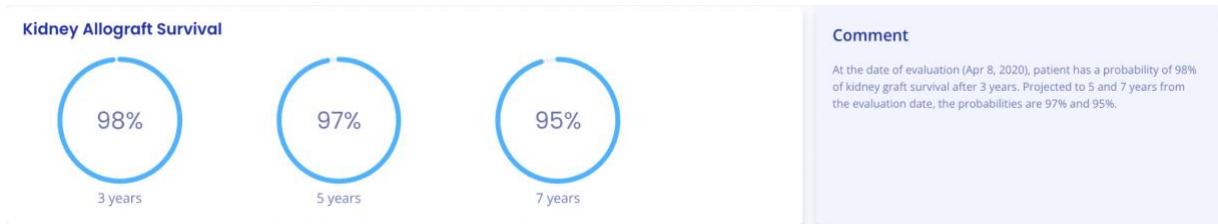


You can print the Predigraft report by clicking on "Print". If you created the iBox evaluation by previewing a biological analysis report, you can download the biological analysis report.

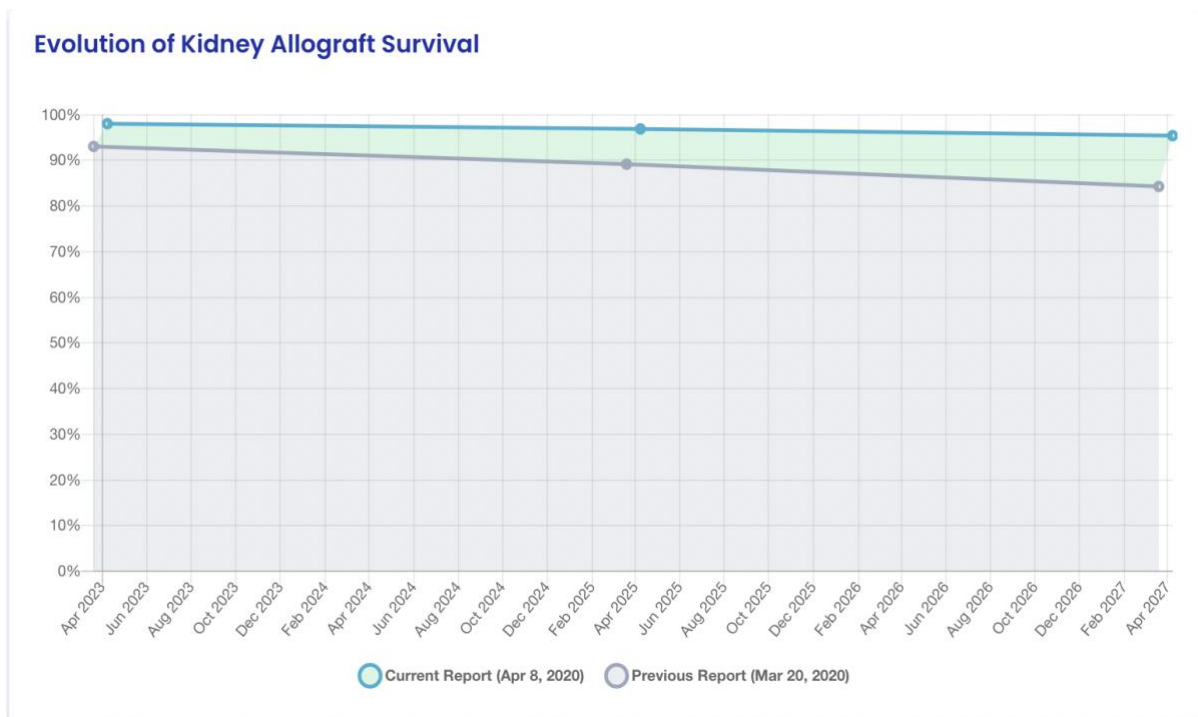
You can delete the report by clicking on "Delete" and specifying the reason in the confirmation window that appears:

- Incorrect data,
- The record is for a different patient,
- The report is a duplicate.

You can visualize the results of the iBox calculation: the probability of kidney graft survival projected at 3 years, 5 years, and 7 years from the evaluation date. The "comments" panel describes the probabilities.



You can view the iBox results of the current report compared to the results of the most recent previous report. The comment panel describes whether the survival probabilities are better or worse since the previous report.



You can visualize the input data that were used to generate the report: date and value for each step of the report creation (Clinical Parameters, Estimated GFR, Proteinuria, DSA, Histology). In the Comment panel, you can find the probability of agreement of the iBox model based on the input data (C-stat). Click on the "publication" link to access the Paris Transplant Group publication about the iBox.

Input data	
ESTIMATED GFR	
eGFR	80,0 mL/min/1,73m ²
Date of eGFR	Mar 20, 2020
PROTEINURIA	
Proteinuria	9 g/g of creatinine
Date of prot.	Apr 2, 2020
DSA	
Not Available	
HISTOLOGY	
Not Available	

14.3. Automatic iBox generation

You have the possibility to create iBox assessments manually, but also automatically. Indeed, the score of the iBox algorithm being calculated thanks to the proteinuria and the GFR, the calculation can be done automatically by the MDRD equation.

