# Qualification of Valab® by the Medical Laboratory

## Quality control, qualification and checks

Ref. VAL-ACC-09
Ed./Rév. 4/A
Date 10/12/2025



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## Contents



# Objective

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 "Valab® Manufacturer's Information for Medical Laboratory Accreditation" (**RD2**) 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 (**RD3**) and Valab® Developer Manual (**RD4**) 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.

# References

## Update impact

Update of the document for Valab® version 16. Main modification is the addition of chapter "Optimize the efficiency and the monitoring of your Valab® with the BI module ValView".

## Valab® website 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.

## Reference documents

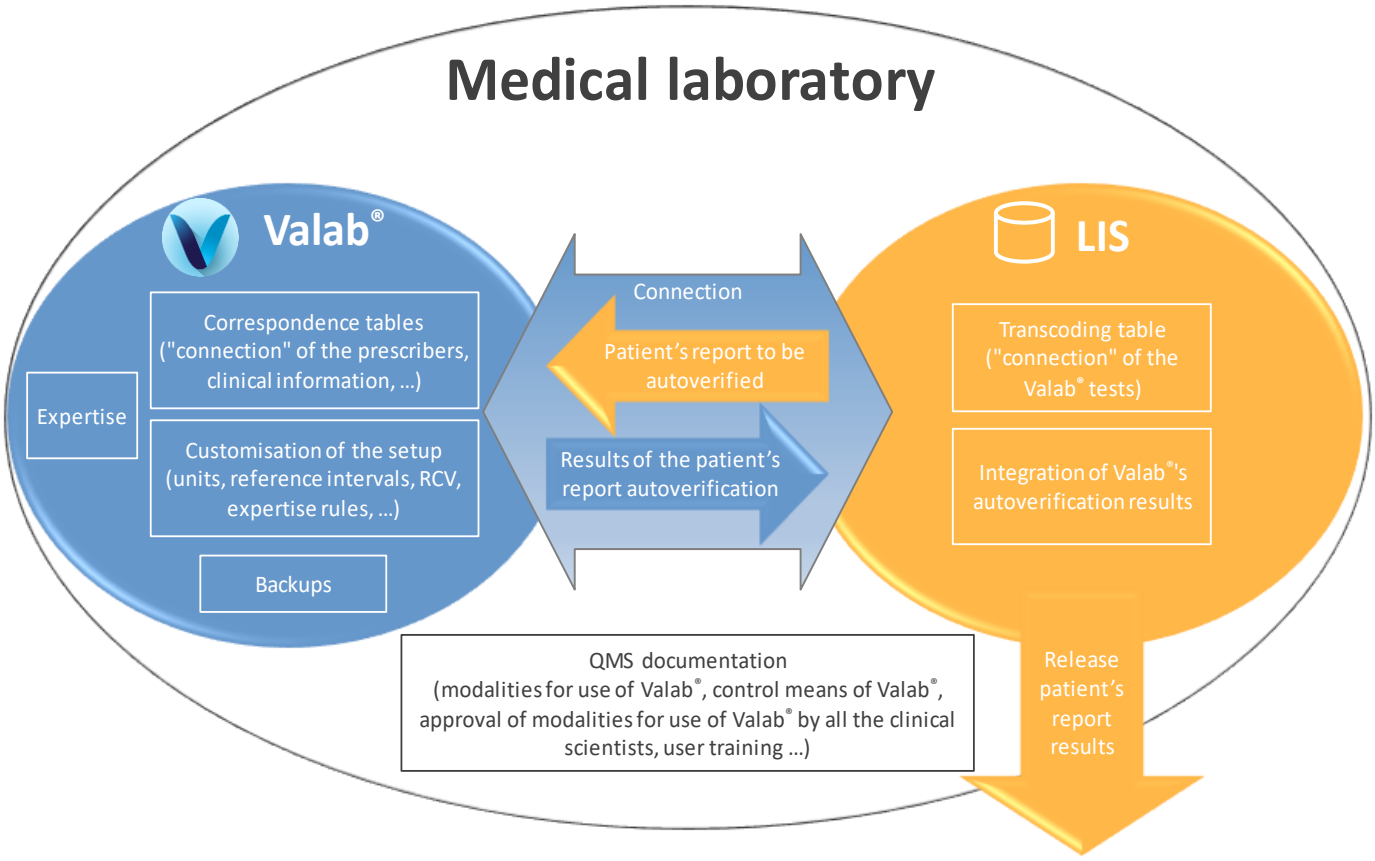
| | |
|---|---|
| **RD1** | Medical laboratories — Requirements for quality and competence ● ISO 15189 |
| **RD2** | Valab® Manufacturer's Information for Medical Laboratory Accreditation (available at www.valab.com) |
| **RD3** | Valab® User Manual (provided in Valab® "DOC" subdirectory) |
| **RD4** | Valab® Developer Manual (provided in Valab® "DOC" subdirectory) |
| **RD5** | Valab® - Backup and Restore (available at www.valab.com) |
| **RD6** | Manuel Qualité VALAB (Valab Quality Manual - only available in French) (available at www.valab.com) |
| **RD7** | Privacy Policy of the VALAB Company (available at www.valab.com) |
| **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 |
| **RD13** | General data protection regulation (GDPR) ● Regulation (EU) 2016/679 |

