Qualification and Validation of Valab®
by the Medical Laboratory
Quality control, qualification and checks

Accreditation aid

1   Object

This document is for medical laboratories that use the Valab® expert system for computer aided biological validation. It is a guide on how to set up procedures for the qualification of Valab® by the medical laboratory. This guide provides an approach and a set of examples allowing the medical laboratory to qualify the use of the Valab® software tool and to ensure control in terms of checks, maintenance and traceability of modifications.

The medical laboratory, on the basis of risk analysis and its knowledge of the product, can decide to implement a different approach and set of procedures for all or part of the examples provided in this guide.

This guide serves as a complement to document **RD3** "Valab® Manufacturer's Information for Medical Laboratory Accreditation" which provides the medical laboratory with manufacturer information from the VALAB company concerning the use of Valab® in an accredited medical laboratory.

For more details on the use of Valab® and on the description of its interface with the LIS, please refer respectively to the *Valab® User Manual* (**RD4**) and *Valab® Developer Manual* (**RD5**) provided with Valab®. Those manuals are available under the "DOC" folder of Valab®.

The records to be kept as proof of the execution and the results of the tests and checks described in the different sections of this document can be stored on any appropriate medium (digital or paper). Their length of conservation must comply with what is defined in the documentation of the QMS of the medical laboratory, the recommended minimum period of time being 24 months.

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The VALAB company is certified ISO 9001 by:

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2 References

2.1 Document change history

Version	Date	Modification description	Author	Modified pages
3/A-Draft	05/01/2018	Updated document for version 14 of Valab®. Added "Life cycle" overview. Added test for processing of an entirely validated report in the qualification test for the connection with the LIS. Revised the continuous monitoring procedure: split up into several tests which can have different frequencies, fine-tuning of the statistics monitoring test, use of Valab®'s Simulation mode for the reproducibility test with the help of an added periodical monitoring check of the LIS ⇔ Valab® connection. Revised the requalification procedures in the event of a modification: split up into several tests adapted for the different modification cases the medical laboratory may be faced with, took into account minor version updates of Valab®, took into account modifications with an exclusively restrictive impact on the possibilities of biological validation using Valab® (simplification). Various minor corrections and updates.	JP. Rogari	All
3/A	27/02/2018	Took into account feedback from clinical scientist reviewers: modified the "life cycle" overview → "Overview of this guide – Life cycle", various minor corrections and additions.	JP. Rogari	§5, §6.1, §7, §8.1.2, §8.2 and §9.2

2.2 Valab® web site www.valab.com

Click the following link to find the current version of this document on the Downloads page of the Valab® web site (www.valab.com).
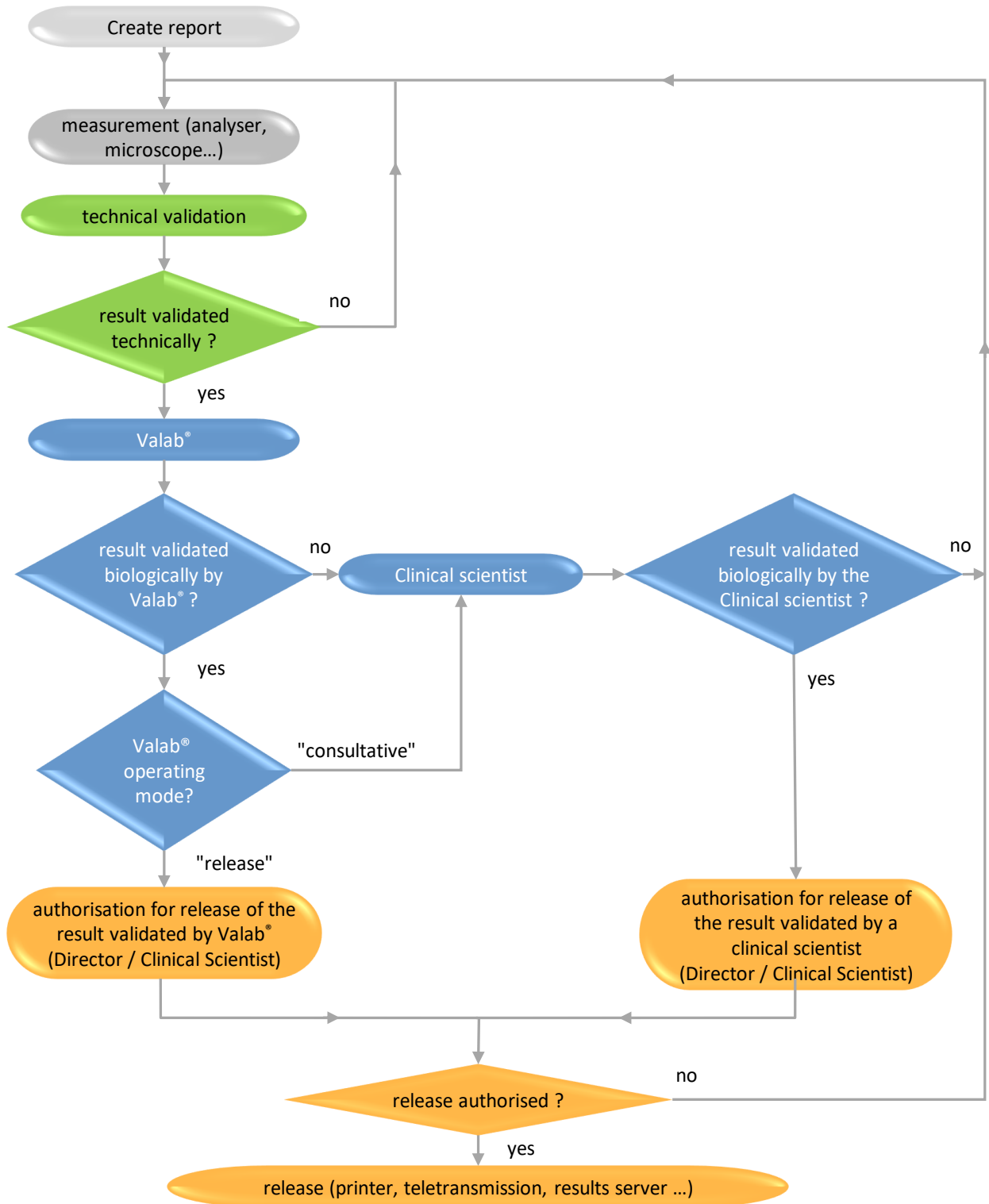
2.3 Reference documents