Thus, for each new biological report containing urine creatinine and urine protein or for each new proteinuria value that you will enter on your patient's chart, a new iBox report will be created automatically, only if an estimated GFR value is already present on your patient's chart and is less than one month old.

Similarly, for each new creatinine or estimated GFR value added to your patient's record, a new iBox report will be created automatically, only if a proteinuria value is already present on your patient's record and is less than one month old.

Note: Each report will be displayed in the same place as the manually created reports and in case of several new data, several reports will be generated the same day.

15. Managing the list of reports

Click on "Predigraft Reports" on the left sidebar to view a list of reports for all patients in the team/department. The list contains the following information:

- Report: report of <full name of patient> (born on <patient date of birth>),
- Evaluation date: date of step 2) "Estimated GFR" when creating the report,
- Time after Tx: the time between transplant date and evaluation date,
- 3 years, 5 years, 7 years: the probability of renal graft survival at 3 years, 5 years, and 7 years after the evaluation date,
- Created on: the date the report was created.

When the page loads, the list is automatically ordered by the Evaluation Date column.

iBox evaluations

Q Search... 10 ▾

Report ▾	Evaluation date ▾	Time after Tx ▾	3 years ▾	5 years ▾	7 years ▾	Created ▾
Report for Roger R GERBI (born Jun 28, 1950)	Sep 20, 2021	1 year	95 %	92 %	88 %	Sep 21, 2021
Report for Roger R GERBI (born Jun 28, 1950)	Sep 20, 2021	1 year	99 %	98 %	97 %	Sep 21, 2021
Report for Roger R GERBI (born Jun 28, 1950)	Sep 20, 2021	1 year	95 %	92 %	88 %	Sep 21, 2021
Report for Roger R GERBI (born Jun 28, 1950)	Sep 20, 2021	1 year	42 %	25 %	12 %	Sep 21, 2021
Report for Roger R GERBI (born Jun 28, 1950)	Sep 20, 2021	1 year	97 %	95 %	93 %	Sep 20, 2021
Report for Micheal ÓRDAN (born May 4, 1974)	Sep 17, 2021	3 years	6 %	1 %	0 %	Sep 17, 2021
Report for Ryan COCHRANE (born Jul 28, 1980)	Sep 16, 2021	1 year	83 %	74 %	64 %	Sep 16, 2021
Report for Coralie LEVY (born Jul 24, 1995)	Sep 16, 2021	5 years	83 %	74 %	64 %	Sep 16, 2021
Report for Coralie LEVY (born Jul 24, 1995)	Sep 15, 2021	5 years	98 %	97 %	95 %	Sep 17, 2021
Report for Coralie LEVY (born Jul 24, 1995)	Sep 14, 2021	5 years	71 %	58 %	44 %	Sep 14, 2021

Showing 1 to 10 of 433 entries Previous 1 2 3 4 5 6 ... 44 Next


15.1. Search for:

In the search field, you can enter:

- All or part of a patient's name
- A date corresponding to the columns "Evaluation date", "Time after Tx", "Created on" in the format dd/mm/yyyy or /mm or /yyyy

The list of reports corresponding to the search entry is displayed by pressing the "Enter" key on your keyboard.

15.2. Display filter:

Click on the scroll box on the upper right  to change the number of reports displayed on a page. You can display 10, 25, 50, or 100 reports.

15.3. Order the list:

Click on the column header to change whether the list is displayed in ascending or descending order.

15.4. Browse the list:

To browse the list, click on one of the numbers, "Previous" or "Next" from the list.

16. Alerts

16.1. Definition of alerts

Predigraft calculates patient alerts when the following data are added to a patient record:

- Weight data,
- Blood pressure data,
- Values for immunosuppressive drugs C₀ Tacrolimus, C₂ Ciclosporin, C₀ Everolimus or C₀ Sirolimus when creating a Predigraft report,
- Kidney function values for estimated GFR and proteinuria when creating a Predigraft report,
- Kidney Graft Survival Probability during Predigraft Report creation and iBox calculation,

16.2. Alert settings

Predigraft calculates patient alerts based on alert settings. There are three parameter categories:

- Predigraft-level (default): Cibiltech sets the default values
- Team level: the team owner can modify the alert settings for the team. This setting is then applied to all patients in the team.
- Patient-level: department members can change alert settings for each patient. this setting is only valid for the specified patient.

16.2.1. Cibiltech settings: default setting

For the Predigraft level, Cibiltech has defined default values that teams can modify as they see fit.

- 1) Blood pressure:
 - Maximum systolic pressure value: 140 mmHg.
 - Maximum diastolic pressure value: 90 mmHg.
 - Systolic pressure value for hypertension (Grade 3): 180 mmHg.
 - Diastolic pressure value for hypertension (Grade 3): 110 mmHg.

The maximum values for each setting are:

- Maximum systolic pressure value: 250 mmHg
- Maximum diastolic pressure value: 130 mmHg

- 2) Weight

- Weight gain: 1 kg.
- Weight loss in one month: 5%.
- Weight loss in six months: 10%.

