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. It is provided as an example and describes a set of requirements to be implemented by the medical laboratory in order to qualify the use of the Valab® software tool and to ensure control in terms of checks, maintenance and traceability of modifications.

This guide serves as a complement to document **RD5** "Valab® Manufacturer's Information for Medical Laboratory Accreditation" which provides the medical laboratory with 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* (**RD6**) and *Valab® Developer Manual* (**RD7**) provided with Valab®. Those manuals are available under the folder "DOC" of Valab®.

The records to be kept as proof of the execution and the results of the tests and checks described in the different chapters 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: ISO 9001 BUREAU VERITAS Certification

2 References

2.1 Document change history

Version	Date	Modification description	Author	Modified pages
2/B	21/11/2013	Update of the list of reference documents. Addition of the diagram of context of the tests. Consideration of the changes of MMI of Valab® version 12.01.	E. Rogari JP. Rogari	§2.3, §2.4, §4, §5.1, §5.2, §6 to 9, §10.2, §11.2.
2/C	14/09/2015	Update of the contact details in the footer.	E. Delaigue	All
2/D	06/09/2016	Updated the list of reference documents. Modified the recommended conservation period of the records. Processing of a modified report. Reference to Valab® setup information provided in the "Manufacturer's Information" document. Reference to the "Valab® - Backup and Restore" documentation. Traceability of approval of use of the tool by all of the clinical scientists. Minor corrections.	JP. Rogari	§1, §2.3, §4, §5, §6, §7, §8 , §9, §10.3.