RD1	Medical laboratories - Requirements for quality and competence ● ISO 15189
RD2	Guide for the Correct Execution of Tests ● GBEA 2
RD3	Valab® Manufacturer's Information for Medical Laboratory Accreditation (available at www.valab.com) ● VAL-ACC-10
RD4	Valab® User Manual (provided in Valab® "DOC" subdirectory) ● VAL-MU-XX
RD5	Valab® Developer Manual (provided in Valab® "DOC" subdirectory) ● VAL-MU-XX
RD6	Valab® - Backup and Restore (available at www.valab.com) ● VAL-MU-40
RD7	Manuel Qualité Valab (Valab Quality Manual - only available in French) (available at www.valab.com) ● VAL-MQ-01
RD8	Accreditation requirements according to standard NF EN ISO 15189 ● Cofrac / SH REF 02
RD9	Accreditation technical guide for medical laboratories ● Cofrac / SH GTA 01
RD10	Accreditation technical guide to assess the IT systems in medical biology ● Cofrac / SH GTA 02
RD11	Articles L.6211-1 and following of the French Code of Public Health ● CSP
RD12	Articles L.5221-1 and following of the French Code of Public Health ● CSP

2.4 Acronyms

Acronym	Meaning
LIS	Laboratory Information System
NA	Not applicable
NOK	Test result Not OK
OK	Test result OK
QMS	Quality Management System
RCV	Reference Change Value
RD	Reference document
MMI	Man Machine Interface

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# 3   Reminder of the integration of Valab® in the medical laboratory

The following overview shows the functional integration of Valab® in the laboratory process for the validation of patient test results.

Create report

measurement (analyser, microscope…)

technical validation

result validated technically ?
— no
— yes

Valab®

result validated biologically by Valab® ?
— no → Clinical scientist
— yes

Valab® operating mode?
— "consultative"
— "release"

result validated biologically by the Clinical scientist ?
— no
— yes

authorisation for release of the result validated by Valab® (Director / Clinical Scientist)

authorisation for release of the result validated by a clinical scientist (Director / Clinical Scientist)

release authorised ?
— no
— yes

release (printer, teletransmission, results server …)

Colour code :   Technical Validation   Biological Validation   Release Authorisation

![VALAB logo](Accreditation aid)