The maximum values for each setting are:

- Weight gain: 20 kg

3) Immunosuppressive drugs

- C0 Tacrolimus minimum threshold: 4 ng/mL
- C0 Tacrolimus maximum threshold: 12 ng/mL
- C2 Ciclosporin minimum threshold: 600 ng/mL
- C2 Ciclosporin maximum threshold: 1200 ng/mL
- C0 Everolimus minimum threshold: 3 ng/mL
- C0 Everolimus maximum threshold: 8 ng/mL
- C0 Sirolimus minimum threshold: 4 ng/mL
- C0 Sirolimus maximum threshold: 12 ng/mL

The maximum values for each parameter are:

- T0 Tacrolimus minimum threshold: 12 ng/mL
- T0 Tacrolimus maximum threshold: 13 ng/mL
- T2 Ciclosporin minimum threshold: 1000 ng/mL
- T2 Ciclosporin maximum threshold: 1500 ng/mL
- T0 Everolimus minimum threshold: 12 ng/mL
- T0 Everolimus maximum threshold: 13 ng/mL
- T0 Sirolimus minimum threshold: 12 ng/mL
- T0 Sirolimus maximum threshold: 13 ng/mL

4) Blood biology data

- Minimum potassium: 3.2 mmol/L
- Potassium maximum: 5.3 mmol/L
- Minimum hemoglobin: 10 g/dL
- Maximum hemoglobin: 16.5 g/dL
- Minimum HbA1c: 4.5 %
- Maximum HbA1c: 9 %
- Platelets minimum: 80 000 /mm³
- Platelets maximum: 550 000 /mm³
- Neutropenia (minimum neutrophils): 1 000 /mm³
- Troponin maximum: 0.6 µg/L
- Minimum INR: 1
- Maximum INR: 5

The accepted thresholds for each parameter are :

- Potassium minimum: [3 - 3.5] mmol/L
- Maximum potassium: [4.8 - 5.5] mmol/L
- Hemoglobin minimum: [8.5 - 10] g/dL
- Maximum hemoglobin: [16 - 17.5] g/dL
- HbA1c minimum: [4 - 6] %
- HbA1c maximum: [6.5 - 13.5] %
- Platelets minimum: [10 000 - 150 000] /mm³
- Platelets maximum: [550,000 - 1,000,000] /mm³
- Neutropenia (minimum neutrophils) : [500 - 1,000] /mm³
- Troponin maximum: [0.6 - 2] µg/L
- INR minimum: [1 - 3.5]
- Maximum INR: [3.5 - 5]

5) Renal function (estimated GFR, proteinuria)

- Decrease in estimated GFR: 30%.
- Increase in serum creatinine: 50%.
- de novo proteinuria

The maximum values for each parameter are:

- Decrease in estimated GFR: 9999.99%.
- Increase in serum creatinine: 9999.99%.

6) Probability of kidney graft survival

- Decrease in the probability of survival at 3 years: 1%.
- Decrease in the probability of survival at 5 years: 1%.
- Decrease in the probability of survival at 7 years: 1%.

Settings that cannot be changed are:

- de novo proteinuria
- Systolic pressure for hypertension (Grade 3)
- Diastolic pressure for hypertension (Grade 3)
- Weight loss in one month
- Weight loss in six months
- Decrease in the probability of survival at 3 years
- Decreased probability of survival at 5 years
- Decreased probability of survival at 7 years

16.2.2. Team-level configuration

To set up the team alerts, click on "Alerts" in the left sidebar, then click on "Alert Setup".

Alertes				
Paramétrage d'alertes				
Nom	ID	Dernière évaluation	Date de transplantation	Créé le
Sophie Q. Lanreau	68730	26 août 2020	25 août 2015	9 oct. 2020

You will then be taken to the "Team Alert Settings" page.

Team Alert Settings

[Settings History](#) Last modification by Mr Joesph Feeney (1 week ago)

Biology table

Potassium: minimum	3.20	mmol/L	Update
Potassium: maximum	5.30	mmol/L	Update
Hemoglobin: minimum	10.00	g/dL	Update
Hemoglobin: maximum	16.5	g/dL	Update
HbA1c: minimum	4.50	%	Update
HbA1c: maximum	9.00	%	Update
Platelets: minimum	80000	/mm3	Update
Platelets: maximum	550000	/mm3	Update
Neutropenia: minimum	1000	/mm3	Update
Troponin: maximum	0.60	µg/L	Update
INR: minimum	1.00		Update
INR: maximum	5.00		Update
<hr/>			
Tacrolimus: minimum	4	ng/mL	Update
Tacrolimus: maximum	12	ng/mL	Update
Cyclosporine T _r : minimum	600	ng/mL	Update
Cyclosporine T _r : maximum	1200	ng/mL	Update
Everolimus: minimum	3	ng/mL	Update
Everolimus: maximum	8	ng/mL	Update
Sirolimus: minimum	4	ng/mL	Update
Sirolimus: maximum	12	ng/mL	Update

Blood pressure & Weight

Systolic BP: maximum	140	mmHg	Update
Diastolic BP: maximum	90	mmHg	Update
<hr/>			
Weight gain	100	kg	Update

Kidney function

Serum creatinine increase	100	%	Update
<small>Predgraft settings: 50</small>			

Other settings (not customizable)

- De novo proteinuria
- Hypertension (grade 3) : Systolic BP ≥ 180 mmHg
- Hypertension (grade 3) : Diastolic BP ≥ 110 mmHg
- Weight loss in one month ≥ 5 %
- Weight loss in six months ≥ 10 %
- Absolute decrease of 3 years graftsurvival probability ≥ 1 %
- Absolute decrease of 5 years graftsurvival probability ≥ 1 %
- Absolute decrease of 7 years graftsurvival probability ≥ 1 %

To modify a parameter: change the value in the corresponding field and then click on the "Modify" button. A confirmation window will display the following information:

- The parameter value entered,
- The calculation that generates the alert.

