

## Service specification and requirements document

Changes to the
Laboratory Information Management System
(LIMS)
to support

# PATIENT TEST RESULTS DATA PROTECTION AND ACCESS CONTROLS FOR THE PURPOSE OF HEALTHCARE

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## 1.BACKGROUND AND RATIONALE FOR THE PROJECT

### 1.1. Purpose: the patient's test results

The patient's test results (hereinafter referred to as PPS), which are part of the national summary care record (hereinafter referred to as KJ), will provide healthcare professionals with secure access to all types of laboratory and radiology results, regardless of who the test/investigation was requested by and where the test/investigation was carried out.

Healthcare professionals will have access to test results through the dedicated EPJ or by looking the results up in KJ. Residents will be notified when new test results are available and will have access to their own test results via Helsenorge.

A trial of the PPS technology started in October 2022 and the regulations are expected to enter into force from the start of 2025 for the purpose of healthcare.

**NOTE:** This document refers to both test results and diagnostic reports as part of PPS and, even though a diagnostic report will include multiple test results, the document covers the full diagnostic report when describing access restrictions at the time of submitting the request.

NOTE: A separate document will be drawn up for the service specification and requirements document concerning the radiological information system (RIS) and will include details relating to changing needs in radiology activities.

For further information, please see Appendix 1 The patient's test results and purpose healthcare.

### 1.2. Launch of purpose healthcare

All diagnostic reports shall initially be issued from LIMS to the PPS when the regulations enter into force. The requestor must be familiar with whether or not the purpose of a referral is healthcare-related or whether the patient has opted out of test results associated with a single referral being stored in PPS and communicate this accordingly to LIMS.



### 1.3. Launch of purpose healthcare vs long-term target situation

During the initial launch of purpose healthcare, hereinafter referred to as **MVP1**, the focus will be on submitting all diagnostic reports to PPS, provided that the requestor has provided adequate information in the referral for LIMS to submit the diagnostic report(s) to PPS.

PPS will gradually be expanded from an MVP1 with largely external, electronic requests/referrals to include requests/referrals submitted on paper, local requests/referrals at each LIMS and from all health trusts in line with more stakeholders being ready for automated submissions using a purpose of healthcare.

### 1.3.1. MVP1 - initial delivery of purpose of healthcare for LIMS

For LIMS, MVP1 is about being able to receive referrals from external requestors and forward such information to diagnostic reports submitted to the requestor and PPS, see description in the requirement specification below.

Diagnostic reports shall be in accordance with "Result reporting in medical services<sup>1</sup>, in which key details relating to PPS are described in "Use of XML test report v1.4 in PPS - HITS 1249<sup>2</sup>

Residents will be able to view their test results on Helsenorge, either without any form of delay or after 14 working days for some specialisms. For medical genetics, it can take up to three months before residents get access to their own test results, see preliminary principles relating to deferred access for residents on Helsenorge, see Appendix 12<sup>3</sup>. Healthcare professionals will be able to change such automatic deferrals.

For information, external requestors and their referral solutions must similarly be able to specify the correct purpose of the request and whether the patient has opted out of the retention of test results from the request concerned; this is already part of MVP1.

### 1.3.2. Long-term target for PPS

This document describes the requirements for deliveries from LIMS for an MVP1 delivery, but we will also describe the long-term target for PPS with a view to national

 $<sup>^1\,</sup>https://www.ehelse.no/standardisering/standarder/svarrapportering-av-medisinske-tjenester-v1.4$ 

<sup>&</sup>lt;sup>2</sup>https://www.nhn.no/tjenester/pasientens-provesvar/teknisk-beskrivelse-svarmeldinger

<sup>&</sup>lt;sup>3</sup> deferred



implementation. Nevertheless, the target situation is limited to continued submission of test results as diagnostic reports, as is the case today.

LIMS suppliers are free to decide whether it would be sensible to implement support for future changes in needs at this stage.

Prior to the national implementation, all public and private LAB/RAD need to submit all results reports for the purpose of healthcare to PPS and all diagnostic reports not for the purpose of healthcare must be withheld.

All healthcare professionals who initiate a referral process must be familiar with whether or not the purpose is healthcare. LIMS shall ensure that such information can be recorded by healthcare professionals. If the purpose is not healthcare, the diagnostic report must not be submitted to PPS.

The referring healthcare professional who has entered into dialogue with the patient must be able to assist the patient in preventing diagnostic reports from being stored in PPS (reservation), prevent sharing of test results with other healthcare professionals (blocking) or protect the patient from sharing test results based on their own assessments. The same will apply to whether or not it is advisable to present test results to residents as patients on Helsenorge or not (denial). LIMS shall enable healthcare professionals to register such access restrictions.

If there are local access restrictions for a patient at the health trust where LIMS operates, both healthcare professionals and residents should be confident that similar restrictions will also apply to test results submitted to PPS. If the health trust EPJ system does not already communicate such information to PPS, LIMS needs to ensure that such access restrictions are automatically communicated to PPS or that referring healthcare professionals can manually record local access restrictions and that these are then communicated to PPS.

Access restrictions are communicated from LIMS to PPS using an API integration with data protection and access control (PTS-API), initially based on machine-to-machine but when more suppliers have implemented support for HelseID logins in their own EPJs, the API integration requirement will be HelseID user login (using SSO) in order to ensure better authentication and authorisation; see ongoing work in patient record documents regarding certificates from healthcare professionals <sup>4</sup>.

Residents will be able to view most test results without deferred access in Helsenorge.

<sup>&</sup>lt;sup>4</sup> https://utviklerportal.nhn.no/informasjonstjenester/pasientens-journaldokumenter-i-kjernejournal/



### 1.4. Abbreviations

The following abbreviations are used throughout this document.

Abbreviation	Explanation
PPS	Patient test results
KJ	National summary care record
EPJ	Electronic Patient Journal (also known as EHR system)
MVP	Minimum Viable Product
LIMS	Laboratory Information Management System



### 2. FUNCTIONAL REQUIREMENTS for LIMS

When the regulations enter into force, all results reports for the purpose of healthcare will be submitted to PPS. This will require changes in LIMS and each requirement has been assigned a priority and **MVP1** is a minimum solution that must be fully tested in 2024.

A more detailed description of each requirement can be found in the following chapter.

Chapter	Brief description of requirements for LIMS	PRIORITY
3.1.1	LIMS shall submit diagnostic reports in accordance with the	MVP1
	updated "Result reporting in medical services v1.4"5;	
3.1.2	LIMS shall be able to submit a copy of diagnostic reports to PPS.	MVP1
3.1.3	LIMS shall be able to receive code for the purpose with values from the encoder "Purpose of referral" (OID=8312) specified in the referral request and forward the same code value to associated diagnostic reports. Consideration must be given to the fact that the encoder may be updated to include new codes and disable existing codes.	MVP1
3.1.4	and disable existing codes.  LIMS must be able to receive code for opting out with a value from the encoder "Reservation against registration" (OID=3108) in the referral request and forward the same code value to associated diagnostic reports. Consideration must be given to the fact that the encoder may be updated to include new codes and disable existing codes.	MVP1
3.2.1	LIMS must be able to submit a <b>change request</b> for a previously submitted diagnostic report	MVP1
3.2.1.1	LIMS must be able to submit a <b>change</b> to a previously submitted diagnostic report in accordance with "Using diagnostic reports v1.4 in PPS – HITS 1249" <sup>6</sup>	MVP1
3.2.1.2	LIMS must be able to submit a <b>change</b> to entire diagnostic reports as a temporary solution for the cancellation of the entire diagnostic report in MVP1	MVP1
3.2.1.4	LIMS must be able to submit the correct <b>cancellation</b> of the entire diagnostic report during full operation	Full operation

<sup>&</sup>lt;sup>5</sup> https://www.ehelse.no/standardisering/standarder/svarrapportering-av-medisinske-tjenester-v1.4

<sup>&</sup>lt;sup>6</sup> https://www.nhn.no/tjenester/pasientens-provesvar/samarbeidsgrupper-nilar

3.3	Be able to receive <b>CopyDest</b> from the referral request and	Full
	submit a copy of the diagnostic report to the specified copy	operation
	recipient.	
3.4.	Maintain purpose and reservations specified in the	Full
	request/referral and prevent submission to PPS when	operation
	reservation has been set or when the purpose is not healthcare	
3.5.1	Common requirement to specify and change the purpose of the	Full
	request/referral in the LIMS GUI	operation
3.5.2	Ability to specify (and change) the purpose in the LIMS GUI	Full
	using values from the encoder "Purpose of request/referral"	operation
	(OID=8312) so that information about the PURPOSE is included	
	in the diagnostic report.	
3.5.3	Ability to specify (and change) the purpose in the LIMS GUI	Full
*)	using values from the encoder "Purpose of request/referral"	operation
	(OID=8312) in Helsehjelp-API	
3.6.1	Common requirement to specify and change <b>Reservations</b> in the	Full
**)	LIMS GUI.	operation
3.6.2	Ability to specify (and change) reservations in the LIMS GUI	Full
**)	using values from the encoder "Reservation against registration"	operation
	(OID=3108) so that information about any reservations is	
	included in the diagnostic report.	
3.6.3	Ability to <b>specify (and change) reservation</b> in the LIMS GUI using	Full
*)	values from the encoder "Reservation against registration"	operation
**)	(OID=3108) in Helsehjelp-API	
3.7.1	Integration with data protection and access control, PTS-API,	OPTION
	from LIMS	Full
		operation
3.7.2	Ability to configure denial and deferred access in the LIMS GUI	OPTION
	using integration with API for data protection and access control	Full
	(PTS-API)	operation
3.7.3	Ability to configure blocking and protection in the LIMS GUI	OPTION
	using integration with the API for data protection and access	Full
	control (PTS-API)	operation
3.8	Adopt HelseID machine-to-machine (M2M) for integration with	Full
	Helsehjelp-API and PTS-API	operation
3.9	Forward test results requested by referring or attending	Full
	healthcare professionals from LIMS to PPS.	operation

Table 1 Overview of functional requirements and priorities

<sup>\*)</sup> See Chapter 3.4 concerning "Manufacturer who will not require Helsehjelp-API", i.e. where there is no need for integration with Helsehjelp-API and the "purpose" and reservations are managed using internal solutions within each LIMS.

