Material request for surveillance assessments and reassessments
Clinical laboratories SFS-EN ISO 15189:2013 and/or SFS-EN ISO/IEC 17025:2017

Please return this form and its attachments with the grey fields in Sections 1 and 2 completed no later than three (3) weeks before the assessment date (however, no earlier than two (2) months before the assessment).

|  |  |
| --- | --- |
| Testing laboratory | *Laboratory name* |
| Accreditation symbol | *Txxx* |
| Assessment date | *dd.mm.yyyy* |

# CHANGES IN THE LABORATORY ACTIVITIES

Please inform about essential changes in the activities and customers. Essential changes are changes in the legal, financial or organisational situation of activities and changes in the management and technical managers. Changes in the personnel, equipment and its software, facilities, calibration or procedures are also essential.

Note, inform changes in testing methods in detail in List of appendixes, point 3 (also regarding those changes that will not affect the accredited scope description).

Inform changes in the flexible scope in List of appendixes, point 16.

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| ***Please write here*** |

Extensions, reductions and changes into the accredited scope:

Inform about any proposals of extensions, reductions or other updates to the scope in tables 1–3 below.

**Please note that large scope extensions cannot possibly be included in the agenda of the assessment day in concern, and those must be planned separately.**

Table 1. Extensions to the scope

| EXTENSIONS TO THE SCOPE, e.g. new methods and/or matrices and sites(please add rows when needed).Also note language versions. |
| --- |
| **Field of testing(Research / speciality area)** | **Material, product tested** | **Component / parameter / characteristic tested**  | **Test method / standard specification / techniques** | **Site** |
| *Field of testing (Research / Speciality area)* | *Material, product tested* | *Component / parameter / characteristic tested* | *Test method / standard specification / techniques* | *Site* |
| Esim.Kliininen kemia, Erikoiskemia, *Clinical chemistry, Special chemistry* | Esim.Plasma*Plasma* | Esim.Bilirubiini*Bilirubin*Tutkimukseen liittyvä kuntaliiton koodi | Esim.Fotometrinen*Photometric* | Esim.Helsinki*, Helsinki* (tai muu yksilöivä tarkenne) |
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Table 2. Changes/updates to the scope

| CHANGES/UPDATES TO THE SCOPE, e.g. changes in standard versions, code changes from consolidation of municipalities, kit changes (please add rows when needed). **Highlight any changes.**Also note language versions. |
| --- |
| **Field of testing(Research / speciality area)** | **Material, product tested** | **Component / parameter / characteristic tested**  | **Test method / standard specification / techniques** | **Site** |
| *Field of testing (Research / Speciality area)* | *Material, product tested* | *Component / parameter / characteristic tested* | *Test method / standard specification / techniques* | *Site* |
| Esim.Kliininen kemia, Erikoiskemia, *Clinical chemistry, Special chemistry* | Esim.Plasma*Plasma* | Esim.Bilirubiini*Bilirubin*Tutkimukseen liittyvä kuntaliiton koodi | Esim.~~Fotometrinen~~*~~Photometric~~***UUSI TEKNIIKKA Turbidimetrinen** | Esim.Helsinki*, Helsinki* (tai muu yksilöivä tarkenne) |
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Table 3. Reductions to the scope

| REDUCTIONS TO THE SCOPE, for example methods/matrices or sites (please add rows when needed). |
| --- |
| **Field of testing(Research / speciality area)** | **Material, product tested** | **Component / parameter / characteristic tested**  | **Test method / standard specification / techniques** | **Site** |
| *Field of testing (Research / Speciality area)* | *Material, product tested* | *Component / parameter / characteristic tested* | *Test method / standard specification / techniques* | *Site* |
| Esim.Kliininen kemia, Erikoiskemia, *Clinical chemistry, Special chemistry* | Esim.Plasma*Plasma* | Esim.Bilirubiini*Bilirubin*Tutkimukseen liittyvä kuntaliiton koodi | Esim.Fotometrinen*Photometric***POISTETAAN** | Esim.Helsinki*Helsinki* (tai muu yksilöivä tarkenne) |
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# OTHER ASSESSMENT

If you request other assessment in addition to/instead of the accreditation, please mark your option.

We request assessment for

[ ]  Assessment of activities based on national legislation, please name activities and corresponding legislation

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[ ]  Other assessment, please specify

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Laboratory’s representative

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| --- | --- |
| **dd.mm.yyyy** |  |
|  | Name |

#  LIST OF APPENDICES

**To lead assessor:** please return all the material listed below.

**To** **technical assessors:** please return the material listed below regarding their assessment area, apart from Appendix 6 (Management review), and, regarding internal audits, only reports regarding the assessment area in question (Appendix 5).

Please return the **completed material request form** to the lead assessor and technical assessors. Save the form as: *TXXX material yyyy.docx*, where yyyy = assessment year.

1. Information about the laboratory’s technical persons in charge, including changes
2. Handling of risks and opportunities
* Summary of essential procedures concerning the handling of risks and opportunities
* Identified and analysed risks and opportunities
1. Extensions, reductions and updates to the scope

Testing instructions, validation and/or verification data and results from inter-laboratory comparisons (summary and conclusions) related to the possible scope extensions or changes. Note: Also enter information about these changes in Tables 1–3.