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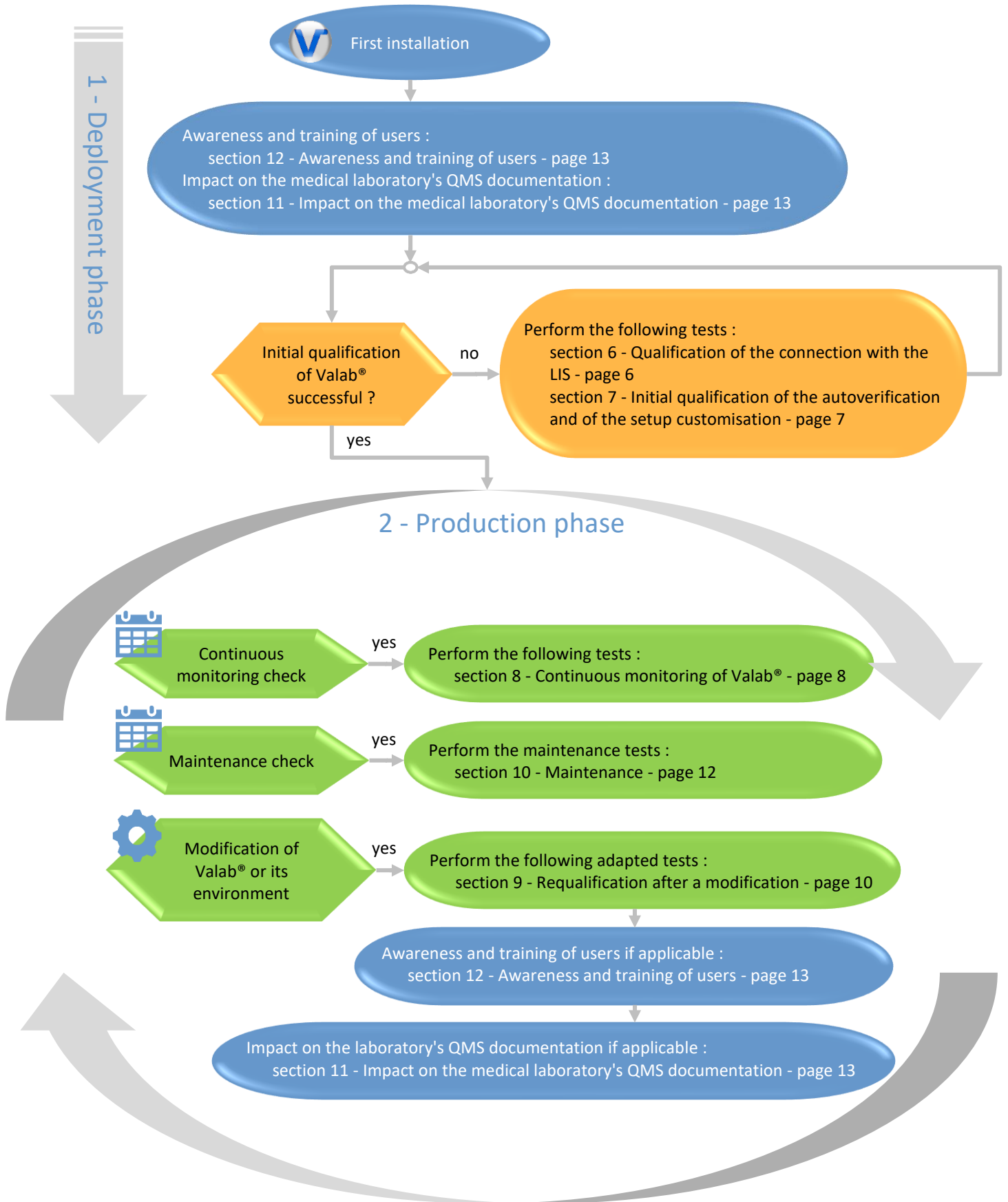Quality control, qualification and checks

4   Test context overview

The following schematic gives an overview of the major areas involved in the use of Valab® in your laboratory that are qualified by the procedure examples provided in the following chapters of this guide.

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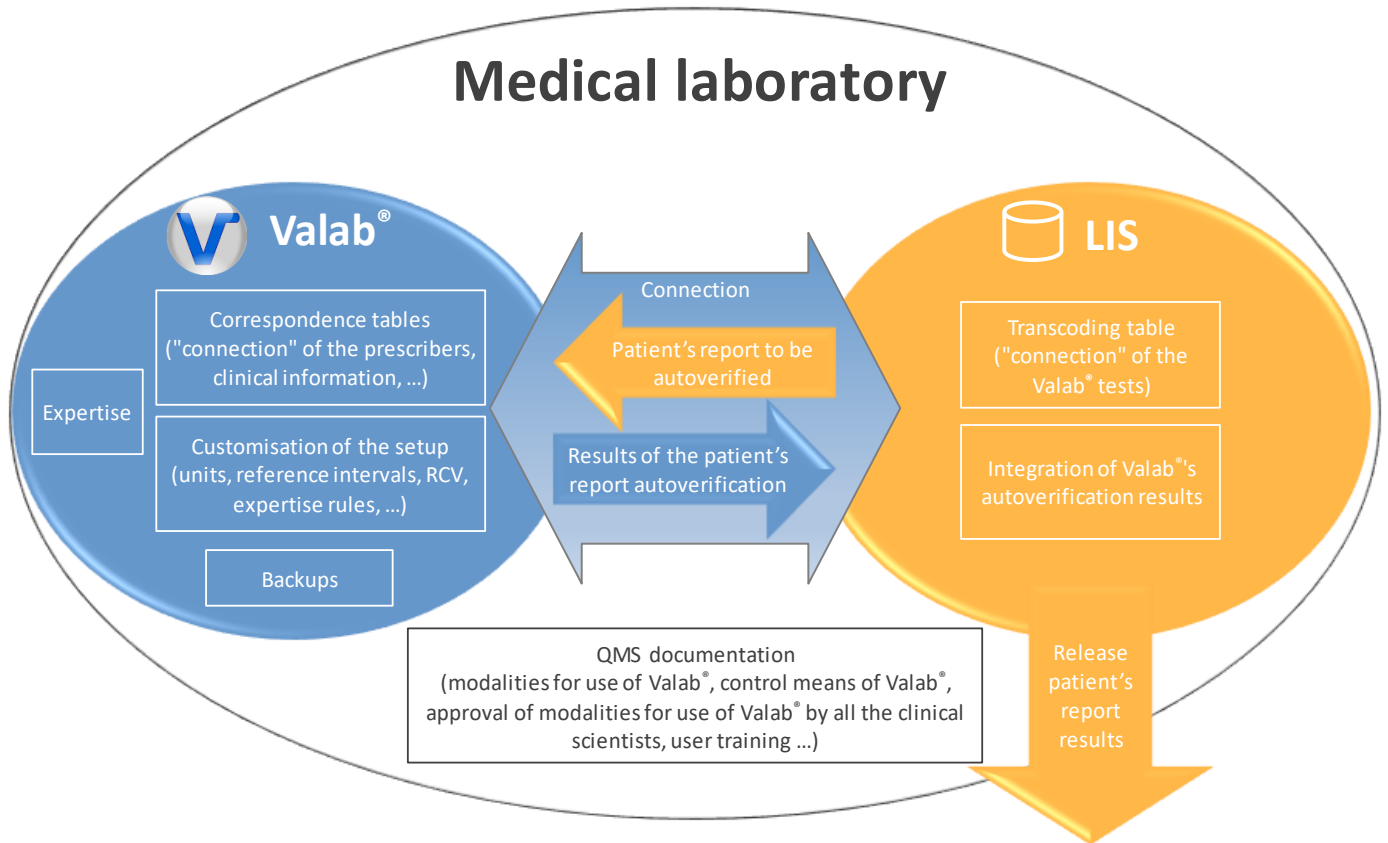
5   Overview of this guide – Life cycle