## Acronyms

| Acronyms | Meaning |
|---|---|
| **LIS** | Laboratory Information System |
| **ML** | Medical Laboratory |
| **NA** | Not Applicable |
| **NOK** | Test result Not OK |
| **OK** | Test result OK |
| **QMS** | Quality Management System |
| **RCV** | Reference Change Value |
| **RD** | Reference Document |

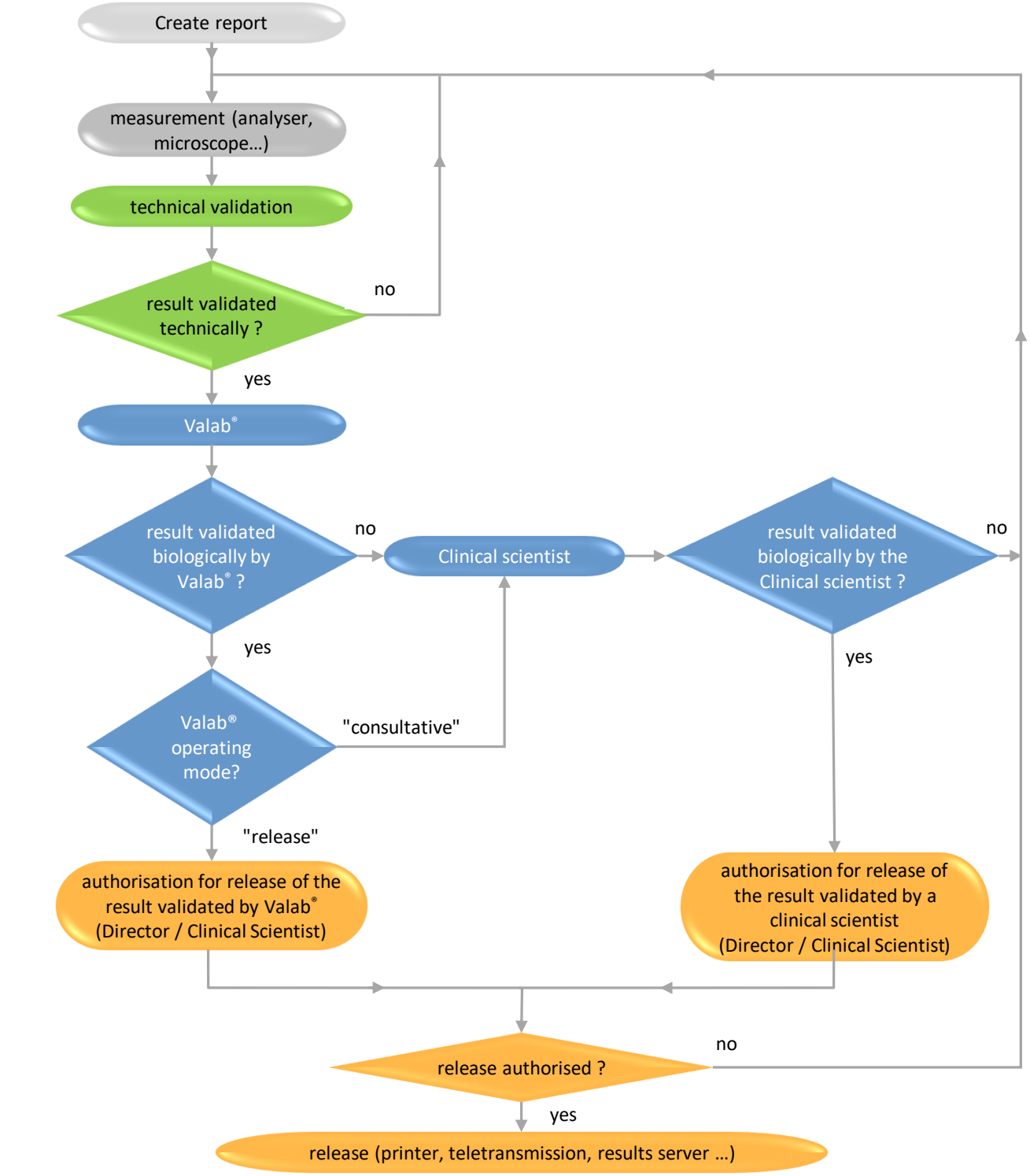
# Test context overview

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.



