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**SFHI CQE Participant's Manual**

Version 5.0 - 06/10/2023

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# Overview and definitions

* The External Quality Control of the Société Francophone d'Histocompatibilité et d'Immunogénétique is designated "CQE SFHI". It offers a range of programs to measure performance in histocompatibility laboratory analysis.
* SFHI's CQE complies with the EFI Standards for Providers *of External Proficiency Testing schemes in H&I*. It is recognized by EFI as a CQE provider [(](https://www.efi-web.org/efi-committees/ept-committee.html)https://www.efi-web.org/efi-committees/ept-committee.html) and meets EFI standards for the accreditation of histocompatibility laboratories (*Standards for Histocompatibility & Immunogenetics Testing* in force).
* The term "Participant" refers to any structure or entity registered in at least one CQE SFHI program.
* The term "Fiscal Year" refers to all samples to be analyzed during a calendar year.
* A "Slice" refers to all the samples for which results are expected at once. A Fiscal Year may be divided into several Slices.
* The Participant's Manual provides general instructions for implementing the various CQE SFHI programs. It is revised annually. However, minor modifications may be made during the year. Any update (modification, removal or addition of an item) deemed major, i.e. impacting the running of the Exercise at any level whatsoever, will be notified via the SFHI website [(http://www.sfhi.eu](http://www.sfhi.eu) , "quality control" menu) and Participants will be informed by e-mail.
* The CQE SFHI is officially located at the following address:

Quality control

Saint-Louis Hospital, APHP

Immunology and Histocompatibility Laboratory

1 Avenue Claude Vellefaux

75475 PARIS Cedex 10

France

Website: [www.sfhi.eu](http://www.sfhi.eu) (Quality control section)

# SFHI CQE annual calendar

* The annual calendar details for each program, no later than 12/31 of the previous year:
* Sample dispatch date
* The deadline for receipt of the Participant's results
* The date of dispatch of the consensus results reports for each Tranche
* The date of dispatch of detailed results for each Tranche
* The date of dispatch of the annual performance certificate

The calendar is e-mailed to participants in year n-1 when registrations for the following year are available, and is also available on the SFHI website (https://www.sfhi.eu/controle-qualite/controle-qualite-externe/documents-generaux).

# Organizing Committee (OC)

* The OC is made up of a director, a treasurer, at least one program manager and at least one quality manager. Any new members (new or replacement) are appointed by the OC by a majority vote, on the basis of unsolicited individual proposals from candidates or after a call for applications.
* OC members may be assisted by one or more external experts (see table below), but these experts are not OC members. A member of the OC may also be an Expert.
* The OC is responsible for developing, reviewing and implementing procedures for planning, program execution and reporting.
* The OC establishes performance criteria in line with those defined by the EFI standards and may advise participants whose performance is unsatisfactory.
* The OC conducts an annual review of all exercises and performances. It also examines participants' suggestions, comments and complaints (e-mails and satisfaction questionnaires) in order to improve the organization of the various programs. A summary of this review and the improvements implemented or planned for the following year is presented between the end of Year n and the first shipment of samples for Year n+1.
* The OC ensures that SFHI EQF programs comply with any accreditation requirements.
* The OC members and experts are :

|  |  |
| --- | --- |
| **CO members** | **Contact** |
| Pr Jean-Luc TAUPIN CO Director Co-manager of Anticorps One Lambda | jean-luc.taupin@aphp.fr  |
| Dr Isabelle JOLLET Co-manager of Anticorps One Lambda | isabelle.jollet@efs.sante.fr |
| Dr Valerie DUBOISAntibodies Manager ImmucorChemicals Manager | valerie.dubois@efs.sante.fr |
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| **Experts** | **Contact** |
| Dr Mehdi ALIZADEHCo-responsible for Chemistry | mehdi.alizadeh@efs.sante.fr |
| Dr Béatrice BARDYExpert HLA Typing | beatrice.bardy@efs.sante.fr  |

# Accreditation and official recognition

* SFHI EQA is listed in the EFI's "Register of EQA Suppliers", available for download at the following link: https://www.efi-web.org/efi-committees/ept-committee.html.
* SFHI's CQE is registered with ANSM.

# Samples

## Number of samples

* The annual number of samples is :
* 12 sera for anti-HLA testing
* 12 sera for identification of anti-HLA Ac, in each class
* 15 DNA for the study of post-allogeneic HSC chimerism
* 12 DNA for low- and/or high-resolution HLA typing and HLA-disease association studies
* During the initial evaluation of a new EQA program, however, the number of samples may be lower than that recommended in the EFI standards.
* If a participant wants to return results with 2 suppliers for more than 12 tests in total, it is necessary to take out 2 subscriptions and return results for at least 10 sera with one main supplier.

## Nature and origin of samples

* **DNA samples are** obtained from voluntary donors of labile blood products or bone marrow.
* **Serum samples** are obtained from voluntary blood donors or multiparous voluntary blood donors.
* Each donor has signed a consent form for laboratory use.
* Samples are subject to Biological Donation Qualification in accordance with Etablissement Français du Sang (EFS) regulations. Like all biological materials, samples must be considered as potentially dangerous and must be handled with care, in compliance with the laboratory's rules of hygiene and safety.

## Sample preparation

To guarantee the homogeneity and quality of the samples sent, strict preparation procedures are followed. The quantity of each serum sample is sufficient to perform the analysis evaluated a minimum of 3 times. The quantity of each DNA sample is sufficient to perform all the molecular biology techniques available in the participating laboratory. Biological material is retained by the program manager(s) for further exploration in the event of a dispute.