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

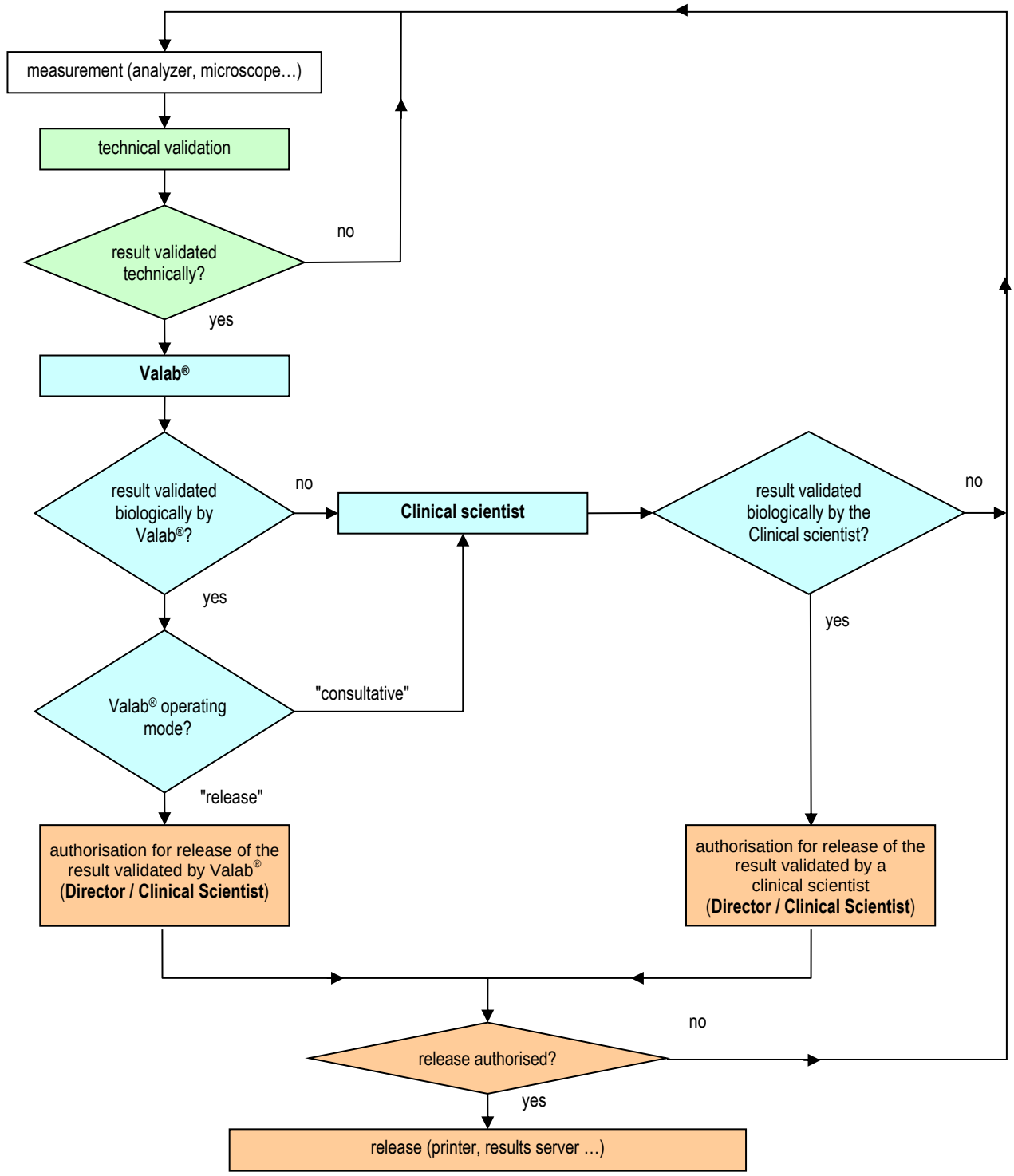
RD1	Medical laboratories - Requirements for quality and competence ● ISO 15189
RD2	Guide for the Correct Execution of Tests ● GBEA 2
RD3	Reference document for the accreditation of medical laboratories aimed at clinical scientists and editors of software for medical laboratories ● SFIL / Accreditation reference document
RD4	Recommendations for the accreditation of medical laboratories - Volume 2 ● SFBC / Annales de Biologie Clinique / Volume 70 / special supplement n°1
RD5	Valab® Manufacturer's Information for Medical Laboratory Accreditation (available at www.valab.com) ● VAL-ACC-10
RD6	Valab® User Manual (provided in Valab® "DOC" subdirectory) ● VAL-MU-XX
RD7	Valab® Developer Manual (provided in Valab® "DOC" subdirectory) ● VAL-MU-XX
RD8	Valab® - Backup and Restore (available at www.valab.com) ● VAL-MU-42
RD9	Valab® Quality Manual (available at www.valab.com) ● VAL-MQ-01
RD10	Accreditation requirements according to standard NF EN ISO 15189 ● Cofrac / SH REF 02
RD11	Accreditation technical guide for medical laboratories ● Cofrac / SH GTA 01
RD12	Accreditation technical guide to assess the IT systems in medical biology ● Cofrac / SH GTA 02
RD13	French Code of Public Health ● CSP
RD14	Ordonnance n° 2010-49 of 13/01/2010, relative to medical laboratories ● Ordonnance n° 2010-49
RD15	Decree n° 2011-1448, of 7/11/2011, relative to the vigilance exercised for health products mentioned in 18° and 19° of article L. 5311-1 of the French Code of Public Health ● Decree n° 2011-1448
RD16	Act n° 2013-442 dated 30/05/2013 concerning medical biology reform ● Act n° 2013-442
RD17	Decree n° 2016-46, dated 26 January 2016, concerning medical biology ● Decree n° 2016-46