# Valab® integration into the ML

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

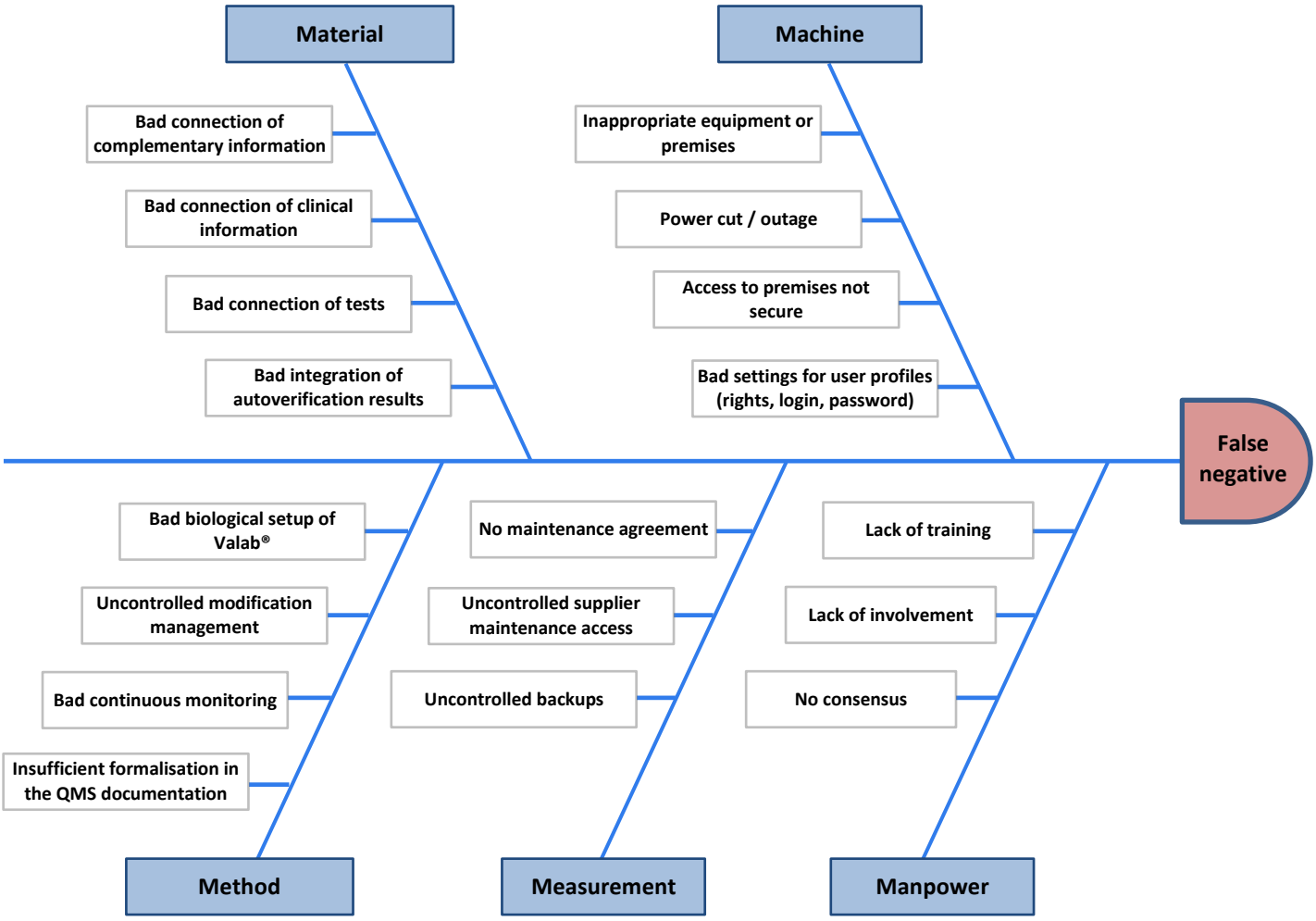


# Example of a Valab® Risk Analysis

The most critical risk identifiable for Valab® would be the automatic biological validation or the automatic release of an "incorrect" result or of a result that the clinical scientist would have liked to have validated manually.

We will call this undesirable effect a "false negative".

The 5M method presented in the form of a cause-and-effect diagram (Ishikawa) allows first of all to identify the different major causes possibly resulting in this undesirable "false negative" effect.




In a second phase, the FMECA method (Failure mode, effects and criticality analysis) allows to classify the different causes identified above in terms of criticality (gravity, frequency and detectability) with regard to the Quality monitoring system that has been set up.