## Sending samples

* Deliveries are made according to the provisional schedule to the address indicated on the order form at the time of registration.
* Samples are transported in packaging suitable for biological samples. CQE SFHI complies with national and international regulations applicable to the transport of biological samples.
* The OC notifies Participants by e-mail of the imminent arrival of samples, and of any delay in shipment.
* DNA is transported at room temperature, and sera at -20°C. Samples must be processed as specified in the provisional timetable.
* Participants must ensure that samples are received correctly and that their integrity is verified. In the event of an anomaly, it is the Participant's responsibility to inform at least one of the program managers concerned.
* Procedures describing all the steps involved in sample preparation and dispatch are available from the CO :
* MO/SFHI/01: Preparation and dispatch of sera for anti-HLA Ac CQE
* MO/SFHI/02: Preparation and dispatch of DNA for CQE Low and/or high resolution HLA typing and HLA/disease association study
* MO/SFHI/04: Preparation and dispatch of DNAs for the Chemicals EQA
* MO/SFHI/05/cell and serum preparation for XM CMF

# Registration

* The CQE SFHI is open to any person or organization wishing to participate. However, consensus and annual performance will only be calculated from the results of Participants who are medical laboratories performing HLA analyses on a routine basis. However, other categories of Participants also have access to the anonymized detailed results of Participants included in the consensus calculations, via the SFHI website.
* Up-to-date SFHI members receive a newsletter inviting them to complete or renew their membership.
* Registration is online only on the SFHI website [(](https://www.sfhi.eu/controle-qualite/abonnement)https://www.sfhi.eu/controle-qualite/abonnement, section accessible to non-members). Registration must be entered with a purchase order number before the deadline indicated for participation to apply to the entire Exercise. After this date, full participation cannot be guaranteed, but it will still be possible if the delivery of samples is compatible with the delivery of the results of the first Tranche within the allotted time (to be discussed on a case-by-case basis). It is the Participant's responsibility to ensure that all contact details, including billing contact and purchase order number, are correct.
* Failure to pay subscription fees will result in suspension of participation.
* The Participant is billed for all program samples received, whether or not results are submitted in return.
* Requests for cancellation of participation must be addressed to the person(s) responsible for the program(s) concerned no later than 1 week before the samples are dispatched.
* By registering, the Participant agrees to analyze the samples and interpret the results obtained in a manner identical to routine samples, and to comply with the expectations set forth in this manual.
* Collusion between laboratories is not permitted: if a laboratory is suspected of collusion, SFHI reserves the right to refuse re-registration.
* The Participant must inform SFHI of the reasons for not sending results (test failures, cessation of activity, etc.) before the end of the exercise.
* Each program must include at least 10 participants, otherwise it is defined as an "inter-laboratory comparison working group".

#  Privacy

* The identity of Participants is not disclosed outside the OC.
* At the time of registration, each Participant is given a unique confidential code that is permanent. This code is not disclosed outside the OC. This code will be :

- used, alone, on global consensus reports (personal data should not be included) and detailed reports

- clarified on individual consensus reports

- specified on individual annual performance reports.

* A laboratory may have a 2ème code if it wishes to participate in a given Exercise with 2 different reagents.
* Participants undertake not to use the reports and data from the CQE programs for any purpose other than internal laboratory use, without the prior agreement of the CO, except in the event that an accreditation body wishes to obtain additional information solely in connection with the audit/inspection of the Participant's laboratory. However, they may communicate the results they have obtained for their structure/entity to whomever they wish.
* CO members' code of conduct: Technicians and biologists involved in the selection, preparation or dispatch of samples are bound by a code of conduct. Sample selectors are not involved in the analysis and reporting of their laboratory's results. The signatories of consensus and performance reports are not the same people who participate in the reporting of their own laboratory's results. The original files obtained during sample selection are available at the source, if necessary, to check that the final result delivered matches the expected result. In exceptional cases, however, a technician or biologist may be asked to return the result of a QAE that he or she has "prepared" (for reasons of staffing levels or maintenance of accreditation), but this must be done as neutrally as possible. Procedures to ensure the probity of OC members are available on request:
* MO/SFHI/01: Preparation and dispatch of sera for anti-HLA Ac CQE
* MO/SFHI/02: Preparation and dispatch of DNAs for CQE Low and/or high resolution HLA typing and HLA-disease association study
* MO/SFHI/04: Preparation and dispatch of DNAs for the Chemicals EQA
* MO/SFHI/05/cell and serum preparation for XM CMF

# Annual performance

* It is established for a Participant on the basis of the samples and/or analytes contained in the sample, for which a consensus has been reached, according to the procedures specified for each EQA program.
* It is communicated at the end of the Fiscal Year, in the form of an individual nominative report, mentioning the Participant's name and confidential code. The report is signed by the director of the Organizing Committee.
* HLA Ac Screening/Identification and HLA Typing / HLA Disease Association Study programs: the report is filed on the CQXplore website by 12/31 of each year at the latest, and is accessible for at least 12 months only after entering a personal password.
* Chemistry program: the report is sent to each Participant by e-mail.
* In the event of unsatisfactory performance, the person in charge of the program concerned will notify the Participant of the unsatisfactory performance by e-mail within 30 days of publication of the detailed results of the Exercise, enclosing a follow-up form. The Participant must complete and return this form within 15 days.