Example of modification of the minimum Tacrolimus threshold, at the team level:

Please confirm the following update ✕

An alert will appear for all patients in the team if:
Potassium < 3.30 mmol/L

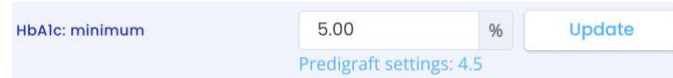
Click on "Modify for all patients" to confirm, or on "Cancel" to cancel the update.

Once you have updated a parameter, a "Parameter History" button allows you to access the history of changes. Next to the history button, a message indicates the date of the last parameter update, as well as the name of the user who performed the action.

Team Alert Settings

Last modification by Prof. Lorena Jast (2 weeks ago)

For each parameter that does not apply the default value, the default value will be displayed below: "Default (Predigraft): <Predigraft setting value>".



The screenshot shows a settings interface for 'HbA1c: minimum'. It features a text input field containing '5.00' followed by a '%' symbol. To the right is an 'Update' button. Below the input field, the text 'Predigraft settings: 4.5' is displayed in a smaller font.

16.2.3. History of team-level configuration

You can access the setting history via the "Alerts" path on the left main menu, "Service Alerts Setting", "Setting History".

The history is displayed in descending order from the most recent to the oldest. In the history you will see:

- The name of the user who changed the settings,
- The date of the change,
- The list of each alert parameter and corresponding value.

Team Alert Settings History ← Back

[Mr Joesph Feeney \[2 : 1 week ago\]](#)

<p>Biology table</p> <p>Potassium (minimum) : 3.20 mmol/L Potassium (maximum) : 5.30 mmol/L Hemoglobin (minimum) : 10.00 g/dL Hemoglobin (maximum) : 16.5 g/dL HbA1c (minimum) : 4.50 % HbA1c (maximum) : 9.00 % Platelets (minimum) : 80000 /mm3 Platelets (maximum) : 550000 /mm3 Neutropenia (polynuclear neutrophils minimum) : 1000 /mm3 Troponin (maximum) : 0.60 µg/L INR (minimum) : 1.00 INR (maximum) : 5.00</p> <p>Tacrolimus (minimum) : 4 ng/mL Tacrolimus (maximum) : 12 ng/mL Ciclosporine T₂ (minimum) : 600 ng/mL Ciclosporine T₂ (maximum) : 1200 ng/mL Everolimus (minimum) : 3 ng/mL Everolimus (maximum) : 8 ng/mL Sirolimus (minimum) : 12 ng/mL Sirolimus (maximum) : 12 ng/mL</p>	<p>Kidney function</p> <p>Serum creatinine increase : 1.00 % De novo proteinuria</p> <p>Blood Pressure</p> <p>Systolic BP (maximum) : 140 mmHg Diastolic BP (maximum) : 90 mmHg Systolic BP for Hypertension (grade 3) : 180 mmHg Diastolic BP for Hypertension (grade 3) : 110 mmHg</p> <p>Weight</p> <p>Weight gain : 1.00 kg Weight loss in 1 month : 5 % Weight loss in 6 months : 10 %</p> <p>Survival Probability</p> <p>Absolute decrease of 3 years graftsurvival probability : 1.00 % Absolute decrease of 5 years graft survival probability : 1.00 % Absolute decrease of 7 years graft survival probability : 1.00 %</p>
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16.2.4. Patient-level configuration

To set up alerts for a patient, access the patient record and click on the three small dots next to the patient's name, then click on "Alert settings". This will take you to the "Alert settings: <full name of patient>".

Patient Alert Settings: Ryan COCHRANE ← Back

[Settings History](#) Last modification by Mr Joesph Feeney 12 (1 week ago)

Biology table

Potassium: minimum	3.20	mmol/L	Update
Potassium: maximum	5.30	mmol/L	Update
Hemoglobin: minimum	10.00	g/dL	Update
Hemoglobin: maximum	16.5	g/dL	Update
HbA1c: minimum	4.50	%	Update
HbA1c: maximum	9.00	%	Update
Platelets: minimum	80000	/mm3	Update
Platelets: maximum	550000	/mm3	Update
Neutropenia: minimum	1000	/mm3	Update
Troponin: maximum	0.60	µg/L	Update
INR: minimum	1.00		Update
INR: maximum	5.00		Update