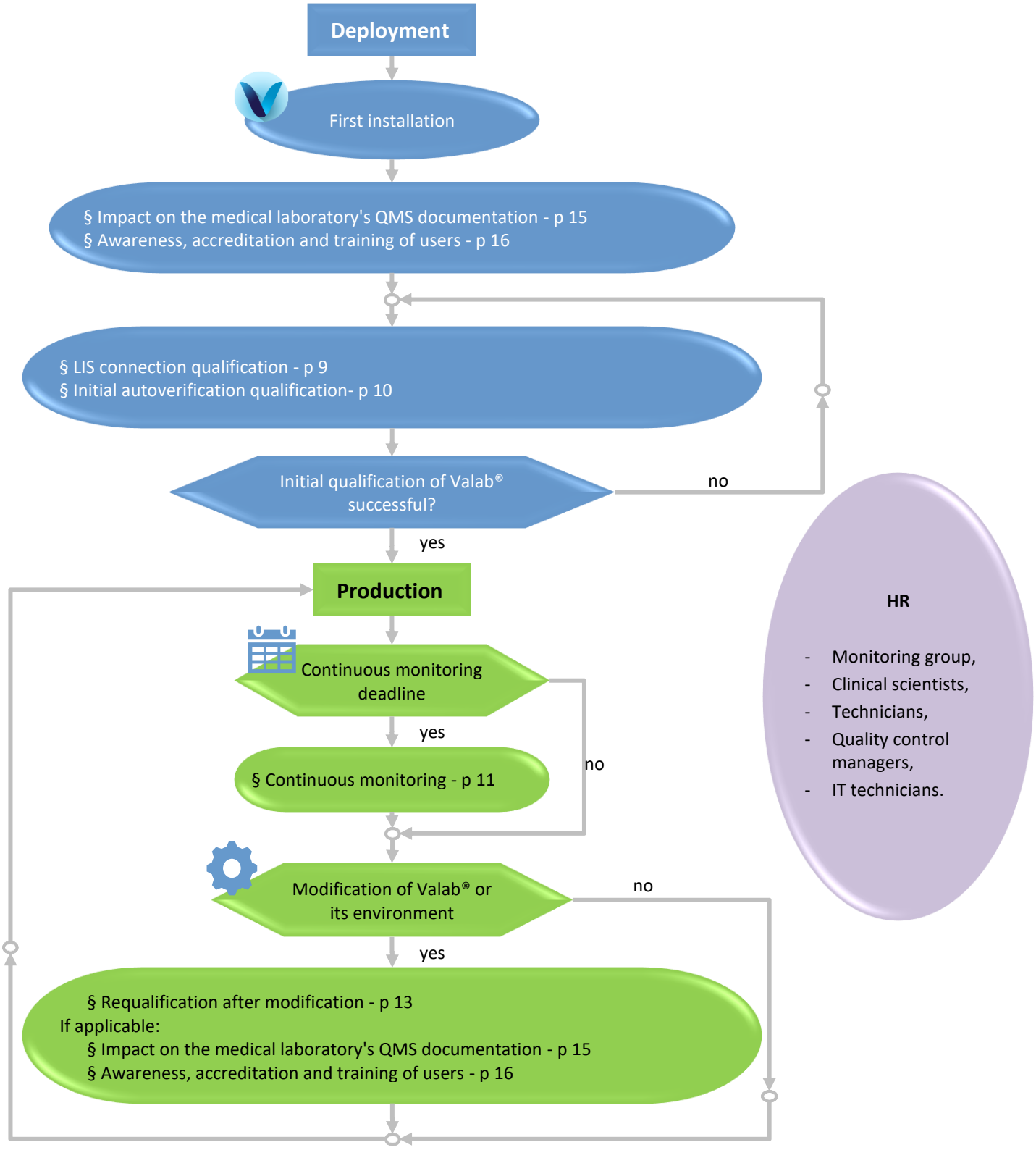
G = Gravity / F = Frequency: 1 = low, 2 = medium, 3 = high, 4 = very high
D = Detectability: 1 = very high, 2 = high, 3 = medium, 4 = low