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

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

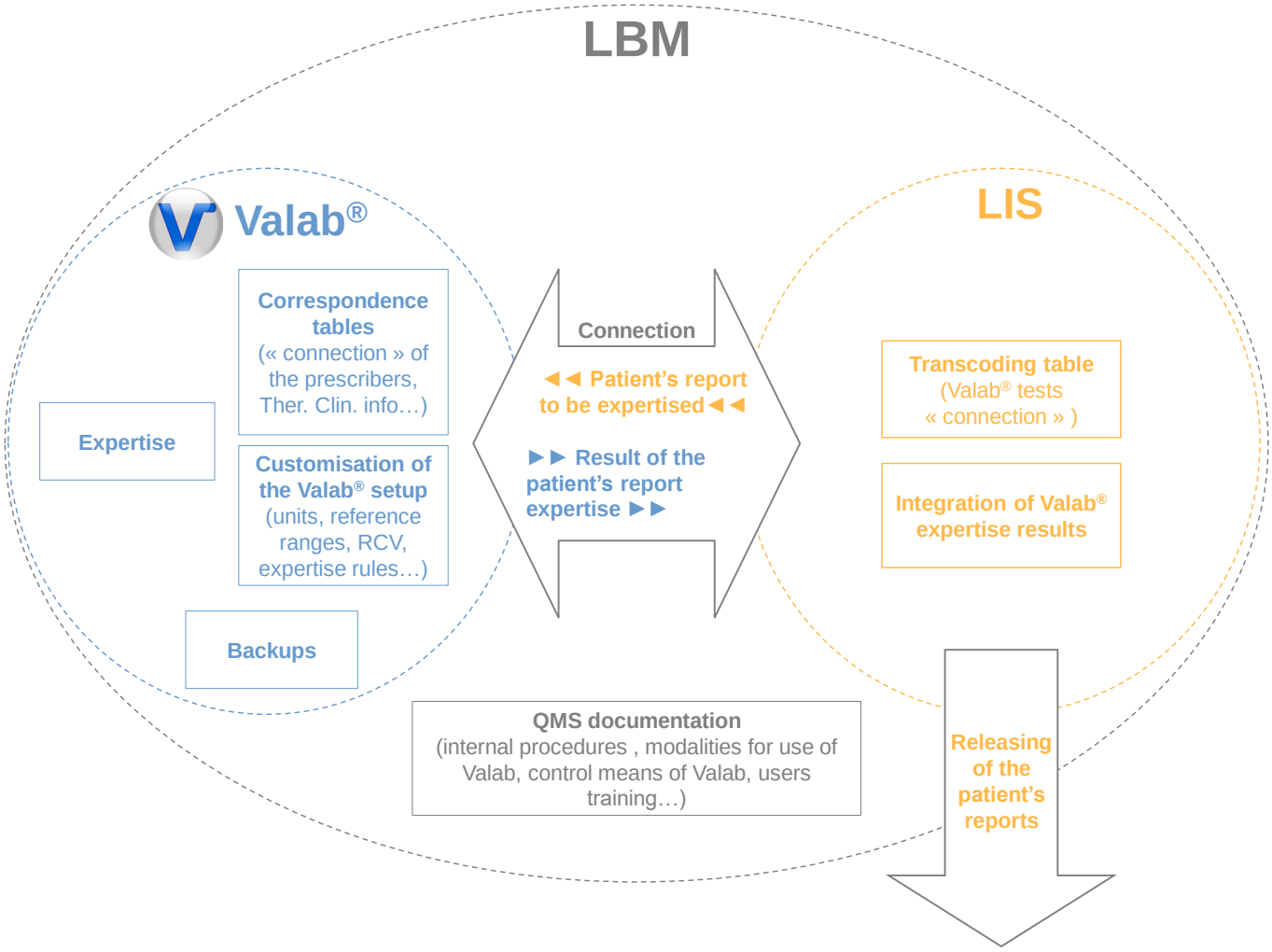
The following overview shows the functional integration of Valab® in the laboratory process for the validation of patient test results.



Colour code: Technical Validation | Biological Validation | Release Authorisation

4 Test context diagramme

The diagram below reminds major items regarding the use of Valab® in your laboratory qualified by the procedure examples provided in the following chapters of this guide.



5 Qualification of the connection with the LIS

This paragraph describes the test procedure to be used to qualify the connection between Valab® and the LIS of the medical laboratory. This procedure must be performed by the medical laboratory after the initial installation of Valab® and after every major modification as described in § "7.1 - Requalification after a major 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 medical 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