Tacrolimus: minimum	4	ng/mL	Update
Tacrolimus: maximum	12	ng/mL	Update
Ciclosporine T ₂ : minimum	600	ng/mL	Update
Ciclosporine T ₂ : maximum	1200	ng/mL	Update
Everolimus: minimum	3	ng/mL	Update
Everolimus: maximum	8	ng/mL	Update
Sirolimus: minimum	4	ng/mL	Update
Sirolimus: maximum	12	ng/mL	Update

Blood pressure & Weight

Systolic BP : maximum	140	mmHg	Update
Diastolic BP : maximum	90	mmHg	Update
Weight gain	1.00	kg	Update

Kidney function

Serum creatinine increase	1.00	%	Update
---------------------------	------	---	--------

Other settings (not customizable)

De novo proteinuria

Hypertension (grade 3) : Systolic BP ≥ 180 mmHg

Hypertension (grade 3) : Diastolic BP ≥ 110 mmHg

Weight loss in one month ≥ 5 %

Weight loss in six months ≥ 10 %

Absolute decrease of 3 years graftsurvival probability ≥ 1 %

Absolute decrease of 5 years graftsurvival probability ≥ 1 %

Absolute decrease of 7 years graftsurvival probability ≥ 1 %

To modify a parameter: change the value in the corresponding field and then click on the “Modify” button.

A confirmation window will display the following information:

- The parameter value entered,
- The calculation that generates the alert.

Click on "Modify for <full patient name>" to validate, or on "Cancel" to cancel the update.

Example of changing the Maximum Systolic Pressure threshold at the patient level:

Please confirm the following update ✕

An alert will appear for the patient Ryan COCHRANE if:
Hemoglobin > 16. g/dL

Cancel
Update for Ryan COCHRANE

Once you have updated an alert parameter at the patient level, a "Parameter History" button allows you to access the modification history. The button does not appear if the parameter has only been changed at the team level.

Next to the history button, a message will display the date of the last update to the patient's alert settings as well as the name of the user who performed the action.

Patient Alert Settings: Ryan COCHRANE

 Settings History

Last modification by Prof. Lorena Jast (1 second ago)

Under each parameter that does not have the default value, a text says: "Default (Service): <value of service setting>".

Hemoglobin: maximum	<input type="text" value="16.0"/>	g/dL	<input type="button" value="Update"/>
	Team settings: 16.5		

16.2.5. History of patient-level settings

To access a patient's alert history, select a patient's record and click on the three small dots next to the patient's name, then click on "Settings History".

The history is sorted with the most recent modification at the top of the page. The history is a list containing:

- The category of the setting: team/department or patient,
- The name of the user who changed the settings,
- The date of the change

Alert History: Ryan COCHRANE (045-222-056) ← Back

Alerts (Sep 16, 2021) Mark as read

There is a reduction of the kidney function (increase of serum creatinine) between Sep 16, 2021 and Sep 16, 2021.

Alerts (Sep 16, 2021) Mark as read

There is a reduction of the kidney function (increase of serum creatinine) between Sep 16, 2021 and Sep 16, 2021.

Alerts (Sep 16, 2021) Mark as read

There is a reduction in probability allograft survival between Jul 28, 2021 and Sep 16, 2021.

Alerts (Sep 21, 2021) Prof. Lorena Jast marked as read this alert 1 second ago

Sep 21, 2021: From last evaluation (Sep 17, 2021), a gain of weight has been observed (+ 20 kg).

16.3. Alert calculation for a patient

Alerts are based on the following information (calculations are available in the Appendix).

1) Blood pressure

The software calculates blood pressure alerts from:

- the most recent date of blood pressure and associated systolic and diastolic pressure values.

2) Weight

The software calculates weight alerts from:

- the most recent date of weight and the corresponding value,
- the previous weight date and the corresponding value.

3) Immunosuppressive drugs

The software calculates immunosuppressive drug alerts on the first validation of data extracted from a biological report, if that report is the most recent analysis date:

- date of the biological analysis,
- T₀ Tacrolimus (ng/mL), T₂ Ciclosporin (ng/mL), T₀ Everolimus (ng/mL), T₀ Sirolimus (ng/mL) values.

4) Blood biological data

The software calculates the blood biological data alerts during the first validation of the data extracted from a biological report, if this report is the most recent analysis date:

- date of the biological analysis,
- Potassium value converted to mmol/L,
- Hemoglobin value converted to g/dL,
- HbA1c (Glycated Hemoglobin) value converted to %,
- Platelet count value converted to /mm³,
- Neutrophil count value converted to /mm³,
- Troponin value converted,
- INR value.

5) Kidney function

Software calculates renal function alerts from two Predigraft reports:

- Orders Predigraft reports by date of assessment (date of step 2) Estimated GFR),
- Selects the most recent report: "current report,
- Selects the previous report: "previous report.

The software selects in both reports: date of estimated GFR, GFR value, creatinine value if filled, proteinuria date, proteinuria value.