#  Luminex anti-HLA screening program

## How works

* Samples for the entire Financial Year are sent to Participants in a single mailing at the beginning of the year.
* The analyses to be carried out are divided into two batches spaced several months apart, according to a pre-established schedule (sample identity and analysis dates) communicated when the samples are sent.
* Registration covers both class I and class II; it is not possible to register for just one class.
* An interim consensus report and an interim detailed report are issued after each Tranche, for the samples studied on the Tranche concerned.
* Consensus and performance are determined in a single way, common to both EFI and SFHI.

## Results to be entered by the Participant

* The term Result refers to the Participant's response entered for a class for a sample. Two Results are therefore expected per sample.
* If the Participant wishes to point out that the Result he/she has entered does not correspond to his/her wishes or requires further information, he/she can do so in a dedicated comment area.
* There are only three possible results: positive, negative or uninterpretable. The mention "grey zone" is not part of the possible Results. A result that is outside the consensus but is accompanied by a comment justifying the choice is generally considered favorably by accreditors.

## Consensus

* If a Participant registers for the Exercise under 2 codes, because he wishes to evaluate his performance with 2 different reagents, his results will only be included in the consensus calculation for one of the reagents, defined as the main one by the Participant.
* A **consensus** for a given sample in a given class is achieved when 75% of the Participants obtain the same Result. There are therefore four possibilities for consensus: positive Class I, negative Class I, positive Class II and negative Class II.
* If no consensus is reached, the Results for the sample in this class are not considered.
* A Participant who has submitted no Result or the Result "uninterpretable" for the 2 classes for a sample is excluded from the consensus calculation for that sample, but is not considered to have provided an inaccurate answer.
* A Participant, who has submitted a Result for only one class of a sample, is considered to have provided an inaccurate answer for the class left unanswered.
* A Participant who submits an "Uninterpretable" result for one of the 2 classes but a "Positive" or "Negative" result for the other class is excluded from the consensus for the class whose result is uninterpretable. Its response is taken into account when calculating the consensus for the other class. Different batches and kits can be analyzed separately. A technique is only analyzed individually if there are at least 5 participants.

## Participant performance

* The Participant's **performance** is defined by the ratio "number of Participant's Results in agreement with the consensus / set of Results having reached the consensus for the samples analyzed by the Participant as part of the Exercise".
* Example: for 12 samples, 24 Results are expected (12 per class), the calculation is made on 24 Results minus those without consensus and minus those for which the Participant has not provided a Result for either of the two classes, or has provided the "uninterpretable" Result.
* **Performance** is considered **satisfactory** when at least 80% of the Results provided (class I and class II analyzed as a whole) are in agreement with the consensus **and** the Results of at least 10 samples have been submitted in the 2 classes over the Exercise.
* **Performance** is considered **unsatisfactory** in all other cases.

## Reports and Certificates

9.5.1 Interim consensus report

* A nominative individual interim report is filed on the CQXplore site after each Tranche: "Attestation SFHI Dépistage VILLE ANNEE". It is accessible only to the Participant.
* It states:
* Dates for sending samples, closing the Tranche, and issuing reports
* The total number of Participants included in the consensus calculations
* Participant's result by sample and class
* The 75% consensus by sample and class
* Percentage of Participant Results in agreement with the 75% consensus on all samples for each class

9.5.2 Detailed interim reports

* They are prepared after each Slice
* They are anonymized and posted on the SFHI website [(](https://www.sfhi.eu/controle-qualite/controle-qualite-externe/depistage-des-anticorps)https://www.sfhi.eu/controle-qualite/controle-qualite-externe/depistage-des-anticorps) before the analysis start date of the next Tranche during the Fiscal Year, and before December 31 following the last Tranche. They are accessible to all Participants.
* They contain the synthesis and detailed analysis of the Results of the Participants included in the consensus calculations.
* They consist of 3 downloadable Results:
* The 1er Results, which can be downloaded from the "YEAR Screening Results Nth Tranche MFI Supplier Lot XX" section, correspond to :
* 1 "Detailed MFI analysis" cover page
* A summary for each serum tested, for all Participants including :
	+ Raw and normalized MFI for each bead
	+ MFI raw of each bead of the associated negative control serum
	+ results of associated calculations of means, medians, standard deviations, CVs and z-scores obtained.
* Participants are ranked by z-score.
* The 2ème results, which can be downloaded from the "ANNEE Résultat dépistage Nème Tranche" section, correspond to :
* 1 "Detailed EQA Analysis" cover page with information on the Tranche
* 1 page describing all Results and consensus calculations performed :
	+ All Results for each Participant in each class
	+ Summary by Participant of the number of samples studied, the number of interpretable Results, the number and percentage of Results outside consensus and the percentage of Results in agreement with consensus (both classes combined).
	+ Percentage of positive and negative results that lead to consensus, and the nature of the consensus (positive or negative).
* Participants are not ranked by performance.
* The 3ème results can be downloaded via the "ANNEE Résultats dépistage Nème tranche Paramètres" link and correspond to :
* 1 "Detailed Parameter Analysis" cover page
* 1 page detailing all reagent batches and technical parameters for all participants.

9.5.3 Annual performance certificate

* A nominative individual annual performance certificate is published and posted on the CQXplore website before December 31st of each Financial Year. It is accessible only to the Participant. It contains :
* Fiscal year
* Participant name and code
* Number of participants
* Number of samples studied by the Participant
* Consensus and Participant Results (per sample)
* Conclusion for the Participant (compliance with reference criteria), in the form of a percentage of Participant Results in line with the consensus among all the consensuses achieved.
* Participant performance, in the form of a "satisfactory" or "unsatisfactory" rating
* It is also supplied in English to facilitate the work of EFI inspectors.