| Potential defect | 5M | Causes | G | F | D | Criticality | Means of control |
|---|---|---|---|---|---|---|---|
| False negative | Material | Bad connection of complementary information | 2 | 3 | 2 | 12 | Qualification of the connection / Data integrity<br>Operating procedures for the setup of complementary information, clinical information and tests in the LIS in order to maintain consistency between the LIS and Valab® (meaning of coded text, test units...)<br>Do not use free text for complementary information and clinical information<br>Activate blocking of reports containing complementary information or clinical information not known by Valab<br>Systematic blocking of tests not known by Valab® |
| | | Bad connection of clinical information | 2 | 3 | 2 | 12 | |
| | | Bad connection of tests | 4 | 2 | 1 | 8 | |
| | | Bad integration of autoverification results | 4 | 2 | 2 | 16 | Qualification of the connection / Data integrity<br>Choice of operating mode (Consultative / Release) |
| | Machine | Inappropriate equipment or premises | 3 | 1 | 1 | 3 | Respect supplier's recommendations |
| | | Power cut / outage | 3 | 2 | 1 | 6 | Redundant server. Inverter.<br>Contingency plan. Maintenance agreement |
| | | Access to premises not secure | 4 | 1 | 1 | 4 | Server in room with secure access |
| | | Bad settings for user profiles (rights, login, password) | 4 | 2 | 1 | 8 | One account per user with the appropriate rights<br>Password renewal |
| | Method | Insufficient formalisation in the QMS documentation | 3 | 2 | 1 | 6 | Formalisation of the different ways to use Valab® and definition of the responsibility of the clinical scientist and the conditions for authorisation of the release of the test result reports (periods of on-call duty, simple / routine reports, ...)<br>Describe the procedures set up to qualify, requalify, monitor and maintain Valab®. Describe how to activate / deactivate Valab and how to choose the "consultative" or "release" Valab® operating mode<br>Formalise modification management |
| | | Bad continuous monitoring | 4 | 2 | 2 | 16 | Internal quality control of Valab® |
| | | Uncontrolled modification management | 4 | 3 | 1 | 12 | Requalification after modification (Valab®, LIS, new analysers, ...)<br>Traceability of modifications |
| | | Bad biological setup of Valab® | 4 | 3 | 1 | 12 | Customisation of the initial Valab® setup. Initial qualification of Valab<br>Train key-contact users for setup |
| | Measurement | Uncontrolled backups | 3 | 1 | 1 | 3 | Qualification of backups. Remote backups |
| | | Uncontrolled supplier maintenance access | 3 | 2 | 1 | 6 | Setting up of a secure remote maintenance access<br>Opening of access to remote maintenance by the medical laboratory<br>Traceability of interventions |
| | | No maintenance agreement | 3 | 1 | 1 | 3 | Setting up of maintenance agreement |
| | Manpower | No consensus | 3 | 1 | 1 | 3 | Participation of all of the clinical scientists during the customisation of the initial Valab® setup<br>Participation of all of the clinical scientists during the initial qualification of Valab®<br>Creation of a board of key contact persons for Valab (at least one clinical scientist per family) |
| | | Lack of involvement | 4 | 2 | 1 | 8 | Setting up of the signatures of the persons responsible for biological validation on the reports of results validated by Valab according to the site, test families and biological validation schedule |
| | | Lack of training | 4 | 2 | 1 | 8 | Training of users |

| Colour code: | | |
|---|---|---|
| | risk controlled | [1; 16] |
| | risk to be monitored | ]16; 32] |
| | high risk | > 32 |

# 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.



# LIS connection qualification

To be performed after the initial installation of Valab® and after certain modifications.

This procedure qualifies 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 by the LIS (Valab® flags), the processing of a modified report, a report validated with Valab® and a report blocked by Valab®.

## Test procedure

| Step | OK / NOK |
|---|---|
| In your LIS, create a test report with all the medical tests connected to Valab® (if required, you can create several reports: Biochemistry, Haematology, fluorinated tubes...). Content of the test report(s):<br>▪ Each test must have a different value (for example: test sequence number);<br>▪ Report number, date of sampling, sex, patient identification, date of birth;<br>▪ A prescriber (specialty, service..), a therapeutic and clinical information item (chemotherapy, infarction, after dialysis...), a technical comment (haemolysed sample, icteric plasma...) | NA |
| ▼ Step ① ▼ | |
| Send this report to Valab® from the LIS [(1)]. | NA |
| In Valab®, print out the report received (File / Open PTD file - Print). | NA |
| In your LIS, check that the report is not released and is proposed to you in a biological validation session. | |
| Check that the report displayed in your LIS matches the report printed out by Valab®:<br>▪ For each medical test result: Value \| Unit \| Valab® autoverification result[(2)];<br>▪ Report number, date of sampling, sex, patient identification, date of birth;<br>▪ Information concerning the prescriber (specialty, emergency context, hospital context), clinical information concerning the patient and technical comment. | |
| ▼ 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 a 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 depending on the Valab® operating mode that this report is proposed:<br>▪ During the biological validation session => “consultative” mode;<br>▪ During the release session or when released according to the requirements for the use of Valab® defined by the medical laboratory. The full name of the clinical scientist is included on the released report => “release” mode. | |

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

*[(2)] If you are using Linked, Redirected or Blind tests, note that those are not directly displayed in the Valab® Simulation window. However, you may check on them by clicking the “History” button of that window.*

## Record the results of the test

Keep a record containing the printouts of the reports by Valab® and by the LIS if applicable, write on them the result of the test and any useful comments, the test date and the full name of the tester.