In addition, information about other changes related to methods and equipment, including

* code changes from consolidation of municipalities
* changes in the instructions like changes in kits
* changes in equipment
1. Management system documentation

Relevant documentation of the management system and technical activities (**technical documentation divided between the fields of assessment**), including

* management system description (quality manual)
* instructions of the operations / instructions of the procedures
* testing instructions and a list of testing instructions
* sampling instructions
* description of flexible scope principles
1. Internal audits

Internal audit plan and reports. **Please include all internal audit reports to the lead assessor’s and corresponding internal audit reports to the technical assessors’ material (reports after previous assessment).**

1. Management review

Management review minutes. **Please include the management review minutes only to the lead assessor’s material (reports after previous assessment).**

1. Internal communication

Possible samples of internal memos related to laboratory internal meetings.

1. Reference to accreditation

New brochures and related material which contain a reference to accreditation or where the accreditation symbol has been used. If the material is published in the Internet, the URL is sufficient.

1. Management of competence, development and maintenance of competence (e.g. maintenance of qualifications)

Summary/report of the management of competence, such as a plan and implementation of personnel training, updating of knowledge and reviews of staff performance (monitoring)

1. Customer service
* Most important customer groups
* Legislation that is complied with in analytics and methods, and demands of the authorities that the laboratory takes into account in its activities
* If the laboratory serves the authorities’ supervising activities, information about the official needs for which methods are used
* Possible changes related to the aforementioned
1. Test amounts and test reports
* Estimate information about test total amounts per method yearly/or per certain period
* Estimate information about test total amounts per sample type yearly/or per certain period
* Patient result total amounts or given test reports under the period
* Patient result total amounts or test reports given accredited under the period
1. Quality assurance

Summary/reporting of the realisation of quality assurance principles (cf. FINAS Policy Document A2)

* Quality assurance plan (annual and long-term)
* Summary and conclusions of the results of inter-laboratory comparisons
* Long-term results (trends) of inter-laboratory comparisons
* Summary of the methods and matrices used in inter-laboratory comparisons when there are several methods and matrices for a single analysis
1. Calibration
* Calibration schedule including information about internal (in-house) calibrations (to which quantities metrological traceability is ensured)
* Instructions of internal calibrations
1. Measurement uncertainty
* Measurement uncertainty calculations/estimations

**The following material shall be provided if required:**

1. A list of available standard versions and/or analytes **(if in the accredited scope)**
* If the standards in the laboratory’s accredited scope used as a method reference are stated without year / include all the existing versions, the laboratory shall deliver an exact list of versions that are used in conjunction with this material request.
* If the number of analytes is indicated in the test type in the laboratory’s scope (quantity in brackets), the laboratory shall provide an accurate list of analytes.
1. Flexible scope **(if in the accredited scope)**

Information about the flexible scope and its use (cf. FINAS Policy Document A3)

* Information about methods within the flexible scope
	+ - An accurate list of the flexible scope methods showing the material/product tested, type of test and test method
		- Review of the use of the flexible scope: period (starting from the previous assessment), matrix, type of test, test method, date of entry into use
* Change-related documents, including validation/verification reports
* Total number of test reports concerning new extensions within the flexible scope
* Summary and conclusions of the results and trends from inter-laboratory comparisons
* Laboratory’s internal instructions related to flexible scope
1. Assessment of the information system **(information to be provided at the separate request of FINAS)**
* Information about how information system maintenance is carried out, including sub-contracting
* Information system documentation and related instructions
* Description of the network
* Information about the information security strategy, password policy, virus protection, backup copy/recovery system
* Training of the personnel and maintenance of the personnel’s competence
* Other possible information and documentation
1. Material for the assessment of activities based on any national legislation or

 other assessment applying this list of appendices
**(if you are requesting assessment based on Section 2 (Other assessment))**

# 4. DOCUMENT DELIVERY TO THE EXTRANET

Documents are asked to be delivered so that there is a separate ZIP file for each assessor, including the material arranged into folders in accordance with the numbering used in the list of appendices (see the image below). The name of the ZIP file must include the accreditation symbol, e.g. **Txxx chemistry.zip, Txxx management system.zip.** Please do not change the numbers of the appendices.

**The compressed file must be in .zip format** – no other compression formats are accepted, such as .rar and .7z. The size of the ZIP files should preferably be less than 50 MB per file.

Documents are asked to be arranged into subfolders in accordance with the 3. List of appendices. Each subfolder shall include in maximum one subfolder level, and the names of folders and files should be kept short to open the ZIP files without any problems.

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Brief extranet instructions:

Go to the “Dokumentit” (Documents) tab and click “Tuo uusia dokumentteja” (Add new documents). Select the folder in which you want to save your file. Subfolders are located under the folder named using your organisation’s accreditation symbol (see the example below):

Txxx 🡪

TXXX Shared

TXXX Customer-FINAS

TXXX Chemistry

TXXX Microbiology

TXXX Sampling

Please save the lead assessor’s material in the Customer-FINAS folder. Save the technical assessors’ material in folders named after each assessment area, e.g. material intended for the technical assessor of chemistry in the “Txxx Chemistry” folder, etc. You can save any material intended for all assessors in the shared folder (content of this folder is shown to all assessor team). Please also save any corrective measures in the Shared folder. The customer has rights to all folders. The technical assessors only have access to the content of the folder intended for their assessment area and the Shared folder.

Select “Asiakkaan aineisto” (Customer material) as the material type.

If required, you can also save individual files other than ZIP files (.docx, .pdf, .xlsx, etc.) in the extranet.

More extranet instructions and videos: [**https://www.finas.fi/Tietoa/Sivut/ohjeet.aspx**](https://www.finas.fi/Tietoa/Sivut/ohjeet.aspx)

**It is important that you notify us by email (****akkreditointi@finas.fi****) after you have uploaded your material to the extranet.**

**If you have any problems, please contact** **akkreditointi@finas.fi**.

**Thank you!**