## 3. GENERAL DESCRIPTION OF REQUIREMENTS AND SOLUTION

Requirements will include all LIMS that produce diagnostic reports that will be sent as copies to PPS, provided that the purpose and reservations are safeguarded.

Additionally, in the lead-up to the national implementation, healthcare professionals must be able to register any access restrictions in internal orders/requests in the associated GUI for each LIMS. These will usually be paper requests. Currently, there is no information about access restrictions included in paper requests and this will be a separate topic for further follow-up.

The background to the described needs is as follows:

- Comply with KJ regulations requirement to store test results with the purpose of healthcare
- Comply with residents' requests to opt out of test results being stored in PPS
- Comply with regulations relating to standards and national e-health solutions, as well as links between requests and associated diagnostic reports <sup>7</sup>
- Comply with Sections 5 and 3.4 of the Patient and User Rights Act relating to residents' access to their own data
- Comply with data protection and access control relating to residents' need to block access for healthcare professionals

### 3.1. Referral and diagnostic reporting

To ensure that information provided by the requestor/referrer in the referral request is taken into account in PPS, it is critical that the identification of both the referral request and the diagnostic report is unambiguous and in accordance with the standard for diagnostic reporting and referral.

This also applies to information included from the referral request, as well as the ability to submit a copy of the diagnostic report to the party listed as a copy recipient in the referral request.

<sup>7</sup> 

https://sarepta.helsedir.no/standard/Retningslinjer%20 for%20 bruk%20 av%20 rekvisisjon%20 og%20 svarrapport



### 3.1.1. Using diagnostic reports v.1.4 in LIMS – MVP1

As MVP1 relates to external requestors using their own or regional referral solutions (e.g. HP Link, Dips Interactor, Furst forum, etc.), the basis for diagnostic report v1.4 will be created in the referral request.

For further information about the IDs used in both referral requests and diagnostic reports, see Appendix 11 – "Link between referral and diagnostic report".

See also Technical specification of PPS at nhn.no<sup>8</sup>

#### REQUIREMENT to submit externally requested test results to PPS

- LIMS shall use the correct profile of Diagnostic report v1.4 <sup>9</sup>, regardless of the version of the referral request and this shall be in accordance with the standard for diagnostic reporting
- The referral ID, RekvisisjonsID (ServReport.ServReq.ID) constitutes information from external requestors in MVP1 and is a required field in both the referral request and diagnostic report and must always be set to "ZERO" in the diagnostic report if no ServReq.ID can be found.
  - 1. ServReq.ID shall not be empty or just <ld/>
  - 2. If a referral is split into multiple referrals, RekvisjonsID (ServReq.ID) must be retained for all new referrals for each service provider.
- The diagnostic report ID, SvarrapportID (ServReport.ServProvId) must be globally unique and the same SvarrapportID (ServReport.ServProvID) must be used for all change requests for the same referral and service provider.
  - An example of a globally unique ID is "Serial number + HER-ID for department X"
  - 2. The same original SvarrapportID must be used in the event of changes to the original test/investigation
  - 3. When dividing the original referral for multiple service providers, each referral shall be considered a single referral and each service provider shall have a unique SvarrapportID (ServReport.ServProvId).
- Result reports shall not include errors in the form validation or omitted content.
   test-xml can be uploaded for content and form validation.<sup>10</sup>
  - 1. Description of diagnostic report v1.4 in PPS HITS 1249
  - 2. Practical use of XML in healthcare requests<sup>11</sup>
  - 3. Fields should not be empty, e.g. ServReport.IssueDate
  - 4. All fields must contain the proper use of CS and CV with associated text, see Chapter 5.5 of the standard for diagnostic reporting.

<sup>&</sup>lt;sup>8</sup> https://www.nhn.no/tjenester/pasientens-provesvar

<sup>&</sup>lt;sup>9</sup> https://www.ehelse.no/standardisering/standarder/svarrapportering-av-medisinske-tjenester-v1.4

<sup>&</sup>lt;sup>10</sup> https://samsvar.nhn.no/validering/xml

<sup>&</sup>lt;sup>11</sup> Practical use of XML in healthcare requests - updated.pdf (ehelse.no)



- PPS will return Negative AppRec if the content of the diagnostic report is not in accordance with the standard for diagnostic reporting or references between content in the diagnostic report are not unambiguously described.
  - 1. Testing variations of XML must be performed by submitting test data to PPS during testing.
  - 2. Follow-up on any non-conformities in negative apprec must be ongoing.
- Proper use of diagnostic reporting is not limited to the examples above, which are included as examples only.

### 3.1.2. Submitting a copy of the diagnostic report to PPS – MVP1

All test results from external requestors must be submitted to PPS as part of MVP1. Information about PPS as a copy recipient can also be found in referral requests, but this is not a requirement for submitting copies from external requestors.

### REQUIREMENT to submit a copy of the diagnostic report to PPS

• LIMS shall be able to submit a copy of the diagnostic report to PPS when the requestor is external (e.g. if the referral originates from Dips Interactor, HP Link, etc.)

### 3.1.3. Forwarding PURPOSE from referral request to diagnostic report - MVP1

There are many information elements to forward from the referral request to the diagnostic report and these are described in the standard for diagnostic reporting. Here are some critical elements that MUST be in place for PPS.

### Requirement for LIMS to forward PURPOSE to diagnostic report

- LIMS shall be able to receive information about the PURPOSE specified in the referral (using values from the encoder "Purpose of referral" (OID=8312) and forward this purpose code to the diagnostic report (see appendix for examples)
  - 1. The encoder may change over time to include new codes and code texts and LIMS must support changes to the encoder.
  - 2. It must be easy for the LIMS administrator to include encoder changes.
- The requestor ID for the referral must be forwarded to the diagnostic report under ServReq.ID
- If the **Service Provider ID** for the referral (ServReq.ServProvId) is included in the referral request, this must be forwarded to ServReport.ServReq.IdByServProvider in the diagnostic report



 All fields that must be forwarded from the referral request to the diagnostic report are described in the standard for diagnostic reporting and the aforementioned points should be considered examples only.

### 3.1.4. Forwarding RESERVATION from referral to diagnostic report - MVP1

There are many information elements to forward from the referral request to the diagnostic report and these are described in the standard for diagnostic reporting. Here are some critical elements that MUST be in place for PPS.

### Requirement for LIMS to forward RESERVATION to the diagnostic report

- LIMS must be able to receive information about **RESERVATION** using values from the encoder "Reservation against registration" (OID=3108) in the referral and forward the code to the diagnostic report (see appendix for examples).
  - 1. The encoder may change over time to include new codes and code texts and LIMS must support changes to the encoder.
  - 2. It must be easy for the LIMS administrator to include encoder changes.
- The requestor ID for the referral must be forwarded to the diagnostic report under ServReq.ID
- If the **Service Provider ID** for the referral (ServReq.ServProvId) is included in the referral request, this must be forwarded to ServReport.ServReq.IdByServProvider in the diagnostic report
- All fields that must be forwarded from the referral request to the diagnostic report are described in the standard for diagnostic reporting and the aforementioned points should be considered examples only.

### Change to previously submitted diagnostic reports – MVP1

### 3.2.1. Change to a previously submitted diagnostic report – MVP1.

If parts of a previously submitted diagnostic report include errors or the diagnostic report is updated to include new test results, this must be communicated electronically as a change request.

If the entire content of a previously submitted diagnostic report is incorrect or the content otherwise needs to be removed as the basis for treatment for a patient, requestor and any

copy recipients, this must be communicated electronically as a cancellation request and the reason for cancellation must be specified. Information about the reason and the content in previously submitted diagnostic reports will remain accessible with LIMS for any subsequent follow-up.

For all changes, the status both at diagnostic report level (OID=7309 and OID=7306) and test/investigation level (OID=8270 and OID=8245) must be specified in the diagnostic report. A combination of these values will form the basis for the status displayed in the test results in e.g. the KJ portal, see explanation in Chapters 3.3 and 3.4 "Use of diagnostic report v1.4 in PPS – HITS 1249"12

All changes shall be in accordance with the "Use of standards Request for medical services and diagnostic reporting in medical services" <sup>13</sup>

In case of full operation and national adoption, the requirement will be to submit a cancellation request for the entire diagnostic report, for which the history shall remain available in LIMS.

#### LIMS requirements relating to changes to previously submitted diagnostic reports

- When submitting a change request, it is important to ensure that it is complete
- Diagnostic reports that are changed must include the same IDs as the original request in accordance with Diagnostic reporting in medical services v.1.4<sup>14</sup>

### 3.2.1.1. Change in parts of a diagnostic report - MVP1

A diagnostic report may include multiple test results or investigation results and the status at both diagnostic report level (OID=7309 and OID=7306) and test/investigation level (OID=8270 and OID=8245) must be specified in the event of changes. A combination of these values will form the basis for the status displayed in the test results in e.g. the KJ portal, see explanation in Chapters 3.3 and 3.4 "Use of diagnostic report v1.4 in PPS – HITS 1249"15

### LIMS requirements relating to changes to parts of a diagnostic report - MVP1

 The status code for changes at diagnostic report level shall be in accordance with "HITS 1249" (OID=7309 and OID=7306)

<sup>&</sup>lt;sup>12</sup> https://www.nhn.no/tjenester/pasientens-provesvar/samarbeidsgrupper-nilar

<sup>&</sup>lt;sup>13</sup> https://www.ehelse.no/standardisering/standarder/bruk-av-standardene-rekvirering-av-medisinske-tjenester-og-svarrapportering-av-medisinske-tjenester

<sup>&</sup>lt;sup>14</sup> https://www.ehelse.no/standardisering/standarder/svarrapportering-av-medisinske-tjenester-v1.4

<sup>&</sup>lt;sup>15</sup> https://www.nhn.no/tjenester/pasientens-provesvar/teknisk-beskrivelse-svarmeldinger



• The status codes for each test/investigation in the same diagnostic report shall be in accordance with "HITS 1249" (OID=8270 and OID=8245)

### 3.2.1.2. Change (cancellation) of the entire diagnostic report for MVP1

As a workaround for LIMS being unable to submit a cancellation request for the full diagnostic report correctly, MVP1 will allow for a change request to be submitted in which all test results/investigations are cancelled/deleted.