The following schematic gives an overview of this guide and indicates the sections applicable to the different situations of the life cycle of Valab® in the medical laboratory.

1 - Deployment phase

First installation

Awareness and training of users :
    section 12 - Awareness and training of users - page 13
Impact on the medical laboratory's QMS documentation :
    section 11 - Impact on the medical laboratory's QMS documentation - page 13

Initial qualification of Valab® successful ?

no → Perform the following tests :
    section 6 - Qualification of the connection with the LIS - page 6
    section 7 - Initial qualification of the autoverification and of the setup customisation - page 7

yes

2 - Production phase

Continuous monitoring check — **yes** → Perform the following tests :
    section 8 - Continuous monitoring of Valab® - page 8

Maintenance check — **yes** → Perform the maintenance tests :
    section 10 - Maintenance - page 12

Modification of Valab® or its environment — **yes** → Perform the following adapted tests :
    section 9 - Requalification after a modification - page 10

Awareness and training of users if applicable :
    section 12 - Awareness and training of users - page 13

Impact on the laboratory's QMS documentation if applicable :
    section 11 - Impact on the medical laboratory's QMS documentation - page 13

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6 Qualification of the connection with the LIS

Procedure used to qualify the connection between Valab® and the LIS of the medical laboratory. To be performed after the initial installation of Valab® and after certain modifications (see section 9 - "Requalification after a modification").

This procedure checks the following points:

▪ the validity of the transcoding table of the LIS used to "connect" the tests of the LIS to Valab®

▪ the correspondence of the test units between the LIS and Valab®

▪ the validity of the integration of the autoverification results of Valab® by the LIS (Valab® flags)

▪ the processing of a modified report

▪ the processing of a report entirely validated by Valab®

6.1 Test procedure

Step	result OK / NOK
In your LIS, create a test report containing all the medical tests connected to Valab® (if required, you can create several reports: Biochemistry, Haematology, Cockcroft man / woman, fluorinated tubes, . . .). Content of the test report(s): ▪ each test must have a different value (for example: test sequence number) ▪ report number, sex, last name, first name, date of birth ▪ a prescriber (speciality, FU,...) ▪ a therapeutic and clinical information item (chemotherapy, infarction, after dialysis,...) ▪ a technical comment (hemolysed sample, icteric plasma,...) ▪ date and time of day the sample was taken or, failing this, the date and time of day the request was entered	NA
▼ Step ① ▼	
Send this report to Valab® from the LIS [1].	NA
In Valab®, print out the report received (**File - Open PTD file**) - Enter the report N° - Click the **Refresh** button 🖼 - Double-click the desired file in the list - **Print**).	NA
In your LIS, check that the report is proposed to you in a biological validation session.	
Check that the report displayed in your LIS matches the report printed out by Valab®: ▪ for each medical test result: Value | Unit | Valab® autoverification result ▪ report number, sex, last name, first name, date of birth ▪ information concerning the prescriber (speciality, emergency context, hospital context) ▪ clinical information concerning the patient ▪ technical comment ▪ date and time of day the sample was taken or, failing that, of when the request was entered	
▼ Processing a modified report ▼	
In the LIS, modify a value of a medical test in a test report.	
Repeat Step 1 described above paying particular attention to the processing of the modified test.	
▼ Processing an entirely validated report ▼	
In the LIS, create a test report containing only one test connected to Valab® with a "normal" value and compatible clinical information (a "normally normal" report which should be validated by Valab®).	NA
Send this report to Valab® from the LIS [1].	NA
In Valab®, print out the report received (**File - Open PTD file - Print**).	NA
In the LIS, check that this report is proposed for authorisation for release by a qualified person or is released according to the requirements for the use of Valab® defined in the medical laboratory's QMS documentation. The full name of the medical clinical scientist is included on the released report.	