5.1 Test procedure

step	comment	result OK / NOK
Create an "imaginary" patient report (test report) in your LIS containing all the medical tests connected to Valab®. If required, this test can be broken down into modules or groups of tests (for example: a Biochemistry patient's report, a Haematology patient's report, …). The test report(s) must contain the following information: ▪ Each medical test result of the report must have a different value (for example: test sequence number) ▪ Complete the general information concerning the "imaginary" test patient (report / request number, sex , last name, first name, date of birth) ▪ Specify a prescriber (speciality , FU, ...) ▪ Specify a therapeutic and clinical information comment for the "imaginary" test patient (for example: chemotherapy , infarction , after dialysis, ...) ▪ Specify a technical / complementary information comment (for example: hemolysed sample, icteric plasma, air in syringe, ...) ▪ Specify the information concerning the "imaginary" test sample (date and time of day the sample was taken or, failing this, date and time of day of the recording of the request).		NA
Send this report to Valab® from your LIS (in general, the report is sent to Valab® by the LIS once the tests that it contains have been technically validated).		NA
In Valab®, open the report received by Valab® (**File - Open PTD file**).		NA
Print out the report displayed by Valab® (**Print** button).		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:
  ▪ medical test result value
  ▪ medical test result unit
  ▪ autoverification result provided by Valab® for the medical test result
▪ general information concerning the patient (report / request number, sex, last name, first name, date of birth)
▪ information concerning the prescriber (speciality, emergency context, hospital context)
▪ therapeutic and clinical information concerning the patient
▪ technical comment / complementary information
▪ information about the sample (date and time of day the sample was taken or, failing that, date and time of day of the recording of the request)		

step	comment	result OK / NOK
▼ Processing a modified report ▼		
In your LIS, modify a value of a medical test of (one of) the test report(s). The aim of the modification is to modify the Valab® autoverification result.		
Send this report to Valab® again from your LIS (as a general rule, the report is sent to Valab® by the LIS if the medical tests that it contains have been technically validated).		N.A.
In Valab®, open the report received by Valab® (**File - Open PTD file** menu option).		N.A.
Print out the report displayed by Valab® (**Print** button).		N.A.
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 from Valab®, in particular for the modified medical test: ▪ for each medical test result: ▫ medical test result value ▫ medical test result unit ▫ autoverification result provided by Valab® for the medical test result ▪ general information about the patient (report/request N°, sex, last name, first name, date of birth) ▪ information about the prescriber (speciality, emergency context, hospital context) ▪ therapeutic and clinical information about the patient ▪ technical comment / complementary Information ▪ information about the sample (date and time sample was taken or, failing that, date and time request was recorded)		

5.2 Record the results of the test

Keep a record (electronic file / pdf, paper printout) containing the printout of the report(s) made from Valab® and the one made from the LIS if applicable, write on it the result of the test procedure and any useful comments, the date the test procedure was performed, and the last name and first name of the qualified person who performed the test.

6 Initial qualification of the Valab® autoverification and of the customisation of the Valab® setup

This paragraph describes the test procedure to apply to qualify the autoverification performed by Valab® and the customisation of the Valab® setup performed by the medical laboratory. This procedure must be performed by the medical laboratory after the initial installation of Valab®.

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 of this test is based mainly on using Valab® in consultative mode during a given period or for a given volume of reports. In this mode, all the reports verified by Valab® (validated and non-validated reports) are proposed by the LIS to the clinical scientists for "manual" validation. In this way, the clinical scientists can monitor the relevance of the autoverification performed by Valab® and finalise the customisation of the Valab® parameter (see the "Customisation of parameter settings" section of document **RD5** "Valab® Manufacturer's Information"). During this phase, the Valab® key contact clinical scientists of the medical laboratory are accompanied, for the analysis of the production data, by the "biological expertise" Customer Support team of the VALAB company to finalise the customisation of the Valab® setup and in order to obtain an operation of Valab® adapted to the population, the specifics, and the requirements of the medical laboratory.

After finalising the customisation of the parameter settings, consultative mode is maintained by the medical laboratory for a period of time or for a volume of reports necessary for the acceptance of the operation of Valab® (example time period: 15 days continuous, then 1 week with 3 days, then 1 week with 2 days. Then the following month 1 day a week every week / Example of volume of reports: > 5000 reports for a medical laboratory processing 1000 reports per day). This qualification must be performed over a sufficient and meaningful period of activity of the medical laboratory or for a sufficient and significant volume of reports.

During this acceptance period, the medical laboratory also checks the Valab® activity statistics (**View - Statistics**) in order to monitor the coherence and / or consistency of the validation and refusal rates for each medical test.