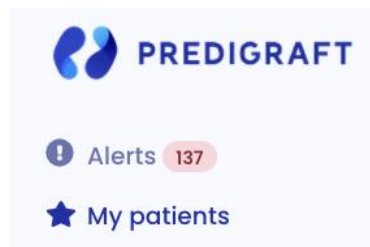
6) Probability of renal graft survival


The software calculates renal graft survival probability alerts from two Predigraft reports:

- Orders Predigraft reports by assessment date (date of step 2) estimated GFR),
- 1-year analysis, if a 5% decrease in 7-year kidney graft probability occurred between 2 reports,
- 1-year analysis, if a 5% decrease in 7-year kidney graft probability occurred between one report and the nearest biopsy,

16.4. Management of the list of patients on alert

Click on "Alerts" on the left sidebar for a list of patients on alert.



A counter of patients on alert  is displayed on the left sidebar Alerts. If the counter is not visible, there are no patients on alert.

Alertes				
Paramétrage d'alertes				
Nom	ID	Dernière évaluation	Date de transplantation	Créé le
Sophie Q. Lanreau	68730	26 août 2020	25 août 2015	9 oct. 2020

The list of patients on alert contains:

- Patient's full name,
- Patient ID,
- Latest assessment date: last date of the "Estimated GFR" stage entered during creation of a Predigraft report for this patient,
- Patient transplant date,
- Date of creation of the patient record.

You can click on one of the lines in the list of patients on alert to access the corresponding patient record.

16.5. Managing an alert

If a patient is on alert, the alerts are visible from the patient record.



Each alert contains:

- The date of creation of the alert,
- Details of the alert,
- A "Mark as read" button.

Mark as read

If you click on "Mark as read", this action is recorded in the database and means that you are aware of the alert. The button is changed to "Read on <date and time> by <user>" and this message is visible to all team members.

An alert marked as read is moved to the alert history page, accessible through the "Alert History" button on the patient page.

Alert History

The Alert History page lists a patient's alerts, displaying the most recent first. The history page lists read alerts (gray) and unread alerts (red). You can read an alert from this page.



16.6. Daily notification of your patients' activity

If you are a member of a team, you will receive a daily email about the Predigraft activity of your patients in the "My Patients" list. This email contains the following information:

- The number of your patients in the "My Patients" list who have a weight or blood pressure alert,
- The number of documents imported by your patients, present in the "My

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- patients" list, the previous day,
- The number of unread conversations to date with your patients present in the "My Patients" list,
- The number of new biopsy reports available.

Note: The clinical and biological data as well as the documents are not contained in the email.

If you are the owner of a team, you will receive a daily email about the Predigraft activity of all the patients in your department. This email contains the following information:

- The number of your patients in the "My Patients" list who have an alert on their weight or blood pressure,
- The number of patients not in the "My Patients" list of any member of your team who have alerts on their weight and blood pressure,
- The number of documents imported by your patients, present in the "My Patients" list, the previous day,
- The number of documents imported by patients not in the "My Patients" list of any of your team members,
- The number of unread conversations to date with your patients in the "My Patients" list,
- The number of unread conversations to date with patients not in any team member's "My Patients" list,
- The number of new biopsy reports available.

Note: Clinical and biological data and documents are not contained in the email.

17. Patient application

From the patient application, the patient can send you clinical and biological data:

- Weight,
- Blood pressure,
- Biological analysis report.

You can directly consult the data sent by the patient in his corresponding patient record.

18. Support/Maintenance

For any questions, requests, or reports of malfunction, please send an email to support@cibiltech.com

MATERIOVIGILANCE: Any incident or risk of serious incident (defined according to article L5212-2 of the Public Health Code) detected during the use of the medical device Predigraft must be reported to the manufacturer at the following address: contact@cibiltech.com

You must report any event to the competent authority of the Member State in which you are established: https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_vigilance_contact_points.pdf

19. Personal data

For any questions, requests or statements regarding your personal data, please refer to Cibiltech's Privacy Policy, available online on the company's website: www.cibiltech.com.

20. Appendix

20.1. Input Parameters

1. Transplant and evaluation date

The transplant date must be filled in with the day, month, and year.

The evaluation date is the date on which the creatinine measurement was performed. This date may be different from the date of the medical appointment. This date is used as a reference for all other measurements taken. It must be completed with the day, month, and year.

2. Estimated glomerular filtration rate (eGFR)

Glomerular filtration rate (GFR) is the primary measure of kidney function. It can be measured or estimated from validated formulas that have been published in scientific journals. The equation that was used to develop and validate the iBox is the one used in the Modification of Diet in Renal Disease (MDRD) study:

Estimated GFR (mL/min/1.73 m²) = $186 \times (\text{Scr}/88.4)^{-1.154} \times (\text{Age})^{-0.203} \times (0.742 \text{ if female})$ (International Unit)

3. Proteinuria

Proteinuria is a marker of kidney damage. It can be tested with a urine test strip. If positive, it is confirmed and quantified on a 24-hour urine collection (result in mg/24h), or when 24-hour urine collection is not possible, on a urine sample taken at any time of day and by the proteinuria/creatinuria ratio (result in mg/g or mg/mmol).

Proteinuria is measured on the same day as creatinine. A delay of up to 15 days between the measurement of creatinine and the estimation or measurement of proteinuria is tolerated.