# Initial autoverification qualification

To be performed after the initial installation of Valab® and, in a lighter version [1], after certain modifications.

This procedure qualifies the validity of the autoverification results, the validity of the customisation of the setup, the correct processing of the autoverification results by the LIS, the acceptance of the use of Valab® by all the clinical scientists and the transition to the production phase.

The principle is based on the use of Consultative mode, which enables double validation of reports (Valab® and the clinical scientist). During this phase, the clinical scientists monitor the relevance of the autoverification performed by Valab® and finalize the customisation of the setup in order to obtain the desired operation. They are accompanied by the Biological Expertise Support Team of the VALAB Company and / or by the distributor [2].

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

## Test procedure

| Step | OK / NOK |
|---|---|
| Activate the consultative mode in the LIS. Or else, activate the consultative mode proposed by Valab®. | NA |
| ▼ Over a period of time or volume of reports to be defined by the medical laboratory ▼ | |
| During the LIS biological validation, clinical scientists verify the relevance of the Valab® autoverification:<br>▪ 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;<br>▪ The medical test results validated biologically by Valab® should in fact be validated;<br>▪ The contextual data of the patient reports is correctly taken into account by Valab® (age, sex, prescribers, therapeutic and clinical information, complementary information). | |
| The clinical scientists check the global statistics (number and % of reports validated by Valab®) and the coherence and/or consistency of the validation/refusal rates for each test[2]. | |
| ▼ Qualification successful, transition to production phase ▼ | |
| Record the approval of Valab® usage requirements by all clinical scientists for traceability (see section "Record the approval of Valab® usage requirements by all clinical scientists for traceability"). | |
| Run the part "▼ Processing a validated report ▼" from section "LIS connection qualification" paying particular attention to the different reports disseminated both internal and external. | |
| In the LIS, create a test report containing only one medical test connected to Valab® with a critical value. Send this report to Valab® from the LIS [1].<br>In Valab®, print out the report received (File - Open PTD file - Print).<br>In your LIS, check that the report is not released and is proposed to you in a biological validation session. | NA |

*[1] When the test is run again following certain modifications (see section "Requalification after 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 (e.g. 1 day).*

*[2] The statistics monitoring and analysis are facilitated with the optional BI module ValView (see section "Optimize the efficiency and the monitoring of your Valab® with the BI module ValView").*

## Record the results of the test

At the end of this period, the medical laboratory keeps a record 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, the extracts of the Valab® logbook containing the modifications made during the qualification period, the Valab® activity statistics for the acceptance period, the printouts of the Valab® test reports, the results of the test and any useful comments, the test date and the full name of the tester.

# Continuous monitoring

## Test procedure

This procedure relies on 5 complementary assessment criteria, the monitoring of drift, reproducibility, relevance, connection with the LIS and maintenance.

## Stability of the statistics / Drift

To be performed at a frequency to be defined by the ML (e.g. monthly or quarterly).

| Step | OK / NOK |
|---|---|
| Extract the statistics for the period since the last check and compare [2] the obtained listing with the one obtained during the last check in order to verify that:<br>▪ The overall statistic "NVR % of NER" (number of validated reports as a % of the number of autoverified reports) is equal to the reference value ± a percentage defined by the medical laboratory (e.g. ±5%); | |
| ▪ The ratio NER/NRR from the overall statistic (number of autoverified reports / number of received reports) is close to 1 or is close to or greater than the value from the last check; | |
| ▪ Column (NER): the parameter "Origin of the report" (% of reports verified containing a prescriber declared in the Valab® prescribers table) is close to 100%, or is close to or greater than the value from the last check; | |
| ▪ Column (NER): the percentages for the "Clinical and Therapeutic Information" and "Complementary Information" parameters globally reflect the percentages of patient reports of your medical laboratory containing these types of information respectively, or are close to or greater than the values measured during the last check. | |

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

*[2] The statistics monitoring and analysis are facilitated with the optional BI module ValView (see section "Optimize the efficiency and the monitoring of your Valab® with the BI module ValView").*

## Pool of "test" reports / Reproducibility

To be performed at a frequency defined by the ML (e.g. every 6 months) and after certain modifications.