#### LIMS requirements relating to workaround for the cancellation of all test results - MVP1

- If the full diagnostic report needs to be cancelled and there is no solution in place to submit cancellations at diagnostic report level, MVP1 will allow for this to be solved by submitting a change request at diagnostic report level (M) in which all analyses/investigations are cancelled (C) or removed – subject to a requirement to include an explanatory text in the "Comment on the diagnostic report" attribute (ServReport.Comment), see Appendix 10 Examples of the cancellation of a diagnostic report.
- In the event of change requests, complete diagnostic reports must always be submitted in accordance with the "Use of standards Request for medical services and diagnostic reporting in medical services"
- Status codes for changing entire diagnostic reports or individual analyses/investigations in a single diagnostic report shall be in accordance with HITS 1249

### 3.2.1.3. Correct cancellation of entire diagnostic report - FULL OPERATION.

If the entire diagnostic report is to be cancelled or deleted, a cancellation request (C) must be submitted for the entire diagnostic report, with an explanation of the reason for the cancellation or deletion as a "comment on the diagnostic report (Comment)". This shall be the case regardless of what LIMS does with the diagnostic report, i.e. whether manual deletion or cancellation is required.

### Requirements for the proper use of cancellation of entire diagnostic reports in LIMS

 When the entire diagnostic report needs to be cancelled, a cancellation request (C) must be submitted for the entire diagnostic report in accordance with the standard



for diagnostic reporting, with a comment on the reason for the cancellation of the diagnostic report (ServReport.Comment).

- The use of status codes shall be in accordance with HITS 1249.
- When cancelling entire diagnostic reports, it is not necessary to include analyses/investigations; see Appendix 10 Examples of cancellation of entire diagnostic reports

## 3.3. Proper use of CopyDest from referral request - Full operation

In accordance with the royal decree, all test results from all enterprises should generally be submitted to PPS if the purpose is healthcare and the resident has not opted out of retention. During the early launch of purpose healthcare, there will be several issues with regard to what to submit or not and several solutions have therefore been established to ensure that test results that can be submitted are submitted and that only test results that will be retained in the solution are retained.

One of the solutions is to specify <u>PPS</u> as the copy recipient in the referral request, which must, according to the standard for diagnostic reporting, be interpreted in so far that a copy of the diagnostic report must be submitted to the specified recipient (not submitted as a copy of the referral).

It is important to ensure that this is not a requirement for submission to PPS and in the event of national implementation "all" test results must be submitted to PPS regardless of whether or not PPS has been specified in CopyDest.

### Requirements relating to the proper use of CopyDest in LIMS – Full operation

- LIMS should be able to receive a referral with PPS set as the recipient in CopyDest and submit a copy of the diagnostic report to CopyDest.
- However, LIMS must NOT submit a copy to PPS if:
  - 1. the referral includes RESERVATION and this has been set to "R"
  - 2. the referral includes a PURPOSE that is NOT HEALTHCARE
  - 3. Nevertheless, in the event that a copy is submitted erroneously, PPS will delete the diagnostic report before it is stored based on the same information relating to Reservation or Purpose in the diagnostic report.



### 3.4. Preventing submission to PPS – Full Operation

The KJ regulations do not provide for the retention of test results for purposes other than healthcare, such as test results for the purposes of control and sanctions, in PPS. Test results that residents have opted out of storing must also not be stored in the solution.

In an MVP1, the NHN will be able to delete test results that should not have been submitted to PPS on behalf of health trusts based on the information provided to NHN in Diagnostic Report v1.4 or Helsehjelp-API, but the aim is for LIMS to prevent such test results from being submitted.

### For manufacturers that will not require Helsehjelp-API

If a laboratory or radiology unit manages the submission to PPS only for the purpose of healthcare and the residents' right to reservation has been safeguarded by all requestors linked to the internal request solution, there will no requirement for the laboratory/radiology unit to use Helshjelp-API. Once the data controller has carried out a risk assessment on the solution, the laboratory/radiology unit can be omitted from checks against Helsehjelp-API when receiving diagnostic reports submitted to PPS in MVP1 and in full operation.

### Requirement for LIMS to withhold test results not to be submitted to PPS

- LIMS shall be able to withhold diagnostic reports for which <Reservation V="R"</li>
   DN="Reservation" S="2.16.578.1.12.4.1.1.3108" /> has been actively configured in the referral and/or diagnostic report.
  - 1. The same applies to LIMS/RIS that receive information about Reservation set by requestors in internal request solutions that do not require Helsehjelp-API.
- LIMS shall be able to withhold diagnostic reports **that are not HHJ** <TextCode V="HHJ" S="2.16.578.1.12.4.1.1.8312" DN="Helsehjelp" /> set in the referral and/or diagnostic report.
  - 1. The same applies to LIMS/RIS that receive information about purposes other than healthcare set by requestors in internal request solutions that do not require Helsehjelp-API.
- LIMS shall take into account the fact that encoding and associated code values will change over time, including the code values that will prevent submission to PPS.
- Until such diagnostic reports can be withheld by LIMS, NHN will be able to delete diagnostic reports that should not be retained and return a positive APPREC (as the request will not include errors or omissions indicating that a negative APPREC should be issued).

• If you need to know the reason why a submitted diagnostic report has not been retained, an enquiry can be raised with the NHN Customer Centre in accordance with the management routing (which is in development as of May 2024).

## 3.5. Specifying the purpose of the referral in LIMS GUI – Full operation

The KJ regulations do not provide for the retention of test results for purposes other than healthcare, such as test results for the purposes of control and sanctions, in PPS. For example, tests relating to blood donations, autopsies etc. also should not be covered by PPS.

The responsibility for determining whether the purpose is healthcare or not falls to the requestor, who needs to have solutions in place to specify this as early as possible in the referral process, where encoder OID=8312 and associated purpose codes with a description of each purpose code must be used. This will also apply to changes to configured purpose codes. The code values in the encoder may be changed as needed by the Norwegian Directorate of Health.

A referral may also be submitted on paper and when paper referrals include information about the PURPOSE of the referral, it must be possible to enter this information in LIMS.

LIMS suppliers must therefore implement support for requestors to be able to specify the purpose of the referral as a coded value in the **Referral request**<sup>16</sup> (see appendix for example referral requests) and/or the **Diagnostic Report** 

IF LIMS does not receive the PURPOSE as part of the referral request and/or it is not forwarded to the Diagnostics Report, the PURPOSE code must be submitted to the new NHN **Helsehjelp-API**<sup>17</sup> (M2M) in order to always specify the same purpose of the referral using the same code value and referral ID (ServReq.ID). This can alternatively be communicated by requestors via internal request solutions for manufacturers that do not require Helsehjelp-API, see Chapter 3.4.

In case of conflicting information about the purpose code for a referral ID in Helsehjelp-API and as forwarded from the referral request to the diagnostic report, the last purpose code received will be used.

<sup>&</sup>lt;sup>16</sup> https://sarepta.helsedir.no/standard/Rekvirering%20av%20medisinske%20tjenester/1.6

<sup>&</sup>lt;sup>17</sup> https://utviklerportal.nhn.no/



### 3.5.1. Common to the specification of PURPOSE from OID=8312 in LIMS GUI

Common REQUIREMENT to use OID=8312 to specify the purpose of the referral and identify the referral in the referral request and diagnostic report – OR using Helsehjelp-API

- The requestor must easily be able to see and select **purpose codes with associated descriptions** from OID=8312 for the requestor in the referral solution.
- The list from OID=8312 must be updated **dynamically**
- Settings must be configurable using **default values**, e.g. per user and/or organisation
- The referral ID (ServReq.ID) is the identifier that links the referral and the diagnostic report together and this MUST be **UUID** and available to the requestor in the event of any enquiries.
- If present, the service provider's referral identifier (ServReq.ServProvId) must be **globally unique** (this must be specified by the associated LIMS and not the referral solution) and must be available to the requestor in the event of any enquiries.
- Personnel without HPR numbers must be able to specify purpose codes on behalf of the requestor.

In the event of referrals with multiple purposes, separate referrals should be created with and without a purpose of healthcare. The purpose can be configured only for the entire referral, not for individual investigations in a referral.

### 3.5.2. Specifying and changing the code for PURPOSE in the diagnostic report from LIMS GUI

The Norwegian Directorate of Health has created encoder OID=8312 with associated purpose codes and this must be used as a CODED VALUE in the referral request. This has been described in the updated HIS 80821:2014 – Medical Services Referrals v1.6, Chapter 5.1.3, see also Appendix 9 for Purpose and Reservations in referrals and results

#### REQUIREMENT for purpose code in referral requests – diagnostic report

- Common requirements have been described above
- A purpose code from OID=8312 must always be included in the referral request and forwarded to the diagnostic report from LIMS
  - Alternatively, the same purpose code can be communicated in the internal request solution, see Chapter 3.4
- The requestor should be able to change the purpose code for a submitted referral request and submit the update as a change in the referral request (must be implemented by LAB/RAD if the test/investigation has not yet started) for the same referral ID.



### 3.5.3. Specifying and changing PURPOSE code in HELSEHJELP-API

Even though purpose codes must be specified in the referral request, it will take a long time before all LIMS have implemented support to add this to referral requests and/or forward purpose codes to diagnostic report(s), as well as establishing procedures to prevent the submission of "purposes other than healthcare" to PPS.

A new HELSEHJELP-API has therefore been established so that it can be specified directly when the purpose of a referral is healthcare. The HELSEHJELP-API does not require user login, but does require M2M and will only include information about the referral ID (UUID, specified in HIS 80821:2014 – Referral for Medical Services v1.6) and, if applicable, Lab ID (ServProvId) and associated purpose code OID=8312. Information about who has submitted information and when it was submitted must also be included. A description of the HELSEHJELP-API will be made available in the NHN Developer Portal in June 2024.

The HELSEHJELP-API will enable NHN to retain submitted diagnostic reports linked to the purpose of the referral only when the purpose has been specified as healthcare. Similarly, local ICT companies will be able to establish their own message brokers with integrations to the HELSEHJELP-API and thereby permit submission to PPS only when a purpose of healthcare has been specified. Regional ICT companies can alternatively query the HELSEHJELP-API to determine whether the test results should be submitted or not.