[1] As a general rule, the report is sent to Valab® as soon as the tests have been technically validated.

6.2 Record the results of the test

Keep a record (electronic file / pdf, paper) containing the printouts of the reports by Valab® and by the LIS if applicable, write on them the result of the test procedure and any useful comments, the date the test procedure was performed, and the full name of the qualified person who performed the test.

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7 Initial qualification of the autoverification and of the setup customisation

Procedure used to qualify the Valab® autoverification and setup customisation. To be performed after the initial installation of Valab® and, in a lighter version [1], after certain modifications.

This procedure checks the following points:

- the validity of the autoverification results provided by Valab®
- the validity of the customisation of the Valab® setup performed by the medical laboratory
- the correct processing by the LIS of the autoverification results provided by Valab®
- the acceptance of the use of the Valab® tool by the medical laboratory

The principle is based on use in consultative mode allowing a double validation of the reports (Valab® and the clinical scientist / pathologist). During this phase, the clinical scientists monitor the relevance of the autoverification performed by Valab® and finalise the customisation of the setup in order to obtain the most suitable operation for the population and the special characteristics and requirements of the medical laboratory (see the "Customisation of parameter settings" section of document **RD3** "Valab® Manufacturer's Information"). They are accompanied by the Biological Expertise Support Team of the VALAB Company.

After finalising the customisation of the setup, consultative mode is maintained by the medical laboratory for a period of activity or a volume of reports significant and necessary for the acceptance of the operation of Valab® (example time period: 15 days / example volume of reports: > 5000 reports for a medical laboratory processing 1000 reports per day).

7.1 Test procedure

Step	result OK / NOK
Activate the "Use Valab® in consultative mode" option if available in the LIS. If not, activate the global consultative mode option proposed by Valab® (**Autoverify mode - Consultative mode - On**).	NA
▼ For a period or a volume of reports to be defined by the medical laboratory ▼	
The clinical scientists, during their biological validation sessions on the LIS, check the relevance of the autoverification results returned by Valab®: - the medical test results which should not be validated by Valab® appear with an autoverification code "not validated by Valab®" when displayed by the LIS - the medical test results validated biologically by Valab® should in fact be validated - the contextual data (age, sex, prescribers, therapeutic and clinical information, complementary information) of the patients' reports is correctly taken into account by Valab®	
The clinical scientists check the global statistics (number and % of reports validated by Valab®) and also the coherence and / or consistency of the validation and refusal rates for each test (**View - Statistics** menu).	

[1] *When the test is played again following certain modifications (see section "9 - Requalification after a modification"), the phase of finalising the customisation of the setup is not applicable. The procedure is limited therefore to performing the steps of the above table on a limited volume of reports or over a limited period of time (e.g. 1 day).*

7.2 Record the results of the test

At the end of this period, the medical laboratory keeps a record (electronic file, pdf, paper printout) approved by a qualified person certifying that the biological validation assistance provided by Valab® has been qualified by the medical laboratory over a period of "X" weeks by using consultative mode corresponding to a check of the processing of "N" patient reports.

In particular the record must contain a list of the parameter settings of Valab® corresponding to the end of the qualification period (**View - Tests** menu, **Print / Export** button), the extracts of the Valab® logbook containing the modifications made during the qualification period (**View - Log** menu, select the period concerned, **Print / Export** button), the Valab® activity statistics for the acceptance period (**View - Statistics** menu, select the period concerned, **Print / Export** button), the results of the test procedure and any useful comments, the date the test procedure was performed, the full name of the qualified person who performed the test.

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8   Continuous monitoring of Valab®

Procedure used to continuously monitor Valab® to make sure that there is no drift in operation.

8.1   Test procedure

This procedure relies on 4 complementary assessment criteria described in the following paragraphs (monitoring of drift, relevance, reproducibility and the connection with the LIS).

8.1.1   Stability of the statistics

Extraction and analysis of the activity statistics in order to detect a possible drift. To be performed at a frequency to be defined by the medical laboratory (e.g. monthly or quarterly).

Step	result OK / NOK
Extract the activity statistics for the period since the last check (e.g. previous month, previous quarter,... - **View - Statistics** menu, select the period, click the **Print / Export** button).	NA
Check on the listing obtained that the overall statistic "NVR % of NER" (number of validated reports expressed as a % of the number of autoverified reports) is equal to the reference value defined by the medical laboratory [1] +/- a percentage defined by the medical laboratory (e.g. +/- 5%).	
Compare [2] the listing obtained with the one obtained during the last check in order to verify that: ▪ There is no drift of the column NDPV % of NPR for each test (number of times the test has been validated as a percentage of the number of reports containing the test).	
▪ The column (NER) of the parameter "Origin of the report" (% of reports verified containing a prescriber declared in the Valab® prescribers correspondence table) is close to 100%, or is close to or greater than the value measured during the last check.	
▪ The column (NER) percentages for the "Clinical and Therapeutic Information" and "Complementary Information" parameters globally reflect the percentages of patient reports of your medical laboratory containing respectively "Clinical and Therapeutic Information" and "Complementary Information", or are close to or greater than the values measured during the last check.	