The pool is established once to be used as a reference. It can however be adapted according to any changes that have occurred between two checks. It contains "test" reports and / or anonymized patients reports.

| Content of the reports | Points checked |
|---|---|
| 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 |
| 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. (e.g. typical reports of the medical laboratory with values situated just outside the limits of validation criteria, or reports with critical or regulatory tests like K+, troponin, platelets…) [1]. | Valab® "P", "C", "A", "D" and "V" flags |
| Several reports judged to be validated by Valab®. (e.g. typical reports of the medical laboratory with values situated just below the limits of Valab®s validation criteria). | Valab® "V" flag |

[1] Some examples of basic *quality control* reports are available as an example in the directory "Valab_directory\POOL_CQ".

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

## Sampling of patients' reports / Relevance

To be performed at a frequency and on a volume of reports to be defined by the ML (e.g. 30 reports per month or "(square root of (number of reports processed per year)) / 12" reports per month).

| Step | OK / NOK |
|---|---|
| Examples of possible sampling solutions. Listed in descending order of effectiveness / relevance:<br>▪ Examine a series of reports generated by the LIS after autoverification by Valab® or;<br>▪ Activate the consultative mode of the LIS or, failing that, the one of Valab® (Autoverify mode - Consultative mode - On) for a sufficient period (e.g. ½ day per month) or;<br>▪ Examine a series of reports using Valab®s Simulation mode. | NA |
| The clinical scientists of the ML examine the sampled reports to check the relevance of the autoverification (this allows 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):<br>▪ The reports and tests that should be blocked by Valab® are correctly blocked by Valab®<br>▪ The reports and tests validated by Valab® are rightfully validated | |

## 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 | OK / NOK |
|---|---|
| If the test described in section "LIS connection qualification" was already run less than 18 months ago, re-schedule a check of the connection with the LIS on "the date when the test was run + the period defined by the medical laboratory (e.g. +18 months)".<br>If not, run the test described in section "LIS connection qualification". | |

## Maintenance

Valab® maintenance operations to be performed at regular intervals by the Medical Laboratory.

| Step | OK / NOK |
|---|---|
| Correct any Valab® correspondence table errors if required (Correspondence tables menu). | |
| Check on a sample of the correspondence tables (Correspondence tables menu) that the content is consistent with the labels sent to Valab® by the LIS. | |
| Check and correct any connection errors between Valab® and the LIS (Ms-Cx button on the Valab® lower panel). | |
| Check and correct any Valab® system errors if required (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 **RD5** "Valab® - Backup and Restore"). | |

# Record the results of the test

Keep a record corresponding to the checks carried out, the listing of the statistics provided by Valab® and/or the list of the reports in the test pool 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 recording of the test described in section "LIS connection qualification" and/or the listing of the logbook worth the acceptation of potential setting modifications. Indicate on these documents the results of the test and any useful comments, the test date and the full name of the tester.

# Requalification after modification

## Test procedure

### Change of Valab® version

| Step | OK / NOK |
|---|---|
| *Note: The VALAB company proposes an "Implementation and qualification by remote servicing of the Valab® updating supplied with the qualification report." This servicing covers the functional non regression, it exempts you from running the tests from this paragraph.*<br>*You must therefore keep the report supplied and, in addition, realise a simple check of the reboot by verifying the compliance of the autoverification on some patient reports after reboot.* | |
| 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... | NA |
| After the update, check that the "Sys" button on the lower panel is not magenta. | |
| Use the extract made previously of the log to check that the modifications are still applied in the settings (View - Tests, Correspondence tables - Manage correspondence tables, ...). | |
| ▼ Step ① ▼ | |
| In the case of a major version change (e.g. V15.xx to V16.xx):<br>a. Run the test described in section "LIS connection qualification";<br>b. Run the test described in section "Pool of "test" reports / Reproducibility";<br>c. Run, in a lighter version (e.g. consultative mode over 1 day only), the test described in section "Initial autoverification qualification". | |
| In the case of a minor version change (e.g. Vxx.01 to Vxx.02), evaluate the need to re-run all or part of the tests listed in step ①, based on a risk analysis of the modifications made between the versions (see the release notes). | |

### Backup restore after an incident

| Step | 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... | 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, Correspondence tables - Manage correspondence tables.) | |
| Run the test described in section "Pool of "test" reports / Reproducibility". | |

### Change of LIS version or change of LIS

| Step | OK / NOK |
|---|---|
| See the recommendations of the LIS provider. | |
| In the case of a change of LIS version, run the test described in section "LIS connection qualification". | |
| 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. | |

### New analyser or changes to an analyser having an impact on your Valab® setup

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

# Modification of the Valab setup

Requalification 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,...), or following the connection of a new test to Valab®.

This procedure qualifies: the validity of the autoverification results provided by Valab®, 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 for the processing of the test(s) concerned.

This check is based on the use of Consultative mode on the test(s) concerned by the change, which allows a double validation of the reports containing the aforementioned. During this phase, the clinical scientists check the relevance of the autoverification results for the reports containing the aforementioned.