6.1 Test procedure

step	comment	result OK / NOK
Activate the "Use Valab® in consultative mode" option of your LIS. If your LIS does not propose this functionality, activate the consultative mode option proposed by Valab® (**Autoverify mode - Consultative mode - On**).		NA
▼ Over a given period or a volume of reports to be defined by the medical laboratory ▼		
The clinical scientists of the medical laboratory, during their biological validation sessions through 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 of the patient reports is correctly taken into account by Valab® (age, sex, prescribers, therapeutic and clinical information, complementary information)		
The clinical scientists of the medical laboratory print out the activity statistics of Valab® (**View - Statistics**, select all the specialities) over the observation period in order to validate the number of reports seen in consultative mode.		
They 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 medical test.		

6.2 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 printout of the parameter settings of Valab® corresponding to the end of the qualification period (**View - Tests** select all the specialities), the part of the Valab® logbook containing the modifications made during the acceptance period (**View - Log**, click the **External editor** button and print the part concerned from the external editor), the Valab® activity statistics for the acceptance period, the results of the test procedure and any useful comments, the date the test procedure was performed, the last name and first name of the qualified person who performed the test.

7 Requalification after a modification

7.1 Requalification after a major modification

This paragraph describes the test procedure to be applied to requalify Valab® following a major modification. At this level, different types of major modifications can be identified:

- change of LIS
- backup recovery after an incident
- change to a new major version of Valab®
- change to a new major version of the LIS (see also the recommendations of the LIS supplier)
- connection of a new analyser or replacement of an analyser processing tests which are connected to Valab®
- . . .

The procedure applied here is to be adapted and assessed by the medical laboratory according to the type of major modification that occurs.

7.1.1 Test procedure

type of applicable major modification	step	comment	result OK / NOK
▪ Backup recovery after an incident ▪ Change to a new major version of Valab®	Print out the part of the Valab® logbook containing the latest "important" modifications (modification of the parameter settings for a medical test, for the autoverification setup, ...) applied to your Valab® (**View - Log** menu, click the **External editor** button and print out the part concerned from the external editor). Check on the printout obtained that these modifications do in fact correspond to the latest "important" modifications applied to your Valab®. Check that these modifications are still applied in the parameter settings of your Valab® (**View - Tests** menu ...).		
▪ Backup recovery after an incident ▪ Change to a new major version of Valab® ▪ Change of LIS ▪ Change to a new major version of the LIS	Run the test described in § "5 - Qualification of the connection with the LIS".		
▪ Backup recovery after an incident ▪ Change to a new major version of Valab® ▪ Change of LIS ▪ Change to a new major version of the LIS	Run the pool of dummy test reports for the test described in § "8 - Continuous monitoring of Valab®"		
▪ Change of LIS	Run more lightly (shorter period of time or fewer reports), if applicable, the test described in § "6 - Initial qualification of the Valab® autoverification and of the customisation of the Valab® setup".		

7.1.2 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 major modification. The record must in particular contain the recordings indicated for the different test items carried out, the description of the major modification which made the requalification necessary, the results of the test procedure and any useful comments if applicable, the date the test procedure was performed, the last name and first name of the qualified person who performed the test.

7.2 Requalification after a minor modification

This section describes the test procedure to be applied to requalify Valab® following a minor modification of the Valab® parameter settings for a medical test or a group of medical tests (for example: units, limits, RCV, autoverification, sensitivity settings, ...), or following the connection of a new medical test to Valab® (for example: adding a new Auto-Expert test).

The points qualified by this procedure are:

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

The principle of this test is based mainly on the activation in Valab® for a given period of the "test-specific consultative mode" option for the medical test(s) concerned. This mode ensures that all of the reports autoverified by Valab® that contain this/these medical test(s) (validated and not validated reports) are proposed by the LIS to the clinical scientists for "manual" validation. In this way, the clinical scientists can monitor the relevance of the autoverification results returned by Valab® for the reports containing results for these tests.

This "test-specific consultative mode" option is maintained by the medical laboratory for the medical tests concerned for the necessary length of time required to validate the acceptance of the use of Valab® (for example: 1 full week, then 2 days in the following week, then 1 day of the week after).