[1] *The reference value is determined from the statistics of the initial qualification or revised during continuous monitoring or requalification actions for example.*

[2] *This comparison can be facilitated by using the "export in Excel format" functions proposed by Valab® from version 14.*

8.1.2   Sampling of patients' reports

Sampling of patients' reports to be checked by the clinical scientists after autoverification by Valab® (relevance check). To be performed at a frequency and on a volume of reports to be defined by the medical laboratory (e.g. 30 reports per month or "(square root of (number of reports processed per year)) / 12" reports per month).

Step	result OK / NOK
A number of sampling solutions are possible, some of which are listed below in descending order of effectiveness / relevance: ▪ Examine a series of reports generated by the LIS after autoverification by Valab® or; ▪ Activate the consultative mode of the LIS or, if this is not possible, activate the consultative mode proposed by Valab® (**Autoverify mode - Consultative mode - On** menu option) for a sufficient period of time (e.g. ½ day per month) or; ▪ Examine a series of reports using Valab's® Simulation mode (**File - Open PTD file**).	NA
The clinical scientists of the medical laboratory examine the sampled reports to check the relevance of the autoverification performed by Valab® (this allows in particular to check that the contextual data in the reports is correctly taken into account by Valab® - age, sex, prescribers, therapeutic and clinical information, complementary information, information about the sample): ▪ the reports and/or tests that should be blocked by Valab® are correctly blocked by Valab® ▪ the reports and/or tests validated by Valab® are rightfully validated	

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8.1.3 Pool of "test" reports

The use of a pool of "test" reports (set of reports for testing) allowing to monitor the reproducibility of the autoverification results provided by Valab®. To be performed at a frequency to be defined by the medical laboratory (e.g. every 6 months) and after certain modifications (see section 9 - "Requalification after a modification").

This pool of test reports is established once and for all by the medical laboratory witht the help of the Valab® Simulation mode (**View - Simulation**). The same pool of reports is used for each check in order to build a reference. It can however be adapted / enhanced according to any changes that have occurred between two checks (see section 9 - "Requalification after a modification"). The reports of the pool can for example contain critical or regulatory tests (e.g. K+, troponin, platelets, PO2, ßHCG, HIV, …) or frequently used tests.

Here is an example of a pool of test reports (see the examples provided in the directory "*Valab_directory*\POOL_CQ"):

content of the reports	points verified
A report for which all the tests have a high critical value.	Valab® "P" flag
A report for which all the tests have a low critical value (if applicable).	Valab® "P" flag
Several reports containing tests with results which have been chosen for their alert value or critical value and their capacity to allow the rules to operate in a complex situation. These reports can for example correspond to typical reports of the medical laboratory with values situated just outside the limits of Valab®'s validation criteria.	Valab® "P", "C", "A", "D" and "V" flags
Several reports judged to be validatable by Valab®. These reports can for example correspond to typical reports of the medical laboratory with values situated just below the limits of Valab®'s validation criteria.	Valab® "V" flag

Step	result OK / NOK
For each test report of the pool: ▪ Autoverify the report in Simulation mode in Valab (**File - Open PTD file**) ▪ Check that the autoverification flag for each test in the "test" report corresponds to what is expected	

8.1.4 Connection with the LIS

Check of the connection with the LIS. To be performed at a frequency to be defined by the medical laboratory (e.g. every 18 months).

Step	result OK / NOK
▪ If the test described in section 6 - "Qualification of the connection with the LIS" was run less than 18 months ago as part of a requalification after a modification, re-schedule a check of the connection with the LIS on "the date when the test of section 6 was last run + the period defined by the medical laboratory (e.g. +18 months). ▪ If not, run the test described in section 6 - "Qualification of the connection with the LIS".	

8.2 Record the results of the test

Keep a record (electronic file, pdf, paper) corresponding to the checks carried out:

▪ the listing of the statistics provided by Valab® and/or

▪ the length of time operated in consultative mode and the corresponding number of reports and/or the list of sample reports and/or

▪ the list of the reports in the test pool and/or

▪ the recording of the test described in section 6 - "Qualification of the connection with the LIS".

Indicate on these documents the results of the test procedure and any useful comments, the date the test procedure was performed, and the full name of the qualified person who performed/supervised the test.

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9 Requalification after a modification

Requalification procedures following a modification of Valab® or of its environment. The list of modifications envisaged here is not exhaustive and the procedures applied should be adapted and evaluated by the medical laboratory according to the modification and its potential impact.

9.1 Test procedure

The following paragraphs describe the test procedure to be applied according to the modification.