# Luminex "Anti-HLA Acid Identification" program

## Exercise sequence

* The program concerns only the "single antigen" technique
* Registration covers class I and class II; it is not possible to register for just one class.
* Samples for the entire Financial Year are sent to Participants in a single mailing at the beginning of the year.
* Analyses are divided into two batches spaced several months apart, according to a pre-established schedule (sample identity and analysis dates) communicated at the time of sample dispatch.
* Class I and Class II are considered separately, with samples identified differently in Class I and Class II.
* An interim consensus report and an interim detailed report are issued after each Tranche, for the samples studied on the Tranche concerned.
* Consensus and performance are determined in two different, complementary ways. The calculation method used for EFI accreditation purposes is the one that complies with EFI standards.

## Results to be entered by the Participant

* The term Result refers to the response of the Participant entered for an antigen, which is therefore the level of precision retained for the analysis. For a sample, there are as many expected Results as there are antigens studied by the reagent kit used.
* If the Participant wishes to point out that the Result he/she has entered does not correspond to his/her wishes or requires further information, he/she can do so in a dedicated comment area.
* **For the "CQE" result**, there are only two possible results for each antigen: positive or negative. Grey zone" is not a possible result. An "uninterpretable" result is only possible if it concerns the entire sample.
* **For the "CRISTAL" mode extension,** there are three possible results: permitted, forbidden or grey zone.
* **To extend the program to include MFI analysis**, sample data are retrieved directly from FUSION or MATCH IT software into CQXplore.
* Results must be interpreted in accordance with SFHI's Anticorps technical recommendations (document available on the SFHI website https://www.sfhi.eu/ressources-scientifiques/recommandations). A procedure for entering Anticorps into CQXplore is also available on the SFHI website (https://www.sfhi.eu/controle-qualite/controle-qualite-externe/documents-generaux).
* A result that is not part of the consensus, but is accompanied by a comment justifying the choice, is generally viewed favorably by accreditors.

## Interpretation in EFI mode of "CQE" results

### Consensus

* If a Participant registers for the Exercise under 2 codes, because he wishes to evaluate his performance with 2 different reagents, his results will only be included in the consensus calculation for one of the reagents, defined as the main one by the Participant.
* **Consensus** is defined for each antigen. It is obtained when :
* ***75% of participants obtained the same result for antibody assignment ("Positive consensus"),***
* ***95% of participants obtain the same result for the absence of an antibody ("consensus Negative"),***
* Consensus is calculated only for antigens common to all suppliers.
* Individual kits can be analyzed separately. A kit is only analyzed individually if there are at least 5 participants.
* If consensus is not reached for an antigen in a sample, this antigen is not considered for the calculation of Participant performance. Ex: for 12 samples in class I, with 79 antigens studied per sample, 948 Results are expected (either positive or negative), the calculation is made on 948 results minus those without consensus.
* A Participant who has submitted no Result or an uninterpretable result for a sample is excluded from the consensus calculation for that sample, but is not considered to have provided an inaccurate Result. A Participant who has submitted at least one Result for a sample but has not submitted a Result for at least one antigen in that sample is considered to have provided an inaccurate response for that/those antigen(s). The consensus calculation for this antigen will exclude this Participant.

### 10.3.2 Participant's annual performance

* It is calculated at year-end and expressed as a %, as follows:
* ***For positive antigens: number of "Positive Consensus" antigens correctly determined by the Participant / total number of "Positive Consensus" antigens for the samples analyzed by the Participant.***
* ***For negative antigens: number of "Negative Consensus" antigens correctly determined by the Participant / total number of "Negative Consensus" antigens for the samples analyzed by the Participant.***
* The Participant's performance is determined by class and by distinguishing between positive and negative antigens. Performance is **satisfactory** if it reaches 75% for each of these 4 criteria (positive/negative antigens in class I/class II) **and if** the Participant has submitted at least one Result (positive or negative) per sample for at least 10 samples of the Exercise. A total of 5 criteria must be met to obtain a satisfactory performance.
* In all other cases, performance is **unsatisfactory**. There is no calculation of overall performance (positive and negative antigens as a whole) by class, nor for class I and class II as a whole.

## Interpretation in SFHI mode of CQE results

### Consensus

The difference with EFI is that a "Negative Consensus" for an antigen is obtained when ***75% of the Participants obtain the same Result for the absence of an antibody***.

### Compliance

* The notion of conformity by sample is introduced, and is determined by class.
* **For a given sample,** the Participant is declared compliant for the analysis of positive or negative antigens when it agrees with the consensus for at least 80% of the antigens respectively positive or negative.

### Participant's annual performance

* The difference with EFI is that it takes into account samples and not just antigens: percentage performance represents the ratio "***number of conform samples / total number of samples for which the Participant has returned a Result for at least one antigen***".
* Performance is determined by class and by distinguishing between positive and negative antigens, but at sample level. It is **satisfactory** if it reaches 75% for each of these 4 criteria (positive/negative antigens in class I / class II for samples) **and** if the Participant has submitted at least one Result (positive or negative) per sample for at least 10 samples of the Exercise. A total of 5 criteria must be met to obtain a satisfactory performance.
* In all other cases, performance is **unsatisfactory**. There is no calculation of overall performance (positive and negative antigens as a whole) by class, nor for class I and class II as a whole.