4. anti-HLA donor specific antibodies

The presence of donor-specific anti-HLA antibodies (DSA) is assessed regularly after a kidney transplant. The measurement is carried out by solid phase analysis. The current preferred method is flow cytometry using fluorescent microbeads. The result is provided by the HLA laboratory. It can be qualitative (positive or negative) or quantitative. The mean value of the fluorescence intensity (MFI) of the immunodominant DSA (i.e. DSA with the highest MFI) should be reported. The date of the DSA test should not be more than 2 months from the evaluation date.

5. Histology

A pathology report is provided after a kidney transplant biopsy. This report provides a histological description with a diagnostic result as well as a semi-quantitative description of the basic histological lesions according to the Banff classification system. The clinician has the option to enter the reported diagnoses or the Banff histological scores. The date of biopsy should not exceed 2 months from the date of assessment.

20.2 Appendix 2: Calculation of alerts

1) Blood pressure

The software calculates blood pressure alerts from:

- the most recent date of blood pressure and corresponding systolic and diastolic pressure values
Systolic blood pressure is referred to as "SP" below. Diastolic blood pressure is referred to as "PAD".

Calculation of alerts:

IF PAS > blood_pressure high_systolic: "On the <DATE>, systolic blood pressure is above the target set for <NAME> FIRST NAME>: <PAS VALUE> mmHg. »

IF PAD > blood_pressure high_diastolic: "On the <DATE>, diastolic blood pressure is above the target set for <NAME> <FIRST NAME>: <PAD VALUE> mmHg. »

IF PAS >= 180 OR PAD >= 110: "On <DATE>, a grade 3 blood pressure was observed for <NAME> <FIRST NAME> (<PAS VALUE> / <PAD VALUE> mmHg)".

2) Weight

The software calculates Weight alerts from:

- the most recent date of weight and corresponding value
- the previous weight date and the corresponding value

Calculation of alerts:

IF Weight_gain >= Weight_gain_kg:

"< RECENT DATE>: Since the last evaluation date (<PREVIOUS DATE>), a change in weight has been observed for <NAME> <FIRST NAME> (+ <DIFFERENCE BETWEEN WEIGHTS> kg)".

ELSE IF

Difference between dates is one month or less AND Weight loss >= Weight loss_percentage one_month_ago (5%)

OR

The difference between the dates corresponds to one month to six months AND Weight Loss >= Weight loss_percentage six_months_ago (10%):

"< RECENT DATE> : Since the last evaluation date (<PREVIOUS DATE>), weight loss has been observed in <NAME> <FIRST NAME> (- <DIFFERENCE BETWEEN WEIGHTS> kg)".

3) Immunosuppressive drugs

The software calculates immunosuppressive drug alerts on the first validation of data extracted from a biological report, if that report is the most recent analysis date and T₀ Tacrolimus, T₂ Ciclosporin, T₀ Everolimus, T₀ Sirolimus values

Calculation of alerts:

IF T₀ Tacrolimus < trough_levels low_tacrolimus OR > trough_levels high_tacrolimus: "<DATE>: The residual tacrolimus concentration is outside the target defined for <NAME> <FIRST NAME> (T0: <VALUE> ng/mL).

IF T₂ Cyclosporine < trough_levels low_cyclosporine OR > trough_levels high_cyclosporine: "<DATE> : The concentration of cyclosporine 2 hours after dosing (T2) is outside the target defined for <NAME> <FIRST NAME> (C2: <VALUE> ng/mL)."

IF T₀ Sirolimus < trough_levels low_everolimus OR > trough_levels high_everolimus: "<DATE>: The residual concentration of sirolimus is outside the target defined for <NAME> <FIRST NAME> (T0: <VALUE> ng/mL)."

IF T₀ Everolimus < trough_levels low_sirolimus OR > trough_levels high_sirolimus: "<DATE>: The residual concentration of everolimus is outside the target defined for <NAME> <FIRST NAME> (T0: <VALUE> ng/mL).

4) Kidney function

The software calculates blood biology data alerts on the first validation of data extracted from a biology report, if that report is the most recent analysis date:

- date of the biological analysis,
- Potassium value converted to mmol/L,
- Hemoglobin value converted to g/dL,
- HbA1c (Glycated Hemoglobin) value converted to %,
- Platelet count value converted to /mm³,
- Neutrophil count value converted to /mm³,
- Troponin value converted to µg/l,
- INR value.

Calculation of alerts :

IF Potassium < bio__potassium__low__mmol_l OR > bio__potassium__high__mmol_l:
"<DATE>: Potassium is below/above the defined threshold: <VALUE> mmol/L."

IF Hemoglobin < bio__hemoglobin__low__g_dl OR > bio__hemoglobin__high__g_dl:
"<DATE>: Hemoglobin is below/above the defined threshold <VALUE> g/dL."

IF HbA1c < bio__hab1c__low__percentage OR > bio__hab1c__high__percentage:
"<DATE>: Glycated hemoglobin is below/above the defined threshold: <VALUE> %."

IF Platelets < bio__platelets__low__per_mm3 OR > bio__platelets__high__per_mm3:
"<DATE>: Platelets are below/above the defined threshold: <VALUE> /mm³."