### REQUIREMENT to specify purpose code in HELSEHJELP-API for LIMS

This will apply to LIMS without solutions to specify purpose codes in referral requests and/or forward to diagnostic reports in cases where the manufacturer is exempt from using Helsehjelp-API (see Chapter 3.4)

The Helsehjelp-API will be used for all referral/request solutions to specify a single purpose code for a single referral as specified above.

- The integration has been established in accordance with the description of the Helsehjelp-API in the NHN Developer Portal <sup>18</sup>
  - o The referral ID must be included
  - o The service provider's identification of the referral must be included
  - The enterprise must be identified
  - o HelseID M2M
  - o etc
- Common requirements for the purpose code above
- The purpose code from OID=8312 must always be included in Helsehjelp-API for the referral.

<sup>18</sup> https://utviklerportal.nhn.no/



 Provide the requestor with the opportunity to change the purpose code for a submitted referral request and submit this update as a new purpose code to Helsehjelp-API based on the same referral ID (ServReq.Id).

### 3.6. Patients must be able to opt out of retention

Please see NB under the table for functional requirements in Chapter 2.

Currently, residents can opt out of retention in Helsenorge, where it is possible to opt out of the use of the KJ or all test results being retained in KJ. In such cases, all new or existing test results will be deleted by NHN.

However, residents also have the right to opt out of test results from the referral being stored in PPS. This must be specified by the requestor and it must be possible to specify reservation in the referral request.

A referral may also be submitted on paper and when paper referrals include information about the RESERVATION in the referral, it must be possible to enter this information in LIMS.

For information, diagnostic reports from LAB/RAD must include information about the specified code value for reservation in the referral request and referrals for which Reservation has been specified must not be submitted from LAB/RAD to PPS. Before all LAB/RAD have implemented support for this, NHN will, on behalf of each health trust, delete "erroneously submitted" diagnostic reports before these are stored in PPS.

LIMS suppliers must therefore implement support for requestors to be able to specify RESERVATION as a coded value in the **Referral request** (see appendix for example referral requests) and/or the **Diagnostics Report.** 

IF LIMS is not able to include RESERVATION in the referral request and/or forward to the Diagnostics Report, the RESERVATION code must be submitted to the new NHN **Helsehjelp-API** (M2M) so that the same Reservation code can always be submitted for the same referral ID (ServReq.ID) or communicated from requestors via internal request solutions for manufacturers not required to use Helsehjelp-API; see Chapter 3.4.



### 3.6.1. Common to the indication/change of reservation in LIMS GUI

REQUIREMENT to use OID=3108 to specify any reservation against the retention of test results associated with the referral and identification of the referral in both the referral request AND Helsehjelp-API

- The requestor must easily be able to view and select **code values for reservations with associated descriptions** in the referral solution.
- The list must be updated dynamically.
- Settings must be configurable using default values, e.g. per user and/or organisation.
- The referral ID (ServReq.ID) is the identifier that links the referral and the diagnostic report together and this MUST be **UUID** and available to the requestor in the event of any enquiries.
- The service provider's identification of the referral (ServReq.ServProvId) must be **globally unique** and available to the requestor in the event of any enquiries.
- Personnel without HPR numbers must be able to specify "reservation" on behalf of the requestor.

In the event of referrals with multiple purposes, separate referrals should be created with and without a purpose of healthcare.

### 3.6.2. Update referral request with code OID=3108

#### REQUIREMENT to specify reservation against retention in referral request

The use of Reservation (OID=3108) has already been described in the message standard for referrals and diagnostic reporting and must be implemented in referral solutions to specify if diagnostic reports associated with the referral should not be retained in PPS.

- The reservation code (OID=3108) must always be included in the referral request (and forwarded to the response report by LAB/RAD)
- The requestor should be able to change the reservation code for a submitted referral request and submit the update as a change in the referral request (must be implemented by LAB/RAD if the test/investigation has not yet started) for the same referral ID.
- Information about Reservation must be forwarded in the diagnostic report.

See also Appendix 9 for Purpose and reservation in referrals and diagnostics requests

### 3.6.3. Update Helsehjelp-API with code OID=3108

REQUIREMENT to support the configuration of "Reservation" in Helsehjelp-API for LIMS without a solution to specify Reservation code in referral requests and/or forward to diagnostic report



#### when not exempted from using the Helsehjelp-API (see Chapter 3.4)

- The integration has been established in accordance with the description of the Helsehjelp-API in the NHN Developer Portal
  - o The referral ID must be included
  - The service provider's identification of the referral must be included
  - The enterprise must be identified
  - o HelseID M2M
  - o etc
- The code from OID=3108 must always be transmitted to the new Helsehjelp-API for this referral
- Provide the requestor with the opportunity to change the reservation code for a submitted referral request and submit this update as a new reservation code to Helsehjelp-API based on the same referral ID (ServReq.Id).

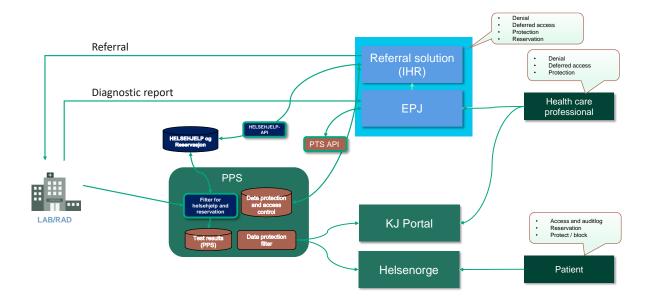


Figure 1 Simple solution diagram for LIMS

## 3.7. Data protection and access control – Option, full operation

This chapter looks at the need to configure or change access controls for <u>internal referrals</u> initiated at each health trust and not from external referrals for which the responsibility falls to the external requestor.



A need to specify/change access controls may arise in connection with:

- Refused or deferred access for patients to view their test results in Helsenorge
- Healthcare professionals being barred from viewing test results as requested by the patient
- Patient protected from test results being shared with other healthcare professionals

If the resident has permission to configure their own privacy settings in Helsenorge, these settings shall apply to all healthcare professionals for the health data for which restrictions have been set in national solutions. However, if there is already a **local barrier** configured for a patient in a health trust, this could be an access barrier for an entire department within the health trust, a given HPR number etc,. and could apply to some or all information contained in medical records. The scope of local barriers can also vary between health regions and within each region and each health trust.

In the lead-up to full production of PPS, such local barriers at each health trust must be communicated to Data protection and access controls, using the PTS-API as this will ensure compliance with the LIMS requirement for any known local barriers.

The internal requestor, or others who are aware of a need to configure access restrictions, may also look up the patient's data in the KJ Portal. Here, healthcare professionals will be able to specify/change privacy settings in KJ Portal's (temporary) access control solution or under the Test results tab in KJ Portal for test results already received.

Whether LIMS also needs to have a separate integration with PTS-API from the LIMS GUI must be clarified in each case, but this has still been described here as a requirement for LIMS that actually have a need to specify access restrictions in their own solution.

### 3.7.1. Requirement for integration with PTS API from LIMS GUI

If residents are unable to configure access restrictions in Helsenorge or if existing local barriers at the health trust are not communicated to PTS-API from EPJ, there could be a need to specify/change access controls when e.g. a patient is admitted to a hospital and referred for analyses or investigations the resident does not wish to share with other healthcare professionals. This could also include information that healthcare professionals wish to withhold from the patient.

The LIMS GUI for internal referrals must therefore be integrated with the API for data protection and access control (PTS-API) in order to deny or defer access for the patient in Helsenorge (OID=9603) and to bar or protect against sharing with healthcare professionals

(OID=9063 and OID=7608), cf. the definition of terms from the Norwegian Directorate of E-Health<sup>19</sup>.

### 3.7.2. Common to integrations with PTS-API in LIMS GUI

The LIMS referral solution must be integrated with the API for data protection and access control (PTS-API) in order to manage any privacy settings that the requestor wishes to configure/change at the time of submitting the referral.

**REQUIREMENT for integration with PTS-API to configure or change all types of access restrictions** based on code values from the "Codes for access restrictions in treatment-oriented health registers" encoder (OID=9603 and OID=7608)

- Integration with PTS API in accordance with the specification 20
- The requestor must easily be able to view and select **code values for denied/deferred access for residents with associated descriptions** (OID=9603) in the referral solution.
- Requestors must easily be able to view and select barriers/protection for healthcare professionals with associated descriptions and use values from the "Codes for access restrictions in treatment-oriented health registers" encoder (OID=9603) and "Scope of consent or reservation in Helsenorge" encoder (OID=7608) in the referral solution.
- Both lists must update dynamically.
- Access restrictions must be configurable using default values, e.g. per user and/or organisation.
- The referral ID (ServReq.ID) is the identifier that links the referral and the diagnostic report together and this MUST be **UUID** and available to the requestor in the event of any enquiries.
- When the service provider's identifier for the referral (ServReq.ServProvId) has been specified, it must be globally unique.
- If present, the service provider's referral identifier (ServReq.ServProvId) must be **globally unique** (this must be specified by the associated LIMS and not the referral solution) and must be available to the requestor in the event of any enquiries.
- Personnel without HPR numbers must be able to configure barriers or protection on behalf of the requestor.

 $<sup>\</sup>frac{19}{https://www.nhn.no/tjenester/pasientens-provesvar/nilar-personvern-og-informasjonssikkerhet/Reservasjon\%20-\%20ordforklaring$ 

<sup>&</sup>lt;sup>20</sup> https://utviklerportal.nhn.no/informasjonstjenester/pts/



### 3.7.3. Configuring/changing denied/deferred access using code values from OID=9603

Information disclosed through laboratory and radiology results constitutes a new category of health information to what is currently available to the patient via helsenorge.no. The legislator's intention is for test results to be quickly available and for most test results to be available immediately, including for patients. In some cases, laboratory and radiology results may include information that may have major consequences for the patient.

Some test results and radiology descriptions should therefore not be disclosed to the patient before the requestor or attending physician has assessed the test results and considered whether the patient should be contacted before the results are disclosed to the patient.

The Norwegian Directorate of Health therefore has a responsibility to draw up guidelines on what should be shown with deferred access. and not to the resident- These guidelines will describe the diagnostic reports associated with each specialism that will be disclosed to residents without any deferral in Helsenorge and which specialisms will defer access for a given number of days. It is also assumed that differentiation will be made in relation to the number of days, e.g. 14 days for one specialism and 90 days for others. PPS will automatically disclose test results to residents based on these configurations after the specified number of days has elapsed. The number of days and associated specialisms will be changed by the Norwegian Directorate of Health as needed.