## Reports and certificates of EQA results

### Individual interim consensus and compliance report of CQE results

* It is prepared after each Slice
* It is registered on the CQXplore website: Attestation SFHI CQE SAG VILLE ANNEE. It is accessible only to the Participant.
* It is established using SFHI criteria.
* It states:
* Dates for sending samples, closing the Tranche, and issuing the report
* The number of Participants included in consensus calculations
* Number of antigens included in the "Consensus Positive", "Consensus Negative" or "Non-Consensus", per sample and per class
* The Participant's result per sample and per class, expressed as
	+ In % of conforming antigens for "Consensus Positive" and "Consensus Negative
	+ In conclusion, for each of these categories
* An overall conclusion specifying the % of samples conforming to the "Positive consensus" and the % of samples conforming to the "Negative consensus".

### Detailed interim reports on EQA results.

* They are prepared after each Slice
* They are anonymized and deposited on the https://www.sfhi.eu/controle-qualite/controle-qualite-externe/identification-des-anticorps website before the analysis start date of the next Tranche during the Fiscal Year, and before December 31 following the last Tranche. They are accessible to all Participants.
* They contain a summary and detailed analysis of the Results of Participants who are medical laboratories performing HLA analyses on a routine basis.
* Participants are not ranked according to their performance.
* They consist of 2 downloadable Results :
* The 1er results can be downloaded via the "YEAR SAG Results Nth Parameter Slice" link and correspond to :
* 1 "Detailed Parameter Analysis" cover page
* 1 page detailing all reagent batches and technical parameters for all Class I participants
* 1 page detailing all reagent batches and technical parameters for all Class II participants
* The 2ème Results can be downloaded via the link "YEAR Results SAG class (I or II) Nth Supplier bracket" corresponds to :
* 1 "Detailed EQA Analysis" cover page with information on the Tranche
* 8 pages for positive and negative consensuses in SFHI mode or EFI mode in class I and class II percentages, per sample and per Participant
* 1 page with captions for detailed reports and performance certificates
* 1 page per sample of the Exercise for the positive/negative Results per antigen for each Participant with the percentage of positive/negative Results per antigen, and the consensus obtained per antigen and the synthesis per Participant of the number of samples studied, the number of interpretable Results, the number and percentage of Results outside consensus and the percentage of Results in agreement with the consensus (the two classes combined) as well as the percentages of positive and negative Results allowing or not a consensus to be reached and the nature of this consensus (positive or negative).

### Annual performance certificate EQA results

* It is individual and nominative, and is deposited on the CQXplore site before December 31 of each year and accessible only to the Participant.
* It comprises 2 sections: "Results analyzed according to SFHI criteria" and "Results analyzed according to EFI criteria".
* It contains :
* Fiscal year
* Participant name and code
* Number of participants
* Number of samples studied by the Participant per class
* Consensus and Results for the Participant (per sample and per class), with the numbers of positive and negative consensus antigens per sample, the numbers of consensus antigens correctly identified by the Participant per sample, and the percentage of compliance for these consensus antigens per sample (SFHI criteria) or the total number of antigens correctly identified by the Participant over the entire Exercise (EFI criteria).
	+ Conclusion for each class for the Participant in compliance with the SFHI or EFI reference criteria, in the form of a percentage of samples or antigens, respectively, in compliance with the consensus among all the consensuses achieved, for positive antigens and for negative antigens, per class.
	+ Participant performance, in the form of "satisfactory for all 5 criteria" or "unsatisfactory for at least one of the 5 criteria".
* It is also supplied in English to facilitate the work of EFI inspectors.

## Extension of the program to include "CRISTAL" mode analysis

The program offers each Participant with access to CRISTAL (software used by the Agence de la Biomédecine in France to allocate transplants and manage the organ waiting list) to provide the Results for each sample of the Exercise as he/she would have entered them, i.e. in prohibited/permitted/grey zone antigen format, for the antigens recognized by Cristal (thus excluding C and DP).

### Interpretation

* Consensus
* It is defined by antigen, in prohibited, permitted and gray zones.
* It is reached when 75% of Participants obtain the same Result for the assignment of a prohibited, permitted or grey zone antigen.
* Compliance
* It is determined by sample
* For a given sample, the Participant is declared compliant for the analysis of prohibited, permitted or grey zone antigens when it agrees with the consensus for at least 80% of the antigens respectively prohibited, permitted or grey zone.
* Annual performance
* As a percentage, it represents the ratio of "number of compliant samples/total number of samples analyzed by the Participant".
* It is calculated by class
* It is **satisfactory** if it reaches 75% **and** if the Participant has submitted at least one Result per sample for at least 10 samples of the Fiscal Year.
* In all other cases, the Participant's performance is **unsatisfactory.**

### Reports of results analyzed in "CRISTAL" mode

#### 10.6.2.1 CRISTAL individual interim consensus and compliance report

* It is prepared after each Slice
* It is registered on the CQXplore website "Attestation SFHI CRISTAL SAG VILLE ANNEE" and is accessible only to the Participant.
* It states:
* Dates for sending samples, closing the Tranche, and issuing results
* The number of program participants concerned by CRISTAL
* The number of antigens included in the "Prohibited Consensus", "Permitted Consensus", "Grey Zone Consensus" and "Non-Consensus", per sample and per class.
* The conclusion for the Participant per sample, expressed in
	+ % of antigens conforming to the "Consensus Prohibited", "Consensus Permitted" and "Consensus Grey Zone" criteria
	+ Conclusion of conformity for each of these categories
* the overall conclusion for the Participant, specifying the percentage of compliant samples for prohibited, permitted and grey zone antigens.