During this acceptance period, the medical laboratory also checks the Valab® activity statistics (**View - Statistics**) in order to monitor the coherence and/or consistency of the validation and refusal rates for the medical test(s) concerned.

7.2.1 Test procedure

step	comment	result OK / NOK
Use Valab® to activate the "test-specific consultative mode" option for the medical test(s) concerned (**View - Tests**, double-click the medical test(s) concerned, activate the **Biology\Critical\Consultative mode** option).		NA
▼ Over a period of time or volume of reports to be defined by the medical laboratory ▼		
The clinical scientists of the medical laboratory, during their biological validation sessions through the LIS, check the relevance of the autoverification results returned by Valab®: ▪ the medical test results which should be blocked by Valab® are displayed as "blocked by Valab®" by the LIS, and in particular for the medical test(s) concerned ▪ the medical test results validated biologically by Valab® are validated when they should be, and in particular the medical test(s) concerned ▪ 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 of the medical laboratory check the activity statistics of Valab® (**View - Statistics** and select all the specialities) in order to validate the global statistics (% of reports validated by Valab®) and also the coherence and/or consistency of the validation or refusal rates for each medical test, in particular for the medical test(s) concerned.		

7.2.2 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 requalified by the medical laboratory over a period of "X" weeks, following a minor modification to a medical test or a group of medical tests, by using the "test-specific consultative mode" option for the medical test(s) concerned corresponding to a check of the processing of "N" patient reports containing the medical test(s) concerned (column NPR of the activity statistics).

The record must in particular contain the Valab® activity statistics for the acceptance period, the results of the test procedure and any useful comments if applicable, the date on which the test procedure was performed, the last name and first name of the qualified person who performed the test, and the description of the modifications which made the requalification necessary.

8 Continuous monitoring of Valab®

This paragraph describes the test procedure to be applied in order to continuously monitor the correct operation of Valab®. This procedure must be performed according to a frequency to be defined by the medical laboratory (for example monthly, quarterly or half-yearly). It allows a global and regular check that there is no drift in the operation of Valab®. It relies on 3 complementary assessment criteria:

- the printout and analysis of the activity statistics to look for a possible drift
- the sampling of patient reports (for example 30 real patient reports per month, or the "(square root of (number of reports processed per year)) / 12" reports per month) to be checked by the clinical scientist after being verified by Valab® (relevance check)
- the use of a pool of "dummy" reports (set of reports for testing) allowing to monitor the reproducibility of the autoverification results provided by Valab®. This pool must be established once and for all by the medical laboratory and the same pool of reports must be used for each check in order to form a reference. It can however be adapted / enhanced according to any modifications of Valab® occurring between two checks. The reports of the pool can for example contain critical tests on a life-critical or regulatory level (for example: K+, troponin, haemoglobin, platelets, APTT, PO2, ßHCG, HIV, …), or tests performed frequently by the medical laboratory. The following table provides an example of the definition of the pool of "dummy" test reports, for each report in the pool it must be defined whether the expected result is the validation or "blocking" of the report. It is not necessary to test all the reports of the pool during each check, a rotation can be set up in order to test alternately for example half of the pool during each check.

Content of the reports	Points verified
▼ A report entirely validated ▼	
Report for which all the tests have a "normal" value and the clinical information is compatible with these normal values ("normally normal" report which must be biologically validated by Valab®).	Path of a report entirely validated by Valab®.
▼ Reports not validated / "review" of the autoverification results ▼ (see examples provided in the directory "Valab_directory\POOL_CQ")	
A report for which all the tests have a high critical value.	Valab® flag "P"
A report for which all the tests have a low critical value (if applicable).	Valab® flag "P"
A report without anteriority of which at least one test has a value outside its biological reference interval (without internal coherence).	Valab® flag "C"
A report with previous results of which at least one test has a variation outside the RCV ("abnormal" variation, without internal coherence).	Valab® flag "A"
A report containing a data item or a test outside the domain of Valab® (for example: prescriber in mandatory validation, test in consultative mode, ...).	Valab® flag "D"
A report for which at least one test must be validated biologically by Valab®, and other tests causing errors of correlation, anteriority, domain and outside critical limits in Valab®.	Valab® flags "P", "C", "A", "D" and "V"