This test-specific Consultative mode is maintained by the ML for the duration necessary to validate the proper functioning of Valab® (e.g. 1 week).

| Step | OK / NOK |
|---|---|
| Assess the impact of the modifications on the tests described in section "LIS connection qualification" and section "Pool of "test" reports / Reproducibility". Re-run these tests if required. | |
| Activate "individual Consultative mode" on the test(s) concerned. | NA |
| ▼ Over a period of time or a defined number of reports (as determined by the ML) ▼ | |
| The clinical scientists check the relevance of the Valab® autoverification during their manual biological validation in the LIS, with particular focus on the test(s) concerned:<br>▪ Tests that should be blocked by Valab® are displayed as "blocked by Valab®" in the LIS<br>▪ Tests biologically validated by Valab® are rightfully validated<br>▪ Contextual data of the patients' reports is correctly taken into account by Valab® (age, sex, prescribers, therapeutic and clinical information, complementary information) | |
| The clinical scientists check the 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, particularly for the test(s) concerned. | |

*[1] If the modification consists in making Valab® more restrictive relating to one or more of the settings listed below and if the ML accepts the risk of making Valab® less effective, the requalification may be limited to checking that no data entry errors have occurred, by verifying that the new configuration corresponds to what is intended by the ML: Reduction of the RCV; activation or reduction of maximum and critical deltas; decreasing sensitivity; tighter validation limits for results without anteriority. As for changes to the reference intervals and critical limits, side effects on the inter-parametric autoverification rules and/or autoverification trends cannot be excluded, and their impact may not be systematically restrictive.*

*[2] Statistical monitoring and analysis are facilitated with the optional BI module ValView (see section "Optimize the efficiency and the monitoring of your Valab® with the BI module ValView").*

# Record the results of the test

Keep a record 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 and any useful comments if applicable, the test date and the full name of the tester.

# Impact on the medical laboratory's QMS documentation

## Formalize the way that the Valab® software is used

The ML must formalize the way that the Valab® software is used. It must in particular, indicate that it uses the Valab® computer aided validation software, describe the conditions of service and define the responsibility of the clinical scientist and also the conditions of authorisation of release of the laboratory reports.

In all cases, it is important to indicate that all the laboratory reports of the ML are released under the responsibility of the clinical scientist, including those verified with the help of the Valab® computer aided validation software. In this respect, all laboratory reports issued by the ML 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). Isolated statements of the form "validated by the expert system" are not acceptable.

## Identify the means of control of the Valab® software

The internal procedures must describe the process 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" (e.g. cross-reference to the Valab® User Manual).

After any modification of a parameter setting of the LIS, the need for modification in Valab® (units, correspondence tables,…) must be evaluated 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.

The medical laboratory should have enabled operation in fail-safe mode in the event that Valab® breaks down.

## Record the approval of Valab® usage requirements by all clinical scientists for traceability.

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.

# Awareness, accreditation and training of users

## 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.

## 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.

## Accreditation of the users

Provide for the accreditation to the Valab® use as part of the QMS process of the Medical Laboratory for the accreditation addressed to the clinical scientists (new collaborators, substitutes ...).

# Optimize the efficiency and the monitoring of your Valab® with the BI module ValView

This optional module offers 8 key indicators grouped in 4 dashboards to help you further the efficiency of Valab®, facilitate the continuous monitoring and improve your control over Valab®:

- Dashboard – *Laboratory activity*: contains two indicators to visualize Valab®s global activity:
    - A graph showing the evolution of global statistical indicators over a defined period (number of reports received, examined and validated per day, month, quarter or year)
    - A graph showing the hourly flow of runs submitted to Valab® by the LIS on a given day
- Dashboard – *Interpretation and reference*: contains three statistical indicators that enable standardized interpretation and continuous monitoring over a defined period with daily, monthly, quarterly, or yearly granularity:
    - A table listing global statistical indicators and their drifts (autoverification rate, validation rate and reject rate (by type))
    - Two graphs showing the evolution of autoverification rate and validation rate relative to the respective reference rate defined by the ML
- Dashboard – *Top blocked tests*: contains two indicators identifying tests with the highest rejection rates and those causing the most laboratory report blockage over a defined period with daily, monthly, quarterly, or yearly granularity:
    - A table listing the most frequently rejected tests, by type of rejection (correlation, anteriority or critical values)
    - A table listing the most frequently rejected tests among the most commonly performed tests. The definition of “most common” is user-configurable
- Dashboard – *Drift per test*: contains a indicator that enables identification and standard interpretation of most commonly performed tests with the highest validation rate drift over a defined period with daily, monthly, quarterly, or yearly granularity. The definition of “most common” is user-configurable:
    - A table lists the upward drift and the other table the downward drift