#### 10.6.2.2 Detailed interim report CRISTAL

* It is prepared after each Slice
* It is anonymized and posted on [www.sfhi.eu](http://www.sfhi.eu) before the start of analysis for the next Tranche during the Fiscal Year, and before December 31st following the last Tranche. It is accessible to all Participants "ANNEE Résultats SAG Nème Tranche CRISTAL".
* It contains :
* 1 "Analysis CRISTAL synthesis" cover sheet, summarizing the information for the year
* 6 pages for positive consensus, grey zone and negative percentages in class I and class II, per sample and per Participant
* 1 page per Exercise sample for positive / grey zone / negative Results per antigen for each Participant with the percentage of positive / grey zone / negative Results per antigen, and the consensus obtained per antigen.

## Extension of the program to "MFI" mode analysis

* The program asks all Participants to provide the raw and corrected MFI (mean fluorescence intensity) data measured for each bead in each sample of the Exercise.
* An independent analysis is carried out for each supplier, with no lower limit on the number of Participants.
* A report is issued at the end of each Tranche, and posted on the SFHI website "ANNEE Résultats SAG Cl (I ou II) MFI Fournisseur Lot XX Nème tranche". This report contains :
	+ 1 "detailed MFI analysis" cover page, summarizing information for the financial year
	+ 1 page table of contents with color legend
	+ 6 pages per Slice sample, presenting raw MFI and then Baseline data for One Lambda, and raw MFI and then MFI-LRA data for Immucor, per bead (allele or combination of alleles) tested, for each Participant, with mean and median MFI, standard deviation and CV% obtained for each bead, and mean and median MFI data for beads with MFI >300 and all beads for each Participant, as well as the Z-score obtained for each Participant for beads with MFI>300
	+ MFI data are ranked in descending order of the mean of all laboratory values, and laboratories in ascending Z-score order. For a given sample, this order is retained for the presentation of normalized data.
* This extension of the program is not accompanied by consensus or compliance calculations. The Z-score enables each Participant to situate themselves and, if necessary, explore a situation they consider unsatisfactory, by taking into account their performance in the EQF section of the program. No annual performance certificate is issued for this extension of the program.

# HLA typing program low and/or high resolution

## Exercise sequence

* The program concerns only HLA typing by molecular biology
* Registration covers class I and class II, with generic resolution (first field) and/or high resolution (first two fields).
* Samples for the entire Financial Year are sent to Participants in a single mailing at the beginning of the year.
* Analyses are divided into two batches spaced several months apart, according to a pre-established schedule (sample identity and analysis dates) communicated at the time of sample dispatch.
* An interim consensus report and a detailed interim report are issued after each Tranche 1, for the samples studied on the Tranche concerned. A final consensus report and a final interim report are issued after Tranche 2 for all samples.

## Results to be entered by the Participant

Typing results are entered into CQxplore.

EQA data entry :

* For correct data entry, it is important to have previously defined your PLCs in the "Administration" tab🡪 PLC management



* EFI is asking laboratories to prospectively define :
* The main techniques used individually or in combination to achieve results

- Additional techniques used occasionally, in rare cases, in combination cases, in combination with the main technique

* SFHI EQA samples can be tested on the "low-resolution" or "high-resolution" program with one main technique +/- one additional technique.
* For each sample,
* It is necessary to specify the main technique, the machine, the supplier and the nomenclature used.
* If the sample is tested using another technique, this additional technique, the automaton, the supplier and the nomenclature used must also be specified.

Entering EQA typing :

* All fields must be completed. When you have finished entering data, check the box that replaces all empty boxes in **NT** for "not tested", before moving on to the next sample.
* Results are entered according to the current official nomenclature. Results in serological equivalents are not accepted.
* There's a box to put a letter after the typing (N for Nul, L for Low Expression, P for P-Group, G for G-Group).
* A box corresponds to a field. Render results in ascending order (e.g. DRB1\*03, DRB1\*04 and not DRB1\*04, DRB1\*03).
* For inter-laboratory comparison, we encourage you to enter the 3rd and 4th fields if your analysis allows.
* Homozygous results should be doubled to facilitate analysis.
* Special input of DRB3, DRB4, DRB5 results (=DRB345) :

- If DRB345 homozygosity is confirmed, the result must be entered twice,

- If the DRB1 haplotype is known to have no associated DRB345 genes, indicate **NP** for "not present".

- Indicate **NT** if one or all DRB345 genes have not been tested

*Examples:*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | 1er DRB3 | 2ème DRB3 | 1er DRB4 | 2ème DRB4 | 1er DRB5 | 2ème DRB5 |
| DRB1\*13 :01 ; DRB345 not tested | NT |  |  |  | NT |  |  |  | NT |  |  |  | NT |  |  |  | NT |  |  |  | NT |  |  |  |
| DRB1\*13:01,- ; DRB3\*02:02,- | 02 | 02 |  |  | 02 | 02 |  |  | NP |  |  |  | NP |  |  |  | NP |  |  |  | NP |  |  |  |
| DRB1\*04:01,\*13:01 ; DRB3\*02:02 ; DRB4\*01:01 | 02 | 02 |  |  | NP |  |  |  | 01 | 01 |  |  | NP |  |  |  | NP |  |  |  | NP |  |  |  |
| DRB1\*04:01,\*13:01 ; DRB3\*02:02 ; DRB45 not tested | 02 | 02 |  |  | NP |  |  |  | NT |  |  |  | NT |  |  |  | NT |  |  |  | NT |  |  |  |
| DRB1\*01:01,\*13:01 ; DRB3\*02:02 | 02 | 02 |  |  | NP |  |  |  | NP |  |  |  | NP |  |  |  | NP |  |  |  | NP |  |  |  |

* If amplification fails, indicate **NA** for "non-amplified" in the first field.
* In the case of a new allele, enter **NEW** in the appropriate field.