Requestors will also be able to change the number of days that will elapse before residents get access via Helsenorge and will also be able to deny access for residents in general based on the needs described in the Norwegian Patient and User Rights Act (e.g. danger to life and health etc.)

Settings configured by the requestor will apply to the entire referral, including all associated diagnostic reports, change requests etc. and the strictest rule shall apply in case of doubt.

In the event of any changes to access restrictions (denied and deferred access) configured in PTS as a change to the referral (ServReq.ID) or changes made by other healthcare professionals after the diagnostic report was received (ServReport.ServProvId), the latest information relating to access restrictions will apply to the referral or diagnostic report in question.

REQUIREMENT for integration with PTS-API for denied and deferred access for residents



- If no access restrictions are configured at the time of referral, the resident will be able to view their test results in Helsenorge based on the number of days specified in "Guidelines for deferred access for residents".
- At the time of referral, requestors must be able to configure code values to provide
  access for residents without deferral, code values to further defer the patient's
  access or code values to deny access in general until a new code that does not
  entail denial is configured.
- Provide the requestor with the opportunity to change access restriction codes for a submitted referral request and submit this update as a new access restriction code to PTS-API based on the same referral ID (ServReq.Id).

### 3.7.4. Barrier with code OID=7608 and Protection OID=9603

The requestor should be able to assist residents in configuring barriers to disclosure to other healthcare professionals by specifying the appropriate code from OID=7608 at the time of referral. Information about barriers or blocking will apply to all test results or all test results from a given period of time and the barrier shall apply to all healthcare professionals and can be revoked subject to consent or in an emergency situation, whereas blocking will always apply but only to named healthcare professionals.

Both barriers and blocking must be updated as part of the resident's privacy settings in Helsenorge and residents can change these settings as needed.

Requestors who know patients well can also protect patients by configuring a barrier or block against the disclosure of test results with other healthcare professionals if they believe the patient would object to such disclosure. Residents can ask healthcare professionals to change configured protection but will not be able to change this themselves.

### REQUIREMENT for integration with PTS-API for barriers and blocking

- Residents must configure access restrictions themselves in Helsenorge and, if no
  access restrictions are specified at the time of referral, test results will be disclosed
  to attending healthcare professionals based on the resident's own settings.
- At the time of referral, requestors should be able to assist residents by specifying the code value for **barriers or blocks** from OID=7608 in PTS-API and these can be modified by the resident in Helsenorge as needed<sup>21</sup>.

<sup>&</sup>lt;sup>21</sup> https://www.nhn.no/tjenester/pasientens-provesvar/nilar-personvern-og-informasjonssikkerhet/Personvernsinnstillinger\_innbygger

- A barrier and block will apply to all diagnostic reports at all times or for a given time period.
- A block must also include the HPR number for blocked healthcare professionals<sup>22</sup>
- If the HPR number is unknown, please contact Helsenorge for support by calling +47 23 32 70 00 and stating the name of the healthcare professional in question.
- At the time of referral, requestors should be able to protect the patient by entering
  the code value "NORS" from OID=9603 in the PTS-API. This can only be changed by
  healthcare professionals. Protection will not synchronise with PVK settings
  configured in Helsenorge and can therefore also be used to communicate local
  barriers known to the requestor within their own unit:
  - Protection can be applied to a single referral/diagnostic report, all diagnostic reports at all times or all diagnostic reports for a given period of time.
  - Protection can be applied to all healthcare professionals or selected healthcare professionals
- Provide the requestor with the opportunity to change barrier/protection codes for a submitted referral request and submit this update as a new barrier/protection code to PTS-API based on the same referral ID (ServReq.Id).

### 3.8. Adopting trust frameworks, HelselD and DPOP

Even though both Helsehjelp-API and PTS-API currently allow for the use of HelseID M2M, the requirements will be tightened to require user login via HelseID. The aim of the trust framework is for the development and disclosure of health data to be faster, more accurate, more unified and with higher levels of information security, data protection and focus on patient safety. Annual revisions to the trust framework must be expected.

Suppliers must start the process of implementing support for adopting the trust framework as a generic solution for new APIs from NHN as described in github.

- NHN has described the information elements required for each API and which can be submitted without the information being used for logging, authentication and/or authorisation in the NHN Developer Portal
- All information elements linked to the KJ regulations (test results, critical information etc.) are subject to patient consent, alternatively with implicit consent

<sup>&</sup>lt;sup>22</sup> https://www.nhn.no/tjenester/pasientens-provesvar/nilar-personvern-og-informasjonssikkerhet/innsynsrett-for-innbygger



for general practitioners etc. See description "access-basis" under "Authorization" for Prøvesvar-API on the NHN Developer Portal.

When EPJ suppliers establish <u>HelselD login</u> in their own EPJ – LIMS must also be able to support SSO in order to write and/or read from the PTS-API using HelselD user logins.

The referral provider must establish support for <u>DPOP</u>, with the gradual introduction of DPOP requirements for each service. For Helsehjelp-API and PTS-API, this will not be a requirement in 2024 but may become a requirement in 2025.

#### **Trust framework – Certificate**

One of the goals for 2024 is to apply the trust framework for all services included in the Digital Interaction initiative. An agreement has been reached as to how this will be resolved in the sector and this is currently being tested in Patient Health Records as the first service <sup>23</sup>.

The goal is for suppliers to carry out a 'single' job in order to establish the solution and for the principles to be reused for all services that share health data going forward. The implementation should take into account the fact that the services have somewhat different characteristics and regulations and this should be managed by developing logic to control the attributes applicable to the Certificate associated with each service using parameters.

### REQUIREMENT to use HelseID M2M to adopt the API – Full operation

 Suppliers must implement the use of HelseID M2M as described in the NHN Developer Portal for each of the PTS-API and Helsehjelp-API services.

### 3.9. Ability to forward test results upon request

LIMS must be able to forward diagnostic reports upon request from the requestor as initiated by the patient. Examples of this include patients in a coma with a local care number and many important tests/investigations having been conducted without the information being communicated to the patient's KJ.

The patient can then contact the attending healthcare professionals or the requestor, who will in turn contact the LAB/RAD to request that all test results relating to the event be forwarded.

<sup>&</sup>lt;sup>23</sup> Patient Health Records in the KJ - NHN Developer Portal



Each LIMS will determine whether the diagnostic report also needs to be resubmitted to everyone who has previously received the diagnostic report or whether LIMS will develop a better solution to forward diagnostic reports to specific recipients only.

#### **REQUIREMENT to forward diagnostic reports from LIMS to PPS:**

• Upon request, it must be possible to forward a copy of the diagnostic report to PPS

### 3.10. Proposed solution for access restrictions

This example is intended only as a proposal and does not provide any guidance as to how IHR suppliers should make choices as simple as possible for their requestors. Even though the requestor is responsible for communicating the purpose, reservation status and access restrictions, the aim must be to ensure that requestors experience changes to be minimally disruptive elements

The interface for access restrictions is closely linked to the specification of the PURPOSE of the referral, as well as whether the resident wishes to exercise their right of reservation in relation to retention. It is also linked to the patient or healthcare professional's need to block disclosure to other healthcare professionals or the healthcare professional's need to deny or defer the patient's access to their own test results in Helsenorge.

Default values can also be used so that healthcare professionals' work processes change only if it is necessary to change settings.

The example below shows a proposed compilation of default values, but this is an example only and should not be interpreted as guidance for the solution:

- The test results from this referral have a purpose of healthcare
  - a. (Purpose code "HHJ" Healthcare (OID=8312) entered in referral request)
  - b. (Purpose code "HHJ" Healthcare (OID=8312) transmitted M2M using the Helsehjelp-API integration machine-readable, for the same referral ID)
- The patient has not exercised their right of reservation against the test results being retained in PPS
  - a. (Reservation OID=3108 set as the default for anything other than "R" in the referral request)
  - b. (Reservation OID=3108 set as the default for anything other than "R" in Helsehjelp-API, transmitted M2M, machine-readable, for the same referral ID)
- The test results from this referral will be submitted as a copy to PPS in KJ (\*\*\*)
  - a. (IF "HHJ" and "NOT "R" enter PPS as CopyDest in the referral request)
  - b. This could, for example, be standardised using on/off for each unit/LIMS, etc.)
- There is no need to restrict access for the patient beyond the recommended rules for deferred access a. (PTS-API for denied and deferred access for residents is "asleep")
- There is no need to restrict disclosure of test results to other healthcare professionals from this referral
  - a. (PTS-API for barring or protection is "asleep")



### Appendix 1 PPS and purpose Healthcare

The Norwegian Ministry of Health and Social Care has adopted amendments to Section 4 of the KJ regulations and the regulations now provide for the retention of laboratory and radiology results (test results).

The regulatory changes are, among other things, a follow-up to the amendments to the Norwegian Health Record Act of 2 June 2023, cf. Prop.91 L (2022-2023) Changes to the Norwegian Health Record Act, etc. (patient test results in KJ) and Innst.406 L (2022-2023) The legislative decision amended the regulatory basis linked to the KJ in Section 13 of the Norwegian Health Record Act. The amendment allows for more types of information to be included in KJ, including test results.

The KJ regulations state that the purpose of the information must be healthcare, which means that the requestor must be able to specify the purpose of a referral. The resident must also be able to exercise their right of reservation (opt out) against test results from the specific referral being stored in PPS (this is in addition to the reservation options available in Helsenorge, where residents can opt-out of having a KJ or the entire test results service).

In both of these cases, it must be possible to specify both purpose and reservation choice in the referral request and in the new API (Helsehjelp-API) to ensure that only relevant test results are submitted and/or retained in PPS.

Patient rights must be safeguarded in accordance with the settings configured by the resident or healthcare professionals.

In order to configure access restrictions before a patient sample is taken for testing at a laboratory or a radiology referral is made, it is necessary to ensure that the referral solution is integrated with the data protection and access control API (PTS-API).

With such an integration, suppliers will be able to contribute to improved and more secure disclosure of health data between healthcare actors, while also safeguarding residents' access rights when it comes to accessing their own data in Helsenorge. PPS is the initial user of PTS-API and the aim is for this to also be adopted for use in other national e-health solutions.