8.1 Test procedure

step	comment	result OK / NOK
▼ N° 1 - Check of activity statistics - frequency to be determined by the medical laboratory ▼		
Use Valab® to periodically print out the Valab® activity statistics of the latest elapsed period since the last check (for example: the previous month, the previous quarter ...): **View - Statistics**, select the period, select all the specialities, click the **Print** button).		NA
Compare the printout obtained with that obtained during the last check, in order to check that there is no drift at the level of: ▪ the global statistics ▪ the alarm indicators and / or rejection / validation rates for each medical test		

step	comment	result OK / NOK
Check on the printout obtained that: ▪ The ratio between the value of the global counters NER and NRR (NER / NRR) is close to 1 (a value too far below 1 indicates problems with the connection or parameter settings, too many correspondence tables items in mandatory validation, or the Valab® licence level has been exceeded), or is close to or greater than the value measured during the last check. ▪ 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) of the "Clinical and Therapeutic Information" and "Complementary Information" parameters globally reflects the % of patient reports of your medical laboratory containing respectively "Clinical and Therapeutic Information" and "Complementary Information", or is close to or greater than the values measured during the last check.		
▼ N° 2 - Check on a sample of patient reports - frequency and volume to be determined by the medical laboratory ▼		
A number of solutions are possible to set up the sampling, according to the way your laboratory and your LIS operate. They are listed below in decreasing order of efficacy / suitability: ▪ check a series of result reports printed out from the LIS after validation by Valab®, or ▪ activate the "use Valab® in consultative mode" option of your LIS or, if this option is not available in the LIS, activate the consultative mode proposed by Valab® (**Autoverify mode - Consultative mode - On**) for a sufficient period of time (for example: half a day each month), or ▪ review a series of reports in a Valab® **Simulation** session (**File - Open PTD file**).		NA
The clinical scientists of the medical laboratory check the relevance of the autoverification results returned by Valab® for the sampled reports (this allows in particular to check that the contextual data of the reports is correctly taken into account by Valab® - age, sex, prescribers, therapeutic and clinical information, complementary information, information concerning the sample): ▪ the reports and/or medical test results that should be blocked by Valab® effectively are "blocked by Valab®" ▪ the reports and/or medical test results validated by Valab® should effectively be validated		
▼ N° 3 - Reproducibility check on the pool of "dummy" test reports - Reports and frequency to be determined by the medical laboratory ▼		
Use your LIS to send the pool of dummy test reports to Valab®.		NA
Use your LIS to check that the test reports are correctly processed: ▪ the report which should be validated by Valab® is proposed for release authorisation by an approved 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 ▪ the other test reports are proposed in a biological validation session and the display of the autoverification results provided by Valab® for each medical test result of each report is as expected		

8.2 Record the results of the test

Keep a record (electronic file, pdf, paper printout) containing the printout of the statistics provided by Valab®, the length of time operated in consultative mode and the corresponding number of reports and/or the list of sample reports, the list of dummy reports of the test pool, indicate on them the results of the test procedure and any useful comments, the date the test procedure was performed, and the last name and first name of the qualified person who performed the test.

9 Maintenance of Valab®

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.

9.1 Maintenance procedure

step	comment	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).		
Print out the part of the Valab® logbook containing the modifications made since the last maintenance session (**View - Log**, click the **External editor** button, then print out the part concerned using the external editor).		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 **RD8** "Valab® - Backup and Restore").		

9.2 Record the results of the maintenance

Keep a record (electronic file, pdf, paper printout) containing the printout 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 last name and first name of the qualified person who performed the procedure.

10 Impact on the medical laboratory's QMS documentation

10.1 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 (periods of on-call duty, simple / routine reports, etc.).

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 assumed 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.

10.2 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 provide the means to implement the appropriate corrective action.

10.3 Record for traceability purposes the approval of the requirements for the use of Valab® by all of the clinical scientists of the medical laboratory

All of the clinical scientists of the medical laboratory 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.

11 Awareness and training of users

11.1 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 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.

11.2 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 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.