9.1.1 Change of Valab® version

Step	result OK / NOK
Prior to the update, extract the part of the log containing the latest important modifications made to Valab® (i.e. that may have an impact on autoverification results): biological setup, autoverification rules, correspondence tables, ... (**View - Log**, select the period concerned, **Print/Export** button).	NA
After the update, check that the "Sys" indicator on the Valab lower panel is not magenta and doesn't indicate any errors.	
Use the extract made previously of the log to check that the modifications are still applied in the settings (**View - Tests** menu option, **Correspondence tables - Manage correspondence tables** menu option, . . .).	
▼ Step ① ▼	
In the case of a major version change (e.g. V11.xx to V12.xx): ▪ Run the test described in section 6 - "Qualification of the connection with the LIS" ▪ Run the test described in section 8.1.3 - "Pool of "test" reports" ▪ Run, in a lighter version (e.g. consultative mode over 1 day only), the test described in section 7 - "Initial qualification of the autoverification and of the setup customisation"	
In the case of a minor version change (e.g. Vxx.01 to Vxx.02/03/04), on the basis of a risk analysis corresponding to the modifications made by the minor version(s) (see the release note for the minor version(s)), evaluate the need to re-run all or part of the tests listed in step ①.	

9.1.2 Backup restore after an incident

Step	result OK / NOK
After the restore, extract the part of the log containing the latest important modifications made to Valab® (i.e. that may have an impact on autoverification results): biological setup, autoverification rules, correspondence tables . . . (**View - Log** - select the period concerned - **Print/Export** button).	NA
Use the extract of the log made previously to check that the modifications do in fact correspond to the latest important modifications made to Valab® (refer to your traceability records: continuous monitoring of Valab®, initial qualification / requalification of Valab®, …).	
Use the extract of the log made previously to check that these modifications are still applied in the settings (**View - Tests** menu option, **Correspondence tables - Manage correspondence tables** menu option, . . .).	
Run the test described in section 8.1.3 - "Pool of "test" reports".	

9.1.3 Change of LIS version or change of LIS

Step	result OK / NOK
See the recommendations of the LIS provider.	
In the case of a change of LIS version, run the test described in section 6 - "Qualification of the connection with the LIS".	
In the case of a change of LIS, please contact your VALAB Technical Support person to find out if a VALAB Technical Support intervention is necessary to allow reconnection.	

9.1.4 New analyser or connection to a new analyser having an impact on your Valab® setup

Step	result OK / NOK
Run the test described in section 9.1.5 - "Modification of the Valab setup".	

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9.1.5 Modification of the Valab setup

Requalification procedure following a modification [1] of the Valab® parameter settings for a single test or a group of tests (e.g. units, limit values, RCV, autoverification rules, sensitivity settings, new analyser,...), or following the connection of a new test to Valab® (e.g. adding a new Auto-Expert test, connecting a new analyser,...).

The following points are qualified by this procedure:

- the validity of the autoverification results provided by Valab® for the test(s) concerned
- the correct processing by the LIS of the autoverification results provided by Valab® for the test(s) concerned
- the acceptance of the use of the Valab® tool by the medical laboratory for the processing of the test(s) concerned

This check is based on the activation in Valab® of consultative mode for a specific test which allows a double validation of the reports containing the test(s) in consultative mode. During this phase, the clinical scientists check the relevance of the autoverification results returned by Valab® for the reports containing this/these test(s).

This test-specific consultative mode is kept active by the medical laboratory for the length of time necessary for the acceptance of the use of Valab® (e.g. 1 week).

Step	result OK / NOK
Assess the impact of the modifications on the tests described in section 6 - "Qualification of the connection with the LIS" and section 8.1.3 - "Pool of "test" reports". Re-run these tests if required.	
Activate consultative mode for the specific test(s) concerned (**View - Tests** - double-click the test(s) concerned - check the **Biology - Consultative mode** checkbox).	NA
▼ Over a period of time or volume of reports to be defined by the medical laboratory ▼	
The clinical scientists, during their biological validation sessions on the LIS, check the relevance of the autoverification results returned by Valab®: ▪ the tests which should be blocked by Valab® are displayed as "blocked by Valab®" on the LIS, in particular for the test(s) concerned ▪ the tests biologically validated by Valab® are rightfully validated, in particular the test(s) concerned ▪ the contextual data of the patients' reports is correctly taken into account by Valab® (age, sex, prescribers, therapeutic and clinical information, complementary information), in particular for the test(s) concerned	
The clinical scientists check the statistics (**View - Statistics**) in order to validate the global statistics (% of reports validated by Valab®), the number of patients' reports containing the test(s) concerned (NPR column of the activity statistics), and the coherence and/or consistency of the validation or refusal rates for each test, in particular for the test(s) concerned.	