IF Neutrophils < bio__neutropenia__low__per_mm3:
"<DATE>: Neutropenia was detected: <VALUE>/mm³."

IF Troponin > bio__troponin__high__ug_l:
"<DATE>: Troponin is above the defined threshold (<VALUE> µg/L)."

IF INR < bio__inr__low OR > bio__inr__high:
"<DATE>: INR is below/above the defined threshold <VALUE>."

5) Kidney function

The software calculates renal function alerts from two Predigraft reports:

- Orders the Predigraft reports by date of assessment (date of step 2) Estimated GFR),
- Selects the most recent report: "current report,
- Selects the previous report: "previous report.

The software selects in both reports: date of estimated GFR, GFR value, creatinine value if informed, proteinuria date, proteinuria value

Calculation of alerts:

IF the GFR value of the current report is reduced by "kidney_function__egfr_reduction" or more, compared to the GFR value of the previous report:

"Kidney function has decreased (decrease in estimated GFR) between <PREVIOUS REPORT DATE> and <CURRENT REPORT DATE>"

IF the serum creatinine value of the current report is increased by "kidney_function__serum_creatinine_increase" or more, compared to the serum creatinine value of the previous report:

"Kidney function decreased (serum creatinine decreased) between <PREVIOUS REPORT DATE> and <CURRENT REPORT DATE>."

IF proteinuria value was 0 in the previous report and is greater than 0 in the current report:

"Kidney function decreased (de novo proteinuria) between <PREVIOUS REPORT DATE> and <CURRENT REPORT DATE>."

6) Probability of renal graft survival.

The software calculates renal function alerts from two Predigraft reports:

- Orders the Predigraft reports by date of assessment (date of step 2) Estimated GFR),
- Selects the most recent report: "current report,
- Selects the previous report: "previous report.

Software selects from both reports: projected survival probabilities at 3 years, 5 years, 7 years.

Calculation of alerts:

IF probability of survival at 3 years of the current report < probability of survival at 3 years of the previous report with a precision of survival_probability__3y_reduction (1%)

OR

5-year survival probability of the current report < 5-year survival probability of the previous report with a precision of survival_probability__5y_reduction (1%)

OR

7-year survival probability of current report < 7-year survival probability of previous report with a precision of survival_probability__7y_reduction (1%) :

"The probability of renal graft survival decreased between <PREVIOUS REPORT DATE> and <CURRENT REPORT DATE>."

20.3 Appendix 3: Biological Table Reference Units

Values stored in Predigraft but not displayed in the biological table are shown in italics.

“Blood” part

- Glycated hemoglobin: %.
- Glucose: mmol/L
- Sodium: mmol/L
- Potassium: mmol/L
- Total CO₂: mmol/L
- Protein: g/L
- Urea: mmol/L
- Creatinine: μmol/L
- eGFR: mL/min/1.73m²
- Calcium: mmol/L
- Phosphorus: mmol/L
- Magnesium: mmol/L
- Uric acid: μmol/L
- Total Bilirubin: μmol/L
- Conjugated Bilirubin: μmol/L
- ALT: IU/L
- AST: IU/L
- Alkaline phosphatase: IU/L
- Gamma GT: IU/L
- LDH: IU/L
- CPK: IU/L
- Amylase: IU/L
- Lipase: IU/L
- Total cholesterol: mmol/L
- HDL total cholesterol: mmol/L
- LDL cholesterol: mmol/L
- Triglycerides: mmol/L
- Troponin: ng/L
- Haptoglobin: g/L
- Ferritin: μg/L
- Saturated transferrin coefficient: %.
- PTH: ng/L
- 25-hydroxyvitamin D: ng/mL
- Di-hydroxyvitamin D: pg/mL
- Patient prothrombin time: seconds
- Prothrombin time control: seconds
- PT: %.
- INR (ratio)
- APTT ratio
- Patient aPTT: seconds
- Control aPTT: seconds
- Fibrinogen activity: g/L
- Anti-Xa: Xa/mL
- CRP: mg/L
- AB antibody assay: titre
- Hematies: 10¹²/L
- Hematocrit: %.
- Hemoglobin: g/dL



- VGM: fL
- Reticulocytes: 109/L
- Schizocytes : %
- Leukocytes: 109/L
- Neutrophils: 109/L
- Eosinophilic Polynuclei: 109/L
- Basophilic Polynuclear Cells: 109/L
- Lymphocytes: 109/L
- Monocytes: 109/L
- Platelets: 109/L
- BK: log copies/mL
- CMV: log copies/mL
- HIV: log copies/mL
- HBV: log copies/mL
- HCV: log copies/mL
- Ciclosporin T0: ng/mL
- Ciclosporin T2: ng/mL
- Tacrolimus T0: ng/mL
- Sirolimus T0: ng/mL
- Everolimus T0: ng/mL
- PSA : ng/mL

“Urine” part

- Urine volume: L/24h
- Urine protein: g/L
- Protein-creatinine ratio: g/g
- Urea: mmol/L
- Urine Creatinine: mmol/L
- Urine Sodium: mmol/L
- Urine potassium: mmol/L
- Urinary red blood cells: /mm³
- Urinary leukocytes: /mm³
- Microbiology (text)