*Example* for a new allele A\*02, write A\*| 02 | NEW | | | |.

* The comment area is strictly reserved for ambiguities.
* For the generic level result, only a result in the first field is expected.
	+ Do not indicate the most probable allele, nor specify the serological equivalent in the commentary.
	+ Do not indicate "presence of a DRB345" if the typing of the first field is unknown.

## Consensus and compliance

### Consensus

* HLA typing **consensus** is determined by at least **75% of Participants reporting the same results** (a minimum of 5 results is required to establish consensus).
* For samples that do not reach the 75% consensus, a reference typing performed in an EFI-accredited laboratory will be used.
* For each locus, consensus is established for the first and second fields of each allele.

### Compliance

* For the "low resolution" program :

All the first fields reported for each locus must agree with the consensus.

*Errors include* :

* First field typing different from the consensus.
* An ambiguity in the first field is indicated in the "ambiguities" zone.

However, an exception will be made for the DPB1 locus. Indeed, if two alleles have an identical exon 2 but a different first field, the ambiguity must absolutely be reported in the dedicated "ambiguities" zone for the result to be taken into account.

Example: DPB1\*04 ambiguity DPB1\*105

* For the "High resolution" program :

All first and second fields reported for each locus must agree with the consensus.

The third and fourth fields reported will not be taken into account for compliance. However, they will enable the participant to compare himself to other centers and to compare sequencing techniques using the detailed report.

*Errors include*

* First field and/or second field typing different from the consensus (unless the latter has been correctly moderated by P-group or G-group membership).
* An ambiguity concerning exon 2 or 3 (class I) or exon 2 (class II) or a null allele reported in the dedicated "ambiguities" zone.

## Performance

* Performance is established on the main technique for the samples tested for each program.
* Performance according to EFI criteria is established only if 10 or more samples have been tested.
* Performance on the additional technique is left to the discretion of the laboratory.
* If a sample is tested, typing of at least the A, B and DRB1 genes is expected.
* Performance is satisfactory if 90% of typings agree with the consensus. An error on one locus makes the whole typing unsatisfactory.

## Typing" program reports and certificates

* The interim report is prepared after the first Tranche. It is submitted to the [CQXplore](http://www.sfhi.eu) website during the Fiscal Year, before the start date of the next Tranche.
* Detailed analyses containing anonymized results from each laboratory are posted on <https://www.sfhi.eu/controle-qualite/controle-qualite-externe/typage-hla> after each tranche. The final report, the annual performance certificate and the annual performance certificate translated into English are available after the 2nd tranche on the CQXplore website.
* These documents are nominative and accessible only to the Participant. They contain :
* Fiscal year
* Participant name and code
* Number of participants
* Number of samples studied by the 2-digit and 4-digit Participant
	+ Results and consensus for the Participant per sample
	+ Conclusion for each typing for the Participant in the form of a percentage of the number of alleles conforming to the consensus in relation to the number of alleles assigned and according to the EFI criteria.

# HLA Disease Program

## Exercise sequence

* The program uses HLA typing to determine the presence or absence of susceptibility to a disease (Spondyloarthropathy, Behçet's disease, Chorioretinopathy, Celiac disease, Type 1 diabetes, Rheumatoid arthritis, Narcolepsy) or hypersensitivity to a drug (Abacavir).
* Samples are sent to Participants at the beginning of the year for the entire financial year.
* Analyses are divided into two batches spaced several months apart, according to a pre-established schedule (sample identity and analysis dates) communicated at the time of sample dispatch.
* If the Participant is enrolled in both the HLA Typing Program and the HLA Disease Program, he/she must perform the typing in accordance with the HLA Typing Program expectations before performing the HLA Disease analysis.
* If the Participant is registered for the HLA Disease Program only, he/she may type the samples for the HLA Disease analysis as he/she sees fit.
* An interim consensus report and a detailed interim report are issued after Tranche 1, for the samples concerned. A final consensus report and a final interim report are issued after Tranche 2 for all samples.

## Results to be entered by the Participant

Typing results are entered into CQxplore.

* For each sample, it is necessary to indicate **P** for Presence or **A** for Absence of susceptibility for each disease or for each drug hypersensitivity.
* For each untested susceptibility, enter **NT** for "not tested".

## Consensus and compliance

### Consensus

Consensus Presence/Absence of susceptibility is determined by at least **75% of Participants returning the same results**.

### Compliance

The result entered by the Participant must agree with the consensus. If there is no consensus, the result entered will not be considered.

## Performance

* Performance is established for each disease susceptibility or drug hypersensitivity for the samples analyzed.
* Performance is satisfactory for a susceptibility if 90% of samples agree with the consensus. At least 10 samples must be analyzed for performance to be calculated.