[1] *If the modification consists of a restriction of the operation of Valab® for one or more of the settings listed below and if the medical laboratory accepts the risk of making Valab® less effective, the requalification can be limited to simply checking that there haven't been any entry errors by checking after their entry that the new settings correspond to those desired by the medical laboratory:*

- *reduced RCV value*
- *activation of or reduced maximum delta value*
- *activation of or reduced critical maximum delta value*
- *reduced sensitivity*
- *narrowing of the validation limits for a result with no previous result*

With regard to the reference intervals and critical limits, possible side effects affecting the inter-parametric autoverification rules and/or the autoverification trends, mean that we cannot guarantee that the consequences will be systematically restrictive.

9.2 Record the results of the test

Keep a record (electronic file, pdf, paper printout) approved by a qualified person certifying that the biological validation assistance provided by Valab® has been requalified by the medical laboratory following a modification. The record must in particular contain the records specified in the different sections for the different tests run, the description of the modification which made the requalification necessary, the results of the test procedure and any useful comments if applicable, the date on which the test procedure was performed, and the full name of the qualified person who performed/supervised the test.

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10 Maintenance

To guarantee correct operation of the system, Valab® maintenance operations must be performed at regular intervals.

This paragraph provides a procedure describing the different maintenance operations.

10.1 Maintenance procedure

Step	result OK / NOK
Correct any Valab® correspondence table errors if required (**Correspondence tables - Manage correspondence table errors**).	
Check a sample of the content of the Valab® correspondence tables (**Correspondence tables - Manage correspondence tables**). Check that the content of the correspondence tables is consistent with the coded text (labels) sent to Valab® by the LIS.	
Check and correct any connection errors between Valab® and the LIS if required (click the **Ms-Cx** button on the Valab® lower panel).	
Check and correct any Valab® system errors if required (click the **Sys** button on the Valab® lower panel).	
Extract the part of the log containing the modifications made since the last maintenance session (**View - Log**, select the period concerned, **Print/Export** button).	NA
Using the printout, check and approve the modifications made to Valab® since the last check.	
Make sure that the solution implemented to back up the Valab® data is functional (see document **RD6** "Valab® - Backup and Restore").	

10.2 Record the results of the maintenance

Keep a record (electronic file, pdf, paper printout) containing the extract of the logbook, the acceptance of any modifications to the parameter settings, indicate on them the results of the maintenance procedure and any useful comments, the date the procedure was performed, and the full name of the qualified person who performed the procedure.

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11 Impact on the medical laboratory's QMS documentation

11.1 Formalise the way that the Valab® software is used

The medical laboratory must formalise in its QMS documentation the way that the Valab® computer aided validation software is used. To this end it must in particular, indicate that it uses the Valab® computer aided validation software, describe the conditions of service in which the tool is implemented and define the responsibility of the clinical scientist and also the conditions of authorisation of release of the results reports.

In all cases, it is important to indicate that all the medical test results released by the medical laboratory are done so under the responsibility of the clinical scientist, including those verified with the help of the Valab® computer aided validation software. In this respect, all the results reports issued by the medical laboratory are considered to have been validated by the clinical scientist and must bear his/her signature (first name, last name and signature configured in the LIS). Inscriptions of the form "validated by expert system" are not acceptable.

11.2 Identify the means of control of the Valab® software

The internal procedures of the medical laboratory must be adapted in order to describe the procedures set up to qualify, requalify, monitor and maintain the Valab® tool. The corresponding recording of results and their archiving must also be defined.

The medical laboratory must describe, in the appropriate procedure, how to activate / deactivate Valab® and how to choose the desired Valab® operating mode, "consultative" or "release".

After any modification of a parameter setting in the LIS, the medical laboratory must evaluate the need for modification in Valab® (units, correspondence tables, …) and vice-versa. It is important that the medical laboratory adapts its internal procedures at this level.

In case of operating problems detected when running a test / maintenance procedure, the laboratory must implement appropriate corrective action.

11.3 Record for traceability purposes the approval of the requirements for the use of Valab® by all of the clinical scientists

All of the clinical scientists that will use the Valab® computer aided validation software must have approved all of the requirements for its use. This approval must be recorded for traceability purposes.

12 Awareness and training of users

12.1 Training of users

All laboratory personnel who use the Valab® software must be trained on how it works and how to use it. For this purpose, when Valab® is installed, the future key-contact users of the system are trained by an agent of the VALAB company.

The term "user" must be understood in a broad sense, to cover not only the direct users of Valab® (key contact staff authorised to set up, check or otherwise interact with the software), but all the laboratory staff validating reports containing tests connected to Valab®.

At this level the medical laboratory must make provision to integrate the training actions concerning the Valab® software into the training plan of the personnel concerned. Training is recommended both for new users and for existing users when they update to a new major release of Valab®. The traceability of these training actions must be recorded and archived.

12.2 Awareness of the users

As a complement to the means of control of Valab® implemented and formalised by the medical laboratory, it must be remembered that a "natural" review of the autoverification results provided by Valab® for each test result of a patient's report is performed informally by the clinical scientist during his/her biological validation sessions within the LIS (display of the Valab® autoverification flags in the LIS).

This informal review is carried out on all of the reports when Valab® is used in "consultative" mode, and on the reports not validated when it is used in "release" mode.

It is important to make the clinical scientists aware of this informal review.