See further information about PPS at NHN.no<sup>24</sup>

<sup>&</sup>lt;sup>24</sup> https://www.nhn.no/tjenester/pasientens-provesvar



## Appendix 2 Description of Data Protection and Access Control (PTS)

### **Description of Data Protection and Access Control**

The specification of requirements and solutions below uses terms relating to data protection and access control as defined by Hdir (formerly the Norwegian Directorate of E-Health):

The following terms are defined:

- Access restriction
- Denial
- Protection
- Barring
- Deferred access for residents
- Reservation
- Privacy settings

Patient test results must comply with statutory requirements relating to data protection and patient safety, cf. the Norwegian Patient and User Rights Act and the Norwegian Personal Data Act.

### a) Deferred access for patients in Helsenorge

Information must be shared with patients in a considerate manner and healthcare professionals must, to the extent possible, ensure that the recipient has understood the content and the significance of the information. Furthermore, it can be inferred from the requirement set out in Section 4 of the Healthcare Professionals Act that healthcare professionals must perform their duties in accordance with requirements relating to professional integrity and compassionate care and that health data must be communicated to patients in a considerate manner.

Deferred access to PPS refers to a machine-readable mechanism that ensures that test results for certain specialisms are made available to residents after a given period of time (e.g. 14 calendar days) after becoming available to healthcare professionals. The purpose is to allow for treatment providers to make contact and provide guidance in line with professional integrity and compassionate health care before the resident reads the test results. Other test results from other specialisms can be made available without deferral. The Norwegian Directorate of Health manages the process of recommending which specialisms will be subject to deferred access.

### b) Denial

Please refer to Section 5-1(2) of the Norwegian Patient and User Rights Act. Please note that PPS provides healthcare professionals with the possibility to view/configure/repeal denied and deferred access via the KJ portal after test results have become available. In order for such settings to be configured prior to sampling, the general practitioner's referral solution (EPJ/IHR) must be integrated with data protection and access control (PTS-API).

### c) Protection

Over time, PTS will be able to collect access restrictions where healthcare personnel have protected access by other healthcare professionals if there is reason to believe that this is desired by the patient. Protection will be communicated to PTS via API from the healthcare professional's EPJ/IHR or KJ portal in the same way as denied or deferred access.

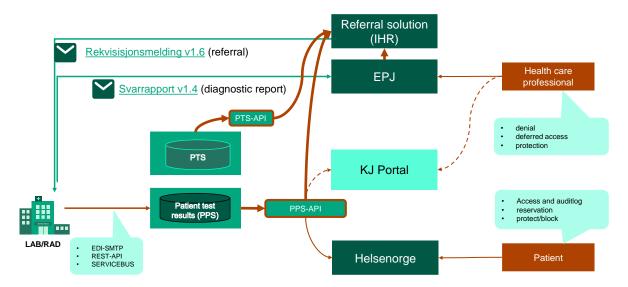


Figure 2 Simple system diagram



## Appendix 3 Background to establishing data protection and access control (PTS)

Residents must be able to object to the disclosure of their health data by requesting that parts or all of the journal are blocked for selected healthcare professionals, a group of healthcare professionals or units. The current practice is for residents to contact each unit individually to object to disclosure. None of the units currently offer self-service functionality.

When introducing new national e-health solutions that support the disclosure of health data for the purpose of providing, administering or quality-assuring healthcare, residents' right to object to such disclosure must be safeguarded. The rights of residents are, among other things, reflected in the medical records act, the KJ regulations, the prescription provider regulations and the patient and user rights act.

In Akson SSD, it was noted that this requirement should, to the extent possible, be solved as similarly as possible across national e-health solutions and that settings should be managed via a shared service. Due to the fact that each national e-health solution is governed specifically, it can be challenging to establish shared access restrictions.

Currently, there is a national data protection service for the health and social care sector in which residents, via helsenorge.no, can manage healthcare professionals' access to data in the KJ, prescription providers and certain national registers. The overarching need is to further develop the existing national data protection service in Helsenorge (Data protection component – PVK) to include functionality allowing residents to access a self-service solution to manage access restrictions (privacy settings) in a single location for all national e-health solutions and to share health data between units within the health and social care sector.

Initially, this further development will cover the need for access restrictions, including privacy settings, in PPS. Healthcare professionals or residents should be able to configure, change and read access restrictions in a single location where healthcare professionals can configure access restrictions in a relevant system while residents configure access restrictions via helsenorge.no. The solution pattern for the collection and disclosure of access restrictions between NHN and units within the health and social care sector should be reusable in other national e-health solutions, such as patient medical records and patient measurement data. "Non-digital" residents must be assisted in objecting to sharing of data without having to use helsenorge.no.

The national data protection service has been endorsed and requested through the programme for digital interaction (PDS) (requirement #16) and will be gradually realised. In the first instance, this means that the national data protection service will only establish functionality corresponding to the need for access restrictions in PPS.

Residents' need for access restrictions will be based on established functionality and interfaces (PVK) to bar or block all or selected healthcare professionals' access to health data, with test results as the category of health data access that restrictions can be linked to in PPS. Residents' access restrictions should be available to all units.

This means that PTS will be established as a service that manages the functional needs to safeguard patient safety and residents' right to object to disclosure and will communicate the needs as access restrictions between units in the health and social care sector, national e-health solutions and helsenorge.no.

The further development of a national data protection service or access control service will initially involve the establishment of PTS for the collection and disclosure of access restrictions associated with PPS as a national e-health solution.

Example code values used for denial, deferred access, barring and protection from OID=9603 and OID=7608

N = No special access restrictions have been configured NORU (OID=9603) = Access restriction which means that selected health data is made available to residents after a specified period of time. Access restrictions may be configured by healthcare professionals or automated rules.

NORN\_XXX (OID=9603) = Denial due to various reasons (patient access in HN)

NORS (OID=9603) = Access restriction that entails residents barring all or parts of the data in a treatment-oriented health register so that the data is not made available to individual healthcare professionals or groups of healthcare professionals. Will also be used in cases where healthcare professionals protect access by other healthcare professionals if there is reason to believe that the patient would have wanted such access restrictions.

SP (OID=7608) = Access restrictions that entail residents barring all or parts of the data contained in a treatment-oriented health register so that the data is not made available to individual healthcare professionals or groups of healthcare professionals. Healthcare professionals with professional needs can still gain access in an emergency/subject to the resident's consent. Such barring can be changed by residents in Helsenorge.

BL (OID=7608) = Blocking access to health data. Healthcare professionals cannot gain access to health data before the block is revoked by the resident. Blocking configurations can be changed by residents in Helsenorge.

NORS, SP and BL also entail use in which healthcare professionals configure a barrier or blocking on behalf of residents via their own specialist system.



# Appendix 4 Background to Patient test results (PPS)

PPS with access restrictions is one of multiple building blocks to support "One resident – one record" and the aim is to make relevant health data available to healthcare professionals who provide treatment to patients regardless of where such treatment is delivered and where the health data originates from, while also contributing to residents gaining greater ownership of their own health data.

PPS will provide healthcare professionals with access to test results relevant to treatment and alleviate the need to chase necessary information, which could contribute to faster diagnoses, improved decision-making bases, more accurate treatment levels and improved quality in health services. Test results are made available to healthcare professionals via the KJ, either in the KJ portal or as an integrated part of the value chain in the healthcare professionals' own EPJ.

EPJ suppliers must implement support for the integration with the prøvesvar-API. This will provide general practitioners with access to view all diagnostic reports in PPS in their own interface, including those requested by others, and collate these within their own interface, e.g. Labark. It is important to ensure that healthcare professionals can easily identify externally requested test results.

Considering that the diagnostic reports in PPS originate from many different laboratories using different analysis methods and reference ranges and that these are made available as FHIR resources, it is important to ensure that any collation and trending of the same analysis codes over time clearly shows variations in reference ranges, analysis methods etc.

Other requirements include ensuring that healthcare professionals at the named unit actually request access to test results and that such data is secured by HelselD as described in the NHN Developer Portal. Considering that PPS are subject to the KJ regulations, healthcare professionals should be able to access test results, subject to bars set by residents, by obtaining consent from the patient or overriding access in emergency situations. Descriptions of such data elements from the trust framework can be found in the NHN Developer Portal.



# Appendix 5 PPS Short and long-term targets

### MVP1 - Initial delivery of purpose healthcare for the service as a whole

In MVP1, as the initial delivery of purpose healthcare, the ambition is limited to apply to externally requested test results with a purpose of healthcare (general practitioner, out-of-hours medical service etc.) submitted from public or private laboratories or radiology units (hereinafter referred to as LAB/RAD).

Residents have a right of access and can exercise their data protection rights via Helsenorge and can also request assistance from requestors. Residents will also be notified of new test results and will be able to view test results from several specialisms without deferred access in Helsenorge, while other specialisms will be subject to automatic deferral ranging from 14-90 days. The requestor should be able to change such general deferral periods.

Requestors must be able to specify the purpose of the referral in the referral solution, as well as whether residents have opted out of retention (or change the default settings) in both the existing referral request and in the new Helsehjelp-API. On behalf of health trusts, Norsk helsenett will be able to ensure that only relevant data is stored in PPS.

Requestors must comply with the patient and user rights act by specifying access restrictions for residents where necessary and restricting sharing with healthcare professionals in a single referral solution.

If it becomes necessary to make changes to a submitted referral, requestors can change and submit a change request to the laboratory or radiology systems (hereinafter referred to as LIMS). Changes can be made until the time of sampling or until analyses have been initiated. After this time, it is possible to re-request new investigations in addition to the original referral. This will also apply to the following changes:

- If the patient wishes to change the code for the configured RESERVATION
- If the requestor wishes to change the code for the configured PURPOSE

In addition, the same information must be updated for the same referral in Helsehjelp-API, so that NHN always uses the most recent information about purpose and reservation as the basis for validation of any diagnostic reports received. This will also apply to any changes to access controls configured at the time of referral using the PTS-API integration:

• If the requestor wishes to change the configured ACCESS RESTRICTIONS



### Long-term target for PPS and nationwide implementation

This document describes the requirements for deliveries from LIMS for an MVP1 delivery, but we will also describe the long-term target for PPS with a view to national implementation. Nevertheless, the target situation is limited to continued submission of test results as diagnostic reports, as is the case today.