## Reports and certificates from the "HLA and Disease" program

* The interim report is prepared after the first Tranche. It is submitted to the [CQXplore](http://www.sfhi.eu) website during the Fiscal Year, before the start date of analyses for the next Tranche.
* Detailed analyses containing anonymized results from each laboratory are posted on <https://www.sfhi.eu/controle-qualite/controle-qualite-externe/typage-hla> after each tranche. The final report and annual performance certificate are available after the 2nd tranche on the CQXplore website.
* These documents are nominative and accessible only to the Participant. They contain :
* Fiscal year
* Participant name and code
* Number of participants
* Number of samples analyzed by the Participant
	+ Participant results and consensus by sample and susceptibility
	+ Performance by susceptibility

#  CSH post-allograft chemotherapy

## Exercise sequence

* The program covers STR (Short tandem Repeats), quantitative PCR, digital PCR and NGS techniques.
* Registration covers the use of one or more techniques of similar or different sensitivity
* Samples for the entire Exercise are sent to Participants in a single shipment.
* The term Result refers to the Participant's response entered for quantification.
* Each Participant must indicate the positivity threshold used in his laboratory for the rendering of the Result.
* Techniques with different levels of sensitivity (STR vs. sensitive techniques) are considered separately, with samples identified differently according to the desired level of quantification.
* Techniques with similar sensitivity levels (Q-PCR, dd-PCR and NGS) are analyzed by technique and overall.
* Consensus and performance are determined by the z-score value obtained for each sample.

## Consensus

* Results are expressed as % recipient and % donor for each sample.
* A z-score will be calculated for each Participant's Result according to the following formula: z-score = (Result - target value) / standard deviation (the target value is defined by the average of the results obtained by all participants for a given technique).
* The z-score is considered :
* **Compliant** when within the range (-2; +2)
* **"alert**" in the range (-3 to -2; +2 to +3)
* **Non-conforming** below -3 and above +3
* A consensus is reached when the Participant's result is within +/-2 standard deviations (SD) of the mean result of all Participants (target value). If the number of Participants is <10, the expected result is specified by the manager.
* A Participant who has not submitted any Results for a sample is excluded from the consensus calculation for that sample, but is not considered to have provided an inaccurate response.
* The various techniques are analyzed separately, and globally for sensitive techniques.

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## Performance

* The Participant's **performance is** defined by the ratio "number of Participant's Results in agreement with the consensus / set of Results having reached the consensus for the samples analyzed by the Participant as part of the Exercise".
* **Performance** is considered **satisfactory** when at least 90% of the Results provided are in agreement with the consensus **and** the Results of at least 10 samples have been submitted over the Exercise.
* An "alert" result is considered satisfactory
* **Performance** is considered **unsatisfactory** in all other cases.

## Chemistry" program reports and certificate

### Reports

* An individual annual report is e-mailed to each participant within 1 month of the end of the financial year.
* It states:
* Dates for sending samples, closing the Tranche, and issuing reports
* The total number of Participants included in the consensus calculations
* The Participant's Result for each sample
* The Participant's position in relation to other Participants
* 3 detailed, anonymized annual reports are available on the SFHI website: https://www.sfhi.eu/controle-qualite/controle-qualite-externe/chimerisme :
	+ The report downloadable via the link "ANNEE\_Z score technique" corresponds to all the Z-scores obtained by all the participants for the sensitive techniques (quantitative PCR/ NGS/ digital PCR) and for the STR technique.
	+ The report, downloadable via the "ANNEE-Résultats technique" link, details for all participants and for each sample, according to technique, the results obtained, as well as the mean, median and standard deviation.
	+ The report, downloadable via the "ANNEE-Comments" link, details the technical parameters (technology, reagents, threshold) of all participants.

### Annual performance certificate

* The annual performance report will be sent by e-mail to Participants, and is individual and nominative.
* The Participant's annual performance is considered satisfactory when at least 10 samples have been tested during the year and the Result is included in the consensus for at least 80% of these samples.
* It summarizes the Participant's results for each sample and concludes on the Participant's performance. It contains :
* Name and contact details of EQA supplier
* Name of laboratory and director
* Laboratory number
* Fiscal year
* Performance assessment

# Claims and requests for information

## Concerning consensus, conformity of a result and samples

* The Participant shall send a substantiated complaint by e-mail to the person in charge of the program concerned. An acknowledgement of receipt must be returned to the Participant within 10 working days of the e-mail being sent.
* In the event of an error by SFHI, the results will be rectified and a new report will be drawn up within 10 working days of dispatch of the acknowledgement of receipt.
* If SFHI's liability is not proven, the claim will be examined at the next OC meeting. An e-mail reply will be sent to the Participant within 10 working days.

## Other claims and requests

* The Participant sends his or her reasoned request by e-mail to the manager of the program concerned. An acknowledgement of receipt must be returned to the Participant within 10 working days of the e-mail being sent.
* These claims will be processed within 30 days of dispatch of the acknowledgement of receipt.

#  Satisfaction questionnaire

It is proposed at the end of each year to assess the satisfaction of participating laboratories and improve the service provided.

#  Annual review

* It is organized by the CO
* It takes place after the end of the last Fiscal Year of year n (at least when the EQA results for the last Tranche have been provided to the Participants, ideally when all the detailed results have been published) and before the first SFHI EQA samples for year n+1 are sent out.
* The following points are discussed:
* Performance report for each EQA program
* CRISTAL and MFI results for the "Ac identification" program
* Summary of claims received during the year
* Satisfaction survey results
* Discussion with the audience
* A report of this meeting has been drawn up and made available to SFHI CQE participants at [www.sfhi.eu](http://www.sfhi.eu), along with the slide show presented at the meeting.
* Annual get-together for participants