LIMS suppliers are free to decide whether it would be sensible to implement support for future changes at this stage.

In the next stage and with a view to the long-term target, all public and private LAB/RAD must submit all test results with the purpose of healthcare to PPS.

Local access restrictions at each health trust must be forwarded to NHN so that residents can be assured that similar restrictions will also apply to PPS as a national solution.

Residents must be able to view the majority of test results without deferred access in Helsenorge in line with experiences from neighbouring countries such as Sweden and Denmark.

Both external and internal requestors at each health trust must be able to specify the purpose and any reservations without using Helsehjelp-API and be assured that only the correct data is submitted from LAB/RAD to PPS.

If the patient requests a copy of the test results, the requestor should be able to ask LIMS to forward any earlier test results to PPS so that the resident can access these directly via Helsenorge. This will apply to situations in which important test results end up in EPJ for patients with local healthcare numbers (e.g. no contact with the patient, coma etc.) without information being added to the patient's KJ.

The ability to view previous tests can help determine the scope of an ongoing referral from an EPJ system. An integration with prøvesvar-API will show recent test results and an integration with PTS-API will provide information about whether there are any access restrictions related to these.

When more EPJ suppliers have implemented support for HelseID logins, the requirement for API integration will be HelseID user login (SSO) to ensure more secure authentication and authorisation.

 LIMS and/or ICT solutions linked to health trusts must allow for the prevention of submission of diagnostic reports that should NOT be sent to PPS, and NHN, as the national service provider, MUST prevent any erroneously submitted diagnostic reports from being stored in PPS.

- In cases where the requestor has specified a purpose other than healthcare in the referral request and the Helsehjelp-API with NHN
- In cases where the requestor has entered a code showing that the resident has opted out of the retention of diagnostic reports relating to the referral in the referral request and the Helsehjelp-API with NHN



# Appendix 6 Possible gains associated with MVP1

### **Expected gains with the launch of MVP1**

In order to realise gains in connection with the launch of PPS for the purpose of healthcare, a certain number of diagnostic reports will be required and these must be available to both attending healthcare professionals and residents/relatives via Helsenorge.

### Scope of externally requested test results

With an MVP1 that includes only external requestors (e.g. general practitioners and local authority services etc.), this will correspond to approximately 2.6 million diagnostic reports submitted from public health trusts and around 1.7 million diagnostic reports submitted from private laboratory and radiology units each quarter. These figures from Q1 2024 in the NHN message counter<sup>25</sup> include copies, preliminary and changed diagnostic reports, and an estimate for final diagnostic reports is around 1.5 million per quarter or around 5 million diagnostic reports per year.

### Access to externally requested test results from EPJ and Helsenorge

Healthcare professionals that will have access to such test results must use an EPJ system with access to the KJ portal or integrated using the test results API in the KJ. **During initial launch, the out-of-hours medical service in particular may achieve gains** as it will no longer be necessary to chase information from general practitioners and general practitioners no longer need to spend time forwarding test results.

During the spring of 2023,<sup>26</sup>, the Norwegian Directorate of E-health conducted a survey that found that most EPJs for user groups with a clear professional need support integration with KJ. The majority of EPJs that do not support integrations with the KJ will be integrated with KJ Portal by Q3 2024 and an overview of the EPJ suppliers that currently have access to the KJ is listed on nhn.no<sup>27</sup>.

Additionally, the Q2 2024 announcement from EPJ promised API integrations from general practitioner EPJ, which will lead to even more EPJ systems having access to PPS by 2024/2025.

<sup>&</sup>lt;sup>25</sup> https://meldingsteller.nhn.no/

https://www.ehelse.no/publikasjoner/kartlegging-av-elektroniske-pasientjournalsystemer-og-deres-stotte-for-nasjonale-e-helselosninger/\_/attachment/download/5f2dee5e-9b2c-453a-862b-fcece7c2aff3:c2aa7986924f971da55fecbac21fbf9911c50dab/Kartlegging%20av%20elektroniske%20pasientjournalsystemer%20og%20deres%20st%C3%B8tte%20for%20nasjonale%20e-helsel%C3%B8sninger%20v1.0.pdf

<sup>&</sup>lt;sup>27</sup> https://www.nhn.no/tjenester/kjernejournal/dokumentasjon-for-kjernejournal/kliniske-fagsystemer-med-stotte-for-kjernejournal

For residents and, where applicable, relatives, the early launch with "a few" test results will provide a good introduction to the solution in Helsenorge, with a focus on access rights and data protection.



# Appendix 7 Use cases for access restrictions

# Access restrictions configured by healthcare professionals at the time of referral

As a healthcare professional I need to be able to configure or revoke access restrictions at the time of referral in order to safeguard life and health and provide considerate healthcare before test results become available to residents in Helsenorge.

All test results with a purpose of healthcare must be submitted to PPS and it is only in exceptional circumstances that I need to change default values.

- a) As a healthcare professional, I need to be able to register **paper referrals** in LIMS for the purpose of healthcare, the resident has not expressed a desire for test results not to be stored in PPS and any applicable access restrictions are known.
- b) As a healthcare professional, I need to be able to assist residents in **barring** or **blocking** access to health data for other healthcare professionals right from the time of referral so that I can safeguard patient rights.
- c) As a healthcare professional, I need to be able to **protect** health data from being shared with other healthcare professionals right from the time of referral so that I can safeguard patient rights.
- d) As a healthcare professional, I need to be able to **deny** access for residents right from the time of referral when I know that it is urgently necessary in order to prevent risk to life or health for the patient or user or if access is clearly inadvisable for the sake of people close to the individual
- e) As a healthcare professional, I need to be able to **defer access** to health data for residents at the time of referral to ensure that information relating to illness, treatment and individual follow-up is provided by healthcare professionals before the test results become available to the resident via Helsenorge.
- f) As a healthcare professional, I need to be able to **change** existing access restrictions for test results using a system-generated deferral for residents at the time of referral so that residents can gain earlier or later access to their test results via Helsenorge.
- g) As a healthcare professional, I need to be able to meet residents' need to object to the retention of test results from the referral by specifying **Reservation** in the referral request so that any associated diagnostic reports are not stored in PPS.
- h) As a healthcare professional, I need to be able to specify the **purpose** of the referral. This to ensure that LAB/RAD do not submit diagnostic reports without a purpose of healthcare.
- i) As a healthcare professional, I need to be certain that the settings configured at the time of referral for the **unique** referral request mean that submitted diagnostic report(s) from LAB/RAD to PPS are linked to the specific referral so that data protection and patient safety can be safeguarded.

- j) As a healthcare professional, I would prefer not to have to log in with HelseID for every setting that must be configured in the referral solution. Login credentials should be provided from the EPJ log in with HelseID and passed on to the referral or request solutions.
- k) As a healthcare professional **without an HPR number**, I want to be able to make referrals on behalf of the general practitioner or other healthcare professionals with an HPR number and also update access restrictions on behalf of the HPR number owner.

# Appendix 8 Proposed GUI for access restrictions

This requirement will be the same for Dips Interactor, HP Link, Furst Forum, HP, Arena bookings (AOM) and request solutions in internal LIMS and the example below is provided as a proposal only and does not constitute guidance as to how suppliers make the choices as easy as possible for requestors. Please note that the example is provided in Norwegian only.

The interface for access restrictions is closely linked to the specification of the **purpose** of the referral, as well as whether the resident wishes to exercise their right of reservation in relation to retention. It is also linked to patients' need to **bar** sharing or healthcare professionals' need to **deny** patient access. Default values can also be used here to ensure minimal changes to work processes for healthcare professionals.

Some will be used to update referral requests/diagnostic reports, while some require integrations with e.g. Helsehjelp-API and PTS-API, see descriptions in initial chapters.

Example of settings that <u>CAN</u> be compiled in a single "window" in the referral interface for which default values have been configured and, again, intended only as an example and not as guidance for the solution;

# Rekvisisjonsløsning, IHR etc

Prøvesvarene fra denne bestillingen har formål helsehjelp og kan i tillegg trygt deles med både innbygger og annet helsepersonell

JA (

Alle private og offentlige LAB/RAD skal sende alle prøvesvar til pasientens prøvesvar.

Noen av formålene med pasientens prøvesvar er å bedre pasientsikkerheten ved å tilgjengeliggjøre relevante helsedata fra Nasjonal Kjernejournal (KJ) til behandlende helsepersonell, samt å gi innbyggere et større eierskap til egne helsedata.

- Hvis formålet med denne rekvisisjonen **IKKE** er til helsehjelp, eller pasienten motsetter seg sterkt at disse prøvesvarene lagres i Nasjonal kjernejournal, hindrer du lagring i KJ ved å angi innstillinger her.
- Hvis du som rekvirent vet at det er særskilte behov for å begrense pasientens innsyn i Helsenorge, eller begrense annet helsepersonell sin tilgang til prøvesvarene i KJ, kan disse innstillinger angis her.

Hvis ingen av disse behovene inntreffer, defineres formålet til å være helsehjelp, og en kopi av svarrapporten sendes fortløpende fra lab/rad til pasientens prøvesvar i Nasjonal kjernejournal, og gjøres tilgjengelig for innbyggere i Helsenorge i henhold til <u>Hdir</u> sin plan for utsatt innsyn for pasienten, se <a href="https://www.nhn.no/tjenester/pasientens-provesvar">https://www.nhn.no/tjenester/pasientens-provesvar</a> (lenke til notat utsatt innsyn vil formidles)

See Chapter 3.11 "Proposed solution for access restrictions in LIMS" for further details



# Appendix 9 Example referral and diagnostic report

See examples attached

# Appendix 10 Example of cancellation of the entire diagnostic report

### Appendix 10.1 Cancellation without information elements

When cancelling an entire diagnostic report, it is sufficient to ensure that Message.ServReport.ServType V="C" and DN="Cancellation" with an associated justification for the cancellation of the entire report be entered in Message.ServReport.Comment. Diagnostic reports with V="C" are considered cancellations of the entire diagnostic reports by PPS; see also descriptions of statuses in "Use of diagnostic reports v1.4 in PPS, HITS 1249"<sup>28</sup>.

As with all change requests, cancellation requests must have the same diagnostic report ID, Message.Servreport.ServProvId, as previous diagnostic reports in accordance with Diagnostic reporting in medical services v1.4.<sup>29</sup>

```
EbXml
            Fagmelding
                                         Eventuelle endringer vil bli med når meldingen sendes.
                            Visning
     <!-- DETTE ER EN TESTMELDING MED FIKTIVE PERSONDATA -->
     <Message xmlns="http://www.kith.no/xmlstds/labsvar/2012-02-15" xmlns:xsd="http://www.w3.org/2001/XMLSchema</pre>
       <Type V="SVAR_LAB" DN="Svarrapport-Laboratoriemedisin" />
       <MIGversion>v1.4 2012-02-15</MIGversion>
 4
       <GenDate V="2024-05-16T09:48:02" />
       <MsgId>4b5fee94-5061-4a8d-9d7e-869d722b10df</msgId>
       <Status V="TEST" DN="Melding til testformål" />
 8
       <ServReport>
       <ServType V="C" DN="Kansellering" />
9
         <IssueDate V="2024-05-16T09:48:02" />
10
         <Status V="F" DN="Endelig rapport" />
11
12
         <MsgDescr V="CLIN" DN="Medisinsk biokjemi" />
         <ServProvId>c0ec28c0-daff-4562-9f87-589edda350e6
13
       <Comment>Hele svarrapporten er kansellert pga feil. Historikk forefinnes på laboratoriet.</Comment>
14
15
         <ServRea>
           <IssueDate V="2024-05-16" />
16
17
           <Id>8b804ad8-eec2-450a-a936-fcacf723a87c</Id>
18
         </ServRea>
19
         <Patient>
20
           <Name>Danser, Line</Name>
           <IdByServProvider>10682608</IdByServProvider>
21
           <OffId>13116900216</OffId>
22
23
           <TypeOffId V="FNR" DN="Fødselsnummer" />
24
           <ResponsibleHcp>
             <Relation V="REK" DN="Rekvirent" />
25
26
27
               <Inst>
                 <Name>Kattskinnet legesenter</Name>
```

<sup>&</sup>lt;sup>28</sup> https://www.nhn.no/tjenester/pasientens-provesvar/teknisk-beskrivelse-svarmeldinger

<sup>&</sup>lt;sup>29</sup> https://www.ehelse.no/standardisering/standarder/svarrapportering-av-medisinske-tjenester-v1.4

### Appendix 10.2 Cancellation WITH information elements

The same will apply to cancellation requests that include a status for each test result. Diagnostic reports must include the same diagnostic report ID as previous diagnostic reports in accordance with Diagnostic reporting in medical services v1.4.<sup>30</sup>

```
<?xml version="1.0" encoding="utf-8"?</pre>
<MIGversion>v1.4 2012-02-15</MIGversion>
    <!-- GenDate: reportdatetime
    <GenDate V="2023-10-20T13:49:00" />
    <MsgId>61ac6bd9-ddc0-4921-919d-f3c0cdded249</msgId>
   <ServReport>
     <!-- ServType cancelled: C - Request
<ServType V="C" DN="Kansellering" />
                                   - Request cancelled report -->
ering" />
      <!-- IssueDate: sample.createdt -->
<IssueDate V="2023-10-20T13:14:00" />
      <Status V="F" DN="Endelig rapport" />
      <ack V="J" DN="Ja" />
<MsgDescr V="CLIN" DN="Klinisk kjemi" />
      <!-- ServProvId: The same ID for all reports for a single request. SampleId (sample.s_sampleid) --> <ServProvId>23KT20299</ServProvId>
       Comment>LVMS MÅ LEGGE INN KANSELLERING KOMMENTAR PÅ RAPPORT-NIVÅ</Comment>
        <!-- IssueDate: request.createdt The time the request was created -->
        <IssueDate V="2023-10-20T13:14:00"</pre>
        <MsgDescr V="CLIN" DN="Klinisk kjemi" />
        <Id>NULL</Id>
        <!-- ReceiptDate: sample.receiveddt - The date and time the sample was received -->
        <ReceiptDate V="2023-10-20T13:14:00" />
        <!-- IdByServProvider:
                                  ample.s sampleid - The lab's ID -->
        <IdByServProvider>23KT20299</IdByServProvider>
      </servReq>
      <Patient>
        <Sex V="1" DN="Mann" />
        <!-- Name: samplepoint.w_lastname Patient name formatted as lastname, firstname -->
        <Name>Klubben, Kai Jack</Name>
        <!-- OffId: samplepoint.w code
        <offid>09090950972</offid>
        <TypeOffId V="FNR" DN="Fødselsnummer" />
        <Address>
          <Type V="H" DN="Bostedsadresse" />
              - StreetAdr: samplepoint.w_address1 -->
          <StreetAdr>Sagveien 11
          <!-- PostalCode: samplepoint.w_postalcode --> <PostalCode>0459</PostalCode>
          <!-- City: samplepoint.w_city -->
          <City>OSLO</City>
        </Address>
        <AnalysedSubject>
          <CollectedSample>
            <ResultItem>
            <!-- TextResult: The element not included for cancelled result -->
            <ServType V="C" DN="Kansellering" />
             <Investigation>
              <!-- Id: 7280 : External code defined for the test -->
<Id V="NPU20025" S="2.16.578.1.12.4.1.1.7280" DN="B-Direkte antiglobulintest (DAT) " />
            </Investigation>
            <InvDate V="2023-10-20T13:49:00" />
                 StatusInvestigation: Cancelled
            <StatusInvestigation V="14" DN="Undersøkelse slettet" />
             <!-- refAnalysedSubject:
                                      sampleitems.w sampleitemid A reference to the analysed subject -->
            <RefAnalysedSubject>23KT20299-001</RefAnalysedSubject>
            <Accredited V="true" /3
```

... and the same ServType V="C" DN="Cancellation" for all associated investigations/tests.

<sup>30</sup> https://www.ehelse.no/standardisering/standarder/svarrapportering-av-medisinske-tjenester-v1.4

# Appendix 11 "Link between referral and diagnostic report"

When information relating to access restrictions has been configured by the requestor at the time of referral, only the referral request identifier will be used to safeguard such settings for patients. Access restrictions are communicated via the referral or via the API for healthcare and/or data protection and access control.

It is therefore essential that the referral identifier forwards this link to <sup>31</sup> the diagnostic reports so that it is safeguarded when the diagnostic report is received by PPS. The fields relating to the elements that link referrals and diagnostic reports are highlighted in bold in the description below.

### **Referral request**

Message.Msgld – UUID from referral system for unique referral – always unique

- ServReq.Id UUID from referral system
  - The same ID shall be attached in the event of a referral being broken down/forwarded into multiple deliveries from multiple LIMS.
  - All LIMS/internal booking solutions are encouraged to establish support to include ServReq.Id as a UUID in their own referral systems, including for internal referrals. This to ensure the uniqueness of the referral without requiring any major changes for LID (Laboratory ID for the referral).
- ServReq.ServProvId LID from LIMS or IHR system

If the service provider's ID of the sample vial is included, this will be included on the vial, otherwise the requestor's sample ID will be included on the vial.

Reinvestigation. AnalysedSubject. IdByRequester - The requestor's sample identifier. ReqInvestigation. AnalysedSubject. IdByServProv – The service provider's sample identifier.

<sup>&</sup>lt;sup>31</sup> <a href="https://www.ehelse.no/standardisering/standarder/kobling-av-relaterte-meldinger-med-bruk-av-identifikatorer">https://www.ehelse.no/standardisering/standarder/kobling-av-relaterte-meldinger-med-bruk-av-identifikatorer</a>

### **Diagnostic report**

Message.Msgld – UUID from LIMS for unique diagnostic report – always unique

- Svarrapport-ID, ServReport.**ServProvID** must be **globally unique** to the diagnostic report in accordance with the message standard (e.g. serial number + HER-ID for the department conducting the analysis). The same ID must always be used in the event of changes to previously submitted diagnostic reports.
  - When conducting analyses under the same referral (ServReq.Id) at different LABs/service providers (e.g. by forwarding/breaking down a referral), each of these MUST have a unique diagnostic report ID (ServReport.ServProvId) for the diagnostic reports produced by each LAB.
- ServReport.ServReq.Id UUID from referral system in referral request (otherwise ZERO) and the same ServReq.ID must be included when breaking down a referral into multiple diagnostic reports from multiple LIMS. Unless set to "ZERO", this will be the most important link between the referral request and the diagnostic report.
- ServReport.ServReq.IdByServProvider LID (laboratory ID) from LIMS or IHR system retrieved from ServReq.ServProvId in the referral request. When LID is available in the referral request and ServReq.ID is "ZERO", this will be the most important link between the referral request and the diagnostic report.

ServReport.AnalysedSubject.Number – unique serial number from ...

ServReport.AnalysedSubject.IdByRequester – the analysis ID is retrieved from the referral ServReport.AnalysedSubject.IdByServProvider – the laboratory's unique serial number for the analysis

ServReport.ResultItem.RefAnalysedSubject – indicates the laboratory's unique analysis ID ServReport.IdResultItem – serial number retrieved from ...?

```
<Type V="SVAR LAB" DN="Svarrapport-Laboratoriemedisin" />
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```

Example diagnostic report including information forwarded from referral.



# Appendix 12 Principles for deferred access (not finally adopted)

#### Test results to be shown to residents without deferred access:

- Medical microbiology
- Clinical pharmacology
- Medical biochemistry\*
- Immunology and transfusion medicine\*

The classification of different investigations will be performed based on the specialism assigned to the analyses in the Norwegian Laboratory Encoder and the message type \* except if medical genetics is assigned as a secondary specialism

### Test results to be shown to residents with deferred access:

- Pathology
- Imaging
- Nuclear medicine
- Investigations specified using local codes
- Medical genetics \*\*

The classification of different investigations will be performed based on the specialism assigned to the analyses in the Norwegian Laboratory Encoder and the message type

\*\* Includes test results submitted with a message type of medical genetics, and those configured with medical genetics as the primary or secondary specialism in the Norwegian Laboratory Encoder. A gross list must be established.

#### Number of days of deferred access:

#### Pathology, imaging, nuclear medicine and local codes:

- General deferral of 14 calendar days
- Requestors can manually release the report earlier, but the report will automatically be released to the resident after 14 calendar days

#### **Medical genetics:**

- General deferral of 3 months
- The requestor can manually release reports earlier, but the report will automatically be released to the resident after 3 months